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LIMITE

AGRILEG 72 VETER 42 PHARM 27 MI 338 IA 125 CODEC 755

WORKING DOCUMENT

From:	Presidency
To:	Delegations
Subject:	Proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products

Delegations will find in <u>Annex</u> a table presenting:

- First column: The text of the Commission proposal;
- Second column: The amendments of the European Parliament adopted on 9 March 2016;
- Third column: The Council's initial negotiation mandate endorsed by Coreper 1 on 20 December 2017*:
- Fourth column: The draft revised negotiation mandate proposed by the Presidency**.
- (*) In the third column, changes compared to the Commission's proposal are marked in **bold** (added text) and in [...] (deleted text).
- (**) In the fourth column, the proposed changes compared to the initial negotiation mandate (column three) are indicated in <u>bold and underlined</u> and strikethrough, and the cells including those changes are highlighted.

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<u>ANNEX</u>

Proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Proposal for a		Proposal for a	Proposal for a
REGULATION OF THE		REGULATION OF THE	REGULATION OF THE
EUROPEAN PARLIAMENT AND		EUROPEAN PARLIAMENT AND	EUROPEAN PARLIAMENT AND
OF THE COUNCIL		OF THE COUNCIL	OF THE COUNCIL
on veterinary medicinal products		on veterinary medicinal products	on veterinary medicinal products
(Text with EEA relevance)		(Text with EEA relevance)	(Text with EEA relevance)
THE EUROPEAN		THE EUROPEAN	THE EUROPEAN
PARLIAMENT AND THE		PARLIAMENT AND THE	PARLIAMENT AND THE
COUNCIL OF THE		COUNCIL OF THE	COUNCIL OF THE
EUROPEAN UNION,		EUROPEAN UNION,	EUROPEAN UNION,
Having regard to the Treaty on the		Having regard to the Treaty on the	Having regard to the Treaty on the
Functioning of the European Union,		Functioning of the European Union,	Functioning of the European Union,
and in particular Articles 114 and		and in particular Articles 114 and	and in particular Articles 114 and
168(4)(b) thereof,		168(4)(b) thereof,	168(4)(b) thereof,
Having regard to the proposal from		Having regard to the proposal from	Having regard to the proposal from
the European Commission,		the European Commission,	the European Commission,
After transmission of the draft		After transmission of the draft	After transmission of the draft
legislative act to the national		legislative act to the national	legislative act to the national
Parliaments,		Parliaments,	Parliaments,
Having regard to the opinion of the		Having regard to the opinion of the	Having regard to the opinion of the
European Economic and Social		European Economic and Social	European Economic and Social
Committee,		Committee,	Committee ¹ ,

OJ C , , p. .

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Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
Having regard to the opinion of the		Having regard to the opinion of the	Having regard to the opinion of the
Committee of the Regions,		Committee of the Regions,	Committee of the Regions ² ,
Acting in accordance with the		Acting in accordance with the	Acting in accordance with the
ordinary legislative procedure,		ordinary legislative procedure,	ordinary legislative procedure,
Whereas:		Whereas:	Whereas:
(1) Directive 2001/82/EC of the		(1) Directive 2001/82/EC of the	(1) Directive 2001/82/EC of the
European Parliament and of the		European Parliament and of the	European Parliament and of the
Council and Regulation (EC) No		Council and Regulation (EC) No	Council ³ and Regulation (EC) No
726/2004 of the European Parliament		726/2004 of the European Parliament	726/2004 of the European Parliament
and of the Council constitute the		and of the Council constitute the	and of the Council ⁴ constitute the
Union regulatory framework for the		Union regulatory framework for the	Union regulatory framework for the
placing on the market, manufacture,		placing on the market, manufacture,	placing on the market, manufacture,
import, export, supply,		import, export, supply,	import, export, supply,
pharmacovigilance, control and the		pharmacovigilance, control and the	pharmacovigilance, control and the
use of veterinary medicinal products.		use of veterinary medicinal products.	use of veterinary medicinal products.

² OJ C , , p. .

³ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

⁴ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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(2) In the light of the experience acquired and following the assessment by the Commission of the functioning of the market for veterinary medicinal products, the legal framework for veterinary medicinal products should be adapted to scientific progress, the current market conditions and economic reality.	 AM I (2) In the light of the experience acquired and following the assessment by the Commission of the functioning of the market for veterinary medicinal products, the legal framework for veterinary medicinal products should be adapted to scientific progress, the current market conditions and economic reality, with respect to 	(2) In the light of the experience acquired and following the assessment by the Commission of the functioning of the market for veterinary medicinal products, the legal framework for veterinary medicinal products should be adapted to scientific progress, the current market conditions and economic reality while continuing	(2) In the light of the experience acquired and following the assessment by the Commission of the functioning of the market for veterinary medicinal products, the legal framework for veterinary medicinal products should be adapted to scientific progress, the current market conditions and economic reality while continuing
	animals, nature and their	to ensure a high level of animal	to ensure a high level of protection
	interaction with man.	health and animal welfare and	<u>of</u> animal health, and animal
		safeguarding public health.	welfare <u>and environment</u> and
			safeguarding public health.
(3) The legal framework should		(3) The legal framework should	(3) The legal framework should
take into account the needs of the		take into account the needs of the	take into account the needs of the
businesses in the veterinary		businesses in the veterinary	businesses in the veterinary
pharmaceutical sector and trade in		pharmaceutical sector and trade in	pharmaceutical sector and trade in
veterinary medicinal products within		veterinary medicinal products within	veterinary medicinal products within
the Union. It should also integrate		the Union. It should also integrate	the Union. It should also integrate
the major policy objectives set out in		the major policy objectives set out in	the major policy objectives set out in
the Communication from the		the Communication from the	the Communication from the
Commission of 3 March 2010		Commission of 3 March 2010	Commission of 3 March 2010
"Europe 2020 A Strategy for smart,		"Europe 2020 A Strategy for smart,	"Europe 2020 A Strategy for smart,
sustainable and inclusive growth".		sustainable and inclusive growth"	sustainable and inclusive growth" ⁵ .
(4) Experience has shown that the		(4) Experience has shown that the	(4) Experience has shown that the
needs of the veterinary sector differ		needs of the veterinary sector differ	needs of the veterinary sector differ

⁵ COM(2010) 2020 final, 3.3.2010.



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substantially from those of the		substantially from those of the	substantially from those of the
human sector in relation to		human sector in relation to	human sector in relation to
medicines. In particular, the drivers		medicines. In particular, the drivers	medicines. In particular, the drivers
for investment for the human and the		for investment for the human and the	for investment for the human and the
veterinary medicines markets are		veterinary medicines markets are	veterinary medicines markets are
different. For example, in the		different. For example, in the	different. For example, in the
veterinary sector there are many		veterinary sector there are many	veterinary sector there are many
different animal species, which		different animal species, which	different animal species, which
creates both a fragmented market and		creates both a fragmented market and	creates both a fragmented market and
the need for major investments in		the need for major investments in	the need for major investments in
order to extend the authorisation of		order to extend the authorisation of	order to extend the authorisation of
medicines existing for one animal		medicines existing for one animal	medicines existing for one animal
species to another. Moreover, the		species to another. Moreover, the	species to another. Moreover, the
price-setting mechanisms in the		price-setting mechanisms in the	price-setting mechanisms in the
veterinary sector follow a completely		veterinary sector follow a completely	veterinary sector follow a completely
different logic. Consequently, prices		different logic. Consequently, prices	different logic. Consequently, prices
for veterinary medicines are typically		for veterinary medicines are typically	for veterinary medicines are typically
substantially lower than for		substantially lower than for	substantially lower than for
medicinal products for human use.		medicinal products for human use.	medicinal products for human use.
The size of the animal		The size of the animal	The size of the animal
pharmaceutical industry is only a		pharmaceutical industry is only a	pharmaceutical industry is only a
small fraction of the size of the		small fraction of the size of the	small fraction of the size of the
pharmaceutical industry for human		pharmaceutical industry for human	pharmaceutical industry for human
medicines.It is therefore appropriate		medicines. It is therefore appropriate	medicines.It is therefore appropriate
to develop a regulatory framework		to develop a regulatory framework	to develop a regulatory framework
addressing the characteristics and		addressing the characteristics and	addressing the characteristics and
specificities of the veterinary sector,		specificities of the veterinary sector,	specificities of the veterinary sector,
which cannot be considered as a		which cannot be considered as a	which cannot be considered as a
model for the human medicines		model for the human medicines	model for the human medicines
market.		market.	market.



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(5) The provisions of this act aim		(5) The provisions of this act aim	(5) The provisions of this act aim
to reduce administrative burden,		to reduce administrative burden,	to reduce administrative burden,
enhance the internal market and		enhance the internal market and	enhance the internal market and
increase the availability of veterinary		increase the availability of veterinary	increase the availability of veterinary
medicinal products, while		medicinal products, while	medicinal products, while
guaranteeing the highest level of		guaranteeing the highest level of	guaranteeing the highest level of
public and animal health and		public and animal health and	public and animal health and
environmental protection.		environmental protection.	environmental protection.
		(5a) Identification of packs of	(5a) Identification of packs of
		veterinary medicinal products via	veterinary medicinal products via
		identification codes is common	identification codes is common
		practice in several Member States.	practice in several Member States.
		These Member States have	These Member States have
		developed integrated electronic	developed integrated electronic
		systems at national level for the	systems at national level for the
		proper functioning of such codes,	proper functioning of such codes,
		linked to national databases.	linked to national databases.
		However, the introduction of a	However, the introduction of a
		harmonised EU-wide system has	harmonised EU-wide system has
		not been the subject of any	not been the subject of any
		assessment as to costs and	assessment as to costs and
		administrative consequences.	administrative consequences.
		Instead, the possibility should be	Instead, the possibility should be
		given for Member States to decide	given for Member States to decide
		at national level on whether or not	at national level on whether or not
		to adopt a system for identification	to adopt a system for identification
		codes to be added to the	codes to be added to the
		information on the outer	information on the outer
		packaging of the veterinary	packaging of the veterinary
		medicinal products.	medicinal products.

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		(5b) The existing systems for	(5b) The existing systems for
		identification codes currently used	identification codes currently used
		at national level vary and there is	at national level vary and there is
		no standard format. The	no standard format. The
		possibility should be provided for	possibility should be provided for
		the future development of an EU-	the future development of an EU-
		wide harmonised identification	wide harmonised identification
		code through an empowerment for	code through an empowerment for
		the Commission to adopt uniform	the Commission to adopt uniform
		rules on such a code. The adoption	rules on such a code. The adoption
		by the Commission of such rules	by the Commission of such rules
		would not prevent Member States	would not prevent Member States
		from choosing whether or not to	from choosing whether or not to
		use such a identification code.	use such a identification code.
	AM 2		
(6) Animals may suffer from a	(6) Despite the measures that	(6) Despite the measures that	(6) Despite the measures that
broad range of diseases which can be	farmers take on good hygiene, feed,	farmers take on good hygiene,	farmers and other operators are
prevented or treated. The impact of	management and biosecurity,	feed, management and biosecurity,	obliged to take on the basis of rules
animal diseases and the measures	Aanimals may suffer from a broad	a nimals may suffer from a broad	adopted at Union level regarding
necessary to control them can be	range of diseases which can need to	range of diseases which need to be	health of kept animals, good
devastating for individual animals,	be prevented or treated by veterinary	prevented or treated by veterinary	animal husbandry, good hygiene,
animal populations, animal keepers	medicinal products for both animal	medicinal products for both	feed, management and biosecurity,
and the economy. Animal diseases	health and welfare reasons. The	animal health and welfare reasons.	animals may suffer from a broad
transmissible to humans may also	impact of animal diseases and the	The impact of animal diseases and	range of diseases which need to be
have a significant impact on public	measures necessary to control them	the measures necessary to control	prevented or treated by veterinary
health. Therefore sufficient and	can be devastating for individual	them can be devastating for	medicinal products for both
effective veterinary medicinal	animals, animal populations, animal	individual animals, animal	animal health and welfare reasons.
products should be available in the	keepers and the economy. Animal	populations, animal keepers and the	The impact of animal diseases and
Union in order to ensure high	diseases transmissible to humans	economy. Animal diseases	the measures necessary to control
standards of animal and public	may also have a significant impact	transmissible to humans may also	them can be devastating for



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health, and for the development of	on public health. Therefore sufficient	have a significant impact on public	individual animals, animal
the agriculture and aquaculture	and effective veterinary medicinal	health. Therefore sufficient and	populations, animal keepers and the
sectors.	products should be available in the		economy. Animal diseases
sectors.		effective veterinary medicinal	
	Union in order to ensure high	products should be available in the	transmissible to humans may also
	standards of animal and public	Union in order to ensure high	have a significant impact on public
	health, and for the development of	standards of animal and public	health. Therefore sufficient and
	the agriculture and aquaculture	health, and for the development of	effective veterinary medicinal
	sectors. To that end, good	the agriculture and aquaculture	products should be available in the
	husbandry and management	sectors.	Union in order to ensure high
	practices should be put in place in		standards of animal and public
	order to improve animal welfare,		health, and for the development of
	limit the spread of diseases, prevent		the agriculture and aquaculture
	antimicrobial resistance and ensure		sectors.
	proper nutrition of livestock.		
	AM 3		
(7) This Regulation should set	(7) This Regulation should set	(7) This Regulation should set	(7) This Regulation should set
high standards of quality, safety and	high standards of quality, safety and	high standards of quality, safety and	high standards of quality, safety and
efficacy for veterinary medicinal	efficacy for veterinary medicinal	efficacy for veterinary medicinal	efficacy for veterinary medicinal
products in order to meet common	products in order to meet common	products in order to meet common	products in order to meet common
concerns as regards the protection of	concerns as regards the protection of	concerns as regards the protection of	concerns as regards the protection of
public and animal health. At the	public and animal health and the	public and animal health and the	public and animal health and the
same time, this Regulation should	<i>environment</i> . At the same time, this	environment. At the same time, this	environment. At the same time, this
harmonise the rules for the	Regulation should harmonise the	Regulation should harmonise the	Regulation should harmonise the
authorisation of veterinary medicinal	rules for the authorisation of	rules for the authorisation of	rules for the authorisation of
products and the placing of them on	veterinary medicinal products and	veterinary medicinal products and	veterinary medicinal products and
the Union market.	the placing of them on the Union	the placing of them on the Union	the placing of them on the Union
	market.	market.	market.



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	AM 4		
	(7a) This Regulation aims at		
	ensuring a high level of protection		
	of both animal and human health		
	while securing the protection of the		
	environment. Therefore, the		
	precautionary principle should be		
	applied. This Regulation should		
	ensure that industry demonstrates		
	that pharmaceutical substances or		
	veterinary medicinal products		
	produced or placed on the market		
	have no harmful effects on human		
	or animal health nor have any		
	unacceptable effects on the		
	environment.		
		(7a) However, this Regulation	(7a) However, <u>tThis</u> Regulation
		shall not apply to veterinary	shall should not apply to
		medicinal products which have not	veterinary medicinal products
		undergone an industrial process	which have not undergone an
		as, for example non-processed	industrial process as, for example
	<u> </u>	blood.	non-processed blood.
			(7aa) Antiparasitics include also
			substances with repelling activity
			that are presented for use as
			veterinary medicinal products.

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		(7b) Since there is to date	(7b) Since there is to date
		insufficient information on	insufficient information on
		traditional herbal products used to	traditional herbal products used to
		treat animals in order to allow the	treat animals in order to allow the
		setting up of a simplified system,	setting up of a simplified system,
		the possibility of introducing such	the possibility of introducing such
		a simplified system should be	a simplified system should be
		examined by the Commission	examined by the Commission
		based on the information provided	based on the information provided
		by the Member States on the use of	by the Member States on the use of
		such products on their territory.	such products on their territory.
		(7c) This Regulation applies to	(7c) This Regulation applies to
		veterinary medicinal products,	veterinary medicinal products,
		fincluding for the purpose of what	including for the purpose of what
		in Directive 2001/82/EC was	in Directive 2001/82/EC was
		referred to as 'pre-mixes' and	referred to as 'pre-mixes' and
		which are considered in this	which are considered in this
		Regulation as one of the	Regulation as one of the
		pharmaceutical forms of a	pharmaceutical forms of a
		veterinary medicinal product] for	veterinary medicinal product for
		the time up until these products	the time up until these products
		are included in medicated feed or	are included in medicated feed or
		intermediate products, after which	intermediate products, after which
		the medicated feed Regulation	the medicated feed Regulation
		(XX) applies to the exclusion of	(XX) applies to the exclusion of
		this Regulation.	this Regulation.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		(7d) To ensure the proper	(7d) To ensure the proper
		administration and appropriate	administration and appropriate
		dosing of certain veterinary	dosing of certain veterinary
		medicinal products which are to be	medicinal products which are to be
		administered orally in feed or	administered orally in feed or
		drinking water to animals,	drinking water to animals,
		especially in case of treatment of	especially in case of treatment of
		groups of animals, it shall be	groups of animals, it shall be
		properly described in the product	properly described in the product
		information. Additional	information. Additional
		instructions for cleaning the	instructions for cleaning the
		equipment used for administration	equipment used for administration
		of those products should be set out	of those products should be set out
		to avoid cross-contamination and	to avoid cross-contamination and
		reduce antimicrobial resistance.	reduce antimicrobial resistance.
		In order to improve the effective	In order to improve the effective
		and safe use of veterinary	and safe use of veterinary
		medicinal products authorized and	medicinal products authorized
		prescribed for oral administration	and prescribed for oral
		via other routes than medicated	administration via other routes
		feed, such as mixing of water for	than medicated feed, such as
		drinking with a veterinary	mixing of water for drinking with
		medicinal product or as manual	a veterinary medicinal product or
		mixing of a veterinary medicinal	as manual mixing of a veterinary
		product into feed and	medicinal product into feed and
		administered by the animal keeper	administered by the animal keeper
		to food producing animals,	to food producing animals,
		implementing powers should be	implementing powers should be
		conferred on the Commission. The	conferred on the Commission
		Commission should take into	should, where necessary, adopt

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550 mai - 2014/0257 (COD)		account scientific	delegated acts. The Commission
		recommendations of the Agency,	should take into account scientific
		for example concerning measures	recommendations of the Agency,
		to minimize over-dosage or under-	for example concerning measures
		dosage, unintended administration	to minimize over-dosage or under-
		to non-target animals, the risk of	dosage, unintended administration
		cross-contamination and	to non-target animals, the risk of
		dissemination in the environment	cross-contamination and
		of these products.	dissemination in the environment
		-	of these products.
(8) With a view to harmonising the		(8) With a view to harmonising the	(8) With a view to harmonising the
internal market for veterinary		internal market for veterinary	internal market for veterinary
medicinal products in the Union and		medicinal products in the Union and	medicinal products in the Union and
improving their free movement, rules		improving their free movement, rules	improving their free movement, rules
should be established concerning the		should be established concerning the	should be established concerning the
procedures for authorisation of such		procedures for authorisation of such	procedures for authorisation of such
products that ensure the same		products that ensure the same	products that ensure the same
conditions for all applications and a		conditions for all applications and a	conditions for all applications and a
transparent framework for all		transparent framework for all	transparent framework for all
interested parties.		interested parties.	interested parties.

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	AM 5	Č Č	
(9) The scope of the mandatory	(9) The scope of the mandatory	(9) The scope of the mandatory	(9) The scope of the mandatory
use of a centralised authorisation	use of a centralised authorisation	use of a centralised authorisation	use of a centralised authorisation
procedure under which the	procedure under which the	procedure under which the	procedure under which the
authorisations are valid throughout	authorisations are valid throughout	authorisations are valid throughout	authorisations are valid throughout
the Union should cover inter alia	the Union should cover inter alia	the Union should cover inter alia	the Union should cover inter alia
products containing new active	products containing new active	products containing new active	products containing new active
substances and products which	substances and products which	substances and products which	substances and products which
contain or consist of engineered	contain or consist of engineered	contain or consist of engineered	contain or consist of engineered
tissues or cells. At the same time, in	tissues or cells. At the same time, in	tissues or cells, including novel	tissues or cells, including novel
order to ensure the widest possible	order to ensure the widest possible	therapy veterinary medicinal	therapy veterinary medicinal
availability of veterinary medicinal	availability of veterinary medicinal	products with the exclusion of	products with the exclusion of
products in the Union, the centralised	products in the Union, the centralised	blood components, like plasma,	blood components, like plasma,
authorisation procedure should be	authorisation procedure should be	platelet concentrates or red cells.	platelet concentrates or red cells.
extended to allow for applications for	extended to allow for applications for	At the same time, in order to ensure	At the same time, in order to ensure
authorisations under that procedure	authorisations under that procedure	the widest possible availability of	the widest possible availability of
to be submitted for any veterinary	to be submitted for any veterinary	veterinary medicinal products in the	veterinary medicinal products in the
medicinal product, including for	medicinal product, including for	Union, the centralised authorisation	Union, the <u>access of small and</u>
generics of nationally authorised	generics of nationally authorised	procedure should be extended to	medium-sized enterprises (SMEs)
veterinary medicinal products.	veterinary medicinal products. The	allow for applications for	to the centralised authorisation
	use of the centralised procedure	authorisations under that procedure	procedure should be <u>facilitated by</u>
	should be encouraged in every way,	to be submitted for any veterinary	all appropriate means, and its use
	in particular by facilitating access	medicinal product, including for	should be extended to allow for
	for small and medium-sized	generics of nationally authorised	applications for authorisations under
	enterprises (SMEs).	veterinary medicinal products.	that procedure to be submitted for
			any veterinary medicinal product,
			including for generics of nationally
			authorised veterinary medicinal
			products.
		(9a) The replacement or the	(9a) The replacement or the



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		addition of a new antigen or a new	addition of a new antigen or a new
		strain in case of already authorised	strain in case of already authorised
		immunological veterinary	immunological veterinary
		medicinal products against e.g.	medicinal products against e.g.
		avian influenza, bluetongue, foot	avian influenza, bluetongue, foot
		and mouth disease or equine	and mouth disease or equine
		influenza should not be considered	influenza should not be considered
		as adding a new active substance.	as adding a new active substance.
(10) The national procedure for		(10) The national procedure for	(10) The national procedure for
authorising veterinary medicinal		authorising veterinary medicinal	authorising veterinary medicinal
products should be maintained		products should be maintained	products should be maintained
because of varying needs in different		because of varying needs in different	because of varying needs in different
geographical areas of the Union as		geographical areas of the Union as	geographical areas of the Union as
well as the business models of small		well as the business models of small	well as the business models of small
and medium sized enterprises		and medium sized enterprises	and medium sized enterprises
(SMEs). It should be ensured that		(SMEs). It should be ensured that	(SMEs). It should be ensured that
marketing authorisations granted in		marketing authorisations granted in	marketing authorisations granted in
one Member State are recognised in		one Member State are recognised in	one Member State are recognised in
other Member States.		other Member States.	other Member States.
(11)In order to help applicants, and		(11) In order to help applicants, and	(11) In order to help applicants, and
in particular SMEs, to comply with		in particular SMEs, to comply with	in particular SMEs, to comply with
the requirements of this Regulation,		the requirements of this Regulation,	the requirements of this Regulation,
Member States should provide		Member States should provide	Member States should provide
advice to the applicants, for example		advice to the applicants []. This	advice to the applicants []. This
by establishing helpdesks. This		advice should be provided in	advice should be provided in
advice should be provided in		addition to the operational guidance	addition to the operational guidance
addition to the operational guidance		documents and other advice and	documents and other advice and
documents and other advice and		assistance provided by the European	assistance provided by the European
assistance provided by the European		Medicines Agency.	Medicines Agency.
Medicines Agency.			



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(12) In order to avoid unnecessary		(12) In order to avoid unnecessary	(12) In order to avoid unnecessary
administrative and financial burdens		administrative and financial burdens	administrative and financial burdens
for applicants and competent		for applicants and competent	for applicants and competent
authorities, a full in-depth		authorities, a full in-depth	authorities, a full in-depth
assessment of an application for the		assessment of an application for the	assessment of an application for the
authorisation of a veterinary		authorisation of a veterinary	authorisation of a veterinary
medicinal product should be carried		medicinal product should be carried	medicinal product should be carried
out only once. It is appropriate		out only once. It is appropriate	out only once. It is appropriate
therefore to lay down special		therefore to lay down special	therefore to lay down special
procedures for the mutual		procedures for the mutual	procedures for the mutual
recognition of national		recognition of national	recognition of national
authorisations.		authorisations.	authorisations.
(13) Moreover, rules should be		(13) Moreover, rules should be	(13) Moreover, rules should be
established under the mutual		established under the mutual	established under the mutual
recognition procedure to resolve any		recognition procedure to resolve any	recognition procedure to resolve any
disagreements between competent		disagreements between competent	disagreements between competent
authorities in a coordination group of		authorities in a coordination group	authorities in a coordination group
the Member States without undue		for mutual recognition and	for mutual recognition and
delay.		decentralised procedures for	decentralised procedures for
		veterinary medicinal products	veterinary medicinal products
		("the coordination group") []	("the coordination group") []
		without undue delay. This	without undue delay. This
		Regulation also sets new tasks to	Regulation also sets new tasks to
		the coordination group, including	the coordination group, including
		drawing up an annual list of	drawing up an annual list of
		reference veterinary medicinal	reference veterinary medicinal
		products which are to be subject	products which are to be subject
		to harmonisation of the summary	to harmonisation of the summary
		of product characteristics, issuing	of product characteristics, issuing
		recommendations on	recommendations on



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
		pharmacovigilance and the involvement in the signal management process.	pharmacovigilance and the involvement in the signal management process.
(14) Where a Member State or the Commission considers that there are reasons to believe that a veterinary medicinal product may present a potential serious risk to human or animal health or to the environment, a scientific evaluation of the product should be undertaken at Union level, leading to a single decision on the area of disagreement, binding on the Member States concerned, being taken on the basis of an overall benefit-risk assessment.	AM 6 (14) Where a Member State or the Commission considers that there are reasons to believe that a veterinary medicinal product may present a potential serious risk to human or animal health or to the environment, a scientific evaluation of the product should be undertaken at Union level, leading to a single decision on the area of disagreement, binding on the Member States concerned, being taken on the basis of an overall benefit-risk assessment. <i>The</i> <i>authorisation procedure for</i> <i>veterinary medicinal products</i> <i>should be adjusted so as to</i> <i>eliminate other administrative</i> <i>procedures that might hamper the</i> <i>development of research and</i> <i>innovation for the purpose of</i> <i>identifying new medicines.</i>	(14) Where a Member State, [] the Commission or the marketing authorisation holder considers that there are reasons to believe that a veterinary medicinal product may present a potential serious risk to human or animal health or to the environment, a scientific evaluation of the product should be undertaken at Union level, leading to a single decision on the area of disagreement, binding on the Member States concerned, being taken on the basis of an overall benefit-risk assessment.	(14) Where a Member State, [] the Commission or the marketing authorisation holder considers that there are reasons to believe that a veterinary medicinal product may present a potential serious risk to human or animal health or to the environment, a scientific evaluation of the product should be undertaken at Union level, leading to a single decision on the area of disagreement, binding on the Member States concerned, being taken on the basis of an overall benefit-risk assessment.

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(15) No veterinary medicinal		(15) No veterinary medicinal	(15) No veterinary medicinal
product should be allowed to be		product should be allowed to be	product should be allowed to be
placed on the market or used in the		placed on the market [] in the	placed on the market [] in the
Union unless it has been authorised,		Union unless it has been authorised,	Union unless it has been authorised,
and its quality, safety and efficacy		and its quality, safety and efficacy	and its quality, safety and efficacy
have been demonstrated.		have been demonstrated.	have been demonstrated.
(16) Where a veterinary medicinal		(16) Where a veterinary medicinal	(16) Where a veterinary medicinal
product is intended for food-		product is intended for food-	product is intended for food-
producing animal species, a		producing animal species, a	producing animal species, a
marketing authorisation should only		marketing authorisation should only	marketing authorisation should only
be granted if the pharmacologically		be granted if the pharmacologically	be granted if the pharmacologically
active substances which the product		active substances which the product	active substances which the product
contains are allowed in accordance		contains are allowed in accordance	contains are allowed in accordance
with Commission Regulation (EU)		with Regulation (EC) No 470/2009	with Regulation (EC) No 470/2009
No $37/2010^6$ for the species for		and any acts adopted on the basis	and any acts adopted on the basis
which the veterinary medicinal		thereof [] for the species for	thereof $[]^7$ for the species for
product is intended.		which the veterinary medicinal	which the veterinary medicinal
		product is intended.	product is intended.

⁶ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

⁷ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p.11).

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(17) However, there may be situations where no suitable authorised veterinary medicinal product is available. In those situations, by way of exception, veterinarians should be allowed to prescribe other medicinal products to the animals under their responsibility in conformity with strict rules and in the interest of animal health or animal welfare only. In case of food- producing animals, veterinarians should ensure that an appropriate withdrawal period is prescribed, so that harmful residues of those medicinal products do not enter the food chain.	AM 7 (17) However, there may be situations where no suitable authorised veterinary medicinal product is available. In those situations, by way of exception, veterinarians should be allowed to prescribe other medicinal products to the animals under their responsibility in conformity with strict rules and in the interest of animal health or animal welfare only. <i>In such cases,</i> <i>antimicrobial medicinal products</i> <i>for human use could be employed</i> <i>only subject to the issuing of a</i> <i>prescription by a veterinarian and</i> <i>the granting of authorisation by the</i> <i>veterinary authority responsible for</i> <i>monitoring the work of the</i> <i>veterinarian in question.</i> In case of food-producing animals, veterinarian should ensure that an appropriate withdrawal period is prescribed, so that harmful residues of those medicinal products do not enter the food chain, <i>and particular</i> <i>care should therefore be taken when</i> <i>administering antibiotics to food-</i> <i>producing animals.</i>		(17) However, there may be situations where no suitable authorised veterinary medicinal product is available. In those situations, by way of exception, veterinarians should be allowed to prescribe other medicinal products to the animals under their responsibility in conformity with strict rules and in the interest of animal health or animal welfare only. In case of food- producing animals, veterinarians should ensure that an appropriate withdrawal period is prescribed, so that harmful residues of those medicinal products do not enter the food chain, and particular care should therefore be taken when administering antimicrobials.
	AM 8		



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(18) Member States should be able	(18) Member States should be able	(18) Member States should be able	(18) Member States should be able
to allow exceptional use of	to allow <i>temporary</i> exceptional use	to allow exceptional use of	to allow exceptional use of
veterinary medicinal products	of veterinary medicinal products	veterinary medicinal products	veterinary medicinal products
without a marketing authorisation	without a marketing authorisation	without a marketing authorisation	without a marketing authorisation
where it is necessary to respond to	where it is necessary to respond to	where it is necessary to respond to	where it is necessary to respond to
Union listed diseases and where the	Union listed diseases or new	Union listed diseases or emerging	Union listed diseases or emerging
health situation in a Member State so	diseases and where the health	diseases and where the health	diseases and where the health
requires.	situation in a Member State so	situation in a Member State so	situation in a Member State so
-	requires.	requires.	requires.
(19) Taking into account the need		(19) Taking into account the need	(19) Taking into account the need
for simple rules on changes to the		for simple rules on changes to the	for simple rules on changes to the
marketing authorisations of		marketing authorisations of	marketing authorisations of
veterinary medicinal products, only		veterinary medicinal products, only	veterinary medicinal products, only
changes that may affect animal		changes that may affect animal	changes that may affect animal
health, public health or the		health, public health or the	health, public health or the
environment should require a		environment should require a	environment should require a
scientific assessment.		scientific assessment.	scientific assessment.
	AM 9		
(20) Directive $2010/63/EU$ of the	(20) Directive 2010/63/EU of the	(20) Directive $2010/63/EU$ of the	(20) Directive 2010/63/EU of the
European Parliament and of the	European Parliament and of the	European Parliament and of the	European Parliament and of the
Council lays down provisions on the	Council lays down provisions on the	Council lays down provisions on the	Council ⁸ lays down provisions on the
protection of animals used for	protection of animals used for	protection of animals used for	protection of animals used for
scientific purposes based on the	scientific purposes based on the	scientific purposes based on the	scientific purposes based on the
principles of replacement, reduction	principles of replacement, reduction	principles of replacement, reduction	principles of replacement, reduction
and refinement. Clinical trials for	and refinement. Clinical trials for	and refinement. Clinical trials for	and refinement. Clinical trials for
veterinary medicinal products are	veterinary medicinal products are	veterinary medicinal products are	veterinary medicinal products are
exempted from that Directive. The	exempted from that Directive. The	exempted from that Directive. The	exempted from that Directive. The

⁸ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

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design and performance of clinical	design and performance of clinical	design and performance of clinical	design and performance of clinical
trials, which provide essential	trials, which provide essential	trials, which provide essential	trials, which provide essential
information on the safety and	information on the safety and	information on the safety and	information on the safety and
efficacy of a veterinary medicinal	efficacy of a veterinary medicinal	efficacy of a veterinary medicinal	efficacy of a veterinary medicinal
product, should be such as to provide	product, should be such as optimised	product, should be [] optimised in	product, should be [] optimised in
the most satisfactory results whilst	<i>in order</i> to provide the most	order to provide the most	order to provide the most
using the minimum number of	satisfactory results whilst using the	satisfactory results whilst using the	satisfactory results whilst using the
animals, the procedures should be	minimum number of animals, the	minimum number of animals, the	minimum number of animals, the
the least likely to cause pain,	procedures should be the least likely	procedures should be the []	procedures should be the []
suffering or distress to animals and	to cause designed to avoid causing	designed to avoid causing pain,	designed to avoid causing pain,
should take into account the	pain, suffering or distress to animals	suffering or distress to animals and	suffering or distress to animals and
principles established by Directive	and should take into account the	should take into account the	should take into account the
2010/63/EU.	principles established by Directive	principles established by Directive	principles established by Directive
	2010/63/EU.	2010/63/EU and the guidelines of	2010/63/EU, <u>including the use of</u>
		the International Cooperation on Harmonisation of Technical	alternative test methods wherever
		Requirements for Registration of	<u>possible</u> , and the guidelines of the International Cooperation on
		Veterinary Medicinal Products	Harmonisation of Technical
		('VICH').	Requirements for Registration of
		(vien).	Veterinary Medicinal Products
			('VICH').
(21) The principles of replacement,		(21) The principles of replacement,	(21) The principles of replacement,
reduction and refinement concerning		reduction and refinement concerning	reduction and refinement concerning
the care and use of live animals for		the care and use of live animals for	the care and use of live animals for
scientific purposes should therefore		scientific purposes should therefore	scientific purposes should therefore
be taken into account during the		be taken into account during the	be taken into account during the
design and performance of clinical		design and performance of clinical	design and performance of clinical
trials.		trials.	trials.
(22) It is recognised that improved		(22) It is recognised that improved	(22) It is recognised that improved
access to information contributes to		access to information contributes to	access to information contributes to



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public awareness, gives the public		public awareness, gives the public	public awareness, gives the public
the opportunity to express its		the opportunity to express its	the opportunity to express its
observations and enables authorities		observations and enables authorities	observations and enables authorities
to take due account of those		to take due account of those	1 1
observations. Regulation (EC) No		observations. Regulation (EC) No	observations. The general public
1049/2001 of the European		1049/2001 of the European	should therefore have access to
Parliament and of the Council gives		Parliament and of the Council gives	information in the product
the fullest possible effect to the right		the fullest possible effect to the right	database, the pharmacovigilance
of public access to documents and		of public access to documents and	database and the manufacturing
lays down the general principles and		lays down the general principles and	and wholesale distribution
limits on such access. The European		limits on such access. The European	database, after the deletion of any
Medicines Agency should therefore		Medicines Agency should therefore	commercially confidential
give the widest possible access to the		give the widest possible access to the	information by the competent
documents carefully balancing the		documents carefully balancing the	authority. Regulation (EC) No
right for information with existing		right for information with existing	1049/2001 of the European
data protection requirements. Certain		data protection requirements. Certain	Parliament and of the Council ⁹ gives
public and private interests, such as		public and private interests, such as	the fullest possible effect to the right
regarding the protection of personal		regarding the protection of personal	of public access to documents and
data, or the protection of		data, or the protection of	lays down the general principles and
commercially confidential		commercially confidential	limits on such access. The European
information, should be protected by		information, should be protected by	Medicines Agency should therefore
way of exceptions in accordance		way of exceptions in accordance	give the widest possible access to the
with Regulation (EC) No 1049/2001.		with Regulation (EC) No 1049/2001.	documents carefully balancing the
6 ()			right for information with existing
			data protection requirements. Certain
			public and private interests, such as
			regarding the protection of personal

⁹ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

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	AM 10		data, or the protection of commercially confidential information, should be protected by way of exceptions in accordance with Regulation (EC) No 1049/2001.
(23) Companies have less interest in developing veterinary medicinal products for markets of a limited size. In order to promote the availability of veterinary medicinal products within the Union for those markets, in some cases it should be possible to grant marketing authorisations without a complete application dossier having been submitted, on the basis of a benefit- risk assessment of the situation and, where necessary, subject to specific obligations. In particular, this should be possible in the case of veterinary medicinal products for use in minor species or for the treatment or prevention of diseases that occur infrequently or in limited geographical areas.	(23) Companies have less interest in developing veterinary medicinal products for markets of a limited size. In order to promote the availability of veterinary medicinal products within the Union for those markets, in some exceptional cases it should be possible to grant marketing authorisations without a complete application dossier having been submitted, on the basis of a benefit- risk assessment of the situation and, where necessary, subject to specific obligations. In particular, this should be possible in the case of veterinary medicinal products for use in minor species or for the treatment or prevention of diseases that occur infrequently or in limited geographical areas. Such products should only be used on the basis of	(23) Companies have less interest in developing veterinary medicinal products for markets of a limited size. In order to promote the availability of veterinary medicinal products within the Union for those markets, in some cases it should be possible to grant marketing authorisations without a complete application dossier having been submitted, on the basis of a benefit- risk assessment of the situation and, where necessary, subject to specific obligations. In particular, this should be possible in the case of veterinary medicinal products for use in minor species or for the treatment or prevention of diseases that occur infrequently or in limited geographical areas.	(23) Companies have less interest in developing veterinary medicinal products for markets of a limited size. In order to promote the availability of veterinary medicinal products within the Union for those markets, in some cases it should be possible to grant marketing authorisations without a complete application dossier having been submitted, on the basis of a benefit- risk assessment of the situation and, where necessary, subject to specific obligations. In particular, this should be possible in the case of veterinary medicinal products for use in minor species or for the treatment or prevention of diseases that occur infrequently or in limited geographical areas.
	a prescription.		
(24) Environmental risk		(24) Environmental risk	(24) Environmental risk
assessments should be mandatory for		assessments should be mandatory for	assessments should be mandatory for



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all new applications for a marketing		all new applications for a marketing	all new applications for a marketing
authorisation and should consist of		authorisation and should consist of	authorisation and should consist of
two phases. In the first phase the		two phases. In the first phase the	two phases. In the first phase the
extent of environmental exposure of		extent of environmental exposure of	extent of environmental exposure of
the product, its active substances and		the product, its active substances and	the product, its active substances and
other constituent should be		other constituent should be	other constituent should be
estimated, while in the second phase		estimated, while in the second phase	estimated, while in the second phase
the effects of the active residue		the effects of the active residue	the effects of the active residue
should be assessed.		should be assessed.	should be assessed.
			(24a) Where there is concern that
			a pharmaceutical substance could
			pose serious risk to the
			environment, it may be
			appropriate to consider that
			substance in the context of Union
			environmental legislation. In
			particular, under the Water
			Framework Directive, it may be
			appropriate to identify the
			substance as a substance for
			inclusion in the surface water
			watch list, in order to gather
			monitoring data on it. It may be
			appropriate to include it in the list
			of priority substances and to set an
			environmental quality standard
			for it, as well as to identify
			measures to reduce its emissions to
			the environment. These could
			include measures to reduce
			Include Incasules to reduce



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			emissions from manufacturing by
			following Best Available
			Techniques (BAT) under the
			Industrial Emissions Directive ,
			particularly if the emission of
			active pharmaceutical ingredients
			have been identified as a key
			environmental issue during the
			drafting or revision of relevant
			Best Available Technique
			Reference Documents (BREFs)
			and their accompanying BAT
			Conclusions.
	AM 11		
(25) Tests, pre-clinical studies and	(25) Tests, pre-clinical studies and	(25) Tests, pre-clinical studies and	
clinical trials represent a major	clinical trials represent a major	clinical trials represent a major	clinical trials represent a major
investment for companies which they	investment for companies which they	investment for companies which they	investment for companies which they
need to make in order to submit the	need to make in order to submit the	need to make in order to submit the	need to make in order to submit the
necessary data with the application	necessary data with the application	necessary data with the application	necessary data with the application
for a marketing authorisation or to	for a marketing authorisation or to	for a marketing authorisation or to	for a marketing authorisation or to
establish a maximum residue limit	establish a maximum residue limit	establish a maximum residue limit	establish a maximum residue limit
for pharmaceutical active substances	for pharmaceutical active substances	for [] pharmacologically active	for [] pharmacologically active
in the veterinary medicinal product.	in the veterinary medicinal product.	substances of [] the veterinary	substances of [] the veterinary
That investment should be protected in order to stimulate research and	That investment should be protected in order to stimulate research and	medicinal product. That investment	medicinal product. That investment
		should be protected in order to	should be protected in order to
innovation, so that it is ensured the	innovation, <i>in particular on</i>	stimulate research and innovation, in	stimulate research and innovation, in
necessary veterinary medicinal	veterinary medicinal products for	particular on veterinary medicinal	particular on veterinary medicinal
products are available in the Union. For that reason data submitted to a	<i>minor species and antimicrobials</i> , so that it is ansured the neargonet	products for minor species and antimicrobials, so that it is ensured	products for minor species and
	that it is ensured the necessary	,	antimicrobials, so that it is ensured
competent authority or the Agency	veterinary medicinal products are	the necessary veterinary medicinal	the necessary veterinary medicinal

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should be protected against use by other applicants. That protection should, however, be limited in time in order to allow competition.	available in the Union. For that reason data submitted to a competent authority or the Agency should be protected against use by other applicants. That protection should, however, be limited in time in order to allow competition.	products are available in the Union. For that reason data submitted to a competent authority or the Agency should be protected against use by other applicants. That protection should, however, be limited in time in order to allow competition. Similar protection of investments should be applied to studies supporting a new pharmaceutical form, administration route or dosage reducing the antimicrobial or antiparasitic resistance or improving the benefit-risk balance.	products are available in the Union. For that reason data submitted to a competent authority or the Agency should be protected against use by other applicants. That protection should, however, be limited in time in order to allow competition. Similar protection of investments should be applied to studies supporting a new pharmaceutical form, administration route or dosage reducing the antimicrobial or antiparasitic resistance or improving the benefit-risk balance.
	AM 12 (25a) Research should be incentivised, not only through the commercial protection of innovative active substances, but also through the protection of significant investments in data generated to improve or maintain on the market an existing veterinary medicinal product. In such cases, only the new data package would benefit from the period of protection and not the active substance or any associated products.		
(26) Certain particulars and documents that are normally to be		(26) Certain particulars and documents that are normally to be	(26) Certain particulars and documents that are normally to be



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submitted with an application for a		submitted with an application for a	submitted with an application for a
marketing authorisation should not		marketing authorisation should not	marketing authorisation should not
be required if a veterinary medicinal		be required if a veterinary medicinal	be required if a veterinary medicinal
product is a generic medicinal		product is a generic medicinal	product is a generic medicinal
product of a veterinary medicinal		product of a veterinary medicinal	product of a veterinary medicinal
product that is authorised or has been		product that is authorised or has been	product that is authorised or has been
authorised in the Union.		authorised in the Union.	authorised in the Union.
	AM 13		
(27) It is recognised that the	(27) It is recognised that the	(27) It is recognised that the	(27) It is recognised that the
potential effect of a product on the	potential effect of a product on the	potential effect of a product on the	potential effect of a product on the
environment may depend on the	environment may depend on the	environment may depend on the	environment may depend on the
volume used and the resulting	volume used and the resulting	volume used and the resulting	volume used and the resulting
amount of the pharmaceutical	amount of the pharmaceutical	amount of the pharmaceutical	amount of the pharmaceutical
substance that may reach the	substance that may reach the	substance that may reach the	substance that may reach the
environment. Therefore, where there	environment. Therefore, where there	environment. Therefore, where there	environment. Therefore, where there
is evidence that a constituent of a	is evidence that a constituent of a	is evidence that a constituent of a	is evidence that a constituent of a
medicinal product for which a	medicinal product for which a	medicinal product for which a	medicinal product for which a
generic application for a marketing	generic application for a marketing	generic application for a marketing	generic application for a marketing
authorisation is submitted is a hazard	authorisation is submitted is a hazard	authorisation is submitted is a hazard	authorisation is submitted is a hazard
for the environment, it is appropriate	for the environment, it is appropriate	for the environment, it is appropriate	for the environment, it is appropriate
to require data on the potential effect	to require data on the potential effect	to require data on the potential effect	to require data on the potential effect
on the environment in order to	on the environment in order to	on the environment in order to	on the environment in order to
safeguard the environment. In such	safeguard the environment. In such	safeguard the environment. In such	safeguard the environment. In such
cases applicants should endeavour to	cases applicants should endeavour to	cases applicants should endeavour to	cases applicants should endeavour to
join efforts in generating such data in	join efforts in generating such data in	join efforts in generating such data in	join efforts in generating such data in
order to reduce costs and to reduce	order to reduce costs and to reduce	order to reduce costs and to reduce	order to reduce costs and to reduce
testing on vertebrate animals.	testing on vertebrate animals. <i>The</i>	testing on vertebrate animals. The	testing on vertebrate animals. The
	current impact assessment system	establishment of a single European	establishment of a single European
	results in repetitive and potentially	assessment of the environmental	assessment of the environmental
	divergent assessments of	properties of active substances for	properties of active substances for

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	substances' environmental properties. That can lead to divergent decisions being taken on products with similar effects on the environment, especially in the case of products authorised before the environmental impact assessment was carried out. The establishment of a single centralised assessment of the environmental properties of active substances for veterinary use by means of a monograph system could be a potential alternative. The Commission should therefore submit a report to the European Parliament and the Council examining the feasibility of monographs and potential alternative options as soon as possible.	veterinary use by means of a monograph system could be a potential alternative. The Commission should therefore submit a report to the European Parliament and the Council examining the feasibility of active substance based review system ('monographs') and other potential alternatives for environmental risk assessment of veterinary medicinal products, accompanied if appropriate by a legislative proposal.	veterinary use by means of a monograph system could be a potential alternative. The Commission should therefore submit a report to the European Parliament and the Council examining the feasibility of active substance based review system ('monographs') and other potential alternatives for environmental risk assessment of veterinary medicinal products, accompanied if appropriate by a legislative proposal.

(2 20 rej ve of be tes as en	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
(2 20 rej ve of be tes as em with (28) The protection of technical documentation should be applied to new veterinary medicinal products, as well as to data developed for		by Coreper on 20 December 2017	proposed by the Presidency
(28) The protection of technical documentation should be applied to new veterinary medicinal products, as well as to data developed for	AM 14 (27a) In accordance with Directive 2010/63/EU, it is necessary to replace, reduce or refine testing on wertebrate animals. Implementation of this Regulation should therefore be based on the use of alternative test methods, suitable for the assessment of health and environmental hazards of products, wherever possible.		
with or referring to an existing marketing authorisation, for example in the case of extending use of an existing product to an additional animal species. In this case the variation or marketing authorisation application may refer partly to data submitted in a former marketing authorisation or variation applications, and should include new data specifically developed to support the required innovation of the existing product. (29) Differences in the		 (28) The protection of technical documentation should be applied to new veterinary medicinal products, as well as to data developed for supporting innovations of products with or referring to an existing marketing authorisation []. In this case the variation or marketing authorisation application may refer partly to data submitted in a former marketing authorisation or variation applications, and should include new data specifically developed to support the required innovation of the existing product. (29) Differences in the 	 (28) The protection of technical documentation should be applied to new veterinary medicinal products, as well as to data developed for supporting innovations of products with or referring to an existing marketing authorisation []. In this case the variation or marketing authorisation application may refer partly to data submitted in a former marketing authorisation or variation applications, and should include new data specifically developed to support the required innovation of the existing product. (29) Differences in the



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
manufacturing process of biological		manufacturing process of biological	manufacturing process of biological
products or a change in the excipient		products or a change in the excipient	products or a change in the excipient
used may lead to differences in the		used may lead to differences in the	used may lead to differences in the
generic product characteristics. In an		generic product characteristics. In an	generic product characteristics. In an
application for generic biological		application for generic biological	application for generic biological
veterinary medicinal product the		veterinary medicinal product the	veterinary medicinal product the
bioequivalence should be		bioequivalence should be	bioequivalence should be
demonstrated in order to ensure,		demonstrated in order to ensure,	demonstrated in order to ensure,
based on the existing knowledge,		based on the existing knowledge,	based on the existing knowledge,
that quality, safety and efficacy are		that quality, safety and efficacy are	that quality, safety and efficacy are
similar.		similar.	similar.
(30) In order to avoid unnecessary		(30) In order to avoid unnecessary	(30) In order to avoid unnecessary
administrative and financial burdens		administrative and financial burdens	administrative and financial burdens
both for the competent authorities		both for the competent authorities	both for the competent authorities
and for the pharmaceutical industry,		and for the pharmaceutical industry,	and for the pharmaceutical industry,
as a general rule a marketing		as a general rule a marketing	as a general rule a marketing
authorisation for a veterinary		authorisation for a veterinary	authorisation for a veterinary
medicinal product should be granted		medicinal product should be granted	medicinal product should be granted
for an unlimited period of time.		for an unlimited period of time.	for an unlimited period of time.
Conditions for renewing the approval		Conditions for renewing the approval	Conditions for renewing the approval
of a marketing authorisation should		of a marketing authorisation should	of a marketing authorisation should
be imposed only exceptionally and		be imposed only exceptionally and	be imposed only exceptionally and
should be duly justified.		should be duly justified.	should be duly justified.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
	AM 15		
(31) It is recognised that, in some			
cases, a scientific risk assessment			
alone cannot provide all the			
information on which a risk			
management decision should be			
based, and other relevant factors			
should be taken into account	should <i>also</i> be taken into account	should also be taken into account	should also be taken into account
including societal, economical,	including societal, economical,	including societal, economical,	including societal, economical,
ethical, environmental and welfare			
factors and the feasibility of controls.			
	AM 16		
(32) In certain circumstances where			
a significant animal or public health	a significant animal, environmental	a significant animal or public health	a significant animal or public health
concern exists but scientific	or public health concern exists but	concern exists but scientific	concern exists but scientific
uncertainty persists, appropriate	scientific uncertainty persists,	uncertainty persists, appropriate	uncertainty persists, appropriate
measures can be adopted taking into	appropriate measures can be adopted	measures can be adopted taking into	measures can be adopted taking into
account Article 5(7) of the WTO	taking into account Article 5(7) of	account Article 5(7) of the WTO	account Article 5(7) of the WTO
Agreement on the Application of	the WTO Agreement on the	Agreement on the Application of	Agreement on the Application of
Sanitary and Phytosanitary Measures	Application of Sanitary and	Sanitary and Phytosanitary Measures	Sanitary and Phytosanitary Measures
which has been interpreted for the	Phytosanitary Measures which has	which has been interpreted for the	which has been interpreted for the
Union in the Communication from	been interpreted for the Union in the	Union in the Communication from	Union in the Communication from
the Commission on the precautionary	Communication from the	the Commission on the precautionary	the Commission on the precautionary
principle. In such circumstances,	Commission on the precautionary	principle. In such circumstances,	principle ¹⁰ . In such circumstances,
Member States or the Commission	principle. In such circumstances,	Member States or the Commission	Member States or the Commission
should seek to obtain additional	Member States or the Commission	should seek to obtain additional	should seek to obtain additional
information necessary for a more	should seek to obtain additional	information necessary for a more	information necessary for a more
objective assessment of the particular	information necessary for a more	objective assessment of the particular	objective assessment of the particular

¹⁰ Communication from the Commission on the precautionary principle, COM (2000) 1 (final).

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
concern and should review the	objective assessment of the particular	concern and should review the	concern and should review the
measure accordingly within a	concern and should review the	measure accordingly within a	measure accordingly within a
reasonable period of time.	measure accordingly within a	reasonable period of time.	reasonable period of time.
	reasonable period of time.		
	AM 17		
(33) Antimicrobial resistance to	(33) Antimicrobial resistance to	(33) Antimicrobial resistance to	(33) Antimicrobial resistance to
human and veterinary medicinal	human and veterinary medicinal	human and veterinary medicinal	human and veterinary medicinal
products is a growing health problem	products is a growing health problem	products is a growing health problem	products is a growing health problem
in the Union and worldwide. Many	in the Union and worldwide, thus	in the Union and worldwide. Many	in the Union and worldwide. Many
of the antimicrobials used in animals	involving a common responsibility	of the antimicrobials used in animals	of the antimicrobials used in animals
are also used in humans. Some of	of all actors concerned. Many of the	are also used in humans. Some of	are also used in humans. Some of
those antimicrobials are critical for	antimicrobials used in animals are	those antimicrobials are critical for	those antimicrobials are critical for
preventing or treating life-	also used in humans. Some of those	preventing or treating life-	preventing or treating life-
threatening infections in humans. In	antimicrobials are <i>highly</i> critical for	threatening infections in humans. In	threatening infections in humans. In
order to fight antimicrobial	preventing or treating life-	order to fight antimicrobial	order to fight antimicrobial
resistance a number of measures	threatening infections in humans and	resistance a number of measures	resistance a number of measures
should be taken. It needs to be	their use on animals, whether or not	should be taken. It needs to be	should be taken. Due to the
ensured that appropriate warnings	covered by the terms of a marketing	ensured that appropriate warnings	complexity of the problem, its
and guidance are included on the	authorisation, should be prohibited.	and guidance are included on the	cross-border dimension and the
labels of veterinary antimicrobials.	In order to fight antimicrobial	labels of veterinary antimicrobials.	high economic burden, its impact
Use not covered by the terms of the	resistance a number of measures	Use not covered by the terms of the	goes beyond its severe
marketing authorisation of certain	should be taken. It needs to be	marketing authorisation of certain	consequences for human and
new or critically important	ensured that <i>measures are</i>	new or critically important	animal health and has become a
antimicrobials for humans should be	proportionally applied in both the	antimicrobials for humans should be	global public health concern that
restricted in the veterinary sector.	human and animal sectors and that	restricted in the veterinary sector.	affects the whole of society and
The rules for advertising veterinary	appropriate warnings and guidance	The rules for advertising veterinary	requires urgent and coordinated
antimicrobials should be tightened,	are included on the labels of <i>human</i>	antimicrobials should be tightened,	intersectoral action in accordance
and the authorisation requirements	and veterinary antimicrobials. Use	and the authorisation requirements	with the "One Health" approach.
should sufficiently address the risks	not covered by the terms of the	should sufficiently address the risks	Such action includes strengthening
and benefits of antimicrobial	marketing authorisation of certain	and benefits of antimicrobial	of the prudent use of

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
veterinary medicinal products.	new or critically important	veterinary medicinal products.	antimicrobials, avoiding their
	antimicrobials for humans should be		routine prophylactic and
	restricted in the veterinary sector.		metaphylactic use, actions to
	The rules for advertising veterinary		restrict the use in animals of
	antimicrobials should be tightened,		antimicrobials that are of critical
	and the authorisation requirements		for preventing or treating life-
	should sufficiently address the risks		threatening infections in humans
	and benefits of antimicrobial		and encouraging and incentivizing
	veterinary medicinal products.		the development of new antibiotics.
			It <u>also</u> needs to be ensured that
			appropriate warnings and guidance
			are included on the labels of
			veterinary antimicrobials. Use not
			covered by the terms of the
			marketing authorisation of certain
			new or critically important
			antimicrobials for humans should be
			restricted in the veterinary sector.
			The rules for advertising veterinary
			antimicrobials should be tightened,
			and the authorisation requirements
			should sufficiently address the risks
			and benefits of antimicrobial
			veterinary medicinal products.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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(34) It is necessary to mitigate the		(34) It is necessary to mitigate the	(34) It is necessary to mitigate the
risk of development of antimicrobial		risk of development of antimicrobial	risk of development of antimicrobial
resistance to human and veterinary		resistance to human and veterinary	resistance to human and veterinary
medicinal products. Therefore, an		medicinal products. Therefore, an	medicinal products. Therefore, an
application for an antimicrobial		application for an antimicrobial	application for an antimicrobial
veterinary medicinal product should		veterinary medicinal product should	veterinary medicinal product should
contain information about the		contain information about the	contain information about the
potential risks that use of the product		potential risks that use of the product	potential risks that use of the product
may lead to the development of		may lead to the development of	may lead to the development of
antimicrobial resistance in humans or		antimicrobial resistance in humans or	antimicrobial resistance in humans or
animals or in organisms associated		animals or in organisms associated	animals or in organisms associated
with them. In order to ensure a high		with them. In order to ensure a high	with them. In order to ensure a high
level of public and animal health,		level of public and animal health,	level of public and animal health,
veterinary antimicrobials should only		veterinary antimicrobials should only	veterinary antimicrobials should only
be authorised following a careful		be authorised following a careful	be authorised following a careful
scientific benefit-risk assessment. If		scientific benefit-risk assessment. If	scientific benefit-risk assessment. If
necessary, conditions should be laid		necessary, conditions should be laid	necessary, conditions should be laid
down in the marketing authorisation		down in the marketing authorisation	down in the marketing authorisation
in order to restrict the use of the		in order to restrict the use of the	in order to restrict the use of the
product. This should include		product. This should include	product. This should include
restrictions on the use of the		restrictions on the use of the	restrictions on the use of the
veterinary medicinal product not in		veterinary medicinal product not in	veterinary medicinal product not in
accordance with the terms of the		accordance with the terms of the	accordance with the terms of the
marketing authorisation, in particular		marketing authorisation, in particular	marketing authorisation, in particular
the summary of product		the summary of product	the summary of product
characteristics of the veterinary		characteristics of the veterinary	characteristics of the veterinary
medicinal product.		medicinal product.	medicinal product.



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)	AM 18 (34a) The routine prophylactic and metaphylactic use of antimicrobials on groups of food-producing animals should be brought to an end. Disease should be prevented not by routine recourse to antimicrobials but by good hygiene, husbandry and housing, and sound	by Coreper on 20 December 2017	proposed by the Presidency
 (35) The combined use of several antimicrobial active substances may represent a particular risk with respect to the development of antimicrobial resistance. Combinations of antimicrobial substances should therefore only be authorised where evidence is provided that the benefit-risk balance of the combination is favourable. 	 management practices. AM 19 (35) The combined use of several antimicrobial active substances may represent a particular risk with respect to the development of antimicrobial resistance. Combinations of antimicrobial substances should therefore only be authorised exceptionally where evidence is provided that the long-term benefit-risk balance of the combination is favourable. 	(35) The combined use of several antimicrobial active substances may represent a particular risk with respect to the development of antimicrobial resistance. []	(35) The combined use of several antimicrobial active substances may represent a particular risk with respect to the development of antimicrobial resistance [], which should be taken into account when assessing whether to authorise a veterinary medicinal product.
(36) The development of new antimicrobials has not kept pace with the increase of resistance to existing antimicrobials. Given the limited innovation in developing new antimicrobials it is essential that the efficacy of existing antimicrobials is	AM 20 (36) The development of new antimicrobials has not kept pace with the increase of resistance to existing antimicrobials. Given the limited innovation in developing new antimicrobials it is essential that the efficacy of existing antimicrobials is	(36) The development of new antimicrobials has not kept pace with the increase of resistance to existing antimicrobials. Given the limited innovation in developing new antimicrobials it is essential that the efficacy of existing antimicrobials is	(36) The development of new antimicrobials has not kept pace with the increase of resistance to existing antimicrobials. Given the limited innovation in developing new antimicrobials it is essential that the efficacy of existing antimicrobials is

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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maintained for as long as possible.	maintained for as long as possible.	maintained for as long as possible.	maintained for as long as possible.
The use of antimicrobials in	The use of antimicrobials in	The use of antimicrobials in []	The use of antimicrobials in []
veterinary medicinal products may	veterinary medicinal products may	medicinal products used in animals	medicinal products used in animals
accelerate the emergence and spread	accelerate the emergence and spread	may accelerate the emergence and	may accelerate the emergence and
of resistant micro-organisms and	of resistant micro-organisms and	spread of resistant micro-organisms	spread of resistant micro-organisms
may compromise the effective use of	may compromise the effective use of	and may compromise the effective	and may compromise the effective
the already limited number of	the already limited number of	use of the already limited number of	use of the already limited number of
existing antimicrobials to treat	existing antimicrobials to treat	existing antimicrobials to treat	existing antimicrobials to treat
human infections. Therefore the	human infections. Therefore, the	human infections. Therefore, the	human infections. Therefore, the
misuse of antimicrobials should not	misuse of antimicrobials should not	misuse of antimicrobials should not	misuse of antimicrobials should not
be allowed.	be allowed. <i>Preventive treatments</i>	be allowed. Antimicrobial	be allowed. Antimicrobial
	using antimicrobials should be	medicinal products should not be	medicinal products should not be
	regulated more strictly and	used for prophylaxis unless in well-	used for prophylaxis unless in well-
	recommended only in certain	defined cases for the treatment of a	defined cases for the treatment of
	specific, well-defined cases, in	restricted number of animals when	an <u>individual animal or</u> restricted
	compliance with animal health,	the risk for infection is very high	number of animals when the risk
	biosecurity and nutritional	or its consequences are likely to be	for infection is very high or its
	requirements.	severe. Antibiotic medicinal	consequences are likely to be
		products should not be used for	severe. Antibiotic medicinal
		prophylaxis unless in exceptional	products should not be used for
		cases only for the treatment of	prophylaxis unless in exceptional
		individual animals.	cases only for the <u>administration</u>
			treatment of to an individual
			animal. <u>Antimicrobial medicinal</u>
			products should be used for
			metaphylaxis only when the risk of
			spread of an infection or of an
			<u>infectious disease in a group of</u>
			animals is high and where no
			appropriate alternatives are



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
			available. Such restrictions should
			allow the decrease of prophylactic
			and metaphylactic use in animals
			towards representing a smaller
			proportion of total antimicrobial
			<u>use in animals.</u>
		(36a) In order to strengthen	(36a) In order to strengthen
		Member States' national policies	Member States' national policies
		on prudent use of antimicrobials,	on prudent use of antimicrobials,
		especially those antimicrobials	especially those antimicrobials
		which are important for the	which are important for the
		treatment of infections in humans,	treatment of infections in humans,
		but which are also necessary for	but which are also necessary for
		the use in the veterinary medicine,	the use in the veterinary medicine,
		it may be necessary to restrict or	it may be necessary to restrict or
		prohibit their use. Therefore the	prohibit their use. Therefore the
		Member States should be	Member States should be
		permitted following scientific	permitted following scientific
		recommendations, to define	recommendations, to define
		restrictive conditions for their use,	restrictive conditions for their use,
		e.g. conditioning their prescription	e.g. conditioning their prescription
		to the realisation of antimicrobial	to the realisation of antimicrobial
		susceptibility testing to ensure that	susceptibility testing to ensure that
		there is no other antimicrobials	there is no other antimicrobials
		available sufficiently effective or	available sufficiently effective or
		appropriate to treat diagnosed	appropriate to treat diagnosed
		disease.	disease.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
(37) In order to preserve as long as possible the efficacy of certain antimicrobials in the treatment of infections in humans, it may be necessary to reserve those antimicrobials for humans only. Therefore it should be possible to decide that certain antimicrobials, following the scientific recommendations of the Agency, should not be available on the market in the veterinary sector.	AM 21 (37) In order to preserve as long as possible the efficacy of certain antimicrobials in the treatment of infections in humans, it may be is necessary to reserve those antimicrobials for humans only. Therefore As a baseline, that should apply for the highest priority critically important antimicrobials identified by the World Health Organisation (WHO). Moreover, it should be possible to decide that other critically important certain antimicrobials, following the scientific recommendations of the Agency, should not be available on the market in the veterinary sector.	 (37) In order to preserve as long as possible the efficacy of certain antimicrobials in the treatment of infections in humans, it may be necessary to reserve those antimicrobials for humans only. Therefore it should be possible to decide that certain antimicrobials, following the scientific recommendations of the Agency, should not be available on the market in the veterinary sector. When deciding, the Commission should also take into account available recommendations on the matter provided for by the European Food Safety Agency (EFSA), other relevant Union Agencies, and_international organisations as the World Health Organisation and the Codex Alimentarius. 	 (37) In order to preserve as long as possible the efficacy of certain antimicrobials in the treatment of infections in humans, it may be necessary to reserve those antimicrobials for humans only. Therefore it should be possible to decide that certain antimicrobials, following the scientific recommendations of the Agency, should not be available on the market in the veterinary sector. When deciding, the Commission should also take into account available recommendations on the matter provided for by the European Food Safety Agency Authority (EFSA), and other relevant Union Agencies, which in turn also take into account any relevant recommendations from and international organisations, such as the World Health Organisation, the World Animal Health Organisation and the Codex Alimentarius.



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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	AM 22		
	(37a) As antimicrobial resistance to		
	human and veterinary medicinal		
	products is a growing health		
	problem in the Union and		
	worldwide, action also needs to be		
	taken in the field of human		
	medicine, for example in the form		
	of an instrument incentivising the		
	development of new antibiotics for		
	human use similar to that already		
	proposed within this Regulation.		
	AM 23		
(38) If an antimicrobial is	(38) If an antimicrobial is	(38) If an antimicrobial is	(38) If an antimicrobial is
administered and used incorrectly,	administered and used incorrectly,	administered and used incorrectly,	administered and used incorrectly,
this presents a risk to public or	this presents a risk to public or	this presents a risk to public or	this presents a risk to public or
animal health. Therefore	animal health. Therefore	animal health. Therefore	animal health. Therefore
antimicrobial veterinary medicinal	antimicrobial veterinary medicinal	antimicrobial veterinary medicinal	antimicrobial veterinary medicinal
products should only be available on	products should only be available on	products should only be available on	products should only be available on
veterinary prescription. Persons	veterinary prescription. Persons	veterinary prescription. []	veterinary prescription. []
having the right to prescribe have a	having the right to prescribe have a	Veterinarians have a key role in	Veterinarians have a key role in
key role in ensuring prudent use of	key role in ensuring prudent use of	ensuring prudent use of	ensuring prudent use of
antimicrobials and consequently they	antimicrobials and consequently.	antimicrobials and consequently they	antimicrobials and consequently they
should not be influenced, directly or	Veterinarians have a legal	should not be influenced, directly or	should-not be influenced, directly or
indirectly, by economic incentives	obligation, which is part of their	indirectly, by economic incentives	indirectly, by economic incentives
when prescribing those products.	professional code of conduct, to	when prescribing those products.	when prescribing those products.
Therefore the supply of veterinary	ensure responsible use of veterinary	Furthermore, [] the supply of	Furthermore, [] the supply of
antimicrobials by those health	medicinal products. Tthey should	veterinary medicinal products []	veterinary medicinal products []
professionals should be restricted to	not be influenced, directly or	by [] veterinarians should be	by [] veterinarians should be
the amount required for treatment of	indirectly, by economic incentives	restricted to the amount required for	restricted to the amount required for

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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the animals under their care.	when prescribing those products.	treatment of the animals under their	treatment of the animals under their
	The animal health industry and	care.	care.prescribe such products based
	veterinarians should together		on their knowledge of
	promote responsible use. Therefore	All concerned stakeholders should	antimicrobial resistance, their
	the supply of veterinary	together promote prudent use of	epidemiological and clinical
	antimicrobials by those health	antimicrobials.	knowledge and their
	professionals veterinarians or other		understanding of the risk factors
	persons authorised under national		for the individual animal or group
	<i>law</i> should be restricted to the		of animals. In addition, the
	amount required for treatment of the		veterinarians should respect their
	animals under their care, and only		professional code of conduct.
	once a veterinary diagnosis has		Veterinarians should ensure that
	been established following a clinical		they are not in a situation of
	examination of the animal, or, in		conflict of interest when
	exceptional cases, in the light of		prescribing medicines, while
	continuous health checks on the		recognizing their legitimate
	animal.		activity of retail in accordance
			with national law, in particular not
			to be influenced, directly or
			indirectly, by economic incentives
			when prescribing those products.
			Furthermore, the supply of
			veterinary medicinal products by
			veterinarians should be restricted
			to the amount required for
			treatment of the animals under
			<u>their care.</u>
			All concerned stakeholders should
			together promote prudent use of
			antimicrobials.



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
	AM 24		
	(38a) Prudent use of antimicrobials	(38a) Prudent use of antimicrobials	(38a) Prudent use of antimicrobials
	is a cornerstone in addressing	is a cornerstone in addressing	is a cornerstone in addressing
	antimicrobial resistance. The	antimicrobial resistance. It is	antimicrobial resistance. It is
	Guidelines for the prudent use of	therefore important that guidance	therefore important that guidance
	antimicrobials in veterinary	on prudent use of antimicrobials in	on prudent use of antimicrobials in
	medicine, elaborated by the	veterinary medicine is further	veterinary medicine <u>is taken into</u>
	Commission, need to be considered	elaborated.	account and further elaborated.
	by Member States.	In addition, Member States should	The identification of risk factors
		be allowed to take further	and the development of criteria for
		restrictive measures to implement	initiation of administration of
		national policy on prudent use of	antimicrobials, as well as the
		antimicrobials, provided that those	identification of alternative
		measures do not unduly restrict	measures, could help in avoiding
		the functioning of the internal	the unnecessary use of
		market.	antimicrobial medicinal products,
			including through metaphylaxis
			In addition, Member States should
			be allowed to take further
			restrictive measures to implement
			national policy on prudent use of
			antimicrobials, provided that those
			measures do not unduly restrict
			the functioning of the internal
			market.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
	AM 25		
	(38b) In order to facilitate		
	responsible use of antimicrobials,		
	there is an imperative need for		
	rapid, reliable and efficacious		
	veterinary diagnostics both to		
	identify the cause of disease and to		
	perform antibiotic sensitivity testing.		
	That would facilitate correct		
	diagnosis, allow for a targeted use		
	of antimicrobials, support using as		
	<i>little as possible critically important</i>		
	antimicrobials and therefore, inhibit		
	the development of antimicrobial		
	resistance. There is clear need for		
	future innovation specifically for		
	pen-site diagnosis, and a need to		
	consider carefully whether there is a		
	case for more harmonisation and		
	regulation in this sector.		

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
	AM 26		
(39) It is important to consider the			
international dimension of the			
development of antimicrobial	development of antimicrobial	development of antimicrobial	development of antimicrobial
resistance when assessing the			
benefit-risk balance of certain			
veterinary antimicrobials in the			
Union. Any measure restricting the			
use of those products may affect the			
trade of products of animal origin or			
the competitiveness of certain animal			
production sectors in the Union.			
Moreover, antimicrobial resistant	Moreover, aAntimicrobial resistant	Moreover, antimicrobial resistant	Moreover, a <u>A</u> ntimicrobial resistant
organisms can spread to humans and			
animals in the Union through	animals in the Union through	animals in the Union through	animals in the Union and third
consumption of products of animal	consumption of products of animal	consumption of products of animal	countries through consumption of
origin imported from third countries,	origin imported from third countries,	origin imported from third countries,	products of animal origin from the
from direct contact with animals or	from direct contact with animals or	from direct contact with animals or	Union or imported from third
humans in third countries or by other	humans in third countries or by other	humans in third countries or by other	countries, from direct contact with
means. Therefore, measures	means. Therefore, measures	means. Therefore, measures	animals or humans in third countries
restricting the use of veterinary	restricting the use of veterinary	restricting the use of veterinary	or by other means. Therefore,
antimicrobials in the Union should	antimicrobials in the Union should	antimicrobials in the Union should	measures restricting the use of
be based on scientific advice and	be based on scientific advice and	be based on scientific advice and	veterinary antimicrobials in the
should be considered in the context	should be considered in the context	should be considered in the context	Union should be based on scientific
of cooperation with third countries	of cooperation with third countries	of cooperation with third countries	advice and should be considered in
and international organisations	and international organisations	and international organisations	the context of cooperation with third
addressing antimicrobial resistance	addressing active in advocating the	addressing antimicrobial resistance	countries and international
in order the ensure consistency with	creation of an international strategy	in order the ensure consistency with	organisations. addressing For those
their activities and policies.	to combat antimicrobial resistance,	their activities and policies.	reasons it should also be ensured,
	in order the ensure consistency with		in a non-discriminatory and

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	their activities and policies in line		proportionate manner, that
	with the recent Global Action Plan		operators in third countries
	adopted by the WHO.		respect certain basic conditions
			relating to antimicrobial resistance
			for animals and products of animal
			origin exported to the Union. Any
			such action should fully respect
			Union obligations under relevant
			international agreements. This
			should contribute to the
			international fight against
			antimicrobial resistance, in order the
			ensure consistency with their
			activities and policies in particular
			in line with the WHO Global
			Action Plan and the World
			Organisation for Animal Health
			Strategy on Antimicrobial
			Resistance and the Prudent Use of
			Antimicrobials.
	AM 27		
(40) There is still a lack of	(40) There is still a lack of	(40) There is still a lack of	(40) There is still a lack of
sufficiently detailed and comparable	sufficiently detailed and comparable	sufficiently detailed and comparable	sufficiently detailed and comparable
data at Union level to determine the	data at Union level to determine the	data at Union level to determine the	data at Union level to determine the
trends and identify possible risk	trends and identify possible risk	trends and identify possible risk	trends and identify possible risk
factors that could lead to the	factors that could lead to the	factors that could lead to the	factors that could lead to the
development of measures to limit the	development of measures to limit the	development of measures to limit the	development of measures to limit the
risk from antimicrobial resistance	risk from antimicrobial resistance	risk from antimicrobial resistance	risk from antimicrobial resistance
and to monitor the effect of measures	and to monitor the effect of measures	and to monitor the effect of	and to monitor the effect of
already introduced. Therefore it is	already introduced. Therefore it is	measures already introduced.	measures already introduced.



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important to collect data on the sales	important to collect data on the sales	Therefore it is important to []	Therefore it is important to
and use of antimicrobials in animals,	and use of antimicrobials in animals,	continue the collection of data on	continue the collection of <u>such</u>
data on the use of antimicrobials in	data on the use of antimicrobials in	the sales of antibiotics used in	data [] on the sales of
humans and data on antimicrobial	humans and data on antimicrobial	animals and, further develop also	antibiotics used in animals and
resistant organisms found in animals,	resistant organisms found in animals,	the collection of data on the sales	further develop <u>it in line with a</u>
humans and food. To ensure that the	humans and food. Better data are	and use of all other antimicrobials	<u>stepwise approach.</u> -also the
information collected can be used	needed on how, when, where and	used in animals. This data, when	collection of data on the sales and
effectively, appropriate rules should	why antimicrobials are being used.	available, should be analysed with	use of all other antimicrobials
be laid down concerning the	Therefore, the data collected should	data on the use of antimicrobials in	used in animals. This data, when
collection and the exchange of data.	be broken down by type of	humans and data on antimicrobial	available, should be analysed with
The Member States should be	antimicrobial, species, disease or	resistant organisms found in	data on the use of antimicrobials in
responsible for collecting data on the	<i>infection treated.</i> To ensure that the	animals, humans and food. To	humans and data on antimicrobial
use of antimicrobials under the	information collected can be used	ensure that the information collected	resistant organisms found in
coordination of the Agency.	effectively, appropriate rules should	can be used effectively, appropriate	animals, humans and food. To
	be laid down concerning the	technical rules should be laid down	ensure that the information collected
	collection and the exchange of data.	concerning the collection and the	can be used effectively, appropriate
	The Member States should be	exchange of data. The Member	technical rules should be laid down
	responsible for collecting data on the	States should be responsible for	concerning the collection and the
	use of antimicrobials under the	collecting data on the sales and use	exchange of data. The Member
	coordination of the Agency.	of antimicrobials used in animals	States should be responsible for
		under the coordination of the	collecting data on the sales and use
		Agency. It should be possible to	of antimicrobials used in animals
		make further adjustments to the	under the coordination of the
		obligations on data collection	Agency. It should be possible to
		when the procedures in the	make further adjustments to the
		Member States for the collection	obligations on data collection
		of data on sales and use of	when the procedures in the
		antimicrobials are sufficiently	Member States for the collection
		reliable.	of data on sales and use of
			antimicrobials are sufficiently



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			reliable.
	AM 28		
	(40a) Commercial sensitivity should		
	not be used as an excuse to deny		
	citizens access to information about		
	chemicals affecting their bodies or		
	those of other non-target species in		
	the wider environment. Maximum		
	transparency should be ensured		
	while protecting the most		
	commercially sensitive information.		
(41) The majority of the veterinary		(41) The majority of the veterinary	(41) The majority of the veterinary
medicinal products on the market		medicinal products on the market	medicinal products on the market
have been authorised under national		have been authorised under national	have been authorised under national
procedures. The lack of		procedures. The lack of	procedures. The lack of
harmonisation of summary of		harmonisation of summary of	harmonisation of summary of
product characteristics for veterinary		product characteristics for veterinary	product characteristics for veterinary
medicinal products authorised		medicinal products authorised	medicinal products authorised
nationally in more than one Member		nationally in more than one Member	nationally in more than one Member
State creates additional and		State creates additional and	State creates additional and
unnecessary barriers for the		unnecessary barriers for the	unnecessary barriers for the
circulation of veterinary medicinal		circulation of veterinary medicinal	circulation of veterinary medicinal
products within the Union. It is		products within the Union. It is	products within the Union. It is
necessary to harmonise those		necessary to harmonise those	necessary to harmonise those
summaries of product characteristics.		summaries of product characteristics	summaries of product characteristics
In order to avoid unnecessary costs		at least in regards to dosage, uses	at least in regards to dosage, uses
and burdens for the Member States,		and warnings of the veterinary	and warnings of the veterinary
the Commission and the		medicinal products. [].	medicinal products. [].
pharmaceutical industry, and in order			
to increase the availability of			

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veterinary medicinal products as fast			
as possible, it should be possible to			
harmonise summaries of the products			
characteristics for certain veterinary			
medicinal products in accordance			
with an administrative procedure,			
while taking on board the risk to			
public and animal health and to the			
environment. This harmonisation			
exercise should cover veterinary			
medicinal products authorised before			
2004. ¹¹ .			
(42) In order to reduce		(42) In order to reduce	(42) In order to reduce
administrative burden and maximise		administrative burden and maximise	administrative burden and maximise
the availability of veterinary		the availability of veterinary	the availability of veterinary
medicinal products in the Member		medicinal products in the Member	medicinal products in the Member
States, simplified rules should be laid		States, simplified rules should be laid	States, simplified rules should be laid
down as to how their packaging and		down as to how their packaging and	down as to how their packaging and
labelling are to be presented. The		labelling are to be presented. The	labelling are to be presented. The
textual information provided should		textual information provided should	textual information provided should
be reduced and, if possible, replaced		be reduced and, if possible, []	be reduced and, if possible, []
by pictograms and abbreviations.		pictograms and abbreviations might	pictograms and abbreviations might
Pictograms and abbreviations should		be developed and used as an	be developed and used as an
be standardised across the Union.		alternative to such textual	alternative to such textual
Care should be taken so that those		information Pictograms and	information Pictograms and
rules do not jeopardise public and		abbreviations should be standardised	abbreviations should be standardised
animal health and environmental		across the Union. Care should be	across the Union. Care should be

¹¹ Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (OJ L 136, 30.4.2004, p. 58).

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safety.			
		jeopardise public and animal health	jeopardise public and animal health
(42) In a fitting Manula States		and environmental safety.	and environmental safety.
(43) In addition, Member States		(43) In addition, Member States	(43) In addition, Member States
should be empowered to choose the		should be empowered to choose the	should be empowered to choose the
language of the text used in the		language of the text used in the []	language of the text used in the []
packaging and labelling of veterinary		summary of product	summary of product
medicinal products authorised in		characteristics, labelling and	characteristics, labelling and
their territory. The package leaflet,		package leaflet of veterinary	package leaflet of veterinary
however, should be provided in the		medicinal products authorised in	medicinal products authorised in
official language or languages of the		their territory. []	their territory. []
Member State.			
(44) With a view to increasing		(44) With a view to increasing	(44) With a view to increasing
availability of veterinary medicinal		availability of veterinary medicinal	availability of veterinary medicinal
products in the Union it should be		products in the Union it should be	products in the Union it should be
possible to grant more than one		possible to grant more than one	possible to grant more than one
marketing authorisation for a specific		marketing authorisation for a specific	marketing authorisation for a specific
veterinary medicinal product to the		veterinary medicinal product to the	veterinary medicinal product to the
same marketing authorisation holder		same marketing authorisation holder	same marketing authorisation holder
in the same Member State. In that		in the same Member State. In that	in the same Member State. In that
case all product-related		case all product-related	case all product-related
characteristics of the product and		characteristics of the product and	characteristics of the product and
data in support of the applications for		data in support of the applications for	data in support of the applications for
the product should be identical.		the product should be identical.	the product should be identical.
However, multiple applications for a		However, multiple applications for a	However, multiple applications for a
specific product should not be used		specific product should not be used	specific product should not be used
to circumvent the principles of		to circumvent the principles of	to circumvent the principles of
mutual recognition, and therefore		mutual recognition, and therefore	mutual recognition, and therefore
this type of applications in different		this type of applications in different	this type of applications in different
Member States should take place		Member States should take place	Member States should take place



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inside the procedural framework for		inside the procedural framework for	inside the procedural framework for
mutual recognition.		mutual recognition.	mutual recognition.
(45) Pharmacovigilance rules are		(45) Pharmacovigilance rules are	(45) Pharmacovigilance rules are
necessary for the protection of public		necessary for the protection of	necessary for the protection of
and animal health and the		public and animal health and the	public and animal health and the
environment. Collection of		environment. Collection of	environment. Collection of
information on adverse events should		information on suspected adverse	information on suspected adverse
contribute to the good usage of		events should contribute to the good	events should contribute to the good
veterinary medicinal products.		usage of veterinary medicinal	usage of veterinary medicinal
		products.	products.
			(45aa) Environmental incidents
			observed following the
			administration of a veterinary
			medicinal product to an animal
			shall also be reported as suspected
			adverse events. Such incidents may
			consist for example in a significant
			increase of soil contamination by a
			substance to levels considered
			harmful for the environment or
			high concentrations of veterinary
			medicinal products in drinking
			water produced from surface
			water.
		(45a) The competent authorities,	(45a) The competent authorities,
		the Agency and marketing	the Agency and marketing
		authorisation holders should	authorisation holders should
		encourage and facilitate the	encourage and facilitate the
		reporting of suspected adverse	reporting of suspected adverse
		events in particular by	events in particular by

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538 IIIIai - 2014/0257 (COD)		veterinarians and other health	veterinarians and other health
		care professionals where such	care professionals where such
		events occur during the conduct of their duties.	events occur during the conduct of
		their duties.	their duties <u>, as well as facilitating</u>
			that veterinarians can receive
			appropriate feed back on
			reporting made.
(46) In the light of the experience		(46) In the light of the experience	(46) In the light of the experience
acquired it has become clear that it is		acquired it has become clear that it is	acquired it has become clear that it is
necessary to take measures to		necessary to take measures to	necessary to take measures to
improve the operation of the		improve the operation of the	improve the operation of the
pharmacovigilance system. It should		pharmacovigilance system. It should	pharmacovigilance system. It should
integrate and monitor data at Union		integrate and monitor data at Union	integrate and monitor data at Union
level. It is the interest of the Union to		level. It is the interest of the Union to	level. It is the interest of the Union to
ensure that the veterinary		ensure that the veterinary	ensure that the veterinary
pharmacovigilance systems for all		pharmacovigilance systems for all	pharmacovigilance systems for all
authorised veterinary medicinal		authorised veterinary medicinal	authorised veterinary medicinal
products are consistent. At the same		products are consistent. At the same	products are consistent. At the same
time, it is necessary to take account		time, it is necessary to take account	time, it is necessary to take account
of changes arising as a result of		of changes arising as a result of	of changes arising as a result of
international harmonisation of		international harmonisation of	international harmonisation of
definitions, terminology and		definitions, terminology and	definitions, terminology and
technological developments in the		technological developments in the	technological developments in the
field of pharmacovigilance.		field of pharmacovigilance.	field of pharmacovigilance.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD) (47) Holders of marketing authorisations should be responsible for continuously carrying out pharmacovigilance of the veterinary medicinal products they place on the market. They should collect reports on adverse events relating to their products, including those concerning use outside the terms of the granted marketing authorisation.		by Coreper on 20 December 2017 (47) Holders of marketing authorisations should be responsible for continuously carrying out pharmacovigilance in order to ensure the continuous evaluation of the benefit-risk balance of the veterinary medicinal products they place on the market. They should collect reports on suspected adverse events relating to their products, including those concerning use outside the terms of the granted	proposed by the Presidency(47) Holders of marketing authorisations should be responsible for continuously carrying out pharmacovigilance in order to ensure the continuous evaluation of the benefit-risk balance of the veterinary medicinal products they place on the market. They should collect reports on suspected adverse events relating to their products, including those concerning use outside the terms of the granted
(48) It is necessary to increase the shared use of resources between authorities, and to enhance efficiency of the pharmacovigilance system. Data collected should be uploaded to a single reporting point to ensure that the information is shared. The competent authorities should use those data to ensure the continuous safety and efficacy of the veterinary medicinal products that are on the market.		 outside the terms of the granted marketing authorisation. (48) It is necessary to increase the shared use of resources between authorities, and to enhance efficiency of the pharmacovigilance system. Data collected should be uploaded to a single reporting point to ensure that the information is shared. The competent authorities should use those data to ensure the continuous assessment of the benefit-risk balance [] of the veterinary medicinal products that are on the market. 	 outside the terms of the granted marketing authorisation. (48) It is necessary to increase the shared use of resources between authorities, and to enhance efficiency of the pharmacovigilance system. Data collected should be uploaded to a single reporting point to ensure that the information is shared. The competent authorities should use those data to ensure the continuous assessment of the benefit-risk balance [] of the veterinary medicinal products that are on the market.



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(49) It is necessary, in specific cases, or from a public health and animal health perspective, to complement the safety and efficacy data available at the time of authorisation with additional information following the placing of the product on the market. Therefore the obligation to conduct post- authorisation studies should be imposed on the marketing authorisation holder.	AM 29 (49) It is necessary, <i>I</i> in specific cases <i>it is necessary</i> , from a public health, and animal health <i>or</i> <i>environmental</i> perspective, to complement the safety and efficacy data available at the time of authorisation with additional information following the placing of the product on the market. Therefore the obligation to conduct post- authorisation studies should be imposed on the marketing authorisation holder.	(49) [] In specific cases, it is necessary or from a public health and animal health perspective, to complement the safety and efficacy data available at the time of authorisation with additional information following the placing of the product on the market. Therefore the obligation to conduct post- authorisation studies [] may be imposed on the marketing authorisation holder.	(49) [] In specific cases, it is necessary or from a public health, and animal health <u>and environment</u> perspective, to complement the safety and efficacy data available at the time of authorisation with additional information following the placing of the product on the market. Therefore the obligation to conduct post-authorisation studies [] may be imposed on the marketing authorisation holder.
(50) A pharmacovigilance database at Union level should be established to record and integrate information of adverse events for all veterinary medicinal products authorised in the Union. That database should improve detection of adverse events and should allow and facilitate the pharmacovigilance surveillance and work-sharing between the competent authorities.	AM 30 (50) A pharmacovigilance database at Union level should be established to record and integrate information of adverse events for all veterinary medicinal products authorised in the Union. That database should improve detection of adverse events and should allow and facilitate the pharmacovigilance surveillance and work-sharing between the competent authorities and other concerned authorities, including environmental protection agencies and food safety authorities both at national and Union level.	(50) A pharmacovigilance database at Union level should be established to record and integrate information of suspected adverse events for all veterinary medicinal products authorised in the Union. That database should improve detection of suspected _adverse events and should allow and facilitate the pharmacovigilance surveillance and work-sharing between the competent authorities. The pharmacovigilance database should take into account mechanisms for exchanging data with the existing national	(50) A pharmacovigilance database at Union level should be established to record and integrate information of suspected adverse events for all veterinary medicinal products authorised in the Union. That database should improve detection of suspected _adverse events and should allow and facilitate the pharmacovigilance surveillance and work-sharing between the competent authorities. The pharmacovigilance database should take into account mechanisms for exchanging data with the existing national

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		pharmacovigilance databases.	pharmacovigilance databases.
		(50a) The procedures that	(50a) The procedures that
		competent authorities and the	competent authorities and the
		Agency will adopt in order to	Agency will adopt in order to
		evaluate the suspected adverse	evaluate the suspected adverse
		events that they receive should	events that they receive should
		comply with the implementing act	comply with the implementing act
		on measures on good	on measures on good
		pharmacovigilance practice	pharmacovigilance practice
		adopted by the Commission and,	adopted by the Commission and,
		as appropriate, be based on a	as appropriate, be based on a
		common standard derived from	common standard derived from
		the current Commission guidelines	the current Commission guidelines
		on pharmacovigilance for	on pharmacovigilance for
		veterinary medicinal products.	veterinary medicinal products.
		The evaluation performed by the	The evaluation performed by the
		competent authority or the Agency	competent authority or the Agency
		in this way may be one of the	in this way may be one of the
		means by which it is determined	means by which it is determined
		whether there is any change to the	whether there is any change to the
		benefit-risk balance of those	benefit-risk balance of those
		veterinary medicinal products. It	veterinary medicinal products. It
		is however emphasised that the	is however emphasised that the
		'signal management process' is the	'signal management process' is the
		'gold standard' for this purpose	'gold standard' for this purpose
		and proper attention should be	and proper attention should be
		given to it.	given to it.
		The signal management process	The signal management process



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		consists of tasks of signal	consists of tasks of signal
		detection, validation,	detection, validation,
		confirmation, analysis and	confirmation, analysis and
		prioritisation, assessment and	prioritisation, assessment and
		recommendation for action.	recommendation for action.
(51) It is necessary to exercise		(51) It is necessary to exercise	(51) It is necessary to exercise
control over the entire chain of		control over the entire chain of	control over the entire chain of
distribution of veterinary medicinal		distribution of veterinary medicinal	distribution of veterinary medicinal
products, from manufacture or		products, from manufacture or	products, from manufacture or
import into the Union through supply		import into the Union through supply	import into the Union through supply
to the end-user. Veterinary medicinal		to the end-user. Veterinary medicinal	to the end-user. Veterinary medicinal
products from third countries should		products from third countries should	products from third countries should
comply with the same requirements		comply with the same requirements	comply with the same requirements
which apply to products		which apply to products	which apply to products
manufactured in the Union, or with		manufactured in the Union, or with	manufactured in the Union, or with
requirements which are recognised to		requirements which are recognised to	requirements which are recognised to
be at least equivalent thereto.		be at least equivalent thereto.	be at least equivalent thereto.
			(51a) Parallel trade in veterinary
			medicinal products authorised
			under national, decentralised,
			mutual recognition or subsequent
			recognition procedure should be
			regulated to ensure that the
			principles of the free movement of
			goods are restricted only for the
			purpose of safeguarding public
			and animal health in a harmonised
			manner, respecting the case law of
			the Court. Any administrative
			procedures put in place should not



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			introduce an excessive burden, in
			particular, any approval of a
			licence for the parallel trade
			should be based on a simplified
			procedure. Such parallel trade
			concerns products traded from one
			Member State to another and is
			distinct from imports in that the
			latter are products coming from
			third countries into the Union.
(52) In order to facilitate the		(52) In order to facilitate the	(52) In order to facilitate the
movement of veterinary medicinal		movement of veterinary medicinal	movement of veterinary medicinal
products and to prevent checks		products and to prevent checks	products and to prevent checks
carried out in one Member State		carried out in one Member State	carried out in one Member State
being repeated in others, minimum		being repeated in others, minimum	being repeated in others, minimum
requirements should be applied to		requirements should be applied to	requirements should be applied to
veterinary medicinal products		veterinary medicinal products	veterinary medicinal products
manufactured in or imported from third countries.		manufactured in or imported from third countries.	manufactured in or imported from third countries.
third countries.	AM 314	third countries.	third countries.
	_		
	(52a) In order to ensure that the		
	imports from third countries of		
	veterinary medicinal products,		
	active substances, intermediate		
	products and excipients used as starting materials have been		
	manufactured in accordance with		
	the animal welfare standards		
	established in the Union, unlike for		
	instance the current production		



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338 mai - 2014/0237 (COD)	method utilised in third countries for "pregnant mare serum gonadotropin" (PMSG), the Commission should revise Directive 91/412/EEC and include animal welfare standards in the good manufacturing practice for	by Coreper on 20 December 2017	proposed by the Tresidency
(53) The quality of veterinary	veterinary medicinal products.	(53) The quality of veterinary	(53) The quality of veterinary
medicinal products manufactured		medicinal products manufactured	medicinal products manufactured
within the Union should be		within the Union should be	within the Union should be
guaranteed by requiring compliance		guaranteed by requiring compliance	guaranteed by requiring compliance
with the principles of good		with the principles of good	with the principles of good
manufacturing practice for medicinal		manufacturing practice for medicinal	manufacturing practice for medicinal
products irrespective of the final		products irrespective of the final	products irrespective of the final
destination of the medicinal		destination of the medicinal	destination of the medicinal
products.		products.	products.
		(53a) The good manufacturing practices referred to in this Regulation should take into account the standards of animal welfare when active substances are prepared from animals. Measures for the prevention or minimisation of discharge of active substances into the environment should be also be taken into account. Any such measures should only be adopted following an evaluation of their impact.	(53a) The good manufacturing practices referred to in this Regulation should take into account the <u>Union and</u> <u>international</u> standards of animal welfare when active substances are prepared from animals. Measures for the prevention or minimisation of discharge of active substances into the environment should be also be taken into account. Any such measures should only be adopted following an evaluation of



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			their impact.
		(53b) In order to ensure the	(53b) In order to ensure the
		uniform application of principles	uniform application of principles
		of good manufacturing practices	of good manufacturing practices
		and good distribution practices,	and good distribution practices,
		the compilation of Union	the compilation of Union
		procedures for inspections and	procedures for inspections and
		exchange of information should	exchange of information should
		serve as a basis for competent	serve as a basis for competent
		authorities when performing	authorities when performing
		controls on manufacturers and	controls on manufacturers and
		wholesale distributors.	wholesale distributors.
		(53c) Although inactivated	(53c) Although inactivated
		immunological veterinary	immunological veterinary
		medicinal products referred to in	medicinal products referred to in
		Article 2(2a) should be	Article 2(2a) should be
		manufactured in accordance with	manufactured in accordance with
		the principles of good	the principles of good
		manufacturing practice, detailed	manufacturing practice, detailed
		guidelines of good manufacturing practice should specifically be	guidelines of good manufacturing practice should specifically be
		prepared for these products as the	prepared for these products as the
		way they are manufactured is	way they are manufactured is
		different from industrially	different from industrially
		prepared products. This would	prepared products. This would
		preserve their quality without	preserve their quality without
		hindering their manufacturing and	hindering their manufacturing and
		availability.	availability.
(54) Companies should be in		(54) Companies should be in	(54) Companies should be in
possession of an authorisation to be		possession of an authorisation to be	possession of an authorisation to be

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able to wholesale or retail veterinary		able to wholesale [] veterinary	able to wholesale [] veterinary
medicinal products, so as to		medicinal products and comply with	medicinal products and comply with
guarantee that such medicines are		the principles of good distribution	the principles of good distribution
appropriately stored, transported and		practices , so as to guarantee that	practices , so as to guarantee that
handled. It should be the		such medicines are appropriately	such medicines are appropriately
responsibility of the Member States		stored, transported and handled. It	stored, transported and handled. It
to ensure that those conditions are		should be the responsibility of the	should be the responsibility of the
met. Those authorisations should be		Member States to ensure that those	Member States to ensure that those
valid throughout the Union.		conditions are met. Those	conditions are met. Those
vand unoughout the official.		authorisations should be valid	authorisations should be valid
		throughout the Union and should	throughout the Union and should
		also be required in case of parallel	also be required in case of parallel
		trade of veterinary medicinal	trade of veterinary medicinal
		products.	products.
(55) In order to ensure		(55) In order to ensure	(55) In order to ensure
transparency, a database should be		transparency, a database should be	transparency, a database should be
established at Union level for the		established at Union level for the	established at Union level for the
purposes of publishing a list of		purposes of publishing a list of	purposes of publishing a list of
wholesale distributors who have		wholesale distributors who have	wholesale distributors who have
been found to comply with		been found to comply with	been found to comply with
applicable Union legislation		applicable Union legislation	applicable Union legislation
following an inspection by the		following an inspection by the	following an inspection by the
competent authorities of a Member		competent authorities of a Member	competent authorities of a Member
State.		State.	State.
State.		State.	State.

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	AM 31		
(56) The conditions governing the	(56) The conditions governing the	(56) The conditions governing the	(56) The conditions governing the
supply of veterinary medicinal	supply of veterinary medicinal	supply of veterinary medicinal	supply of veterinary medicinal
products to the public should be	products to the public should be	products to the public should be	products to the public should be
harmonised in the Union. Veterinary	harmonised in the Union. Veterinary	harmonised in the Union. Veterinary	harmonised in the Union. Veterinary
medicinal products should only be	medicinal products should only be	medicinal products should only be	medicinal products should only be
supplied by persons authorised to do	supplied by veterinarians or other	supplied by persons authorised to do	supplied by persons authorised to do
so by the Member State where they	persons authorised to do so by the	so by the Member State where they	so by the Member State where they
are established. At the same time, in	Member State where they are	are established. At the same time, in	are established. At the same time, in
order to improve access to veterinary	established. However, Member	order to improve access to veterinary	order to improve access to veterinary
medicinal products in the Union,	States which do not allow	medicinal products in the Union,	medicinal products in the Union,
retailers that are authorised to supply	prescriptions to be issued by persons	retailers that are authorised to supply	retailers that are authorised to supply
veterinary medicinal products by the	other than veterinarians could	veterinary medicinal products by the	veterinary medicinal products by the
competent authority in the Member	refuse to recognise prescriptions	competent authority in the Member	competent authority in the Member
State where they are established	issued by persons other than	State where they are established	State where they are established
should be allowed to sell prescription	veterinarians in other Member	should be allowed to sell [] non-	should be allowed to sell [] non-
and non-prescription veterinary	States in accordance with their	prescription veterinary medicinal	prescription veterinary medicinal
medicinal products via the Internet to	national laws. At the same time, in	products [] at a distance to buyers	products [] at a distance to buyers
buyers in other Member States.	order to improve access to veterinary	in other Member States. However,	in other Member States. However,
	medicinal products in the Union,	taking into account that in some	taking into account that in some
	retailers that are authorised to supply	Member States, it is current	Member States, it is current
	veterinary medicinal products by the	practice to sell veterinary	practice to sell veterinary
	competent authority in the Member	medicinal products subject to	medicinal products subject to
	State where they are established	prescription at a distance,	prescription at a distance,
	should be allowed to sell prescription	Member States should be allowed	Member States should, subject to
	and nonprescription veterinary	to continue such practice within	certain conditions, be allowed to
	medicinal products, except for	their territory. In such a case,	continue such practice within their
	antimicrobials, via the Internet to	Member States should take	territory. In such a case, Member
	buyers in <i>their own or</i> other Member	appropriate measures to avoid	States should take appropriate
	States. In order to minimise the risk	unintended consequences of such	measures to avoid unintended

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	to animal and human health, online	supply and establish rules on	consequences of such supply and
	sales of antimicrobials should be	appropriate penalties.	establish rules on appropriate
	prohibited.		penalties.
		(56a) Veterinarians should always	(56a) Veterinarians should always
		issue a veterinary prescription	issue a veterinary prescription
		when supplying a prescription	when supplying a prescription
		only veterinary medicinal product	only veterinary medicinal product
		and not administering it	and not administering it
		themselves. Whenever the	themselves. Whenever the
		veterinarians administers such	veterinarians administers such
		medicinal products themselves it	medicinal products themselves it
		should be left up to national	should be left up to national
		provisions to specify whether a	provisions to specify whether a
		veterinary prescription needs to be	veterinary prescription needs to be
		issued. However, veterinarians	issued. However, veterinarians
		should always keep records of the	should always keep records of the
		medicinal products that they have	medicinal products that they have
	A M 22	administered.	administered.
	AM 32		
	(56a) In order to ensure that the		
	lines of distribution and the supply of veterinary medicines are not		
	restricted, where Member States		
	have a legally defined,		
	professionally qualified animal		
	medicines advisor, the		
	professionally qualified animal		
	medicines advisors should continue		
	to prescribe and supply certain		
	veterinary medicines.		
	veterinary meatcines.		



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	AM 33		
	(56b) Any ban on veterinarians		
	supplying medicines could make it		
	impossible for some Member States		
	to maintain a network of		
	veterinarians covering all of their		
	territory. Such territorial coverage		
	is of key importance in ensuring		
	high- quality epidemiological		
	monitoring of existing and		
	emerging diseases.		
	AM 34		
(57) The illegal sale of veterinary			
medicinal products to the public via	medicinal products to the public via	medicinal products to the public []	medicinal products to the public []
the Internet may represent a threat to	the Internet may represent a threat to	at a distance may represent a threat	at a distance may represent a threat
public and animal health, as falsified	public and animal health, as falsified	to public and animal health, as	to public and animal health, as
or substandard medicines may reach	or substandard medicines may reach	falsified or substandard medicines	falsified or substandard medicines
the public in this way. It is necessary	the public in this way. It is necessary	may reach the public in this way. It is	may reach the public in this way. It is
to address this threat. Account	to address this threat. A system	necessary to address this threat.	necessary to address this threat.
should be taken of the fact that	should be introduced to ensure that	Account should be taken of the fact	Account should be taken of the fact
specific conditions for supply of	such products are properly sold and	that specific conditions for supply of	that specific conditions for supply of
medicinal products to the public have	that controls are placed on the	medicinal products to the public have	medicinal products to the public have
not been harmonised at Union level	distribution and falsification of	not been harmonised at Union level	not been harmonised at Union level
and, therefore, Member States may	substances that are potentially	and, therefore, Member States may	and, therefore, Member States may
impose conditions for supplying	dangerous for human use. Account	impose conditions for supplying	impose conditions for supplying
medicinal products to the public	should be taken of the fact that	medicinal products to the public	medicinal products to the public
within the limits of the Treaty.	specific conditions for supply of	within the limits of the Treaty.	within the limits of the Treaty.
	medicinal products to the public have		
	not been harmonised at Union level		
	and, therefore,. To minimise the		



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	risks to animal and human health,		
	the online sale of antimicrobials		
	should be prohibited. Member States		
	<i>might</i> impose conditions for		
	supplying medicinal products to the		
	public within the limits of the Treaty.		
(58) When examining the		(58) When examining the	(58) When examining the
compatibility with Union law of the		compatibility with Union law of the	compatibility with Union law of the
conditions for the supply of		conditions for the supply of	conditions for the supply of
medicinal products, the Court of		medicinal products, the Court of	medicinal products, the Court of
Justice of the European Union has		Justice of the European Union has	Justice of the European Union has
recognised, in the context on		recognised, in the context on	recognised, in the context on
medicinal products for human use,		medicinal products for human use,	medicinal products for human use,
the very particular nature of		the very particular nature of	the very particular nature of
medicinal products whose		medicinal products whose	medicinal products whose
therapeutic effects distinguish them		therapeutic effects distinguish them	therapeutic effects distinguish them
substantially from other goods. The		substantially from other goods. The	substantially from other goods. The
Court of Justice has also held that		Court of Justice has also held that	Court of Justice has also held that
health and life of humans rank		health and life of humans rank	health and life of humans rank
foremost among the assets and		foremost among the assets and	foremost among the assets and
interests protected by the Treaty and		interests protected by the Treaty and	interests protected by the Treaty and
that it is for Member States to		that it is for Member States to	that it is for Member States to
determine the level of protection		determine the level of protection	determine the level of protection
which they wish to afford to public		which they wish to afford to public	which they wish to afford to public
health and the way in which that		health and the way in which that	health and the way in which that
level has to be achieved. Since that		level has to be achieved. Since that	level has to be achieved. Since that
level may vary from one Member		level may vary from one Member	level may vary from one Member
State to another, Member States must		State to another, Member States must	State to another, Member States must
be allowed some discretion as		be allowed some discretion as	be allowed some discretion as
regards the conditions for the supply		regards the conditions for the supply	regards the conditions for the supply

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on their territory of medicinal		on their territory of medicinal	on their territory of medicinal
products to the public. Therefore		products to the public. Therefore	products to the public. Therefore
Member States should be able to		Member States should be able to	Member States should be able to
subject the supply of medicinal		subject the supply of medicinal	subject the supply of medicinal
products offered for sale at a distance		products offered for sale at a distance	products offered for sale at a distance
by means of information society		by means of information society	by means of information society
services to conditions justified by the		services to conditions justified by the	services to conditions justified by the
protection of public health. Such		protection of public health. Such	protection of public health. Such
conditions should not unduly restrict		conditions should not unduly restrict	conditions should not unduly restrict
the functioning of the internal		the functioning of the internal	the functioning of the internal
market.		market.	market.
	AM 35		
	(58a) Member States should, after	(58a) Member States should be	(58a) Member States should be
	informing the Commission, be able	able to subject the supply of	able to subject the supply of
	to subject the supply of veterinary	veterinary medicinal products	veterinary medicinal products
	medicinal products offered for sale	offered for retail to stricter	offered for retail to stricter
	to stricter conditions justified by the	conditions justified by the	conditions justified by the
	protection of public health, animal	protection of public health	protection of public health <u>, animal</u>
	health and the environment,	provided that these conditions are	health or environment, provided
	provided that these conditions are	proportionate to the risk and do	that these conditions are
	proportionate to the risk and do not	not unduly restrict the functioning	proportionate to the risk and do
	unduly restrict the functioning of the internal market.	of the internal market.	not unduly restrict the functioning of the internal market.
(59) In order to ensure high	the internat market.	(59) In order to ensure high	(59) In order to ensure high
standards and safety of the veterinary		standards and safety of the veterinary	standards and safety of the veterinary
medicinal products offered for sale at		medicinal products offered for sale at	medicinal products offered for sale at
a distance, the public should be		a distance, the public should be	a distance, the public should be
assisted in identifying websites		assisted in identifying websites	assisted in identifying websites
which are legally offering such		which are legally offering such	which are legally offering such
medicinal products. A common logo		medicinal products. A common logo	medicinal products. A common logo



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should be established, which is		should be established, which is	should be established, which is
recognisable throughout the Union,		recognisable throughout the Union,	recognisable throughout the Union,
while allowing for the identification		while allowing for the identification	while allowing for the identification
of the Member State where the		of the Member State where the	of the Member State where the
person offering veterinary medicinal		person offering veterinary medicinal	person offering veterinary medicinal
products for sale at a distance is		products for sale at a distance is	products for sale at a distance is
established. The Commission should		established. The Commission should	established. The Commission should
develop the design for such a logo.		develop the design for such a logo.	develop the design for such a logo.
Websites offering veterinary		Websites offering veterinary	Websites offering veterinary
medicinal products for sale at a		medicinal products for sale at a	medicinal products for sale at a
distance to the public should be		distance to the public should be	distance to the public should be
linked to the website of the		linked to the website of the	linked to the website of the
competent authority concerned. The		competent authority concerned. The	competent authority concerned. The
websites of the competent authorities		websites of the competent authorities	websites of the competent authorities
of Member States, as well as that of		of Member States, as well as that of	of Member States, as well as that of
the European Medicines Agency,		the European Medicines Agency,	the European Medicines Agency,
should give an explanation of the use		should give an explanation of the use	should give an explanation of the use
of the logo. All those websites		of the logo. All those websites	of the logo. All those websites
should be linked in order to provide		should be linked in order to provide	should be linked in order to provide
comprehensive information to the		comprehensive information to the	comprehensive information to the
public.		public.	public.
(60) Collection systems for the		(60) Collection systems for the []	(60) Collection systems for the []
take-back of unused or expired		disposal of waste veterinary	disposal of waste veterinary
veterinary medicinal products should		medicinal products should continue	medicinal products should continue
continue to be in place in the		to be in place in the Member States	to be in place in the Member States
Member States in order to control		in order to control any risk that such	in order to control any risk that such
any risk that such products might		products might raise with regard to	products might raise with regard to
raise with regard to the protection of		the protection of animal, human	the protection of animal, human
animal, human health or the		health or the environment.	health or the environment.
environment.			



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(61) Advertising, even on non-		(61) Advertising, even on non-	(61) Advertising, even on non-
prescription medicinal products,		prescription medicinal products,	prescription medicinal products,
could affect public and animal health		could affect public and animal health	could affect public and animal health
and distort competition. Therefore,		and distort competition. Therefore,	and distort competition. Therefore,
advertising of veterinary medicinal		advertising of veterinary medicinal	advertising of veterinary medicinal
products should satisfy certain		products should satisfy certain	products should satisfy certain
criteria. Persons qualified to		criteria. Persons qualified to	criteria. Persons qualified to
prescribe or supply can properly		prescribe or supply can properly	prescribe or supply can properly
evaluate the information available in		evaluate the information available in	evaluate the information available in
advertising because of their		advertising because of their	advertising because of their
knowledge, training and experience		knowledge, training and experience	knowledge, training and experience
in animal health. The advertising of		in animal health. The advertising of	in animal health. The advertising of
veterinary medicinal products to		veterinary medicinal products to	veterinary medicinal products to
persons who cannot properly		persons who cannot properly	persons who cannot properly
appreciate the risk associated with		appreciate the risk associated with	appreciate the risk associated with
their use may lead to medicine		their use may lead to medicine	their use may lead to medicine
misuse or overconsumption which is		misuse or overconsumption which is	misuse or overconsumption which is
liable to harm public or animal		liable to harm public or animal	liable to harm public or animal
health, or the environment.		health, or the environment.	health, or the environment.
		However, in order to preserve the	However, in order to preserve the
		animal health status in their	animal health status in their
		territory, Member States should	territory, Member States should
		be able to allow under restricted	be able to allow under restricted
		conditions advertising of	conditions advertising of
		immunological veterinary	immunological veterinary
		medicinal products also to	medicinal products also to
		professional animal keepers.	professional animal keepers.

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		(61a) With regard to the	(61a) With regard to the
		advertising of veterinary medicinal	advertising of veterinary medicinal
		products, Member States'	products, Member States'
		experience has shown that it is	experience has shown that it is
		necessary to put emphasis on the	necessary to put emphasis on the
		distinction between feed and	distinction between feed and
		biocidal products on the one hand	biocidal products on the one hand
		and veterinary medicinal products	and veterinary medicinal products
		on the other hand, because that	on the other hand, because that
		distinction is often misrepresented	distinction is often misrepresented
		in advertising.	in advertising.
		(61b) The rules of advertisement	(61b) The rules of advertisement
		in this Regulation are to be seen as	in this Regulation are to be seen as
		specific rules that comprise the	specific rules that comprise the
		general rules in Directive	general rules in Directive
		2006/114/EC.	2006/114/EC ¹² .
	AM 36		
(62) Where medicinal products are	(62) Where medicinal products are	(62) Where medicinal products are	(62) Where medicinal products are
authorised within a Member State	authorised within a Member State	authorised within a Member State	authorised within a Member State
and have been prescribed in that	and have been prescribed in that	and have been prescribed in that	and have been prescribed in that
Member State by a member of a	Member State by a member of a	Member State by a veterinarian []	Member State by a veterinarian []
regulated animal health profession	regulated animal health profession	for an individual animal or group of	for an individual animal or group of
for an individual animal or group of	veterinarian or other persons	animals, it should in principle be	animals, it should in principle be
animals, it should in principle be	authorised to do so under national	possible for that veterinary	possible for that veterinary
possible for that veterinary	<i>law</i> for an individual animal or group	prescription to be recognised and for	prescription to be recognised and for
prescription to be recognised and for	of animals, it should in principle be	the medicinal product to be	the medicinal product to be
the medicinal product to be	possible for that veterinary	dispensed in another Member State.	dispensed in another Member State.

¹² Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (OJ *L* 376, 27.12.2006, *p*. 21–27)

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dispensed in another Member State.	prescription to be recognised and for	The removal of regulatory and	The removal of regulatory and
The removal of regulatory and	the medicinal product to be	administrative barriers to such	administrative barriers to such
administrative barriers to such	dispensed in another Member State,	recognition should not affect any	recognition should not affect any
recognition should not affect any	provided that the other Member	professional or ethical duty for	professional or ethical duty for
professional or ethical duty for	State authorises persons with	veterinarians [] to refuse to	veterinarians [] to refuse to
dispensing professionals to refuse to	similar qualifications to issue	dispense the medicine stated in the	dispense the medicine stated in the
dispense the medicine stated in the	prescriptions. The removal of	prescription.	prescription.
prescription.	regulatory and administrative		
	barriers to such recognition should		
	not affect any professional or ethical		
	duty for dispensing professionals to		
	refuse to dispense the medicine		
	stated in the prescription.		
(63) The implementation of the		(63) The implementation of the	(63) The implementation of the
principle of recognition of		principle of recognition of	principle of recognition of
prescriptions should be facilitated by		prescriptions should be facilitated by	prescriptions should be facilitated by
the adoption of a standard		the adoption of a model format []	the adoption of a model format []
prescription, listing the essential		for veterinary prescription, listing	for veterinary prescription, listing
information necessary to ensure the		the essential information necessary	the essential information necessary
safe and efficacious use of the		to ensure the safe and efficacious use	to ensure the safe and efficacious use
product. Nothing should prevent		of the product. Nothing should	of the product. Nothing should
Member States from having further		prevent Member States from having	prevent Member States from having
elements in their prescriptions, as		further elements in their veterinary	further elements in their veterinary
long as this does not prevent		prescriptions, as long as this does not	prescriptions, as long as this does not
prescriptions from other Member		prevent veterinary prescriptions	prevent veterinary prescriptions
States from being recognised.		from other Member States from	from other Member States from
		being recognised.	being recognised.

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(64) Information on veterinary		(64) Information on veterinary	(64) Information on veterinary
medicinal products is essential in		medicinal products is essential in	medicinal products is essential in
order to enable health professionals,		order to enable health professionals,	order to enable health professionals,
authorities and undertakings to make		authorities and undertakings to make	authorities and undertakings to make
informed decisions. A key aspect is		informed decisions. A key aspect is	informed decisions. A key aspect is
the creation of a European database		the creation of a European database	the creation of a European database
that should collate information on		that should collate information on	that should collate information on
marketing authorisations granted in		marketing authorisations granted in	marketing authorisations granted in
the Union. The database should		the Union. The database should	the Union. The database should
enhance overall transparency,		enhance overall transparency,	enhance overall transparency,
streamline and facilitate the flow of		streamline and facilitate the flow of	streamline and facilitate the flow of
information between authorities and		information between authorities and	information between authorities and
prevent multiple reporting		prevent multiple reporting	prevent multiple reporting
requirements.		requirements.	requirements.
	AM 295		
(65) The verification of compliance	(65) The verification of compliance	(65) The verification of compliance	(65) The verification of compliance
with the legal requirements through	with the legal requirements through	with the legal requirements through	with the legal requirements through
controls is of fundamental	controls is of fundamental	controls is of fundamental	controls is of fundamental
importance to ensure that the	importance to ensure that the	importance to ensure that the	importance to ensure that the
objectives of the Regulation are	objectives of the Regulation are	objectives of the Regulation are	objectives of the Regulation are
effectively achieved across the	effectively achieved across the	effectively achieved across the	effectively achieved across the
Union. Therefore the competent	Union. Therefore the competent	Union. Therefore the competent	Union. Therefore the competent
authorities of the Member States	authorities of the Member States	authorities of the Member States	authorities of the Member States
should have the power to perform	should have the power to perform	should have the power to perform	should have the power to perform
inspections at all stages of	inspections at all stages of	inspections at all stages of	inspections at all stages of
production, distribution and use of	production, distribution and use of	production, distribution and use of	production, distribution and use of
veterinary medicinal products. In	veterinary medicinal products and	veterinary medicinal products. In	veterinary medicinal products. In
order to preserve the effectiveness of	should publish annual inspection	order to preserve the effectiveness of	order to preserve the effectiveness of
the inspections, authorities should	<i>reports</i> . In order to preserve the	the inspections, authorities should	the inspections, authorities should
have the possibility to perform	effectiveness of the inspections,	have the possibility to perform	have the possibility to perform



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unannounced inspections.	authorities should have the	unannounced inspections.	unannounced inspections.
	possibility to perform all inspections		
	should be unannounced inspections.		
(66) The frequency of controls		(66) The frequency of controls	(66) The frequency of controls
should be established by the		should be established by the	should be established by the
competent authorities having regard		competent authorities having regard	competent authorities having regard
to the risk and to the level of		to the risk and to the level of	to the risk and to the level of
compliance expected in the different		compliance expected in the different	compliance expected in the different
situations. This approach should		situations. This approach should	situations. This approach should
allow authorities to allocate		allow authorities to allocate	allow authorities to allocate
resources where the risk is the		resources where the risk is the	resources where the risk is the
highest. In some cases, however,		highest. In some cases, however,	highest. In some cases, however,
controls should be performed		controls should be performed	controls should be performed
irrespective of the level of risk or		irrespective of the level of risk or	irrespective of the level of risk or
expected non-compliance, for		expected non-compliance, for	expected non-compliance, for
example prior to granting		example prior to granting	example prior to granting
manufacturing authorisations.		manufacturing authorisations.	manufacturing authorisations.
	AM 38		5
(67) In certain cases failures in	(67) In certain cases failures in	(67) In certain cases failures in	(67) In certain cases failures in
Member States' control system can	Member States' control system can	Member States' control system can	Member States' control system can
substantially hinder the achievement	substantially hinder the achievement	substantially hinder the achievement	substantially hinder the achievement
of the objectives of this Regulation	of the objectives of this Regulation	of the objectives of this Regulation	of the objectives of this Regulation
and may lead to the emergence of	and may lead to the emergence of	and may lead to the emergence of	and may lead to the emergence of
risks to public and animal health and	risks to public and animal health and	risks to public and animal health and	risks to public and animal health and
the environment. To ensure a	the environment. The Commission	the environment. To ensure a	the environment. To ensure a
harmonised approach to inspections	should To ensure a harmonised	harmonised approach to inspections	harmonised approach to inspections
throughout the Union, the	approach to inspections throughout	throughout the Union, the	throughout the Union, the
Commission should be able to carry	the Union, the Commission and	Commission should be able to carry	Commission should be able to carry
out audits in the Member States to	should be able to carry out audits in	out audits in the Member States to	out audits in the Member States to
verify the functioning of national	the Member States to verify the	verify the functioning of national	verify the functioning of national



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control systems.	functioning of national control	control systems. These audits	control systems. These audits
control systems.	systems.	should be carried out so as to	should be carried out so as to
	systems.	avoid unnecessary administrative	avoid unnecessary administrative
		burden and, as far as possible,	burden and, as far as possible,
		coordinated with Member States	coordinated with Member States
		and with any other Commission audits foreseen under the 'Official	and with any other Commission audits foreseen under the 'Official
		Controls Regulation'.	Controls Regulation'.
(68) In order to ensure		(68) In order to ensure	(68) In order to ensure
transparency, impartiality and		transparency, impartiality and	transparency, impartiality and
consistency in the level of		consistency in the level of	consistency in the level of
enforcement activities by Member		enforcement activities by Member	enforcement activities by Member
States, it is necessary for Member		States, it is necessary for Member	States, it is necessary for Member
States to set up an appropriate		States to set up an appropriate	States to set up an appropriate
framework for penalties with a view		framework for penalties with a view	framework for penalties with a view
to imposing effective, proportionate		to imposing effective, proportionate	to imposing effective, proportionate
and dissuasive penalties for non-		and dissuasive penalties for non-	and dissuasive penalties for non-
compliance, as non-compliance can		compliance to this Regulation, as	compliance to this Regulation, as
result in damage to animal and		non-compliance can result in damage	non-compliance can result in damage
public health and the environment.		to animal and public health and the	to animal and public health and the
		environment.	environment.

EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
	by Coreper on 20 December 2017	proposed by the Presidency
		N.B.: According to the memorandum of understanding between the institutions, a unique recital should preferably list all provisions containing implementing and delegated powers. It should be drafted at a later stage by lawyer linguists and relevant recitals of the Commission proposal consequently deleted.
	(69) At the same time, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of laying down the procedure for investigating the infringements and the imposition of fines to the holders of marketing authorisations granted under this Regulation for centrally authorised product , the maximum amounts of these penalties as well as the conditions and methods for their collection.	(69) At the same time, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of laying down the procedure for investigating the infringements and the imposition of fines to the holders of marketing authorisations granted under this Regulation for centrally authorised product , the maximum amounts of these penalties as well as the conditions and methods for their collection.
	(70) Companies and authorities are frequently confronted with the need to distinguish between veterinary medicinal products, feed additives, biocidal products and other products. In order to avoid inconsistencies in	(70) Companies and authorities are frequently confronted with the need to distinguish between veterinary medicinal products, feed additives, biocidal products and other products. In order to avoid inconsistencies in the treatment of such products, to
	EP amendment	by Coreper on 20 December 2017 (69) At the same time, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of laying down the procedure for investigating the infringements and the imposition of fines to the holders of marketing authorisations granted under this Regulation for centrally authorised product , the maximum amounts of these penalties as well as the conditions and methods for their collection. (70) Companies and authorities are frequently confronted with the need to distinguish between veterinary medicinal products, feed additives, biocidal products and other products.



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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increase legal certainty, and to		increase legal certainty, and to	increase legal certainty, and to
facilitate the decision process by		facilitate the decision process by	facilitate the decision process by
Member States, a coordination group		Member States, a coordination group	Member States, a coordination group
of Member States should be		of Member States should be	of Member States should be
established, and among other tasks it		established, and among other tasks it	established, and among other tasks it
should provide on a case-by-case		should provide on a case-by-case	should provide on a case-by-case
basis a recommendation whether a		basis a recommendation whether a	basis a recommendation whether a
product falls within the definition of		product falls within the definition of	product falls within the definition of
a veterinary medicinal product. In		a veterinary medicinal product. In	a veterinary medicinal product. In
order to ensure legal certainty the		order to ensure legal certainty the	order to ensure legal certainty the
Commission may decide whether a		Commission may decide whether a	Commission may decide whether a
specific product is a veterinary		specific product is a veterinary	specific product is a veterinary
medicinal product.		medicinal product.	medicinal product.
	AM 39		
(71) Having regard to the special			
characteristics of homeopathic	characteristics of homeopathic	characteristics of homeopathic	characteristics of homeopathic
veterinary medicinal products,	veterinary medicinal products,	veterinary medicinal products,	veterinary medicinal products,
especially the constituents of these			
products, it is desirable to establish a			
special, simplified registration	special, simplified registration	special, simplified registration	special, simplified registration
procedure and to provide specific			
provisions for labelling for certain	provisions for labelling for certain	provisions for [] package leaflet	provisions for [] package leaflet
homeopathic veterinary medicinal	homeopathic veterinary medicinal	for certain homeopathic veterinary	for certain homeopathic veterinary
products which are placed on the	products which are placed on the	medicinal products which are placed	medicinal products which are placed
market without therapeutic	market without therapeutic	on the market without []	on the market without []
indications. Immunological	indications. Immunological	indications []. The quality aspect	indications []. The quality aspect
homeopathic products cannot follow	homeopathic products cannot follow	of a homeopathic medicinal product	of a homeopathic medicinal product
the simplified registration procedure	the simplified registration procedure	is independent of its use so no	is independent of its use so no
as immunologicals may initiate a	as immunologicals may initiate a	specific provisions should apply with	specific provisions should apply with
response at a high dilution rate. The	response at a high dilution rate. The	regard to the necessary quality	regard to the necessary quality

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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quality aspect of a homeopathic	quality aspect of a homeopathic	requirements and rules.	requirements and rules. Moreover,
medicinal product is independent of	medicinal product is independent of		while the use of homeopathic
its use so no specific provisions	its use so no specific provisions		veterinary medicinal products
should apply with regard to the	should apply with regard to the		authorised under this Regulation is
necessary quality requirements and	necessary quality requirements and		regulated in the same way as other
rules.	rules. Furthermore, it is desirable to		authorised veterinary medicinal
	generally allow, under specific		products, the use of registered
	conditions, the use of homeopathic		homeopathic veterinary medicinal
	medicinal products designed for		products is not regulated in this
	human use, including		Act. The use of such registered
	immunological homeopathic		products is therefore subject to
	products that have a potency		national law which is also the case
	starting from D4, on all animals,		as regards homeopathic medicinal
	including food producing animals.		products registered in accordance
			with Directive 2001/83/EC.
	AM 40		
	(71a) The usual rules governing the		
	authorisation to market veterinary		
	medicinal products should be		
	applied to homeopathic veterinary		
	medicinal products marketed with		
	therapeutic indications or in a form		
	which might present risks which		
	should be balanced against the		
	desired therapeutic effect. Member		
	States should be able to apply		
	particular rules for the evaluation		
	of the results of tests and trials		
	intended to establish the safety and		
	efficacy of these medicinal products		



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
<u>536 mai - 2014/0237 (COD)</u>	for pet animals and exotic species, provided that they notify these rules to the Commission.	by Coreper on 20 December 2017	proposed by the rresidency
(72) In order to follow the scientific developments of the sector, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of amending the rules on designation of homeopathic veterinary medicinal products for which registration procedure should be allowed.		(72) []	(72) []
(73) In order to protect public health, animal health and the environment, the activities and tasks attributed to the Agency in this Regulation should be adequately funded. Those activities, services and tasks should be funded through fees charged to enterprises. Those fees, however, should not affect the right of Member States to charge fees for activities and tasks at national level.	AM 41 (73) In order to protect public health, animal health and the environment, the activities and tasks attributed to the Agency in this Regulation should be adequately funded. Those activities, services and tasks, <i>including the establishment of</i> <i>new information technology</i> <i>services with the aim of reducing</i> <i>bureaucracy</i> , should be funded through fees charged to enterprises <i>and through an increased financial</i> <i>contribution from the Commission</i> . Those fees, however, should not affect the right of Member States to charge fees for activities and tasks at		(73) In order to protect public health, animal health and the environment, the activities and tasks attributed to the Agency in this Regulation should be adequately funded. Those activities, services and tasks should be funded through fees charged to enterprises. Those fees, however, should not affect the right of Member States to charge fees for activities and tasks at national level.



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)	national level.	by Coreper on 20 December 2017	proposed by the Presidency
(74) In order to ensure that annexes	national level.	(74) In order to ensure that the	(74) In order to ensure that the
to this Regulation are adapted to the		requirements regarding the	requirements regarding the
technical and scientific		technical documentation on the	technical documentation on the
developments, the power to adopt		quality, safety and efficacy [] are	quality, safety and efficacy [] are
acts in accordance with Article 290		adapted to the technical and	adapted to the technical and
of the Treaty should be delegated to		scientific developments, the power to	scientific developments, the power to
the Commission.		adopt acts in accordance with Article	adopt acts in accordance with Article
		290 of the Treaty should be	290 of the Treaty should be
		delegated to the Commission.	delegated to the Commission.
		(74a) It is generally accepted that	(74a) It is generally accepted that
		the existing requirements	the existing requirements
		regarding the technical	regarding the technical
		documentation on the quality,	documentation on the quality,
		safety and efficacy of veterinary	safety and efficacy of veterinary
		medicinal products presented	medicinal products presented
		when applying for a marketing	when applying for a marketing
		authorisation in Annex I of	authorisation in Annex I of
		Directive 2001/82/EC as last	Directive 2001/82/EC as last
		amended in 2009 work sufficiently	amended in 2009 work sufficiently
		well in practice. Therefore, there is	well in practice. Therefore, there is
		no urgent need to substantially	no urgent need to substantially
		change those requirements.	change those requirements.
		However, there is a need to adjust	However, there is a need to adjust
		those requirements in order to	those requirements in order to
		respond to the identified	respond to the identified
		discrepancies with the	discrepancies with the international scientific progress or
		international scientific progress or latest developments, including	latest developments, including
		guidance from VICH, WHO,	guidance from VICH, WHO,
		guiuance from vich, who,	guiuance from vich, who,



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		OECD standards, taking into	OECD standards, taking into
		account also the need to develop	account also the need to develop
		specific requirements for novel	specific requirements for novel
		therapy veterinary medicinal	therapy veterinary medicinal
		products while avoiding major	products while avoiding major
		overhaul of the current provisions,	overhaul of the current provisions,
		in particular not altering its	in particular not altering its
		structure.	structure.
(75) In order to adapt this		(75) In order to adapt this	(75) In order to adapt this
Regulation to the scientific		Regulation to the scientific	Regulation to the scientific
developments of the sector, the		developments of the sector, the	developments of the sector, the
power to adopt acts in accordance		power to adopt acts in accordance	power to adopt acts in accordance
with Article 290 of the Treaty should		with Article 290 of the Treaty should	with Article 290 of the Treaty should
be delegated to the Commission in		be delegated to the Commission in	be delegated to the Commission in
respect of the use of a product		respect of the use of a product	respect of the use of a product
outside the terms of the granted		outside the terms of the granted	outside the terms of the granted
marketing authorisation, in particular		marketing authorisation, in particular	marketing authorisation, in particular
regarding establishing a list of		regarding establishing a list of	regarding establishing a list of
antimicrobial veterinary medicinal		antimicrobial veterinary medicinal	antimicrobial veterinary medicinal
products for which such use should		products for which such use should	products for which such use should
be prohibited.		be prohibited.	be prohibited.
(76) In order to adapt this		(76) []	(76) []
Regulation to the scientific			
developments of the sector, the			
power to adopt acts in accordance			
with Article 290 of the Treaty should			
be delegated to the Commission in			
respect of amending the list of			
groups of veterinary medicinal			
products for which the centralised			



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
authorisation procedure shall be			
compulsory.			
(77) In order to adapt this			(77) In order to adapt this
Regulation to the scientific			Regulation to the scientific
developments of the sector, the			developments of the sector, the
power to adopt acts in accordance			power to adopt acts in accordance
with Article 290 of the Treaty should			with Article 290 of the Treaty should
be delegated to the Commission in			be delegated to the Commission in
respect of establishing detailed rules			respect of establishing detailed rules
on the principles for the refusal or			on the principles for the refusal or
restriction of marketing			restriction of marketing
authorisations of antimicrobial			authorisations of antimicrobial
veterinary medicinal products, in			veterinary medicinal products, in
particular with a view to preserving			particular with a view to preserving
the efficacy of certain active			the efficacy of certain active
substances in treating infections in			substances in treating infections in
humans.			humans.
(78) In order to exercise its			(78) In order to exercise its
supervisory powers effectively, the			supervisory powers effectively, the
power to adopt acts in accordance			power to adopt acts in accordance
with Article 290 of the Treaty should			with Article 290 of the Treaty should
be delegated to the Commission in			be delegated to the Commission in
respect of laying down the procedure			respect of laying down the procedure
for investigating the infringements			for investigating the infringements
and the imposition of fines or			and the imposition of fines or
periodic penalty payments to the			periodic penalty payments to the
holders of marketing authorisations			holders of marketing authorisations
granted under this Regulation, the			granted under this Regulation, the
maximum amounts of these penalties			maximum amounts of these penalties
as well as the conditions and			as well as the conditions and



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methods for their collection.			methods for their collection.
(79) In order to introduce			(79) In order to introduce
harmonised standards within the			harmonised standards within the
Union for the methods of gathering			Union for the methods of gathering
data on the use of antimicrobials and			data on the use of antimicrobials and
the methods of transferring of these			the methods of transferring of these
data to the Commission, the power to			data to the Commission, the power to
adopt acts in accordance with Article			adopt acts in accordance with Article
290 of the Treaty should be			290 of the Treaty should be
delegated to the Commission in			delegated to the Commission in
respect of establishing rules on these			respect of establishing rules on these
methods.			methods.
(80) In order to ensure uniform			
conditions for the implementation of			
this Regulation, implementing			
powers should be conferred on the			
Commission. Those powers should			
be exercised in accordance with			
Regulation (EU) No 182/2011 of the			
European Parliament and of the			
Council ¹³ .			



¹³ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
		(80a)When providing services in	(80a)When providing services in
		another Member State	another Member State
		veterinarians should follow any	veterinarians should follow any
		national rules present in the host	national rules present in the host
		Member State pursuant to	Member State pursuant to
		Directive 2005/36 EC on	Directive 2005/36 EC on
		Recognition of Professional	Recognition of Professional
		qualifications and Directive	qualifications and Directive
		2006/123 EC on Services in the	2006/123 EC on Services in the
		Internal Market.	Internal Market.
(81) Taking into account the main		(81) Taking into account the main	(81) Taking into account the main
changes that should be made to the		changes that should be made to the	changes that should be made to the
existing rules, and aiming to improve		existing rules, and aiming to improve	existing rules, and aiming to improve
the functioning of the internal		the functioning of the internal	the functioning of the internal
market, a regulation is the		market, a regulation is the	market, a regulation is the
appropriate legal instrument to		appropriate legal instrument to	appropriate legal instrument to
replace Directive 2001/82/EC in		replace Directive 2001/82/EC in	replace Directive 2001/82/EC in
order to lay down clear, detailed and		order to lay down clear, detailed and	order to lay down clear, detailed and
directly applicable rules. Moreover, a		directly applicable rules. Moreover, a	directly applicable rules. Moreover, a
regulation ensures that legal		regulation ensures that legal	regulation ensures that legal
requirements are implemented at the		requirements are implemented at the	requirements are implemented at the
same time and in a harmonised		same time and in a harmonised	same time and in a harmonised
manner throughout the Union.		manner throughout the Union.	manner throughout the Union.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
		by Coreper on 20 December 2017	proposed by the Presidency
(82) Since the objectives of this		(82) Since the objectives of this	(82) Since the objectives of this
Regulation, namely to establish rules		Regulation, namely to establish rules	Regulation, namely to establish rules
on veterinary medicinal products		on veterinary medicinal products	on veterinary medicinal products
ensuring the protection of human and		ensuring the protection of human and	ensuring the protection of human and
animal health and the environment as		animal health and the environment as	animal health and the environment as
well as the functioning of the internal		well as the functioning of the internal	well as the functioning of the internal
market, cannot be sufficiently		market, cannot be sufficiently	market, cannot be sufficiently
achieved by the Member States, but		achieved by the Member States, but	achieved by the Member States, but
can rather, by reason of its effects, be		can rather, by reason of its effects, be	can rather, by reason of its effects, be
better achieved at Union level, the		better achieved at Union level, the	better achieved at Union level, the
Union may adopt measures, in		Union may adopt measures, in	Union may adopt measures, in
accordance with the principle of		accordance with the principle of	accordance with the principle of
subsidiarity as set out in Article 5 of		subsidiarity as set out in Article 5 of	subsidiarity as set out in Article 5 of
the Treaty on European Union. In		the Treaty on European Union. In	the Treaty on European Union. In
accordance with the principle of		accordance with the principle of	accordance with the principle of
proportionality, as set out in that		proportionality, as set out in that	proportionality, as set out in that
Article, this Regulation does not go		Article, this Regulation does not go	Article, this Regulation does not go
beyond what is necessary in order to		beyond what is necessary in order to	beyond what is necessary in order to
achieve those objectives,		achieve those objectives,	achieve those objectives,
HAVE ADOPTED THIS		HAVE ADOPTED THIS	HAVE ADOPTED THIS
REGULATION:		REGULATION:	REGULATION:

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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Chapter I		Chapter I	Chapter I
Subject matter, scope and		Subject matter, scope and	Subject matter, scope and
definitions		definitions	definitions
Article 1		Article 1	Article 1
Subject matter		Subject matter	Subject matter
	AM 42		
This Regulation lays down rules for	This Regulation lays down rules for	This Regulation lays down rules for	This Regulation lays down rules for
the placing on the market,	the placing on the market,	the placing on the market, []	the placing on the market, []
manufacture, import, export, supply,	development, manufacture, import,	manufactur ing , import, export,	manufacturing, import, export,
pharmacovigilance, control and use	export, wholesale distribution, retail	supply, distribution,	supply, distribution ,
of veterinary medicinal products.	supply, pharmacovigilance, control	pharmacovigilance, control and use	pharmacovigilance, control and use
	and use of veterinary medicinal	of veterinary medicinal products.	of veterinary medicinal products.
	products.		
	AM 43		
	1a. Member States may impose		
	stricter conditions, justified on		
	grounds of public health, animal		
	health and environmental		
	protection, for the use and retail of		
	veterinary medicinal products on		
	their territory, provided that these		
	conditions are proportionate to the		
	risk and do not unduly restrict the		
	functioning of the internal market.		

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	AM 44		
	1b. The Member States shall		
	notify the measures referred to in		
	paragraph 1a to the Commission.		
Article 2		Article 2	Article 2
Scope		Scope	Scope
1. This Regulation shall apply to		1. This Regulation shall apply to	1. This Regulation shall apply to
veterinary medicinal products		veterinary medicinal products	veterinary medicinal products
prepared industrially or by a method		prepared industrially or by a method	prepared industrially or by a method
involving an industrial process and		involving an industrial process and	involving an industrial process and
intended to be placed on the market.		intended to be placed on the market.	intended to be placed on the market.
2. In addition to the products		2. In addition to the products	2. In addition to the products
referred to in paragraph 1, Chapter VI		referred to in paragraph 1, []	referred to in paragraph 1, []
shall also apply to active substances,		Articles 98a and 98b shall also	Articles 98a and 98b shall also
intermediate products and excipients		apply to active substances, [] used	apply to active substances, [] used
used as starting materials in veterinary		as starting materials in veterinary	as starting materials in veterinary
medicinal products.		medicinal products.	medicinal products.
		2a. In addition to the products	2a. In addition to the products
		referred to in paragraph 1,	referred to in paragraph 1,
		Articles 98a, 110, 112, 122, 124,	Articles 98a, 110, 112, 122, 124,
		125 and 133 shall also apply to	125 and 133 shall also apply to
		inactivated immunological	inactivated immunological
		veterinary medicinal products	veterinary medicinal products
		which are manufactured from	which are manufactured from
		pathogens and antigens obtained	pathogens and antigens obtained
		from an animal or animals in an	from an animal or animals in an
		epidemiological unit and used for	epidemiological unit and used for
		the treatment of that animal or	the treatment of that animal or
		those animals in the same	those animals in the same
		epidemiological unit or for the	epidemiological unit or for the

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		treatment of animals in a unit	treatment of animals in a unit
		having confirmed epidemiological	having confirmed epidemiological
		link.	link.
		2b. By way of derogation from	2b. By way of derogation from
		paragraphs 1 and 2, only Articles	paragraphs 1 and 2, only Articles
		98a, 51, 52, 122, 123, 125, 133 and	98a, 51, 52, 122, 123, 125, 133 and
		section 6 of Chapter IV shall apply	section 6 of Chapter IV shall apply
		to veterinary medicinal products	to veterinary medicinal products
		authorised in accordance with	authorised in accordance with
		Article 5(6).	Article 5(6).
		2c. By way of derogation from	2c. By way of derogation from
		paragraph 1, Articles 5 to 12a, 15	paragraph 1, Articles 5 to 12a, 15
		to 28, 30 to 50, 54 to 70, 82 to 86,	to 28, 30 to 50, 54 to 70, 82 to 86,
		98b, 103, 111, 111a, 113, 115 to	98b, 103, 111, 111a, 113, 115 to
		119, 129a, 131 and 135 of this	119, 129a, 131 and 135 of this
		Regulation shall not apply to	Regulation shall not apply to
		homeopathic veterinary medicinal	homeopathic veterinary medicinal
		products which are registered in	products which are registered in
		accordance with Article 89.	accordance with Article 89.
3. In addition to the products		3. In addition to the products	3. In addition to the products
referred to in paragraph 1, Chapter		referred to in paragraph 1, Chapter	referred to in paragraph 1, Chapter
VII shall also apply to:		VII shall also apply to:	VII shall also apply to:
(a) substances that have anabolic,		(a) substances that have anabolic,	(a) substances that have anabolic,
anti-infectious, anti-parasitic, anti-		anti-infectious, anti-parasitic, anti-	anti-infectious, anti-parasitic, anti-
inflammatory, hormonal or		inflammatory, hormonal, narcotic or	inflammatory, hormonal, narcotic or
psychotropic properties and that may		psychotropic properties and that may	psychotropic properties and that may
be used in animals;		be used in animals;	be used in animals;

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
(b) veterinary medicinal products		(b) veterinary medicinal products	(b) veterinary medicinal products
prepared in a pharmacy in accordance		prepared in a pharmacy or by a	prepared in a pharmacy or by a
with a veterinary prescription for an		person permitted to do so under	person permitted to do so under
individual animal or a small group of		national law, in accordance with a	national law, in accordance with a
animals ('magistral formula');		veterinary prescription for an	veterinary prescription for an
		individual animal or a small group of	individual animal or a small group of
		animals ('magistral formula');	animals ('magistral formula');
(c) veterinary medicinal products		(c) veterinary medicinal products	(c) veterinary medicinal products
prepared in a pharmacy in accordance		prepared in a pharmacy in	prepared in a pharmacy in
with the directions of a		accordance with the directions of a	accordance with the directions of a
pharmacopoeia and intended to be		pharmacopoeia and intended to be	pharmacopoeia and intended to be
supplied directly to the end-user		supplied directly to the end-user	supplied directly to the end-user
('officinal formula').		('officinal formula'). Such officinal	('officinal formula'). Such officinal
		formula shall be subject to a	formula shall be subject to a
		veterinary prescription when	veterinary prescription when
		intended for food producing	intended for food producing
		animals.	animals.
4. This Regulation shall not apply		4. This Regulation shall not apply	4. This Regulation shall not apply
to:		to:	to:
(a) inactivated immunological		[]	[]
veterinary medicinal products which			
are manufactured from pathogens and			
antigens obtained from an animal or			
animals from a holding and used for			
the treatment of that animal or those			
animals in the same locality;			

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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(b) veterinary medicinal products		(b) veterinary medicinal products	(b) veterinary medicinal products
containing autologous or allogeneic		containing autologous or allogeneic	containing autologous or allogeneic
cells or tissues that have not been		cells or tissues that have not been	cells or tissues that have not been
subjected to an industrial process;		subjected to an industrial process;	subjected to an industrial process;
(c) veterinary medicinal products		(c) veterinary medicinal products	(c) veterinary medicinal products
based on radio-active isotopes;		based on radio-active isotopes;	based on radio-active isotopes;
(d) feed additives as defined in		(d) feed additives as defined in	(d) feed additives as defined in
Regulation (EC) No 1831/2003 of the		Regulation (EC) No 1831/2003 of	Regulation (EC) No 1831/2003 of
European Parliament and of the		the European Parliament and of the	the European Parliament and of the
Council;		Council;	Council ¹⁴ ;
(e) veterinary medicinal products		(e) veterinary medicinal products	(e) veterinary medicinal products
intended for research and		intended for research and	intended for research and
development.		development.	development.
	AM 45		
	(ea) substances or preparations		
	which are intended exclusively		
	for external use in animals, to		
	clean or groom them or to alter		
	their appearance or body odour,		
	provided that no substances or		
	preparations subject to veterinary		
	prescription have been added to		
	them;		

¹⁴ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 55, 28.3.2011, p. 13).

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	AM 46 (eb) medicated feed and intermediate products as defined, respectively, in points (a) and (b) of Article 2(2) of Regulation (EÚ)/ of the European Parliament and of the Council ¹⁵⁺ AM 47 (ec) feedingstuffs as defined in	(f) medicated feed and intermediate products as defined in Regulation (EU) No [XXXX].	(f) medicated feed and intermediate products as defined in Regulation (EU) No [XXXX].
	Regulation (EU) No 767/2009 of the European Parliament and of the Council.		
		5. This Regulation shall, except as regards the centralised marketing authorisation procedure, be without prejudice to national provisions on fees.	5. This Regulation shall, except as regards the centralised marketing authorisation procedure, be without prejudice to national provisions on fees.
		5a. Nothing in this Regulation shall prevent a Member State from maintaining or introducing on its territory any national control	5a. Nothing in this Regulation shall prevent a Member State from maintaining or introducing on its territory any national control
		measure it deems appropriate regarding narcotic and psychotropic substances.	measure it deems appropriate regarding narcotic and psychotropic substances.
Article 3 Conflict of laws		Article 3 Conflict of laws	Article 3 Conflict of laws

¹⁵ Regulation (EÚ) of the European Parliament and the Council of... on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC (OJL...).

⁺ OJ: Please insert the number in the text, and in the footnote, the number, date and publication reference of document COD 2014/0255.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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1. Where a veterinary medicinal		1. Where a veterinary medicinal	1. Where a veterinary medicinal
product referred to in Article 2(1) also		product referred to in Article 2(1)	product referred to in Article 2(1)
falls within the scope of Regulation		also falls within the scope of	also falls within the scope of
(EU) No 528/2012 of the European		Regulation (EU) No 528/2012 of the	Regulation (EU) No 528/2012 of the
Parliament and of the Council ¹⁶ or		European Parliament and of the	European Parliament and of the
Regulation (EC) No 1831/2003 of the		Council or Regulation (EC) No	Council or Regulation (EC) No
European Parliament and of the		1831/2003 of the European	1831/2003 of the European
Council, and there is a conflict		Parliament and of the Council, and	Parliament and of the Council, and
between the provisions of this		there is a conflict between the	there is a conflict between the
Regulation and the provisions of		provisions of this Regulation and the	provisions of this Regulation and the
Regulation (EU) No 528/2012 or		provisions of Regulation (EU) No	provisions of Regulation (EU) No
Regulation (EC) No 1831/2003, the		528/2012 or Regulation (EC) No	528/2012 or Regulation (EC) No
provisions of this Regulation shall		1831/2003, the provisions of this	1831/2003, the provisions of this
prevail.		Regulation shall prevail.	Regulation shall prevail.
	AM 48		
	1a. In cases of doubt, taking		
	into account all its		
	characteristics, as to whether a		
	product may fall within the		
	definition of a veterinary		
	medicinal product within the		
	meaning of Article 4(1), or		
	within the definition of a product		
	covered by other Union		
	legislation, the provisions of this		
	Regulation shall prevail.		
2. The Commission may, by		2. [] For the purpose of	2. [] For the purpose of

¹⁶ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

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means of implementing acts, adopt		paragraph 1, the Commission may,	paragraph 1, the Commission may,
decisions on whether a specific		by means of implementing acts,	by means of implementing acts,
product or group of products is to be		adopt decisions on whether a specific	adopt decisions on whether a specific
considered as a veterinary medicinal		product or group of products is to be	product or group of products is to be
product. Those implementing acts		considered as a veterinary medicinal	considered as a veterinary medicinal
shall be adopted in accordance with		product. Those implementing acts	product. Those implementing acts
the examination procedure referred to		shall be adopted in accordance with	shall be adopted in accordance with
in Article 145(2).		the examination procedure referred	the examination procedure referred
		to in Article $145(2)$.	to in Article $145(2)$.
Article 4		Article 4	Article 4
Definitions		Definitions	Definitions
For the purposes of this Regulation,		For the purposes of this Regulation,	For the purposes of this Regulation,
the following definitions shall apply:		the following definitions shall apply:	the following definitions shall apply:
(1) 'veterinary medicinal product'		(1) 'veterinary medicinal product'	(1) 'veterinary medicinal product'
means any substance or combination		means any substance or combination	means any substance or combination
of substances which fulfils at least one		of substances which fulfils at least	of substances which fulfils at least
of the following conditions:		one of the following conditions:	one of the following conditions:
(a) it is presented as having		(a) it is presented as having	(a) it is presented as having
properties for treating or preventing		properties for treating or preventing	properties for treating or preventing
disease in animals;		disease in animals;	disease in animals;
	AM 49		
(b) its purpose is to be used in or	(b) its purpose is to <i>it may</i> be	(b) its purpose is to be used in or	(b) its purpose is to be used in or
administered to animals with a view to	used in, or administered to,	administered to animals with a view	administered to animals with a view
restoring, correcting or modifying	animals with a view <i>either</i> to	to restoring, correcting or modifying	to restoring, correcting or modifying
physiological functions by exerting a	restoring, correcting or modifying	physiological functions by exerting a	physiological functions by exerting a
pharmacological, immunological or	physiological functions by	pharmacological, immunological or	pharmacological, immunological or
metabolic action, or to making a	exerting a pharmacological,	metabolic action;	metabolic action;
medical diagnosis;	immunological or metabolic		
_	action, or to making a medical		
	diagnosis;		



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		(ba) its purpose is to be used in animals with a view to making a medical diagnosis [];	(ba) its purpose is to be used in animals with a view to making a medical diagnosis [];
(c) its purpose is to be used for euthanasia of animals;	AM 50 (c) its purpose is to it may be used for euthanasia of in animals;	(c) its purpose is to be used for euthanasia of animals;	(c) its purpose is to be used for euthanasia of animals;
(2) 'substance' means any matter of the following origin:	AM 51 2. 'substance' means any matter of the following <i>irrespective of its</i> origin <i>which</i> <i>may be</i> :	(2) 'substance' means any matter of the following origin:	(2) 'substance' means any matter of the following origin:
(a) human,	AM 52 (a) human, for example human blood and human blood products;	(a) human,	(a) human,
(b) animal,	AM 53 (b) animal, for example micro- organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;	(b) animal,	(b) animal,
(c) vegetable,	AM 54 (c) vegetable, for example micro-organisms, plants, parts of plants, vegetable secretions, extracts;	(c) vegetable,	(c) vegetable,

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	AM 55		
	(ca) fungal;		
	AM 56		
	(cb) microbial;		
	AM 57		
(d) chemical;	(d) chemical, <i>for example</i>	(d) chemical;	(d) chemical;
	elements, naturally occurring		
	chemical materials and chemical		
	products obtained by chemical		
	change or synthesis;		
	AM 58		
	(da) mineral.		
	AM 59		
	2a. 'active substance' means a	(2a) 'active substance' means any	(2a) 'active substance' means any
	substance with a	substance or mixture of substances	substance or mixture of substances
	pharmacological activity;	intended to be used in the	intended to be used in the
		manufacture of a veterinary	manufacture of a veterinary
		medicinal product that, when used	medicinal product that, when used
		in its production, becomes an active ingredient of that product;	in its production, becomes an
		(2b) 'excipient' means any	active ingredient of that product; (2b) 'excipient' means any
		constituent of a veterinary	constituent of a veterinary
		medicinal product other than	medicinal product other than
		active substance(s) and packaging	active substance(s) and packaging
		material;	material;
	AM 60		
(3) 'immunological veterinary	3. 'immunological veterinary	(3) 'immunological veterinary	(3) 'immunological veterinary
medicinal product' means a veterinary	medicinal product' means a	medicinal product' means a	medicinal product' means a
medicinal product consisting of	veterinary medicinal product	veterinary medicinal product []	veterinary medicinal product []
vaccines, toxins, sera or allergen	consisting of, such as vaccines,	intended to be administered to an	intended to be administered to an



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products and intended to be	toxins, sera or allergen products	animal in order to produce active or	animal in order to produce active or
administered to an animal in order to	and intended to be administered to	passive immunity or to diagnose its	passive immunity or to diagnose its
produce active or passive immunity or	an animal in order to produce	state of immunity;	state of immunity;
to diagnose its state of immunity;	active or passive immunity or to		
	diagnose its state of immunity;		
(4) 'biological veterinary medicinal		(4) 'biological veterinary	(4) 'biological veterinary
product' means a veterinary medicinal		medicinal product' means a	medicinal product' means a
product an active substance of which		veterinary medicinal product where	veterinary medicinal product where
is a biological substance;		an active substance [] is a	an active substance [] is a
		biological substance;	biological substance;
(5) 'biological substance' means a		(5) 'biological substance' means a	(5) 'biological substance' means a
substance that is produced by or		substance that is produced by or	substance that is produced by or
extracted from a biological source and that needs for its characterisation and		extracted from a biological source and that needs for its characterisation	extracted from a biological source and that needs for its characterisation
the determination of its quality a		and the determination of its quality a	and the determination of its quality a
combination of physico-chemical- biological testing, together with		combination of physico-chemical- biological testing, together with	combination of physico-chemical- biological testing, together with
knowledge of the production process		knowledge of the production process	knowledge of the production process
and its control;		and its control;	and its control;
(6) 'generic veterinary medicinal		(6) 'generic veterinary medicinal	(6) 'generic veterinary medicinal
product' means a veterinary medicinal		product' means a veterinary	product' means a veterinary
product which has the same		medicinal product which has the	medicinal product which has the
qualitative and quantitative		same qualitative and quantitative	same qualitative and quantitative
composition of active substances and		composition of active substances and	composition of active substances and
the same pharmaceutical form as the		the same pharmaceutical form as the	the same pharmaceutical form as the
reference medicinal product, and with		reference veterinary medicinal	reference veterinary medicinal
regard to which appropriate		product, and with regard to which	product, and with regard to which
bioavailability studies have		[] bioequivalence with the	[] bioequivalence with the
demonstrated a bioequivalence with		reference veterinary medicinal	reference veterinary medicinal
the reference veterinary medicinal		product has been demonstrated;	product has been demonstrated;

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product;		ý t	
		(6a) 'reference veterinary medicinal product' means a veterinary medicinal product authorised within the meaning of the provisions referred to in Article 5(1), based on an application in accordance with the provisions of Article 7;	(6a) 'reference veterinary medicinal product' means a veterinary medicinal product authorised within the meaning of the provisions referred to in Article 5(1), based on an application in accordance with the provisions of Article 7;
(7) 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States;	AM 61 7. 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States; <i>a homeopathic veterinary</i> <i>medicinal product may contain a</i> <i>number of active ingredients;</i> AM 62 7a. 'herbal medicinal product' means any medicinal product,	(7) 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States;	(7) 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States;
	exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more		



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(8) 'antimicrobial resistance' means the ability of microorganisms to survive or to grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to inhibit or kill microorganisms of the same species;	AM 63 8. 'antimicrobial resistance' means the ability of microorganisms to survive or to grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to inhibit halt the growth of or kill microorganisms of the same species;	(8) 'antimicrobial resistance' means the ability of micro-organisms to survive or to grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to inhibit or kill microorganisms of the same species;	(8) 'antimicrobial resistance' means the ability of micro-organisms to survive or to grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to inhibit or kill microorganisms of the same species;
	AM 64 8a. 'antimicrobial' means any compound with a direct action on micro-organisms used for treatment or prevention of infections; antimicrobials include antibacterials, anti- virals, anti-fungals and anti- protozoals; in the context of this Regulation, an antimicrobial substance refers to an antibacterial;	(8a) 'antimicrobial' means any substance with a direct action on micro-organisms used for treatment or prevention of infections including antibiotics, antivirals, antifungals and anti- protozoals;	(8a) 'antimicrobial' means any substance with a direct action on micro-organisms used for treatment or prevention of infections including antibiotics, antivirals, antifungals and anti- protozoals;

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	AM 65		
	8b. 'antiparasitic' means a		(8aa) 'antiparasitic' means a
	medicinal product or substance		substance that kills or interrupts
	used in the treatment of parasitic		the development of parasites, used
	diseases attributable to various		for the purpose of treating or
	causes;		preventing an infection, infestation
			or disease caused or transmitted
			by parasites, including substances
			with a repelling activity.
	AM 66		
	8c. 'antibacterial' means a	(8b) 'antibiotic' means any	(8b) 'antibiotic' means any
	compound with a direct action on	substance with a direct action on	substance with a direct action on
	bacteria used for treatment or	bacteria used for treatment or	bacteria used for treatment or
	prevention of infections;	prevention of infections;	prevention of infections;
		(8c) 'metaphylaxis' means the	(8c) 'metaphylaxis' means the
		treatment of a group of animals	treatment of administration of a
		after the diagnosis of clinical	medicinal product to a group of
		disease in part of the group, with	animals after the diagnosis of
		the aim of treating the clinically	clinical disease in part of the group
		sick animals and controlling the	has been established, with the aim
		spread of the disease to animals in	of treating the clinically sick
		close contact and at risk which	animals and controlling the spread
		may already be subclinically	of the disease to animals in close
		infected;	contact and at risk which may
			already be subclinically infected;

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		(8e) 'prophylaxis' means the treatment of an animal or group of animals, before clinical signs of a disease in order to prevent the occurrence of disease or infection;	(8e) 'prophylaxis' means the treatment of <u>administration of a</u> <u>medicinal product to an animal or</u> group of animals before clinical signs of a disease, in order to prevent the occurrence of disease or infection;
(9) 'clinical trial' means a study which aims to examine under field conditions the safety or efficacy of a veterinary medicinal product or both under normal conditions of animal husbandry or as part of normal veterinary practice for the purpose of obtaining a marketing authorisation or a change thereof;	AM 67 9. 'clinical trial' means a study which aims to examine under field conditions the safety or efficacy of a veterinary medicinal product or both under normal conditions of animal husbandry or as part of normal veterinary practice for the purpose of obtaining a marketing authorisation or a change thereof;	(9) 'clinical trial' means a study which aims to examine under field conditions the safety or efficacy of a veterinary medicinal product or both under normal conditions of animal husbandry or as part of normal veterinary practice for the purpose of obtaining a marketing authorisation or a change thereof;	(9) 'clinical trial' means a study which aims to examine under field conditions the safety or efficacy of a veterinary medicinal product or both under normal conditions of animal husbandry or as part of normal veterinary practice for the purpose of obtaining a marketing authorisation or a change thereof;
(10) 'pre-clinical study' means a study not covered by the definition of clinical trial which aims to investigate the safety or efficacy of a veterinary medicinal product for the purpose of obtaining a marketing authorisation or a change thereof;	AM 68 10. 'pre-clinical study' means a study not covered by the definition of clinical trial which aims to investigate the safety or efficacy of a veterinary medicinal product for the purpose of obtaining a marketing authorisation or a change thereof ;	(10) 'pre-clinical study' means a study not covered by the definition of clinical trial which aims to investigate the safety or efficacy of a veterinary medicinal product for the purpose of obtaining a marketing authorisation or a change thereof;	(10) 'pre-clinical study' means a study not covered by the definition of clinical trial which aims to investigate the safety or efficacy of a veterinary medicinal product for the purpose of obtaining a marketing authorisation or a change thereof;

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(11) 'benefit-risk balance' means an evaluation of the positive effects of the veterinary medicinal product in relation to the following risks relating to the use of that product:	AM 69 11. 'benefit-risk balance' means an evaluation of the positive therapeutic effects of the veterinary medicinal product in relation to the following risks relating to the use of that product:	(11) 'benefit-risk balance' means an evaluation of the positive effects of the veterinary medicinal product in relation to the following risks relating to the use of that product:	(11) 'benefit-risk balance' means an evaluation of the positive effects of the veterinary medicinal product in relation to the following risks relating to the use of that product:
 (a) any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health; (b) any risk of undesirable effects on the environment; (c) any risk relating to the development of antimicrobial resistance; 		 (a) any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health; (b) any risk of undesirable effects on the environment; (c) any risk relating to the development of [] resistance; 	 (a) any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health; (b) any risk of undesirable effects on the environment; (c) any risk relating to the development of [] resistance;
(12) 'common name' means the international non-proprietary name recommended by the World Health Organisation for a veterinary medicinal product, or, if one does not exist, the name generally used;	AM 70 (12) 'common name' means the international non-proprietary name recommended by the World Health Organisation for a veterinary medicinal product, or, if one does not exist, the <i>usual common</i> name generally used;	(12) 'common name' means the international non-proprietary name recommended by the World Health Organisation for a substance [] or, if one does not exist, the name generally used;	(12) 'common name' means the international non-proprietary name recommended by the World Health Organisation for a substance [] or, if one does not exist, the name generally used;

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		(12a) 'name of the veterinary	(12a) 'name of the veterinary
		medicinal product' means either an	medicinal product' means either
		invented name not liable to	an invented name not liable to
		confusion with the common name,	confusion with the common name,
		or a common or scientific name	or a common or scientific name
		accompanied by a trademark or the	accompanied by a trademark or
		name of the marketing	the name of the marketing
		authorisation holder;	authorisation holder;
(13) 'strength' means the content		(13) 'strength' means the content of	(13) 'strength' means the content
of active substances in a veterinary		active substances in a veterinary	of active substances in a veterinary
medicinal product, expressed		medicinal product, expressed	medicinal product, expressed
quantitatively per dosage unit, per		quantitatively per dosage unit, per unit	quantitatively per dosage unit, per
unit of volume or per unit of weight		of volume or per unit of weight	unit of volume or per unit of weight
according to the pharmaceutical		according to the pharmaceutical form;	according to the pharmaceutical
form;			form;
(14) 'competent authority' means		(14) 'competent authority' means an	(14) 'competent authority' means
an authority designated by a Member		authority designated by a Member	an authority designated by a Member
State in accordance with Article 136;		State in accordance with Article 136;	State in accordance with Article 136;
(15) 'labelling' means information		(15) 'labelling' means information on	(15) 'labelling' means information
on the immediate packaging or the		the immediate packaging or the outer	on the immediate packaging or the
outer packaging;		packaging;	outer packaging;
(16) 'outer packaging' means		(16) 'outer packaging' means	(16) 'outer packaging' means
packaging in which is placed the		packaging in which is placed the	packaging in which is placed the
immediate packaging;		immediate packaging;	immediate packaging;

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(17) 'immediate packaging' means		(17) 'immediate packaging' means	(17) 'immediate packaging' means
the container or any other form of		the container or any other form of	the container or any other form of
packaging that is in direct contact		packaging that is in direct contact	packaging that is in direct contact
with the veterinary medicinal		with the veterinary medicinal	with the veterinary medicinal
product;		product;	product;
(18) 'package leaflet' means a documentation leaflet on a veterinary medicinal product which contains information to ensure its safe and efficacious use;	AM 71 (18) 'package leaflet' means a documentation leaflet on a an information leaflet attached to a veterinary medicinal product which is intended for a user of the veterinary medicinal product and which contains information to ensure its safe and efficacious use which are compliant with the information provided for in the summary of product characteristics of the veterinary medicinal product;	(18) 'package leaflet' means a documentation leaflet on a veterinary medicinal product which contains information to ensure its safe and efficacious use;	(18) 'package leaflet' means a documentation leaflet on a veterinary medicinal product which contains information to ensure its safe and efficacious use;
(19) 'letter of access' means an original document, signed by the data owner or its representative, which states that the data may be used for the benefit of a third party by the competent authorities, the Agency or the Commission for the purposes of this Regulation;		(19) 'letter of access' means an original document, signed by the data owner or its representative, which states that the data may be used for the benefit of [] the applicant in relation to the competent authorities, the Agency or the Commission for the purposes of this Regulation;	(19) 'letter of access' means an original document, signed by the data owner or its representative, which states that the data may be used for the benefit of [] the applicant in relation to the competent authorities, the Agency or the Commission for the purposes of this Regulation;



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(20) 'limited market' means a		(20) 'limited market' means a	(20) 'limited market' means a
market for one of the following		market for one of the following	market for one of the following
product types:		product types:	product types:
(a) veterinary medicinal products		(a) veterinary medicinal products	(a) veterinary medicinal products
for the treatment or prevention of		for the treatment or prevention of	for the treatment or prevention of
diseases that occur infrequently or in		diseases that occur infrequently or in	diseases that occur infrequently or in
limited geographical areas;		limited geographical areas;	limited geographical areas;
(b) veterinary medicinal products for animal species other than cattle, sheep, pigs, chickens, dogs and cats;	AM 72 (b) veterinary medicinal products for animal species other than cattle, sheep, pigs, chickens, dogs, and cats, salmon and sheep reared for their meat;	(b) veterinary medicinal products for animal species other than cattle, sheep for meat production , pigs, chickens, dogs and cats;	(b) veterinary medicinal products for animal species other than cattle, sheep for meat production , pigs, chickens, dogs and cats;
(21) 'pharmacovigilance' means the process of monitoring and investigating adverse events;	AM 73 21. 'pharmacovigilance' means the process of monitoring and investigating scientific, control and administrative activities relating to detection, reporting, assessment, understanding, prevention and communication of adverse events which include continuous evaluation of the risk-benefit balance of veterinary medicinal products;	(21) 'pharmacovigilance' means the [] science and activities relating to the detection, assessment, understanding and prevention of suspected adverse events or any other problem related to a medicinal product;	(21) 'pharmacovigilance' means the [] science and activities relating to the detection, assessment, understanding and prevention of suspected adverse events or any other problem related to a medicinal product;

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
 (22) 'pharmacovigilance system master file' means a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised veterinary medicinal products; (23) 'control' means any task performed by a competent authority, including inspections, for the verification of compliance with this 		 (22) 'pharmacovigilance system master file' means a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised veterinary medicinal products; (23) 'control' means any task performed by a competent authority [] for the verification of compliance with this Regulation; 	 (22) 'pharmacovigilance system master file' means a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised veterinary medicinal products; (23) 'control' means any task performed by a competent authority [] for the verification of compliance with this Regulation;
Regulation; (24) 'veterinary prescription' means any prescription for a veterinary medicinal product issued by a professional person qualified to do so in accordance with applicable national law;	AM 74 24. 'veterinary prescription' means any prescription for a veterinary medicinal product issued by a <i>veterinarian or another</i> professional person qualified to do so in accordance with applicable national law <i>once a veterinary diagnosis has</i> <i>been established following a clinical</i> <i>examination of the animal</i> ;	(24) 'veterinary prescription' means a document issued by a veterinarian [] for a veterinary medicinal product or a medicinal product for human use [] for its use in animal(s);	(24) 'veterinary prescription' means a document issued by a veterinarian [] for a veterinary medicinal product or a medicinal product for human use [] for its use in animal(s);
(25) 'withdrawal period' means the minimum period between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal which under normal conditions of use is necessary to	AM 75 25. 'withdrawal period' means the minimum period <i>necessary</i> between the last administration of a veterinary medicinal product to an animal <i>under normal conditions of use</i> , and the production of foodstuffs from that animal, <i>for the purpose of</i>	(25) 'withdrawal period' means the minimum period between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal which under normal conditions of use is necessary to	(25) 'withdrawal period' means the minimum period between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal which under normal conditions of use is necessary to



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ensure that such foodstuffs do not	ensuring which under normal	ensure that such foodstuffs do not	ensure that such foodstuffs do not
contain residues in quantities	conditions of use is necessary to	contain residues in quantities	contain residues in quantities
harmful to public health;	ensure that such foodstuffs do not	harmful to public health;	harmful to public health;
-	contain residues in quantities		_
	harmful to public health greater than		
	the maximum limits established		
	under Regulation (EC) No 470/2009		
	of the European Parliament and of		
	the Council ¹⁷ ;		
	AM 76		
(26) 'making available on the	26. 'making available on the	(26.) []	(26.) []
market' means any supply of a	market' means any supply of a		
veterinary medicinal product for	veterinary medicinal product for		
distribution, consumption or use on	distribution, consumption or use on		
the Union market in the course of a	the Union market of a Member State		
commercial activity, whether in	in the course of a commercial		
return for payment or free of charge;	activity, whether in return for		
	payment or free of charge;		
(27) 'placing on the market' means	F	(27) 'placing on the market' means	(27) 'placing on the market' means
the first making available of a		the first making available of a	the first making available of a
veterinary medicinal product on the		veterinary medicinal product on the	veterinary medicinal product on the
Union market.		whole of the Union market or in one	whole of the Union market or in one
		or more Member States, as	or more Member States, as
		applicable;	applicable;

¹⁷ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152,16.6.2009, p. 11).

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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	AM 77		
	27a. 'essentially similar product'		
	means a generic product that		
	satisfies the criteria of having the		
	same qualitative and quantitative		
	composition in terms of active		
	substances, of having the same		
	pharmaceutical form, and of being		
	bioequivalent to the original		
	product, unless it is apparent in the		
	light of scientific knowledge that it		
	differs from the original product as		
	regards safety and efficacy;		
	AM 78		
	27b. 'marketing authorisation		
	holder' means the holder of a		
	marketing authorisation granted in		
	accordance with this Regulation;		
	AM 79		
	27c. 'good animal husbandry'		
	means the management and care of		
	farm animals by humans for profit		
	whilst ensuring the health and		
	welfare of these animals by		
	respecting and safeguarding the		
	specific needs of each species and		
	by minimising as much as possible		
	the need to use veterinary		
	pharmaceutical products;		
	AM 80		





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	27d. 'responsible use of veterinary		
	medicinal products' means ensuring		
	good husbandry and management		
	practices such as biosecurity		
	measures aiming to keep groups of		
	animals healthy or to limit the		
	spread of disease within an animal		
	population, as well as asking		
	veterinary advice, following		
	vaccination programmes and		
	prescription instructions, and		
	ensuring good hygiene, appropriate		
	nutrition and regular monitoring of		
	health and welfare;		
	AM 81		
	27e. 'adverse events' means any of		
	the undesirable events set out in		
	Article 73(2);		
	AM 82		
	27f. 'serious adverse events'		
	means any adverse event which		
	results in death, is life-threatening,		
	results in significant disability or		
	incapacity, is a congenital anomaly		
	or birth defect, or which results in		
	permanent or prolonged signs in the		
	animals treated;		

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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	AM 83		
	27g. 'curative (therapeutic)		
	treatment' means the treatment of		
	an ill animal or group of animals,		
	when the diagnosis of disease or		
	infection has been made;		
	AM 84		
	27h. 'control treatment		
	(metaphylaxis)' means the		
	treatment of a group of animals		
	after the diagnosis of clinical		
	disease in part of the group, with		
	the aim of treating the clinically		
	sick animals and controlling the		
	spread of the disease to animals in		
	close contact and at risk which may		
	already be subclinically infected;		
	the presence of such a disease in the		
	group shall be established before		
	the product is used;		
	AM 85		
	27i. 'preventive treatment		
	(prophylaxis)' means the treatment		
	of an animal or a group of animals		
	before clinical signs of disease		
	emerge, in order to prevent the		
	occurrence of disease or infection;		

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
558 IIIIai - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
	AM 86		
	(27j) 'parallel importation' means		
	the importation into a Member State		
	of a veterinary medicinal product		
	authorised in another Member State		
	in accordance with this Regulation		
	and having the same characteristics		
	as the veterinary medicinal product		
	authorised in the Member State of		
	import, in particular with:		
	(a) the same qualitative and		
	quantitative composition in terms of		
	active substances and excipients		
	and the same pharmaceutical form;		
	(b) the same therapeutic		
	indications and target species.		
	The medicinal product authorised		
	in the Member State and the		
	product imported in parallel shall		
	have been either harmonised under		
	Article 69 or 70 or authorised in		
	accordance with Articles 46 and 48;		
	AM 87		
	(27k) 'parallel distribution' means		
	distribution from one Member State		
	to another Member State of a		
	veterinary medicinal product		
	authorised under a centralised		
	procedure by an establishment		
	authorised as referred to in Article		



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
550 mai 201 //0257 (COD)	105 which is independent of the holder of the marketing authorisation;		proposed by the Tresidency
	AM 88 (271) 'wholesale distribution ' means all activities consisting of procuring, holding, supplying or exporting veterinary medicinal products, whether in return for payment or free of charge, apart from retail supply; such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorised or entitled to supply medicinal products to the public in accordance with applicable national law;	(28) 'wholesale distribution' means all activities consisting of procuring, holding, supplying or exporting veterinary medicinal products whether for profit or not, apart from retail supply of veterinary medicinal products to the public.	(28) 'wholesale distribution' means all activities consisting of procuring, holding, supplying or exporting veterinary medicinal products whether for profit or not, apart from retail supply of veterinary medicinal products to the public.
	AM 89 (27m) 'name of veterinary medicinal product' means the name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trademark or the name of the marketing authorisation holder;		

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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	AM 90		
	(27n) 'pre-mix for medicated		
	feedingstuffs' means any veterinary		
	medicinal product prepared in		
	advance with a view to the		
	subsequent <i>manufacture of</i>		
	medicated feeding stuffs in		
	accordance with Regulation (EU) of		
	the European Parliament and of the		
	Council. ¹⁸		
		(29) 'aquatic species' means	(29) 'aquatic species' means
		species as defined in Article 4(3) of	species as defined in Article 4(3) of
		Regulation (EU) 2016/429 <u>:</u>	Regulation (EU) 2016/429 ¹⁹ <u>:</u>
		(30) 'Agency' means the	(30) 'Agency' means the
		European Medicines Agency as	European Medicines Agency as
		established by Regulation (EC) No	established by Regulation (EC) No
		726/2004;	726/2004;
		(31) 'food producing animals'	(31) 'food producing animals'
		means food producing animals as	means food producing animals as
		defined in Article 2 (b) of	defined in Article 2 (b) of
		Regulation (EC) No 470/2009;	Regulation (EC) No 470/2009 ²⁰ ;
		(32) 'variation' means a change to	(32) 'variation' means a change to
		the terms of the marketing	the terms of the marketing

¹⁸ *OJ: please insert the number in the document 2014/0255(COD).*

¹⁹ To avoid duplication of definitions, only refers to Article 4(3)in Regulation (EU) 2016/429 (Animal Health Law).

Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p.11).

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		authorisation for a veterinary	authorisation for a veterinary
		medicinal product as referred to in	medicinal product as referred to in
		Article 31;	Article 31;
		(33) 'advertising of veterinary	(33) 'advertising of veterinary
		medicinal products' means the	medicinal products' means the
		making of a representation in any	making of a representation in any
		form in connection with veterinary	form in connection with veterinary
		medicinal products in order to	medicinal products in order to
		promote the supply, distribution,	promote the supply, distribution,
		sale, prescription or use of	sale, prescription or use of
		veterinary medicinal products	veterinary medicinal products
		comprising also the supply of	comprising also the supply of
		samples and sponsorships;	samples and sponsorships;
		(34) 'signal management process'	(34) 'signal management process'
		means a process for performing	means a process for performing
		active surveillance of	active surveillance of
		pharmacovigilance data for	pharmacovigilance data for
		veterinary medicinal products []	veterinary medicinal products []
		in order to assess the	in order to assess the
		pharmacovigilance data and	pharmacovigilance data and
		determine whether there is any	determine whether there is any
		change to the benefit-risk balance	change to the benefit-risk balance
		of those veterinary medicinal	of those veterinary medicinal
		products, with a view to detecting	products, with a view to detecting
		risks to animal health, public	risks to animal health, public
		health and protection of the	health and protection of the
		environment;	environment;
		(35) 'potential serious risk to	(35) 'potential serious risk to
		human or animal health or for the	human or animal health or for the
		environment' means a situation	environment' means a situation

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		where there is a significantly high	where there is a significantly high
		probability that a serious hazard	probability that a serious hazard
		resulting from the use of a	resulting from the use of a
		veterinary medicinal product will	veterinary medicinal product will
		affect human or animal health or	affect human or animal health or
		the environment;	the environment;
		(36) 'novel therapy veterinary	(36) 'novel therapy veterinary
		medicinal product' means a	medicinal product' means a
		veterinary medicinal product	veterinary medicinal product
		specifically designed for gene	specifically designed for gene
		therapy, regenerative medicine,	therapy, regenerative medicine,
		tissue engineering, blood product	tissue engineering, blood product
		therapy, phage therapy, a	therapy, phage therapy, a
		veterinary medicinal product	veterinary medicinal product
		issued from nanotechnologies, or	issued from nanotechnologies, or
		any other therapy which is	any other therapy which is
		considered as nascent field in	considered as nascent field in
		veterinary medicine;	veterinary medicine;
		(37) 'epidemiological unit'means	(37) 'epidemiological unit'means
		an epidemiological unit as defined	an epidemiological unit as defined
		in Article 4(39) of Regulation (EU)	in Article 4(39) of Regulation (EU)
		2016/429.	2016/429.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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Chapter II		Chapter II Marketing and harden	Chapter II
Marketing authorisations –		Marketing authorisations –	Marketing authorisations –
general provisions and rules on		general provisions and rules on	general provisions and rules on
applications		applications	applications
Section 1		Section 1	Section 1
General provisions		General provisions	General provisions
Article 5		Article 5	Article 5
Marketing authorisations		Marketing authorisations	Marketing authorisations
1. A veterinary medicinal product shall be placed on the market only when a marketing authorisation has been granted in respect of the product by a competent authority in accordance with Articles 44, 46 or 48 or by the Commission in accordance with Article 40.	 AM 91 1. Without prejudice to other provisions of this Regulation, A a veterinary medicinal product shall be placed on the market of a Member State only when a marketing authorisation has been granted in respect of the product by a competent authority of that Member State in accordance with Articles 44, 46 or 48 or by the Commission in accordance with Article 40 this Regulation. 	1. A veterinary medicinal product shall be placed on the market only when a marketing authorisation has been granted [] by a competent authority or by the Commission, as applicable, in accordance with Articles 40, 44, 46, [] 48, 48a or 49 [].	1. A veterinary medicinal product shall be placed on the market only when a marketing authorisation has been granted [] by a competent authority or by the Commission, as applicable, in accordance with Articles 40, 44, 46, [] 48, 48a or 49 [].
2. A marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period of time.	AM 92 2. A marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period of time, unless risks to public health, animal health and the environment are detected or new scientific knowledge gives grounds for reexamination of the benefit risk balance. In such	2. A marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period of time.	2. A marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period of time.

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	situations Member States or the Commission shall refer the matter to the Agency in accordance with the procedure described in Article 84.		
	When a previously authorised veterinary medicinal product has not been present on the market in any Member State for a period of five consecutive years, the authorisation granted for that veterinary medicinal product shall cease to be valid.		
	The competent authority may, in exceptional circumstances, and on human or animal health grounds, grant an exemption from the termination of validity referred to in the second subparagraph. Such exemptions shall be duly justified.		
	The marketing authorisation holder shall be responsible for marketing the medicinal product. The designation of a representative shall not relieve the marketing authorisation holder of its legal responsibility.		



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558 final - 2014/0257 (COD) 3. Decisions to grant, refuse,		by Coreper on 20 December 2017 3. Decisions to grant, refuse,	proposed by the Presidency3. Decisions to grant, refuse,
8,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		- 8,,,,	<i>b</i> , <i>j</i> , <i>j</i> ,
suspend, withdraw or vary a		suspend, [] revoke or [] amend	suspend, [] revoke or [] amend
marketing authorisation shall be		by way of a variation a marketing	by way of a variation a marketing
made public.		authorisation shall be made public.	authorisation shall be made public.
4. Applicants for marketing		4. [] A marketing	4. [] A marketing
authorisations and marketing		authorisation for a veterinary	authorisation for a veterinary
authorisation holders shall be		medicinal product shall only be	medicinal product shall only be
established in the Union.		granted to an applicant	granted to an applicant established
		established in the Union. The	in the Union. The requirement to
		requirement to be established in	be established in the Union shall
		the Union shall also apply to	also apply to marketing
		marketing authorisation holders.	authorisation holders.
		5. A marketing authorisation	5. A marketing authorisation
		for a veterinary medicinal product	for a veterinary medicinal product
		intended for one or more food	intended for one or more food
		producing animals may only be	producing animals may only be
		granted if the pharmacologically	granted if the pharmacologically
		active substance(s) is allowed in	active substance(s) is allowed in
		accordance with Regulation (EC)	accordance with Regulation (EC)
		No 470/2009 and any acts adopted	No 470/2009 and any acts adopted
		on the basis thereof for the animal	on the basis thereof for the animal
		species concerned.	species concerned.
		6. [] In the case of veterinary	6 ²¹ . [] In the case of veterinary
		medicinal products [] intended	medicinal products [] intended
		[] for aquarium or pond animals,	[] for aquarium or pond animals,
		ornamental fish, cage birds, homing	ornamental fish, cage birds, homing
		pigeons, terrarium animals, small	pigeons, terrarium animals, small
		rodents, ferrets and rabbits which	rodents, ferrets and rabbits which

²¹ Ex Article 120 amended.



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		are exclusively kept [] as pets	are exclusively kept [] as pets
		[], Member States may permit	[], Member States may permit
		exemptions [] from this Article	exemptions [] from this Article
		[], provided that such products	[], provided that such products
		[] are not subject to a veterinary	[] are not subject to a veterinary
		prescription and that all []	prescription and that all []
		necessary measures are [] in place	necessary measures are [] in place
		in the Member State to prevent	in the Member State to prevent
		unauthorised use of the veterinary	unauthorised use of the veterinary
		medicinal products for other	medicinal products for other
		animals.	animals.
Article 6		Article 6	Article 6
Submission of applications for		Submission of applications for	Submission of applications for
marketing authorisations		marketing authorisations	marketing authorisations
1. Applications shall be submitted		1. Applications shall be submitted	1. Applications shall be submitted
to the competent authority where		to the competent authority where	to the competent authority where
they concern the granting of		they concern the granting of	they concern the granting of
marketing authorisations in		marketing authorisations in	marketing authorisations in
accordance with any of the following		accordance with any of the following	accordance with any of the following
procedures:		procedures:	procedures:
(a) the national procedure laid		(a) the national procedure laid	(a) the national procedure laid
down in Articles 42, 43 and 44;		down in Articles 42[] and 44;	down in Articles 42[] and 44;
(b) the decentralised procedure		(b) the decentralised procedure	(b) the decentralised procedure
laid down in Articles 45 and 46;		laid down in Articles 45 and 46;	laid down in Articles 45 and 46;
	AM 93		
(c) the mutual recognition	(c) the mutual recognition	(c) the mutual recognition	(c) the mutual recognition
procedure laid down in Articles 47	procedure laid down in Articles 47,	procedure laid down in Articles 47	procedure laid down in Articles 47
and 48.	and 48 and 57.	and 48;	and 48;
		(d) the subsequent recognition	(d) the subsequent recognition
		procedure laid down in Article	procedure laid down in Article

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		48a.	48a.
2. Applications for the granting of marketing authorisations in accordance with the centralised marketing authorisation procedure laid down in Articles 38 to 41 shall be submitted to the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004.		2. Applications for the granting of marketing authorisations in accordance with the centralised marketing authorisation procedure laid down in Articles 38 to 41 shall be submitted to the Agency [].	2. Applications for the granting of marketing authorisations in accordance with the centralised marketing authorisation procedure laid down in Articles 38 to 41 shall be submitted to the Agency [].
3. Applications shall be submitted electronically. For applications submitted in accordance with the centralised marketing authorisation procedure, the formats made available by the Agency shall be used.	AM 94 3. Applications shall be submitted electronically or saved in exceptional circumstances and following agreement with a competent authority or in the case of centralised application,- For applications submitted in accordance with the Agency. The Commission, in collaboration with the Member States and with centralised marketing authorisation procedure, the formats made available by the Agency shall be used adopt detailed guidelines on the format of electronic applications.	3. Applications shall be submitted electronically [] and the formats made available by the Agency shall be used.	3. Applications shall be submitted electronically [] and the formats made available by the Agency shall be used.

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4. The applicant shall be responsible for the accuracy of the documents and data submitted.		 4. The applicant shall be responsible for the accuracy of the information and documentation [] submitted. 	4. The applicant shall be responsible for the accuracy of the information and documentation [] submitted.
5. Within 15 days of receipt of the application, the competent authority or the Agency shall notify the applicant of whether all data required in accordance with Article 7 have been presented.	AM 95 5. Within 15 days of receipt of the application-Without prejudice to specific provisions related to the mutual recognition procedure or the decentralised procedure, the competent authority or the Agency shall, within 15 days of receipt of the application, notify the applicant of whether the formal requirements laid down in this Regulation for the application concerned all data required in accordance with Article 7 have been presented-met and whether the application can be subject to scientific assessment.	 5. Within 15 days of receipt of the application, the competent authority or the Agency, as applicable, shall notify the applicant of whether all [] information and documentation required in accordance with Article 7 have been [] submitted and the application is valid. 	5. Within 15 days of receipt of the application, the competent authority or the Agency, as applicable , shall notify the applicant of whether all [] information and documentation required in accordance with Article 7 have been [] submitted and the application is valid .
6. Where the competent authority or the Agency considers that the application is incomplete, it shall inform the applicant accordingly and shall set a time limit for submitting the missing information.	Subject to setemigie assessment.	6. Where the competent authority or the Agency, as applicable , considers that the application is incomplete, it shall inform the applicant accordingly and shall set a time limit for submitting the missing information and documentation . If the applicant fails to provide the missing information and documentation within the time	6. Where the competent authority or the Agency, as applicable , considers that the application is incomplete, it shall inform the applicant accordingly and shall set a time limit for submitting the missing information and documentation . If the applicant fails to provide the missing information and documentation within the time

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		limit set, the application shall be	limit set, the application shall be
		considered to have been	considered to have been
		withdrawn.	withdrawn.
		7. If the applicant fails to	7. If the applicant fails to
		provide a complete translation of	provide a complete translation of
		the required documentation	the required documentation
		within a period of six months from	within a period of six months from
		having received the information	having received the information
		referred to in Article 46(5), 48(5b)	referred to in Article 46(5), 48(5b)
		and Article 48a(2), the application	and Article 48a(2), the application
		shall be considered to have been	shall be considered to have been
		withdrawn.	withdrawn.
		Article 6a	Article 6a
		<i>Languages</i> ²²	Languages
		1. The language or languages of	1. The language or languages of
		the summary of the product	the summary of the product
		characteristics and the information	characteristics and the information
		on the labelling and on the package	on the labelling and on the package
		leaflet shall, unless the Member	leaflet shall, unless the Member
		State [] determines[]	State [] determines[]
		otherwise, be the official language	otherwise, be the official language
		or languages of the [] Member	or languages of the [] Member
		State where the veterinary medicinal	State where the veterinary medicinal
		product is made available on the	product is made available on the
		market.	market.

²² Ex Article 14

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		2. []	2. []
		3. Veterinary medicinal products	3. Veterinary medicinal products
		may be labelled in several	may be labelled in several
		languages.	languages.
Section 2		Section 2	Section 2
Dossier requirements		Dossier requirements	Dossier requirements
Article 7		Article 7	Article 7
Data to be submitted with the		Data to be submitted with the	Data to be submitted with the
application		application	application
1. An application for a marketing		1. An application for a marketing	1. An application for a marketing
authorisation shall contain the		authorisation shall contain the	authorisation shall contain the
following information:		following []:	following []:
(a) the administrative information		(a) the [] information set out in	(a) the [] information set out in
set out in Annex I;		Annex I;	Annex I;
(b) technical documentation		(b) technical documentation	(b) technical documentation
satisfying the requirements set out in		necessary for demonstrating the	necessary for demonstrating the
Annex II;		quality, safety and efficacy of the	quality, safety and efficacy of the
		veterinary medicinal product in	veterinary medicinal product in
		accordance with the requirements	accordance with the requirements
		set out in [Annex II];	set out in Annex II;
(c) the information to be provided		(c) []	(c) []
in the immediate packaging, outer			
packaging and the package leaflet in			
accordance with Articles 9 to 14.			
		(ca) a summary of the	(ca) a summary of the
		pharmacovigilance system master	pharmacovigilance system master
		file.	file.



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
2. Where the application concerns		2. Where the application concerns	2. Where the application concerns
an antimicrobial veterinary medicinal		an antimicrobial veterinary medicinal	an antimicrobial veterinary medicinal
product, the following shall be		product, the following shall be	product, the following shall be
submitted in addition to the		submitted in addition to the	submitted in addition to the
information listed in paragraph 1:		information and technical	information and technical
		documentation listed in paragraph	documentation listed in paragraph
		1:	1:
	AM 96	(a) documentation on [] the	(a) documentation on [] the
(a) documentation on the direct or	(a) documentation on the direct or	direct or indirect risks, to public or	direct or indirect risks, to public or
indirect risks to public or animal	indirect risks to public or animal	animal health or to the environment	animal health or to the environment
health of use of the antimicrobial	health or the environment of use of	of use of the antimicrobial veterinary	of use of the antimicrobial veterinary
veterinary medicinal product in	the antimicrobial veterinary	medicinal product in animals,	medicinal product in animals,
animals,	medicinal product in animals,		
	AM 97		
(b) information about risk	(b) information about risk	(b) information about risk	(b) information about risk
mitigation measures to limit	mitigation measures to limit	mitigation measures to limit	mitigation measures to limit
antimicrobial resistance development	antimicrobial resistance development	antimicrobial resistance development	antimicrobial resistance development
related to the use of veterinary	related to the use of veterinary	related to the use of veterinary	related to the use of veterinary
medicinal product.	medicinal product, <i>including</i>	medicinal product.	medicinal product.
	specifications that the product is not to be used as a routine prophylactic		
	or metaphylactic measure in food-		
	producing animals, and is not to be		
	used in prophylactic group		
	treatments where there has been no		
	diagnosis of disease.		

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 3. Where the application concerns a veterinary medicinal product intended for food-producing target species and containing pharmacologically active substances that are not listed in Table 1 of the Annex to Regulation (EU) No 37/2010 for the animal species in question, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council²³ shall be submitted in addition to the information listed in paragraph 1. 	AM 98 3. Where the application concerns a veterinary medicinal product intended for food-producing target species and containing pharmacologically active substances that are not listed in Table 1 of the Annex to Regulation (EU) No 37/2010 for the animal species in question, a document <i>shall be</i> <i>submitted in addition to the</i> <i>information listed in paragraph 1 of</i> <i>this Article</i> certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council ²⁵ shall be submitted in addition to the information listed in paragraph 1 and that at least six months has elapsed	 Where the application concerns a veterinary medicinal product intended for food-producing [] animals and containing pharmacologically active substances that are not [] allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof for the animal species [] concerned, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with that Regulation [] shall be submitted in addition to the information listed in paragraph 1. 	3. Where the application concerns a veterinary medicinal product intended for food-producing [] animals and containing pharmacologically active substances that are not [] allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof for the animal species [] concerned, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with that Regulation [] shall be submitted in addition to the information listed in paragraph 1.
	from submission of such		
	application.		
4. Paragraph 3 shall not apply to		4. Paragraph 3 shall not apply to	4. Paragraph 3 shall not apply to

²³ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate
veterinary medicinal products intended for animals of the equidae family that have been declared as not being intended for slaughter for human consumption in accordance with Commission Regulation (EC) 504/2008 ²⁴ and the active substances contained in those veterinary medicinal products are not listed in Table 2 of the Annex to Regulation (EU) No 37/2010.		by Coreper on 20 December 2017 veterinary medicinal products intended for animals of the equidae family that have been declared as not being intended for slaughter for human consumption in [] the single lifetime identification document referred to in Article 114(1)(c) of Regulation (EU) 2016/429 and any acts adopted on the basis thereof and the active substances contained in those veterinary medicinal products are not [] allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis	veterinary medicinal products intended for animals of the equidae family that have been declared as not being intended for slaughter for human consumption in [] the single lifetime identification document referred to in Article 114(1)(c) of Regulation (EU) 2016/429 and any acts adopted on the basis thereof and the active substances contained in those veterinary medicinal products are not [] allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis
5. Where the application concerns a veterinary medicinal product containing or consisting of genetically modified organisms within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council the application shall in addition to the documents listed in		 thereof. 5. Where the application concerns a veterinary medicinal product containing or consisting of genetically modified organisms within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council the application shall in addition to the documents listed in 	thereof.5. Where the application concerns a veterinary medicinal product containing or consisting of genetically modified organisms within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council25 the application shall in addition to the documents listed in

²⁴ Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae (OJ L 149, 7.6.2008, p. 3).

²⁵ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p.1).

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paragraph 1 be accompanied by:		paragraph 1 of this Article be accompanied by:	paragraph 1 of this Article be accompanied by:
 (a) a copy of the written consent of		(a) a copy of the written consent of	(a) a copy of the written consent of
the competent authorities to the		the competent authorities to the	the competent authorities to the
deliberate release into the		deliberate release into the	deliberate release into the
environment of the genetically		environment of the genetically	environment of the genetically
modified organisms for research and		modified organisms for research and	modified organisms for research and
development purposes, as provided		development purposes, as provided	development purposes, as provided
for in Part B of Directive		for in Part B of Directive	for in Part B of Directive
2001/18/EC;		2001/18/EC;	2001/18/EC;
(b) the complete technical file		(b) the complete technical file	(b) the complete technical file
supplying the information required		supplying the information required	supplying the information required
under Annexes III and IV to		under Annexes III and IV to	under Annexes III and IV to
Directive 2001/18/EC;		Directive 2001/18/EC;	Directive 2001/18/EC;
(c) the environmental risk		(c) the environmental risk	(c) the environmental risk
assessment in accordance with the		assessment in accordance with the	assessment in accordance with the
principles set out in Annex II to		principles set out in Annex II to	principles set out in Annex II to
Directive 2001/18/EC; and		Directive 2001/18/EC; and	Directive 2001/18/EC; and
(d) the results of any investigations		(d) the results of any investigations	(d) the results of any investigations
performed for the purposes of		performed for the purposes of	performed for the purposes of
research or development.		research or development.	research or development.



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6. Where the application is submitted in accordance with the national procedure laid down in Articles 42, 43 and 44, the applicant shall, in addition to the information listed in paragraph 1, submit a declaration stating that he has not submitted an application for a marketing authorisation for the veterinary medicinal product in another Member State.		6. Where the application is submitted in accordance with the national procedure laid down in Articles 42 [] and 44, the applicant shall, in addition to the information listed in paragraph 1 of this Article, submit a declaration stating that he has not submitted an application for a marketing authorisation and, if applicable, a marketing authorisation has not been granted for the same veterinary medicinal product in another Member State or	6. Where the application is submitted in accordance with the national procedure laid down in Articles 42 [] and 44, the applicant shall, in addition to the information listed in paragraph 1 of this Article, submit a declaration stating that he has not submitted an application for a marketing authorisation and, if applicable, a marketing authorisation has not been granted for the same veterinary medicinal product in another Member State or
7. The Commission shall be		in the Union.	in the Union.
7. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to amend Annexes I and II to adapt the information and documentation requirements to technical and scientific progress.		7. [].	7. [].
Section 3 Clinical trials		Section 3 Clinical trials	Section 3 Clinical trials
Article 8 Approval of clinical trials		Article 8 []Clinical trials	Article 8 []Clinical trials
1. An application for the approval of a clinical trial shall be submitted to a competent authority of the		1. An application for the approval of a clinical trial shall be submitted in accordance with national law to	1. An application for the approval of a clinical trial shall be submitted in accordance with national law to
Member State in which the clinical trial is to take place.		a competent authority of the Member State in which the clinical trial is to	a competent authority of the Member State in which the clinical trial is to



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550 mai 201 //0257 (COD)		take place.	take place.
2. Approvals of clinical trials shall be granted on condition that food-producing animals used in the clinical trials or their produce do not enter the human food chain unless:	AM 100 2. Approvals of clinical trials shall be granted on condition that food-producing animals used in the clinical trials or their produce do not enter the human food chain unless: Member States shall not permit test animals to be used as a source of foodstuffs for human consumption unless the competent authorities have established an appropriate withdrawal period. Such period shall either:	2. Approvals of clinical trials shall be granted on condition that food-producing animals used in the clinical trials or their produce do not enter the [] food chain unless a suitable withdrawal period has been set by the competent authority.	2. Approvals of clinical trials shall be granted on condition that food-producing animals used in the clinical trials or their produce do not enter the [] food chain unless a suitable withdrawal period has been set by the competent authority.
 (a) the tested product is a veterinary medicinal product authorised for the food-producing species used in the clinical trial, and the withdrawal period set out in the summary of the product characteristics is respected, or 	(a) the tested product is a veterinary medicinal product authorised for the food producing species used in the clinical trial, and the withdrawal period set out in the summary of the product characteristics is respected, or be at least as long as the withdrawal period laid down in Article 117, including, where appropriate, a safety factor reflecting the nature of the substance being tested; or	[]	[]

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(b) the tested product is an authorised veterinary medicinal product for target species other than the food-producing species used in the clinical trial and the withdrawal period set out in accordance with Article 117 is respected.	(b) the tested product is an authorised veterinary medicinal product for target species other than the food-producing species used in the clinical trial and the withdrawal period set out in accordance with Article 117 is respected. if maximum residue limits have been established by the Union in accordance with Regulation (EC) No 470/2009, the period shall be such as to ensure that those residue limits will not be exceeded in foodstuffs.		[]
3. The competent authority shall issue a decision on the approval of a clinical trial within 60 days after the receipt of an application. Where the competent authority has not notified the applicant of its decision within that time limit, the clinical trial shall be considered to have been approved.		3. The competent authority shall issue a decision to approve or refuse [] a clinical trial within 60 days of [] the receipt of a valid application. []	3. The competent authority shall issue a decision to approve or refuse [] a clinical trial within 60 days of [] the receipt of a valid application. []
4. The clinical trials referred to in		4. The clinical trials referred to in	4. The clinical trials referred to in
paragraph 1 shall be carried out		paragraph 1 shall be carried out	paragraph 1 shall be carried out
taking due account of the standards		taking due account of [] the	taking due account of [] the
set by the international guidelines on		international guidelines on good	international guidelines on good
good clinical practice of the		clinical practice of the International	clinical practice of the International
International Cooperation on		Cooperation on Harmonisation of	Cooperation on Harmonisation of
Harmonisation of Technical		Technical Requirements for	Technical Requirements for
Requirements for Registration of		Registration of Veterinary Medicinal	Registration of Veterinary Medicinal
Veterinary Medicinal Products.		Products.	Products.



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	AM 101		
	4a. The principles of replacement,		
	reduction and refinement		
	concerning the care and use of live		
	animals for scientific purposes shall		
	be taken into account during the		
	design and performance of clinical		
	trials.		
5. Results of clinical trials shall		5. Data stemming from []	5. Data stemming from []
be submitted with the application for		clinical trials shall be submitted with	clinical trials shall be submitted with
a marketing authorisation for the		the application for a marketing	the application for a marketing
purposes of providing the		authorisation for the purposes of	authorisation for the purposes of
documentation referred to in Article		providing the documentation referred	providing the documentation referred
7(1)(b).		to in Article 7(1)(b).	to in Article 7(1)(b).
6. Data stemming from clinical		6. Data stemming from clinical	6. Data stemming from clinical
trials conducted outside the Union		trials conducted outside the Union	trials conducted outside the Union
may be taken into consideration for		may be taken into consideration for	may be taken into consideration for
the assessment of an application for a		the assessment of an application for a	the assessment of an application for a
marketing authorisation only if those		marketing authorisation only if those	marketing authorisation only if those
trials were designed, implemented		trials were designed, implemented	trials were designed, implemented
and reported in accordance with the		and reported in accordance with []	and reported in accordance with []
standards set by the international		the international guidelines on good	the international guidelines on good
guidelines on good clinical practice		clinical practice of the International	clinical practice of the International
of the International Cooperation on		Cooperation on Harmonisation of	Cooperation on Harmonisation of
Harmonisation of Technical		Technical Requirements for	Technical Requirements for
Requirements for Registration of		Registration of Veterinary Medicinal	Registration of Veterinary Medicinal
Veterinary Medicinal Products.		Products.	Products.
	AM 102		
	6a. The holder of the clinical trial		
	authorisation shall notify the		



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	competent authority of every serious		
	adverse event and all human		
	adverse reactions shall be notified		
	promptly and in any case not later		
	than 15 days following receipt of the		
	information.		
Section 4		Section 4	Section 4
Labelling and package leaflet		Labelling and package leaflet	Labelling and package leaflet
Article 9		Article 9	Article 9
Labelling of the immediate		Labelling of the immediate	Labelling of the immediate
packaging of veterinary medicinal		packaging of veterinary medicinal	packaging of veterinary medicinal
products		products	products
1. The immediate packaging of a		1. The immediate packaging of a	1. The immediate packaging of a
veterinary medicinal product shall		veterinary medicinal product shall	veterinary medicinal product shall
contain only the following		contain [] the following	contain [] the following
information:		information and shall, subject to	information and shall, subject to
		Article 10(3), contain no other	Article 10(3), contain no other
		information:	information:
(a) the name of the veterinary		(a) the name of the veterinary	(a) the name of the veterinary
medicinal product, followed by its		medicinal product, followed by its	medicinal product, followed by its
strength and pharmaceutical form;		strength and pharmaceutical form;	strength and pharmaceutical form;
(b) a statement of the active		(b) a statement of the active	(b) a statement of the active
substances expressed qualitatively		substances expressed qualitatively	substances expressed qualitatively
and quantitatively per unit or		and quantitatively per unit or	and quantitatively per unit or
according to the form of		according to the form of	according to the form of
administration for a particular		administration for a particular	administration for a particular
volume or weight, using their		volume or weight, using their	volume or weight, using their
common names;		common names;	common names;
(c) the batch number, preceded by		(c) the batch number, preceded by	(c) the batch number, preceded by
the word "Lot";		the word "Lot";	the word "Lot";



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(d) the name or corporate name or		(d) the name or corporate name or	(d) the name or corporate name or
logo name of the marketing		logo name of the marketing	logo name of the marketing
authorisation holder;		authorisation holder;	authorisation holder;
(e) the target species;		(e) the target species;	(e) the target species;
(f) the expiry date, in the format:		(f) the expiry date, in the format:	(f) the expiry date, in the format:
"mm/yyyy", preceded by the		"mm/yyyy", preceded by the	"mm/yyyy", preceded by the
abbreviation "Exp.";		abbreviation "Exp.";	abbreviation "Exp.";
(g) special storage precautions, if		(g) special storage precautions, if	(g) special storage precautions, if
any.		any;	any;
		(h)	(h)
		(i) route of administration	(i) route of administration
		(j) if applicable, the withdrawal	(j) if applicable, the withdrawal
		period, even if it is zero.	period, even if it is zero.
	AM 103		
	1a. In exceptional cases,		
	additional information in		
	accordance with Article 30 may be		
	included, on request of the		
	applicant or the competent authority		
	when it is absolutely necessary to		
	ensure the safe and correct		
	administration of the product.		
2. The information listed in		2. The information listed in	2. The information listed in
paragraph 1 shall appear in easily		paragraph 1 shall appear in easily	paragraph 1 shall appear in easily
legible and clearly comprehensible		legible and clearly comprehensible	legible and clearly comprehensible
characters, or, where appropriate,		characters, or [] in abbreviations	characters, or [] in abbreviations
abbreviations or pictograms common		or pictograms common throughout	or pictograms common throughout
throughout the Union.		the Union as listed in accordance	the Union as listed in accordance
		with Article 15(1).	with Article 15(1).
	AM 103		



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	2a. In addition, all the		
	information listed in points (a) to		
	(g) of paragraph 1 shall also appear		
	in a format that is electronically		
	readable, such as a barcode. Data		
	shall be made available for other		
	documentation systems through		
	standards interface.		
		3. Notwithstanding paragraph	3. Notwithstanding paragraph
		1, a Member State may decide	1, a Member State may decide
		that, on the immediate packaging	that, on the immediate packaging
		of a veterinary medicinal product	of a veterinary medicinal product
		made available in its territory, an	made available in its territory, an
		identification code shall be added	identification code shall be added
		to the information required under	to the information required under
		paragraph 1.	paragraph 1.
Article 10		Article 10	Article 10
Labelling of the outer packaging of		Labelling of the outer packaging of	Labelling of the outer packaging of
veterinary medicinal products		veterinary medicinal products	veterinary medicinal products
1. The outer packaging of a		1. The outer packaging of a	1. The outer packaging of a
veterinary medicinal product shall		veterinary medicinal product shall	veterinary medicinal product shall
contain only the following		contain [] the following	contain [] the following
information:		information and shall contain no	information and shall contain no
		other information:	other information:
(a) the information listed in Article		(a) the information listed in Article	(a) the information listed in Article
9(1);		9(1);	9(1);

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(b) the contents by weight, volume		(b) the contents by weight, volume	(b) the contents by weight, volume
or number of immediate packaging		or number of immediate packaging	or number of immediate packaging
units of the veterinary medicinal		units of the veterinary medicinal	units of the veterinary medicinal
product;		product;	product;
(c) warning that the veterinary		(c) warning that the veterinary	(c) warning that the veterinary
medicinal product must be kept out		medicinal product must be kept out	medicinal product must be kept out
of the sight and reach of children;		of the sight and reach of children;	of the sight and reach of children;
(d) warning that the veterinary	AM 104	(d) warning that the veterinary	(d) warning that the veterinary
medicinal product is for animal	(d) <i>a common pictogram</i> warning	medicinal product is "for animal	medicinal product is "for animal
treatment only;	that the veterinary medicinal product	treatment only";	treatment only";
	is for animal treatment only;		
(e) recommendation to read the		(e) without prejudice to Article	(e) without prejudice to Article
package leaflet;		12(4), recommendation to read the	12(4), recommendation to read the
		package leaflet;	package leaflet;
	AM 104	(f) []	(f) []
(f) requirement to use take-back	(f) requirement to use take-back		
schemes for veterinary medicinal	schemes for veterinary medicinal		
products for the disposal of unused	products for the disposal of unused		
veterinary medicinal products or waste materials derived from the use	veterinary medicinal products or waste materials derived from the use		
of such products and, if appropriate, additional precautions as regarding	of such products and, if appropriate, additional precautions as regarding		
hazardous waste disposal of unused	hazardous waste disposal of unused		
veterinary medicinal products or	veterinary medicinal products or		
waste materials derived from the use	waste materials derived from the use		
of such products;	of such products in accordance with		
are produced,	the applicable law;		

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(g) in case of homeopathic		(g) in case of homeopathic	(g) in case of homeopathic
veterinary medicinal products, the		veterinary medicinal products, the	veterinary medicinal products, the
statement "homeopathic veterinary		statement "homeopathic veterinary	statement "homeopathic veterinary
medicinal product".		medicinal product";	medicinal product";
		(h) in case of veterinary	(h) in case of veterinary
		medicinal products not subject to a	medicinal products not subject to a
		veterinary prescription, the	veterinary prescription, the
		indication(s);	indication(s);
		(i) the marketing authorisation	(i) the marketing authorisation
		number.	number.
	AM 104		
	1a. In exceptional cases,		
	additional information in		
	accordance with Article 30 may be		
	included, on request of the		
	applicant or the competent authority		
	when it is absolutely necessary to		
	ensure safe and correct		
	administration of the product.		
		1a. Notwithstanding paragraph	1a. Notwithstanding paragraph
		1, a Member State may decide	1, a Member State may decide
		that, on the outer packaging of a	that, on the outer packaging of a
		veterinary medicinal product	veterinary medicinal product
		made available in its territory, an	made available in its territory, an
		identification code shall be added	identification code shall be added
		to the information required under	to the information required under
		paragraph 1. Such <u>a</u> code may be	paragraph 1. Such <u>a</u> code may be
		used to replace the marketing	used to replace the marketing
		authorisation number referred to	authorisation number referred to
		in paragraph (1)(i).	in paragraph (1)(i).



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2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or, where appropriate, abbreviations or pictograms common throughout the Union.	AM 104 2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, <i>as well as in machine-</i> <i>readable format</i> , or, where appropriate, abbreviations or pictograms common throughout the Union.	2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or [] in abbreviations or pictograms common throughout the Union, as listed in accordance with Article 15(1).	2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or [] in abbreviations or pictograms common throughout the Union, as listed in accordance with Article 15(1).
3. Where there is no outer packaging, all the particulars listed in paragraph 1 shall appear on the immediate packaging. <i>Article 11</i> <i>Labelling of small immediate</i> <i>packaging units of veterinary</i> <i>medicinal products</i>		3. Where there is no outer packaging, all the particulars listed in paragraphs 1 and 1a shall appear on the immediate packaging. <i>Article 11</i> <i>Labelling of small immediate</i> <i>packaging units of veterinary</i> <i>medicinal products</i>	3. Where there is no outer packaging, all the particulars listed in paragraphs 1 and 1a shall appear on the immediate packaging. <i>Article 11</i> <i>Labelling of small immediate</i> <i>packaging units of veterinary</i> <i>medicinal products</i>
By way of derogation from Article 9, small immediate packaging units shall contain only the following information:		1. By way of derogation from Article 9, [] immediate packaging units which are too small to contain in a readable form the information referred to in that Article shall contain [] the following information and shall contain no other information:	1. By way of derogation from Article 9, [] immediate packaging units which are too small to contain in a readable form the information referred to in that Article shall contain [] the following information and shall contain no other information:
 (a) the name of veterinary medicinal product; the name of veterinary medicinal product; (b) the quantitative particulars of 	AM 105 (b) the quantitative particulars of	(a) the name of veterinary medicinal product;(b) the quantitative particulars of	(a) the name of veterinary medicinal product;(b) the quantitative particulars of



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the active substances;	the active substances, unless the product exists in only one concentration or the concentration is reflected in the name;	the active substances;	the active substances;
(c) the batch number, preceded by the word "Lot";		(c) the batch number, preceded by the word "Lot";	(c) the batch number, preceded by the word "Lot";
(d) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp.".		(d) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp."	(d) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp."
		2. The packaging units referred to in paragraph 1 shall have an outer-packaging fulfilling the requirements set out in Article 10(1), (1a) and (2).	2. The packaging units referred to in paragraph 1 shall have an outer-packaging fulfilling the requirements set out in Article 10(1), (1a) and (2).
	AM 105 In exceptional cases, additional information in accordance with Article 30 may be included, on request of the applicant or the competent authority when it is absolutely necessary to ensure safe and correct administration of the product.		

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		Article 11a	Article 11a
		By way of derogation from Articles	By way of derogation from Articles
		9(1), 10(1) and 11(1), Member	9(1), 10(1) and 11(1), Member
		States may, within their territory,	States may, within their territory,
		on request of the applicant, allow	on request of the applicant, allow
		him to include on the immediate	him to include on the immediate
		package or outer packaging of a	package or outer packaging of a
		veterinary medicinal product	veterinary medicinal product
		additional useful information	additional useful information
		which is compatible with the	which is compatible with the
		summary of the product	summary of the product
		characteristics, to the exclusion of	characteristics, to the exclusion of
		any advertising of a veterinary	any advertising of a veterinary
A .: 1 12		medicinal product. Article 12	medicinal product. Article 12
Article 12			
Package leaflet of veterinary		Package leaflet of veterinary	Package leaflet of veterinary
medicinal products	AM 106	medicinal products	medicinal products
1 The meetro a leaflet shell be		1 The meetings leaflet shall be	1. The package leaflet shall be
1. The package leaflet shall be available for each veterinary	1. The package leaflet shall be <i>directly</i> available for <i>with</i> each	1. The package leaflet shall be made readily available by the	made readily available by the
medicinal product and shall contain	veterinary medicinal product and	made readily available by the marketing authorisation holder	marketing authorisation holder
at least the following information:	shall contain at least the following	[] for each veterinary medicinal	[] for each veterinary medicinal
at least the following information.	information:	product and shall contain at least the	product and shall contain at least the
		following information:	following information:
(a) the name or corporate name		(a) the name or corporate name	(a) the name or corporate name
and permanent address or registered		and permanent address or registered	and permanent address or registered
place of business of the marketing		place of business of the marketing	place of business of the marketing
authorisation holder and of the		authorisation holder and of the	authorisation holder and of the
manufacturer and, where applicable,		manufacturer and, where applicable,	manufacturer and, where applicable,
of the representative of the marketing		of the representative of the marketing	of the representative of the marketing

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authorisation holder;		authorisation holder;	authorisation holder;
(b) the name of the veterinary		(b) the name of the veterinary	(b) the name of the veterinary
medicinal product or, where		medicinal product followed by its	medicinal product followed by its
applicable, a list of the names of the		strength and pharmaceutical form	strength and pharmaceutical form
veterinary medicinal product, as		[];	[];
authorised in different Member			
States;			
		(ba) qualitative and quantitative	(ba) qualitative and quantitative
		composition of the active	composition of the active
		substance(s);	substance(s);
(c) the strength and		(c) []	(c) []
pharmaceutical form of the			
veterinary medicinal product;			
(d) the target species, the dosage for each species, the method and route of administration and advice on correct administration, if necessary;	AM 106 (d) the target species, the dosage for each species, the method and route of administration and, <i>if</i> <i>necessary</i> , advice on correct administration, <i>if</i> necessary;	(d) the target species, the dosage for each species, the method and route of administration and, if necessary , advice on correct administration [];	(d) the target species, the dosage for each species, the method and route of administration and, if necessary , advice on correct administration [];
(e) the therapeutic indications;		(e) the []indications for use;	(e) the []indications for use ;
(f) the contra-indications and		(f) the contra-indications and	(f) the contra-indications and
adverse events in so far as this		adverse events [];	adverse events [];
information is necessary for the use			
of the veterinary medicinal product;			
(g) the withdrawal period, even if		(g) if applicable , the withdrawal	(g) if applicable , the withdrawal
this is nil, in the event that the target		period, even if this is [] zero ;	period, even if this is [] zero ;
species are food-producing animals;			
(h) special storage precautions, if		(h) special storage precautions, if	(h) special storage precautions, if
any;		any;	any;



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 (i) information essential for safety or health protection, including any special precautions relating to use and any other warnings; 		(i) information essential for safety or health protection, including any special precautions relating to use and any other warnings;	(i) information essential for safety or health protection, including any special precautions relating to use and any other warnings;
(j) requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, additional precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products;	AM 106 (j) requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, additional precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products in accordance with the applicable law;	(j) [] information on the collection systems referred to in Article 122 applicable to the veterinary medicinal product in question;	(j) [] information on the collection systems referred to in Article 122 applicable to the veterinary medicinal product in question;
 (k) the marketing authorisation number; (l) in case of generic veterinary medicinal products, the statement 'generic veterinary medicinal 	AM 106 (k) the marketing authorisation number;	 (k) the marketing authorisation number; (1) [] 	 (k) the marketing authorisation number; (1)-[]
product'; (m) in case of homeopathic veterinary medicinal products, the statement "homeopathic veterinary medicinal product".		(m) []	(m) -[]

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	AM 106 (ma) qualitative and quantitative composition.		
		(l) contact details to report suspected adverse events to the marketing authorisation holder or to its representative, as appropriate;	(1) contact details to report suspected adverse events to the marketing authorisation holder or to its representative, as appropriate;
		(o) classification of the veterinary medicinal product as referred to in Article 29.	(o) classification of the veterinary medicinal product as referred to in Article 29.
2. The package leaflet may bear additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation, provided that the information is not promotional. This additional information shall appear in the package leaflet clearly separated from the information referred to in paragraph 1.		2. The package leaflet may bear additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation, provided that the information is not promotional. Th at additional information shall appear in the package leaflet clearly separated from the information referred to in paragraph 1.	2. The package leaflet may bear additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation, provided that the information is not promotional. That additional information shall appear in the package leaflet clearly separated from the information referred to in paragraph 1.
3. The package leaflet shall be written and designed to be clear and understandable, in terms that are comprehensible to the general public.	 AM 106 3. The package leaflet shall be written and designed to be clear, <i>readable</i> and understandable, in terms that are comprehensible to the general public. 	3. The package leaflet shall be written and designed to be readable , clear and understandable, in terms that are comprehensible to the general public. Member States may decide that it shall be made available on paper, or electronically, or both.	3. The package leaflet shall be written and designed to be readable , clear and understandable, in terms that are comprehensible to the general public. Member States may decide that it shall be made available on paper, or



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			electronically, or both.
		4. By derogation from paragraph	4. By derogation from
		1, the information required in	paragraph 1, the information
		accordance with this Article may, alternatively, be provided on the	required in accordance with this Article may, alternatively, be
		packaging of the veterinary	provided on the packaging of the
		medicinal product.	veterinary medicinal product.
		Article 12a	Article 12a
		The information listed in Articles 9	The information listed in Articles 9
		to 12 shall comply with the summary of the product	to 12 shall comply with the summary of the product
		characteristics as set out in Article	characteristics as set out in Article
		30.	30.
Article 13		Article 13	Article 13
Package leaflet of homeopathic		Package leaflet of registered	Package leaflet of registered
veterinary medicinal products		homeopathic veterinary medicinal products	homeopathic veterinary medicinal products
By way of derogation from Article		By way of derogation from Article	By way of derogation from Article
12(1), the package leaflet for		12(1), the package leaflet for	12(1), the package leaflet for
homeopathic veterinary medicinal		homeopathic veterinary medicinal	homeopathic veterinary medicinal
products registered in accordance with Articles 89 to 90 shall contain		products registered in accordance with Articles 89 [] shall contain [], at	products registered in accordance with Articles 89 [] shall contain
only the following information:		least, the following information:	[], at least, the following
,,,,			information:
	AM 107		



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(a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the European Pharmacopoeia or, in the absence thereof, of the pharmacopoeias currently used officially in Member States;	 (a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the European Pharmacopoeia or, in the absence thereof, of the pharmacopoeias currently used officially in Member States; <i>if the homeopathic veterinary medicinal product is composed of more than one stock, the scientific names of the stocks may be supplemented by a brand name in the label;</i> 	(a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the European Pharmacopoeia or, in the absence thereof, of the pharmacopoeias currently used officially in Member States;	(a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the European Pharmacopoeia or, in the absence thereof, of the pharmacopoeias currently used officially in Member States;
(b) name and address of the marketing authorisation holder and, where appropriate, of the manufacturer;		(b) name and address of the registration [] holder and, where appropriate, of the manufacturer;	(b) name and address of the registration [] holder and, where appropriate, of the manufacturer;
(c) method of administration and, if necessary, route;		(c) method of administration and, if necessary, route;	(c) method of administration and, if necessary, route;
(d) the expiry date, in the format "mm/yyyy", preceded by the abbreviation "Exp.";	AM 107 (d) the expiry date, in the format "mm/yyyy", preceded by the abbreviation "Exp.";	(d) -[]	(d) -[]
 (e) pharmaceutical form; (f) special storage precautions, if any; 		(e) pharmaceutical form;(f) special storage precautions, if any;	(e) pharmaceutical form;(f) special storage precautions, if any;

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(g) target species;	AM 107 (g) target species as well as dosage levels for the different target species;	(g) target species;	(g) the target species and, where appropriate, dosage for each such species;
(h) a special warning if necessary for the medicinal product;		 (h) a special warning if necessary for the homeopathic veterinary medicinal product; 	(h) a special warning if necessary for the homeopathic veterinary medicinal product;
(i) the batch number, preceded by the word "Lot";	AM 107 (i) the batch number, preceded by the word "Lot";	(i) []	(i) []
(j) registration number;(k) withdrawal period, if applicable.		(j) registration number;(k) withdrawal period, if applicable.	(j) registration number;(k) withdrawal period, if applicable.
(1) the statement "homeopathic veterinary medicinal product". <i>Article 14</i>		(1) the statement "homeopathic veterinary medicinal product". <u>Article 14</u>	(1) the statement "homeopathic veterinary medicinal product". <u>Article 14</u> <u>Languages</u> ²⁶
Languages1. The language or languages ofthe information on the labelling shallbe determined by Member Statewhere the veterinary medicinalproduct is made available on themarket.		[]	[]

²⁶ moved to new Article 6a

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2. Member States shall		[]	[]
communicate the languages			
determined by them for the purpose			
of paragraph 1 to the Commission. The Commission shall make this			
information public.3. Veterinary medicinal products		[]	
may be labelled in several languages.		[]	[]
Article 15		Article 15	Article 15
Abbreviations and pictograms		[] Implementing powers with	[] Implementing powers with
common throughout the Union		respect to section 4	respect to section 4
		0. The Commission may, by	0. The Commission may <u>shall</u> ,
		means of implementing acts,	when appropriate, by means of
		provide uniform rules on the	implementing acts, provide
		identification code referred to in $Articles 0(3)$ and $10(1c)$. These	uniform rules on the identification code referred to in Articles 9(3)
		Articles 9(3) and 10(1a). Those implementing acts shall be adopted	and 10(1a). Those implementing
		in accordance with the examination	acts shall be adopted in accordance
		procedure referred to in Article	with the examination procedure
		145(2).	referred to in Article 145(2).
The Commission shall, by means of		1. The Commission shall, by	1. The Commission shall, by
implementing acts, adopt a list of the		means of implementing acts, adopt a	means of implementing acts, adopt a
abbreviations and pictograms		list of the abbreviations and	list of the abbreviations and
common throughout the Union to be		pictograms common throughout the	pictograms common throughout the
used for the purposes of Article 9(2)		Union to be used for the purposes of	Union to be used for the purposes of
and Article 10(2). Those		Article 9(2) and Article 10(2). Those	Article 9(2) and Article 10(2). Those
implementing acts shall be adopted		implementing acts shall be adopted in	implementing acts shall be adopted
in accordance with the examination		accordance with the examination	in accordance with the examination
procedure referred to in Article		procedure referred to in Article	procedure referred to in Article
145(2).		145(2).	145(2).



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		2. The Commission shall, by	2. The Commission shall, by
		means of implementing acts,	means of implementing acts,
		provide uniform rules on the size of	provide uniform rules on the size
		packaging units referred to in	of packaging units referred to in
		Article 11. Those implementing acts	Article 11. Those implementing
		shall be adopted in accordance with	acts shall be adopted in accordance
		the examination procedure referred	with the examination procedure
		to in Article 145(2).	referred to in Article 145(2).
Section 5		Section 5	Section 5
Dossier requirements for generic,		Specific requirements for generic,	Specific requirements for generic,
combination and hybrid veterinary		combination and hybrid veterinary	combination and hybrid veterinary
medicinal products and for		medicinal products and for	medicinal products and for
applications based on informed		applications based on informed	applications based on informed
consent and bibliographic data		consent and bibliographic data	consent and bibliographic data
Article 16		Article 16	Article 16
Generic veterinary medicinal		Generic veterinary medicinal products	Generic veterinary medicinal
products			products
1. By way of derogation from		1. By way of derogation from	1. By way of derogation from
Article 7(1)(b), an application for a		Article 7(1)(b), it shall not be	Article 7(1)(b), it shall not be
marketing authorisation for a generic		required that an application for a	required that an application for a
veterinary medicinal products shall		marketing authorisation for a generic	marketing authorisation for a generic
not contain the documentation on		veterinary medicinal product []	veterinary medicinal product []
safety and efficacy if all the		contains the documentation on safety	contains the documentation on safety
following conditions are fulfilled:		and efficacy if all the following	and efficacy if all the following
		conditions are fulfilled:	conditions are fulfilled:

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		(aa) bioavailability studies have demonstrated its bioequivalence with the reference veterinary medicinal product or a justification is provided as to why such studies	(aa) bioavailability studies have demonstrated its bioequivalence with the reference veterinary medicinal product or a justification is provided as to why
		were not performed;	such studies were not performed;
(a) the application satisfies the requirements set out in Annex III;		(a) the application satisfies the requirements set out in Annex II[];	(a) the application satisfies the requirements set out in Annex II[];
(b) the applicant can demonstrate that the application concerns a generic veterinary medicinal product of a veterinary medicinal product which has been authorised by a Member State or by the Commission, and the period of protection of the technical documentation in respect of that reference veterinary medicinal product laid down in Articles 34 and 35 has elapsed or is due to elapse in less than 2 years ('reference veterinary medicinal product');		(b) the applicant [] demonstrates that the application concerns a generic veterinary medicinal product of a reference veterinary medicinal product [] for which the period of protection of the technical documentation [] laid down in Articles 34 and 35 has elapsed or is due to elapse in less than 2 years [];	(b) the applicant [] demonstrates that the application concerns a generic veterinary medicinal product of a reference veterinary medicinal product [] for which the period of protection of the technical documentation [] laid down in Articles 34 and 35 has elapsed or is due to elapse in less than 2 years [];
(c) documentation referred to in Article 7(1)(b) is available for the reference veterinary medicinal product to the competent authority or to the Agency.		(c) []	(c) []

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	AM 108		
2. For the purpose of this Section,	2. For the purpose of this	2. [] Where the active substance	2. [] Where the active
where the active substance consists	Section, where the active substance	of a generic veterinary medicinal	substance of a generic veterinary
of salts, esters, ethers, isomers and	consists of salts, esters, ethers,	product consists of salts, esters,	medicinal product consists of salts,
mixtures of isomers, complexes or	isomers and mixtures of isomers,	ethers, isomers and mixtures of	esters, ethers, isomers and mixtures
derivatives differing from the active	complexes or derivatives differing	isomers, complexes or derivatives	of isomers, complexes or derivatives
substance used in the reference	from the active substance used in	differing from the active substance	differing from the active substance
veterinary medicinal product, it shall	the reference veterinary medicinal	used in the reference veterinary	used in the reference veterinary
be considered to be the same active	product, it shall be considered to be	medicinal product, it shall be	medicinal product, it shall be
substance as that used in the	the same active substance as that	considered to be the same active	considered to be the same active
reference veterinary medicinal	used in the reference veterinary	substance as that used in the reference	substance as that used in the
product, unless it differs significantly	medicinal product, unless it differs	veterinary medicinal product, unless it	reference veterinary medicinal
in respect of properties with regard	significantly in respect of properties	differs significantly in respect of	product, unless it differs significantly
to safety or efficacy. Where it differs	with regard to safety, or efficacy	properties with regard to safety or	in respect of properties with regard
significantly in respect of those	and behaviour of residues Where	efficacy.	to safety or efficacy.
properties, the applicant shall submit	it differs significantly in respect of	Where it differs significantly in	Where it differs significantly in
additional information in order to	those properties, the applicant shall	respect of those properties, the	respect of those properties, the
prove the safety and/or efficacy of	submit additional information in	applicant shall submit additional	applicant shall submit additional
the various salts, esters or derivatives	order to prove the safety and/or	information in order to prove the	information in order to prove the
of the authorised active substance of	efficacy of the various salts, esters	safety and/or efficacy of the various	safety and/or efficacy of the various
the reference veterinary medicinal	or derivatives of the authorised	salts, esters or derivatives of the	salts, esters or derivatives of the
product.	active substance of the reference	authorised active substance of the	authorised active substance of the
	veterinary medicinal product.	reference veterinary medicinal	reference veterinary medicinal
		product.	product.

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		2a. Where several immediate-	2a. Where several immediate-
		release oral pharmaceutical forms	release oral pharmaceutical forms
		of a generic veterinary medicinal	of a generic veterinary medicinal
		product are presented, they shall	product are presented, they shall
		be considered to be the same	be considered to be the same
		pharmaceutical form.	pharmaceutical form.
3. Where the reference veterinary		3. Where the reference veterinary	3. Where the reference veterinary
medicinal product was not authorised		medicinal product [] is not	medicinal product [] is not
in the Member State in which the		authorised in the Member State in	authorised in the Member State in
application for the generic medicinal		which the application for the generic	which the application for the generic
product is submitted, or the		medicinal product is submitted, or	medicinal product is submitted, or
application is submitted in		the application is submitted in	the application is submitted in
accordance with Article 38(3) where		accordance with Article 38(3) where	accordance with Article 38(3) where
the reference medicinal product was		the reference medicinal product []	the reference medicinal product []
authorised in a Member State, the		is authorised in a Member State, the	is authorised in a Member State, the
applicant shall indicate in its		applicant shall indicate in its	applicant shall indicate in its
application the Member State in		application the Member State in	application the Member State in
which the reference veterinary		which the reference veterinary	which the reference veterinary
medicinal product has been		medicinal product has been	medicinal product has been
authorised.		authorised.	authorised.
4. The competent authority or the		4. The competent authority or the	4. The competent authority or the
Agency may request information on		Agency, as applicable, may request	Agency, as applicable, may request
the reference veterinary medicinal		information on the reference	information on the reference
product from the competent authority		veterinary medicinal product from	veterinary medicinal product from
of the Member State where it was		the competent authority of the	the competent authority of the
authorised. Such information shall be		Member State where it [] is	Member State where it [] is
transmitted to the requestor within 30		authorised. Such information shall be	authorised. Such information shall be
days of receipt of the request.		transmitted to the requestor within 30	transmitted to the requestor within 30
		days of receipt of the request.	days of receipt of the request.
5. The summary of the product		5. The summary of the product	5. The summary of the product

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characteristics of the generic		characteristics of the generic	characteristics of the generic
veterinary medicinal product shall be		veterinary medicinal product shall be	veterinary medicinal product shall be
identical to that of the reference		[] essentially similar to that of the	[] essentially similar to that of the
veterinary medicinal product.		reference veterinary medicinal	reference veterinary medicinal
However, that requirement shall not		product. However, that requirement	product. However, that requirement
apply to those parts of the summary		shall not apply to those parts of the	shall not apply to those parts of the
of the product characteristics of the		summary of the product	summary of the product
reference veterinary medicinal		characteristics of the reference	characteristics of the reference
product that refer to indications or		veterinary medicinal product that	veterinary medicinal product that
pharmaceutical forms which are still		refer to indications or pharmaceutical	refer to indications or pharmaceutical
covered by patent law at the time		forms which are still covered by	forms which are still covered by
when the generic veterinary		patent law at the time when the	patent law at the time when the
medicinal product is authorised.		generic veterinary medicinal product	generic veterinary medicinal product
		is authorised.	is authorised.
	AM 109		
6. A competent authority or the	6. A The applicant shall submit	6. A competent authority or the	6. A competent authority or the
Agency may require the applicant to	to the competent authority or the	Agency, as applicable, may require	Agency, as applicable, may require
provide safety data concerning the	Agency, on their request, may	the applicant to provide safety data	the applicant to provide safety data
potential risks posed by the generic	require the applicant to provide	concerning the potential risks posed	concerning the potential risks posed
veterinary medicinal product to the	safety data concerning the potential	by the generic veterinary medicinal	by the generic veterinary medicinal
environment in case the marketing	risks posed by the generic veterinary	product to the environment in case	product to the environment in case
authorisation for the reference	medicinal product to the	the marketing authorisation for the	the marketing authorisation for the
veterinary medicinal product was	environment in case the marketing	reference veterinary medicinal	reference veterinary medicinal
granted before 20 July 2000 or in	authorisation for the reference	product was granted before [] 7	product was granted before [] 7 <u>1</u>
case the second phase environmental	veterinary medicinal product was	October 2005 [].	October 2005 ²⁷ [].
risk assessment was required for the	granted before 20 July 2000 or in		
reference veterinary medicinal	case the second phase environmental		
product.	risk assessment was required for the		

²⁷ The date of the start of use of the Veterinary International Conference on Harmonization (VICH) guideline 38.



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	reference veterinary medicinal if		
	there are well founded reasons to		
	believe that authorisation can result		
	in an increased risk to the		
	environment from the generic		
	product as compared to the		
	<i>reference</i> product.		
7. The Commission shall be		7[]	7[]
empowered to adopt delegated acts			
in accordance with Article 146			
concerning amendments to Annex III			
in order to adapt the requirements to			
technical and scientific progress.		28	
		Article 16a ²⁸	Article 16a
		Hybrid veterinary medicinal	Hybrid veterinary medicinal
		products	products
		1. By way of derogation from	1. By way of derogation from
		Article 16(1), the results of	Article 16(1), the results of
		appropriate pre-clinical studies and	appropriate pre-clinical studies and
		/or clinical trials shall be required	/or clinical trials shall be required
		when the product does not meet all	when the product does not meet all
		the characteristics of a generic	the characteristics of a generic
		veterinary medicinal product	veterinary medicinal product
		because:	because:
		(a) there are changes in the active	(a) there are changes in the active
		substance(s), []indications for use,	substance(s), []indications for use ,
		strength, pharmaceutical form or	strength, pharmaceutical form or
		route of administration of the generic	route of administration of the generic

²⁸ Ex Article 18

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		veterinary medicinal product	veterinary medicinal product
		compared to the reference veterinary	compared to the reference veterinary
		medicinal product, or	medicinal product, or
		(b) bioavailability studies cannot	(b) bioavailability studies cannot
		be used to demonstrate	be used to demonstrate
		bioequivalence with the reference	bioequivalence with the reference
		veterinary medicinal product, or	veterinary medicinal product, or
		(c) there are differences relating to	(c) there are differences relating to
		raw materials or in manufacturing	raw materials or in manufacturing
		processes of the biological veterinary	processes of the biological veterinary
		medicinal product and the reference	medicinal product and the reference
		biological veterinary medicinal	biological veterinary medicinal
		product.	product.
		2. The pre-clinical studies or	2. The pre-clinical studies or
		clinical trials for a hybrid	clinical trials for a hybrid
		veterinary medicinal product may	veterinary medicinal product may
		be conducted with batches of the	be conducted with batches of the
		reference product [] authorised in	reference product [] authorised in
		the Union or in third countries.	the Union or in third countries.
		[] The applicant shall demonstrate	[] The applicant shall demonstrate
		[] that the [] reference product	[] that the [] reference product
		in third countries has been	in third countries has been
		authorised in accordance with	authorised in accordance with
		requirements equivalent to those	requirements equivalent to those
		established for the reference	established for the reference
		veterinary medicinal product and	veterinary medicinal product and
		are so highly similar that they can	are so highly similar that they can
		substitute [] each other in the	substitute [] each other in the
		clinical trials.	clinical trials.



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Article 17 Combination veterinary medicinal products		Article 17 Combination veterinary medicinal products	Article 17 Combination veterinary medicinal products
By way of derogation from Article 7(1)(b) an application for a marketing authorisation for a veterinary medicinal product containing a combination of active substances that have each already been used in authorised veterinary medicinal products, but have not hitherto been authorised in that combination ('combination veterinary medicinal product') shall satisfy the following criteria:	AM 110 By way of derogation from Article 7(1)(b) an application for a marketing authorisation for a veterinary medicinal product containing a combination of active substances that have each already been used in authorised veterinary medicinal products, but have not hitherto been authorised in that combination ('combination veterinary medicinal product') shall satisfy the following criteria:	By way of derogation from Article 7(1)(b) in the case of veterinary medicinal products containing active substances used in the composition of authorised veterinary medicinal products it shall not be required to provide safety and efficacy data relating to each individual active substance. []	By way of derogation from Article 7(1)(b) in the case of veterinary medicinal products containing active substances used in the composition of authorised veterinary medicinal products it shall not be required to provide safety and efficacy data relating to each individual active substance. []
(a) the application satisfies the requirements set out in Annex III;(b) the applicant can demonstrate		(а) [] (b) []	(a)[] (b)[]
 that the veterinary medicinal product is a combination of reference veterinary medicinal products as referred to in Article 16(1)(b); (c) documentation referred to in Article 7(1)(b) is available for the reference veterinary medicinal products to the competent authority or to the Agency; 		(e) []	(e) []
(d) documentation on the safety of		(d) []	(d) []



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that combination is provided.			
Article 18		Article 18 ²⁹	Article 18
Hybrid veterinary medicinal		[]	[]
products			
1. By way of derogation from		[]	[]
Article 16(1), the results of			
appropriate pre-clinical studies and			
clinical trials shall be required when			
the product does not meet all the			
characteristics of a generic veterinary			
medicinal product because:			
(a) there are changes in the active		[]	[]
substance(s), therapeutic indications,			
strength, pharmaceutical form or			
route of administration of the generic			
veterinary medicinal product			
compared to the reference veterinary			
medicinal product, or			
(b) bioavailability studies cannot		[]	[]
be used to demonstrate			
bioequivalence with the reference			
veterinary medicinal product, or			

²⁹ Moved to new Article 16a.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
(c) there are differences relating to		[]	[]
raw materials or in manufacturing			
processes of the biological veterinary			
medicinal product and the reference			
biological veterinary medicinal			
product.			
2. The pre-clinical studies or		[]	[]
clinical trials may be conducted with			
batches of reference products manufactured in the Union or in third			
countries.			
When the batches are manufactured		[]	[]
in third countries, the applicant shall			
demonstrate by state of the art			
analytical tests that the two reference			
products are so highly similar that			
they can substitute to each other in			
the clinical trials.			
Article 19		Article 19	Article 19
Application based on informed		Application based on informed	Application based on informed
consent		consent	consent
By way of derogation from Article		By way of derogation from Article	By way of derogation from Article
16(1)(b), an applicant for a		$[\dots]$ 7(1)(b), an applicant for a	$[\dots]$ 7(1)(b), an applicant for a
marketing authorisation for a generic		marketing authorisation for a []	marketing authorisation for a []
veterinary medicinal product shall		veterinary medicinal product shall not	veterinary medicinal product shall
not be required to provide the		be required to provide the technical	not be required to provide the
documentation on safety and efficacy		documentation on quality , safety and	technical documentation on quality,
if he demonstrates in the form of a		efficacy if he demonstrates in the form	safety and efficacy if he
letter of access that he is allowed to		of a letter of access that he is allowed	demonstrates in the form of a letter
use the documentation on safety and		to use [] that documentation []	of access that he is allowed to use



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efficacy referred to in Article 7(1)(b)		submitted in respect of the []	[] that documentation []
which is available for the reference		authorised veterinary medicinal	submitted in respect of the []
veterinary medicinal product.		product.	authorised veterinary medicinal
			product.
Article 20		Article 20	Article 20
Application based on bibliographic		Application based on bibliographic	Application based on bibliographic
data		data	data
1. By way of derogation from		1. By way of derogation from	1. By way of derogation from
Article 7(1)(b), the applicant shall		Article 7(1)(b), the applicant shall not	Article 7(1)(b), the applicant shall
not be required to provide the		be required to provide the	not be required to provide the
documentation referred to therein if		documentation [] on safety and	documentation [] on safety and
he demonstrates that the active		efficacy if he demonstrates that the	efficacy if he demonstrates that the
substances of the veterinary		active substances of the veterinary	active substances of the veterinary
medicinal product have been in well-		medicinal product have been in well-	medicinal product have been in well-
established veterinary use within the		established veterinary use within the	established veterinary use within the
Union for at least 10 years, that their		Union for at least 10 years, that their	Union for at least 10 years, that their
efficacy is documented and that they		efficacy is documented and that they	efficacy is documented and that they
provide an acceptable level of safety.		provide an acceptable level of safety.	provide an acceptable level of safety.
2. The application shall satisfy		2. The application shall satisfy the	2. The application shall satisfy
the requirements set out in Annex III.		requirements set out in Annex II[].	the requirements set out in Annex
			II[].

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Section 6		Section 6	Section 6
Dossier requirements for		Marketing authorisations for []	Marketing authorisations for []
applications for limited market		limited markets and in exceptional	limited markets and in exceptional
and in exceptional circumstances		circumstances	circumstances
Article 21		Article 21	Article 21
Reduced data requirements for		[] Applications for limited markets	[] Applications for limited markets
applications for limited markets			
	AM 111		
1. By way of derogation from Article 7(1)(b), a marketing authorisation for a veterinary medicinal product intended for a limited market shall be granted although the quality and/or efficacy documentation required in accordance with Annex II has not been provided, if all the following conditions are met:	1. By way of derogation from Article 7(1)(b), a marketing authorisation for a veterinary medicinal product intended for a limited market shall be granted although even when, for objective, verifiable reasons, the applicant is unable to provide the quality and/or efficacy documentation required in accordance with Annex II, subject to the has not been provided, if all the following conditions are met:	1. By way of derogation from Article 7(1)(b), the applicant shall not be required to provide [] a comprehensive safety and/or efficacy documentation required in accordance with Annex II[] if all the following conditions are met:	1. By way of derogation from Article 7(1)(b), the applicant shall not be required to provide [] a comprehensive safety and/or efficacy documentation required in accordance with Annex II[] if all the following conditions are met:
(a) the benefit of the immediate availability on the market of the veterinary medicinal product to the animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided;		(a) the benefit of the [] availability on the market of the veterinary medicinal product to the animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided;	(a) the benefit of the [] availability on the market of the veterinary medicinal product to the animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided;
(b) the applicant provides the evidence that the veterinary		(b) the applicant provides the evidence that the veterinary medicinal	(b) the applicant provides the evidence that the veterinary



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
medicinal product is intended for a		product is intended for a limited	medicinal product is intended for a
limited market.		market.	limited market.
2. By way of derogation from Article 5(2), a marketing authorisation for a limited market shall be granted for a period of 3 years.	AM 111 2. By way of derogation from Article 5(2), a marketing authorisation for a limited market shall be granted for a period of 3 <i>five</i> years. At the end of that period, the holder may request, in the light of scientific data and on grounds of pharmacovigilance and efficiency, that this authorisation be converted into an open-ended authorisation.	2 .[]	2.[]
3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment of quality and/or efficacy has been conducted due to the lack of comprehensive efficacy and/or quality data.	AM 111 3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment of <i>information on its</i> quality and/or efficacy has been conducted due to the lack of comprehensive efficacy and/or quality data submitted. The packaging shall bear a warning with the same information.	3. Where a veterinary medicinal product has been granted a marketing authorisation in accordance with the terms of this Article, the summary of product characteristics shall clearly state that only a limited assessment of [] safety and/or efficacy has been conducted due to the lack of comprehensive [] safety and/or efficacy data.	3. Where a veterinary medicinal product has been granted a marketing authorisation in accordance with the terms of this Article, the summary of product characteristics shall clearly state that only a limited assessment of [] safety and/or efficacy has been conducted due to the lack of comprehensive [] safety and/or efficacy data.

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	AM 111		
	<i>3a. A veterinary medicinal</i>		
	product that has been granted		
	marketing authorisation in		
	accordance with this Article may		
	only be issued on the basis of a		
	prescription.	20	
		Article 21a ³⁰	Article 21a
		Validity [] of a marketing	Validity [] of a marketing
		authorisation for a limited market and	authorisation for a limited market
		procedure for its re-examination	and procedure for its re-
			examination
		0. By way of derogation from	0. By way of derogation from
		Article 5(2), a marketing	Article 5(2), a marketing
		authorisation for a limited market	authorisation for a limited market
		shall be valid for a period of 3 years.	shall be valid for a period of 3-<u>5</u>
			years.
		1. Before the expiry of the period	1. Before the expiry of the period
		of validity [] referred to in	of validity [] referred to in
		paragraph 0, marketing	paragraph 0, marketing
		authorisations for a limited market	authorisations for a limited market
		granted in accordance with Article 21	granted in accordance with Article
		shall be re-examined on application	21 shall be re-examined on <u>the basis</u>
		from the marketing authorisation	of an application from the marketing
		holder including an updated benefit-	authorisation holder including an
		risk assessment.[]	updated benefit-risk
			assessment.[]

 30 ex Article 82.



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		2. The application for a re- examination shall be submitted to the competent authority that granted the authorisation or to the Agency, as applicable , at least 6 months before the expiry of the period of validity referred to in paragraph 0 , [] and shall demonstrate that the conditions referred to in Article 21(1) continue to be fulfilled [].	2. The application for a re- examination shall be submitted to the competent authority that granted the authorisation or to the Agency, as applicable , at least 6 months before the expiry of the period of validity referred to in paragraph 0 , [] and shall <u>be limited to</u> demonstrat <u>ing</u> e that the conditions referred to in Article 21(1) continue to be fulfilled [].
		3. When an application for re- examination has been submitted, the [] marketing authorisation for a limited market shall remain valid until a decision [] has been adopted by the competent authority or the Commission, as applicable .	3. When an application for re- examination has been submitted, the [] marketing authorisation for a limited market shall remain valid until a decision [] has been adopted by the competent authority or the Commission, as applicable .
		4. The competent authority or the Agency, as applicable, shall assess the [] application for a re- examination and extend the validity of the marketing authorisation for a period of five years [] if the benefit-risk balance [] remains positive.	4. The competent authority or the Agency, as applicable , shall assess the-[] application <u>s</u> for a re- examination and extend the validity of the marketing authorisation for a by additional periods of five years if the benefit-risk balance [] remains positive.

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		5. The competent authority or the	5. The competent authority or the
		Commission, as applicable, may at	Commission, as applicable, may at
		any time grant a marketing	any time grant a marketing
		authorisation valid for an unlimited	authorisation valid for an unlimited
		period of time in respect of a	period of time in respect of a
		veterinary medicinal product	veterinary medicinal product
		authorised for a limited market,	authorised for a limited market,
		provided that the holder of the	provided that the holder of the
		marketing authorisation for a limited	marketing authorisation for a limited
		market submits the missing [] data	market submits the missing [] data
		on [] safety and/or efficacy []	on [] safety and/or efficacy []
		referred to in Article 21(1).	referred to in Article 21(1).
Article 22		Article 22	Article 22
Data requirements for applications		[] Applications in exceptional	[] Applications in exceptional
in exceptional circumstances		circumstances	circumstances
	AM 113		
1. By way of derogation from	1. By way of derogation from	[]By way of derogation from	[]By way of derogation from
Article 7(1)(b), in exceptional	Article 7(1)(b), in exceptional	Article 7(1)(b), in exceptional	Article 7(1)(b), in exceptional
circumstances related to animal or	circumstances related to animal or	circumstances related to animal or	circumstances related to animal or
public health, where the applicant	public health, <i>including unmet</i>	public health, [] an [] applicant	public health, []an [] applicant
has demonstrated that for objective,	needs with respect to animal health,	may submit an application which	may submit an application which
verifiable reasons he is unable to	where the applicant has	does not meet all requirements of	does not meet all requirements of
provide the quality, safety and/or	demonstrated that for objective,	that provision, for which the	that provision, for which the
efficacy documentation required in	verifiable reasons he is unable to	benefit of the immediate	benefit of the immediate
accordance with Part 1, Part 2 and	provide the quality, safety and/or	availability on the market of the	availability on the market of the
Part 3 of Annex II, a marketing	efficacy documentation required in	concerned veterinary medicinal	concerned veterinary medicinal
authorisation may be granted subject	accordance with Part 1, Part 2 and	product to the animal or public	product to the animal or public
to any of the following:	Part 3 of Annex II, a marketing	health outweighs the risk inherent	health outweighs the risk inherent
	authorisation may be granted subject	in the fact that certain	in the fact that certain
	to any of the following:	documentation has not been	documentation has not been



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		1 ,	1 /
		applicant shall be required to demonstrate [] that for objective	applicant shall be required to demonstrate[] that for objective
		and verifiable reasons [] the	and verifiable reasons [] the
		quality, safety and/or efficacy documentation required in	quality, safety and/or efficacy documentation required in
		accordance with [] Annex II	accordance with [] Annex II
		cannot be provided.	cannot be provided.
		Article 22a	Article 22a
		Terms of the marketing	Terms of the marketing
		authorisation in exceptional circumstances	authorisation in exceptional circumstances
		1. In exceptional circumstances	1. In exceptional circumstances
		referred to in Article 22, a	referred to in Article 22, a
		marketing authorisation may be	marketing authorisation may be
		granted [] subject to [] one or	granted [] subject to [] one or
		more of the following requirements	more of the following requirements
		for the marketing authorisation holder:	for the marketing authorisation holder:
(a) a many inclusion to interaction			
(a) a requirement to introduce conditions or restrictions, in		(a) a requirement to introduce conditions or restrictions, in	(a) a requirement to introduce conditions or restrictions, in
,		· · · · · · · · · · · · · · · · · · ·	<i>,</i>
particular concerning the safety of		particular concerning the safety of	particular concerning the safety of
the veterinary medicinal product;	A N. 4. 11.2	the veterinary medicinal product;	the veterinary medicinal product;
(\mathbf{h}) a maximum and the metificity \mathbf{h}	AM 113	(h) a manimum and the metify the the	(h) a manimum at to matify to the
(b) a requirement to notify the	(b) a requirement to notify the	(b) a requirement to notify to the	(b) a requirement to notify to the
competent authorities of any incident	competent authorities of any incident	competent authorities or the	competent authorities or the
relating to the use of the veterinary	<i>adverse event</i> relating to the use of	Agency, as applicable, of any []	Agency, as applicable, of any []
medicinal product;	the veterinary medicinal product;	adverse event relating to the use of	adverse event relating to the use of
		the veterinary medicinal product;	the veterinary medicinal product;
	AM 113		

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(c) a requirement to conduct post-	(c) a requirement to conduct	(c) a requirement to conduct post-	(c) a requirement to conduct post-
authorisation studies.	provide further data based on either	authorisation studies.	authorisation studies.
	post-authorisation studies or on data		
	collected on the performance of the		
	product in the field, where data		
	from the field is identified as more		
	appropriate based on a risk-benefit		
	assessment.		
	AM 113		
2. By way of derogation from	2. By way of derogation from	2. []	2. []
Article 5(2), a marketing	Article 5(2), The continuation of a		
authorisation in exceptional	marketing authorisation in		
circumstances shall be granted for a	exceptional circumstances granted in		
period of 1 year.	accordance with paragraph 1 shall		
	be granted for a period of 1 year tied		
	to an annual review of the		
	conditions set out in that paragraph,		
	until all those conditions are		
	fulfilled.		
	AM 113		
3. Where a medicinal product has	3. Where a medicinal product has	3. Where a veterinary medicinal	3. Where a veterinary medicinal
been granted a marketing	been granted a marketing	product has been granted a marketing	product has been granted a marketing
authorisation in accordance with this	authorisation in accordance with this	authorisation in accordance with the	authorisation in accordance with the
Article, the summary of product	Article, the summary of product	terms of this Article, the summary of	terms of this Article, the summary of
characteristics shall clearly state that	characteristics shall clearly state that	product characteristics shall clearly	product characteristics shall clearly
only a limited assessment of quality,	only a limited assessment of quality,	state that only a limited assessment	state that only a limited assessment
safety and/or efficacy has been	safety and/or efficacy has been	of quality, safety and/or efficacy has	of quality, safety and/or efficacy has
conducted due to the lack of	conducted due to the lack of	been conducted due to the lack of	been conducted due to the lack of
comprehensive quality, safety and/or	comprehensive quality, safety and/or	comprehensive quality, safety and/or	comprehensive quality, safety and/or
efficacy data.	efficacy data. The packaging shall	efficacy data.	efficacy data.



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	bear a warning with the same information.		
	AM 113 3a. The competent authority or		
	the Commission may at any time grant a valid marketing		
	authorisation for an unlimited period of time, provided that no		
	safety or efficacy problems have been reported with the product in		
	use and the marketing authorisation holder has supplied the missing		
	quality, safety and efficacy information set out in paragraph 1.		
	AM 113 3b. A veterinary medicinal		
	product that has been granted		
	marketing authorisation in accordance with this Article may		
	only be issued on the basis of a prescription.		

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, í		Article 22b ³¹	Article 22b
		Validity of a marketing	Validity of a marketing
		authorisation in exceptional	authorisation in exceptional
		circumstances and procedure for its	circumstances and procedure for its
		re-examination	re-examination
		0. By way of derogation from	0. By way of derogation from
		Article 5(2), a marketing	Article 5(2), a marketing
		authorisation in exceptional	authorisation in exceptional
		circumstances shall be valid for a	circumstances shall be valid for a
	L	period of 1 year.	period of 1 year.
		1. Before the expiry of the period	1. Before the expiry of the period
		of validity [] referred to in	of validity [] referred to in
		paragraph 0, marketing	paragraph 0, marketing
		authorisations granted in accordance	authorisations granted in accordance
		with Article 22 and 22a shall be re-	with Article 22 and 22a shall be re-
		examined on application from the	examined on application from the
		marketing authorisation holder	marketing authorisation holder
		including an updated benefit-risk	including an updated benefit-risk
		assessment.	assessment.
		2. The [] application for re-	2. The [] application for re-
		examination shall be submitted to	examination shall be submitted to
		the competent authority that granted	the competent authority that granted
		the authorisation or the Agency, as	the authorisation or the Agency, as
		applicable, at least 3 months before	applicable, at least 3 months before
		the expiry of the [] period of	the expiry of the [] period of
		validity referred to in paragraph	validity referred to in paragraph
		0, and shall demonstrate that the	0, and shall demonstrate that the
	L	exceptional circumstances related	exceptional circumstances related

³¹ ex Article 83

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		to animal health or public health	to animal health or public health
		remain.	remain.
		3. When an application for re-	3. When an application for re-
		examination has been submitted, the	examination has been submitted, the
		marketing authorisation shall remain	marketing authorisation shall remain
		valid until a decision [] has been	valid until a decision [] has been
		adopted by the competent authority	adopted by the competent authority
		or the Commission, as applicable.	or the Commission, as applicable.
		3a. The competent authority or	3a. The competent authority or
		the Agency, as applicable, shall	the Agency, as applicable, shall
		assess the application and extend	assess the application and extend
		the validity of the marketing	the validity of the marketing
		authorisation for one year if the	authorisation for one year if the
		benefit-risk balance remains	benefit-risk balance remains
		positive.	positive.
		4. The competent authority or the	4. The competent authority or the
		Commission, as applicable, may at	Commission, as applicable, may at
		any time grant a marketing	any time grant a marketing
		authorisation valid for an unlimited	authorisation valid for an unlimited
		period of time in respect of a	period of time in respect of a
		veterinary medicinal product	veterinary medicinal product
		authorised in accordance with	authorised in accordance with
		Article 22 and 22a, provided that	Article 22 and 22a, provided that
		the marketing authorisation holder	the marketing authorisation holder
		submits the missing [] data on	submits the missing [] data on
		quality, safety and/or efficacy	quality, safety and/or efficacy
		referred to in Article 22[].	referred to in Article 22[].
Section 7		Section 7	Section 7
Examination of applications and		Examination of applications and	Examination of applications and
granting of marketing		basis for granting marketing	basis for granting marketing

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
authorisations		authorisations	authorisations
Article 23		Article 23	Article 23
Examination of applications		Examination of applications	Examination of applications
1. The competent authority or the		1. The competent authority or the	1. The competent authority or the
Agency to which the application has		Agency, as applicable, to which the	Agency, as applicable, to which the
been submitted in accordance with		application has been submitted in	application has been submitted in
Article 6 shall:		accordance with Article 6 shall:	accordance with Article 6 shall:
(a) verify that the documentation		(a) verify that the data []	(a) verify that the data []
submitted complies with the		submitted complies with the	submitted complies with the
requirements laid down in Article		requirements laid down in Article	requirements laid down in Article
7(1) and is satisfactory for granting a		7[];	7[];
marketing authorisation;			
(b) assess the veterinary medicinal		(b) assess the veterinary medicinal	(b) assess the veterinary medicinal
product regarding the quality, safety		product regarding the quality, safety	product regarding the quality, safety
and efficacy documentation		and efficacy documentation	and efficacy documentation
provided.		provided.	provided.
		(c) draw up a conclusion on the	(c) draw up a conclusion on the
		benefit-risk balance for the	benefit-risk balance for the
		veterinary medicinal product.	veterinary medicinal product.
2. During the process of assessing		2. During the process of assessing	2. During the process of assessing
applications for marketing		applications for marketing	applications for marketing
authorisations for veterinary		authorisations for veterinary	authorisations for veterinary
medicinal products containing or		medicinal products containing or	medicinal products containing or
consisting of genetically modified		consisting of genetically modified	consisting of genetically modified
organisms as referred to in Article		organisms as referred to in Article	organisms as referred to in Article
7(5), the necessary consultations		7(5), the necessary consultations	7(5), the necessary consultations
shall be held by the Agency with the		shall be held by the Agency with the	shall be held by the Agency with the
bodies set up by the Union or		bodies set up by the Union or	bodies set up by the Union or
Member States in accordance with		Member States in accordance with	Member States in accordance with
Directive 2001/18/EC.		Directive 2001/18/EC.	Directive 2001/18/EC.



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Article 24		Article 24	Article 24
Requests to laboratories in the		Requests to laboratories in the	Requests to laboratories in the
course of the examination of		course of the examination of	course of the examination of
applications		applications	applications
1.The competent authority or the		1.The competent authority or the	1. The competent authority or the
Agency examining the application		Agency, as applicable , examining	Agency, as applicable, examining
may require an applicant to provide		the application may require an	the application may require an
samples of the veterinary medicinal		applicant to provide [] to the	applicant to provide [] to the
product to the Union reference		Union reference laboratory, an	Union reference laboratory, an
laboratory, an Official Medicines		Official Medicines Control	Official Medicines Control
Control Laboratory or a laboratory		Laboratory or a laboratory that a	Laboratory or a laboratory that a
that a Member State has designated		5	5
e		Member State has designated for that	Member State has designated for that
for that purpose to:		purpose to, samples which are	purpose to, samples which are
		necessary to:	necessary to:
(a) test the veterinary medicinal		(a) test the veterinary medicinal	(a) test the veterinary medicinal
product, its starting materials and if		product, its starting materials and if	product, its starting materials and if
necessary intermediate products or		necessary intermediate products or	necessary intermediate products or
other constituent materials in order to		other constituent materials in order to	other constituent materials in order to
ensure that the control methods		ensure that the control methods	ensure that the control methods
employed by the manufacturer and		employed by the manufacturer and	employed by the manufacturer and
described in the application		described in the application	described in the application
documents are satisfactory;		documents are satisfactory;	documents are satisfactory;
(b) verify, using samples provided		(b) verify [] that, in case of	(b) verify [] that, in case of
by the applicant, that the analytical		veterinary medicinal products	veterinary medicinal products
detection method proposed by the		intended for food producing	intended for food producing
applicant for the purposes of safety		animals, the analytical detection	animals, the analytical detection
tests and residue tests is satisfactory		method proposed by the applicant for	method proposed by the applicant for
and suitable for use to reveal the		the purposes of [] residue	the purposes of [] residue
presence of residue levels,		depletion tests is satisfactory and	depletion tests is satisfactory and
particularly those exceeding the		suitable for use to reveal the presence	suitable for use to reveal the



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maximum residue level of the		of residue levels, particularly those	presence of residue levels,
pharmacologically active substance		exceeding the maximum residue	particularly those exceeding the
established by the Commission in		level of the pharmacologically active	maximum residue level of the
accordance with Regulation (EC) No		substance established by the	pharmacologically active substance
470/2009 and Commission Decision		Commission in accordance with	established by the Commission in
$2002/657/EC^{32}$.		Regulation (EC) No 470/2009 and	accordance with Regulation (EC) No
		for official controls of animals and	470/2009 and for official controls
		products of animal origin in	of animals and products of animal
		accordance with Regulation (EU)	origin in accordance with
		No 2017/625 [].	Regulation (EU) No 2017/625 [].
2. The time limits laid down in		2. The time limits laid down in	2. The time limits laid down in
Articles 40, 44, 46 and 48 shall be		Articles 40, 44, 46, [] 48 and 48a	Articles 40, 44, 46, [] 48 and 48a
suspended until the samples		shall be suspended until the samples	shall be suspended until the samples
requested in accordance with		requested in accordance with	requested in accordance with
paragraph 1 have been provided.		paragraph 1 of this Article have	paragraph 1 of this Article have
		been provided.	been provided.
Article 25		Article 25	Article 25
Information on manufacturers		Information on manufacturers	Information on manufacturers <u>in</u>
			third countries
	AM 114		
The competent authority shall	The competent authority shall	The competent authority [] or the	The competent authority [] or the
ascertain that the manufacturers of	ascertain that the manufacturers of	Agency, as applicable, to which the	Agency, as applicable, to which the
veterinary medicinal products from	veterinary medicinal products from	application has been submitted in	application has been submitted in
third countries are able to	third countries comply with	accordance with Article 6, may	accordance with Article 6, may
manufacture the veterinary medicinal	applicable Union law, are able to	request the relevant competent	request the relevant competent
product concerned and/or carry out	manufacture the veterinary medicinal	authority to forward to it the	authority to forward to it the
control tests in accordance with the	product concerned and/or carry out	information ascertaining that the	information ascertaining that the

³² Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results, (OJ L 221, 17.8.2002, p. 8).

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methods described in the	control tests in accordance with the	manufacturers of veterinary	manufacturers of veterinary
documentation submitted in support	methods described in the	medicinal products are able to	medicinal products shall ascertain,
of the application in accordance with	documentation submitted in support	manufacture the veterinary medicinal	through the procedure in Articles
Article 7(1).	of the application in accordance with	product concerned and/or carry out	91 to 93, that the manufacturers of
	Article 7(1) and that they minimise	control tests in accordance with the	veterinary medicinal products
	environmental pollution.	methods described in the	from third countries are able to
	•	documentation submitted in support	manufacture the veterinary medicinal
		of the application in accordance with	product concerned and/or carry out
		Article 7(1).	control tests in accordance with the
			methods described in the
			documentation submitted in support
			of the application in accordance with
			Article 7(1). <u>A competent authority</u>
			or the Agency, as applicable, may
			request the relevant competent
			<u>authority to present information</u>
			ascertaining that the
			manufacturers of veterinary
			medicinal products are able to
			carry out the activities referred to
			in this Article.
Article 26		Article 26	Article 26
Information to the applicant		Additional information [] from the	Additional information [] from the
		applicant	applicant
The competent authority or the		The competent authority or the	The competent authority or the
Agency to which the application has		Agency, as applicable, to which the	Agency, as applicable, to which the
been submitted in accordance with		application has been submitted in	application has been submitted in
Article 6 shall inform the applicant if		accordance with Article 6 shall	accordance with Article 6 shall
the documentation submitted in		inform the applicant if the	inform the applicant if the
support of the application is		documentation submitted in support	documentation submitted in support



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insufficient. The competent authority		of the application is insufficient. The	of the application is insufficient. The
or the Agency shall request the		competent authority or the Agency,	competent authority or the Agency,
applicant to provide the		as applicable, shall request the	as applicable, shall request the
documentation within a given		applicant to provide [] additional	applicant to provide [] additional
deadline. In such case the time limits		information [] within a given	information [] within a given
laid down in Articles 40, 44, 46 and		deadline. In such case the time limits	deadline. In such case the time limits
48 shall be suspended until the		laid down in Articles 40, 44, 46, []	laid down in Articles 40, 44, 46, []
deadline has elapsed.		48 and 48a shall be suspended until	48 and 48a shall be suspended until
		the [] additional information has	the [] additional information has
		been provided.	been provided.
Article 27		Article 27	Article 27
Withdrawal of applications	l	Withdrawal of applications	Withdrawal of applications
1. An applicant may withdraw his		1. An applicant may withdraw his	1. An applicant may withdraw his
application for marketing		application for marketing	application for marketing
authorisation submitted to a		authorisation submitted to a	authorisation submitted to a
competent authority or the Agency at		competent authority or the Agency,	competent authority or the Agency,
any time before the decision referred		as applicable, at any time before the	as applicable, at any time before the
to in Article 31 or 32 has been taken.		decision referred to in Article []	decision referred to in Article []
		40, 44, 46, 48 or 48a has been taken.	40, 44, 46, 48 or 48a has been taken.
2. If an applicant withdraws his		2. If an applicant withdraws his	2. If an applicant withdraws his
application for marketing		application for a marketing	application for a marketing
authorisation submitted to a		authorisation submitted to a	authorisation submitted to a
competent authority or the Agency		competent authority or the Agency,	competent authority or the Agency,
before the assessment of the		as applicable, before the []	as applicable, before the []
application as referred to in Article		examination of the application as	examination of the application as
23 has been completed, the applicant		referred to in Article 23 has been	referred to in Article 23 has been
shall communicate its reasons for		completed, the applicant shall	completed, the applicant shall
doing so to the competent authority		communicate its reasons for doing so	communicate its reasons for doing so
or the Agency to which the		to the competent authority or the	to the competent authority or the
application was submitted in	L	Agency, as applicable, to which the	Agency, as applicable, to which the



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accordance with Article 6.		application was submitted in	application was submitted in
		accordance with Article 6.	accordance with Article 6.
3. If an assessment report or, in		3. [] In case of a centralised	3. [] In case of a centralised
case of the centralised authorisation		authorisation procedure, the	authorisation procedure, <u>The</u>
procedure, the opinion, has been		Agency shall make publicly	competent authorities or the
drawn up, it shall be made public by		available the information that the	Agency, as applicable, shall make
the competent authorities or the		application has been withdrawn	publicly available the information
Agency, after deletion of any		together with [] the opinion, []	that the application has been
commercially confidential		already drawn up, [] after deletion	withdrawn together with [] the
information.		of any commercially confidential	opinion, [] already drawn up, []
		information.	after deletion of any commercially
			confidential information.
Article 28		Article 28	Article 28
Outcome of the assessment		Outcome of the assessment	Outcome of the assessment
1. In case of favourable		1. The competent authority or	1. The competent authority or
assessment to grant a marketing		the Agency, as applicable,	the Agency, as applicable,
authorisation, the competent		examining the application in	examining the application in
authority or the Agency examining		accordance with Article 23, shall	accordance with Article 23, shall
the application shall prepare an		prepare, respectively, an	prepare, respectively, an
opinion including the following		assessment report or an opinion. In	assessment report or an opinion. In
documents:		case of a favourable assessment [],	case of a favourable assessment [],
		that assessment report or opinion	that assessment report or opinion
		shall include the following []:	shall include the following []:
(a) a summary of the product		(a) a summary of the product	(a) a summary of the product
characteristics containing the		characteristics containing the	characteristics containing the
information laid down in Article 30;		information laid down in Article 30;	information laid down in Article 30;

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(b) details of any conditions or restrictions to be imposed as regards the supply or use of the veterinary medicinal product concerned, including the classification of a veterinary medicinal product in accordance with Article 29;		(b) details of any conditions or restrictions to be imposed as regards the supply or safe and effective use of the veterinary medicinal product concerned, including the classification of a veterinary medicinal product in accordance with	(b) details of any conditions or restrictions to be imposed as regards the supply or safe and effective use of the veterinary medicinal product concerned, including the classification of a veterinary medicinal product in accordance
(c) details of any conditions or restrictions which should be imposed as regards the safe and effective use of the veterinary medicinal product;		Article 29; (c) []	with Article 29; (c) []
(d) the approved text of the labelling and package leaflet.		(d) the [] text of the labelling and package leaflet referred to in Articles 9 to 12 .	(d) the [] text of the labelling and package leaflet referred to in Articles 9 to 12 .
		1a. In case of an unfavourable assessment, the assessment report or the opinion, referred to in paragraph 1, shall contain the justification for arriving at the outcome.	1a. In case of an unfavourable assessment, the assessment report or the opinion, referred to in paragraph 1, shall contain the justification for arriving at the outcome.
2. Where the application concerns a veterinary medicinal product for food-producing target species, the competent authority or the Agency shall prepare a statement related to the maximum residue levels of the pharmaceutical active substance in relation to specific foodstuffs and species, as established by the		2. []	2. []



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Commission in accordance with			proposed by the residency
Regulation (EC) No 470/2009.			
3. Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission may require the marketing authorisation holder to conduct post-authorisation studies in order to ensure that the benefit-risk balance remains positive with a view to the possible development of	AM 115 3. Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission may <i>shall</i> require the marketing authorisation holder to conduct post-authorisation studies in order to ensure that the benefit-risk balance remains positive with a view to the possible development of	3. [] ³³	3. []
antimicrobial resistance.	antimicrobial resistance.		
Article 29		Article 29	Article 29
Requirement for a veterinary		[] Classification of veterinary	[] Classification of veterinary
prescription		medicinal products	medicinal products
1. A competent authority or the Commission shall classify the following veterinary medicinal products as subject to veterinary prescription:	AM 116&298 1. A competent authority or the Commission shall classify t <i>T</i> he following veterinary medicinal products as <i>shall be</i> subject to <i>mandatory</i> veterinary prescription:	1. The competent authority or the Commission, as applicable, granting a marketing authorisation as referred to in Article 5(1) shall classify the following veterinary medicinal products as subject to veterinary prescription:	1. The competent authority or the Commission, as applicable, granting a marketing authorisation as referred to in Article 5(1) shall classify the following veterinary medicinal products as subject to veterinary prescription:

 $[\]overline{^{33}}$ Moved to Article 31.

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(a) veterinary medicinal products		(a) veterinary medicinal products	(a) veterinary medicinal products
which contain psychotropic drugs or		which contain [] narcotic drugs or	which contain [] narcotic drugs or
narcotics, including those covered by		psychotropic substances, or	psychotropic substances, or
the United Nations Single		substances frequently used in the	substances frequently used in the
Convention on Narcotic Drugs of		illicit manufacture of these drugs	illicit manufacture of these drugs
1961 as amended by the 1972		or substances including those	or substances including those
Protocol and the United Nations		covered by the United Nations Single	covered by the United Nations Single
Convention on Psychotropic		Convention on Narcotic Drugs of	Convention on Narcotic Drugs of
Substances of 1971;		1961 as amended by the 1972	1961 as amended by the 1972
		Protocol, and the United Nations	Protocol, and the United Nations
		Convention on Psychotropic	Convention on Psychotropic
		Substances of 1971 and the United	Substances of 1971 and the United
		Nations Convention against Illicit	Nations Convention against Illicit
		Traffic in Narcotic Drugs and	Traffic in Narcotic Drugs and
		Psychotropic Substances of 1988	Psychotropic Substances of 1988
		or by Union legislation on drug	or by Union legislation on drug
		precursors;	precursors;
(b) veterinary medicinal products		(b) veterinary medicinal products	(b) veterinary medicinal products
for food-producing animals;		for food-producing animals;	for food-producing animals;
(c) antimicrobial veterinary		(c) antimicrobial veterinary	(c) antimicrobial veterinary
medicinal products;		medicinal products;	medicinal products;
(d) products intended for		(d) veterinary medicinal products	(d) veterinary medicinal products
treatments of pathological processes		intended for treatments of	intended for treatments of
which require a precise prior		pathological processes which require	pathological processes which require
diagnosis or the use of which may		a precise prior diagnosis or the use of	a precise prior diagnosis or the use of
have effects which impede or		which may have effects which	which may have effects which
interfere with subsequent diagnostic		impede or interfere with subsequent	impede or interfere with subsequent
or therapeutic measures;		diagnostic or therapeutic measures;	diagnostic or therapeutic measures;
		(dd) veterinary medicinal	(dd) veterinary medicinal
		products used for euthanasia of	products used for euthanasia of



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		animals;	animals;
(e) officinal formulae intended for food-producing animals;		$(e) - []^{34};$	(e) [];
(f) veterinary medicinal products containing an active substance that has been authorised for less than 5 years in the Union.		(f) veterinary medicinal products containing an active substance that has been authorised for less than 5 years in the Union.	(f) veterinary medicinal products containing an active substance that has been authorised for less than 5 years in the Union.
	AM 116&298 (fa) veterinary medicinal products for which marketing authorisations have been granted in accordance with Article 21 and/or 22.		
		(g) immunological veterinary medicinal products;	(g) immunological veterinary medicinal products;
		(h) without prejudice to Council Directive 96/22/EC, veterinary	(h) without prejudice to Council Directive 96/22/EC ³⁵ , veterinary
		medicinal products containing an active substance s having a	medicinal products containing an active substance s having a
		hormonal or thyrostatic action and beta-agonists.	hormonal or thyrostatic action and beta-agonists.

³⁴ Point(e) is covered by the addition to Article 2(3)(c).

 ³⁵ Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ L 125, 23.5.1996, p.3).

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 2. A competent authority or the Commission may classify a veterinary medicinal product as subject to veterinary prescription where special precautions are contained in the summary of product characteristics referred to in Article 30, and in particular potential risks to: (a) the target species, (b) the person administering the 	AM 116&298 Ia. Member States may on their territories provide for additional legal subcategories in accordance with the respective national law. AM 116&298 2. A competent authority or the Commission may classify a A veterinary medicinal product may be classified as subject to mandatory veterinary prescription where special precautions are contained in the summary of product characteristics referred to in Article 30, and in particular potential risks to:	2. The [] competent authority or the Commission, as applicable, may classify a veterinary medicinal product as subject to veterinary prescription if it is classified as a narcotic drug in accordance with national legislation or where special precautions are contained in the summary of product characteristics referred to in Article 30. [] (a) (b)	2. The [] competent authority or the Commission, as applicable, may classify a veterinary medicinal product as subject to veterinary prescription if it is classified as a narcotic drug in accordance with national legislation or where special precautions are contained in the summary of product characteristics referred to in Article 30. [] (a)
products to the animal, (c) the environment.		(c)	(c)
 3. By the way of derogation from paragraph 1, a competent authority or the Agency may not classify a veterinary medicinal product as subject to veterinary prescription if all of the following conditions are fulfilled: 	 AM 116&298 By the way of derogation from paragraph 1, a competent authority or the Agency Commission may not elassify exempt a veterinary medicinal product as subject to from a mandatory veterinary prescription if all of the following conditions are fulfilled: 	 By the way of derogation from paragraph 1, [] the competent authority or the [] Commission, as applicable, may, except as regards veterinary medicinal products referred to in paragraphs 1(a), 1(c), 1(dd) and 1(h), [] classify a veterinary medicinal product as not subject to veterinary prescription if 	3. By the way of derogation from paragraph 1, [] the competent authority or the [] Commission, as applicable, may, except as regards veterinary medicinal products referred to in paragraphs 1(a), 1(c), 1(dd) and 1(h), [] classify a veterinary medicinal product as not subject to veterinary prescription if



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558 IIIai - 2014/0257 (COD)		by Coreper on 20 December 2017 all of the following conditions are	proposed by the Presidency all of the following conditions are
		fulfilled:	fulfilled:
(a) the administration of the		(a) the administration of the	(a) the administration of the
veterinary medicinal product is		veterinary medicinal product is	veterinary medicinal product is
restricted to pharmaceutical forms		restricted to pharmaceutical forms	restricted to pharmaceutical forms
requiring no particular knowledge or		requiring no particular knowledge or	requiring no particular knowledge or
skill in using the products;		skill in using the products;	skill in using the products;
(b) the veterinary medicinal		(b) the veterinary medicinal	(b) the veterinary medicinal
product does not present a direct or		product does not present a direct or	product does not present a direct or
indirect risk, even if administered		indirect risk, even if administered	indirect risk, even if administered
incorrectly, to the animal(s) treated,		incorrectly, to the animal(s) treated	incorrectly, to the animal(s) treated
to the person administering the		or to other animals, to the person	or to other animals, to the person
product or to the environment;		administering the product or to the	administering the product or to the
		environment;	environment;
	AM 116&298		
(c) the summary of the product	(c) the summary of the product	(c) the summary of the product	(c) the summary of the product
characteristics of the veterinary	characteristics of the veterinary	characteristics of the veterinary	characteristics of the veterinary
medicinal product does not contain	medicinal product does not contain	medicinal product does not contain	medicinal product does not contain
any warnings of potential serious	any warnings of potential serious	any warnings of potential serious	any warnings of potential serious
side effects deriving from its correct	side effects adverse events-deriving	adverse events [] deriving from	adverse events [] deriving from
use;	from its correct use;	its correct use;	its correct use;
(d) neither the veterinary		(d) neither the veterinary	(d) neither the veterinary
medicinal product nor any other		medicinal product nor any other	medicinal product nor any other
product containing the same active		product containing the same active	product containing the same active
substance has previously been the		substance has previously been the	substance has previously been the
subject of frequent adverse event		subject of frequent adverse event	subject of frequent adverse event
reporting;		reporting;	reporting;



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(e) the summary of the product		(e) the summary of the product	(e) the summary of the product
characteristics does not refer to		characteristics does not refer to	characteristics does not refer to
contraindications related to other		contraindications related to other	contraindications related to other
veterinary medicinal products		veterinary medicinal products	veterinary medicinal products
commonly used without prescription;		commonly used without prescription;	commonly used without prescription;
	AM 116&298		
(f) the veterinary medicinal	(f) the veterinary medicinal	(f) the veterinary medicinal	(f) the veterinary medicinal
product is not subject to special	product is not subject to special	product is not subject to special	product is not subject to special
storage conditions;	storage conditions;	storage conditions;	storage conditions;
(g) there is no risk for public		(g) there is no risk for public	(g) there is no risk for public
health as regards residues in food		health as regards residues in food	health as regards residues in food
obtained from treated animals even		obtained from treated animals even	obtained from treated animals even
where the veterinary medicinal		where the veterinary medicinal	where the veterinary medicinal
products are used incorrectly;		products are used incorrectly;	products are used incorrectly;
	AM 116&298		
(h) there is no risk to public or	h) there is no risk to public or	(h) there is no risk to public or	(h) there is no risk to public or
animal health as regards the	animal health as regards the	animal health as regards the	animal health as regards the
development of resistance to	development of antiparasic	development of resistance to []	development of resistance to []
anthelmintic substances even where	resistance to anthelmintic substances	substances even where the veterinary	substances even where the veterinary
the veterinary medicinal products	even where the veterinary medicinal	medicinal products containing those	medicinal products containing those
containing those substances are used	products containing those substances	substances are used incorrectly.	substances are used incorrectly.
incorrectly.	are used incorrectly.		
	AM 117		
	<i>3a. Notwithstanding paragraph 1,</i>		
	medicinal products for veterinary		
	use may be used without		
	prescription if:		
	(a) they are registered as single		
	homeopathic products and released		
	for sale in pharmacies, have a		



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	dilution of not less than D4 (1:10 000) and are not produced using alcohol; (b) they are registered as complex homeopathic products, contain no individual components below a dilution of D4, are released for sale in pharmacies and are not produced using alcohol.		
Article 30 Summary of the product characteristics		Article 30 Summary of the product characteristics	Article 30 Summary of the product characteristics
1. The summary of the product characteristics referred to in Article 28(1)(a) shall contain the following information:		1. The summary of the product characteristics referred to in Article 28(1)(a) shall contain, in the order indicated below , the following information:	1. The summary of the product characteristics referred to in Article 28(1)(a) shall contain, in the order indicated below , the following information:
(a) name of the veterinary medicinal product followed by its strength and pharmaceutical form;		 (a) name of the veterinary medicinal product followed by its strength and pharmaceutical form and, where applicable, a list of the names of the veterinary medicinal product, as authorised in different Member States³⁶; 	(a) name of the veterinary medicinal product followed by its strength and pharmaceutical form and, where applicable, a list of the names of the veterinary medicinal product, as authorised in different Member States ³⁷ :

³⁶ 37

This wording is moved here from Article 12(1)(b). This wording is moved here from Article 12(1)(b).

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(b) qualitative and quantitative composition of the active substances or other constituents stating the common name or the chemical description of the substances or other constituents;	AM 118 (b) qualitative and quantitative composition of the active substances or other and all the essential constituents stating the common name or the chemical description of the substances or other constituents;	(b) qualitative and quantitative composition of the active substance(s) []and qualitative composition of excipients and other consistuents stating their common name or their chemical description and, if that knowledge is essential for proper administration of the veterinary medicinal product, their quantitative composition;	(b) qualitative and quantitative composition of the active substance(s) []and qualitative composition of excipients and other consistuents stating their common name or their chemical description and, if that knowledge is essential for proper administration of the veterinary medicinal product, their quantitative composition;
(c) clinical information:		(c) clinical information:	(c) clinical information:
(i) target species,		(i) target species;	(i) target species;
(ii) indications for use,		(ii) indications for use for each target species ,	(ii) indications for use for each target species,
(iii) contra-indications,		(iii) contra-indications,	(iii) contra-indications,
(iv) special warnings for each target species,		(iv) special warnings [],	(iv) special warnings [],
(v) special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals,		 (v) special precautions for use, including in particular special precautions for safe use in the target species, special precautions to be taken by the person administering the veterinary medicinal product to the animals and special precautions for the protection of the environment; 	 (v) special precautions for use, including in particular special precautions for safe use in the target species, special precautions to be taken by the person administering the veterinary medicinal product to the animals and special precautions for the protection of the environment;
(vi) frequency and seriousness of	AM 119 (vi) frequency and seriousness of	(vi) frequency and seriousness of	(vi) frequency and seriousness of

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adverse events,	adverse events reactions,	adverse events,	adverse events,
(vii) use during pregnancy, lactation		(vii) use during pregnancy, lactation	(vii) use during pregnancy, lactation
or lay,		or lay,	or lay,
(viii) interaction with other		(viii) interaction with other	(viii) interaction with other
medicinal products and other forms		medicinal products and other forms	medicinal products and other forms
of interaction,		of interaction,	of interaction,
(ix) administration route and		(ix) administration route and	(ix) administration route and
amounts to be administered,		dosage [],	dosage [],
(x) overdose symptoms and		(x) [] symptoms of overdose	(x) [] symptoms of overdose
emergency procedures and antidotes		and, where applicable, emergency	and, where applicable, emergency
in the event of overdose, where		procedures and antidotes in the event	procedures and antidotes in the event
applicable,		of overdose, [],	of overdose, [],
(xi) where appropriate, special		(xi) [] special [] restrictions	(xi) [] special [] restrictions
indications or restrictions for use in		for use,	for use,
accordance with Articles 107 to 109,			
(xii) where appropriate, an		(xii) []	(xii) []
indication of classification of an			
antimicrobial regarding its strategic			
use,			
	AM 120		
(xiii) special conditions for use,	(xiii) special conditions for use,	(xiii) special conditions for use,	(xiii) special conditions for use,
including restrictions on the use of	including restrictions on the use of	including restrictions on the use of	including restrictions on the use of
antimicrobials in order to limit the	antimicrobials in order to limit the	antimicrobial and antiparasitic	antimicrobial and antiparasitic
risk of development of antimicrobial	risk of development of antimicrobial	veterinary medicinal products in	veterinary medicinal products in
resistance,	resistance, and specifying that the	order to limit the risk of development	order to limit the risk of development
	product is not allowed to be used as	of [] resistance,	of [] resistance,
(d) with drowed rearised in also the	a routine preventive measure,	(d) (viiii) if applicable with trans	(d) (viiii) if applicable with drawn
(d) withdrawal periods, including		(d) (xiiii) if applicable, withdrawal	$\frac{d}{d}$ (xiiii) if applicable, withdrawal
animal species/foodstuffs		periods[] including when it is	periods[] including when it is
combinations;		zero [],	zero [],



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(e) pharmacological information:		(e) pharmacological information:	(e) pharmacological information:
		(oi) Anatomical Therapeutic	(oi) Anatomical Therapeutic
		Chemical Veterinary Code (ATC	Chemical Veterinary Code (ATC
		Vet Code);	Vet Code);
(i) pharmacodynamics,		(i) pharmacodynamics,	(i) pharmacodynamics,
(ii) pharmacokinetics,		(ii) pharmacokinetics,	(ii) pharmacokinetics,
		In case of an immunological	In case of an immunological
		veterinary medicinal product,	veterinary medicinal product,
		instead of points (0i), (i) and (ii)	instead of points (0i), (i) and (ii)
		immunological information;	immunological information;
(iii) pharmaceutical particulars,		(eb)[] pharmaceutical	(eb)[] pharmaceutical
		particulars:	particulars:
	AM 121		
	(iiia) list of excipients,		
	AM 122		
	(ea) information from the		
	environmental risk assessment of		
	the product, in particular		
	environmental endpoints and risk		
	characterisation data, including		
	ecotoxicological information on		
	effects on non-target species and		
	persistence of active substances and		
	active metabolites in soil and water;		

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(iv) major incompatibilities,		(i[]) major incompatibilities,	(i[]) major incompatibilities,
(v) shelf life, where applicable		([] ii) shelf life, where	([] ii) shelf life, where
after reconstitution of the medicinal		applicable after reconstitution of the	applicable after reconstitution of the
product or after the immediate		medicinal product or after the	medicinal product or after the
packaging has been opened for the		immediate packaging has been	immediate packaging has been
first time,		opened for the first time,	opened for the first time,
(vi) special precautions for storage,		([] iii) special precautions for	([] iii) special precautions for
		storage,	storage,
(vii) nature and composition of		(iv[]) nature and composition	(iv[]) nature and composition
immediate packaging,		of immediate packaging,	of immediate packaging,
(viii) requirement to use take-back		(viii) requirement to use take-back	(viii) requirement to use take-back
schemes for veterinary medicinal		schemes for veterinary medicinal	schemes for veterinary medicinal
products for the disposal of unused		products for the disposal of unused	products for the disposal of unused
veterinary medicinal products or		veterinary medicinal products or	veterinary medicinal products or
waste materials derived from the use		waste materials derived from the use	waste materials derived from the use
of such products and, if appropriate,		of such products and, if appropriate,	of such products and, if appropriate,
additional precautions regarding		additional precautions regarding	additional precautions regarding
hazardous waste disposal of unused		hazardous waste disposal of unused	hazardous waste disposal of unused
veterinary medicinal products or		veterinary medicinal products or	veterinary medicinal products or
waste materials derived from the use		waste materials derived from the use	waste materials derived from the use
of such products;		of such products;	of such products;
(f) name of the marketing		(f) name of the marketing	(f) name of the marketing
authorisation holder;		authorisation holder;	authorisation holder;
(g) marketing authorisation		(g) marketing authorisation	(g) marketing authorisation
number(s);		number(s);	number(s);
(h) if applicable, date of the first		(h) [] date of the first	(h) [] date of the first
authorisation;		marketing authorisation;	marketing authorisation;

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(i) the date of the last revision of the summary of the product		(i) [] date of the last revision of the summary of the product	(i) [] date of the last revision of the summary of the product
 characteristics; (j) if applicable, for products authorised in accordance with Article 21 or Article 22, the statement 		 characteristics; (j) if applicable, for products [] referred to in Article 21 or Article 22a, the statement 'marketing 	 characteristics; (j) if applicable, for products [] referred to in Article 21 or Article 22a, the statement 'marketing
'market authorisation granted for a limited market/exceptional circumstances and therefore assessment based on customised requirements for documentation'.		authorisation granted for a limited market/exceptional circumstances and therefore assessment based on customised requirements for documentation'.	authorisation granted for a limited market/exceptional circumstances and therefore assessment based on customised requirements for documentation'.
		(k) information on the collection systems referred to in Article 122 applicable to the veterinary medicinal product in question;	(k) information on the collection systems referred to in Article 122 applicable to the veterinary medicinal product in question;
		(l) classification of the veterinary medicinal product as referred to in Article 29 per Member State in which it is authorised.	(l) classification of the veterinary medicinal product as referred to in Article 29 per Member State in which it is authorised.
	AM 123 (ja) when the veterinary medical product is authorised to be administered via medicated feed, information on the possibility to		
	have interaction between the veterinary medicinal products and the feed impairing the safety or the efficacy of the medicated feed shall be provided through a list of		



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	incompatibilities.		
2. In case of generic veterinary		2. In case of generic veterinary	2. In case of generic veterinary
medicinal products, the parts of the		medicinal products, the parts of the	medicinal products, the parts of the
summary of the product		summary of the product	summary of the product
characteristics of the reference		characteristics of the reference	characteristics of the reference
veterinary medicinal product that		veterinary medicinal product that	veterinary medicinal product that
refer to indications or pharmaceutical		refer to indications or pharmaceutical	refer to indications or pharmaceutical
forms which are protected by patent		forms which are protected by patent	forms which are protected by patent
law in a Member State at the time of		law in a Member State at the time of	law in a Member State at the time of
placing the generic veterinary		placing the generic veterinary	placing the generic veterinary
medicinal product on the market may		medicinal product on the market may	medicinal product on the market may
be omitted.		be omitted.	be omitted.
Article 31		Article 31	Article 31
Decisions granting marketing		Decisions granting marketing	Decisions granting marketing
authorisations		authorisations	authorisations
1. Decisions granting marketing		1. Decisions granting marketing	1. Decisions granting marketing
authorisations shall be taken on the		authorisations referred to in Article	authorisations referred to in Article
basis of the documents prepared in		5(1) shall be taken on the basis of the	5(1) shall be taken on the basis of the
accordance with Article 28 and shall		documents prepared in accordance	documents prepared in accordance
set out the conditions attached to the		with Article 28(1) and shall set out	with Article 28(1) and shall set out
placing on the market of the		[] any conditions attached to the	[] any conditions attached to the
veterinary medicinal product and the		placing on the market of the	placing on the market of the
summary of the product		veterinary medicinal product and the	veterinary medicinal product and the
characteristics ('terms of the		summary of the product	summary of the product
marketing authorisation').		characteristics ('terms of the	characteristics ('terms of the
		marketing authorisation').	marketing authorisation').

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 The competent authority or the Commission shall make the decision granting the marketing authorisation publicly available and record it in the database referred to in Article 51. 		2	2.
		³⁸ 2a. Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission may require the marketing authorisation holder to conduct post-authorisation studies in order to ensure that the benefit- risk balance remains positive given the potential development of antimicrobial resistance.	2a. Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission may require the marketing authorisation holder to conduct post-authorisation studies in order to ensure that the benefit- risk balance remains positive given the potential development of antimicrobial resistance.
	AM 124 2a. Where two products have the same therapeutic effect, comparative assessments may be carried out. In such a case, the products that are hazardous to the environment or to the treated animals shall be substituted by the less hazardous products having the same therapeutic effects.		
Article 32 Decisions refusing marketing	£ 33	Article 32 Decisions refusing marketing	Article 32 Decisions refusing marketing

ex Article 28(3)

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authorisations		authorisations	authorisations
		0. Decisions refusing marketing	0. Decisions refusing marketing
		authorisations referred to in	authorisations referred to in
		Article 5(1) shall be taken on the	Article 5(1) shall be taken on the
		basis of the documents prepared in	basis of the documents prepared in
		accordance with Article 28(1a) and	accordance with Article 28(1a) and
		shall be duly justified and include	shall be duly justified and include
		the reasons for refusal.	the reasons for refusal.
1. The marketing authorisation		1. A marketing authorisation shall	1. A marketing authorisation shall
shall be refused on any of the		be refused on any of the following	be refused on any of the following
following grounds:		grounds:	grounds:
		(aa) the application does not comply with the relevant provisions of this Chapter;	(aa) the application does not comply with the relevant provisions of this Chapter;
(a) the benefit-risk balance of the veterinary medicinal product is unfavourable;		 (a) the benefit-risk balance of the veterinary medicinal product is unfavourable; 	 (a) the benefit-risk balance of the veterinary medicinal product is unfavourable;
(b) the applicant has not provided sufficient information on the quality, safety or efficacy of the veterinary medicinal product;		(b) the applicant has not provided sufficient information on the quality, safety or efficacy of the veterinary medicinal product;	(b) the applicant has not provided sufficient information on the quality, safety or efficacy of the veterinary medicinal product;
(c) the product is a zootechnical veterinary medicinal product or a performance enhancer, and the applicant has not sufficiently demonstrated the benefits of the product to the animal health and welfare or public health;		(c)	(c)

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(d) the product is an antimicrobial veterinary medicinal product presented for use as performance enhancer in order to promote the growth of treated animals or to increase yields from treated animals;	AM 125 (d) the product is an antimicrobial veterinary medicinal product presented for use as performance enhancer in order to promote the growth of treated animals or to increase yields from treated animals, or as a routine prophylactic in food producing animals, or to be added to feed or water for mass medication when no disease has been diagnosed in any of the animals;	(d) the veterinary medicinal product is an antimicrobial veterinary medicinal product presented for use as performance enhancer in order to promote the growth of treated animals or to increase yields from treated animals;	(d) the veterinary medicinal product is an antimicrobial veterinary medicinal product presented for use as performance enhancer in order to promote the growth of treated animals or to increase yields from treated animals;
(e) the withdrawal period is not long enough to ensure food safety;	AM 126 (e) the proposed withdrawal period to ensure food safety is not long enough to ensure food safety well justified, or the proposed withdrawal period by the Agency or by the competent authorities is not taken into account;	(e) the proposed withdrawal period is not long enough to ensure food safety or is insufficiently substantiated ;	(e) the proposed withdrawal period is not long enough to ensure food safety or is insufficiently substantiated ;
(f) information to be provided in the immediate packaging, the outer packaging and the package leaflet of the veterinary medicinal product does not comply with the requirements set out in Articles 9 to 11;		(f)	(f)
(g) risk for public health in case of development of antimicrobial resistance outweighs the benefits of		(g) the risk for public health in case of development of antimicrobial resistance or antiparasitic	(g) the risk for public health in case of development of antimicrobial resistance or antiparasitic



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the product to animal health;		resistance outweighs the benefits of the product to animal health;	resistance outweighs the benefits of the product to animal health;
	AM 127 (ga) the product is a substance of high concern;		
	AM 128 (gb) active substances within the product which meet the criteria for being persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to EMA guidelines, or are considered as having endocrine- disrupting properties that risk causing adverse effects in the environment;		
(h) the product has no therapeutic effect or the applicant has not provided sufficient proof of such effect as regards the target species;		 (h) [] the applicant has not provided sufficient proof of [] efficacy as regards the target species; 	(h) [] the applicant has not provided sufficient proof of [] efficacy as regards the target species;
	AM 129 (ha) the product poses significantly higher risks to the treated animal, public health or the environment compared to the standard reference treatment;		

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	AM 130 (hb) unacceptable side effects or secondary effects on the treated animal;		
(i) the qualitative or quantitative composition of the product is not as stated in the application.		(i) the qualitative or quantitative composition of the product is not as stated in the application[];	(i) the qualitative or quantitative composition of the product is not as stated in the application[];
		(j) risks to public health, animal health or for the environment are not sufficiently addressed; or,	(j) risks to public health, animal health or for the environment are not sufficiently addressed; or,
		 (k) the active substance within the product meets the criteria for being persistent, bioaccumulative and toxic or very persistent and very bioaccumulative and the product is intended to be used in food producing animals, unless it is shown by evidence that the active substance is essential to prevent or control a serious risk to animal health. 	 (k) the active substance within the product meets the criteria for being persistent, bioaccumulative and toxic or very persistent and very bioaccumulative and the product is intended to be used in food producing animals, unless it is shown by evidence that the active substance is essential to prevent or control a serious risk to animal health.
2. A marketing authorisation for an antimicrobial veterinary medicinal product shall be refused if the antimicrobial is reserved for treatment of certain infections in humans.	 AM 132 A marketing authorisation for an antimicrobial veterinary medicinal product shall be refused if the antimicrobial is reserved for treatment of certain infections in humans <i>within the meaning of</i> <i>paragraph 4</i>. AM 133 	2. A marketing authorisation for an antimicrobial veterinary medicinal product shall be refused if the antimicrobial is reserved for treatment of certain infections in humans as provided for in paragraph 4.	2. A marketing authorisation for an antimicrobial veterinary medicinal product shall be refused if the antimicrobial is reserved for treatment of certain infections in humans as provided for in paragraph 4.



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3. The Commission shall be	3. The Commission shall be	3. The Commission shall []	3. The Commission shall []
empowered to adopt delegated acts	empowered to adopt delegated acts	adopt delegated acts in accordance	adopt delegated acts in accordance
in accordance with Article 146 in	in accordance with Article 146 and	with Article 146 supplementing the	with Article 146 supplementing the
order to establish rules for the	taking into consideration the	rules of this Regulation concerning	rules of this Regulation concerning
designation of the antimicrobials	scientific advice of the Agency in	the establishment of criteria []	the establishment of criteria []
which are to be reserved for	order to establish rules for the	for the designation of the	for the designation of the
treatment of certain infections in	designation of the antimicrobials	antimicrobials which are to be	antimicrobials which are to be
humans in order to preserve the	which are to be reserved for	reserved for treatment of certain	reserved for treatment of certain
efficacy of certain active substances	treatment of certain infections in	infections in humans in order to	infections in humans in order to
in humans.	humans in order to preserve the	preserve the efficacy of [] those	preserve the efficacy of [] those
	efficacy of certain active substances	antimicrobials.	antimicrobials.
	in humans.		
	The Agency, in its advice, shall		
	consider appropriate designations at		
	the class, substance or even the indication level and shall consider		
	also the route of administration.		
	Member States which implement or		
	wish to implement stricter rules		
	shall be allowed to do so.		
	AM 134		
4. The Commission shall, by	4. The Commission shall, by	4. The Commission shall, by	4. The Commission shall, by
means of implementing acts,	means of implementing acts <i>and</i>	means of implementing acts,	means of implementing acts,
designate antimicrobials or groups of	taking into consideration the	designate antimicrobials or groups of	designate antimicrobials or groups of
antimicrobials reserved for treatment	scientific advice of the Agency as	antimicrobials reserved for treatment	antimicrobials reserved for treatment
of certain infections in humans.	well as the work already carried out	of certain infections in humans.	of certain infections in humans.
Those implementing acts shall be	by the WHO, designate	Those implementing acts shall be	Those implementing acts shall be
adopted in accordance with the	antimicrobials or groups of	adopted in accordance with the	adopted in accordance with the



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examination procedure referred to in Article 145(2).	antimicrobials reserved for treatment of certain infections in humans. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). Such designations, where relevant, shall be done at the class, substance or even the indication level and	examination procedure referred to in Article 145(2).	examination procedure referred to in Article 145(2).
	shall consider also the route of administration.	5. The Commission shall take into account of the scientific advice of the Agency, the European Food Safety Authority (EFSA) and other relevant Union agencies, when adopting the acts referred to in	5. The Commission shall take into account of the scientific advice of the Agency, the European Food Safety Authority (EFSA) and other relevant Union agencies, when adopting the acts referred to in
		paragraphs 3 and 4.	paragraphs 3 and 4.
Section 8 Protection of technical documentation		Section 8 Protection of technical documentation	Section 8 Protection of technical documentation
Article 33 Protection of technical documentation		Article 33 Protection of technical documentation	Article 33 Protection of technical documentation
1. Without prejudice to the requirements and obligations laid down in Directive 2010/63/EU, technical documentation on quality,		1. Without prejudice to the requirements and obligations laid down in Directive 2010/63/EU, technical documentation on quality,	1. Without prejudice to the requirements and obligations laid down in Directive 2010/63/EU, technical documentation on quality,
safety and efficacy originally		safety and efficacy originally	safety and efficacy originally



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submitted with a view to obtaining a		submitted with a view to obtaining a	submitted with a view to obtaining a
marketing authorisation or a		marketing authorisation or a	marketing authorisation or a
variation thereof shall not be used by		variation thereof shall not be []	variation thereof shall not be []
other applicants for a marketing		referred to by other applicants for a	referred to by other applicants for a
authorisation or a variation of the		marketing authorisation or a	marketing authorisation or a
terms of a marketing authorisation		variation of the terms of a marketing	variation of the terms of a marketing
for a veterinary medicinal product		authorisation for a veterinary	authorisation for a veterinary
unless:		medicinal product unless:	medicinal product unless:
(a) the period of the protection of		(a) the period of the protection of	(a) the period of the protection of
technical documentation as set out in		technical documentation as set out in	technical documentation as set out in
Articles 34 and 35 has elapsed, or		Articles 34 and 35 has elapsed, or is	Articles 34 and 35 has elapsed, or is
		due to elapse in less than 2 years,	due to elapse in less than 2 years,
(b) the applicants have obtained		(b) the applicants have obtained	(b) the applicants have obtained
written agreement in the form of a		written agreement in the form of a	written agreement in the form of a
letter of access with regard to that		letter of access with regard to that	letter of access with regard to that
documentation.		documentation.	documentation.
2. The protection of the technical		2. The protection of the technical	2. The protection of the technical
documentation as referred to in		documentation as referred to in	documentation as referred to in
paragraph 1 ('the protection of		paragraph 1 ('the protection of	paragraph 1 ('the protection of
technical documentation') shall also		technical documentation') shall also	technical documentation') shall also
apply in Member States where the		apply in Member States where the	apply in Member States where the
product is not authorised or is no		veterinary medicinal product is not	veterinary medicinal product is not
longer authorised.		authorised or is no longer authorised.	authorised or is no longer authorised.

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3. Any marketing authorisation or		3. [] Marketing authorisation	3. [] Marketing authorisation
variation to the terms of a marketing		or a variation to the terms of a	or a variation to the terms of a
authorisation differing from the		marketing authorisation differing	marketing authorisation differing
previously granted marketing		from the previously granted	from the previously granted
authorisation only with regard to		marketing authorisation only with	marketing authorisation only with
strengths, pharmaceutical forms,		regard to target species, strengths,	regard to target species, strengths,
administration routes or		pharmaceutical forms, administration	pharmaceutical forms, administration
presentations shall be regarded as the		routes or presentations shall be	routes or presentations shall be
same marketing authorisation as the		regarded as the same marketing	regarded as the same marketing
one previously granted for the		authorisation as the one previously	authorisation as the one previously
purpose of applying the rules of the		granted to the same marketing	granted to the same marketing
protection of technical		authorisation holder for the	authorisation holder for the
documentation.		purpose of applying the rules of the	purpose of applying the rules of the
		protection of technical	protection of technical
		documentation.	documentation.
	AM 301		
	<i>3a.</i> Safety information with		
	regard to the environmental effects		
	of veterinary medicinal products		
	shall not be protected.		

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Article 34		Article 34	Article 34
Periods of the protection of technical		Periods of the protection of technical	Periods of the protection of technical
documentation		documentation	documentation
1. The period of the protection of		1. The period of the protection of	1. The period of the protection of
technical documentation shall be:		technical documentation shall be:	technical documentation shall be:
	AM 136	(a) 10 years for the veterinary	(a) 10 years for the veterinary
(a) 10 years for the veterinary	(a) 10 years for the veterinary	medicinal products for cattle, sheep	medicinal products for cattle, sheep
medicinal products for cattle, sheep,	medicinal products for cattle, sheep	for meat production, pigs, chickens,	for meat production, pigs, chickens,
pigs, chickens, dogs and cats;	(reared for meat), pigs, chickens,	dogs and cats;	dogs and cats;
	salmon, dogs and cats;		
	AM 136		
(b) 14 years for antimicrobial	(b) 14 years for antimicrobial	(b) 14 years for antimicrobial	(b) 14 years for antimicrobial
veterinary medicinal products for	veterinary medicinal products for	veterinary medicinal products for	veterinary medicinal products for
cattle, sheep, pigs, chickens, dogs	cattle, sheep, pigs, chickens, salmon,	cattle, sheep for meat production,	cattle, sheep for meat production,
and cats containing an antimicrobial	dogs and cats containing an	pigs, chickens, dogs and cats	pigs, chickens, dogs and cats
active substance which has not been	antimicrobial active substance which	containing an antimicrobial active	containing an antimicrobial active
an active substance in a veterinary	has not been an active substance in a	substance which has not been an	substance which has not been an
medicinal product authorised within	veterinary medicinal product	active substance in a veterinary	active substance in a veterinary
the Union on the date of the	authorised within the Union on the	medicinal product authorised within	medicinal product authorised within
submission of the application;	date of the submission of the	the Union on the date of the	the Union on the date of the
	application;	submission of the application;	submission of the application;
	AM 136		
(c) 18 years for veterinary	(c) 18 20 years for veterinary	(c) 18 years for veterinary	(c) 18 years for veterinary
medicinal products for bees;	medicinal products for bees;	medicinal products for bees;	medicinal products for bees;
(d) 14 years for veterinary		(d) 14 years for veterinary	(d) 14 years for veterinary
medicinal products for animal		medicinal products for animal	medicinal products for animal
species other than listed in paragraph		species other than listed in paragraph	species other than listed in paragraph
1(a) and (c).		1(a) and (c).	1(a) and (c).
2. The protection shall apply from		2. The protection shall apply from	2. The protection shall apply from
the day when the marketing		the day when the marketing	the day when the marketing



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authorisation for the veterinary		authorisation for the veterinary	authorisation for the veterinary
medicinal product was granted in		medicinal product was granted in	medicinal product was granted in
accordance with Article 7.		accordance with the provisions	accordance with the provisions
		referred to in Article [] 5(1).	referred to in Article [] 5(1).
	AM 136		
	2a. Where the veterinary		
	medicinal product has been		
	authorised for more than one		
	species, the period shall be extended		
	in accordance with the prolongation		
	periods provided for in Article 35.		
	AM 312		
	Article 34a		
	Period of protection of new data		
	packages related to existing		
	veterinary medicinal products		
	1. Any new studies and trials,		
	submitted by the applicant for a		
	marketing authorisation to the		
	competent authorities for an		
	existing veterinary medicinal		
	product no longer covered by any		
	protection period shall benefit from		
	a stand-alone period of protection of		
	four years, provided that they are:		

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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	(a) needed to extend a marketing		
	authorisation in respect of dosages,		
	pharmaceutical forms or routes of		
	administration;		
	(b) needed for a reevaluation		
	requested by the Agency or the		
	competent authorities post-		
	authorisation, unless they have been		
	requested by competent authorities		
	as a follow-up to post authorisation		
	pharmacovigilance concerns, or		
	requested as a condition of		
	authorisation or as a post-		
	authorisation commitment at the		
	time of authorisation. Each period		
	of protection shall operate		
	independent from any other that		
	may operate concurrently and shall		
	therefore not be cumulated.		
	2. No other applicant may use		
	the results of these trials or studies		
	for commercial purposes during		
	that four year period without the		
	written consent of the holder of the		
	marketing authorisation in the form		
	of a letter of access to those trials or		
	studies.		

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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Article 35		Article 35	Article 35
Prolongation of the periods of the		Prolongation of the periods of the	Prolongation of the and additional
protection of technical		protection of technical	periods of the protection of technical
documentation		documentation	documentation
	AM 138		
1. Where a variation is approved	1. Where <i>the first marketing</i>	1. Where a variation is approved	1. Where the first marketing
in accordance with Article 65	authorisation is granted for more	in accordance with Article 65	authorisation is granted for more
extending the marketing	<i>than one species or</i> a variation is	extending the marketing	than one species listed
authorisation to another species	approved in accordance with Article	authorisation to another species	<u>in Article 34(1)(a) or (b), or</u> a
listed in Article 34(1)(a), the period	65 extending the marketing	listed in Article $34(1)(a)$, the period	variation is approved in accordance
of the protection provided for in that	authorisation to another species	of the protection provided for in that	with Article 65 extending the
Article shall be prolonged by 1 year	listed in Article $34(1)(a)$, the period	Article shall be prolonged by 1 year	marketing authorisation to another
for each additional target species,	of the protection provided for in that	for each additional target species,	species listed in Article 34(1)(a) <u>or</u>
provided that the variation has been	Article 34 shall be prolonged by 1	provided that the variation has been	(b), the period of the protection
submitted at least 3 years before the	<i>two</i> years for each additional target	submitted at least 3 years before the	provided for in that Article shall be
expiration of the protection period	species in the original dossiers,	expiration of the protection period	prolonged by 1 year for each
laid down in Article 34(1)(a).	provided that the variation has been	laid down in Article 34(1)(a).	additional target species, provided
	submitted at least 3 years before the		that <u>, in case of a</u> the variation, the
	expiration of the protection period		application has been submitted at
	laid down in Article 34(1)(a). <i>The</i>		least 3 years before the expiration of
	information on the submission for		the protection period laid down in
	extension of the marketing		Article 34(1)(a) <u>or (b).</u>
	authorisation shall be made publicly		
	available.		
	AM 138		
2. Where a variation is approved	2. Where <i>the first marketing</i>	2. Where a variation is approved	2. Where the first marketing
in accordance with Article 65	authorisation is granted for more	in accordance with Article 65	authorisation is granted for more
extending the marketing	than one species or a variation is	extending the marketing	than one species listed in Article
authorisation to a another species not	approved in accordance with Article	authorisation to a another species not	<u>34(1)(d) or</u> a variation is approved in
listed in Article 34(1)(a), the period	65 extending the marketing	listed in Article 34(1)(a), the period	accordance with Article 65 extending

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
of the protection provided for in Article 34 shall be prolonged by 4 years.	authorisation to a another species not listed in Article 34(1)(a), the period of the protection provided for in Article 34 shall be prolonged by 4 years, provided that the variation has been submitted at least three years before the expiration of the protection period laid down in Article 34. The information on the submission for extension of the marketing authorisation shall be made publicly available.	of the protection provided for in Article 34 shall be prolonged by 4 years, provided that the variation has been submitted at least 3 years before the expiration of the protection period laid down in Article 34(1)(a).	the marketing authorisation to a another species not listed <u>referred to</u> in Article 34(1)(a), the period of the protection provided for in Article 34 shall be prolonged by 4 years, provided that, in case of a the variation, the application has been submitted at least 3 years before the expiration of the protection period laid down in Article 34(1)(a)(d).
3. The period of the protection of the first marketing authorisation prolonged by any additional periods of protection due to any variations or new authorisations belonging to the same marketing authorisation ('overall period of the protection of technical documentation') shall not exceed 18 years.	AM 138 3. The period of the protection of the first marketing authorisation prolonged by any additional periods of protection due to any variations or new authorisations belonging to the same marketing authorisation ('overall period of the protection of technical documentation') shall not exceed 18 14 years for products referred to in Article 34(1)(a). For products referred to in Article 34(1)(b) and (d), this period shall not exceed 18 years.	3. The period of the protection provided for in Article 34 of the first marketing authorisation prolonged by any additional periods of protection due to any variations or new authorisations belonging to the same marketing authorisation []shall not exceed 18 years.	3. The period of the protection provided for in Article 34 of the first marketing authorisation prolonged by any additional periods of protection due to any variations or new authorisations belonging to the same marketing authorisation []shall not exceed 18 years.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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	AM 138		
4. Where an applicant for a	4. Where an applicant for a	4. Where an applicant for a	4. Where an applicant for a
marketing authorisation for a	marketing authorisation for a	marketing authorisation for a	marketing authorisation for a
veterinary medicinal product or for a	veterinary medicinal product or for a	veterinary medicinal product or for a	veterinary medicinal product or for a
variation to the terms of the	variation to the terms of the	variation to the terms of [] a	variation to the terms of [] a
marketing authorisation submits an	marketing authorisation submits an	marketing authorisation submits an	marketing authorisation submits an
application in accordance with	application in accordance with	application in accordance with	application in accordance with
Regulation (EC) No 470/2009 for the	Regulation (EC) No 470/2009 for the	Regulation (EC) No 470/2009 for the	Regulation (EC) No 470/2009 for the
establishment of a maximum residue	establishment of a maximum residue	establishment of a maximum residue	establishment of a maximum residue
limit, together with clinical trials	limit, together with clinical trials	limit, together with safety and	limit, together with safety and
during the application procedure,	during the application procedure,	residues tests and pre-clinical and	residues tests and pre-clinical and
other applicants shall not use those	other applicants shall not use those	clinical trials during the application	clinical trials during the application
trials for a period of 5 years from the	the results of these trials for	procedure, other applicants shall not	procedure, other applicants shall not
granting of the marketing	commercial purposes for a period of	[] refer to results of those tests	[] refer to results of those tests
authorisation for which they were	5 years from the granting of the	and trials for a period of 5 years	and trials for a period of 5 years
carried out, unless the other applicant	marketing authorisation for which	from the granting of the marketing	from the granting of the marketing
has obtained written agreement in the	they were carried out, unless the	authorisation for which they were	authorisation for which they were
form of a letter of access with regard	other applicant has obtained written	carried out []. The prohibition on	carried out []. The prohibition on
to those trials.	agreement in the form of a letter of	using those results shall not apply,	using those results shall not apply,
	access with regard to those trials.	insofar as the other applicants have	insofar as the other applicants have
		obtained [] a letter of access with	obtained [] a letter of access with
		regard to those tests and trials.	regard to those tests and trials.
		5. If a variation to the terms of	5. If a variation to the terms of
		the marketing authorisation	the marketing authorisation
		approved in accordance with	approved in accordance with
		Article 65, involves a change to the	Article 65 involves a change to
		pharmaceutical form,	the pharmaceutical form,
		administration route or dosage for	administration route or dosage,
		the purposes of reducing the	for the purposes of reducing
		antimicrobial or antiparasitic	which is considered by the Agency

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017 resistance, or improves the benefit- risk balance of the veterinary medicinal product, the results of the concerned pre-clinical studies or clinical trials shall benefit from 4 years protection. The prohibition on using those results shall not apply, insofar as the other applicants have obtained a letter of access with regard to those tests and trials.	Draft revised negotiation mandate proposed by the Presidency or the competent authorities referred to in Article 64 to have demonstrated: (a) a reduction in the antimicrobial or antiparasitic resistance, or, (b) an improvement of the benefit- risk balance of the veterinary medicinal product, the results of the concerned pre-clinical studies or clinical trials shall benefit from 4 years protection. The prohibition on using those results shall not apply, insofar as the other applicants have obtained a letter of access with regard to those tests and trials.
Article 36		Article 36	Article 36
Patent-related rights		Patent-related rights	Patent-related rights
Conducting the necessary studies,		Conducting the necessary studies,	Conducting the necessary studies,
tests and trials with a view to		tests and trials with a view to	tests and trials with a view to
applying for a marketing		applying for a marketing	applying for a marketing
authorisation in accordance with		authorisation in accordance with	authorisation in accordance with
Article 16 and the consequential		Article 16 and the [] requirements	Article 16 and the [] requirements
practical requirements shall not be		set out there in shall not be regarded	set out there in shall not be regarded
regarded as contrary to patent-related		as contrary to patent-related rights or	as contrary to patent-related rights or
rights or to supplementary-protection		to supplementary-protection	to supplementary-protection
certificates for medicinal products.		certificates for medicinal products as	certificates for medicinal products as

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		defined in Article 1(a) of Regulation (EC) No 469/2009.	defined in Article 1(a) of Regulation (EC) No 469/2009 ³⁹ .
Chapter III		Chapter III	Chapter III
Procedures for granting marketing		Procedures for [] marketing	Procedures for [] marketing
authorisations		authorisations	authorisations
Section 1		Section 1	Section 1
Marketing authorisations valid		Marketing authorisations valid	Marketing authorisations valid
throughout the Union ('centralised		throughout the Union ('centralised	throughout the Union ('centralised
marketing authorisations')		marketing authorisations')	marketing authorisations')
Article 38		Article 38	Article 38
Scope of the centralised marketing		Scope of the centralised marketing	Scope of the centralised marketing
authorisation procedure		authorisation procedure	authorisation procedure
1. Centralised marketing authorisations shall be granted by the Commission in accordance with this Section. They shall be valid throughout the Union.	AM 139 1. Centralised marketing authorisations shall be granted by the Commission in accordance with this Section. They shall be valid throughout the Union and considered the priority procedure. The Commission and the Agency shall develop and encourage use of the centralised procedure, particularly by facilitating access for SMEs.	1. Centralised marketing authorisations shall [] be valid throughout the Union.	1. Centralised marketing authorisations shall [] be valid throughout the Union.

³⁹ Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

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2. Centralised marketing		2. Centralised marketing	2. Centralised marketing
authorisation procedure shall apply		authorisation procedure shall apply	authorisation procedure shall apply
in respect of the following veterinary		in respect of the following veterinary	in respect of the following veterinary
medicinal products:		medicinal products:	medicinal products:
(a) veterinary medicinal products		(a) veterinary medicinal products	(a) veterinary medicinal products
developed by means of one of the		developed by means of one of the	developed by means of one of the
following biotechnological		following biotechnological	following biotechnological
processes:		processes:	processes:
(i) recombinant DNA		(i) recombinant DNA technology;	(i) recombinant DNA technology;
technology;			
(ii) controlled expression of		(ii) controlled expression of genes	(ii) controlled expression of genes
genes coding for		coding for biologically active	coding for biologically active
biologically active		proteins in prokaryotes and	proteins in prokaryotes and
proteins in prokaryotes		eukaryotes including	eukaryotes including
and eukaryotes including		transformed mammalian cells;	transformed mammalian cells;
transformed mammalian			
cells;			
(iii) hybridoma and		(iii) hybridoma and monoclonal	(iii) hybridoma and monoclonal
monoclonal antibody		antibody methods;	antibody methods;
methods;			
(b) veterinary medicinal products		(b) veterinary medicinal products	(b) veterinary medicinal products
intended primarily for use as		intended primarily for use as	intended primarily for use as
performance enhancers in order to		performance enhancers in order to	performance enhancers in order to
promote the growth of treated		promote the growth of treated	promote the growth of treated
animals or to increase yields from		animals or to increase yields from	animals or to increase yields from
treated animals;		treated animals;	treated animals;

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(c) veterinary medicinal products containing an active substance which has not been authorised as a veterinary medicinal product within the Union at the date of the submission of the application;	AM 141 (c) veterinary medicinal products containing an active substance which has not been authorised as a veterinary medicinal product within the Union at the date of the submission of the application, with the exception of veterinary medicinal products subject to authorisation under Articles 21 and 22;	(c) veterinary medicinal products containing an active substance which has not been authorised as a veterinary medicinal product within the Union at the date of the submission of the application;	(c) veterinary medicinal products containing an active substance which has not been authorised as a veterinary medicinal product within the Union at the date of the submission of the application;
(d) biological veterinary medicinal products which contain or consist of engineered allogeneic tissues or cells;		(d) biological veterinary medicinal products which contain or consist of engineered allogeneic tissues or cells;	(d) biological veterinary medicinal products which contain or consist of engineered allogeneic tissues or cells;
		(da) novel therapy veterinary medicinal products;	(da) novel therapy veterinary medicinal products;
(e) generic veterinary medicinal products of reference veterinary medicinal products authorised under the centralised authorisation procedure.	AM 142 (e) generic veterinary medicinal products of reference veterinary medicinal products authorised under the centralised authorisation procedure.	(e) []	(e) []
	AM 143	2a. Points (d) and (da) of paragraph 2 shall not apply to veterinary medicinal products consisting exclusively of blood components.	2a. Points (d) and (da) of paragraph 2 shall not apply to veterinary medicinal products consisting exclusively of blood components.
3. For veterinary medicinal	3. For veterinary medicinal	3. For veterinary medicinal	3. For veterinary medicinal



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products other than those listed in	products other than those listed in	products other than those listed in	products other than those listed in
paragraph 2 a centralised marketing	paragraph 2 a centralised marketing	paragraph 2 <u>,</u> a centralised marketing	paragraph 2 <u>,</u> a centralised marketing
authorisation may be granted if no	authorisation may <i>also</i> be granted if	authorisation may be granted if no	authorisation may be granted if no
other marketing authorisation has	no other marketing authorisation has	other marketing authorisation has	other marketing authorisation has
been granted for the veterinary	been granted for the veterinary	been granted for the veterinary	been granted for the veterinary
medicinal product within the Union.	medicinal product within the Union.	medicinal product within the Union.	medicinal product within the Union.
	AM 144		
4. The Commission, taking into	4. The Commission, taking into	4[]	4[]
account the state of animal and	account the state of animal and		
public health in the Union, shall be	public health in the Union, shall be		
empowered to adopt delegated acts	empowered to adopt delegated acts		
in accordance with Article 146 in	in accordance with Article 146 in		
order to amend the list set out in	order to amend the list set out in		
paragraph 2.	paragraph 2.		
Article 39		Article 39	Article 39
Application for centralised		Application for centralised	Application for centralised
marketing authorisation		marketing authorisation	marketing authorisation
1. Applications for centralised		1. An application for centralised	1. An application for centralised
marketing authorisations shall be		marketing authorisations shall be	marketing authorisations shall be
submitted to the Agency. The		submitted to the Agency. The	submitted to the Agency. The
application shall be accompanied by		application shall be accompanied by	application shall be accompanied by
the fee payable to the Agency for the		the fee payable to the Agency []	the fee payable to the Agency []
examination of the application.		for the examination of the	for the examination of the
		application.	application.
2. The application for a		2. The application for a	2. The application for a
centralised authorisation of		centralised marketing authorisation	centralised marketing authorisation
veterinary medicinal product shall		of a veterinary medicinal product	of a veterinary medicinal product
state a single name for the veterinary		shall state a single name for the	shall state a single name for the
medicinal product to be used		veterinary medicinal product to be	veterinary medicinal product to be
throughout the Union.		used throughout the Union.	used throughout the Union.



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3. Translations of the labelling,		3[]	3. []
package leaflet and the summary of			
the product characteristics shall be			
submitted in the languages			
determined by the Member States in			
accordance with Article 14.			
Article 40		Article 40	Article 40
Procedure for centralised marketing		Procedure for centralised marketing	Procedure for centralised marketing
authorisation		authorisation	authorisation
1. Centralised marketing		1. []	1. []
authorisations shall be granted by the			
Commission following an			
assessment by the Agency.			
2. As an outcome of the		2. The Agency shall assess the	2. The Agency shall assess the
assessment of an application for		application referred to in Article	application referred to in Article
marketing authorisation for a		39. As an outcome of the assessment	39. As an outcome of the assessment
veterinary medicinal product, the		[] the Agency shall [] prepare	[] the Agency shall [] prepare
Agency shall draw up an opinion as		an opinion containing the	an opinion containing the
referred to in Article 28.		information [] referred to in	information [] referred to in
		Article 28.	Article 28.
3. The opinion shall be given		3. The opinion shall be given	3. The opinion shall be given
within 210 days of receipt of a valid		within 210 days of receipt of a valid	within 210 days of receipt of a valid
application. Exceptionally, where a		application. Exceptionally, where a	application. Exceptionally, where a
particular expertise is required, the		particular expertise is required, the	particular expertise is required, the
deadline may be extended by a		deadline may be extended by a	deadline may be extended by a
maximum of 90 days.		maximum of 90 days.	maximum of 90 days.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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4. When an application is		4. When an application is	4. When an application is
submitted for a marketing		submitted for a marketing	submitted for a marketing
authorisation in respect of veterinary		authorisation in respect of veterinary	authorisation in respect of veterinary
medicinal products of major interest,		medicinal products of major interest,	medicinal products of major interest,
particularly from the point of view of		particularly from the point of view of	particularly from the point of view of
animal health and therapeutic		animal health and therapeutic	animal health and therapeutic
innovation, the applicant may request		innovation, the applicant may request	innovation, the applicant may request
an accelerated assessment procedure.		an accelerated assessment procedure.	an accelerated assessment procedure.
The request shall be duly		The request shall be duly	The request shall be duly
substantiated. If the Agency accepts		substantiated. If the Agency accepts	substantiated. If the Agency accepts
the request, the time limit of 210		the request, the time limit of 210	the request, the time limit of 210
days shall be reduced to 150 days.		days shall be reduced to 150 days.	days shall be reduced to 150 days.
5. The opinion of the Agency		5. The opinion of the Agency	5. The opinion of the Agency
shall be forwarded to the applicant.		shall be forwarded to the applicant.	shall be forwarded to the applicant.
Within 15 days of receipt of the		Within 15 days of receipt of the	Within 15 days of receipt of the
opinion the applicant may provide		opinion the applicant may provide	opinion the applicant may provide
written notice to the Agency that he		written notice to the Agency that he	written notice to the Agency that he
wishes to request a re-examination of		wishes to request a re-examination of	wishes to request a re-examination of
the opinion. In such case, Article 41		the opinion. In such case, Article 41	the opinion. In such case, Article 41
shall apply.		shall apply.	shall apply.
6. After the completion of the		6. [] In case the applicant has	6. [] In case the applicant has
procedure referred to in paragraph 5		not provided written notice in	not provided written notice in
the opinion shall be forwarded		accordance with paragraph 5, []	accordance with paragraph 5, []
without delay to the Commission.		the Agency [] shall, without	the Agency [] shall, without
		undue delay, forward its opinion to	undue delay, forward its opinion to
		the Commission.	the Commission.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	7. The Commission may request
7. The Commission may request		7. The Commission may request	
clarifications from the Agency as		clarifications from the Agency as	clarifications from the Agency as
regards the content of the opinion, in		regards the content of the opinion, in	regards the content of the opinion, in
which case the Agency shall provide		which case the Agency shall provide	which case the Agency shall provide
a response to this request within 90		a response to this request within 90	a response to this request within 90
days.		days.	days.
		7a. The applicant shall submit to	7a. The applicant shall submit to
		the Agency the necessary	the Agency the necessary
		translations of the summary of	translations of the summary of
		product characteristics, package	product characteristics, package
		leaflet and labelling in accordance	leaflet and labelling in accordance
		with Article 6a, within the time	with Article 6a, within the time
		limit set by the Agency, but at the	limit set by the Agency, but at the
		latest on the date the draft decision	latest on the date the draft decision
		is forwarded to the competent	is forwarded to the competent
		authorities in accordance with	authorities in accordance with
		paragraph 8.	paragraph 8.
8. Within 15 days of receipt of		8. Within 15 days of receipt of	8. Within 15 days of receipt of
the opinion, the Commission shall		the opinion, the Commission shall	the opinion, the Commission shall
prepare a draft of the decision to be		prepare a draft [] decision to be	prepare a draft [] decision to be
taken in respect of the application.		taken in respect of the application.	taken in respect of the application.
Where a draft decision envisages		Where a draft decision envisages	Where a draft decision envisages
granting of a marketing		granting of a marketing	granting of a marketing
authorisation, it shall include or		authorisation, it shall include []	authorisation, it shall include []
make reference to the documents		the opinion prepared in	the opinion prepared in
listed in Article 28. Where the draft		accordance with paragraph 1.	accordance with paragraph 2.
decision is not in accordance with		Where the draft decision is not in	Where the draft decision is not in
the opinion of the Agency, the		accordance with the opinion of the	accordance with the opinion of the
Commission shall annex a detailed		Agency, the Commission shall annex	Agency, the Commission shall annex
explanation of the reasons for the		a detailed explanation of the reasons	a detailed explanation of the reasons



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differences. The draft decision shall		for the differences. The draft	for the differences. The draft
be forwarded to Member States and		decision shall be forwarded to the	decision shall be forwarded to the
the applicant.		competent authorities of Member	competent authorities of Member
		States and to the applicant.	States and to the applicant.
9. The Commission shall, by		9. The Commission shall, by	9. The Commission shall, by
means of implementing acts, take a		means of implementing acts, take a	means of implementing acts, take a
final decision on the granting of a		[] decision on the granting or	[] decision on the granting or
centralised marketing authorisation.		refusal of a centralised marketing	refusal of a centralised marketing
Those implementing acts shall be		authorisation in accordance with	authorisation in accordance with
adopted in accordance with the		this Section on the basis of the	this Section on the basis of the
examination procedure referred to in		opinion prepared by the Agency.	opinion prepared by the Agency.
Article 145(2).		Those implementing acts shall be	Those implementing acts shall be
		adopted in accordance with the	adopted in accordance with the
		examination procedure referred to in	examination procedure referred to in
		Article 145(2).	Article 145(2).
10. The Agency shall disseminate		10. []	10. []
the documents referred to in Article			
28 to the applicant.			
11. The Agency shall make the		11. The Agency shall make the	11. The Agency shall make the
opinion publicly available, after		opinion publicly available after	opinion publicly available after
deleting any commercially		deleting any commercially	deleting any commercially
confidential information.		confidential information. ⁴⁰	confidential information.

⁴⁰ The original paragraph 11 is reinstated.

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Article 41		Article 41	Article 41
Re-examination of the opinion of the		Re-examination of the opinion of the	Re-examination of the opinion of the
Agency		Agency	Agency
1. Where the applicant requests a		1. Where the applicant requests a	1. Where the applicant requests a
re-examination of the opinion in		re-examination of the opinion in	re-examination of the opinion in
accordance with Article 40(5), he		accordance with Article $40(5)$, he	accordance with Article $40(5)$, he
shall forward to the Agency detailed		shall forward to the Agency detailed	shall forward to the Agency detailed
grounds for the request within 60		grounds for the request within 60	grounds for the request within 60
days after receipt of the opinion.		days after receipt of the opinion.	days after receipt of the opinion.
2. Within 60 days after receipt of		2. Within 90 [] days after	2. Within 90 [] days after
the grounds for the request, the		receipt of the detailed grounds for	receipt of the detailed grounds for
Agency shall re-examine its opinion.		the request, the Agency shall re-	the request, the Agency shall re-
The reasons for the conclusions		examine its opinion. The []	examine its opinion. The []
reached shall be annexed to the		conclusions reached and the reasons	conclusions reached and the reasons
opinion.		for the conclusions shall be annexed	for the conclusions shall be annexed
		to the opinion and shall form an	to the opinion and shall form an
		integral part thereof.	integral part thereof.
3. Within 15 days after its		3. Within 15 days after [] the	3. Within 15 days after [] the
adoption, the Agency shall forward		re-examination of its opinion, the	re-examination of its opinion, the
its opinion to the Commission and		Agency shall forward its opinion to	Agency shall forward its opinion to
the applicant.		the Commission and the applicant.	the Commission and the applicant.
		4. Subsequent to the procedure	4. Subsequent to the procedure
		set out in paragraph 3 of this	set out in paragraph 3 of this
		Article, paragraphs (7) to (11) of	Article, paragraphs (7) to (11) of
		Article 40 shall apply.	Article 40 shall apply.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Section 2		Section 2	Section 2
Marketing authorisations valid in		Marketing authorisations valid in	Marketing authorisations valid in
a single Member State ('national		a single Member State ('national	a single Member State ('national
marketing authorisation')		marketing authorisation')	marketing authorisation')
Article 42		Article 42	Article 42
Scope of national marketing		Scope of national marketing	Scope of national marketing
authorisation		authorisation	authorisation
National marketing authorisations		1. National marketing	1. National marketing
shall be granted by the competent		authorisations shall be granted by the	authorisations shall be granted by the
authorities in accordance with this		competent authorities in accordance	competent authorities in accordance
Section and applicable national		with this Section and applicable	with this Section and applicable
provisions. A national marketing		national provisions. A national	national provisions. A national
authorisation shall be valid in the		marketing authorisation shall be	marketing authorisation shall be
Member State which granted it.		valid only in the Member State of	valid only in the Member State of
		the competent authority which	the competent authority which
		granted it.	granted it.
National marketing authorisations		2. National marketing	2. National marketing
shall only be granted in respect of		authorisations shall not [] be	authorisations shall not [] be
veterinary medicinal products not		granted in respect of veterinary	granted in respect of veterinary
falling within the scope of Article		medicinal products [] falling	medicinal products [] falling
38(2).		within the scope of Article 38(2) or	within the scope of Article 38(2) or
		for which a national marketing	for which a national marketing
		authorisation has been granted or	authorisation has been granted or
		an application in accordance with	an application in accordance with
		this Section is pending in another	this Section is pending in another
		Member State or in the Union.	Member State or in the Union.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Article 43		Article 43	Article 43
Applications for national marketing		[]	[]
authorisations			
Competent authorities shall verify		[]	[]
whether an application for a national			
marketing authorisation has been			
submitted or granted for the same			
veterinary medicinal product in			
another Member State. Where that is			
the case, the competent authority of			
that Member State shall decline to			
assess the application and inform the			
applicant of the possibility to submit			
an application under the mutual			
recognition procedure or the			
decentralised authorisation			
procedure.			
Article 44		Article 44	Article 44
Procedure for national marketing		Procedure for national marketing	Procedure for national marketing
authorisation		authorisation	authorisation
1. The procedure for granting a		1. The procedure for granting or	1. The procedure for granting or
national marketing authorisation for		refusing a national marketing	refusing a national marketing
a veterinary medicinal product shall		authorisation for a veterinary	authorisation for a veterinary
be completed within a maximum of		medicinal product shall be completed	medicinal product shall be completed
210 days after the submission of the		within a maximum of 210 days after	within a maximum of 210 days after
complete application.		the submission of the valid []	the submission of the valid []
		application.	application.



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
350 mai 201 //0257 (COD)		1a. The competent authority	1a. The competent authority
		shall prepare an assessment report	shall prepare an assessment report
		containing the information	containing the information
		referred to in Article 28.	referred to in Article 28.
2. Competent authorities shall		2. Competent authorities shall	2. Competent authorities shall
make the assessment report publicly		make the assessment report publicly	make the assessment report publicly
available, after deleting any		available, after deleting any	available, after deleting any
commercially confidential		commercially confidential	commercially confidential
information.		information.	information.
Section 3		Section 3	Section 3
Marketing authorisations valid in		Marketing authorisations valid in	Marketing authorisations valid in
several Member States		several Member States	several Member States
('decentralised marketing		('decentralised marketing	('decentralised marketing
authorisations')		authorisations')	authorisations')
Article 45		Article 45	Article 45
Scope of decentralised marketing		Scope of decentralised marketing	Scope of decentralised marketing
authorisation		authorisation	authorisation
1. Decentralised marketing		1. Decentralised marketing	1. Decentralised marketing
authorisations shall be granted by the		authorisations shall be granted by the	authorisations shall be granted by the
competent authorities in accordance		competent authorities in the	competent authorities in the
with this Section. They shall be valid		Member States where the	Member States where the
in the Member States stated therein.		applicant seeks to obtain a	applicant seeks to obtain a
		marketing authorisation	marketing authorisation
		('concerned Member States') in	('concerned Member States') in
		accordance with this Section. They	accordance with this Section. They
		shall be valid in those Member States	shall be valid in th os e Member States
		[].	[].

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
2. Decentralised marketing		2. Decentralised marketing	2. Decentralised marketing
authorisations shall only be granted		authorisations shall not [] be	authorisations shall not [] be
in respect of veterinary medicinal		granted in respect of veterinary	granted in respect of veterinary
products for which no national		medicinal products for which a []	medicinal products for which a []
marketing authorisation has been		national marketing authorisation has	national marketing authorisation has
granted at the time of application for		been granted or for which an	been granted or for which an
a decentralised marketing		application for a marketing	application for a marketing
authorisation and which does not fall		authorisation is pending at the time	authorisation is pending at the time
within the scope of Article 38(2).		of the application for a decentralised	of the application for a decentralised
		marketing authorisation [] or	marketing authorisation [] or
		which [] fall within the scope of	which [] fall within the scope of
		Article 38(2).	Article 38(2).
Article 46		Article 46	Article 46
Procedure for decentralised		Procedure for decentralised	Procedure for decentralised
marketing authorisation		marketing authorisation	marketing authorisation
	AM 145	1. An application for	1. An application for
1. Applications for decentralised	1. Applications <i>and the dossier</i>	decentralised marketing	decentralised marketing
marketing authorisation shall be	for decentralised marketing	authorisation shall be submitted to	authorisation shall be submitted to
submitted to the Member State	authorisation shall be submitted to	the competent authority in the	the competent authority in the
chosen by the applicant ('reference	all the Member States. <i>tT</i> he Member	Member State chosen by the	Member State chosen by the
Member State').	State chosen by the applicant <i>shall</i>	applicant to prepare an assessment	applicant to prepare an assessment
	<i>be the</i> ('reference Member State').	report and to act in accordance	report and to act in accordance
		with the provisions in this Section	with the provisions in this Section
		('reference Member State') and to	('reference Member State') and to
		the competent authorities in the	the competent authorities in the
		other concerned Member States.	other concerned Member States.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
	AM 146	2. The application shall list the	2. The application shall list the
2. The application shall list	2. The application shall list	concerned Member States [].	concerned Member States [].
Member States where the applicant	Member States where the applicant		
seeks to obtain a marketing	seeks to obtain a marketing		
authorisation ('Member States	authorisation ('Member States		
concerned').	concerned'). The applicant shall		
	send to all Member States		
	concerned an application identical		
	to that submitted to the reference		
	Member State, including an		
	identical dossier as provided under		
	Article 7.		2. If the same knows in the start hat
		2a. If the applicant indicates that one or more of the concerned	2a. If the applicant indicates that one or more of the concerned
		Member States shall no longer be considered as such, the competent	Member States shall no longer be considered as such, the competent
		authorities in those Member States	authorities in those Member States
		shall provide to the competent	shall provide to the competent
		authority in the reference Member	authority in the reference Member
		State and to the competent	State and to the competent
		authorities in the other concerned	authorities in the other concerned
		Member States any information	Member States any information
		they consider relevant relating to	they consider relevant relating to
		the withdrawal of the application.	the withdrawal of the application.
3. Within 120 days of receipt of a		3. Within 120 days of receipt of a	3. Within 120 days of receipt of a
valid application, the reference		valid application, the competent	valid application, the competent
Member State shall prepare an		authority in the reference Member	authority in the reference Member
assessment report. The assessment		State shall prepare an assessment	State shall prepare an assessment
report together with the approved		report containing the information	report containing the information
summary of the product		referred to in Article 28 and shall	referred to in Article 28 and shall

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
characteristics and text to appear in		forward it to the competent	forward it to the competent
the labelling and package leaflet		authorities in the other concerned	authorities in the other concerned
shall be forwarded to all Member		Member States and to the applicant	Member States and to the applicant
States and the applicant, together		[].	[].
with the list of the Member States			
concerned.			
4. Within 90 days after receipt of		4. Within 90 days after receipt of	4. Within 90 days after receipt of
the documents referred to in		the assessment report [] referred	the assessment report [] referred
paragraph 3, Member States shall		to in paragraph 3, the competent	to in paragraph 3, the competent
examine the assessment report, the		authorities in the other concerned	authorities in the other concerned
summary of the product		Member States [] shall examine it	Member States [] shall examine it
characteristics, the labelling and the		[] and inform the competent	[] and inform the competent
package leaflet and inform the		authority in the reference Member	authority in the reference Member
reference Member State of whether		State of whether they have [] any	State of whether they have [] any
they have no objections to the		objection to [] it on the ground	objection to [] it on the ground
assessment report, summary of		that it would pose a potential	that it would pose a potential
product characteristics, labelling and		serious risk to human or animal	serious risk to human or animal
package leaflet.		health or for the environment. The	health or for the environment. The
		assessment report resulting from	assessment report resulting from
		this examination shall be	this examination shall be
		forwarded by the competent	forwarded by the competent
		authority in the reference Member	authority in the reference Member
		State to the competent authorities	State to the competent authorities
		in the other concerned Member	in the other concerned Member
		States and to the applicant.	States and to the applicant.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		4a. If requested by the	4a. If requested by the
		competent authorities in the	competent authorities in the
		reference Member State or in	reference Member State or in
		another concerned Member State,	another concerned Member State,
		the coordination group shall be	the coordination group shall be
		convened to examine the	convened to examine the
		assessment report within the	assessment report within the
		period referred to in paragraph 4.	period referred to in paragraph 4.
5. Where all Member States agree,		5. Where [] the assessment	5. Where [] the assessment
the reference Member State shall		report is favourable and where no	report is favourable and where no
record the agreement, close the		competent authority has informed	competent authority has informed
procedure and inform the applicant		the competent authority in the	the competent authority in the
and the Member States accordingly.		reference Member State of an	reference Member State of an
Each Member State from the list		objection thereto, as set out in	objection thereto, as set out in
referred to in paragraph 2 shall grant a		paragraph 4, the latter shall record	paragraph 4, the latter shall record
marketing authorisation in conformity		[] that there is an agreement,	[] that there is an agreement,
with the approved assessment report,		close the procedure and inform the	close the procedure and inform the
summary of the product		applicant and the competent	applicant and the competent
characteristics, labelling and package		authorities in all Member States	authorities in all Member States
leaflet within 30 days of the receipt of		accordingly, without undue delay.	accordingly, without undue delay.
the information regarding the		[] The competent authorities in	[] The competent authorities in
agreement from the reference Member		the concerned Member States shall	the concerned Member States shall
State.		grant a marketing authorisation in	grant a marketing authorisation in
		conformity with the assessment	conformity with the assessment
		report within 30 days of the receipt	report within 30 days of the receipt
		of both the information on the	of both the information on the
		agreement from the competent	agreement from the competent
		authority in the reference Member	authority in the reference Member
		State and also the complete	State and also the complete
		translations of the summary of	translations of the summary of

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Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		product characteristics, labelling	product characteristics, labelling
		and package leaflet from the	and package leaflet from the
		applicant, whichever is submitted the	applicant, whichever is submitted
		latest.	the latest.
		5a. Where the assessment report	5a. Where the assessment report
		is unfavourable and where none of	is unfavourable and where none of
		the concerned competent	the concerned competent
		authorities has informed the	authorities has informed the
		competent authority in the	competent authority in the
		reference Member State of an	reference Member State of an
		objection thereto, as set out in	objection thereto, as set out in
		paragraph 4, the competent	paragraph 4, the competent
		authority in the reference Member	authority in the reference Member
		State shall record that there is a	State shall record that there is a
		refusal to grant the marketing	refusal to grant the marketing
		authorisation, close the procedure	authorisation, close the procedure
		and inform the applicant and the	and inform the applicant and the
		competent authorities in all	competent authorities in all
		Member States accordingly,	Member States accordingly,
		without undue delay.	without undue delay.
		5b. Where a competent authority	5b. Where a competent authority
		informs the competent authority in	informs the competent authority in
		the reference Member State of an	the reference Member State of an
		objection in accordance with	objection in accordance with
		paragraph 4, the procedure set out	paragraph 4, the procedure set out
		in Article 49 shall apply.	in Article 49 shall apply.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
6. If at any stage of the procedure a		6. If at any stage of the procedure	6. If at any stage of the procedure
Member State concerned invokes the		the competent authority in a	the competent authority in a
reasons referred to in Article 113(1)		concerned Member State []	concerned Member State []
for prohibiting the veterinary		invokes the reasons referred to in	invokes the reasons referred to in
medicinal product it shall no longer be		Article 113(1) for prohibiting the	Article 113(1) for prohibiting the
considered as a Member State where		veterinary medicinal product, that	veterinary medicinal product, that
the applicant seeks to obtain a		Member State [] shall no longer	Member State [] shall no longer
marketing authorisation. However, a		be considered as a concerned	be considered as a concerned
Member State having invoked those		Member State. []	Member State. []
reasons may subsequently recognise			
the marketing authorisation in			
accordance with Article 57.			
7. Competent authorities shall		7. The c ompetent authority in the	7. The c ompetent authority in the
make the assessment report publicly		reference Member State shall make	reference Member State shall make
available, after deleting any		the assessment report publicly	the assessment report publicly
commercially confidential		available, after deleting any	available, after deleting any
information.		commercially confidential	commercially confidential
		information.	information.
		Article 46a	Article 46a
		Request by the applicant for re-	Request by the applicant for re-
		examination of the assessment	examination of the assessment
		report	report
		1. Within 15 days after receipt	1. Within 15 days after receipt
		of the assessment report referred	of the assessment report referred
		to in Article 46(4) the applicant	to in Article 46(4) the applicant
		may provide written notice to the	may provide written notice to the
		competent authority in the	competent authority in the
		reference Member State	reference Member State
		requesting a re-examination of the	requesting a re-examination of the
		assessment report. In that case, the	assessment report. In that case, the



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		applicant shall forward to the	applicant shall forward to the
		competent authority in the	competent authority in the
		reference Member State detailed	reference Member State detailed
		grounds for the request within 60	grounds for the request within 60
		days after receipt of that	days after receipt of that
		assessment report. The competent	assessment report. The competent
		authority in the reference Member	authority in the reference Member
		State shall without delay forward	State shall without delay forward
		this request and the detailed	this request and the detailed
		grounds to the coordination group.	grounds to the coordination group.
		2. Within 60 days after receipt	2. Within 60 days after receipt
		of the detailed grounds for the	of the detailed grounds for the
		request for re-examination of the	request for re-examination of the
		assessment report, the	assessment report, the
		coordination group shall re-	coordination group shall re-
		examine the assessment report.	examine the assessment report.
		The conclusions reached and the	The conclusions reached and the
		reasons for the conclusions shall be	reasons for the conclusions shall be
		annexed to the assessment report	annexed to the assessment report
		and shall form an integral part	and shall form an integral part
		thereof.	thereof.
		3. Within 15 days after the re-	3. Within 15 days after the re-
		examination of the assessment	examination of the assessment
		report, the competent authority in	report, the competent authority in
		the reference Member State shall	the reference Member State shall
		forward the assessment report to	forward the assessment report to
		the applicant.	the applicant.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		4. Subsequent to the procedure	4. Subsequent to the procedure
		set out in paragraph 3 of this	set out in paragraph 3 of this
		Article, paragraphs (5), (5a), (6)	Article, paragraphs (5), (5a), (6)
		and (7) of Article 46 shall apply.	and (7) of Article 46 shall apply.
Section 4		Section 4	Section 4
Mutual recognition of marketing		Mutual recognition of marketing	Mutual recognition of marketing
authorisations granted by national		authorisations granted by national	authorisations granted by national
authorities		authorities	authorities
Article 47		Article 47	Article 47
Scope of mutual recognition marketing		Scope of mutual recognition of	Scope of mutual recognition of
authorisation		marketing authorisations	marketing authorisations
A national marketing authorisation for		A national marketing authorisation	A national marketing authorisation
a veterinary medicinal product shall be		for a veterinary medicinal product,	for a veterinary medicinal product,
recognised by other Member States in		granted in accordance with Article	granted in accordance with Article
accordance with the procedure laid		44, shall be recognised [] in other	44, shall be recognised [] in other
down in Article 48.		Member States in accordance with	Member States in accordance with
		the procedure laid down in Article 48	the procedure laid down in Article 48
		[].	[].
Article 48		Article 48	Article 48
Procedure for mutual recognition		Procedure for mutual recognition of	Procedure for mutual recognition of
marketing authorisation		marketing authorisations	marketing authorisations
	AM 147		
1. Applications for mutual	1. Applications <i>and the dossier</i>	1. An application for mutual	1. An application for mutual
recognition of marketing	for mutual recognition of marketing	recognition of a marketing	recognition of a marketing
authorisations shall be submitted to the	authorisations shall be submitted to	authorisation shall be submitted to	authorisation shall be submitted to
Member State that granted the first	all the Member States. <i>tThe</i>	the competent authority in the	the competent authority in the
national marketing authorisation	Member State that granted the first	Member State that granted the []	Member State that granted the []
("reference Member State").	national marketing authorisation	national marketing authorisation in	national marketing authorisation in
	shall be the ("reference Member	accordance with Article 44	accordance with Article 44
	State ") .	('reference Member State') and to	('reference Member State') and to



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		the competent authorities in the	the competent authorities in the
		Member States where the	Member States where the
		applicant seeks to obtain a	applicant seeks to obtain a
		marketing authorisation	marketing authorisation
		('concerned Member States').	('concerned Member States').
		1a. The application shall list the	1a. The application shall list the
		concerned Member States.	concerned Member States.
	AM 148		
2. A minimum of 6 months shall	2. A minimum of 6 months shall	2. A minimum of 6 months shall	2. A minimum of 6 months shall
elapse between the decision granting	elapse between the decision	elapse between the decision granting	elapse between the decision granting
the first national marketing	granting the first national marketing	the [] national marketing	the [] national marketing
authorisation and the submission of	authorisation and the submission of	authorisation and the submission of	authorisation and the submission of
the application for mutual recognition	the application for mutual	the application for mutual	the application for mutual
of the national marketing	recognition of the national	recognition of th at national	recognition of th at national
authorisation.	marketing authorisation.	marketing authorisation.	marketing authorisation.
		2a. If the applicant indicates that	2a. If the applicant indicates that
		one or more of the concerned	one or more of the concerned
		Member States shall no longer be	Member States shall no longer be
		considered as such, the competent	considered as such, the competent
		authorities in those Member States	authorities in those Member States
		shall provide to the competent	shall provide to the competent
		authority in the reference Member	authority in the reference Member
		State and to the competent	State and to the competent
		authorities in the other concerned	authorities in the other concerned
		Member States, any information	Member States, any information
		they consider relevant relating to	they consider relevant relating to
		the withdrawal of the application.	the withdrawal of the application.



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3. An application for mutual		3. []	3. []
recognition of a marketing			
authorisation shall be accompanied by			
the following:			
(a) an information about the		[]	[]
Member States where the applicant			
seeks to obtain recognition of the			
marketing authorisation;			
(b) copies of marketing		[]	[]
authorisations granted for the			
veterinary medicinal product in other			
Member States;			
	AM 149		
(c) an information about the	(c) an information about the	[]	[]
Member States in which an application	Member States in which an		
for a marketing authorisation	application for a marketing		
submitted by the applicant for the	authorisation submitted by the		
same veterinary medicinal product is	applicant for the same veterinary		
under examination;	medicinal product is under		
(1)	examination;	r 1	
(d) a summary of the product		[]	[]
characteristics proposed by the			
applicant;			
(e) the text to appear in the labelling and package leaflet;		[]	[]
(f) information on refusals to grant a marketing authorisation in the Union		[]	[]
or in a Member State or in a third			
country and the reasons for the refusal.			
	AM 150		
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Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
4. Within 90 days of receipt of a valid application, the reference Member State shall prepare an updated assessment report for the veterinary medicinal product. The updated assessment report together with the approved summary of the product characteristics and the text to appear in the labelling and package leaflet shall be forwarded to all Member States and the applicant, together with the list of Member States where the applicant seeks to obtain recognition of the marketing authorisation ('concerned Member States').	4. Within 90 45 days of receipt of a valid application, the reference Member State shall prepare an updated assessment report for the veterinary medicinal product. The updated assessment report together with the approved summary of the product characteristics and the text to appear in the labelling and package leaflet shall be forwarded to all <i>concerned</i> Member States and the applicant, together with the list of Member States where the applicant seeks to obtain recognition of the marketing authorisation ('concerned Member States').	 4. Within 90 days of receipt of a valid application, the competent authority in the reference Member State shall prepare an updated assessment report containing the information referred to in Article 28 for the veterinary medicinal product [] and shall forward it to the competent authorities in the concerned Member States and to the applicant []. 	 4. Within 90 days of receipt of a valid application, the competent authority in the reference Member State shall prepare an updated assessment report containing the information referred to in Article 28 for the veterinary medicinal product [] and shall forward it to the competent authorities in the concerned Member States and to the applicant [].
5. Within 90 days after receipt of the documents referred to in paragraph 3, Member States shall examine the assessment report, the summary of the product characteristics, the labelling and the package leaflet and inform the reference Member State of whether it has no objections to the assessment report, summary of product characteristics, labelling and package leaflet.		5. Within 90 days after receipt of the updated assessment report [] referred to in paragraph [] 4, the competent authorities in the concerned Member States shall examine [] it and inform the competent authority in the reference Member State of whether [] they have any objections to it on the ground that it would pose a potential serious risk to human or animal health or for the environment. The assessment	5. Within 90 days after receipt of the updated assessment report [] referred to in paragraph [] 4, the competent authorities in the concerned Member States shall examine [] it and inform the competent authority in the reference Member State of whether [] they have any objections to it on the ground that it would pose a potential serious risk to human or animal health or for the environment. The assessment



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		report resulting from this	report resulting from this
		examination shall be forwarded by	examination shall be forwarded by
		the competent authority in the	the competent authority in the
		reference Member State to the	reference Member State to the
		competent authorities in the other	competent authorities in the other
		concerned Member States and to	concerned Member States and to
		the applicant.	the applicant.
		5a. If requested by the	5a. If requested by the
		competent authorities in the	competent authorities in the
		reference Member States or in	reference Member States or in
		another concerned Member State,	another concerned Member State,
		the coordination group shall be	the coordination group shall be
		convened to examine the updated	convened to examine the updated
		assessment report within the	assessment report within the
		period referred to in paragraph 5.	period referred to in paragraph 5.
		5b. Where no competent	5b. Where no competent
		authority of any concerned	authority of any concerned
		Member State has informed the	Member State has informed the
		competent authority in the	competent authority in the
		reference Member State of an	reference Member State of an
		objection to the updated	objection to the updated
		assessment report, as set out in	assessment report, as set out in
		paragraph 5, the latter shall	paragraph 5, the latter shall
		record that there is an agreement,	record that there is an agreement,
		close the procedure and inform the	close the procedure and inform the
		applicant and the competent	applicant and the competent
		authorities in all Member States	authorities in all Member States
		accordingly, without undue delay.	accordingly, without undue delay.
		The competent authorities in the	The competent authorities in the
		concerned Member States shall	concerned Member States shall



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		grant a marketing authorisation in	grant a marketing authorisation in
		conformity with the updated	conformity with the updated
		assessment report within 30 days	assessment report within 30 days
		of the receipt of both the	of the receipt of both the
		information on the agreement	information on the agreement
		from the competent authority in	from the competent authority in
		the reference Member State and	the reference Member State and
		also the complete translations of	also the complete translations of
		the summary of product	the summary of product
		characteristics, labelling and	characteristics, labelling and
		package leaflet from the applicant,	package leaflet from the applicant,
		whichever is submitted the latest.	whichever is submitted the latest.
		5c. Where a competent authority	5c. Where a competent authority
		of any concerned Member State	of any concerned Member State
		informs the competent authority in	informs the competent authority in
		the reference Member State of an	the reference Member State of an
		objection in accordance with	objection in accordance with
		paragraph 5, the procedure set out	paragraph 5, the procedure set out
		in Article 49 shall apply.	in Article 49 shall apply.
6. Where all Member States agree,		6. []	6. []
the reference Member State shall			
record the agreement, close the			
procedure and inform the applicant			
and the Member States accordingly.			
Each Member State referred to in			
paragraph 3 shall grant a marketing			
authorisation in conformity with the			
approved assessment report, summary			
of the product characteristics, labelling			
and package leaflet within 30 days of			



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the receipt of the information regarding the agreement from the reference Member State.			
7. If at any stage of the procedure a concerned Member State invokes the reasons referred to in Article 113(1) for prohibiting the veterinary medicinal product, it shall no longer be considered as a Member State where the applicant seeks to obtain a marketing authorisation. However, a Member State having invoked those reasons may subsequently recognise the marketing authorisation in accordance with Article 57.		7. If at any stage of the procedure the competent authority in a concerned Member State invokes the reasons referred to in Article 113(1) for prohibiting the veterinary medicinal product, [] that Member State shall no longer be considered as a concerned Member State. []	7. If at any stage of the procedure the competent authority in a concerned Member State invokes the reasons referred to in Article 113(1) for prohibiting the veterinary medicinal product, [] that Member State shall no longer be considered as a concerned Member State. []
8. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.		8. The [] competent authority [] in the reference Member State shall make the assessment report publicly available, after deleting any commercially confidential information.	8. The [] competent authority [] in the reference Member State shall make the assessment report publicly available, after deleting any commercially confidential information.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		Section 4a	Section 4a
		Subsequent recognition in the	Subsequent recognition in the
		mutual recognition and	mutual recognition and
		decentralised marketing	decentralised marketing
		authorisation procedures	authorisation procedures
		Article 48a ⁴¹	Article 48a
		Subsequent recognition of marketing	Subsequent recognition of marketing
		authorisations by []	authorisations by []
		additional concerned Member	additional concerned Member
		States	States
		1. After completion of a	1. After completion of a
		decentralised procedure laid down	decentralised procedure laid down
		in Article 46 or a mutual recognition	in Article 46 or a mutual recognition
		procedure laid down in Article 48	procedure laid down in Article 48
		granting a marketing	granting a marketing
		authorisation [], the marketing	authorisation [], the marketing
		authorisation holder may submit an	authorisation holder may submit an
		application for a marketing	application for a marketing
		authorisation for [] the veterinary	authorisation for [] the veterinary
		medicinal product to the competent	medicinal product to the competent
		authorities in additional concerned	authorities in additional concerned
		Member States and to the	Member States and to the
		competent authority in the	competent authority in the
		reference Member State referred	reference Member State referred
		to in Article 46 or 48, as	to in Article 46 or 48, as
		applicable, in accordance with the	applicable, in accordance with the
		procedure laid down in this	procedure laid down in this
		Article. The application shall include	Article. The application shall include

⁴¹ Ex Article 57



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		the following, in addition to the	the following, in addition to the
		data referred to in Article 7:	data referred to in Article 7:
		(a) a list of all decisions granting,	(a) a list of all decisions granting,
		suspending or revoking marketing	suspending or revoking marketing
		authorisations concerning this	authorisations concerning this
		veterinary medicinal product;	veterinary medicinal product;
		(b) [] information on the	(b) [] information on the
		variations introduced since the	variations introduced since the
		marketing authorisation [] by	marketing authorisation [] by
		decentralised procedure laid down	decentralised procedure laid down
		in Article 46(5) or by mutual	in Article 46(5) or by mutual
		recognition procedure laid down in	recognition procedure laid down in
		Article 48(5a) was granted;	Article 48(5a) was granted;
		(c) a summary report on	(c) a summary report on
		pharmacovigilance data.	pharmacovigilance data.
		1a. The competent authority in	1a. The competent authority in
		the reference Member State	the reference Member State
		referred to in Article 46 or 48, as	referred to in Article 46 or 48, as
		applicable, shall within 60 days	applicable, shall within 60 days
		forward to the competent	forward to the competent
		authorities in the additional	authorities in the additional
		concerned Member States the	concerned Member States the
		decision on granting marketing	decision on granting marketing
		authorisation and any variations	authorisation and any variations
		thereto and shall, within that	thereto and shall, within that
		period, prepare and forward an	period, prepare and forward an
		updated assessment report	updated assessment report
		concerning that marketing	concerning that marketing
		authorisation and those variations	authorisation and those variations
		as applicable, and inform the	as applicable, and inform the



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		applicant accordingly.	applicant accordingly.
		2. The competent authority in	2. The competent authority in
		each additional concerned Member	each additional concerned Member
		State shall [] grant a marketing	State shall [] grant a marketing
		authorisation in conformity with the	authorisation in conformity with the
		updated assessment report referred	updated assessment report referred
		to in paragraph 1a [] within 60	to in paragraph 1a [] within 60
		days of receipt of the data referred	days of receipt of the data referred
		to in paragraph 1 and the complete	to in paragraph 1 and the complete
		translations of the summary of	translations of the summary of
		product characteristics, labelling	product characteristics, labelling
		and package leaflet, whichever is	and package leaflet, whichever is
		submitted the latest.	submitted the latest.
		2a. By derogation from	2a. By derogation from
		paragraph 2, if the competent	paragraph 2, if the competent
		authority in an additional	authority in an additional
		concerned Member State has	concerned Member State has
		reasons for refusing the marketing	reasons for refusing the marketing
		authorisation on the ground that it	authorisation on the ground that it
		would pose a potential serious risk	would pose a potential serious risk
		to human or animal health or for	to human or animal health or for
		the environment, it shall, at the	the environment, it shall, at the
		latest within a period of 60 days of	latest within a period of 60 days of
		receipt of both the data referred to	receipt of both the data referred to
		in paragraph 1 and updated	in paragraph 1 and updated
		assessment report referred to in	assessment report referred to in
		paragraph (1a) raise its objections	paragraph (1a) raise its objections
		and provide a detailed statement of	and provide a detailed statement of
		the reasons to the competent	the reasons to the competent
		authority in the reference Member	authority in the reference Member



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		State referred to in Article 46 or	State referred to in Article 46 or
		48, as applicable, and to the	48, as applicable, and to the
		competent authorities in the	competent authorities in the
		concerned Member States,	concerned Member States,
		referred to in those Articles, and to	referred to in those Articles, and to
		the applicant.	the applicant.
		3.&4.[] ⁴²	3.&4.[]
		5. In case of objections in	5. In case of objections in
		accordance with paragraph 2a, the	accordance with paragraph 2a, the
		competent authority in the	competent authority in the
		reference Member State shall take	reference Member State shall take
		any appropriate initiatives, in	any appropriate initiatives, in
		order to seek an agreement as	order to seek an agreement as
		regards the objections made. The	regards the objections made. The
		competent authorities shall use	competent authorities shall use
		their best endeavours to reach an	their best endeavours to reach an
		agreement on the action to be	agreement on the action to be
		taken.	taken.



⁴² Paragraphs 3 and 4 of the Commission proposal are not applicable with the new approach. The products which have been authorised before the date of application of this Regulation can go through the subsequent recognition procedure as foreseen in the new approach, as it is no longer only an administrative procedure.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		6. The competent authority in	6. The competent authority in
		the reference Member State shall	the reference Member State shall
		provide the applicant with the	provide the applicant with the
		opportunity to make his point of	opportunity to make his point of
		view known orally or in writing.	view known orally or in writing.
		7. In case, following the initiatives	7. In case, following the initiatives
		by the competent authority in the	by the competent authority in the
		reference Member State, an	reference Member State, an
		agreement among the competent	agreement among the competent
		authorities in the Member States	authorities in the Member States
		having already granted a	having already granted a
		marketing authorisation and the	marketing authorisation and the
		competent authorities in the	competent authorities in the
		additional concerned Member	additional concerned Member
		States has been found, the	States has been found, the
		competent authorities in the	competent authorities in the
		additional concerned Member	additional concerned Member
		States shall grant a marketing	States shall grant a marketing
		authorisation in accordance with	authorisation in accordance with
		paragraph 2.	paragraph 2.
		8. If the competent authority in	8. If the competent authority in
		the reference Member State has	the reference Member State has
		not been able to find an agreement	not been able to find an agreement
		at the latest within a period of 60	at the latest within a period of 60
		days from the objections referred	days from the objections referred
		to in paragraph 2a were raised, it	to in paragraph 2a were raised, it
		shall refer the application together	shall refer the application together
		with the updated assessment	with the updated assessment
		report referred to in paragraph 1a	report referred to in paragraph 1a
		and the objections of the	and the objections of the



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		competent authorities in the additional concerned Member	competent authorities in the additional concerned Member
		State to the coordination group in	State to the coordination group in
		accordance with the review	accordance with the review
		procedure set out in Article 49.	procedure set out in Article 49.
Section 5		Section 5	Section 5
Coordination group review and scientific re-examination		[] Review procedure []	[] Review procedure []
Article 49		Article 49	Article 49
Coordination group review procedure		[] R eview procedure	[] R eview procedure
1. If a Member State raises, within the time period referred to in Article 46(4) or Article 48(5) its objections to the assessment report, proposed summary of product characteristics or proposed labelling and package leaflet, a detailed statement of the reasons shall be provided to the reference Member State, the other Member States and the applicant. The points of disagreement shall be referred without delay to the coordination group for mutual recognition and decentralised procedures set up by Article 142('the coordination group') by the reference Member State.	AM 151 1. If a Member State raises, within the time period referred to in Article 46(4) or Article 48(5) its objections to the assessment report, proposed summary of product characteristics or proposed labelling and package leaflet, on grounds of a potential serious risk to human or animal health or to the environment, a detailed statement of the reasons shall be provided to the reference Member State, the other Member States and the applicant. The points of disagreement shall be referred without delay to the coordination group for mutual recognition and decentralised procedures set up by	1. If the competent authority in a concerned Member State raises [] according to Article 46(4) [], Article 48(5), Article 48a(8) or Article 64(7aa) any objection as referred to in those provisions to, respectively, the assessment report or the updated assessment report, it shall provide without delay [] a detailed statement of the reasons for any such objection [] to the competent authority in the reference Member State, to the competent authorities in the [] concerned Member States and to the applicant or the marketing authorisation holder. The points of disagreement shall be referred	1. If the competent authority in a concerned Member State raises [] according to Article 46(4) [], Article 48(5), Article 48a(8) or Article 64(7aa) any objection as referred to in those provisions to, respectively, the assessment report or the updated assessment report, it shall provide without delay [] a detailed statement of the reasons for any such objection [] to the competent authority in the reference Member State, to the competent authorities in the [] concerned Member States and to the applicant or the marketing authorisation holder. The points of disagreement shall be referred



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	group') by the reference Member State.	authority [] in the reference Member State to the coordination	authority [] in the reference Member State to the coordination
		group. 1a. The competent authority in	group. 1a. The competent authority in
		the reference Member State shall take any appropriate initiatives in	the reference Member State shall take any appropriate initiatives in
		order to seek an agreement within the period of 90 days as regards	order to seek an agreement within the period of 90 days as regards
		the objection made. 1b. The competent authority in	the objection made. 1b. The competent authority in
		the reference Member State shall provide the applicant or the	the reference Member State shall provide the applicant or the
		marketing authorisation holder with the opportunity to make his	marketing authorisation holder with the opportunity to make his
		point of view known orally or in writing.	point of view known orally or in writing.
2. Within the coordination group, a rapporteur shall be appointed in order	AM 152 2. Within the coordination group, a rapporteur shall be	[]	[]
to prepare a second assessment report for the veterinary medicinal product.	appointed in order to prepare a second assessment report for the		
3. The second assessment report shall be presented by the rapporteur to	veterinary medicinal product.	[]	[]
the coordination group within the period of 90 days. Upon presentation			
of the second assessment report, the coordination group shall adopt an			
opinion by a majority of the votes cast by the members of the coordination			

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group represented at the meeting.			
4. In the event of an opinion in favour of granting a marketing authorisation, the reference Member State shall record the agreement of Member States, close the procedure and inform Member States and the applicant accordingly.	AM 153 4. In the event of an opinion in favour of granting <i>or amending</i> a marketing authorisation, the reference Member State shall record the agreement of Member States, close the procedure and inform Member States and the applicant accordingly.	[]	[]
5. Each Member State concerned shall grant a marketing authorisation in conformity with the agreement within 30 days of receipt of the information regarding the agreement from the reference Member State.		5. [] In case an agreement among the competent authorities referred to in Articles 46(1), 48(1), 48a(1) or 64(1) has been reached, the competent authority in the reference Member State shall close the procedure and inform the applicant or the marketing authorisation holder. The competent authorities in the concerned Member States shall grant or vary a marketing authorisation [].	5. [] In case an agreement among the competent authorities referred to in Articles 46(1), 48(1), 48a(1) or 64(1) has been reached, the competent authority in the reference Member State shall close the procedure and inform the applicant or the marketing authorisation holder. The competent authorities in the concerned Member States shall grant or vary a marketing authorisation [].

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6. In the event of an unfavourable		6 []. When the competent	6 []. When the competent
opinion, the marketing authorisation		authorities referred to in Articles	authorities referred to in Articles
shall be refused by each Member State		46(1), 48(1), 48a(1) and 64(1) reach	46(1), 48(1), 48a(1) and 64(1) reach
concerned within 30 days of		an agreement by consensus to	an agreement by consensus to
acknowledgement of the agreement.		refuse the marketing authorisation	refuse the marketing authorisation
The scientific conclusions and grounds		or to reject the variation, the	or to reject the variation, the
for revocation of the marketing		competent authority in the	competent authority in the
authorisation shall be annexed to the		reference Member State close the	reference Member State close the
unfavourable opinion.		procedure and inform the	procedure and inform the
		applicant or the marketing	applicant or the marketing
		authorisation holder providing the	authorisation holder providing the
		grounds for the refusal or the	grounds for the refusal or the
		rejection. The competent	rejection. The competent
		authorities in the concerned	authorities in the concerned
		Member State shall refuse the	Member State shall refuse the
		marketing authorisation or reject	marketing authorisation or reject
		the variation.	the variation.
		6a. If an agreement between the	6a. If an agreement between the
		competent authorities cannot be	competent authorities cannot be
		reached by consensus, the	reached by consensus, the
		coordination group shall provide	coordination group shall provide
		the Commission with the	the Commission with the
		assessment report referred to in	assessment report referred to in
		Articles 46(4), 48(5), 48a(2a) or	Articles 46(4), 48(5), 48a(2a) or
		64(3), together with information on	64(3), together with information on
		the points of disagreement at the	the points of disagreement at the
		latest within a period of 90 days	latest within a period of 90 days
		from when the objection referred	from when the objection referred
		to in paragraph 1 was raised.	to in paragraph 1 was raised.



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		7. Within 30 ⁴³ days of receipt of	7. Within 30 days of receipt of
		the documents referred to in	the documents referred to in
		paragraph 5b, the Commission	paragraph 5b, the Commission
		shall prepare a draft decision to be	shall prepare a draft decision to be
		taken in respect of the application.	taken in respect of the application.
		The draft decision shall be	The draft decision shall be
		forwarded to the competent	forwarded to the competent
		authorities in the Member States	authorities in the Member States
		and to the applicant or the	and to the applicant or the
		marketing authorisation holder.	marketing authorisation holder.
		8. The Commission may	8. The Commission may
		request clarifications from the	request clarifications from the
		competent authorities and/or the	competent authorities and/or the
		Agency. The time limit laid down	Agency. The time limit laid down
		in paragraph 7 shall be suspended	in paragraph 7 shall be suspended
		until the clarifications have been	until the clarifications have been
		provided.	provided.
		8a. For the purpose of work-	8a. For the purpose of work-
		sharing procedure in respect of	sharing procedure in respect of
		variations requiring assessment in	variations requiring assessment in
		accordance with Article 64,	accordance with Article 64,
		references in this Article to a	references in this Article to a
		competent authority in the	competent authority in the
		reference Member State shall be	reference Member State shall be
		understood as references to a	understood as references to a
		competent authority agreed upon	competent authority agreed upon
		in accordance with Article 63(3),	in accordance with Article 63(3),
		and references to concerned	and references to concerned

⁴³ Same deadline as in Article 40(8).



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		Member States as references to	Member States as references to
		relevant Member States.	relevant Member States.
		9. The Commission shall, by	9. The Commission shall, by
		means of implementing acts, take a decision on the granting, changing,	means of implementing acts, take a decision on the granting, changing ₂
		or refusing or revoking of a	or refusing or revoking of a
		marketing authorisation or	marketing authorisation or
		rejecting the variation. Those	rejecting the variation. Those
		implementing acts shall be adopted	implementing acts shall be adopted
		in accordance with the	in accordance with the
		examination procedure referred to in Article 145(2).	examination procedure referred to in Article 145(2).
Article 50		Article 50	Article 50
Request for scientific re-examination		<i>Request for scientific re-examination</i>	Request for scientific re-examination
Request for scientific re examination	AM 154	Request for setempte re examination	Request for selenific re examination
1. Within 15 days after receipt of	1. Within 15 days after receipt	[]	[]
the assessment report referred to in	of the assessment report referred to		
Article $46(3)$ or in Article $48(4)$ the	in Article 46(3) or in Article 48(4)		
applicant may provide written notice	the applicant may provide written		
to the Agency requesting a re-	notice to the Agency Coordination		
examination of the assessment report.	group requesting a re-examination		
In that case the applicant shall forward	of the assessment report. In that		
to the Agency detailed grounds for the request within 60 days of receipt of the	case the applicant shall forward to the Agency detailed grounds for the		
assessment report. The application	request within 60 days of receipt of		
shall be accompanied by proof of	the assessment report. The		
payment of the fee payable to the	application shall be accompanied		
Agency for the re-examination.	by proof of payment of the fee		
	payable to the Agency for the re-		
	examination.		



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2. Within 120 days of receipt of the		[]	[]
grounds for the request, the Committee for Medicinal Products for			
Veterinary Use set up by Article 139			
('the Committee') shall re-examine the			
assessment report. The reasons for the			
conclusion reached shall be annexed to			
the opinion.			
	AM 155	[]	[]
3. The re-examination procedure	3. The re-examination		
shall deal only with the points of the	procedure shall deal only with the		
assessment report identified by the applicant in the written notice.	points of the assessment report identified by the applicant in the		
applicant in the written notice.	written notice. The Committee		
	shall define the scope of the		
	examination, taking into account		
	the information supplied by the		
	applicant.		
	AM 156	[]	[]
4. Within 15 days of its adoption,	4. Within 15 days of its		
the Agency shall forward the opinion	adoption, the Agency shall forward		
of the Committee to the coordination group, together with a report	the opinion of the Committee to the coordination group <i>Commission</i> ,		
describing the assessment of the	together with a report describing		
veterinary medicinal product by the	the assessment of the veterinary		
Committee and stating the reasons for	medicinal product by the		
its conclusions. Those documents shall	Committee and stating the reasons		
be forwarded to the Commission, to	for its conclusions. Those		
Member States and to the applicant for	documents shall be forwarded to		
information purposes.	the Commission, to Member States		



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	and to the applicant for information purposes.		
5. Upon presentation of the Agency's opinion, the coordination group shall act by the majority of the votes cast by its members represented at the meeting. The reference Member State shall record the agreement, close the procedure and inform the applicant. Article 49 shall apply accordingly. Where the decision is not in accordance with the opinion of the Agency, the coordination group shall annex a detailed explanation of the reasons for the differences.	AM 157 5. Upon presentation of the Agency's opinion, the coordination group shall act by the majority of the votes cast by its members represented at the meeting. The reference Member State shall record the agreement, close the procedure and inform the applicant. Article 49 shall apply accordingly. Where the decision is not in accordance with the opinion of the Agency, the coordination group shall annex a detailed explanation of the reasons for the differences. Within 15 days of receipt of the opinion, the Commission shall prepare a draft of the decision associated with the procedure. If the draft decision proposes that a marketing authorisation be granted, the draft shall include or refer to the documents listed in Article 28. Where the draft decision proposes that a marketing authorisation be		
	refused, the grounds for refusal		



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	shall be stated in accordance with Article 32.		r - r
	Where the draft decision does not concur with the Committee's opinion, the Commission shall attach detailed explanations of the grounds for these differences.		
	The Commission may, by means of implementing acts, take a final decision on the granting of a marketing authorisation under the decentralised or mutual		
	recognition procedure. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).		
	The Agency shall forward to the applicant the documents provided for by Article 28.		
	The Agency shall make the opinion publicly available, after deleting any commercially confidential information.		



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Chapter IV		Chapter IV	Chapter IV
Post marketing authorisation		Post marketing authorisation	Post marketing authorisation
measures		measures	measures
Section 1		Section 1 Union product database	Section 1
Union product database Article 51		Article 51	Union product database Article 51
Union database on veterinary		Union database on veterinary	Union database on veterinary
medicinal products		medicinal products	medicinal products
	AM 158	1. A Union database on	1.A Union database on
1. A Union database on veterinary	1. A Union- <i>wide</i> database on	veterinary medicinal products	veterinary medicinal products
medicinal products ('product	veterinary medicinal products	('product database') shall be set up	('product database') shall be set up
database') shall be set up and	('product database') shall be set up	and maintained by the Agency in	and maintained by the Agency in
maintained by the Agency.	and maintained by the Agency.	collaboration with the Member	collaboration with the Member
		States in accordance with the	States in accordance with the
		provisions in this Section.	provisions in this Section.
2. The product database shall		2. The product database shall	2. The product database shall
contain information on:		contain [] at least the following	contain [] at least the following
		information []:	information []:
	AM 159		
(a) veterinary medicinal products	(a) veterinary medicinal products	(a) for veterinary medicinal	(a) for veterinary medicinal
authorised within the Union by the	authorised within the Union by the	products authorised within the Union	products authorised within the Union
Commission and by the competent	Commission and by the competent	by the Commission and by the	by the Commission and by the
authorities, together with their	authorities, together with their	competent authorities: [] name of	competent authorities: [] name of
summaries of product characteristics,	summaries of product	the veterinary medicinal product,	the veterinary medicinal product,
package leaflets and lists of sites	characteristics, package leaflets and	its active substance(s) and its	its active substance(s) and its
where each product is manufactured;	lists of sites where each product is	strength, summary of product	strength, summary of product
	manufactured and reference	characteristics, package leaflet, the	characteristics, package leaflet, the
	numbers to the pharmacovigilance	assessment report ,[] list of sites	assessment report, [] list of sites
	system master file;	where [] the product is	where [] the product is
		manufactured and the dates of its	manufactured and the dates of its

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		placing on the market in a	placing on the market in a
		Member State;	Member State;
(b) homeopathic veterinary		(b) for [] homeopathic	(b) for [] homeopathic
medicinal products registered within		veterinary medicinal products	veterinary medicinal products
the Union by the Commission and by		registered in accordance with	registered in accordance with
the competent authorities, together		Chapter V within the Union [] by	Chapter V within the Union [] by
with their package leaflet and lists of		the competent authorities: name of	the competent authorities: name of
sites where each product is		the registered_homeopathic	the registered_homeopathic
manufactured;		veterinary medicinal product, []	veterinary medicinal product, []
		package leaflet and lists of sites	package leaflet and lists of sites
		where [] the product is	where [] the product is
		manufactured;	manufactured;
(c) veterinary medicinal products		(c) veterinary medicinal products	(c) veterinary medicinal products
allowed to be used in a Member State		allowed to be used in a Member	allowed to be used in a Member
in accordance with Articles 119 and		State in accordance with Article []	State in accordance with Article []
120.		5(6);	5(6);
		(d) the annual volume of sales	(d) the annual volume of sales
		and information on the availability	and information on the availability
		for each veterinary medicinal	for each veterinary medicinal
		product.	product.
3. Within 12 months from the date		3[]	3[]
of the entry into force of this			
Regulation, the Agency shall make			
public a format for electronic			
submissions of information on			
marketing authorisations of veterinary			
medicinal products granted by the			
competent authorities.			

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		3a. The Commission shall, by	3a. The Commission shall, by
		means of implementing acts, adopt	means of implementing acts, adopt
		the necessary measures and	the necessary measures and
		practical arrangements laying	practical arrangements laying
		down:	down:
		(a) the technical specifications of	(a) the technical specifications of
		the product database including the	the product database including the
		electronic data exchange	electronic data exchange
		mechanism for exchanging with	mechanism for exchanging with
		the existing national systems and	the existing national systems and
		the format for electronic	the format for electronic
		submission;	submission;
		(b) the practical arrangements	(b) the practical arrangements
		for the functioning of the product	for the functioning of the product
		database, in particular to ensure	database, in particular to ensure
		protection of commercially	protection of commercially
		confidential information and	confidential information and
		security of exchange of	security of exchange of
		information;	information;
		(c) detailed specifications of the	(c) detailed specifications of the
		information to be included,	information to be included,
		updated and shared and by whom;	updated and shared and by whom;
		(d) contingency arrangements to	(d) contingency arrangements to
		be applied in case of unavailability	be applied in case of unavailability
		of any of the functionalities of the	of any of the functionalities of the
		product database;	product database;

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017 (e) where appropriate, data to be included in addition to the information of the product database as referred to in paragraph 2. Those implementing acts shall be adopted in accordance with the	Draft revised negotiation mandate proposed by the Presidency (e) where appropriate, data to be included in addition to the information of the product database as referred to in paragraph 2. Those implementing acts shall be adopted in accordance with the
		examination procedure referred to in Article 145(2).	examination procedure referred to in Article 145(2).
4. The competent authorities shall submit information on marketing authorisations granted by them to the product database, using the format referred to in paragraph 3.		4-8. []	4-8. []
5. The Agency shall submit information on marketing authorisations granted by the Commission to the product database, using the format referred to in paragraph 3.		5	5
6. Within 12 months from the date of application of this Regulation, the competent authorities shall submit electronically information on all veterinary medicinal products authorised in their Member State before the date of application of this Regulation to the Agency, using the format referred to in paragraph 3.		6	6



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
7. The Agency shall, in		7	7
collaboration with Member States			
and the Commission, draw up the			
functional specifications for the			
product database.			
8. The Commission shall ensure		8	8.
that information reported to the			
product database is collected,			
collated and made accessible and that			
the information is shared.			
Article 52		Article 52	Article 52
Access to the product database		Access to the product database	Access to the product database
1. The competent authorities, the		1. The competent authorities, the	1. The competent authorities, the
Agency and the Commission shall		Agency and the Commission shall	Agency and the Commission shall
have full access to the information in		have full access to the information in	have full access to the information in
the product database.		the product database.	the product database.
	AM 160		
2. Marketing authorisation	2. Marketing authorisation	2. Marketing authorisation	2. Marketing authorisation
holders shall have full access to the	holders shall have full access to the	holders shall have full access to the	holders shall have full access to the
information in the product database	information in the product database	information in the product database	information in the product database
concerning their own marketing	concerning their own marketing	concerning their own marketing	concerning their own marketing
authorisations.	authorisations and limited access to	authorisations.	authorisations.
	other products.		

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
3. The general public shall have access to information in the product database as regards the list of the authorised veterinary medicinal products, their summaries of product characteristics and package leaflets.	AM 161 3. The general public shall have access to information in the product database as regards the list of the authorised veterinary medicinal products, their summaries of product characteristics, and package leaflets and their environmental data, and all safety information.	3. The general public shall have access to read information in the product database as regards the list of the [] veterinary medicinal products, [] the summary of product characteristics, [] package leaflets [] and assessment reports after the deletion of any commercially confidential information by the competent authority.	3. The general public shall have access to read-information in the product database, without changing the information therein, as regards the list of the [] veterinary medicinal products, [] the summary of product characteristics, [] package leaflets [] and assessment reports after the deletion of any commercially confidential information by the
			competent authority.
Section 2		Section 2	Section 2
Placing on the market		[]	[]
		Collection of data by Member	Collection of data by Member
		States and responsabilities of	States and responsabilities of
		marketing authorisation holders	marketing authorisation holders
Article 53		Article 53	Article 53
Placing on the market		Placing on the market	Placing on the market
1. Marketing authorisation holders shall record in the product database the dates when their authorised veterinary medicinal products are placed on the market in a Member State.		[]	[]

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
 2. Generic veterinary medicinal products shall not be placed on the market until the period of the protection of technical documentation for the reference veterinary medicinal product as set out in Articles 34 and 35 has elapsed. Article 54 Collection of data on the sales and use of antimicrobial veterinary medicinal products 1. Member States shall collect relevant and comparable data on the 	AM 162 1. Member States shall collect relevant and comparable <i>and</i>	[] Article 54 Collection of data on [] antimicrobial []medicinal products used in animals 1. Member States shall collect relevant and comparable data on the	[] Article 54 Collection of data on [] antimicrobial []medicinal products used in animals 1. Member States shall collect relevant and comparable data on the
volume of sales and the use of veterinary antimicrobial medicinal products.	sufficiently detailed data at per- farm level, on the volume of sales in terms of weight and cost for each antimicrobial type and the use of veterinary antimicrobial medicinal products including the species treated, the disease diagnosed and the route of administration.	volume of sales [] of [] antibiotic medicinal products used in animals and, if available, on the volume of sales of other antimicrobial medicinal products used in animals.	volume of sales [] of [] antibiotic medicinal products used in animals and, if available, on the volume of sales of other antimicrobial medicinal products used in animals and the use of antimicrobial medicinal products used in animals, to enable in particular the direct or indirect evaluation of the use in food producing animals at farm level in accordance with this Article and within the time limits set in paragraph 4aa. If the EP accepts the compromise
		Ta. Member States shall take measures aiming to ensure the	<i>If the EP accepts the compromise</i> <i>text in paragraphs 2 to 4a,</i>



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
2. Member States shall send data on the volume of sales and the use of veterinary antimicrobial medicinal products to the Agency. The Agency shall analyse the data and publish an annual report.	AM 163 2. Member States shall send data on the volume of sales and the use of veterinary antimicrobial medicinal products to the Agency. The Agency shall <i>cooperate with</i> <i>other European agencies to</i> analyse the data and publish an annual report <i>which shall also</i> <i>include the corresponding data for</i> <i>human use of antimicrobials as</i> <i>well as the current situation on</i> <i>antimicrobial resistance in the</i> <i>Union and, where appropriate,</i> <i>issue guidelines and</i> <i>recommendations.</i>	 by Coreper on 20 December 2017 collection of the relevant and comparable data on the use of the medicinal products referred to in paragraph 1 and, if available, send the data to the Agency, who shall analyse these data in accordance with paragraph 2. 2. Member States shall send data referred to in paragraph 1 [] to the Agency within the time limit set. The Agency shall cooperate with Member States and with other Union agencies to analyse [] these data and publish an annual report. 	 2. Member States shall send deleted. 2. Member States shall send <u>collated</u> data referred to in paragraph 1 [] on the volume of <u>sales and the use per animal</u> <u>species</u> to the Agency <u>in accordance</u> <u>with paragraph 4aa and within the</u> time limits set <u>therein</u>. The Agency shall cooperate with Member States and with other Union agencies to analyse [] these data and publish an annual report. <u>The</u> <u>Agency shall take into account</u> <u>these data when adopting any</u> <u>relevant guidelines and</u> recommendations.
3. The Commission shall be	recommendations.	3. The Commission shall []	3. The Commission shall []
empowered to adopt delegated acts		adopt delegated acts in accordance	adopt delegated acts in accordance
in accordance with Article 146 in		with Article 146 [] supplementing	with Article 146 [] supplementing
order to establish detailed rules on		the provisions of this Article	the provisions of this Article
the methods of gathering data on the use of antimicrobials and the method		concerning the establishment of	concerning the establishment of <u>the</u>
of transfer of these data to the		detailed rules on the methods of gathering data on the use of the	<u>requirements as regards:</u> (a) the types of antimicrobial s

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Agency.		antimicrobial medicinal products used in animals.	medicinal products used in animals for which data shall be collected; (b) the quality assurance that Member States and the Agency shall put in place to ensure quality and comparability of data. and (c) the detailed rules on the methods of gathering data on the use of the antimicrobial medicinal products used in animals and on the method of transfer of these data to the Agency.
	AM 164 3a. Member States shall collect relevant and comparable data on the volume of sales and the use of anti-parasitic and hormonal veterinary medicinal products, and make these available to the Agency.		

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
4. The Commission may, by		4. The Commission shall [], by	4. The Commission shall [], by
means of implementing acts, set up		means of implementing acts, set up	means of implementing acts, set up
the format and the requirements for		the format and the requirements for	the format and the requirements for
the data to be collected in accordance		the data to be collected in accordance	the data to be collected in accordance
with this Article. Those		with this Article. Those	with this Article. Those implementing
implementing acts shall be adopted		implementing acts shall be adopted	acts shall be adopted in accordance
in accordance with the examination		in accordance with the examination	with the examination procedure
procedure referred to in Article		procedure referred to in Article	referred to in Article 145 (2).
145(2).		145(2).	
			4aa. Member States shall be
			allowed to apply a progressive
			stepwise approach, regarding the
			obligations set out in this Article,
			whereby:
			(i) within three years from the date
			of application as referred to in
			Article 150, data shall be collected
			at least for the species and
			categories included in Commission
			Implementing Decision
			2013/652/EU in its version of
			[date of adoption of this
			Regulation];
			(ii) within five years from the date
			of application as referred to in
			Article 150, data shall be collected
			for all food producing animal
			species,
			(iii) within eight years from the
			date of application as referred to



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
			<u>in Article 150, data shall be</u>
			collected for other animals which
			<u>are bred or kept.</u>
			4a. Nothing in point (iii) in the
			second subparagraph of
			paragraph 4 shall be understood to
			include an obligation to collect
			data from natural persons keeping
			companion animals.
	AM 165		
	4a. Data requirements for		
	adopting those implementing acts		
	shall include animal species, the		
	dose, the duration and type of		
	treatment, the number of animals		
	treated and the administration		
	route or routes. In addition, any		
	off-label use of antimicrobials		
	shall be mandatorily reported to		
	national authorities.		
	AM 166		
	4b. The use of antibiotics in		
	drinking water shall be restricted		
	to cases where most of the animals		
	or the whole herd are sick. Five		
	years after the entry into force of		
	this Regulation, the Commission		
	shall publish a report examining		
	the different routes used to		
	administer antibiotics to food-		



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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	producing animals, and in		
	particular the oral routes used		
	through feed and water, and their		
	subsequent impact on		
	antimicrobial resistance.		
		5. The Commission shall report	If the EP accepts the compromise
		to the European Parliament and to	text in paragraphs 2 to 4a ,
		the Council within five years after	paragraphs 1a, 5 and 6 will be
		the date of application of this	deleted.
		Regulation, on the state of play of	
		the collection of data on the use of	
		antimicrobial medicinal products	
		used in animals in the different	
		Member States.	
		6. As of 5 years after the date of	If the EP accepts the compromise
		application in accordance with	text in paragraphs 2 to 4a,
		Article 150 the Commission is	paragraphs 1a, 5 and 6 will be
		empowered to adopt delegated acts	deleted.
		in accordance with Article 145(2)	
		to amend paragraphs 1 and 1a of	
		this Article imposing on Member	
		States the obligation to collect all	
		the data referred to in those	
		paragraphs, following an	
		assessment that the procedures in	
		the Member States for the	
		collection of data on the volume of	
		sales of antimicrobial medicinal	
		products, other than antibiotic	
		medicinal products, as well as on	



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		the use of antimicrobial medicinal	
		products, are sufficiently reliable	
		and that the data is available.	
Article 55		Article 55	Article 55
Responsibilities of the marketing		Responsibilities of the marketing	Responsibilities of the marketing
authorisation holders		authorisation holders	authorisation holders
		0a. The marketing authorisation	0a. The marketing authorisation
		holder shall be responsible for the	holder shall be responsible for the
		marketing of his veterinary	marketing of his veterinary
		medicinal products. The	medicinal products. The
		designation of a representative	designation of a representative
		shall not relieve the marketing	shall not relieve the marketing
		authorisation holder of his legal	authorisation holder of his legal
		responsibility.	responsibility.
		0b. The marketing authorisation	0b. The marketing authorisation
		holder shall, within the limits of his	holder shall, within the limits of his
		responsibilities, ensure	responsibilities, ensure
		appropriate and continued	appropriate and continued
		supplies of his veterinary	supplies of his veterinary
		medicinal products.	medicinal products.
1. In respect of the manufacturing		1. After a marketing	1. After a marketing
process and control methods stated in		authorisation has been granted,	authorisation has been granted,
the application for a marketing		the marketing authorisation holder	the marketing authorisation holder
authorisation for the veterinary		shall, in respect of the methods of	shall, in respect of the methods of
medicinal product and in order to		manufacture and control [] stated	manufacture and control [] stated
take account of scientific and		in the application for a marketing	in the application for a marketing
technical progress, the marketing		authorisation, [] take account of	authorisation, [] take account of
authorisation holders shall ensure		scientific and technical progress, and	scientific and technical progress, and
that any changes that may be		introduce [] any changes that may	introduce [] any changes that may
required to enable that veterinary		be required to enable [] the	be required to enable [] the

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
medicinal product to be		veterinary medicinal product to be	veterinary medicinal product to be
manufactured and verified by means		manufactured and [] controlled by	manufactured and [] controlled by
of generally accepted scientific		means of generally accepted	means of generally accepted
methods are introduced. The		scientific methods []. The	scientific methods []. The
introduction of such changes shall be		introduction of such changes shall be	introduction of such changes shall be
subject to the procedures laid down		subject to the procedures laid down	subject to the procedures laid down
in Section 4 of this Chapter.		in Section 4 of this Chapter.	in Section 4 of this Chapter.
		1aa. The marketing authorisation	1aa. The marketing authorisation
		holder shall ensure that the	holder shall ensure that the
		summary of product	summary of product
		characteristics, package leaflet and	characteristics, package leaflet and
		labelling is kept up to date with the	labelling is kept up to date with the
		current scientific knowledge.	current scientific knowledge.
		1a. As regards generic	1a. As regards generic
		veterinary medicinal products and	veterinary medicinal products and
		hybrid veterinary medicinal	hybrid veterinary medicinal
		products the marketing	products the marketing
		authorisation holder shall not	authorisation holder shall not
		place such products on the Union	place such products on the Union
		market until the period of the	market until the period of the
		protection of technical	protection of technical
		documentation for the reference	documentation for the reference
		veterinary medicinal product, as	veterinary medicinal product, as
		set out in Articles 34 and 35, has	set out in Articles 34 and 35, has
		elapsed. ⁴⁴	elapsed.
		1b. The marketing authorisation	1b. The marketing authorisation
		holder shall record in the product	holder shall record in the product
		database the dates when its	database the dates when its

⁴⁴ Moved from Article 53(2).



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
556 mai - 2014/0257 (COD)		authorised veterinary medicinal products are placed on the market and information on the availability for each veterinary medicinal product in each relevant Member State and, as applicable, the dates of any suspension or revocation of the concerned marketing authorisations.	authorised veterinary medicinal products are placed on the market and information on the availability for each veterinary medicinal product in each relevant Member State and, as applicable, the dates of any suspension or revocation of the concerned marketing authorisations.
2. Competent authorities may require marketing authorisation holders to provide them with sufficient quantities of the veterinary medicinal products to enable controls to be made on the identification of the presence of residues of the veterinary medicinal products in question.		 2. Upon request of the competent authorities, [] the marketing authorisation holder[] shall [] provide them with sufficient quantities of [] samples to enable controls to be made on [] its veterinary medicinal products [] placed on the Union market. 	 2. Upon request of the competent authorities, [] the marketing authorisation holder[] shall [] provide them with sufficient quantities of [] samples to enable controls to be made on [] its veterinary medicinal products [] placed on the Union market.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
3. Upon request of a competent		3. Upon request of a competent	3. Upon request of a competent
authority, the marketing		authority, the marketing	authority, the marketing
authorisation holder shall provide		authorisation holder shall provide	authorisation holder shall provide
technical expertise to facilitate the		technical expertise to facilitate the	technical expertise to facilitate the
implementation of the analytical		implementation of the analytical	implementation of the analytical
method for detecting residues of the		method for detecting residues of the	method for detecting residues of the
veterinary medicinal products in the		veterinary medicinal products in the	veterinary medicinal products in the
national reference laboratory		European Union [] reference	European Union [] reference
designated under Council Directive		laboratory designated under	laboratory designated under
96/23/EC ⁴⁵ .		Regulation (EU) No 2017/625 [].	Regulation (EU) No 2017/625 [].
4. In order to permit continuous		4. [] The marketing	4. [] The marketing
assessment of the benefit-risk		authorisation holder shall upon	authorisation holder shall upon
balance, a competent authority or the		request by [] a competent	request by [] a competent
Agency may at any time ask the		authority or the Agency, within the	authority or the Agency, within the
marketing authorisation holder to		time limit set, provide [] data	time limit set, provide [] data
forward data demonstrating that the		demonstrating that the benefit-risk	demonstrating that the benefit-risk
benefit-risk balance remains		balance remains favourable.	balance remains favourable.
favourable.			
5. The marketing authorisation		5. The marketing authorisation	5. The marketing authorisation
holder shall without delay inform the		holder shall without delay inform the	holder shall without delay inform the
competent authority or the		competent authority which has	competent authority which has
Commission of any prohibition or		granted the marketing	granted the marketing
restriction imposed by a competent		authorisation, or the Commission,	authorisation, or the Commission,
authority and of any other new		as applicable, of any prohibition or	as applicable, of any prohibition or
information which might influence		restriction imposed by a competent	restriction imposed by a competent
the assessment of the benefits and		authority or an authority of a third	authority or an authority of a third
risks of the veterinary medicinal		country and of any other new	country and of any other new

⁴⁵ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
product concerned.		information which might influence	information which might influence
		the assessment of the benefits and	the assessment of the benefits and
		risks of the veterinary medicinal	risks of the veterinary medicinal
		product concerned, including from	product concerned, including from
		the outcome of the signal	the outcome of the signal
		management process carried out in	management process carried out in
		accordance with Article 81.	accordance with Article 81.
6. Upon request from a competent		6. [] The marketing	6. [] The marketing
authority, the Commission or the		authorisation holder shall provide the	authorisation holder shall provide the
Agency, the marketing authorisation		competent authority, the	competent authority, the
holder shall provide the competent		Commission or the Agency, as	Commission or the Agency, as
authority, the Commission or the		applicable, within the time limit	applicable, within the time limit
Agency with all data in his		set, with all data in his possession	set, with all data in his possession
possession relating to the volume of		relating to the volume of sales of the	relating to the volume of sales of the
sales.		veterinary medicinal product	veterinary medicinal product
		concerned.	concerned.
		6a. The marketing authorisation	6a. The marketing authorisation
		holder shall record in the product	holder shall record in the product
		database the annual volume of	database the annual volume of
		sales for each veterinary medicinal	sales for each veterinary medicinal
		product.	product.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	 Position in the Council as endorsed by Coreper on 20 December 2017 7. The marketing authorisation holder shall without delay inform the competent authority which has granted the marketing authorisation, or the Commission, 	Draft revised negotiation mandate proposed by the Presidency7. The marketing authorisation holder shall without delay inform the competent authority which has granted the marketing authorisation, or the Commission,
		as applicable, of any action to be taken by him to cease the marketing of a veterinary medicinal product prior to taking such action, together with the reasons therefore.	as applicable, of any action to be taken by him to cease the marketing of a veterinary medicinal product prior to taking such action, together with the reasons therefore.
Article 56National helpdesks for small and medium-sized enterprises1.In order to help small and medium-sized enterprises to comply with the requirements of this Regulation, Member States shall establish national helpdesks.		Article 56 []Small and medium-sized enterprises 1. Member States shall, in accordance with their national law, take appropriate measures [] to [] advise small and medium-sized enterprises on compliance [] with the requirements of this Regulation [].	Article 56 []Small and medium-sized enterprises 1. Member States shall, in accordance with their national law, take appropriate measures [] to [] advise small and medium-sized enterprises on compliance [] with the requirements of this Regulation [].
2. National helpdesks shall provide advice to applicants, marketing authorisation holders, manufacturers, importers and any other interested parties which are small or medium-sized enterprises on their responsibilities and obligations under this Regulation and on applications for the authorisation of		2[]	2[]



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
veterinary medicinal products.			
	AM 167		
	Section 2a		
	Imports, parallel imports and		
	parallel distribution		
	AM 168		
	Article 56a		
	Import authorisation		
	1. An import authorisation		
	shall be required for the following		
	actions:		
	(a) the importation of veterinary		
	medicinal products used in the		
	context of Article 8, point (a)(ii) of		
	Article 115(1), point (b) of Article $116(1)$ point (b) of Article $116(2)$		
	116(1), point (b) of Article 116(2) and point (a) of Article 116(3) by a		
	veterinarian or by any person		
	authorised to deliver veterinary		
	medicinal products in the Member		
	States;		
	(b) the parallel importation of		
	veterinary medicinal products by a		
	manufacturer or distributor		
	authorised in a Member State that		
	is independent of the holder of the		
	marketing authorisation. The		
	imported veterinary medicinal		
	product and the national reference		
	medicinal product shall have:		



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	(i) the same qualitative and		
	quantitative composition in terms		
	of active substances and		
	excipients, and the same		
	pharmaceutical form;		
	<i>(ii) the same therapeutic effects</i>		
	and the same target species.		
	The national reference medicinal		
	product and the veterinary		
	medicinal product imported in		
	parallel are required to have been		
	harmonised under Article 69 or		
	70, or authorised in accordance		
	with Articles 46 and 48;		
	(c) the parallel distribution of		
	veterinary medicinal products by a		
	distributor independently of the		
	holder of the marketing		
	authorisation.		
	2. Applications for		
	authorisation for these activities		
	shall be submitted to the national		
	authorities responsible for		
	authorisation as referred to in		
	points (a) and (b) of paragraph 1,		
	and to the Authorisations Agency		
	referred to in point (c) of		
	paragraph 1.		
	The competent authorities and the		



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	Agency shall register the		
	authorisation of parallel		
	importation or parallel distribution		
	that they have granted in the		
	database on veterinary medicinal		
	products established under Article		
	51.		
	3. The veterinary medicinal		
	product imported in parallel or		
	distributed in parallel shall be		
	marketed in the packaging and		
	with labelling in the language(s)		
	stipulated by each Member State		
	of importation or distribution.		
	4. By way of derogation from		
	paragraph 1 of this Article, the		
	authorisation shall not be required		
	for:		
	(a) the importation of veterinary		
	medicinal products by a		
	veterinarian service-provider in		
	accordance with Article 114;		
	(b) the transportation by a		
	holder of a pet animal of		
	veterinary medicinal products		
	required for its treatment other		
	than immunological medicines		
	and within the limit of three		
	months of treatment.		
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	Article 56b		
	Import authorisation applications		
	1. An import authorisation		
	application as referred to in point		
	(a) of Article 56a(1) shall be		
	submitted to the competent		
	authority of the Member State of		
	the importer.		
	These authorisations shall be		
	granted for a single operation.		
	Any change in the information		
	submitted in order to obtain		
	authorisation shall be notified to		
	the competent authority, which		
	shall accordingly alter the initial		
	authorisation if necessary.		
	An import authorisation		
	application shall contain at least		
	the following information:		
	(a) the name of the veterinary		
	medicinal product, its strength, its		
	pharmaceutical form and its		
	therapeutic indications;		

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	(b) the Member State of origin		
	and details of the marketing		
	authorisation;		
	(c) details of the distributor		
	responsible for the sale of the		
	product;		
	(d) the quantities imported.		
	2. An import authorisation		
	application as referred to in point		
	(b) of Article 56a(1) shall be		
	submitted to the competent		
	authority of the Member State of		
	the importer.		
	These authorisations shall be		
	granted for a period of five years.		
	Any change in the information		
	submitted in order to obtain		
	authorisation shall be notified to		
	the competent authority, which		
	shall accordingly alter the initial		
	authorisation if necessary.		
	A parallel import authorisation		
	application shall contain at least		
	the following information:		



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	(a) the name of the veterinary		
	medicinal product, its strength and		
	its pharmaceutical form;		
	(b) details of the imported		
	veterinary medicinal product and		
	of the medicinal product		
	authorised in the Member State of		
	importation, and details of the		
	nature of the relabelling;		
	(c) the name or company name		
	of the applicant;		
	(d) the name or company name		
	or logo of the holder of the		
	marketing authorisation or the		
	number of the marketing		
	authorisation of the reference		
	product and of the imported		
	product;		
	(e) details of the manufacturing		
	site where the veterinary medicinal		
	products are to be relabelled;		
	(f) the name of the qualified		
	person responsible for		
	pharmacovigilance;		
	(g) a declaration that the		
	applicant is independent of the		
	holder of the marketing		
	authorisation.		
	3. An import authorisation		
	application as referred to in point		



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	(c) of Article 56a(1) shall be		
	submitted to the Agency.		
	These authorisations shall be granted for a period of five years.		
	Any change in the information submitted in order to obtain authorisation shall be notified to the Agency, which shall accordingly alter the initial authorisation if necessary.		
	The application shall contain information concerning:		
	(a) the name or company name of the applicant, of the manufacturer involved in relabelling, and the parallel		
	distributor;		
	(b) the name of the qualified		
	person responsible for pharmacovigilance;		
	(c) the Member State of origin and destination.		

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	4. The competent authority or		
	the Agency may suspend or		
	withdraw parallel import or		
	parallel distribution authorisations		
	if Article 56a and paragraphs 1, 2		
	and 3 of this Article are no longer		
	complied with or if the product		
	presents a risk to human or animal		
	health or to the environment.		
Section 3		Section 3	Section 3
Subsequent recognition in the		Subsequent recognition in the	Subsequent recognition in the
mutual recognition and		mutual recognition and	mutual recognition and
decentralised marketing		decentralised marketing	decentralised marketing
authorisation procedures		authorisation procedures	authorisation procedures
Article 57		Article 5746	Article 57
Subsequent recognition of marketing			
authorisations by other Member			
States			
1. After completion of a mutual		[]	[]
recognition procedure laid down in			
Article 48 or a decentralised			
procedure laid down in Article 46,			
the marketing authorisation holder			
may submit an application for a			
marketing authorisation for a			
veterinary medicinal product to			
additional Member States. The			
application shall include the			

⁴⁶ Content of Article 57 has been amended and included in the new Article 48a.



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following:			
(a) a list of all decisions granting		[]	[]
marketing authorisations concerning			
this veterinary medicinal product;			
(b) a list of variations introduced		[]	[]
since the first marketing			
authorisation in the Union was			
granted;			
(c) a summary report on		[]	[]
pharmacovigilance data.			
2. The additional Member State		[]	[]
shall adopt a decision granting a			
marketing authorisation in			
conformity with the assessment			
report referred to in Articles $46(3)$			
and 48(4) or, where appropriate, an updated assessment report, summary			
of the product characteristics,			
labelling and package leaflet within			
30 days of receipt of the documents			
listed in paragraph 1.			
3. Paragraphs 1 and 2 shall not		[]	[]
apply to veterinary medicinal		[]	[]
products that have been authorised			
through a mutual recognition or			
decentralised procedure before the			
date of the application of this			
Regulation.			
4. Recognition of marketing		[]	[]
authorisations for those veterinary			

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medicinal products shall be granted			
in accordance with the procedure laid			
down in Article 48.			
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	Article 57a		
	Subsequent conversion into		
	centralised marketing		
	authorisation		
	1. After completion of a		
	decentralised procedure laid down		
	in Article 46, a mutual recognition		
	procedure laid down in Article 48,		
	or a marketing authorisation		
	harmonisation procedure laid		
	down in Article 69, the marketing		
	authorisation holder may submit		
	an application to convert the		
	existing marketing authorisations		
	for the veterinary medicinal		
	product into a centralised		
	marketing authorisation granted		
	by the Commission which shall be		
	valid throughout the Union.		

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	2. The application for the		
	conversion into a centralised		
	marketing authorisation shall be		
	submitted to the Agency and shall		
	include the following:		
	(a) a list of all decisions		
	granting marketing authorisations		
	concerning this veterinary		
	medicinal product;		
	(b) a list of variations		
	introduced since the first		
	marketing authorisation in the		
	Union was granted;		
	(c) a summary report on		
	pharmacovigilance data.		
	3. Within 30 days of receipt of		
	the documents listed in paragraph		
	2, the Commission shall prepare a		
	draft of the decision granting the		
	Union marketing authorisation in		
	conformity with the assessment		
	report referred to in Articles 46(3),		
	48(4) and 69(3) or, where		
	appropriate, an updated		
	assessment report, a summary of		
	the product characteristics, and a		
	labelling and package leaflet.		

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	4. The Commission shall, by		
	means of implementing acts, take		
	a final decision on the granting of		
	the centralised marketing		
	authorisation.		
	This Article shall only apply to		
	veterinary medicinal products that		
	have been authorised through a		
	mutual recognition procedure, a		
	decentralised procedure or a		
	marketing authorisation		
	harmonisation procedure after the date of the application of this		
	Regulation.		
Section 4		Section 4	Section 4
Changes to marketing		Changes to the terms of the	Changes to the terms of the
authorisations		marketing authorisations	marketing authorisations
Article 58		Article 58	Article 58
Variations to the terms of a		Variations []	Variations []
marketing authorisation			
1. Variation to the terms of a		1 []	1. []
marketing authorisation means a			
change to the terms of the marketing			
authorisation for a veterinary			
medicinal product as referred to in			
Article 31 ('variation').			

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2. The Commission shall, by means of implementing acts, establish a list of variations to the terms of a marketing authorisation for a veterinary medicinal product requiring assessment ('variations requiring assessment'). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article		2. The Commission shall, by means of implementing acts, establish a list of variations [] not requiring assessment []. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	2. The Commission shall, by means of implementing acts, establish a list of variations [] not requiring assessment []. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).
145(2).3. The Commission shall take account of the following criteria when adopting those implementing acts:		3. The Commission shall take account of the following criteria when adopting those implementing acts:	3. The Commission shall take account of the following criteria when adopting those implementing acts:
 (a) the need for a scientific assessment of changes in order to determine the risk to public health, animal health or the environment; (b) whether changes have an impact on the safety and efficacy of the veterinary medicinal product; 		 (a) the need for a scientific assessment of changes in order to determine the risk to public health, animal health or the environment; (b) whether changes have an impact on the quality, safety or [] efficacy of the veterinary medicinal product; 	 (a) the need for a scientific assessment of changes in order to determine the risk to public health, animal health or the environment; (b) whether changes have an impact on the quality, safety or [] efficacy of the veterinary medicinal product;
(c) whether changes imply a significant alteration to the summary of product characteristics.		 (c) whether changes imply [] no more than a minor alteration to the summary of product characteristics; (d) whether changes are of an administrative nature. 	 (c) whether changes imply [] no more than a minor alteration to the summary of product characteristics; (d) whether changes are of an administrative nature.



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Article 59		Article 5947	Article 59
Consequential changes to product		[]	[]
information		[····]	
Where a variation entails		[]	[]
consequential changes to the			
summary of the product			
characteristics, the labelling or the			
package leaflet, those changes shall			
be considered as part of that variation			
for the purposes of the examination			
of the application for a variation.			
Article 60		Article 60	Article 60
Variations to the terms of a		Variations [] that do not require	Variations [] that do not require
marketing authorisation that do not		assessment	assessment
require assessment			
1. Where a variation does not		1. Where a variation [] appears	1. Where a variation [] appears
appear in the list established in		in the list established in accordance	in the list established in accordance
accordance with Article 58(2), the		with Article $58(2)$, the marketing	with Article 58(2), the marketing
marketing authorisation holder shall		authorisation holder shall record	authorisation holder shall record
record the change in the product		within 30 days the change,	within 30 days the change,
database within 12 months following		including as applicable the	including as applicable the
the implementation of the variation.		summary of product	summary of product
		characteristics, labelling or	characteristics, labelling or
		package leaflet in accordance with	package leaflet in accordance with
		the languages referred to in Article	the languages referred to in Article
		6a, in the product database []	6a, in the product database []
		following the implementation [] of	following the implementation [] of
		[] that variation.	[] that variation.

⁴⁷ Moved to a new Article 61a



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2. If necessary, competent		2. If necessary, competent	2. If necessary, competent
authorities or, where the veterinary		authorities or, where the veterinary	authorities or, where the veterinary
medicinal product is authorised		medicinal product is authorised	medicinal product is authorised
under the centralised marketing		under the centralised marketing	under the centralised marketing
authorisation procedure, the		authorisation procedure, the	authorisation procedure, the
Commission shall amend the		Commission, by means of	Commission, by means of
decision granting a marketing		implementing acts, shall amend []	implementing acts, shall amend []
authorisation in accordance with the		the marketing authorisation in	the marketing authorisation in
change.		accordance with the change recorded	accordance with the change recorded
		as referred to in paragraph 1.	as referred to in paragraph 1.
		3. The reference Member State	3. The reference Member State
		or the Commission, where	or the Commission, where
		applicable, shall inform the	applicable, shall inform the
		marketing authorisation holder	marketing authorisation holder
		and the competent authorities in	and the competent authorities in
		the relevant Member States as to	the relevant Member States as to
		whether the variation is approved	whether the variation is approved
		or rejected by recording this	or rejected by recording this
		information in the product	information in the product
		database.	database.
Article 61		Article 61	Article 61
Application for variations requiring		Application for variations requiring	Application for variations requiring
assessment		assessment	assessment
1. Marketing authorisation holder		1. Where a variation does not	1. Where a variation does not
shall submit an application for a		appear in the list established in	appear in the list established in
variation requiring assessment to a		accordance with Article 58(2), the	accordance with Article 58(2), the
competent authority or to the		[] m arketing authorisation holder	[] m arketing authorisation holder
Agency.		shall submit an application for a	shall submit an application for a
		variation requiring assessment to	variation requiring assessment to
		[] the competent authority which	[] the competent authority which



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		has granted the marketing	has granted the marketing
		authorisation or to the Agency, as applicable. The applications shall	authorisation or to the Agency, as applicable. The applications shall
		be submitted electronically.	be submitted electronically.
2. The application referred to in		2. The application referred to in	2. The application referred to in
paragraph 1 shall contain:		paragraph 1 shall contain:	paragraph 1 shall contain:
(a) a description of the variation;		(a) a description of the variation;	(a) a description of the variation;
		(aa) data referred to in Article 7	(aa) data referred to in Article 7
		relevant to the variation in	relevant to the variation in
		question;	question;
(b) reference to marketing		(b) [] details of the marketing	(b) [] details of the marketing
authorisations affected by the		authorisation(s) affected by the	authorisation(s) affected by the
application;		application;	application;
(c) where the variation leads to		(c) where the variation leads to	(c) where the variation leads to
other variations to the terms of the		other consequential variations to the	other consequential variations to the
same marketing authorisation, a		terms of the same marketing	terms of the same marketing
description of those other variations;		authorisation, a description of those	authorisation, a description of those
		other variations;	other variations;
(d) where the variation concerns		(d) where the variation concerns	(d) where the variation concerns
marketing authorisations granted		marketing authorisations granted	marketing authorisations granted
under the mutual recognition or		under the mutual recognition or	under the mutual recognition or
decentralised procedures, a list of		decentralised procedures, a list of	decentralised procedures, a list of
Member States which granted those		Member States which granted those	Member States which granted those
marketing authorisations.		marketing authorisations.	marketing authorisations.

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		Article 61a	Article 61a
		Consequential changes to product information	Consequential changes to product information
		Where a variation entails consequential changes to the summary of the product	Where a variation entails consequential changes to the summary of the product
		characteristics, the labelling or the	characteristics, the labelling or the
		package leaflet, those changes shall	package leaflet, those changes shall
		be considered as part of that	be considered as part of that
		variation for the purposes of the	variation for the purposes of the
		examination of the application for	examination of the application for
		a variation.	a variation.
Article 62		Article 62	Article 62
Groups of variations		Groups of variations	Groups of variations
When applying for several variations		When the marketing authorisation	When the marketing authorisation
to the terms of the same marketing		holder applies for several variations	holder applies for several variations
authorisation, a marketing		[] not appearing in the list	[] not appearing in the list
authorisation holder may submit one		established in accordance with	established in accordance with
application for all variations.		Article 58(2) regarding the same	Article 58(2) regarding the same
		marketing authorisation or for one	marketing authorisation or for one
		variation not appearing in that list	variation not appearing in that list
		in respect of several different	in respect of several different
		marketing authorisations, he []	marketing authorisations, he []
		may submit one application for all	may submit one application for all
		variations.	variations.

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Article 63		Article 63	Article 63
Worksharing procedure		Worksharing procedure	Worksharing procedure
1. When applying for variations		1. When the marketing	1. When the marketing
to the terms of several marketing		authorisation holder applies for one	authorisation holder applies for one
authorisations held by the same		or more variations which are	or more variations which are
marketing authorisation holder and		identical in all relevant Member	identical in all relevant Member
granted by different competent		States and which do not appear in	States and which do not appear in
authorities and/or the Commission,		the list established in accordance	the list established in accordance
the marketing authorisation holder		with Article 58(2), regarding []	with Article 58(2), regarding []
shall submit an application to all		several marketing authorisations	several marketing authorisations
competent authorities concerned and		which are held by the same	which are held by the same
the Agency.		marketing authorisation holder and	marketing authorisation holder and
		which have been granted by	which have been granted by
		different competent authorities	different competent authorities
		and/or the Commission, [] he shall	and/or the Commission, [] he shall
		submit an identical application to	submit an identical application to
		[] competent authorities in all	[] competent authorities in all
		relevant Member States [] and,	relevant Member States [] and,
		in case a variation to a centrally	in case a variation to a centrally
		authorised veterinary medicinal	authorised veterinary medicinal
		product is included, to the Agency.	product is included, to the Agency.
2. Where one of the marketing		2. Where [] any of the	2. Where [] any of the
authorisations referred to in		marketing authorisations referred to	marketing authorisations referred to
paragraph 1 is a centralised		in paragraph 1 is a centralised	in paragraph 1 is a centralised
marketing authorisation, the Agency		marketing authorisation, the Agency	marketing authorisation, the Agency
shall assess the application in		shall assess the application in	shall assess the application in
accordance with the procedure laid		accordance with the procedure laid	accordance with the procedure laid
down in Article 64.		down in Article 64.	down in Article 64.
3. Where none of the marketing		3. Where none of the marketing	3. Where none of the marketing
authorisations referred to in		authorisations referred to in	authorisations referred to in



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paragraph 1 is a centralised		paragraph 1 is a centralised	paragraph 1 is a centralised
marketing authorisation, the		marketing authorisation, the	marketing authorisation, the
coordination group shall assign a		coordination group shall agree upon	coordination group shall agree upon
competent authority among those		[] a competent authority among	[] a competent authority among
having granted the marketing		those having granted the marketing	those having granted the marketing
authorisations to assess the		authorisations to assess the	authorisations to assess the
application in accordance with the		application in accordance with the	application in accordance with the
procedure laid down in Article 64.		procedure laid down in Article 64.	procedure laid down in Article 64.
<u> </u>		4. The Commission may, by	4. The Commission may, by
		means of implementing acts, adopt	means of implementing acts, adopt
		the necessary arrangements	the necessary arrangements
		regarding the functioning of the	regarding the functioning of the
		worksharing procedure. Those	worksharing procedure. Those
		implementing acts shall be adopted	implementing acts shall be adopted
		in accordance with the	in accordance with the
		examination procedure referred to	examination procedure referred to
		in Article 145(2).	in Article 145(2).
Article 64		Article 64	Article 64
Procedure for variations requiring		Procedure for variations requiring	Procedure for variations requiring
assessment		assessment	assessment
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1. If a variation application fulfils	1. If a variation application	1. If an [] application for a	1. If an [] application for a
the requirements laid down in Article	fulfils the requirements laid down	variation fulfils the requirements	variation fulfils the requirements
61, the competent authority or the	in Article 61, the competent	laid down in Article 61, the	laid down in Article 61, the
Agency, or a competent authority	authority or the Agency, or a	competent authority, [] the	competent authority, [] the
assigned in accordance with Article	competent authority assigned in	Agency, [] the competent	Agency, [] the competent
63(3) shall acknowledge receipt of a	accordance with Article 63(3) shall	authority [] agreed upon in	authority [] agreed upon in
complete application.	acknowledge receipt of a complete	accordance with Article 63(3), or the	accordance with Article 63(3), or the
	application in 15 days.	competent authority in the	competent authority in the
		reference Member State, as	reference Member State, as

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		applicable, shall within 30 days	applicable, shall within 30 15 days
		acknowledge receipt of a valid []	acknowledge receipt of a valid []
		application.	application.
2. If the application is		2. If the application is	2. If the application is
incomplete, the competent authority		incomplete, the competent authority,	incomplete, the competent authority,
or the Agency, or a competent		[] the Agency[], [] the	[] the Agency[], [] the
authority assigned in accordance		competent authority [] agreed	competent authority [] agreed
with Article 63(3) shall require the		upon in accordance with Article	upon in accordance with Article
applicant to complete the application		63(3), or the competent authority	63(3), or the competent authority
within a reasonable deadline.		in the reference Member State, as	in the reference Member State, as
		applicable, shall require the []	applicable, shall require the []
		marketing authorisation holder	marketing authorisation holder
		[] to provide the missing	[] to provide the missing
		information and documentation	information and documentation
		within a reasonable deadline.	within a reasonable deadline.
3. The competent authority or the		3. The competent authority, []	3. The competent authority, []
Agency, or a competent authority		the Agency, [] the competent	the Agency, [] the competent
assigned in accordance with Article		authority [] agreed upon in	authority [] agreed upon in
63(3) shall assess the application and		accordance with Article 63(3), or the	accordance with Article 63(3), or the
prepare an opinion on the variation		competent authority in the	competent authority in the
within 60 days following the receipt		reference Member State <u>, a</u> s	reference Member State <u>,</u> as
of a valid application. However,		applicable, shall assess the	applicable, shall assess the
where it is necessary having regard		application and prepare,	application and prepare,
to the urgency of the matter, the		respectively, an assessment report	respectively, an assessment report
opinion shall be adopted without		or an opinion, in accordance with	or an opinion, in accordance with
delay.		Article 28, on the variation. That	Article 28, on the variation. That
		assessment report or opinion shall	assessment report or opinion shall
		be prepared within 60 days	be prepared within 60 days
		following the receipt of a valid []	following the receipt of a valid []
		application. [] In case the	application. [] In case the



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
		assessment of a variation	assessment of a variation
		application requires more time due	application requires more time due
		to its complexity, the competent	to its complexity, the competent
		authority or the Agency may	authority or the Agency may
		extend this time limit to 90 days. In	extend this time limit to 90 days. In
		such a case the competent	such a case the competent
		authority or the Agency, as	authority or the Agency, as
		applicable, shall inform the	applicable, shall inform the
		marketing authorisation holder	marketing authorisation holder
		accordingly.	accordingly.
4. Within the period referred to in		4. Within the period referred to in	4. Within the period referred to in
paragraph 3, the competent authority		paragraph 3, the competent authority	paragraph 3, the competent authority
or the Agency may require the		or the Agency, as applicable , may	or the Agency, as applicable, may
applicant to provide supplementary		require the [] marketing	require the [] marketing
information within a set time limit.		authorisation holder to provide	authorisation holder to provide
The procedure shall be suspended		supplementary information within a	supplementary information within a
until the supplementary information		set time limit. The procedure shall be	set time limit. The procedure shall be
has been provided.		suspended until the supplementary	suspended until the supplementary
^		information has been provided.	information has been provided.
5. The opinion shall be forwarded to the applicant.		5. [] ⁴⁸	5. []

⁴⁸ Moved to paragraph 7a.



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
6. Where the opinion is prepared		6. Where the opinion referred to	6. Where the opinion referred to
by the Agency, the opinion shall be		in paragraph 3 is prepared by the	in paragraph 3 is prepared by the
forwarded to the Commission.		Agency, [] the Agency shall []	Agency, [] the Agency shall []
Where the Agency assesses the		forward [] it to the Commission.	forward [] it to the Commission.
application in accordance with		[] and to the marketing	[] and to the marketing
Article $63(2)$, the opinion shall be		authorisation holder.	authorisation holder.
forwarded to the Commission and all competent authorities concerned.			
		6a. Where the opinion referred	6a. Where the opinion referred
		to in paragraph 3 is prepared by	to in paragraph 3 is prepared by
		the Agency in accordance with	the Agency in accordance with
		Article 63(2), the Agency shall	Article 63(2), the Agency shall
		forward it to all competent	forward it to all competent
		authorities in the relevant Member	authorities in the relevant Member
		States, to the Commission and to	States, to the Commission and to
		the marketing authorisation	the marketing authorisation
		holder.	holder.
7. Where the opinion is prepared		7. Where the [] assessment	7. Where the [] assessment
by a competent authority assigned in		report referred to in paragraph 3	report referred to in paragraph 3
accordance with Article $63(3)$, the		is prepared by the [] competent	is prepared by the [] competent
opinion shall be forwarded to all		authority [] agreed upon in	authority [] agreed upon in
competent authorities concerned.		accordance with Article 63(3), or by	accordance with Article 63(3), or by
		the competent authority in the	the competent authority in the
		reference Member State, [] it	reference Member State, [] it
		shall be forwarded to [] the	shall be forwarded to [] the
		competent authorities in all relevant	competent authorities in all relevant
		Member States and to the	Member States and to the
		marketing authorisation holder.	marketing authorisation holder.
		7aa. If a competent authority does	7aa. If a competent authority does
		not agree with the assessment	not agree with the assessment



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		report referred to in paragraph 7,	report referred to in paragraph 7,
		the review procedure laid down in	the review procedure laid down in
		Article 49 shall apply.	Article 49 shall apply.
		7a. Subject to the outcome of the	7a. Subject to the outcome of the
		procedure provided for in	procedure provided for in
		paragraph 7aa, if applicable, the	paragraph 7aa, if applicable, the
		opinion or the assessment report	opinion or the assessment report
		referred to in paragraph 3 shall be	referred to in paragraph 3 shall be
		forwarded to the marketing	forwarded to the marketing
		authorisation holder without	authorisation holder without
		delay.	delay.
8. Within 15 days of receipt of		8. Within 15 days of receipt of	8. Within 15 days of receipt of
the opinion, the applicant may		the opinion or the assessment	the opinion or the assessment
submit a written request to the		report, the [] marketing	report, the [] marketing
Agency or the competent authority		authorisation holder may submit a	authorisation holder may submit a
for a re-examination of the opinion.		written request to the competent	written request to the competent
Detailed grounds for requesting a re-		authority, the Agency, [] the	authority, the Agency, [] the
examination shall be stated in the		competent authority agreed upon in	competent authority agreed upon in
request or be forwarded to the		accordance with Article 63(3), or	accordance with Article 63(3), or
Agency or to the competent authority		the competent authority in the	the competent authority in the
within 60 days of receipt of the		reference Member State, as	reference Member State, as
opinion.		applicable, for a re-examination of	applicable, for a re-examination of
		the opinion or the assessment	the opinion or the assessment
		report. Detailed grounds for	report. Detailed grounds for
		requesting a re-examination shall be	requesting a re-examination shall be
		[] submitted to the competent	[] submitted to the competent
		authority, the Agency, [] to the	authority, the Agency, [] to the
		competent authority agreed upon in	competent authority agreed upon in
		accordance with Article 63(3) or	accordance with Article 63(3) or
		the competent authority in the	the competent authority in the



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		reference Member State, as	reference Member State, as
		applicable, within 60 days of receipt	applicable, within 60 days of receipt
		of the opinion or the assessment	of the opinion or the assessment
		report.	report.
9. Within 60 days of receipt of		9. Within 60 days of receipt of	9. Within 60 days of receipt of
the grounds for the request, the		the grounds for the request, [] the	the grounds for the request, [] the
Agency or the competent authority		competent authority, the Agency,	competent authority, the Agency,
shall re-examine the points of the		the competent authority agreed	the competent authority agreed
opinion identified in the request for		upon in accordance with Article	upon in accordance with Article
re-examination by the applicant and		63(3) or the competent authority in	63(3) or the competent authority in
adopt a re-examined opinion. The		the reference Member State, as	the reference Member State, as
reasons for the conclusions reached		applicable, shall re-examine the	applicable, shall re-examine the
shall be annexed to the opinion.		points of the opinion or the	points of the opinion or the
		assessment report identified in the	assessment report identified in the
		request for re-examination by the	request for re-examination by the
		[] marketing authorisation	[] marketing authorisation
		holder and adopt a re-examined	holder and adopt a re-examined
		opinion or assessment report. The	opinion or assessment report. The
		reasons for the conclusions reached	reasons for the conclusions reached
		shall be annexed to the opinion or	shall be annexed to the opinion or
		the assessment report.	the assessment report.
Article 65		Article 65	Article 65
Measures to close the procedures for		Measures to close the procedure s for	Measures to close the procedure s for
variations requiring assessment		variations requiring assessment	variations requiring assessment
1. Within 30 days of the		1. Within 30 days of the	1. Within 30 days of the
completion of the procedure laid		completion of the procedure laid	completion of the procedure laid
down in Article 64(6) and (7) a		down in Article 64 [] and of	down in Article 64 [] and of
competent authority or the		receiving the complete translations	receiving the complete translations
Commission shall amend the		of the summary of the product	of the summary of the product
marketing authorisation or reject the		characteristics, labelling and	characteristics, labelling and

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Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
variation and inform the applicant of		package leaflet from the marketing	package leaflet from the marketing
the grounds for the rejection. In case		authorisation holder, the competent	authorisation holder, the competent
of centralised marketing		authority, [] the Commission or	authority, [] the Commission or
authorisation, the Commission shall,		the competent authorities in the	the competent authorities in the
by means of implementing acts, take		Member States listed in	Member States listed in
a final decision amending the			accordance with Article 61(2)(d),
e		accordance with Article 61(2)(d), as applicable, shall amend the	
marketing authorisation or rejecting			as applicable, shall amend the
the variation. These implementing		marketing authorisation or reject the	marketing authorisation or reject the
acts shall be adopted in accordance		variation in line with the opinion or	variation in line with the opinion or
with the examination procedure		the assessment report referred to	the assessment report referred to
referred to in Article 145(2).		in Article 64 and inform the []	in Article 64 and inform the []
		marketing authorisation holder of	marketing authorisation holder of
		the grounds for the rejection.[].	the grounds for the rejection.[].
2. Where the draft decision is not		2. In case of a centralised	2. In case of a centralised
in accordance with the opinion of the		marketing authorisation, the	marketing authorisation, the
Agency, the Commission shall annex		Commission shall prepare a draft	Commission shall prepare a draft
a detailed explanation of the reasons		decision to be taken in respect of	decision to be taken in respect of
for not following the opinion of the		the variation. Where the draft	the variation. Where the draft
Agency.		decision is not in accordance with	decision is not in accordance with
		the opinion of the Agency, the	the opinion of the Agency, the
		Commission shall [] provide a	Commission shall [] provide a
		detailed explanation of the reasons	detailed explanation of the reasons
		for not following the opinion of the	for not following the opinion of the
		Agency. The decision amending the	Agency. The decision amending the
		marketing authorisation or	marketing authorisation or
		rejecting the variation shall be	rejecting the variation shall be
		adopted by the Commission by	adopted by the Commission by
		means of implementing acts. These	means of implementing acts. These
		implementing acts shall be adopted	implementing acts shall be adopted
		in accordance with the	in accordance with the



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017 examination procedure referred to	Draft revised negotiation mandate proposed by the Presidency examination procedure referred to
		in Article 145(2).	in Article 145(2).
3. The competent authority or the Agency shall notify the marketing authorisation holder of the amended marketing authorisation without delay.		3. The competent authority or the [] Commission, as applicable, shall notify the marketing authorisation holder of the amended marketing authorisation without delay.	3. The competent authority or the [] Commission, as applicable, shall notify the marketing authorisation holder of the amended marketing authorisation without delay.
4. The product database shall be updated accordingly.		4. The product database shall be updated accordingly by the competent authority, the Commission, or the competent authorities in the Member States listed in accordance with Article 61(2)(d), as applicable.	4. The product database shall be updated accordingly by the competent authority, the Commission, <u>the Agency</u> , or the competent authorities in the Member States listed in accordance with Article 61(2)(d), as applicable.
Article 66		Article 66- ⁴⁹	Article 66
Coordination group review Where the opinion is prepared by a competent authority assigned in accordance with Article 63(3), each competent authority concerned shall amend the marketing authorisation granted by it or reject the variation in line with the opinion prepared by the competent authority assigned in accordance with Article 63(3).		[]	[]
However, if a competent authority		[]	[[]

⁴⁹ Moved to Article 64(7aa).

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
does not agree with the opinion, the			· · · · · · · · · · · · · · · · · · ·
coordination group review procedure			
laid down in Article 49 shall apply.			
Article 67		Article 67	Article 67
Implementation of variations		Implementation of variations	Implementation of variations
requiring assessment		requiring assessment	requiring assessment
1. A marketing authorisation		1. A marketing authorisation	1. A marketing authorisation
holder may implement a variation		holder may implement a variation	holder may implement a variation
requiring assessment only after a		requiring assessment only after a	requiring assessment only after a
competent authority or the		competent authority or the	competent authority or the
Commission has amended the		Commission, as applicable, has	Commission, as applicable, has
decision granting the marketing		amended the decision granting the	amended the decision granting the
authorisation in accordance with that		marketing authorisation in	marketing authorisation in
variation and the holder has been		accordance with that variation, has	accordance with that variation, has
notified thereof.		set a deadline for the	set a deadline for the
		implementation and has notified	implementation and has notified
		the marketing authorisation []	the marketing authorisation []
		thereof in accordance with Article	thereof in accordance with Article
		65(3).	65(3).
2. Where requested by a		2. Where requested by a	2. Where requested by a
competent authority or the Agency, a		competent authority or the []	competent authority or the []
marketing authorisation holder shall		Commission , a marketing	Commission, a marketing
supply without delay any		authorisation holder shall supply,	authorisation holder shall supply,
information related to a variation to		without delay, any information	without delay, any information
the terms of a marketing		related to the implementation of a	related to the implementation of a
authorisation.		variation [].	variation [].

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Section 5		Section 5	Section 5
Harmonisation of the summaries		Harmonisation of the summaries	Harmonisation of the summaries
of the product characteristics for		of [] product characteristics for	of [] product characteristics for
nationally authorised products		nationally authorised products	nationally authorised products
Article 68		Article 68	Article 68
Preparatory phase of the		[] Scope of the harmonisation []	[] Scope of the harmonisation []
harmonisation exercise		of summary of product	of summary of product
		characteristics of veterinary	characteristics of veterinary
		medicinal product	medicinal product
	AM 172		
	-1a. A single marketing		
	authorisation holder or a group of		
	marketing authorisation holders		
	may, in accordance with Article		
	69, request a harmonisation of		
	different national marketing		
	authorisations that have been		
	granted for a particular veterinary		
	medicinal product.		
	-1b. A harmonised summary of		
	product characteristics shall be		
	prepared for the particular		
	veterinary medicinal product, for		
	which national marketing		
	authorisations have been granted		
	in different Member States. The		
	coordination group shall draw up		
	detailed rules of procedure for		
	harmonisation.		
	-1c. National marketing		





Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
	authorisations may be harmonised with decentralised and/or mutual recognition marketing authorisations if they are for the same product or for essentially similar products. AM 172		
1. A harmonised summary of product characteristics shall be prepared in accordance with the procedure laid down in Article 69 for veterinary medicinal products, other than homeopathic veterinary medicinal products, which have the same qualitative and quantitative composition of their active substances and the same pharmaceutical form and for which national marketing authorisations have been granted in different Member States before 1 January 2004 ('similar products').	1. A hHarmonised summary of product characteristics conditions of use as set out in Article 69(4) shall be prepared in accordance with the procedure laid down in Article 69 for groups of essentially similar veterinary medicinal products, other than homeopathic veterinary medicinal products, which have the same qualitative and quantitative composition of their active substances and the same pharmaceutical form and have been shown to be bio- equivalent ('essentially similar' products) and for which national marketing authorisations have been granted in different Member States before 1 January 2004 ('similar products') before the entry into force of this Regulation.	 [] A harmonised summary of product characteristics shall be prepared in accordance with the procedure laid down in Article 69 and Article 69a for: (a) reference veterinary medicinal products [], which have the same qualitative and quantitative composition of their active substances and the same pharmaceutical form and for which [] marketing authorisations have been granted in accordance with Article 44 in different Member States [] for the same marketing authorisation holder. (b) generic and hybrid veterinary medicinal products. 	 [] A harmonised summary of product characteristics shall be prepared in accordance with the procedure laid down in Article 69 and Article 69a for: (a) reference veterinary medicinal products [], which have the same qualitative and quantitative composition of their active substances and the same pharmaceutical form and for which [] marketing authorisations have been granted in accordance with Article 44 in different Member States [] for the same marketing authorisation holder. (b) generic and hybrid veterinary medicinal products.
2. For the purposes of determining qualitative and		[]	[]



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quantitative composition of the active substances, different salts, esters, ethers, isomers, mixtures of isomers, complexes and derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy.		by Coreper on 20 December 2017	proposed by the Tresidency
Article 69 Procedure for harmonisation of summaries of products characteristics		Article 69 Procedure for harmonisation of summaries of product[] characteristics for the reference veterinary medicinal products	Article 69 Procedure for harmonisation of summaries of product[] characteristics for the reference veterinary medicinal products
1. By [12 months after the date of application of this Regulation for OP to insert the actual date] competent authorities shall provide the coordination group with lists of all products for which national marketing authorisations have been granted before 1 January 2004.	AM 173 1. By [12 months after the date of application of this Regulation for OP to insert the actual date] competent authorities shall provide the coordination group with lists of all products for which national marketing authorisations have been granted before 1 January 2004.	1. [] The competent authorities [] shall submit annually to the coordination group [] a list []of reference veterinary medicinal products and their summary of products characteristics [] for which [] marketing authorisation[] has been granted [] in accordance with Article 44 if, according to the competent authority, they should be subject to the procedure for harmonization of their summaries of product characteristics.	1. [] The competent authorities [] shall submit annually to the coordination group [] a list []of reference veterinary medicinal products and their summary of products characteristics [] for which [] marketing authorisation[] has been granted [] in accordance with Article 44 if, according to the competent authority, they should be subject to the procedure for harmonization of their summaries of product characteristics.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		1a. The marketing authorisation	1a. The marketing authorisation
		holder may apply for the	holder may apply for the
		procedure of harmonisation of	procedure of harmonisation of
		summaries of product	summaries of product
		characteristics for a reference	characteristics for a reference
		veterinary medicinal product by	veterinary medicinal product by
		submitting to the coordination	submitting to the coordination
		group the list of different names of	group the list of different names of
		this veterinary medicinal product	this veterinary medicinal product
		and the different summaries of	and the different summaries of
		product characteristics for which	product characteristics for which
		marketing authorisation has been	marketing authorisation has been
		granted in accordance with Article	granted in accordance with Article
		44 in different Member States.	44 in different Member States.
		1aa. The coordination group shall,	1aa. The coordination group shall,
		taking into account the lists	taking into account the lists
		provided by the Member States in	provided by the Member States in
		accordance with paragraph 1 or	accordance with paragraph 1 or
		any application received from a	any application received from a
		marketing authoristion holder in	marketing authoristion holder in
		accordance with paragraph 1a,	accordance with paragraph 1a,
		draw up annually and publish a	draw up annually and publish a
		list of reference veterinary	list of reference veterinary
		medicinal products which shall be	medicinal products which shall be
		subject to harmonisation of their	subject to harmonisation of their
		summaries of product	summaries of product
		characteristics and shall appoint a	characteristics and shall appoint a
		reference Member State for each	reference Member State for each
		concerned reference veterinary	concerned reference veterinary
		medicinal product.	medicinal product.



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		1aaa. When drawing up this list,	1aaa. When drawing up this list,
		the coordination group may decide	the coordination group may decide
		on prioritising its work on	on prioritising its work on
		harmonisation of summaries of	harmonisation of summaries of
		product characteristics, taking into	product characteristics, taking into
		account the recommendations of	account the recommendations of
		the Agency on class or group of	the Agency on class or group of
		reference veterinary medicinal	reference veterinary medicinal
		products that shall be harmonised	products that shall be harmonised
		in order to protect human or	in order to protect human or
		animal health or the environment.	animal health or the environment <u>,</u>
			including mitigation measures to
			prevent the risk for the
			<u>environment</u> .
		1b. Upon request by the	1b. Upon request by the
		competent authority in the	competent authority in the
		reference Member State referred	reference Member State referred
		to in paragraph 1aa, the marketing	to in paragraph 1aa, the marketing
		authorisation holder shall provide	authorisation holder shall provide
		the coordination group with a	the coordination group with a
		summary detailing the differences	summary detailing the differences
		between the summaries of product	between the summaries of product
		characteristics, his proposal for a	characteristics, his proposal for a
		harmonised summary of product	harmonised summary of product
		characteristics, package leaflet and	characteristics, package leaflet and
		labelling in accordance with	labelling in accordance with
		Article 6a, supported by the	Article 6a, supported by the
		appropriate existing data	appropriate existing data
		submitted in accordance with	submitted in accordance with
		Article 7 relevant to the proposal	Article 7 relevant to the proposal

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		for harmonisation in question.	for harmonisation in question.
2. The coordination group shall establish groups of similar products. For each of the groups of similar products, the coordination group shall appoint one member to act as a rapporteur.	AM 173 2. The coordination group shall establish groups of <i>essentially</i> similar products <i>as identified in</i> <i>point (b) of Article 68(4)</i> . For each of these groups of <i>essentially</i> similar products, the coordination group shall appoint one member to act as a rapporteur.	2. [] Within 180 days of receipt of the information referred to in paragraph 1b the competent authority in the reference Member State shall examine in consultation with the marketing authorisation holder, the documents submitted in accordance with paragraph 1b, prepare a report and submit it to the coordination group and to the marketing authorisation holder.	2. [] Within 180 days of receipt of the information referred to in paragraph 1b the competent authority in the reference Member State shall examine in consultation with the marketing authorisation holder, the documents submitted in accordance with paragraph 1b, prepare a report and submit it to the coordination group and to the marketing authorisation holder.
3. Within 120 days of his appointment, the rapporteur shall present the coordination group a report regarding possible harmonisation of summaries of product characteristics for the similar veterinary medicinal products in the group and propose a harmonised summary of products characteristics.	AM 173 3. Within 120 days of his appointment, the rapporteur shall present the coordination group a report regarding possible proposing harmonisation of summaries of product characteristics for the the conditions of use for the group of essentially similar veterinary medicinal products in the group and propose a harmonised summary of products characteristics or of the marketing authorisation propose a harmonised summary of products characteristics.	3. [] After receipt of the report, if the coordination group agrees by consensus on the harmonised summary of product characteristics, the competent authority in the reference Member State shall record that there is an agreement, close the procedure, inform the marketing authorisation holder accordingly and transmit to him the harmonised summary of product characteristics.	3. [] After receipt of the report, if the coordination group agrees by consensus on the harmonised summary of product characteristics, the competent authority in the reference Member State shall record that there is an agreement, close the procedure, inform the marketing authorisation holder accordingly and transmit to him the harmonised summary of product characteristics.
		3a. The marketing authorisation holder shall submit to the	3a. The marketing authorisation holder shall submit to the

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		competent authorities in each	competent authorities in each
		relevant Member State the	relevant Member State the
		necessary translations of the	necessary translations of the
		summary of product	summary of product
		characteristics, package leaflet and	characteristics, package leaflet and
		labelling in accordance with	labelling in accordance with
		Article 6a, within the time limit set	Article 6a, within the time limit set
		by the coordination group.	by the coordination group.
	AM 173		
4. Harmonised summaries of	4. Harmonised summaries of	4. [] Following agreement in	4. [] Following agreement in
product characteristics for veterinary	product characteristics for	accordance with paragraph 3, the	accordance with paragraph 3, the
medicinal products shall contain all	veterinary medicinal products	competent authorities in each	competent authorities in each
of the following information:	conditions of use shall contain all	relevant Member State shall vary	relevant Member State shall vary
	of at least the following	the marketing authorisation in	the marketing authorisation in
	information:	conformity with the agreement	conformity with the agreement
		within 30 days of the receipt of the	within 30 days of the receipt of the
		documents referred to in	documents referred to in
		paragraph 3a.	paragraph 3a.
			4a. The competent authority in the
			reference Member State shall take
			any appropriate initiatives in
			order to seek an agreement within
			the coordination group before the
			initiation of the procedure set out
			<u>in paragraph 5.</u>

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	AM 173		
(a) all species mentioned in the	(a) all species mentioned in the	[]	[]
marketing authorisations granted by	marketing authorisations granted by		
Member States in respect of the	Member States in respect of the		
similar products in the group;	essentially similar products in the		
	group;		
	AM 173		
(b) all therapeutic indications	(b) all therapeutic indications	[]	[]
mentioned in the marketing	and posology mentioned in the		
authorisations granted by Member	marketing authorisations granted by		
States in respect of the similar products in the group;	Member States in respect of the <i>essentially</i> similar products in the		
products in the group,			
	group; AM 173		
(c) the shortest withdrawal period	(c) the shortest a withdrawal	[]	[]
of those stated in the summaries of	period of those stated in the	[]	[]
the product characteristics.	summaries of the product		
-	characteristics which ensures that		
	consumers are adequately		
	protected-;		
	AM 173		
	(ca) special precautions		
	regarding impact on the		
	environment.		

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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	AM 173 4a. Further than the conditions of use, other elements of the summary of product characteristics and data quality set, may be harmonised.		
5. Upon presentation of a report, the coordination group shall act by a majority of the votes cast by the members of the coordination group represented at the meeting. The rapporteur shall record the agreement, close the procedure and inform Member States and the marketing authorisation holders accordingly.		5. [] In the event of lack of consensus in favour of a harmonised summary of product characteristics, the procedure for a Union interest referral in accordance with Articles 85 to 87 shall apply accordingly.	5. [] In the event of lack of consensus, following the efforts referred to in paragraph 4a, in favour of a harmonised summary of product characteristics, the procedure for a Union interest referral in accordance with Articles 85 to 87 shall apply accordingly.
6. In the event of an opinion in favour of adopting a harmonised summary of the product characteristics, each Member State shall vary a marketing authorisation in conformity with the agreement within 30 days of receipt of the information regarding the agreement from the rapporteur.	AM 173 6. In the event of an opinion in favour of adopting a harmonised summary of the product characteristics conditions of use, each Member State shall vary a the marketing authorisation or authorisations of the products in their territory so that the elements listed in paragraph 4, where they are already included in the summaries of characteristics for a product belonging to that group,	6. [] In order to maintain the level of harmonisation of the summary of product characteristics achieved, any future variation of the concerned marketing authorisations shall follow the mutual recognition procedure.	6. [] In order to maintain the level of harmonisation of the summary of product characteristics achieved, any future variation of the concerned marketing authorisations shall follow the mutual recognition procedure.



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	<i>are</i> in conformity with the agreement within 30 days of receipt of the information regarding the agreement from the rapporteur. <i>Once an opinion in favour of</i> <i>adopting harmonised conditions of</i> <i>use has been issued, marketing</i> <i>authorisations for a particular</i> <i>product shall be eligible to be</i> <i>considered to be mutual</i> <i>recognition marketing</i> <i>authorisations granted under this</i> <i>Regulation.</i>		
7. In the event of an unfavourable opinion, the procedure referred to in Article 49 shall apply.		[]	[]

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		Article 69a	Article 69a
		Procedure for harmonisation of	Procedure for harmonisation of
		summaries of product	summaries of product
		characteristics for generic and	characteristics for generic and
		hybrid veterinary medicinal	hybrid veterinary medicinal
		products	products
		1. When the procedure referred	1. When the procedure referred
		to in Article 69 has been closed and	to in Article 69 has been closed and
		a harmonised summary of product	a harmonised summary of product
		characteristics for a reference	characteristics for a reference
		veterinary medicinal product has	veterinary medicinal product has
		been agreed, the marketing	been agreed, the marketing
		authorisation holders of generic	authorisation holders of generic
		veterinary medicinal products	veterinary medicinal products
		shall apply within 60 days of the	shall apply within 60 days of the
		decision by the competent	decision by the competent
		authorities in each Member State	authorities in each Member State
		and in accordance with Article 61	and in accordance with Article 61
		for the harmonisation of the	for the harmonisation of the
		following sections of the summary	following sections of the summary
		of product characteristics for the	of product characteristics for the
		concerned generic veterinary	concerned generic veterinary
		medicinal products, as	medicinal products, as
		applicable ⁵⁰ :	applicable:
		(a) target species;	(a) target species;
		(b) clinical information referred	(b) clinical information referred
		to in Article 30(1)(c);	to in Article 30(1)(c);
		(c) the withdrawal period.	(c) the withdrawal period.

⁵⁰ See also Recital 41 as amended.



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	El amenument	by Coreper on 20 December 2017	0
558 final - 2014/0257 (COD)			proposed by the Presidency2. By way of derogation from
		2. By way of derogation from	v v 8
		paragraph 1, in case of a	paragraph 1, in case of a
		marketing authorisation for a	marketing authorisation for a
		hybrid veterinary medicinal	hybrid veterinary medicinal
		product supported by additional	product supported by additional
		pre-clinical studies and/or clinical	pre-clinical studies and/or clinical
		trials, the relevant sections of the	trials, the relevant sections of the
		summary of product	summary of product
		characteristics referred to in	characteristics referred to in
		paragraph 1 shall not be	paragraph 1 shall not be
		considered to be subject to	considered to be subject to
		harmonisation.	harmonisation.
		3. The marketing authorisation	3. The marketing authorisation
		holders of generic and hybrid	holders of generic and hybrid
		veterinary medicinal products	veterinary medicinal products
		shall ensure that the summaries of	shall ensure that the summaries of
		product s characteristics shall be	product s characteristics shall be
		essentially similar to that in the	essentially similar to that in the
		reference veterinary medicinal	reference veterinary medicinal
		products.	products.
Article 70		Article 70	Article 70
Harmonisation of summary of		[]	[]
products characteristics following			
reassessment			
	AM 174		
1. By way of derogation from	1. By way of derogation from	[]	[]
Article 69, the Committee may	Article 69, and where		
recommend to the Commission	harmonisation of the conditions of		
groups of similar veterinary	use of a group of products is in the		
medicinal products for which a	interests of public or animal		
producto for which a		1	I



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scientific reassessment is necessary	health at Union level, the		proposed by the Presidency
before a harmonised summary of the	Committee may recommend to the		
product characteristics is prepared.	Commission groups of similar		
r	veterinary medicinal products for		
	which a scientific reassessment is		
	necessary before a harmonised		
	summary of the product		
	characteristics is conditions of use		
	<i>are</i> prepared.		
	AM 174		
	1a. For the purpose of		
	harmonisation under this Article		
	similar veterinary medicinal		
	products shall refer to products,		
	not all of which are bioequivalent,		
	and other than homeopathic		
	veterinary medicinal products, that		
	have the same active substance or		
	active substances and the same		
	pharmaceutical form or a range of		
	veterinary medicinal products		
	belonging to the same therapeutic		
	class.		
	AM 174	[]	[]
2. The Commission shall, by	2. The Commission shall, by		
means of implementing acts, adopt	means of implementing acts, adopt		
decisions on groups of product for	decisions on groups of similar		
which a reassessment is necessary.	products for which a reassessment		
Those implementing acts shall be	is necessary. Those implementing		
adopted in accordance with the	acts shall be adopted in accordance		



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examination procedure referred to in	with the examination procedure		
Article 145(2).	referred to in Article 145(2).		
	AM 174		
3. By way of derogation from	3. By way of derogation from		The list referred to in Article 69(1)
Article 69, veterinary medicinal	Article 69, veterinary medicinal		shall not contain any reference
products authorised before 20 July	products authorised before 20 July		veterinary medicinal product
2000 as well as veterinary medicinal	2000 as well as veterinary		authorised before 1 October 2005,
products authorised after that date	medicinal products authorised after		and which is identified as
but which were identified as	that date but which were identified		potentially harmful to the
potentially harmful to the	as potentially harmful to the		environment and has not been
environment in the course of the	environment in the course of the		subject to an environmental risk
environmental risk assessment shall	environmental risk assessment		assessment.
be reassessed before a harmonised	which have not been subject to an		
summary of the product	environmental risk assessment in		In such a case, the competent
characteristics is prepared.	<i>the Union</i> shall be reassessed		authority shall request the
	assessed in accordance with		marketing authorization holder to
	Annex II before a harmonised		update the relevant environmental
	summary of the product		safety documentation referred to
	characteristics is conditions of use		in Article 7(1) (b), taking into
	are prepared. For that purpose,		account the review referred to in
	marketing authorisation holders		Article 149e, and the
	shall update accordingly the		environmental risk assessment of
	documentation mentioned in point		generic veterinary medicinal
	(b) of Article 7(1).		products of such reference
			medicinal products, if applicable.

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	AM 174		
	<i>3a.</i> By way of derogation from		
	Article 69, antimicrobial		
	veterinary medicinal products		
	shall be reassessed within five		
	years of the entry into force of this		
	Regulation.		
	AM 174		
4. For the purposes of paragraphs	4. For the purposes of		
1 and 3, the procedure for a Union	paragraphs 1, 3 and 3a, the		
interest referral in accordance with	procedure for a Union interest		
Articles 84 to 87 shall apply	referral in accordance with Articles		
accordingly.	84 to 87 shall apply accordingly.		
Article 71		Article 71	Article 71
Position of marketing authorisation		[]	[]
holder			
	AM 175		
Upon request from the coordination	Upon request from the coordination	[]	[]
group or the Agency, holders of the	group or the Agency, holders of the		
marketing authorisations for products	marketing authorisations for		
included in a group of similar	products included in a group of		
products identified for a	similar products identified for a		
harmonisation of the summaries of	harmonisation of the summaries of		
the product characteristics shall	the product characteristics or the		
submit information concerning their	holders of a particular product		
products.	identified for harmonisation of		
	<i>marketing authorisations</i> shall		
	submit information concerning		
	their products.		
Section 6		Section 6	Section 6





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Pharmacovigilance		Pharmacovigilance	Pharmacovigilance
Article 72		Article 72	Article 72
Pharmacovigilance system of the		Pharmacovigilance system of the	Pharmacovigilance system of the
marketing authorisation holder		marketing authorisation holder	marketing authorisation holder
	AM 176	[]	[]
1. Marketing authorisation	1. Marketing authorisation		
holders shall elaborate and maintain	holders shall ensure that risk-		
a system for collecting information	benefit balance of authorised		
on the risks of veterinary medicinal	veterinary medicinal products is		
products as regards animal health,	evaluated on a continuous basis		
public health and the environment	and that appropriate measure are		
enabling them to fulfil their	taken by the marketing		
pharmacovigilance responsibilities	authorisation holders in order to		
listed in Articles 73, 76 and 77	ensure that this balance remains		
('pharmacovigilance system').	positive for the authorised		
	veterinary medicinal products. To		
	this end, the marketing		
	authorisation holders shall		
	elaborate and maintain a system for		
	collecting, <i>investigating</i> ,		
	assessment and communicating of		
	information on the risks adverse		
	events of veterinary medicinal		
	products as regards animal health,		
	public health and the environment.		
	enabling them The system shall		
	serve to coordinate the necessary		
	<i>measures</i> to fulfil the ir		
	pharmacovigilance responsibilities		
	listed in Articles 73, 76 and 77		



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	('pharmacovigilance system').		
2. Competent authorities and the Agency shall supervise the pharmacovigilance systems of marketing authorisation holders.	AM 177 2. Competent authorities and the Agency shall supervise the pharmacovigilance systems of marketing authorisation holders and shall not have any conflict of interest with regard to the marketing authorisation holder.	[]	[]
Article 73		Article 73	Article 73
Union pharmacovigilance system		Union pharmacovigilance system	Union pharmacovigilance system
1. Member States, the Commission, the Agency and marketing authorisation holders shall collaborate in setting up and maintaining a system to monitor the safety of authorised veterinary medicinal products, enabling them to fulfil their responsibilities as listed in Articles 77 and 79 ('Union pharmacovigilance system').	AM 178 1. Member States, the Commission, and the Agency and marketing authorisation holders shall collaborate in setting up, interconnecting and further developing their systems and maintaining a system to monitor the safety, effectiveness and quality of authorised veterinary medicinal products, enabling them in order to fulfil their responsibilities as listed in Articles 77 and 79 ('Union pharmacovigilance system'). Marketing authorisation holders shall set up and maintain a system to monitor the safety, effectiveness and quality of their products,	1. Member States, the Commission, the Agency and marketing authorisation holders shall collaborate in setting up and maintaining a Union pharmacovigilance system to carry out pharmacovigilance tasks with respect to [] the safety and efficacy of authorised veterinary medicinal products in order to ensure continuous assessment of the benefit-risk balance [].	1. Member States, the Commission, the Agency and marketing authorisation holders shall collaborate in setting up and maintaining a Union pharmacovigilance system to carry out pharmacovigilance tasks with respect to [] the safety and efficacy of authorised veterinary medicinal products in order to ensure continuous assessment of the benefit-risk balance [].

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	enabling them to fulfil their responsibilities as listed in Articles 77 and 78.		
2. Competent authorities, the Agency and marketing authorisation holders shall make available to healthcare professionals and animal holders different means of reporting to them the following events whether or not the event is considered to be product-related ('adverse events'):	AM 179 2. Competent authorities, the Agency and marketing authorisation holders shall make available to healthcare professionals, animal holders, <i>environmental authorities</i> <i>of the Member States and other</i> <i>interested parties</i> different means of reporting to them the following events (<i>'adverse events'</i>) whether or not the event is considered to be product-related 'adverse events':	2. Competent authorities, the Agency and marketing authorisation holders shall take appropriate measures to make available [] means [] to report and encourage reporting of the following suspected adverse events []:	2. Competent authorities, the Agency and marketing authorisation holders shall take appropriate <u>the</u> <u>necessary</u> measures to make available [] means [] to report and encourage reporting of the following suspected adverse events []
(a) any response in an animal to a veterinary or human medicinal product, that is noxious and unintended;	(a) any response in an animal to a veterinary or human medicinal product, that is noxious and unintended, <i>regardless of whether or not the event is considered to be product-related and whether or not the product was administered in accordance with the summary of product characteristics;</i>	(a) any unfavourable and unintended reaction [] in any animal to a veterinary [] medicinal product [];	(a) any unfavourable and unintended reaction [] in any animal to a veterinary [] medicinal product [];
(b) any observation of a lack of efficacy of a veterinary medicinal product following administration to an animal in accordance with the summary of product characteristics;	(b) any observation of a lack of efficacy of a veterinary medicinal product, <i>including potential signs of</i> <i>antimicrobial resistance</i> , following administration to <i>its use on</i> an animal in accordance with the summary of product characteristics;	(b) any observation of a lack of efficacy of a veterinary medicinal product following its administration to an animal, whether in accordance with the summary of product characteristics or not ;	(b) any observation of a lack of efficacy of a veterinary medicinal product following its administration to an animal, whether in accordance with the summary of product characteristics or not ;



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(c) any environmental incidents observed following administration of a veterinary medicinal product to an animal;	(c) any environmental incidents observed adverse, unforeseen, or unintended impact in the environment (including ground and surface water) following administration of a veterinary medicinal product to an animal;	(c) any environmental incidents observed following the administration of a veterinary medicinal product to an animal;	(c) any environmental incidents observed following the administration of a veterinary medicinal product to an animal;
 (d) any infringements of withdrawal period following administration to an animal of a veterinary or human medicinal product; 	(d) any infringements of withdrawal period following administration to an animal of a veterinary or human medicinal product;	(d) []	(d) []
(e) any noxious response in humans to a veterinary medicinal product;	(e) any noxious response reaction in humans to a veterinary medicinal product;	(e) any noxious reaction [] in humans exposed to a veterinary medicinal product;	(e) any noxious reaction [] in humans exposed to a veterinary medicinal product;
(f) any finding of an active substance in a produce of a food- producing animal exceeding the levels of residues established in accordance with Regulation (EC) No 470/2009.	(f) any finding of an active substance in a produce of a food- producing animal exceeding the levels of residues established in accordance with Regulation (EC) No 470/2009;	 (f) any finding of a pharmacologically [] active substance or marker residue in a [] product of animal origin [] exceeding the maximum levels of residues established in accordance with Regulation (EC) No 470/2009 after the set withdrawal period has been observed; 	(f) any finding of a pharmacologically [] active substance or marker residue in a [] product of animal origin [] exceeding the maximum levels of residues established in accordance with Regulation (EC) No 470/2009 after the set withdrawal period has been observed;



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	(fa) any suspected unintended transmission via a veterinary medicinal product of any infectious agent.	(g) any suspected transmission of an infectious agent via a veterinary medicinal product.	(g) any suspected transmission of an infectious agent via a veterinary medicinal product.
		(h) any unfavourable and unintended reaction in an animal to a medicinal product for human use.	(h) any unfavourable and unintended reaction in an animal to a medicinal product for human use.
	AM 180 Article 73 - paragraph 2 a (new) 2a. Competent authorities and the Agency shall, in addition to the events provided under paragraph 2, make available to healthcare professionals and animal holders different means of reporting to them any response in an animal to a human medicinal product.		
	AM 181 Article 73 a (new) No later than six months before the date of application of this Regulation, the Commission shall present a report to the European Parliament and the Council on a feasibility study of a substance- based review system ('monographs') and other potential alternatives for the environmental risk assessment of		



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	veterinary medicinal products, to		
	be accompanied, if appropriate, by		
	a legislative proposal.		
Article 74		Article 74	Article 74
Union pharmacovigilance database		Union pharmacovigilance database	Union pharmacovigilance database
	AM 182		
1. The Agency shall establish and	1. The Agency shall establish	1. The Agency shall, in	1. The Agency shall, in
maintain a Union database on	and maintain a Union database on	collaboration with Member States,	collaboration with Member States,
pharmacovigilance of veterinary	pharmacovigilance of veterinary	establish and maintain a Union	establish and maintain a Union
medicinal products (the	medicinal products (the	database on pharmacovigilance for	database on pharmacovigilance for
"pharmacovigilance database").	"pharmacovigilance database"),	the reporting and recording of	the reporting and recording of
	linked to the database on	suspected adverse events referred	suspected adverse events referred
	veterinary medicinal products. The	to in paragraph 2 of Article 73 []	to in paragraph 2 of Article 73 []
	Union database on veterinary	(the "pharmacovigilance database"),	(the "pharmacovigilance database"),
	medicinal products shall be the	[] which shall also include the	[] which shall also include the
	only data entry point for adverse	information on qualified person	information on qualified person
	events reported by the holders of	responsible for pharmacovigilance,	responsible for pharmacovigilance,
	marketing authorisations.	the reference number(s) of the	the reference number(s) of the
	Maintaining the database shall	pharmacovigilance system master	pharmacovigilance system master
	include electronic archiving of the	file, the results and outcomes of the	file, the results and outcomes of the
	original reports, related	signal management process and	signal management process and
	subsequent reports and continuous	results of pharmacovigilance	results of pharmacovigilance
	quality control of the data.	inspections in accordance with	inspections in accordance with
		provisions of Article 128.	provisions of Article 128.

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		1a. The pharmacovigilance database and the product database referred to in Article 51 shall be interconnected.	1a. The pharmacovigilance database and the product database referred to in Article 51 shall be interconnected.
2. The Agency shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the pharmacovigilance database.	AM 183 2. The Agency shall, in collaboration consultation with the Member States and, the Commission and interested parties, draw up the functional specifications for the pharmacovigilance database. These shall include environmental monitoring data which would report undesirable effects on non- target species in the ecosystem, and extend sources of inputs to the pharmacovigilance system to include observation and monitoring by specialists who are not necessarily veterinarians.	2. The Agency shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the pharmacovigilance database.	2. The Agency shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the pharmacovigilance database.
3. The Agency shall ensure that information reported to the pharmacovigilance database is uploaded and made accessible in accordance with Article 75.	AM 184 3. The Agency shall ensure that information reported to the pharmacovigilance database is uploaded and made <i>publicity</i> accessible in accordance with Article 75. AM 185 Article 74 paragraph 3 a (new)	3. The Agency shall ensure that information reported is uploaded in [] the pharmacovigilance database [] and made accessible in accordance with Article 75.	3. The Agency shall ensure that information reported is uploaded in [] the pharmacovigilance database [] and made accessible in accordance with Article 75.



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	3a. The Agency shall ensure that the		
	transfer of information between its		
	pharmacovigilance database and the		
	national pharmacovigilance		
	databases of the individual Member States is safeguarded.		
		4. The system shall be set-up as a	4. The system shall be set-up as a
		data-processing network allowing	data-processing network allowing
		transmission of data between	transmission of data between
		Member States, the Commission,	Member States, the Commission,
		the Agency and the marketing	the Agency and the marketing
		authorisation holders to ensure	authorisation holders to ensure
		that in the event of an alert related	that in the event of an alert related
		to pharmacovigilance data, options	to pharmacovigilance data, options
		for risk management and any	for risk management and any
		appropriate measures can be	appropriate measures can be
		considered as referred to in	considered as referred to in
		Articles 130, 131 and 133.	Articles 130, 131 and 133.
Article 75		Article 75	Article 75
Access to the pharmacovigilance		Access to the pharmacovigilance	Access to the pharmacovigilance
database		database	database
1. The competent authorities shall		1. The competent authorities shall	1. The competent authorities shall
have full access to the		have full access to the	have full access to the
pharmacovigilance database.		pharmacovigilance database.	pharmacovigilance database.
2. Marketing authorisation		2. Marketing authorisation	2. Marketing authorisation
holders shall have access to the		holders shall have access to the	holders shall have access to the
pharmacovigilance database to the		pharmacovigilance database with	pharmacovigilance database with
extent necessary for them to comply		respect to data related to the	respect to data related to the
with their pharmacovigilance		veterinary medicinal products for	veterinary medicinal products for
responsibilities as specified in		which they hold a marketing	which they hold a marketing

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Article 77.		authorisation and to other non- confidential data related to veterinary medicinal products for which they do not hold a marketing authorisation to the extent necessary for them to comply with their pharmacovigilance responsibilities as specified in Article 77, 78 and 81.	authorisation and to other non- confidential data related to veterinary medicinal products for which they do not hold a marketing authorisation to the extent necessary for them to comply with their pharmacovigilance responsibilities as specified in Article 77, 78 and 81.
3. The general public shall have access to the pharmacovigilance database only as regards the following information:		3. The general public shall have access to the pharmacovigilance database [] as regards the following information:	3. The general public shall have access to the pharmacovigilance database [], without changing the information therein as regards the following information:
(a) the number of adverse events reported each year, broken down by product, animal species and type of adverse event;	 AM 186 (a) the number of adverse events reported each year, broken down by <i>type of</i> product <i>and active substance</i>, animal species and type of adverse event; 	(a) the incidence [] of suspected adverse events reported each year, broken down by product, animal species and type of suspected adverse event;	(a) <u>the number and, at the latest</u> <u>within two years from the date of</u> <u>application,</u> the incidence [] of suspected adverse events reported each year, broken down by product, animal species and type of suspected adverse event;
(b) information on the process and outcome of the signal management referred to in Article 81 for veterinary medicinal products and groups of products.		(b) [] the results and outcomes referred to in Article 81(0) that arise from [] the signal management process performed by the marketing authorisation holder [] for veterinary medicinal products [] or groups of veterinary medicinal products.	(b) [] the results and outcomes referred to in Article 81(0) that arise from [] the signal management process performed by the marketing authorisation holder [] for veterinary medicinal products [] or groups of veterinary medicinal products.

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	AM 187		
	Article 75 paragraph " point		
	b a (new)		
	(ba) information about incidence of		
	adverse events.		
	AM 188		
	Article 75 paragraph 3 a (new)		
	3a. Health professionals shall		
	have access to the		
	pharmacovigilance database as		
	regards the following		
	information:		
	(a) the number of adverse events		
	reported each year, broken down		
	by product, animal species and		
	type of adverse event;		
	(b) previous declarations made		
	concerning the same product		
	and the number of cases per		
	species in the previous six		
	months;		
	(c) information on the results of		
	the signal detection system for		
	veterinary medicinal products		
	and groups of products.		

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Article 76		Article 76	Article 76
Adverse events reporting		Reporting and recording of	Reporting and recording of
	A.M. 100	suspected adverse events []	suspected adverse events []
	AM 189	1. Competent authorities shall	1. Competent authorities shall
1. Competent authorities shall	1. Competent authorities shall	record in the pharmacovigilance	record in the pharmacovigilance
record in the pharmacovigilance	record and assess all adverse	database all suspected adverse	database all suspected adverse
database all adverse events which	events of which they learn under	events which were reported to them	events which were reported to them
were reported to them by healthcare	Article 73 and which occur in the	[] and that occurred in the territory	[] and that occurred in the territory
professionals and animal holders and	territory of their Member State	of their Member State, within 30	of their Member State, within 30
that occurred in the territory of their	and shall enter them immediately,	days [] of receipt of the suspected	days [] of receipt of the suspected
Member State, within 30 days	but no later than 15 days following	adverse event report.	adverse event report.
following the receipt of the adverse	the receipt of the information, in		
event report.	<i>the</i> pharmacovigilance database. all		
	Competent authorities shall record		
	any serious adverse events which		
	were reported to them by healthcare		
	professionals and animal holders		
	and that occurred in the territory of		
	their Member State, event in		
	animals, noxious response in		
	humans to a veterinary medicinal		
	product or environmental incident		
	observed following administration		
	of a veterinary medicinal product		
	to an animal within 30 15 days		
	following the receipt of the such an		
	adverse event report.		

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2. Marketing authorisation holders shall record in the pharmacovigilance database all adverse events which were reported to them by healthcare professionals and animal holders and that occurred within the Union or in a third country with regard to their authorised veterinary medicinal products, within 30 days following the receipt of the adverse event report.	AM 190 2. Marketing authorisation holders shall record in the pharmacovigilance database and evaluate all adverse events which were reported to them by healthcare professionals and animal holders and that occurred within the Union or in a third country with regard to their authorised veterinary medicinal products. Serious adverse event in animals, noxious response in humans to a veterinary medicinal product and environmental incidents observed following administration of a veterinary medicinal product to an animal shall be reported within 30 15 days following the receipt of the such adverse event report. Less serious adverse events relating to the use of veterinary medicinal products shall be reported no later than 42 days following receipt of the information. Different requirements shall apply for adverse events observed in clinical trials, as specified in the Good Clinical Practice guidelines for clinical trials.	2. Marketing authorisation holders shall record in the pharmacovigilance database all suspected adverse events which were reported to them [] and that occurred within the Union or in a third country or that have been published in the scientific literature with regard to their authorised veterinary medicinal products, [] without delay and no later than within 30 days [] of [] receipt of the suspected adverse event report.	2. Marketing authorisation holders shall record in the pharmacovigilance database all suspected adverse events which were reported to them [] and that occurred within the Union or in a third country or that have been published in the scientific literature with regard to their authorised veterinary medicinal products, [] without delay and no later than within 30 days [] of [] receipt of the suspected adverse event report.



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		2a. The Agency may request the	2a. The Agency may request the
		marketing authorisation holder for	marketing authorisation holder for
		centrally authorised products, or	centrally authorised products, or
		for nationally authorised products	for nationally authorised products
		in case they fall within the scope of	in case they fall within the scope of
		a Union interest referral, to collect	a Union interest referral, to collect
		specific pharmacovigilance data	specific pharmacovigilance data
		additional to the data listed in	additional to the data listed in
		Article 73(2) and to carry out post	Article 73(2) and to carry out post
		marketing surveillance studies.	marketing surveillance studies.
		The Agency shall state in detail the	The Agency shall state in detail the
		reasons for the request, give an	reasons for the request, give an
		appropriate deadline and inform	appropriate deadline and inform
		competent authorities thereof.	competent authorities thereof.
	AM 191		
3. Competent authorities may, on	3. Competent authorities may,	3. Competent authorities []	3. Competent authorities []
their own initiative or on request	on their own initiative or on <i>a</i>	may request the marketing	may request the marketing
from the Agency, request the	request from the Agency, request	authorisation holder for nationally	authorisation holder for nationally
marketing authorisation holder to	the marketing authorisation holder	authorised veterinary medicinal	authorised veterinary medicinal
collect specific pharmacovigilance	to <i>provide</i> specific	products to collect [] specific	products to collect [] specific
data, in particular regarding the use	pharmacovigilance data, in	pharmacovigilance data, []	pharmacovigilance data, []
of a veterinary medicinal product in	particular such as, information	additional to the data [] listed in	additional to the data [] listed in
specified animal species, in the	relating to ongoing risk-benefit	Article 73(2) [] and to carry out	Article 73(2) [] and to carry out
context of public and animal health,	balance evaluations regarding the	post marketing surveillance	post marketing surveillance
safety of the persons administering	use of a veterinary medicinal	studies. The competent authority	studies. The competent authority
the product, and the protection of the	product in specified animal species,	shall state in detail the reasons for	shall state in detail the reasons for
environment. The authority shall	in the context of public and animal	the request, give an appropriate	the request, give an appropriate
state in detail the reasons for the	health, safety of the persons	deadline and inform other competent	deadline and inform other competent
request and inform other competent	administering the product, and or	authorities and the Agency thereof.	authorities and the Agency thereof.
authorities and the Agency thereof.	the protection of the environment.		

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	The authority shall state in detail		
	the reasons for the request and		
	inform other competent authorities and the Agency thereof.		
	Marketing authorisation holders		
	shall be required to comply with		
	such a request within an		
	appropriate deadline set by the		
	competent authority.		
4. Within 15 days after receipt of	*	4[]	4[]
the request referred to in paragraph			
3, the marketing authorisation holder			
may give written notice to the			
competent authority that he wishes a			
re-examination of the request to			
collect additional specific			
pharmacovigilance data.			6 F]
5. Within 60 days following the		5 []	5 []
receipt of the written notice, the			
competent authority shall re-examine			
the request and provide the marketing authorisation holder with			
its decision.			

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Article 77		Article 77	Article 77
Pharmacovigilance responsibilities		Pharmacovigilance responsibilities	Pharmacovigilance responsibilities
of the marketing authorisation		of the marketing authorisation	of the marketing authorisation
holder		holder	holder
		0. Marketing authorisation	0. Marketing authorisation
		holders shall establish and	holders shall establish and
		maintain a system for collecting,	maintain a system for collecting,
		collating and evaluating	collating and evaluating
		information on the suspected	information on the suspected
		adverse events concerning their	adverse events concerning their
		authorised veterinary medicinal	authorised veterinary medicinal
		products enabling them to fulfil	products enabling them to fulfil
		their pharmacovigilance	their pharmacovigilance
		responsibilities	responsibilities
		('pharmacovigilance system').	('pharmacovigilance system').
		00. The marketing authorisation	00. The marketing authorisation
		holder shall have in place one or	holder shall have in place one or
		more pharmacovigilance system	more pharmacovigilance system
		master files describing in details	master files describing in details
		the pharmacovigilance system with	the pharmacovigilance system with
		respect to his authorised	respect to his authorised
		veterinary medicinal products. For	veterinary medicinal products. For
		each veterinary medicinal product	each veterinary medicinal product
		the marketing authorisation holder	the marketing authorisation holder
		shall not have more than one	shall not have more than one
		pharmacovigilance system master	pharmacovigilance system master
		file.	file.

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		000. The marketing authorisation	000. The marketing authorisation
		holder shall have a local or	holder shall have a local or
		regional representative for the	regional representative for the
		purpose of receiving reports of	purpose of receiving reports of
		suspected adverse events, able to	suspected adverse events, able to
		communicate in the languages of	communicate in the languages of
		the relevant Member States.	the relevant Member States.
	AM 192		
1. The marketing authorisation	1. The marketing authorisation	1. The marketing authorisation	1. The marketing authorisation
holder shall be responsible for the	holder shall be responsible for the	holder shall be responsible for the	holder shall be responsible for the
pharmacovigilance of the products	pharmacovigilance of the products	pharmacovigilance of the veterinary	pharmacovigilance of the veterinary
for which he holds a marketing	for which he holds a marketing	medicinal product [] for which he	medicinal product [] for which he
authorisation.	authorisation and shall take all	holds a marketing authorisation and	holds a marketing authorisation and
	appropriate steps to encourage	shall continuously evaluate by	shall continuously evaluate by
	members of the health professions	approriate means the benefit-risk	approriate means the benefit-risk
	and animal holders to report	balance of this veterinary	balance of this veterinary
	adverse events.	medicinal product and if	medicinal product and if
		necessary, take appropriate	necessary, take appropriate
		measures.	measures.
		1a. The marketing authorisation	1a. The marketing authorisation
		holder shall comply with good	holder shall comply with good
		pharmacovigilance practices for	pharmacovigilance practices for
		veterinary medicinal products.	veterinary medicinal products.
		1b. The Commission shall, by	1b. The Commission shall, by
		means of implementing acts, adopt	means of implementing acts, adopt
		necessary measures on good	necessary measures on good
		pharmacovigilance practices for	pharmacovigilance practices for
		veterinary medicinal products and	veterinary medicinal products and
		also on the format and content of	also on the format and content of
		the pharmacovigilance system	the pharmacovigilance system



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		master file and its summary.	master file and its summary.
		Those implementing acts shall be	Those implementing acts shall be
		adopted in accordance with	adopted in accordance with
		examination procedure referred to in Article 145(2).	examination procedure referred to in Article 145(2).
	AM 193		
2. Where the pharmacovigilance	2. Where the pharmacovigilance	2. Where the pharmacovigilance	2. Where the pharmacovigilance
tasks have been contracted out by the	tasks have been contracted out by	tasks have been contracted out by the	tasks have been contracted out by the
marketing authorisation holder to a	the marketing authorisation holder	marketing authorisation holder to a	marketing authorisation holder to a
third party, those arrangements shall	to a third party (contractor), those	third party, those arrangements shall	third party, those arrangements shall
be set out in details in the	arrangements the responsibilities of	be set out in details in the	be set out in details in the
pharmacovigilance system master	<i>both parties</i> shall be set out in	pharmacovigilance system master	pharmacovigilance system master
file.	details explicitly in a contract and	file.	file.
	in the pharmacovigilance system master file.		
	AM 194		
	Article 77 paragraph 2 a (new)		
	2a. The marketing authorisation		
	holder shall be required to check		
	regularly that the contractor is		
	carrying out the work in		
	accordance with the requirements		
	of the contract.		
	AM 195		
3. The marketing authorisation	3. The marketing authorisation	3. The marketing authorisation	3. The marketing authorisation
holder shall permanently have at his	holder shall permanently have at	holder shall designate [] one or	holder shall designate [] one or
disposal one or more appropriately	his disposal one or more an	more [] qualified persons to carry	more [] qualified persons to carry
qualified persons responsible for	appropriately qualified persons	out the tasks provided for in	out the tasks provided for in
pharmacovigilance. Those persons	person responsible for	Article 78 []. The qualified	Article 78 []. The qualified



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shall reside and operate in the Union. Only one qualified person shall be designated by the marketing authorisation holder per pharmacovigilance system master file.	pharmacovigilance. Those persons That person shall reside and operate in the Union. Only one qualified person shall be designated by the marketing authorisation holder per pharmacovigilance system master file. The qualified person responsible for pharmacovigilance may delegate specific areas of work to appropriately trained staff but shall remain responsible for the marketing authorisation holder's pharmacovigilance system and for the safety profile of his veterinary medicinal products.	person(s) shall reside and operate in the Union. The qualified person(s) shall be appropriately qualified and be permanently at the disposal of the marketing authorisation holder. Only one such qualified person shall be designated [] for each pharmacovigilance system master file.	person(s) shall reside and operate in the Union. The qualified person(s) shall be appropriately qualified and be permanently at the disposal of the marketing authorisation holder. Only one such qualified person shall be designated [] for each pharmacovigilance system master file.
4. Where the tasks of the qualified person responsible for pharmacovigilance listed in Article 78 have been contracted out to a third party, those arrangements shall be detailed in the contract.	AM 196 4. Where the tasks of the qualified person responsible for pharmacovigilance listed in Article 78 have been contracted out to a third party, those the relevant arrangements shall be detailed in the set out explicitly in a contract.	4. [] The tasks of the qualified person responsible for pharmacovigilance listed in Article 78 may be [] contracted out to a third party on the conditions set out in paragraph (3). In such cases those arrangements shall be detailed in the contract and included in the pharmacovigilance system master file.	4. [] The tasks of the qualified person responsible for pharmacovigilance listed in Article 78 may be [] contracted out to a third party on the conditions set out in paragraph (3). In such cases those arrangements shall be detailed in the contract and included in the pharmacovigilance system master file.

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5. The marketing authorisation holder shall, based on pharmacovigilance data and where necessary, submit changes to the terms of a marketing authorisation in accordance with Article 61.		5. The marketing authorisation holder shall, based on the assessment of the pharmacovigilance data, and where necessary, [] submit without undue delay [] an application for a variation [] to the terms of a marketing authorisation in accordance with Article 61.	5. The marketing authorisation holder shall, based on the assessment of the pharmacovigilance data, and where necessary, [] submit without undue delay [] an application for a variation [] to the terms of a marketing authorisation in accordance with Article 61.
6. The marketing authorisation holder shall not communicate information regarding adverse events to the general public in relation to the veterinary medicinal product without giving prior notification of his intention to the competent authority or authorities having granted the marketing authorisation or to the Agency where the marketing authorisation was granted in accordance with the centralised authorisation procedure.	AM 197 6. The marketing authorisation holder shall not communicate information regarding adverse events <i>and potential</i> <i>pharmacovigilance concerns</i> to the general public in relation to the veterinary medicinal product without giving prior notification of his intention sending in advance a <i>copy of that communication</i> to the competent authority or authorities having granted the marketing authorisation or to the Agency where the marketing authorisation was granted in accordance with the centralised authorisation procedure.	6. The marketing authorisation holder shall not make a public announcement [] on pharmacovigilance information [] in relation to [] his [] veterinary medicinal products without giving prior or simultaneous notification of his intention to the competent authority having granted the marketing authorisation or to the Agency, as applicable [].	6. The marketing authorisation holder shall not make a public announcement [] on pharmacovigilance information [] in relation to [] his [] veterinary medicinal products without giving prior or simultaneous notification of his intention to the competent authority having granted the marketing authorisation or to the Agency, as applicable [].

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Where the marketing authorisation	Where the marketing authorisation	[] The marketing authorisation	[] The marketing authorisation
holder communicates such	holder communicates such	holder shall ensure that such public	holder shall ensure that such public
information to the general public, he	information to the general public,	announcement []-is presented	announcement [] is presented
shall ensure that it is presented	he shall ensure that it is presented	objectively and is not misleading.	objectively and is not misleading.
objectively and is not misleading.	objectively and is not misleading.		
	AM 198		
	Article 77 a (new)		
	Single master file		
	The organisation of the		
	pharmacovigilance operations		
	conducted by marketing		
	authorisation holders shall be		
	described in a single master file,		
	which shall be subject to		
	authorisation by the Member		
	States. The single evaluation		
	procedures for these		
	authorisations shall be defined		
	by the Member States and the		
	resulting decisions shall be		
	recognised throughout the		
	Union.		
	The competent authority shall		
	issue a decision on this		
	authorisation within 90 days of		
	the receipt of a complete		
	application.		
	The single master file shall be		
	addressed to the competent		
	authority of the Member State in		



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	which the qualified person designated by the authorisation holder conducts the operations described in this file. The competent authority concerned shall notify its decision to the authorisation holder and shall record it in the Union database on veterinary medicinal products together with a copy of the relevant single master file. The authorisation holder shall also submit to the competent authority any substantive changes to his single master file.		

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Article 78		Article 78	Article 78
Qualified person responsible for pharmacovigilance		Qualified person responsible for pharmacovigilance	Qualified person responsible for pharmacovigilance
Qualified persons responsible for pharmacovigilance as referred to in Article 77(3) shall carry out the following tasks:	AM 199 Qualified persons responsible for pharmacovigilance as referred to in Article 77(3) shall earry out ensure that the following tasks are carried out :	1. The qualified person responsible for pharmacovigilance as referred to in Article 77(3) shall [] ensure that the following tasks are carried out:	1. The qualified person responsible for pharmacovigilance as referred to in Article 77(3) shall [] ensure that the following tasks are carried out:
(a) elaborating and maintaining a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to the veterinary medicinal product for which the authorisation has been granted ('pharmacovigilance system master file') for all products under their responsibility;	AM 199 (a) elaborating and maintaining a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to the veterinary medicinal product for which the authorisation has been granted ('pharmacovigilance system master file') for all products under their responsibility;	(a) elaborating and maintaining the pharmacovigilance system master file [];	(a) elaborating and maintaining the pharmacovigilance system master file [];
(b) allocating reference numbers to the pharmacovigilance system master file and communicating the reference number of the pharmacovigilance master file of each product to the product database;	AM 199 (b) allocating reference numbers to the pharmacovigilance system master file and communicating the <i>relevant</i> reference number of the pharmacovigilance master file of each to the product database <i>for</i> <i>each product</i> ;	(b) allocating reference numbers to the pharmacovigilance system master file and communicating the reference number of the pharmacovigilance system master file [] to the [] pharmacovigilance database for each product;	(b) allocating reference numbers to the pharmacovigilance system master file and communicating the reference number of the pharmacovigilance system master file [] to the [] pharmacovigilance database for each product;
(c) notifying the competent authorities and the Agency of the		(c) notifying the competent authorities and [] the Agency, as	(c) notifying the competent authorities and [] the Agency, as

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place where the qualified person operates and where the pharmacovigilance system master file is accessible in the Union;		applicable, of the place where [] he/she operates [];	applicable, of the place where [] he/she operates [];
(d) establishing and maintaining a system which ensures that all adverse events which are brought to the attention of the marketing authorisation holder are collected and recorded in order to be accessible at least at one site in the Union;	AM 199 (d) establishing and maintaining a system which ensures that all adverse events, <i>including on non-</i> <i>target species and the</i> <i>environment</i> , which are brought to the attention of the marketing authorisation holder are collected and recorded in order to be accessible at least at one site in the Union;	(d) establishing and maintaining a system which ensures that all suspected adverse events which are brought to the attention of the marketing authorisation holder are collected and recorded in order to be accessible at least at one site in the Union;	(d) establishing and maintaining a system which ensures that all suspected adverse events which are brought to the attention of the marketing authorisation holder are collected and recorded in order to be accessible at least at one site in the Union;
(e) preparing the adverse event reports referred to in Article 76;		(e) compiling [] the suspected adverse event reports referred to in paragraph 2 of Article 76, evaluating them, where necessary ,	(e) compiling [] the suspected adverse event reports referred to in paragraph 2 of Article 76, evaluating them, where necessary ,
(f) ensuring that collected adverse event reports are recorded in the pharmacovigilance database;		(f) [] and record[]ing them in the pharmacovigilance database;	(f) [] and record[]ing them in the pharmacovigilance database;
(g) ensuring that any request from the competent authorities or the Agency for the provision of additional information necessary for the evaluation of the benefit-risk balance of a veterinary medicinal product is answered fully and promptly, including providing		(g) ensuring that any request from the competent authorities or the Agency for the provision of additional information necessary for the evaluation of the benefit-risk balance of a veterinary medicinal product is answered fully and promptly [];	(g) ensuring that any request from the competent authorities or the Agency for the provision of additional information necessary for the evaluation of the benefit-risk balance of a veterinary medicinal product is answered fully and promptly [];



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information about the volume of sales or prescriptions of the			
veterinary medicinal product			
concerned;			
(h) providing competent authorities or the Agency with any		(h) providing competent authorities or the Agency, as	(h) providing competent authorities or the Agency, as
other information relevant to		applicable, with any other	applicable, with any other
detecting a change to the benefit-risk		information relevant to detecting a	information relevant to detecting a
balance of a veterinary medicinal		change to the benefit-risk balance of	change to the benefit-risk balance of
product, including appropriate		a veterinary medicinal product,	a veterinary medicinal product,
information on post-marketing surveillance studies;		including appropriate information on post-marketing surveillance studies;	including appropriate information on post-marketing surveillance studies;
(i) evaluating by means of the		(i) [] applying the signal	(i) [] applying the signal
pharmacovigilance system all		management process referred to in	management process referred to in
information, considering options for		Article 81 and ensuring that any	Article 81 and ensuring that any
risk minimisation and prevention and		arrangements for the fulfilment of	arrangements for the fulfilment of
taking appropriate measures if		responsibilities referred to in	responsibilities referred to in
necessary;		paragraph 1 of Article 77 are in	paragraph 1 of Article 77 are in
(j) monitoring the		place; (j) monitoring the	place; (j) monitoring the
pharmacovigilance system and		pharmacovigilance system and	pharmacovigilance system and
ensuring that if needed, an		ensuring that if needed, an	ensuring that if needed, an
appropriate corrective action plan is		appropriate preventive or corrective	appropriate preventive or corrective
prepared and implemented;		action plan is prepared, []	action plan is prepared, []
		implemented and, where necessary,	implemented and, where necessary,
		ensuring changes to the	ensuring changes to the
		pharmacovigilance system master file;	pharmacovigilance system master file;
	AM 199		
(k) ensuring that all personnel	(k) ensuring that all personnel	(k) ensuring that all personnel of	(k) ensuring that all personnel of

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involved in the performance of pharmacovigilance activities receives continued training;	involved in the performance of pharmacovigilance activities receives continued training <i>tailored to their</i> <i>duties, on an ongoing basis;</i> <i>training courses are documented</i> <i>and their effectiveness reviewed;</i>	the marketing authorisation holder involved in the performance of pharmacovigilance activities receives continued training;	the marketing authorisation holder involved in the performance of pharmacovigilance activities receives continued training;
(1) communicating any regulatory measure that is taken in a third country and is based on pharmacovigilance data to the competent authorities and the Agency within 15 days of receipt of such information.	AM 199 (1) communicating any regulatory measure that is taken in another Member State or a third country and is based on pharmacovigilance data to the competent authorities and the Agency within 15 days of receipt of such information; AM 199 (la) conducting for each product an annual risk-benefit review taking into account all pharmacoviligilance surveillance data available on the product concerned, including pharmacoviligance signal monitoring. This review shall be documented by the marketing authorisation holer and the outcome recorded in the pharmacoviligance database. The marketing authorisation holder shall provide the documentation supporting the outcome of the	(1) communicating any regulatory measure that is taken in a third country and is related with pharmacovigilance data [] to the competent authorities and to the Agency within 30 [] days of receipt of such information.	(1) communicating any regulatory measure that is taken in a third country and is related with pharmacovigilance data [] to the competent authorities and to the Agency within <u>21</u> 30 [] days of receipt of such information.



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	review on request from the		
	national competent authority or		
	during the conduct of an		
	inspection carried out in		
	accordance with Article 128;		
	AM 199		
	(lb) the authorisation holder shall		
	be required to ensure that the		
	qualified person responsible for		
	pharmacoviligance is authorised		
	to maintain and further develop		
	the parmacoviligance system and		
	to ensure compliance with		
	requirements		
		2. The qualified person	2. The qualified person
		responsible for pharmacovigilance referred to in Article 77(3) shall be	responsible for pharmacovigilance referred to in Article 77(3) shall be
		the contact point for the marketing	the contact point for the marketing
		authorisation holder regarding	authorisation holder regarding
		pharmacovigilance inspections.	pharmacovigilance inspections.
Article 79		Article 79	Article 79
Pharmacovigilance responsibilities		Pharmacovigilance responsibilities	Pharmacovigilance responsibilities
of the competent authorities and the		of the competent authorities and the	of the competent authorities and the
Agency		Agency	Agency
	AM 200		
1. Competent authorities shall	1. Competent authorities shall	1. Competent authorities shall lay	1. Competent authorities shall lay
evaluate all adverse events reported	evaluate all adverse events reported	down the necessary procedures to	down the necessary procedures to
to them by healthcare professionals	to them by <i>marketing</i>	evaluate [] the results and	evaluate [] the results and
and animal holders, manage risks	authorisation holders, healthcare	outcomes of signal management	outcomes of signal management
and take the measures referred to in	professionals and animal holders,	process recorded in the	process recorded in the



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Articles 130 to 135 concerning marketing authorisations where necessary.	manage risks and take the measures referred to in Articles 130 to 135 concerning marketing authorisations where necessary.	pharmacovigilance database in accordance with paragraph 00 of Article 81 as well as suspected adverse events reported to them, [] consider options for risk management and take [] any appropriate measures referred to in Articles 130 [], 131 and 133 concerning marketing authorisations [].	pharmacovigilance database in accordance with paragraph 00 of Article 81 as well as suspected adverse events reported to them, [] consider options for risk management and take [] any appropriate measures referred to in Articles 130 [], 131 and 133 concerning marketing authorisations [].
2. Competent authorities shall take all appropriate measures to encourage the reporting of adverse events by healthcare professionals and animal holders.		2. []	2. []
3. Competent authorities may		3. Competent authorities may	3. Competent authorities may
impose specific requirements on		impose specific requirements on	impose specific requirements on
veterinarians and other healthcare		veterinarians and other healthcare	veterinarians and other healthcare
professionals in respect of the		professionals in respect of the	professionals in respect of the
reporting of adverse events. The		reporting of suspected adverse	reporting of suspected adverse
Agency and the competent		events. The Agency [] may	events. The Agency [] may
authorities may organise meetings or		organise meetings or a network for	organise meetings or a network for
a network for groups of veterinarians		groups of veterinarians or other	groups of veterinarians or other
or other healthcare professionals,		healthcare professionals, where there	healthcare professionals, where there
where there is a specific need for		is a specific need for collecting,	is a specific need for collecting,
collecting, collating or analysing		collating or analysing specific	collating or analysing specific
specific pharmacovigilance data.		pharmacovigilance data.	pharmacovigilance data.

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4. Competent authorities and the Agency shall provide the general public, veterinarians and other healthcare professionals with all important information on adverse events relating to the use of a veterinary medicinal product in a timely manner electronically or through other publicly available means of communication.	AM 201 4. Competent authorities and the Agency shall provide the general public make public veterinarians and other healthcare professionals with all important information on adverse events relating to the use of a veterinary medicinal product in a timely manner electronically or through other publicly available means of communication. Competent authorities and the Agency shall ensure that veterinarians receive feedback on adverse events reported and regular feedback on all adverse reactions reported.	4. Competent authorities and the Agency shall make publicly available [] all important information on adverse events relating to the use of a veterinary medicinal product. This shall be done in a timely manner [] by any publicly available means of communication with a prior or simultaneous notification to the marketing authorisation holder.	4. Competent authorities and the Agency shall make publicly available [] all important information on adverse events relating to the use of a veterinary medicinal product. This shall be done in a timely manner [] by any publicly available means of communication with a prior or simultaneous notification to the marketing authorisation holder.
5. Competent authorities shall verify by means of inspections referred to in Article 125 that marketing authorisation holders comply with the requirements relating to pharmacovigilance laid down in this Section.		5. Competent authorities shall verify by means of controls and inspections referred to in Articles 125 and 128 that marketing authorisation holders comply with the requirements relating to pharmacovigilance laid down in this Section.	5. Competent authorities shall verify by means of controls and inspections referred to in Articles 125 and 128 that marketing authorisation holders comply with the requirements relating to pharmacovigilance laid down in this Section.

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6. The Agency shall evaluate the		6. The Agency shall lay down	6. The Agency shall lay down
adverse events to the centrally		the necessary procedures to	the necessary procedures to
authorised veterinary medicinal		evaluate [] suspected adverse	evaluate [] suspected adverse
products, manage risks and		events reported to it regarding []	events reported to it regarding []
recommend measures to the		centrally authorised veterinary	centrally authorised veterinary
Commission. The Commission shall		medicinal products, [] and	medicinal products, [] and
take the measures referred to in		recommend risk management	recommend risk management
Articles 130 to 135 concerning		measures to the Commission. The	measures to the Commission. The
marketing authorisations where		Commission shall take [] any	Commission shall take [] any
necessary.		appropriate [] measures referred	appropriate [] measures referred
		to in Articles 130, 131 , and 133 []	to in Articles 130, 131, and 133 []
		concerning marketing authorisations	concerning marketing authorisations
		[].	[].
		7. The competent authority or	7. The competent authority or
		the Agency, as applicable, may at	the Agency, as applicable, may at
		any time request the marketing	any time request the marketing
		authorisation holder to submit a	authorisation holder to submit a
		copy of the pharmacovigilance	copy of the pharmacovigilance
		system master file. The marketing	system master file. The marketing
		authorisation holder shall submit	authorisation holder shall submit
		the copy at the latest seven days	the copy at the latest seven days
		after receipt of the request.	after receipt of the request.
Article 80		Article 80	Article 80
Delegation of tasks by competent		Delegation of tasks by competent	Delegation of tasks by competent
authority		authority	authority
	AM 203		
1. A competent authority may	1. A competent authority may	1. A competent authority may	1. A competent authority may
delegate any of the tasks entrusted to	delegate any of the tasks entrusted	delegate any of the tasks entrusted to	delegate any of the tasks entrusted to
it as referred to in Article 79 to a	to it as referred to in Article 79 to a	it as referred to in Article 79 to a	it as referred to in Article 79 to a
competent authority in another	competent <i>public</i> authority in	competent authority in another	competent authority in another



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Member State subject to the written agreement of the latter.	another Member State subject to the written agreement of the latter.	Member State subject to the written agreement of the latter.	Member State subject to the written agreement of the latter.
2. The delegating competent authority shall inform the		2. The delegating competent authority shall inform the	2. The delegating competent authority shall inform the
Commission, the Agency and other Member States of the delegation in		Commission, the Agency and other [] competent authorities and	Commission, the Agency and other [] competent authorities and
writing. The delegating competent authority and the Agency shall make that information public.		make that information public. []	make that information public. []
Article 81		Article 81	Article 81
Signal management process		Signal management process	Signal management process
		0. Marketing authorisation	0. Marketing authorisation
		holders shall carry out signal	holders shall carry out signal
		management process for their	management process for their
		veterinary medicinal products, if	veterinary medicinal products, if
		necessary taking into account sales	necessary taking into account sales
		data and other relevant	data and other relevant
		pharmacovigilance data of which	pharmacovigilance data of which
		they can reasonably be expected to	they can reasonably be expected to
		be aware of and which may be	be aware of and which may be
		useful for the signal management	useful for the signal management
		process. This data may include	process. This data may include
		scientific information gathered	scientific information gathered
		from scientific literature reviews.	from scientific literature reviews.

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		00. Where the outcome of signal	00. Where the outcome of signal
		management process identifies a	management process identifies a
		change to the benefit-risk balance	change to the benefit-risk balance
		or a new risk, marketing	or a new risk, marketing
		authorisation holders shall notify	authorisation holders shall notify it
		it without delay and no later than	without delay and no later than
		within 30 days to the competent	within 30 days to the competent
		authorities or to the Agency, as	authorities or to the Agency, as
		applicable, and take the necessary	applicable, and take the necessary
		action in accordance with	action in accordance with
		paragraph 5 of Article 77.	paragraph 5 of Article 77.
		All results and outcomes of signal	All results and outcomes of signal
		management process, including a	management process, including a
		conclusion on the benefit-risk	conclusion on the benefit-risk
		balance and the relevant data,	balance, and <u>, if applicable,</u>
		shall be recorded by the	references to relevant scientific
		marketing authorisation holder in	<u>literature</u> the relevant data , shall
		the pharmacovigilance database at	be recorded by the marketing
		least annually.	authorisation holder in the
			pharmacovigilance database at least annually.
		In the case of veterinary medicinal	In the case of veterinary medicinal
		products referred to in Article	products referred to in Article
		38(2)(c), the marketing	38(2)(c), the marketing
		authorisation holder shall record	authorisation holder shall record
		in the pharmacovigilance database	in the pharmacovigilance database
		all results and outcomes of signal	all results and outcomes of signal
		management process, including a	management process, including a
		conclusion on the benefit-risk	conclusion on the benefit-risk
		balance and the relevant data	balance, and, if applicable,



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		according to the frequency specified in the marketing authorisation.	references to relevant scientific <u>literature</u> the relevant data according to the frequency specified in the marketing authorisation.
1. Competent authorities and the Agency shall cooperate in monitoring the data in the pharmacovigilance database to determine whether there is any change to the benefit-risk balance of veterinary medicinal products with a view to detecting risks to animal health, public health and protection of the environment ('signal management process').	AM 204 1. Marketing authorisation holders, competent authorities, other concerned authorities and the Agency shall cooperate in monitoring the data in the pharmacovigilance database to determine whether there is any change to the benefit-risk balance of veterinary medicinal products with a view to detecting risks to animal health, public health and protection of the environment ('signal management process').	1. Competent authorities and the Agency [] may decide to perform targeted signal management process for a given veterinary medicinal product or a group of veterinary medicinal products.	1. Competent authorities and the Agency [] may decide to perform targeted signal management process for a given veterinary medicinal product or a group of veterinary medicinal products.
2. Competent authorities and the Agency shall establish groups of veterinary medicinal products for which signal management process can be combined with a view of detecting risks to animal health, public health and protection of the environment.		2. []	2. []

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3. The Agency and the coordination group shall agree on sharing of the monitoring of data on groups of veterinary medicinal products recorded in the pharmacovigilance database. For each group of veterinary medicinal products a competent authority or the Agency shall be appointed as responsible for the monitoring thereof ('lead authority').	AM 204 3. The Agency and the coordination veterinary pharmacovigilance group shall agree on sharing of the monitoring of data on groups of veterinary medicinal products recorded in the pharmacovigilance database. For each group of veterinary medicinal products a competent authority or the Agency shall be appointed as responsible for the monitoring	3. For the purpose of paragraph 1, the Agency and the coordination group shall [] share the tasks related to the targeted signal management process and shall jointly select for each veterinary medicinal product or group of veterinary medicinal products, a competent authority or the Agency [] as responsible for [] such targeted signal	3. For the purpose of paragraph 1, the Agency and the coordination group shall [] share the tasks related to the targeted signal management process and shall jointly select for each veterinary medicinal product or group of veterinary medicinal products, a competent authority or the Agency [] as responsible for [] such targeted signal
	thereof ('lead authority').	 management ('lead authority'). 3a. When selecting a competent authority or the Agency responsible for the targeted signal management process in accordance with paragraph 3, the Agency and the coordination group shall take into account the fair allocation of tasks and shall avoid duplication of work. 	 management ('lead authority'). 3a. When selecting a competent authority or the Agency responsible for the targeted signal management process in accordance with paragraph 3, the Agency and the coordination group shall take into account the fair allocation of tasks and shall avoid duplication of work.
4. The results of the signal management process shall be agreed upon by the competent authorities and, where appropriate, the Agency. The lead authority shall record the results in the pharmacovigilance database.	AM 204 4. Given that marketing authorisation holders are the primary source of expertise and information concerning the products under their responsibility, the lead authority may where necessary consult them during the	4 . []	4. []

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	<i>signal management process.</i> The results of the signal management process shall be agreed upon by the competent authorities and, where appropriate, the Agency. The lead authority shall record the results in the pharmacovigilance database.		
5. Where necessary, based on the results of the signal management process referred to in paragraph 4 the competent authorities or the Commission shall take appropriate measures as referred to in Articles 130 to 135.		5. Where [] the competent authorities or the Commission, as applicable, consider that follow-up action is necessary, they shall take appropriate measures as referred to in Articles 130, 131 and 133 [].	5. Where [] the competent authorities or the Commission, as applicable, consider that follow-up action is necessary, they shall take appropriate measures as referred to in Articles 130, 131 and 133 [].
Section 7 Re-examination of a marketing authorisation for a limited market and in exceptional circumstances		Section 7 Re-examination of a marketing authorisation for a limited market and in exceptional circumstances	Section 7 Re-examination of a marketing authorisation for a limited market and in exceptional circumstances
Article 82 Procedure for re-examination of a marketing authorisation for a limited market		Article 82 ⁵¹ []	Article 82 [])
1. Before the expiry of the period of validity of 3 years, marketing authorisations for a limited market granted in accordance with Article	AM 205 1. Before the expiry of the period of validity of <i>3 five</i> years, marketing authorisations for a limited market granted in	[]	[]

⁵¹ Moved to new Article 21a.

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21 shall be re-examined on application from the marketing authorisation holder. After the initial re-examination, it shall be re- examined every 5 years.	accordance with Article 21 shall be re-examined on application from the marketing authorisation holder. After the initial re-examination, it shall be re-examined, <i>if necessary</i> , every 5 <i>five</i> years.	× •	
2. The application for a re- examination shall be submitted to the competent authority that granted the authorisation or to the Agency at least 6 months before the expiry of the limited market marketing authorisation and shall demonstrate that the veterinary medicinal product remains for use in a limited market and that the marketing authorisation holder complies, if applicable, with the conditions referred to in Article 21(1).		[]	[]
3. When an application for re- examination has been submitted, the limited market marketing authorisation shall remain valid until a decision on the application has been adopted by the competent authority or the Commission.		[]	[]

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4. The competent authority or the		[]	[]
Agency shall assess the application			
for a re-examination in order to			
ascertain whether the benefit-risk			
balance is positive.			
5. The competent authority or the		[]	[]
Commission may at any time grant a			
marketing authorisation valid for an			
unlimited period of time in respect of			
a veterinary medicinal product			
authorised for a limited market,			
provided that the holder of the			
marketing authorisation for a limited			
market submits the missing			
comprehensive quality and efficacy			
data referred to in Article 21(1).			
Article 83	AM 206	Article 83 ⁵²	Article 83
Procedure for re-examination of a	deleted	[]	[]
marketing authorisation in		[]	[]
exceptional circumstances			
1. Before the expiry of the period	AM 206	[]	[]
of validity of 1 year, marketing	deleted		
authorisations granted in accordance			
with Article 22 shall be re-examined			
on application from the marketing			
authorisation holder.			
2. The application for re-	AM 206	[]	[]
examination shall be submitted to the	deleted		

⁵² Moved to new Article 22b

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competent authority that granted the			
authorisation or the Agency at least 3 months before the expiry of the			
marketing authorisation.			
3. When an application for re-	AM 206	[]	[]
examination has been submitted, the	deleted		[]
marketing authorisation shall remain			
valid until a decision on the			
application has been adopted by the			
competent authority or the			
Commission.			
4. The competent authority or the	AM 206	[]	[].
Commission may at any time grant a	deleted		
marketing authorisation valid for an unlimited period of time, provided			
that the marketing authorisation			
holder submits the missing			
comprehensive safety and efficacy			
data referred to in Article 22(1).			
Section 8		Section 8	Section 8
Union interest referral		Union interest referral	Union interest referral
Article 84		Article 84	Article 84
Scope of the Union interest referral		Scope of the Union interest referral	Scope of the Union interest referral
1. Where the interests of the		1. Where the interests of the	1. Where the interests of the
Union are involved, and in particular		Union are involved, and in particular	Union are involved, and in particular
the interests of public or animal health or of the environment related		the interests of public or animal health or of the environment related	the interests of public or animal health or of the environment related
to the quality, safety or efficacy of		to the quality, safety or efficacy of	to the quality, safety or efficacy of
veterinary medicinal products or the		veterinary medicinal products [],	veterinary medicinal products [],
free movement of products within		[] the marketing authorisation	[] the marketing authorisation
nee movement of products within		L J the marketing autionisation	[] the marketing authorisation

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the Union, any Member State or the		holder, [] one or more	holder, [] one or more
Commission may refer its concern to		competent authority in one or	competent authority in one or
the Agency for the application of the		more Member States or the	more Member States or the
procedure laid down in Article 85.		Commission may refer its concern to	Commission may refer its concern to
The matter of concern shall be		the Agency for the application of the	the Agency for the application of the
clearly identified.		procedure laid down in Article 85.	procedure laid down in Article 85.
		The matter of concern shall be	The matter of concern shall be
		clearly identified.	clearly identified.
		1a. The marketing authorisation	1a. The marketing authorisation
		holder, the concerned competent	holder, the concerned competent
		authority or the Commission shall	authority or the Commission shall
		inform the other concerned parties	inform the other concerned parties
		accordingly.	accordingly.
2. Upon request from the Agency,		2. Upon request from the	2. Upon request from the
Member States and marketing		Agency, competent authorities in	Agency, competent authorities in
authorisation holders shall forward to		the Member States and marketing	the Member States and marketing
the Agency all available information		authorisation holders shall forward to	authorisation holders shall forward to
relating to the Union interest referral.		the Agency all available information	the Agency all available information
		relating to the Union interest referral.	relating to the Union interest referral.
3. Where the referral provided for		3. [] The Agency may limit	3. [] The Agency may limit
in paragraph 1 concerns more than		the [] referral provided for in	the [] referral provided for in
one veterinary medicinal product or a		paragraph 1 to specific parts of the	paragraph 1 to specific parts of the
therapeutic class, the Agency may		terms of the marketing authorisation.	terms of the marketing authorisation.
limit the procedure to specific parts			
of the terms of the marketing			
authorisation.			

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Article 85		Article 85	Article 85
Referral procedure		Referral procedure	Referral procedure
1. The Agency shall publish		1. The Agency shall publish on	1. The Agency shall publish on
information about referrals made in		its website information [] that a	its website information [] that a
accordance with Article 84 on its		referral has been made in	referral has been made in
website. Interested parties shall be		accordance with Article 84 [], and	accordance with Article 84 [], and
invited to provide comments.		shall invite interested parties [] to	shall invite interested parties [] to
invited to provide comments.		provide comments.	provide comments.
2. The Committee shall consider		2. The Agency shall request the	2. The Agency shall request the
the referred matter and shall issue a		Committee referred to in Article	Committee referred to in Article
reasoned opinion within 90 days of		139 to [] consider the referred	139 to [] consider the referred
the date on which the matter was		matter. The Committee [] shall	matter. The Committee [] shall
referred to it. That period may be		issue a reasoned opinion within []	issue a reasoned opinion within []
extended by the Committee for a		120 days of [] the matter []	120 days of [] the matter []
further period of up to 60 days,		being referred to it. That period may	being referred to it. That period may
taking into account the views of the		be extended by the Committee for a	be extended by the Committee for a
marketing authorisation holders		further period of up to 60 days,	further period of up to 60 days,
concerned.		taking into account the views of the	taking into account the views of the
concerned.		marketing authorisation holders	marketing authorisation holders
		concerned.	concerned.
3. Before issuing its opinion, the		3. Before issuing its opinion, the	3. Before issuing its opinion, the
Committee shall provide the		Committee shall provide the	Committee shall provide the
marketing authorisation holder with		marketing authorisation holders	marketing authorisation holders
the opportunity to present		concerned with the opportunity to	concerned with the opportunity to
explanations within a specified time		present explanations within a	present explanations within a
limit. The Committee may suspend		specified time limit. The Committee	specified time limit. The Committee
the time limit referred to in		may suspend the time limit referred	may suspend the time limit referred
paragraph 2 to allow the marketing		to in paragraph 2 to allow the	to in paragraph 2 to allow the
authorisation holder to prepare the		marketing authorisation holders	marketing authorisation holders
explanations.		concerned to prepare the	concerned to prepare the
capitaliations.		concerned to prepare the	concerned to prepare the



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		explanations.	explanations.
4. In order to consider the matter,		4. In order to consider the matter,	4. In order to consider the matter,
the Committee shall appoint one of		the Committee shall appoint one of	the Committee shall appoint one of
its members to act as a rapporteur.		its members to act as a rapporteur.	its members to act as a rapporteur.
The Committee may appoint		The Committee may appoint	The Committee may appoint
independent experts to give advice		independent experts to give advice	independent experts to give advice
on specific questions. When		on specific questions. When	on specific questions. When
appointing such experts, the		appointing such experts, the	appointing such experts, the
Committee shall define their tasks		Committee shall define their tasks	Committee shall define their tasks
and specify the time limit for the		and specify the time limit for the	and specify the time limit for the
completion of these tasks.		completion of these tasks.	completion of these tasks.
5. If it considers it appropriate,		5 . []	5 . []
the Committee may invite any other			
person to provide information			
relating to the matter before it.			
6. Within 15 days after its		6. Within 15 days after its	6. Within 15 days after its
adoption, the Agency shall forward		adoption by the Committee, the	adoption by the Committee, the
the final opinion of the Committee to		Agency shall forward the []	Agency shall forward the []
Member States, the Commission and		opinion [] to Member States, the	opinion [] to Member States, the
the marketing authorisation holder,		Commission and the marketing	Commission and the marketing
together with an assessment report of		authorisation holders concerned,	authorisation holders concerned,
the veterinary medicinal product and		together with an assessment report of	together with an assessment report of
the reasons for its conclusions.		the veterinary medicinal product and	the veterinary medicinal product and
		the reasons for its conclusions.	the reasons for its conclusions.
		7. Within 15 days after receipt	7. Within 15 days after receipt
		of the opinion, the marketing	of the opinion, the marketing
		authorisation holder may notify	authorisation holder may notify
		the Agency in writing of his	the Agency in writing of his
		intention to request a re-	intention to request a re-
		examination of the opinion. In that	examination of the opinion. In that



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		case, he shall forward to the	case, he shall forward to the
		Agency the detailed reasons for the	Agency the detailed reasons for the
		request of examination within 60	request of examination within 60
		days after receipt of the opinion.	days after receipt of the opinion.
		8. Within 60 days following	8. Within 60 days following
		receipt of a request as referred to	receipt of a request as referred to
		in paragraph 7, the Committee	in paragraph 7, the Committee
		shall re-examine its opinion. The	shall re-examine its opinion. The
		reasons for the conclusion reached	reasons for the conclusion reached
		shall be annexed to the assessment	shall be annexed to the assessment
		report referred to in paragraph 6	report referred to in paragraph 6
		of this Article.	of this Article.
Article 86		Article 86	Article 86
Decision following the Union		Decision following the Union	Decision following the Union
interest referral		interest referral	interest referral
1. Within 15 days after receipt of		1. Within 15 days after receipt of	1. Within 15 days after receipt of
the opinion referred to in Article		the opinion referred to in Article	the opinion referred to in Article
85(6), the Commission shall prepare		85(6) and subject to the procedures	85(6) and subject to the procedures
a draft decision. If the draft decision		referred to in paragraphs 7 and 8	referred to in paragraphs 7 and 8
is not in accordance with the opinion		of Article 85, the Commission shall	of Article 85, the Commission shall
of the Agency, the Commission shall		prepare a draft decision. If the draft	prepare a draft decision. If the draft
also set out a detailed explanation of		decision is not in accordance with	decision is not in accordance with
the reasons for the differences in an		the opinion of the Agency, the	the opinion of the Agency, the
annex to the draft decision.		Commission shall also set out a	Commission shall also set out a
		detailed explanation of the reasons	detailed explanation of the reasons
		for the differences in an annex to the	for the differences in an annex to the
		draft decision.	draft decision.



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2. The draft decision shall be		2. The draft decision shall be	2. The draft decision shall be
forwarded to Member States.		forwarded to Member States.	forwarded to Member States.
Article 87		Article 87	Article 87
Commission decision following the		Commission decision following the	Commission decision following the
referral		referral ⁵³	referral
1. The Commission shall, by		[] 3 . The Commission shall,	[] 3 . The Commission shall,
means of implementing acts, take a		by means of implementing acts, take	by means of implementing acts, take
final decision on the Union interest		a [] decision on the Union interest	a [] decision on the Union interest
referral. Those implementing acts		referral. Those implementing acts	referral. Those implementing acts
shall be adopted in accordance with		shall be adopted in accordance with	shall be adopted in accordance with
the examination procedure referred		the examination procedure referred	the examination procedure referred
to in Article $145(2)$. Unless		to in Article 145(2). Unless	to in Article 145(2). Unless
otherwise stated in the referral		otherwise stated in the referral	otherwise stated in the referral
notification in accordance with		notification in accordance with	notification in accordance with
Article 84, the decision shall apply to		Article 84, the decision shall apply to	Article 84, the decision shall apply to
all veterinary medicinal products		[] the veterinary medicinal	[] the veterinary medicinal
subject to the marketing		products [] concerned by the	products [] concerned by the
authorisation that contain the active		referral.	referral.
substance concerned by the referral.			
2. Where the veterinary medicinal		[] 4 . Where the veterinary	[] 4 . Where the veterinary
product has been authorised in		medicinal products concerned by	medicinal products concerned by
accordance with the national, mutual		the referral have [] been	the referral have [] been
recognition or decentralised		authorised in accordance with the	authorised in accordance with the
procedures, the decision referred to		national, mutual recognition or	national, mutual recognition or
in paragraph 1 shall be addressed to		decentralised procedures, the	decentralised procedures, the
all Member States and		decision referred to in paragraph []	decision referred to in paragraph []
communicated to the marketing		3 shall be addressed to all Member	3 shall be addressed to all Member
authorisation holder for information.		States and communicated to the	States and communicated to the

⁵³ Articles 86 and 87 have been merged.



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		marketing authorisation holders concerned for information.	marketing authorisation holders concerned for information.
3. Member States shall take any necessary action with regard to the marketing authorisations for all		[] 5. Competent authorities and marketing authorisation holders concerned [] shall take	[] 5. Competent authorities and marketing authorisation holders concerned [] shall take
veterinary medicinal products concerned to comply with the decision within 30 days of its		any necessary action with regard to the marketing authorisations for [] the veterinary medicinal products	any necessary action with regard to the marketing authorisations for [] the veterinary medicinal products
notification, unless a different period is foreseen in the decision.		concerned to comply with the decision within 30 days of its notification, unless a different period	concerned to comply with the decision within 30 days of its notification, unless a different period
		is foreseen in the decision. Such action shall include, where appropriate, a request to the marketing authorisation holder to	is foreseen in the decision. Such action shall include, where appropriate, a request to the marketing authorisation holder to
		submit an application for a variation referred to in Article 61(1).	submit an application for a variation referred to in Article 61(1).
4. In case of centrally authorised veterinary medicinal products a decision as referred to in paragraph 1		[] 6 . In case of centrally authorised veterinary medicinal products concerned by the referral ,	[] 6 . In case of centrally authorised veterinary medicinal products concerned by the referral ,
shall be addressed to the marketing authorisation holder.		a decision as referred to in paragraph [] 3 shall be addressed to the	a decision as referred to in paragraph [] 3 shall be addressed to the
		marketing authorisation holder and communicated also to the Member States.	marketing authorisation holder and communicated also to the Member States.

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		7. Nationally authorised	7. Nationally authorised
		veterinary medicinal products	veterinary medicinal products
		which have been subject to a	which have been subject to a
		referral procedure shall	referral procedure shall
		henceforth be transferred to a	henceforth be transferred to a
		mutual recognition procedure.	mutual recognition procedure.
Chapter V		Chapter V	Chapter V
Homeopathic veterinary medicinal		Homeopathic veterinary medicinal	Homeopathic veterinary medicinal
products		products	products
Article 88		Article 88	Article 88
Homeopathic veterinary medicinal		Homeopathic veterinary medicinal	Homeopathic veterinary medicinal
products		products	products
	AM 207		
1. By way of derogation from	1. By way of derogation from	1. [] Homeopathic veterinary	1. [] Homeopathic veterinary
Article 5, homeopathic veterinary	Article 5, homeopathic veterinary	medicinal products that satisfy the	medicinal products that satisfy the
medicinal products that satisfy the	medicinal products that satisfy the	[] conditions set out in Article 89	[] conditions set out in Article 89
requirements set out in Article 89	requirements set out in Article 89	[] shall be registered in accordance	[] shall be registered in accordance
and are not immunological	and are not immunological	with Article 90.	with Article 90.
homeopathic veterinary medicinal	homeopathic veterinary medicinal		
products shall be registered in	products shall be registered in		
accordance with Article 90.	accordance with Article 90.		
	Veterinary medicinal products		
	registered or approved in		
	accordance with national rules		
	before 31 December 1993 shall not		
	be affected by this Article.		

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
		1a. Homeopathic veterinary medicinal products that do not meet the conditions set out in Article 89 shall be subject to Article 5.	1a. Homeopathic veterinary medicinal products that do not meet the conditions set out in Article 89 shall be subject to Article 5.
2. The competent authorities shall record homeopathic veterinary medicinal products registered by them in the database referred to in Article 51.		[]	[]
	AM 208 Article 88 paragraph 2 a (new) 2a. The veterinary homeopathic medicinal products not subject to Article 89(1) shall be authorised in accordance with the general regulations. Where the safety tests, preclinical and clinical trials of veterinary homeopathic medicinal products are not subject to Article 89(1), a Member State may introduce or retain on its territory specific rules in accordance with the principles and characteristics as practised in that Member State.		

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
Article 89		Article 89	Article 89
Registration of homeopathic		Registration of homeopathic	Registration of homeopathic
veterinary medicinal products		veterinary medicinal products	veterinary medicinal products
1. Homeopathic veterinary		1. A h omeopathic veterinary	1. A h omeopathic veterinary
medicinal products that satisfy all of		medicinal product that satisfies all of	medicinal product that satisfies all of
the following conditions shall be		the following conditions shall be	the following conditions shall be
subject to a registration procedure:		subject to a registration procedure:	subject to a registration procedure:
(a) the medicinal product is		(a) [] it is administered by a	(a) [] it is administered by a
administered by a route described in		route described in the European	route described in the European
the European Pharmacopoeia or, in		Pharmacopoeia or, in the absence	Pharmacopoeia or, in the absence
the absence thereof, by the		thereof, by the pharmacopoeias	thereof, by the pharmacopoeias
pharmacopoeias currently used		currently used officially in Member	currently used officially in Member
officially in Member States;		States;	States;
(b) there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product shall not contain more than one part per 10 000 of the mother tincture;	AM 209 (b) there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product shall not contain more than one part per 10 000 of the mother tincture, <i>unless</i> <i>the ingredients of the medicinal</i> <i>products are included in Table 1 of</i> <i>Regulation (EU) No 37/2010 with</i> <i>the comment ''No maximum</i> <i>residue level (MRL) required''</i> ;	(b) [] it has a sufficient degree of dilution to guarantee its the safety []; and [] shall not contain more than one part per 10 000 of the mother tincture;	(b) [] it has a sufficient degree of dilution to guarantee its the safety []; and [] shall not contain more than one part per 10 000 of the mother tincture;
(c) no specific therapeutic		(c) it has no [] therapeutic	(c) it has no [] therapeutic
indication appears on the labelling of		indication appearing on its the	indication appearing on its the
the medicinal product or in any		labelling [] or in any information	labelling [] or in any information
information relating thereto.		relating thereto.	relating thereto.
2. The Commission shall be		2. [] Member States may lay	2. [] Member States may lay

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
empowered to adopt delegated acts		down procedures for the	down procedures for the
in accordance with Article 146 in		registration of homeopathic	registration of homeopathic
order to adapt paragraph 1(b) and (c)		veterinary medicinal products in	veterinary medicinal products in
in the light of new scientific		addition to those laid down in this	addition to those laid down in this
evidence.		Chapter.	Chapter.
Article 90			
Requirements and procedure for		Article 90	Article 90
registration of homeopathic		Application [] and procedure for	Application [] and procedure for
veterinary medicinal products		registration of homeopathic	registration of homeopathic
		veterinary medicinal products	veterinary medicinal products
1. The following documents shall		1. The following documents shall	1. The following documents shall
be included in the application for a		be included in the application for a	be included in the application for a
registration of a homeopathic		registration of a homeopathic	registration of a homeopathic
veterinary medicinal product:		veterinary medicinal product:	veterinary medicinal product:
	AM 210		
(a) scientific name or other name	(a) scientific name or other name	(a) scientific name or other name	(a) scientific name or other name
given in a pharmacopoeia of the	given in a pharmacopoeia <i>or</i>	given in a pharmacopoeia of the	given in a pharmacopoeia of the
homeopathic stock or stocks,	documented in a monograph of the	homeopathic stock or stocks,	homeopathic stock or stocks,
together with a statement of the	homeopathic stock or stocks,	together with a statement of the []	together with a statement of the []
various routes of administration,	together with a statement of the	route of administration,	route of administration,
pharmaceutical forms and degree of	various routes of administration,	pharmaceutical form and degree of	pharmaceutical form and degree of
dilution to be registered;	pharmaceutical forms and degree of dilution to be registered;	dilution to be registered;	dilution to be registered;

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
(b) a dossier describing how the		(b) a dossier describing how the	(b) a dossier describing how the
homeopathic stock or stocks is/are		homeopathic stock or stocks is/are	homeopathic stock or stocks is/are
obtained and controlled, and		obtained and controlled, and	obtained and controlled, and
justifying its/their homeopathic		justifying its/their homeopathic []	justifying its/their homeopathic []
nature, on the basis of an adequate		use , on the basis of an adequate	use , on the basis of an adequate
bibliography; in the case of		bibliography; in the case of	bibliography; in the case of
homeopathic veterinary medicinal		homeopathic veterinary medicinal	homeopathic veterinary medicinal
products containing biological		products containing biological	products containing biological
substances, a description of the		substances, a description of the	substances, a description of the
measures taken to ensure the absence		measures taken to ensure the absence	measures taken to ensure the absence
of pathogens;		of pathogens;	of pathogens;
	AM 211 Article 91 paragraph 1 point b a (new) (ba) in addition to a manufacturing authorisation, the manufacturers in question shall be required to have proof and confirmation of compliance with good manufacturing practices ('GMP');		
(c) the manufacturing and control		(c) the manufacturing and control	(c) the manufacturing and control
file for each pharmaceutical form		file for each pharmaceutical form	file for each pharmaceutical form
and a description of the method of		and a description of the method of	and a description of the method of
dilution and potentisation;		dilution and potentisation;	dilution and potentisation;

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(d) the manufacturing authorisation for the veterinary medicinal products concerned;		(d) the manufacturing authorisation for the homeopathic veterinary medicinal products concerned;	(d) the manufacturing authorisation for the homeopathic veterinary medicinal products concerned;
(e) copies of any registrations or authorisations obtained for the same veterinary medicinal products in other Member States;		(e) copies of any registrations [] obtained for the same homeopathic veterinary medicinal products in other Member States;	(e) copies of any registrations [] obtained for the same homeopathic veterinary medicinal products in other Member States;
(f) the text to appear on the outer packaging and immediate packaging of the veterinary medicinal products to be registered;		(f) the text to appear on the package leaflet , outer packaging and immediate packaging of the homeopathic veterinary medicinal products to be registered;	(f) the text to appear on the package leaflet , outer packaging and immediate packaging of the homeopathic veterinary medicinal products to be registered;
(g) data concerning the stability of the medicinal product;		(g) data concerning the stability of the homeopathic veterinary medicinal product;	(g) data concerning the stability of the homeopathic veterinary medicinal product;
(h) in the case of veterinary medicinal products intended for food-producing species, proposed withdrawal period together with all requisite justification;		(h) in the case of homeopathic veterinary medicinal products intended for food-producing [] species, [] the active substances shall be those pharmacologically active substances allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof.	(h) in the case of homeopathic veterinary medicinal products intended for food-producing [] species, [] the active substances shall be those pharmacologically active substances allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof.
 (i) in the case of veterinary medicinal products intended for food-producing species and containing pharmacologically active substances that have not been 		(i) []	(i) []

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included in Regulation (EU) No 37/2010 for the animal species in question, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with			proposed by the residency
 Regulation (EC) No 470/2009. 2. An application for registration may cover a series of medicinal products derived from the same homeopathic stock or stocks. 		2. An application for registration may cover a series of homeopathic veterinary medicinal products of the same pharmaceutical form and derived from the same homeopathic stock or stocks.	2. An application for registration may cover a series of homeopathic veterinary medicinal products of the same pharmaceutical form and derived from the same homeopathic stock or stocks.
3. In a decision concerning registration the competent authority shall determine the conditions under which the homeopathic veterinary medicinal product may be made available to end users in accordance with Article 29.		3. [] The competent authority [] may determine the conditions under which the registered homeopathic veterinary medicinal products may be made available [].	3. [] The competent authority [] may determine the conditions under which the registered homeopathic veterinary medicinal products may be made available [].
4. The procedure of registering a homeopathic veterinary medicinal product shall be completed within 210 days after the submission of a valid application.		4. The procedure of [] registration of a homeopathic veterinary medicinal product shall be completed within 90 [] days after the submission of a valid application.	4. The procedure of [] registration of a homeopathic veterinary medicinal product shall be completed within 90 [] days after the submission of a valid application.

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558 final - 2014/0257 (COD)	E1 amenument	by Coreper on 20 December 2017	proposed by the Presidency
550 mai - 2014/0257 (COD)		5. A registration holder of	5. A registration holder of
		homeopathic veterinary medicinal	homeopathic veterinary medicinal
		products shall be subject to the	products shall be subject to the
		same obligations as a marketing	same obligations as a marketing
		authorisation holder in so far as	authorisation holder in so far as
		the provisions apply to registered	the provisions apply to registered
		homeopathic veterinary medicinal	homeopathic veterinary medicinal
		products in accordance with	products in accordance with
		Article 2c.	Article 2c.
		8	6. A registration for a
		homeopathic veterinary medicinal	homeopathic veterinary medicinal
		product shall only be granted to an	product shall only be granted to an
		applicant established in the Union.	applicant established in the Union.
		The requirement to be established	The requirement to be established
		in the Union shall also apply to	in the Union shall also apply to
		registration holders.	registration holders.
Chapter VI		Chapter VI	Chapter VI
Manufacturing, import and export		Manufacturing, import and export	Manufacturing, import and export
Article 91		Article 91	Article 91
Manufacturing authorisations		Manufacturing authorisations	Manufacturing authorisations
1. A manufacturing authorisation		1. A manufacturing authorisation	1. A manufacturing authorisation
shall be required in order to carry out		shall be required in order to carry out	shall be required in order to carry out
any of the following activities		any of the following activities []:	any of the following activities []:
('manufacturing'):			
(a) to produce or import veterinary		(a) to manufacture []	(a) to manufacture []
medicinal products; or		veterinary medicinal products []	veterinary medicinal products []
		even if intended only for export;	even if intended only for export;

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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(b) to engage in any part of the		(b) to engage in any part of the	(b) to engage in any part of the
process of producing a veterinary		process of manufacturing [] a	process of manufacturing [] a
medicinal product or of bringing a		veterinary medicinal product or of	veterinary medicinal product or of
veterinary medicinal product to its		bringing a veterinary medicinal	bringing a veterinary medicinal
final state, including engaging in the		product to its final state, including	product to its final state, including
processing, assembling, packaging,		engaging in the processing,	engaging in the processing,
labelling, storage, sterilising, testing		assembling, packaging and	assembling, packaging and
or releasing it or any constituent of it		repackaging, labelling and	repackaging, labelling and
for supply as part of that process.		relabelling, storing [], sterilising,	relabelling, storing [], sterilising,
		testing or releasing it [] or supply	testing or releasing it [] or supply
		as part of that process[]; or	as part of that process[]; or
		(c) to import veterinary	(c) to import veterinary
		medicinal products.	medicinal products.
2. Notwithstanding paragraph 1, a		2. Notwithstanding paragraph 1,	2. Notwithstanding paragraph 1,
manufacturing authorisation shall not		Member States may decide that a	Member States may decide that a
be required for preparation, dividing		manufacturing authorisation shall not	manufacturing authorisation shall not
up, changes in packaging or		be required for preparation, dividing	be required for preparation, dividing
presentation where these processes		up, changes in packaging or	up, changes in packaging or
are carried out solely for retail in		presentation of veterinary	presentation of veterinary
accordance with Articles 107 and		medicinal products, where these	medicinal products, where these
108.		processes are carried out solely for	processes are carried out solely for
		retail directly to the public in	retail directly to the public in
		accordance with Articles 107 and	accordance with Articles 107 and
		108.	108.
		2a. Where paragraph 2 is	2a. Where paragraph 2 is
		applied, the package leaflet shall	applied, the package leaflet shall
		be given with each divided part	be given with each divided part
		and the batch number and expiry	and the batch number and expiry
		date shall be clearly indicated.	date shall be clearly indicated.
	AM 212		



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
	Article 91 paragraph 2 subparagraph 1 a (new) A manufacturing authorisation shall also not be required for preparation, filling or changes in packaging or presentation where these processes are carried out solely for dispensing by pharmacists in a pharmacy or by veterinarians in a veterinary practice.		proposed by the rresidency
3. The competent authorities shall		3. The competent authorities shall	3. The competent authorities shall
record the manufacturing		record the manufacturing	record the manufacturing
authorisations granted by them in the		authorisations granted by them in the	authorisations granted by them in the
database on manufacturing, import		database on manufacturing [] and	database on manufacturing [] and
and wholesale distribution set up in		wholesale distribution set up in	wholesale distribution set up in
accordance with Article 94.		accordance with Article 94.	accordance with Article 94.
4. Manufacturing authorisations		4. Manufacturing authorisations	4. Manufacturing authorisations
shall be valid throughout the Union.		shall be valid throughout the Union.	shall be valid throughout the Union.
Article 92		Article 92	Article 92
Requirements for obtaining a		[] Application for manufacturing	[] Application for manufacturing
manufacturing authorisation		authorisation	authorisation
1. Applications for manufacturing		1. An application for a	1. An application for a
authorisations shall be submitted to a		manufacturing authorisation shall be	manufacturing authorisation shall be
competent authority in the Member		submitted to a competent authority in	submitted to a competent authority in
State where the manufacturing site is		the Member State where the	the Member State where the
located.		manufacturing site is located.	manufacturing site is located.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
2. An application for a manufacturing authorisation shall contain at least the following information:		2. An application for a manufacturing authorisation shall contain at least the following information:	2. An application for a manufacturing authorisation shall contain at least the following information:
(a) veterinary medicinal products which are to be manufactured or imported;		(a) veterinary medicinal products[] which are to be manufactured or imported;	(a) veterinary medicinal products[] which are to be manufactured or imported;
		(aa) name and address of the applicant;	(aa) name and address of the applicant;
(b) pharmaceutical forms which are to be manufactured or imported;		(b) pharmaceutical forms which are to be manufactured or imported;	(b) pharmaceutical forms which are to be manufactured or imported;
(c) details about the manufacturing site where the veterinary medicinal products are to be manufactured or tested;	AM 302 Article 92 paragraph 2 point c (c) details about the manufacturing site where the veterinary medicinal products are to be manufactured or tested, <i>including data about emissions,</i> <i>discharges and losses of the active</i> <i>substance and its precursors to the</i> <i>environment</i> ;	(c) details about the manufacturing site where the veterinary medicinal products [] are to be manufactured or imported [];	(c) details about the manufacturing site where the veterinary medicinal products [] are to be manufactured or imported [];
(d) statement to the effect that the applicant fulfils the requirements laid down in Article 98.		(d) a statement to the effect that the applicant fulfils the requirements laid down in Articles 98 and 100 .	(d) a statement to the effect that the applicant fulfils the requirements laid down in Articles 98 and 100.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Article 93		Article 93	Article 93
Granting of manufacturing		[] Procedure for g ranting of	[] Procedure for g ranting of
authorisations		manufacturing authorisations	manufacturing authorisations
1. Before granting a		1. Before granting a	1. Before granting a
manufacturing authorisation, the		manufacturing authorisation, the	manufacturing authorisation, the
competent authority shall carry out		competent authority shall carry out	competent authority shall carry out
an inspection in accordance with		an inspection [] of the	an inspection [] of the
Article 125 of the manufacturing site		manufacturing site [].	manufacturing site [].
where the veterinary medicinal			
products are to be manufactured or			
tested.			
2. An authorisation shall apply		2. [] A manufacturing	2. [] A manufacturing
only to the manufacturing site, the		authorisation shall apply only to the	authorisation shall apply only to the
veterinary medicinal products, and		manufacturing site [] and the	manufacturing site [] and the
the pharmaceutical forms specified		pharmaceutical forms specified in	pharmaceutical forms specified in
in the application.		the application referred to in	the application referred to in
		Article 92.	Article 92.
3. Member States shall lay down		3. Member States shall lay down	3. Member States shall lay down
procedures for granting		procedures for granting or refusing	procedures for granting or refusing
manufacturing authorisations. The		manufacturing authorisations. []	manufacturing authorisations. []
procedures for granting a		Such procedures shall not exceed	Such procedures shall not exceed
manufacturing authorisation shall not		90 days from receipt by the	90 days from receipt by the
exceed 90 days from the day on		competent authority of a	competent authority of a
which the competent authority		manufacturing authorisation	manufacturing authorisation
receives the application.		application.	application.
4. The competent authority may		4. The competent authority may	4. The competent authority may
require the applicant to submit		require the applicant to submit	require the applicant to submit
further information in addition to that		further information in addition to that	further information in addition to that
supplied in the application pursuant		supplied in the application pursuant	supplied in the application pursuant
to Article 92. Where the competent		to Article 92. Where the competent	to Article 92. Where the competent



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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authority exercises this right, the		authority exercises this right, the	authority exercises this right, the
time limit referred to in paragraph 3		time limit referred to in paragraph 3	time limit referred to in paragraph 3
of this Article shall be suspended		of this Article shall be suspended or	of this Article shall be suspended or
until the additional data required has		revoked until the additional data	revoked until the additional data
been submitted.		required has been submitted.	required has been submitted. ⁵⁴
	AM 213		
5. A manufacturing authorisation	Article 93 paragraph 5	5. A manufacturing authorisation	5. A manufacturing authorisation
may be granted conditionally, subject	5. A manufacturing	may be granted conditionally, subject	may be granted conditionally, subject
to a requirement for the applicant to	authorisation may be granted	to a requirement for the applicant to	to a requirement for the applicant to
undertake actions or introduce	conditionally where minor	undertake actions or introduce	undertake actions or introduce
specific procedures within a given	shortcomings are identified,	specific procedures within a given	specific procedures within a given
time period. The manufacturing	subject to a requirement for the	time period. The conditionally	time period. The conditionally
authorisation may be suspended if	applicant to undertake actions or	granted manufacturing authorisation	granted manufacturing authorisation
these requirements are not complied	introduce specific procedures	[] shall be suspended or revoked	[] shall be suspended or revoked
with.	<i>rectify the shortcomings</i> within a	if these requirements are not	if these requirements are not
	given time period. The	complied with.	complied with.
	manufacturing authorisation may	1	1
	be suspended if these requirements		
	are not complied with. <i>The</i>		
	manufacturing authorisation shall		
	be refused if manufacturing		
	causes unacceptable risks to the		
	environment.		

⁵⁴ Will be moved as paragraph 1a in the final text.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Article 94		Article 94	Article 94
Database on manufacturing		Database on manufacturing and	Database on manufacturing and
authorisations		wholesale distribution []	wholesale distribution []
1. A Union database on		1. A Union database on	1. A Union database on
manufacturing, import and wholesale		manufacturing, import and wholesale	manufacturing, import and wholesale
distribution shall be set up and		distribution shall be set up and	distribution shall be set up and
maintained by the Agency		maintained by the Agency	maintained by the Agency
('manufacturing and wholesale		('manufacturing and wholesale	('manufacturing and wholesale
distribution database').		distribution database').	distribution database').
2. The database shall include		2. The manufacturing and	2. The manufacturing and
information on any manufacturing		wholesale distribution database	wholesale distribution database
and wholesale distribution		shall include information regarding	shall include information regarding
authorisations granted by competent		the granting, suspension or	the granting, suspension or
authorities within the Union.		revocation by competent	revocation by competent
		authorities of [] any	authorities of [] any
		manufacturing authorisations, []	manufacturing authorisations, []
		wholesale distribution authorisations,	wholesale distribution authorisations,
		certificates of good manufacturing	certificates of good manufacturing
		practice, and registrations of	practice, and registrations of
		manufacturers, importers and	manufacturers, importers and
		distributors of active substances	distributors of active substances
		[].	[].
3. The Agency shall make public		[]	[]
a format for electronic submissions			
of data to the database.			

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
4. Competent authorities shall		4. Competent authorities shall	4. Competent authorities shall
record in the manufacturing and		record in the manufacturing and	record in the manufacturing and
wholesale distribution database		wholesale distribution database	wholesale distribution database
information on authorisations and		information on manufacturing and	information on manufacturing and
certificates granted in accordance		wholesale distribution	wholesale distribution
with Articles 93, 103 and 105		authorisations and certificates	authorisations and certificates
together with information on the		granted in accordance with Articles	granted in accordance with Articles
veterinary medicinal products		93, 98a and [] 105 [] together	93, 98a and [] 105 [] together
covered by the authorisations, using		with information on[] importers ,	with information on[] importers ,
the format referred to in paragraph 3.		manufacturers and distributors of	manufacturers and distributors of
		active substances registered in	active substances registered in
		accordance with Article 98b.	accordance with Article 98b.
5. The Agency shall, in		5. The Agency shall, in	5. The Agency shall, in
collaboration with Member States		collaboration with Member States	collaboration with Member States
and the Commission, draw up		and the Commission, draw up	and the Commission, draw up
functional specifications for the		functional specifications, including	functional specifications, including
manufacturing and wholesale		the format for electronic	the format for electronic
distribution database.		submissions of data, for the	submissions of data, for the
		manufacturing and wholesale	manufacturing and wholesale
		distribution database.	distribution database.
6. The Agency shall ensure that		6. The Agency shall ensure that	6. The Agency shall ensure that
information reported to the database		information reported to the	information reported to the
is collated and made accessible and		manufacturing and wholesale	manufacturing and wholesale
that the information is shared.		distribution database is collated and	distribution database is collated and
		made accessible and that the	made accessible and that the
		information is shared.	information is shared.
Article 95		Article 9555	Article 95
Access to the database on			

⁵⁵ Articles 94 and 95 have been merged.



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manufacturing authorisations			
1. The competent authorities shall		1.7 The competent authorities shall	1.7 The competent authorities shall
have full access to the database set		have full access to the	have full access to the
up in accordance with Article 94.		manufacturing and wholesale	manufacturing and wholesale
		distribution database [].	distribution database [].
2. Manufacturers and wholesalers		[]	[]
shall have access to the database to			
the extent necessary for them to			
comply with their obligations.			
3. The general public shall have		3.8. The general public shall have	8. The general public shall have
access to information in the database		read only access to information in	read only access to information in
specifying the companies that have		the manufacturing and wholesale	the manufacturing and wholesale
been granted manufacturing or		distribution database. []	distribution database, without
wholesale distribution authorisations			changing the information therein.
and the manufacturing sites and			[]
products concerned by these			
authorisations.			
Article 96		Article 96	Article 96
Changes to manufacturing		Changes to manufacturing	Changes to manufacturing
authorisations on request		authorisations on request	authorisations on request
1. If the holder of a		1. If the holder of a	1. If the holder of a
manufacturing authorisation requests		manufacturing authorisation requests	manufacturing authorisation requests
a change in that manufacturing		a change in that manufacturing	a change in that manufacturing
authorisation, the procedure for		authorisation, the procedure for	authorisation, the procedure for
examining such a request shall not		examining such a request shall not	examining such a request shall not
exceed 30 days from the day on		exceed 30 days from the day on	exceed 30 days from the day on
which the competent authority		which the competent authority	which the competent authority
receives the request. In exceptional		receives the request. In [] justified	receives the request. In [] justified
cases, this period of time may be		cases, including when an inspection	cases, including when an inspection
extended by the competent authority		is necessary, this period of time may	is necessary, this period of time may

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to 90 days.		be extended by the competent	be extended by the competent
		authority to 90 days.	authority to 90 days.
2. The application shall contain		2. The application shall contain a	2. The application shall contain a
description of the requested change		description of the requested change	description of the requested change
and the authorised products affected		[].	[].
by this change.			
3. Within the period referred to in		3. Within the period referred to in	3. Within the period referred to in
paragraph 1, the competent authority		paragraph 1, the competent authority	paragraph 1, the competent authority
may request the holder to provide		may request the holder to provide	may request the holder to provide
supplementary information within a		supplementary information within a	supplementary information within a
set time limit. The procedure shall be		set time limit and may decide to	set time limit and may decide to
suspended until such time as the		perform an inspection. The	perform an inspection. The
supplementary information has been		procedure shall be suspended until	procedure shall be suspended until
provided.		such time as the supplementary	such time as the supplementary
		information has been provided.	information has been provided.
4. The competent authority shall		4. The competent authority shall	4. The competent authority shall
inform the holder of the outcome of		assess the application, inform the	assess the application, inform the
the assessment and where		holder of the outcome of the	holder of the outcome of the
appropriate, amend the		assessment and where appropriate,	assessment and where appropriate,
manufacturing authorisation, and		amend the manufacturing	amend the manufacturing
update, where appropriate, the		authorisation, and update, where	authorisation, and update, where
manufacturing and wholesale		appropriate, the manufacturing and	appropriate, the manufacturing and
distribution database.		wholesale distribution database.	wholesale distribution database.

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Article 97		Article 97 ⁵⁶	Article 97
Manufacturing authorisation for import and export			
1. The manufacturing authorisation shall also be required for imports from and exports to third countries.		[]	[]
2. The requirement referred to in paragraph 1 shall not apply to holders of a wholesale distribution authorisation referred to in Article 104.		[]	[]
Article 98 Obligations of the manufacturing authorisation holders		Article 98 Obligations of the manufacturing authorisation holders	Article 98 Obligations of the manufacturing authorisation holders
The holder of a manufacturing authorisation shall:		1. The holder of a manufacturing authorisation shall:	1. The holder of a manufacturing authorisation shall:
 (a) have at his disposal suitable and sufficient premises, technical equipment and testing facilities for the manufacture, export or import of the veterinary medicinal products stated in the manufacturing authorisation; 		(a) have at his disposal suitable and sufficient premises, technical equipment and testing facilities, for the activities [] stated in [] his manufacturing authorisation;	(a) have at his disposal suitable and sufficient premises, technical equipment and testing facilities, for the activities [] stated in [] his manufacturing authorisation;

⁵⁶ Paragraph 1 of Article 97 has been moved to paragraph 1 of Article 91, amended point (a) and new point (c)

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(b) have at his disposal the services of at least one qualified person within the meaning of Article 100;		 (b) have at his disposal the services of at least one qualified person within the meaning of Article 100 and ensure that the qualified person operates in compliance with that Article; 	 (b) have at his disposal the services of at least one qualified person within the meaning of Article 100 and ensure that the qualified person operates in compliance with that Article;
(c) enable the qualified person referred to in Article 100 to carry out his duties, particularly by placing at his disposal all the necessary technical equipment and testing facilities;	AM 214 Article 98 paragraph 1 point c a (new) (ca) comply with the rules on good manufacturing practice for medicinal products established in the Union and use as starting materials only active substances which have been manufactured in accordance with the rules on good manufacturing practice for starting materials established in	(c) enable the qualified person referred to in Article 100 to carry out his duties, particularly by providing access to all the necessary documents and premises, and by placing at his disposal all the necessary technical equipment and testing facilities;	(c) enable the qualified person referred to in Article 100 to carry out his duties, particularly by providing access to all the necessary documents and premises, and by placing at his disposal all the necessary technical equipment and testing facilities;

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(d) inform the competent authority		(d) [] give at least a 30 days	(d) [] give at least a 30 days
if the qualified person referred to in		prior notice to the competent	prior notice to the competent
Article 100 is replaced;		authority before the replacement	authority before the replacement
		of the qualified person referred to	of the qualified person referred to
		in Article 100, or, if prior notice is	in Article 100, or, if prior notice is
		not possible because the	not possible because the
		replacement is unexpected, inform	replacement is unexpected, inform
		the competent authority	the competent authority
		immediately;	immediately;
(e) have at his disposal the		(e) have at his disposal the	(e) have at his disposal the
services of staff complying with the		services of staff complying with the	services of staff complying with the
legal requirements existing in the		legal requirements existing in the	legal requirements existing in the
Member State concerned as regards		Member State concerned as regards	Member State concerned as regards
both manufacture and controls;		both manufacture and controls;	both manufacture and controls;
(f) allow the representatives of the		(f) allow the representatives of the	(f) allow the representatives of the
competent authority access to his		competent authority access to his	competent authority access to his
premises at any time;		premises at any time;	premises at any time;
(g) keep detailed records of all		(g) keep detailed records of all	(g) keep detailed records of all
veterinary medicinal products		veterinary medicinal products	veterinary medicinal products
supplied by him, including samples,		supplied by him,[] in accordance	supplied by him,[] in accordance
in accordance with Article 99.		with Article 99, and samples of	with Article 99, and samples of
		each batch;	each batch;
		(h) only supply veterinary	(h) only supply veterinary
		medicinal products to wholesale	medicinal products to wholesale
		distributors of veterinary	distributors of veterinary
		medicinal products;	medicinal products;

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		(i) inform the competent	(i) inform the competent
		authority and the marketing	authority and the marketing
		authorisation holder immediately	authorisation holder immediately
		if he obtains information that	if he obtains information that
		veterinary medicinal products	veterinary medicinal products
		which come under the scope of his	which come under the scope of his
		manufacturing authorisation are,	manufacturing authorisation are,
		or are suspected of being, falsified	or are suspected of being, falsified
		irrespective of whether those	irrespective of whether those
		veterinary medicinal products	veterinary medicinal products
		were distributed within the legal	were distributed within the legal
		supply chain or by illegal means,	supply chain or by illegal means,
		including illegal sale by means of	including illegal sale by means of
		information society services;	information society services;
		(j) comply with good	(j) comply with good
		manufacturing practices for	manufacturing practices for
		veterinary medicinal products and	veterinary medicinal products and
		use as starting materials only	use as starting materials only
		active substances which have been	active substances which have been
		manufactured in accordance with	manufactured in accordance with
		good manufacturing practices and	good manufacturing practices and
		distributed in accordance with	distributed in accordance with
		good distribution practices for	good distribution practices for
		active substances;	active substances;
		(k) verify that each	(k) verify that each
		manufacturer, distributor or	manufacturer, distributor or
		importer within the Union from	importer within the Union from
		whom he obtains active substances	whom he obtains active substances
		is registered with the competent	is registered with the competent
		authority of the Member State in	authority of the Member State in



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		which he is established, in	which he is established, in
		accordance with Article 98b;-	accordance with Article 98b; .
		(l) perform audits based on a	(l) perform audits based on a
		risk assessment on the	risk assessment on the
		manufacturer, distributor and	manufacturer, distributor and
		importers from whom he obtains	importers from whom he obtains
		active substances.	active substances.
		2. The Commission shall, by means of implementing acts, adopt measures on good manufacturing practices for veterinary medicinal products and active substances used as starting materials, referred to paragraph 1(j).Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	2. The Commission shall, by means of implementing acts, adopt measures on good manufacturing practices for veterinary medicinal products and active substances used as starting materials, referred to paragraph 1(j).Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).
		<i>Article 98a</i> 57	Article 98a
		Certificates of good manufacturing	Certificates of good manufacturing
		practice	practice
		1. Within 90 days after an	1. Within 90 days after an
		inspection [], the competent	inspection [], the competent
		authority shall issue a certificate of	authority shall issue a certificate of
		good manufacturing practice of the	good manufacturing practice of the
		manufacturer for the	manufacturer for the
		manufacturing site concerned if	manufacturing site concerned if

⁵⁷ ex Article 127amended



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		the inspection establishes [] that	the inspection establishes [] that
		the manufacturer in question is []	the manufacturer in question is []
		in compliance with the requirements	in compliance with the requirements
		as set out in this Regulation and []	as set out in this Regulation and []
		with the implementing act adopted	with the implementing act adopted
		in accordance with Article 98(2).	in accordance with Article 98(2).
		2a. If the outcome of the	2a. If the outcome of the
		inspection as referred to in	inspection as referred to in
		paragraph 1 is that the	paragraph 1 is that the
		manufacturer does not comply	manufacturer does not comply
		with good manufacturing practice,	with good manufacturing practice,
		the information shall be entered	the information shall be entered
		into the database for	into the database for
		manufacturing and wholesale	manufacturing and wholesale
		distribution referred to in Article	distribution referred to in Article
		94.	94.
		3. The conclusions reached	3. The conclusions reached
		following an inspection of a	following an inspection of a
		manufacturer shall be valid	manufacturer shall be valid
		throughout the Union.	throughout the Union.
		<u>4. []</u>	4 . []
		5. Without prejudice to any	5. Without prejudice to any
		arrangements which may have been	arrangements which may have been
		concluded between the Union and a	concluded between the Union and a
		third country, a competent authority,	third country, a competent authority,
		the Commission or the Agency may	the Commission or the Agency may
		require a manufacturer established in	require a manufacturer established in
		a third country to undergo an	a third country to undergo an
		inspection as referred to in paragraph	inspection as referred to in paragraph
	L	1.	1.



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		6. Importers of veterinary	6. Importers of veterinary
		medicinal products, before those	medicinal products, before those
		products are supplied to the	products are supplied to the
		Union, shall ensure that the	Union, shall ensure that the
		manufacturer established in a	manufacturer established in a
		third country is in possession of a	third country is in possession of a
		certificate of good manufacturing	certificate of good manufacturing
		practice issued by a competent	practice issued by a competent
		authority or there is an equivalent	authority or there is an equivalent
		confirmation in case the third	confirmation in case the third
		country is party of an arrangement	country is party of an arrangement
		concluded between the Union and	concluded between the Union and
		the third country.	the third country.
		Article 98b	Article 98b
		Importers, manufacturers and	Importers, manufacturers and
		distributors of active substances	distributors of active substances
		established in the Union	established in the Union
		1. Importers, manufacturers	1. Importers, manufacturers
		and distributors of active	and distributors of active
		substances, used as starting	substances, used as starting
		materials in veterinary medicinal	materials in veterinary medicinal
		products, who are established in	products, who are established in
		the Union, shall register their	the Union, shall register their
		activity with the competent	activity with the competent
		authority of the Member State in	authority of the Member State in
		which they are established and	which they are established and
		shall comply with good	shall comply with good
		manufacturing practice or good	manufacturing practice or good
		distribution practice, as applicable.	distribution practice, as applicable.
		2. The registration form shall	2. The registration form shall

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		include, at least, the following	include, at least, the following
		information:	information:
		(i) name or corporate name and	(i) name or corporate name and
		permanent address;	permanent address;
		(ii) the active substances which	(ii) the active substances which
		are to be imported,	are to be imported,
		manufactured or distributed;	manufactured or distributed;
		(iii) particulars regarding the	(iii) particulars regarding the
		premises and the technical	premises and the technical
		equipment.	equipment.
		3. The persons referred to in	3. The persons referred to in
		paragraph 1 shall submit the	paragraph 1 shall submit the
		registration form to the competent	registration form to the competent
		authority at least 60 days prior to	authority at least 60 days prior to
		the intended start of their activity	the intended start of their activity
		or in the case of importers,	or in the case of importers,
		manufacturers and distributors of	manufacturers and distributors of
		active substances in operation	active substances in operation
		before the date of application of	before the date of application of
		this Regulation, 60 days after the	this Regulation, 60 days after the
		date of application.	date of application.
		4. The competent authority	4. The competent authority
		may, based on a risk assessment,	may, based on a risk assessment,
		decide to carry out an inspection.	decide to carry out an inspection.
		If the competent authority notifies	If the competent authority notifies
		within 60 days of the receipt of the	within 60 days of the receipt of the
		registration form that an	registration form that an
		inspection will be carried out, the	inspection will be carried out, the
		activity shall not begin before the	activity shall not begin before the
	l	competent authority has notified	competent authority has notified



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		that the activity may start. If	that the activity may start. If
		within 60 days of the receipt of the	within 60 days of the receipt of the
		registration form the competent	registration form the competent
		authority has not notified that an	authority has not notified that an
		inspection will be carried out, the	inspection will be carried out, the
		activity may start. In such a case,	activity may start. In such a case,
		the competent authority shall	the competent authority shall
		carry out the inspection and	carry out the inspection and
		communicate to the person(s)	communicate to the person(s)
		referred to in paragraph 1the	referred to in paragraph 1the
		results of the inspection within 60	results of the inspection within 60
		days of the notification of its	days of the notification of its
		intention to carry out the	intention to carry out the
		inspection.	inspection.
		5. The persons referred to in	5. The persons referred to in
		paragraph 1 shall communicate annually to the competent	paragraph 1 shall communicate annually to the competent
		authority an inventory of the	authority an inventory of the
		changes which have taken place as	changes which have taken place as
		regards the information provided	regards the information provided
		in the registration form. Any	in the registration form. Any
		changes that may have an impact	changes that may have an impact
		on the quality or safety of the	on the quality or safety of the
		active substances that are	active substances that are
		manufactured, imported or	manufactured, imported or
		distributed must be notified	distributed must be notified
		immediately.	immediately.

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		7. Competent authorities shall	7. Competent authorities shall
		enter the information provided in	enter the information provided in
		accordance with paragraph 2 of	accordance with paragraph 2 of
		this Article and Article 131(b) in	this Article and Article 131(b) in
		the manufacturing and wholesale	the manufacturing and wholesale
		distribution database referred to	distribution database referred to
		in Article 94.	in Article 94.
		8. This Article shall be without	8. This Article shall be without
		prejudice to Article 98a.	prejudice to Article 98a.
		9. The Commission shall, by	9. The Commission shall, by
		means of implementing acts, adopt	means of implementing acts, adopt
		measures on good distribution	measures on good distribution
		practices for active substances	practices for active substances
		used as starting materials in	used as starting materials in
		veterinary medicinal products.	veterinary medicinal products.
		Those implementing acts shall be	Those implementing acts shall be
		adopted in accordance with the	adopted in accordance with the
		examination procedure referred to	examination procedure referred to
		in Article 145(2).	in Article 145(2).
Article 99		Article 99	Article 99
Record keeping		Record keeping	Record keeping
1. The following information		1. The holder of a	1. The holder of a
shall be recorded in respect of all		manufacturing authorisation shall	manufacturing authorisation shall
veterinary medicinal products		record the following information	record the following information
supplied by the holder of a		[]-in respect of all veterinary	[]-in respect of all veterinary
manufacturing authorisation:		medicinal products supplied by him	medicinal products supplied by him
		[]:	[]:

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(a) date of the transaction,		(a) date of the transaction,	(a) date of the transaction,
(b) name of the veterinary		(b) name of the veterinary	(b) name of the veterinary
medicinal product,		medicinal product, and marketing	medicinal product, and marketing
		authorisation number if	authorisation number if
		applicable, as well as	applicable, as well as
		pharmaceutical form and strength,	pharmaceutical form and strength,
		as appropriate,	as appropriate,
(c) quantity supplied,		(c) quantity supplied,	(c) quantity supplied,
(d) name and address of the		(d) name and address of the	(d) name and address of the
recipient,		recipient,	recipient,
(e) batch number.		(e) batch number,	(e) batch number,
		(f) date of expiry.	(f) date of expiry.
2. The records mentioned in		2. The records mentioned in	2. The records mentioned in
paragraph 1 shall be available for		paragraph 1 shall be available for	paragraph 1 shall be available for
inspection by competent authorities		inspection by competent authorities	inspection by competent authorities
for a period of 3 years.		for [] one year after the date of	for [] one year after the date of
		expiry of the batch or at least five	expiry of the batch or at least five
		years, whichever is the longer.	years, whichever is the longer.
Article 100		Article 100	Article 100
Qualified person for manufacturing		Qualified person responsible for	Qualified person responsible for
		manufacturing and batch release	manufacturing and batch release
1. The holder of a manufacturing		1. The holder of a manufacturing	1. The holder of a manufacturing
authorisation shall have permanently		authorisation shall have permanently	authorisation shall have permanently
and continuously at his disposal the		[] at his disposal the services of at	[] at his disposal the services of at
services of at least one qualified		least one qualified person who fulfils	least one qualified person who fulfils
person who fulfils the conditions laid		the conditions laid down in this	the conditions laid down in this
down in this Article and is		Article and is responsible, in	Article and is responsible, in
responsible, in particular, for		particular, for carrying out the duties	particular, for carrying out the duties
carrying out the duties specified in		specified in this Article [].	specified in this Article [].
Article 101.			



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2. The qualified person shall be in possession of a diploma, certificate or other evidence of appropriate qualification and shall have acquired sufficient experience in the field of manufacturing. The holder of the authorisation may himself assume the responsibility referred to in paragraph 1, if he personally fulfils those conditions as specified above.		2. The qualified person shall [] hold a university degree in one or more of the following scientific disciplines: pharmacy, human medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, or biology. []	2. The qualified person shall [] hold a university degree in one or more of the following scientific disciplines: pharmacy, human medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, or biology. []
		3. The qualified person shall have acquired [] practical experience over at least two years, in one or more undertakings which are authorised manufacturers, in the activities of quality assurance of medicinal products, of qualitative analysis of medicinal products, of quantitative analysis of active substances and the checking necessary to ensure the quality of veterinary medicinal products.	3. The qualified person shall have acquired [] practical experience over at least two years, in one or more undertakings which are authorised manufacturers, in the activities of quality assurance of medicinal products, of qualitative analysis of medicinal products, of quantitative analysis of active substances and the checking necessary to ensure the quality of veterinary medicinal products.
		The duration of practical experience may be reduced by one year where a university course lasts for at least five years and by a year and a half where the course lasts for at least six years.	The duration of practical experience may be reduced by one year where a university course lasts for at least five years and by a year and a half where the course lasts for at least six years.

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		 4. [] The holder of the manufacturing authorisation, if a natural person, may himself assume the responsibility referred to in paragraph 1, if he personally fulfils [] the conditions [] specified in [] paragraphs 2 and 3 []. 5. The competent authority 	4. [] The holder of the manufacturing authorisation, if a natural person, may himself assume the responsibility referred to in paragraph 1, if he personally fulfils [] the conditions [] specified in [] paragraphs 2 and 3 [].
		may lay down appropriate administrative procedures to verify that a qualified person fulfils the conditions referred to in paragraphs 2 and 3.	5. The competent authority may lay down appropriate administrative procedures to verify that a qualified person fulfils the conditions referred to in paragraphs 2 and 3.
Article 101 Batch release of veterinary medicinal products		Article 101 ⁵⁸	Article 101
1. Where veterinary medicinal products have been manufactured by the holder of a manufacturing authorisation, the qualified person for manufacturing shall ensure that each batch of the veterinary medicinal products has been manufactured and tested in compliance with the terms of the marketing authorisation. The qualified person for manufacturing		[] 6. [] The qualified person responsible for manufacturing shall ensure that each batch of the veterinary medicinal products [] is manufactured in compliance with good manufacturing practice, and tested in compliance with the terms of the marketing authorisation. The qualified person for manufacturing shall draw up a control report to this effect. Such	[] 6. [] The qualified person responsible for manufacturing shall ensure that each batch of the veterinary medicinal products [] is manufactured in compliance with good manufacturing practice, and tested in compliance with the terms of the marketing authorisation. The qualified person for manufacturing shall draw up a control report to this effect. Such

⁵⁸ Articles 100 and 101 have been merged.

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shall prepare a report to this effect.		control report shall be valid throughout the Union. [].	control report shall be valid throughout the Union. [].
2. Where veterinary medicinal products have been imported from third countries, the qualified person for manufacturing shall ensure that each imported production batch has undergone in the Union a qualitative and a quantitative analysis of at least all the active substances, and all the other tests necessary to ensure the quality of the veterinary medicinal products in accordance with the requirements of the marketing authorisation.		[] 7. Where veterinary medicinal products are [] imported [], the qualified person responsible for manufacturing shall ensure that each imported production batch has undergone in the Union a full qualitative and a quantitative analysis of at least all the active substances, and all the other tests necessary to ensure the quality of the veterinary medicinal products in accordance with the requirements of the marketing authorisation and that the batch manufactured in compliance with good manufacturing practice.	[] 7. Where veterinary medicinal products are [] imported [], the qualified person responsible for manufacturing shall ensure that each imported production batch has undergone in the Union a full qualitative and a quantitative analysis of at least all the active substances, and all the other tests necessary to ensure the quality of the veterinary medicinal products in accordance with the requirements of the marketing authorisation and that the batch manufactured in compliance with good manufacturing practice.
3. The reports signed by the qualified person as referred to in paragraph 1 shall be valid throughout the Union.		3. [] ⁵⁹	3. []

⁵⁹ Moved to paragraph 6.

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4. The qualified person for		[] 8 . The qualified person	[] 8 . The qualified person
manufacturing shall keep records in		responsible for manufacturing shall	responsible for manufacturing shall
respect of each released production		keep records in respect of each	keep records in respect of each
batch. These records shall be kept up		released production batch. These	released production batch. These
to date as operations are carried out		records shall be kept up to date as	records shall be kept up to date as
and shall remain at the disposal of		operations are carried out and shall	operations are carried out and shall
the competent authority for a period		remain at the disposal of the	remain at the disposal of the
of 5 years.		competent authority for [] one	competent authority for [] one
		year after the date of expiry of the	year after the date of expiry of the
		batch or at least five years,	batch or at least five years,
		whichever is the longer.	whichever is the longer.
5. Where veterinary medicinal		[] 9 . Where veterinary	[] 9 . Where veterinary
products manufactured in the Union		medicinal products manufactured in	medicinal products manufactured in
are imported into the Union from a		the Union are exported and	the Union are exported and
third country, paragraph 1 shall		subsequently imported back into the	subsequently imported back into the
apply.		Union from a third country,	Union from a third country,
		paragraph [] 6 shall apply.	paragraph [] 6 shall apply.
6. Where veterinary medicinal		[] 10 . Where veterinary	[] 10 . Where veterinary
products are imported from third		medicinal products are imported	medicinal products are imported
countries with which the Union has		from third countries with which the	from third countries with which the
made arrangements regarding		Union has made arrangements	Union has made arrangements
application of standards of good		regarding application of standards of	regarding application of standards of
manufacturing practice at least		good manufacturing practice at least	good manufacturing practice at least
equivalent to those laid down in		equivalent to those laid down in	equivalent to those laid down in
Commission Directive 91/412/EEC ⁶⁰		accordance with Article 98(2) []	accordance with Article 98(2) []
and it is demonstrated that the tests		and it is demonstrated that the tests	and it is demonstrated that the tests
referred to in paragraph 1 have been		referred to in paragraph [] 6 have	referred to in paragraph [] 6 have

⁶⁰ Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17/08/1991, p. 70).

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carried out in the exporting country, the competent authority in the Member State of importation may relieve the qualified person of the of		been carried out in the exporting country, the [] qualified person may draw up the control report referred to in paragraph 6 without	been carried out in the exporting country, the [] qualified person may draw up the control report referred to in paragraph 6 without
responsibility for carrying out the tests referred to in paragraph 2.		the necessary tests referred to in paragraph 7 being carried out [], unless the competent authority of the Member State of importation decides otherwise.	the necessary tests referred to in paragraph 7 being carried out [], unless the competent authority of the Member State of importation decides otherwise.
Article 102		Article 102	Article 102
Competent authorities' measures1. The competent authority shallensure that the obligations ofqualified persons referred to inArticle 100 are fulfilled, either bymeans of appropriate administrativemeasures or by making such personssubject to a professional code ofconduct.		[]	[]
2. The competent authority may temporarily suspend such persons upon the commencement of administrative or disciplinary proceedings against them for failure to fulfil their obligations. <i>Article 103</i>		[] Article 103	[] Article 103
Certificates of manufacturing		Certificates of veterinary medicinal	Certificates of veterinary medicinal
<i>authorisations</i> Upon request of the manufacturer or		<i>product</i> [] 1. Upon request of [] a	<i>product</i> [] 1. Upon request of [] a
exporter of veterinary medicinal		manufacturer or an exporter of	manufacturer or an exporter of



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products, or of the authorities of an importing third country, the competent authority shall certify that the manufacturer:		veterinary medicinal products, or of the authorities of an importing third country, the competent authority [] or the Agency shall certify that []:	veterinary medicinal products, or of the authorities of an importing third country, the competent authority [] or the Agency shall certify that []:
(a) holds a manufacturing authorisation for the product in question, or		(a) the manufacturer [] holds a manufacturing authorisation; or [],	(a) the manufacturer [] holds a manufacturing authorisation; or [],
(b) possesses a certificate of good manufacturing practice as referred to in Article 127.		(b) the manufacturer possesses a certificate of good manufacturing practice as referred to in Article [] 98a; or,	(b) the manufacturer possesses a certificate of good manufacturing practice as referred to in Article []98a; or,
		(c) the veterinary medicinal product in question has been granted a marketing authorisation in that Member State, or in the case of a request to the Agency, that it has been granted a centralised marketing authorisation.	(c) the veterinary medicinal product in question has been granted a marketing authorisation in that Member State, or in the case of a request to the Agency, that it has been granted a centralised marketing authorisation.

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When issuing such certificates, the		2. When issuing such certificates,	2. When issuing such certificates,
competent authority shall attach the		the competent authority or the	the competent authority or the
approved summary of the product		Agency shall [] take into account	Agency shall [] take into account
characteristics or, in the absence		the relevant prevailing	the relevant prevailing
thereof, an equivalent document, in		administrative arrangements with	administrative arrangements with
case of veterinary medicinal products		regard to the content and format	regard to the content and format
intended for export which are already		of such certificates.	of such certificates.
authorised in their territory.			
Chapter VII		Chapter VII	Chapter VII
Supply and use		Supply and use	Supply and use
Section 1		Section 1	Section 1
Wholesale distribution		Wholesale distribution	Wholesale distribution
Article 104		Article 104	Article 104
Wholesale distribution of veterinary		Wholesale distribution	Wholesale distribution
medicinal products		authorisations []	authorisations []
1. The wholesale distribution of		1. The wholesale distribution of	1. The wholesale distribution of
veterinary medicinal products shall		veterinary medicinal products shall	veterinary medicinal products shall
be subject to the holding of a		be subject to the holding of a	be subject to the holding of a
wholesale distribution authorisation.		wholesale distribution authorisation.	wholesale distribution authorisation.
Member States shall lay down		[]	[]
procedures for granting a wholesale			
distribution authorisation.			
		1a. The holders of a wholesale	1a. The holders of a wholesale
		distribution authorisation shall be	distribution authorisation shall be
		established in the Union.	established in the Union.
2. Wholesale distribution		2. Wholesale distribution	2. Wholesale distribution
authorisations shall be valid		authorisations shall be valid	authorisations shall be valid
throughout the Union.		throughout the Union.	throughout the Union.
	AM 215		
3. Supplies of small quantities of	Article 104 paragraph 3	3. Member States may decide	3. Member States may decide

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veterinary medicinal products from	3. Supplies of small quantities	that supplies of small quantities of	that supplies of small quantities of
one retailer to another shall not be	of veterinary medicinal products	veterinary medicinal products from	veterinary medicinal products from
regarded as wholesale distribution.	from one retailer to another shall	one retailer to another in the same	one retailer to another in the same
	not be regarded as wholesale	Member State, shall not be subject	Member State, shall not be subject
	distribution. The purchase, sale,	to the requirement of holding a	to the requirement of holding a
	import or export of veterinary	[] wholesale distribution	[] wholesale distribution
	medicinal products or any other	authorisation.	authorisation.
	kind of commercial transaction		
	concerning these medicinal		
	products, whether for profit or not		
	for profit, shall be subject to the		
	possession of a wholesale		
	distribution authorisation for		
	veterinary medicinal products.		
	Such an authorisation shall not		
	apply to the supply, by a		
	manufacturer, of veterinary		
	medicinal products which it has		
	itself manufactured, nor to the		
	retail sale of veterinary medicinal		
	products by persons entitled to		
	conduct such sales in accordance		
	with Article 107.		
		3a. By derogation from	3a. By derogation from
		paragraph 1, a holder of a	paragraph 1, a holder of a
		manufacturing authorisation shall	manufacturing authorisation shall
		not be required to hold a wholesale	not be required to hold a wholesale
		distribution authorisation for the	distribution authorisation for the
		veterinary medicinal products	veterinary medicinal products
		covered by the manufacturing	covered by the manufacturing



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		authorisation.	authorisation.
4. The wholesale distributor shall		$4. []^{61}$	4 . []
have an emergency plan			
guaranteeing the effective			
implementation of any withdrawal			
ordered by the competent authorities			
or the Commission or undertaken in			
cooperation with the manufacturer of			
the veterinary medicinal product in			
question or marketing authorisation			
holder.			
	AM 216		
	Article 104 paragraph 4 a		
	(new)		
	4a. On the basis of the best		
	practices model that already exists		
	for the medicinal products for		
	human use, the Commission shall		
	adopt, within 24 months of the		
	entry into force of this Regulation,		
	principles and guidelines, to which		
	wholesalers shall be obliged to		
	adhere, for best practices in the		
	wholesale distribution of		
	veterinary medicinal products.		

⁶¹ Moved to paragraphs 4-7 of Article 105a.

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	AM 217 Article 104 paragraph 4 b (new) 4b. Wholesalers shall obtain their supplies of medicinal products only from the manufacturer, a person designated by the holder of the marketing authorisation or from persons who themselves hold		
	a wholesale distribution		
	authorisation.		
5. A wholesale distributor shall supply veterinary medicinal products only to persons permitted to carry out retail activities in the Member State in accordance with Article 107(1), other wholesale distributors and exporters of veterinary medicinal products.		5. []	5. []
	AM 218 Article 104 paragraph 5 a (new) 5a. Wholesalers shall comply with		
	the obligations laid down in points (ca) and (cc) of Article 105(3) with regard to supply of medicinal products.		



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		6. The Commission shall, by	6. The Commission shall, by
		means of implementing acts, adopt	means of implementing acts, adopt
		measures on good distribution	measures on good distribution
		practices for veterinary medicinal	practices for veterinary medicinal
		products. Those implementing acts	products. Those implementing acts
		shall be adopted in accordance	shall be adopted in accordance
		with the examination procedure	with the examination procedure
4 1 . 105		referred to in Article 145(2).	referred to in Article 145(2).
Article 105		Article 105	Article 105
Procedure for granting wholesale		Application and procedures for []	Application and procedures for []
distribution authorisations		wholesale distribution authorisations	wholesale distribution authorisations
1. An application for a wholesale		1. An application for a wholesale	1. An application for a wholesale
distribution authorisation shall be		distribution authorisation shall be	distribution authorisation shall be
submitted to the competent authority		submitted to the competent authority	submitted to the competent authority
of the Member State in which the		[] in the Member State where the	[] in the Member State where the
wholesale distributor is established.		site(s) of [] the wholesale	site(s) of [] the wholesale
		distributor is/are located.	distributor is/are located.
2. The procedure for granting a		2. The procedure for granting a	2. The procedure for granting a
wholesale distribution authorisation		wholesale distribution authorisation	wholesale distribution authorisation
shall not exceed 90 days from the		shall not exceed 90 days from the	shall not exceed 90 days from the
date on which the competent		date on which the competent	date on which the competent
authority receives an application.		authority receives an application.	authority receives an application.
3. An applicant shall demonstrate		[] 1a . An applicant shall	[] 1a . An applicant shall
in the application that he fulfils the		demonstrate in the application that	demonstrate in the application that he
following requirements:		he fulfils the following	fulfils the following requirements:
		requirements:	

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(a) has at his disposal technically competent staff and suitable and sufficient premises complying with the requirements laid down by the Member State concerned as regards the storage and handling of veterinary medicinal products;	AM 219 (a) has at his disposal technically competent staff and suitable and sufficient premises complying with the requirements laid down by the Member State concerned as regards the storage and handling of veterinary medicinal products, and which premises representatives of the competent authority may enter at any time;	(a) has at his disposal technically competent staff and in particular at least one person designated as responsible person, meeting the conditions provided for in national law;	(a) has at his disposal technically competent staff and in particular at least one person designated as responsible person, meeting the conditions provided for in national law;
		(aa) has [] suitable and sufficient premises complying with the requirements laid down by the Member State concerned as regards the storage and handling of veterinary medicinal products;	(aa) has [] suitable and sufficient premises complying with the requirements laid down by the Member State concerned as regards the storage and handling of veterinary medicinal products;
(b) has an emergency plan		(b) has [] a plan guaranteeing	(b) has [] a plan guaranteeing
guaranteeing effective		effective implementation of any	effective implementation of any
implementation of any withdrawal		withdrawal or recall ordered by the	withdrawal or recall ordered by the
ordered by the competent authorities		competent authorities or the	competent authorities or the
or the Commission or undertaken in		Commission or undertaken in	Commission or undertaken in
cooperation with the manufacturer of		cooperation with the manufacturer	cooperation with the manufacturer
the veterinary medicinal product in		[] or marketing authorisation	[] or marketing authorisation
question or marketing authorisation		holder of the veterinary medicinal	holder of the veterinary medicinal
holder;		product in question;	product in question;

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 (c) has an appropriate record keeping system ensuring compliance with the requirements referred to in 		 (c) has an appropriate record keeping system ensuring compliance with the requirements referred to in 	 (c) has an appropriate record keeping system ensuring compliance with the requirements referred to in
Article 106.		Article 105a;	Article 105a;
	AM 220	(d) has a statement to the effect	(d) has a statement to the effect
	Article 105 paragraph 3	that he fulfils the requirements	that he fulfils the requirements
	point ca (new)	laid down in Article 105a.	laid down in Article 105a.
	(ca) concerning the supply of		
	medicinal products to persons		
	permitted to carry out retail		
	activities in the Member State in		
	accordance with Article 107(1), is		
	able to guarantee permanently an		
	adequate range of medicinal		
	products to meet the requirements		
	of the territory being supplied and		
	to deliver the supplies requested		
	within a very short time over the		
	whole of the territory in question;		
	AM 221		
	Article 105 paragraph 3		
	point c b (new)		
	(cb) within the limits of his		
	responsibility, ensure appropriate		
	and continued supplies of		
	medicinal products to persons		
	authorised to carry out retail		
	activities in the Member State in		
	accordance with Article 107(1) so		
	that animal health needs in the		



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	Member State in question are		
	covered;		
	AM 222		
	Article 105 paragraph 3		
	point c c (new)		
	(cc) is able to notify the competent		
	authority of any shortage of stock		
	likely to be detrimental to animal		
	health needs in the Member State		
	in question.		
		1b. Member States shall lay	1b. Member States shall lay
		down procedures for granting,	
		refusing, suspending, revoking or	refusing, suspending, revoking or
		changing a wholesale distribution authorisation.	changing a wholesale distribution authorisation.
		2. The procedure for granting, refusing, suspending, revoking or	
		changing [] wholesale	
		distribution authorisation shall not	changing [] wholesale distribution authorisation shall not
		exceed 90 days from the date on	
		which the competent authority	-
		receives [] application in	-
		accordance to national law.	accordance to national law.

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4. The competent authority shall		4. The competent authority shall	4. The competent authority shall
inform the applicant of the outcome		inform the applicant of the outcome	inform the applicant of the outcome
of the evaluation, grant or refuse the		of the evaluation, grant, [] refuse	of the evaluation, grant, [] refuse
wholesale distribution authorisation,		or change the wholesale distribution	or change the wholesale distribution
and upload the relevant information		authorisation, and upload the	authorisation, and upload the
of the authorisation in the		relevant information of the	relevant information of the
manufacturing and wholesale		authorisation in the manufacturing	authorisation in the manufacturing
distribution database.		and wholesale distribution database	and wholesale distribution database
		referred to in Article 94.	referred to in Article 94.
		Article 105a	Article 105a
		Obligations of wholesale	Obligations of wholesale
		distributors	distributors
		1. Wholesale distributors shall	1. Wholesale distributors shall
		obtain veterinary medicinal	obtain veterinary medicinal
		products only from holders of a	products only from holders of a
		manufacturing authorisation or	manufacturing authorisation or
		from other holders of a wholesale	from other holders of a wholesale
		distribution authorisation.	distribution authorisation.
		2. A wholesale distributor shall	2. A wholesale distributor shall
		supply veterinary medicinal	supply veterinary medicinal
		products only to persons permitted	products only to persons permitted
		to carry out retail activities in a	to carry out retail activities in a
		Member State in accordance with	Member State in accordance with
		Article 107(1), other wholesale	Article 107(1), other wholesale
		distributors of veterinary	distributors of veterinary
		medicinal products and to other	medicinal products and to other
		persons or entities in accordance	persons or entities in accordance
		with the national law.	with the national law.
		3. The holder of a wholesale	3. The holder of a wholesale
		distribution authorisation shall	distribution authorisation shall

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		have permanently at his disposal	have permanently at his disposal
		the services of at least one	the services of at least one
		responsible person for wholesale	responsible person for wholesale
		distribution.	distribution.
		4. Wholesale distributors of a	4. Wholesale distributors of a
		veterinary medicinal product shall,	veterinary medicinal product shall,
		within the limits of their	within the limits of their
		responsibility, ensure appropriate	responsibility, ensure appropriate
		and continued supply of such	and continued supply of such
		veterinary medicinal product to	veterinary medicinal product to
		persons authorised to supply	persons authorised to supply
		veterinary medicinal products in	veterinary medicinal products in
		accordance with Article 107(1), so	accordance with Article 107(1), so
		that the needs for animal health in	that the needs for animal health in
		the Member State in question are	the Member State in question are
		covered.	covered.
		5. A wholesale distributor shall	5. A wholesale distributor shall
		comply with the good distribution	comply with the good distribution
		practices for veterinary medicinal	practices for veterinary medicinal
		products as referred to in Article	products as referred to in Article
		104(6).	104(6).
		5a. Wholesale distributors shall	5a. Wholesale distributors shall
		immediately inform the competent	immediately inform the competent
		authority and, where applicable,	authority and, where applicable,
		the marketing authorisation	the marketing authorisation
		holder, of veterinary medicinal	holder, of veterinary medicinal
		products they receive or are	products they receive or are
		offered which they identify as	offered which they identify as
		falsified or suspected to be	falsified or suspected to be
		falsified.	falsified.



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Article 106		Article 106 ⁶²	Article 106
Record keeping requirements for			
wholesale distributors			
1. The wholesale distributor shall		[]6. The wholesale distributor shall	[] 6 . The wholesale distributor shall
keep detailed records. The following		keep detailed records of at least the	keep detailed records of at least the
minimum information shall be		following [] information [] in	following [] information [] in
recorded in respect of each purchase		respect of each [] transaction:	respect of each [] transaction:
and sale transaction:			
(a) date of the transaction;		(a) date of the transaction;	(a) date of the transaction;
(b) name of the veterinary		(b) name of the veterinary	(b) name of the veterinary
medicinal product;		medicinal product including	medicinal product including
		pharmaceutical form and strength,	pharmaceutical form and strength,
		as appropriate;	as appropriate;
(c) batch number,		(c) batch number[];	(c) batch number[];
(d) expiry date of the veterinary		(d) expiry date of the veterinary	(d) expiry date of the veterinary
medicinal product;		medicinal product;	medicinal product;
(e) quantity received or supplied;		(e) quantity received or supplied,	(e) quantity received or supplied,
		stating pack size and number of	stating pack size and number of
		packs;	packs;
(f) name and address of the		(f) name and address of the	(f) name and address of the
supplier in the event of purchase or		supplier in the event of purchase or	supplier in the event of purchase or
of the recipient in the event of sale.		of the recipient in the event of sale.	of the recipient in the event of sale.

⁶² Articles 105a and 106 have been merged.

2. At least once a year the holder of a wholesale distribution authorisation shall carry out a detailed audit of the stock and compare the incoming and outgoing medicinal products with products currently held in stock. Any discrepancies found shall be recorded. The records shall be available for inspection by the competent authorities for a period of three years. I]7. At least once a year the holder of a wholesale distribution authorisation shall carry out a detailed audit of the stock and compare the incoming and outgoing weterinary medicinal products with products currently held in stock. Any discrepancies found shall be recorded. The records shall be available for inspection by the competent authorities for a period of three years. I]7. At least once a year the holder of a wholesale distribution authorisation shall carry out a detailed audit of the stock and compare the incoming and outgoing weterinary medicinal products with products currently held in stock. Any discrepancies found shall be recorded. The records shall be available for inspection by the competent authorities for a period of f] five years. I]6.000000000000000000000000000000000	Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
make permanent and continuous use of the services of at least one qualified person satisfying the conditions set out in this Article, who shall be responsible, in particular, for performing the task specified in Article 104. 2. Qualified persons shall hold a diploma, certificate, or any other form of proof serving to	 558 final - 2014/0257 (COD) 2. At least once a year the holder of a wholesale distribution authorisation shall carry out a detailed audit of the stock and compare the incoming and outgoing medicinal products with products currently held in stock. Any discrepancies found shall be recorded. The records shall be available for inspection by the competent authorities for a period of 	AM 223 Article 106 a (new) Article 106a Qualified persons 1. The holder of a wholesale distribution authorisation shall make permanent and continuous use of the services of at least one qualified person satisfying the conditions set out in this Article, who shall be responsible, in particular, for performing the task specified in Article 104. 2. Qualified persons shall hold a diploma, certificate, or any other	by Coreper on 20 December 2017 []7. At least once a year the holder of a wholesale distribution authorisation shall carry out a detailed audit of the stock and compare the incoming and outgoing veterinary medicinal products with products currently held in stock. Any discrepancies found shall be recorded. The records shall be available for inspection by the competent authorities for a period of	proposed by the Presidency[]7. At least once a year the holderof a wholesale distributionauthorisation shall carry out adetailed audit of the stock andcompare the incoming and outgoingveterinary medicinal products withproducts currently held in stock. Anydiscrepancies found shall berecorded. The records shall beavailable for inspection by thecompetent authorities for a period of



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	properly qualified and have		
	acquired sufficient experience of		
	wholesale distribution. The		
	holder of the authorisation may		
	assume the responsibility		
	referred to in paragraph 1, if		
	that person personally fulfils		
	those conditions as specified		
	above.		
	3. The competent authority shall		
	ensure that the obligations of		
	qualified persons referred to in		
	this Article are fulfilled, either		
	by means of appropriate		
	administrative measures or by		
	making such persons subject to		
	a professional code of conduct.		
	The competent authority may		
	temporarily suspend such		
	persons upon the		
	commencement of		
	administrative or disciplinary		
	proceedings against them for		
	failure to fulfil their obligations.		

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		Article 106a	Article 106a
		Parallel trade in veterinary	Parallel trade in veterinary
		medicinal products ⁶³	medicinal products
		1. For the purpose of parallel	1. For the purpose of parallel
		trade in veterinary medicinal	trade in veterinary medicinal
		products, the wholesale distributor	products, the wholesale distributor
		shall ensure that the veterinary	shall ensure that the veterinary
		medicinal product he intends to	medicinal product he intends to
		source from a Member State	source from a Member State
		('source Member State') and	('source Member State') and
		distribute in another ('destination	distribute in another ('destination
		Member State') share a common	Member State') share a common
		origin with the veterinary	origin with the veterinary
		medicinal product already	medicinal product already
		authorised in the destination	authorised in the destination
		Member State. The veterinary	Member State. The veterinary
		medicinal products are is	medicinal products are is
		considered as sharing a common	considered as sharing a common
		origin if they fulfill the following	origin if they fulfill the following
		conditions:	conditions:
		(a) they have the same	(a) they have the same
		qualitative and quantitative	qualitative and quantitative
		composition in terms of active	composition in terms of active
		substances and excipients, and;	substances and excipients, and;
		(aa) they have the same	(aa) they have the same
		pharmaceutical form, and;	pharmaceutical form, and;
		(b) they have the same clinical	(b) they have the same clinical

⁶³ The term 'parallel distribution' shall be reserved for centrally authorised VMP. These shall continue to be regulated through article 57(1)(o) of Regulation 726/2004, as amended.

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		information and, if applicable,	information and, if applicable,
	1	withdrawal period; and,	withdrawal period; and,
		(bb) they have been manufactured	(bb) they have been manufactured
		by the same manufacturer or by a	by the same manufacturer or by a
		manufacturer working under	manufacturer working under
		licence according to the same	licence according to the same
		formulation;	formulation;
		1a. The veterinary medicinal	1a. The veterinary medicinal
		product obtained from a source	product obtained from a source
		Member State shall comply with	Member State shall comply with
		the labelling and language	the labelling and language
		requirements of the destination	requirements of the destination
		Member State.	Member State.
		2. Competent authorities shall	2. Competent authorities shall
		lay down administrative	lay down administrative
		procedures for the parallel trade in	procedures for the parallel trade in
		veterinary medicinal products and	veterinary medicinal products and
		administrative procedure for the	administrative procedure for the
		approval of the application for	approval of the application for
		paralell trade in such products.	paralell trade in such products.
		3. Competent authorities of the	3. Competent authorities of the
		destination Member State shall	destination Member State shall
		make public the list of veterinary	make public the list of veterinary
		medicinal products that are	medicinal products that are
		parallel traded in that Member	parallel traded in that Member
		State, in the product database as	State, in the product database as
		referred to in Article 51.	referred to in Article 51.
		4. A wholesale distributor who	4. A wholesale distributor who
		is not the marketing authorisation	is not the marketing authorisation
	L	holder shall notify the marketing	holder shall notify the marketing

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		authorisation holder and the	authorisation holder and the
		competent authority of the source	competent authority of the source
		Member State of his intention to	Member State of his intention to
		parallel trade the veterinary	parallel trade the veterinary
		medicinal product to a destination	medicinal product to a destination
		Member State. ⁶⁴	Member State.
		5. A wholesale distributor	5. A wholesale distributor
		intending to parallel trade a	intending to parallel trade a
		veterinary medicinal product to a	veterinary medicinal product to a
		destination Member State shall	destination Member State shall
		comply with at least the following	comply with at least the following
		obligations:	obligations:
		(a) submit a declaration to the	(a) submit a declaration to the
		competent authority in the	competent authority in the
		destination Member State and	destination Member State and
		take appropriate measures to	take appropriate measures to
		ensure that the wholesale	ensure that the wholesale
		distributor in the source Member	distributor in the source Member
		State will keep him informed of	State will keep him informed of
		any pharmacovigilance issues;	any pharmacovigilance issues;
		(b) notify the marketing	(b) notify the marketing
		authorisation holder in the	authorisation holder in the
		destination Member State about	destination Member State about
		the veterinary medicinal product	the veterinary medicinal product
		to be procured from the source	to be procured from the source
		Member State and intended to be	Member State and intended to be
		placed on the market in the	placed on the market in the
		destination Member State at	destination Member State at least

⁶⁴ The substance of this paragraph, with modifications, was taken from Article 104(6).



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		least one month prior to submitting to the competent authority the application for parallel trade of that veterinary medicinal product;	one month prior to submitting to the competent authority the application for parallel trade of that veterinary medicinal product;
		Incurrent product,(c) submit a writtendeclaration to the competentauthority of the destinationMember State that he hasnotified the marketingauthorisation holder in thedestination Member State inaccordance with point (b)together with a copy of thatnotification;	(c) submit a written declaration to the competent authority of the destination Member State that he has notified the marketing authorisation holder in the destination Member State in accordance with point (b) together with a copy of that notification;
		 (d) not trade a veterinary medicinal product which has been recalled from the market of the source Member State or destination Member State for quality, safety or efficacy reasons. (e) collect suspected adverse events and report them to the marketing authorisation holder of the parallel traded veterinary medicinal product. 	 (d) not trade a veterinary medicinal product which has been recalled from the market of the source Member State or destination Member State for quality, safety or efficacy reasons. (e) collect suspected adverse events and report them to the marketing authorisation holder of the parallel traded veterinary medicinal product.

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		6. The following information	6. The following information
		shall be attached to the list	shall be attached to the list
		referred to in paragraph 3 in	referred to in paragraph 3 in
		respect of all veterinary	respect of all veterinary medicinal
		medicinal products:	products:
		(a) name of the veterinary	(a) name of the veterinary
		medicinal product(s);	medicinal product(s);
		(b) active substance(s);	(b) active substance(s);
		(c) pharmaceutical form(s);	(c) pharmaceutical form(s);
		(d) classification of the	(d) classification of the
		veterinary medicinal product(s) in	veterinary medicinal product(s) in
		the destination Member State;	the destination Member State;
		(e) marketing authorisation	(e) marketing authorisation
		number of the veterinary	number of the veterinary
		medicinal product(s) in the	medicinal product(s) in the
		Member State from where it is sourced;	Member State from where it is sourced;
		(f) marketing authorisation	(f) marketing authorisation
		number of the veterinary	number of the veterinary
		medicinal product(s) in the	medicinal product(s) in the
		Member State of destination;	Member State of destination;
		(g) name and address of the	(g) name and address of the
		wholesale distributor in the source	wholesale distributor in the source
		Member State and of the	Member State and of the
		wholesale distributor in the	wholesale distributor in the
		destination Member State.	destination Member State.

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		7. This Article shall not apply to centrally authorised veterinary medicinal products.	7. This Article shall not apply to centrally authorised veterinary medicinal products.
Section 2		Section 2	Section 2
Retail		Retail	Retail
Article 107		Article 107	Article 107
Retail of veterinary medicinal		Retail of veterinary medicinal	Retail of veterinary medicinal
products and record keeping		products and record keeping	products and record keeping
1. The retail of veterinary		1. The rules on [] retail of	1. The rules on [] retail of
medicinal products shall be		veterinary medicinal products shall	veterinary medicinal products shall
conducted only by persons who are		be determined [] by [] national	be determined [] by [] national
permitted to carry out such		law, unless otherwise provided in	law, unless otherwise provided in
operations under national law.		this Regulation .	this Regulation.
		[] 1b. Without prejudice to Article 104(3), retailers of veterinary medicinal products shall obtain veterinary medicinal products only from holders of a wholesale distribution authorisation.	[] 1b. Without prejudice to Article 104(3), retailers of veterinary medicinal products shall obtain veterinary medicinal products only from holders of a wholesale distribution authorisation.
2. Persons qualified to prescribe veterinary medicinal products in accordance with applicable national law shall retail antimicrobial products only for animals which are under their care, and only in the amount required for the treatment	AM 224 Article 107 paragraph 2 2. Persons qualified to prescribe veterinary medicinal products in accordance with applicable national law shall retail antimicrobial products only for animals which are under their <i>immediate</i> care, <i>subject</i> <i>to an appropriate veterinary</i>	2. []	2. []



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concerned.	diagnosis and examination of the		
	<i>animal(s) concerned,</i> and only in		
	the amount required for the		
	treatment concerned. In the case of		
	food-producing animals, the		
	continuation of the treatment with		
	antimicrobial products shall be		
	decided based on a renewed		
	clinical examination by a		
	veterinarian.		
	AM 225		
	Article 107 paragraph 2 a		
	(new)		
	2a. Member States may impose		
	stricter conditions, justified on		
	grounds of public health, animal		
	health and environment		
	protection, for the retail of		
	veterinary medicinal products on		
	their territory, provided that these		
	conditions are proportionate to the		
	risk and do not unduly restrict the		
	functioning of the internal market.		

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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	AM 226		
	Article 107 paragraph 2 b		
	(new)		
	2b. Any commercial participation		
	in companies which trade in,		
	manufacture or import veterinary		
	medicinal products shall be prohibited.		
	AM 227		
	Article 107 paragraph 2 c		
	(new)		
	2c. Given the risks associated with		
	antimicrobial resistance, no		
	economic incentives may be		
	provided in any form, directly or		
	indirectly, by pharmaceutical		
	companies to persons who		
	prescribe veterinary medicinal products.		
	AM 228	3. Retailers of veterinary	3. Retailers of veterinary
3. Retailers of veterinary	3. Retailers of veterinary	medicinal products shall keep	medicinal products shall keep
medicinal products shall keep	medicinal products shall keep	detailed records of the following	detailed records of the following
detailed records of the following	detailed records of the following	information in respect of each	information in respect of each
information in respect of each	information in respect of each	transaction [] of veterinary	transaction [] of veterinary
purchase and sale of veterinary	purchase and sale of veterinary	medicinal products requiring a	medicinal products requiring a
medicinal products:	medicinal products <i>obtainable only</i>	veterinary prescription under	veterinary prescription under
	on prescription:	Article 29:	Article 29:

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)	AM 229	by Coreper on 20 December 2017	proposed by the Presidency
	Article 107 paragraph 3		
	subparagraph 1 a (new)		
	Where they consider it necessary,		
	Member States may require that		
	the obligation to keep the above		
	records likewise apply to the		
	purchase and sale of non-		
	prescription veterinary medicinal products.		
(a) date of the transaction;		(a) date of the transaction;	(a) date of the transaction;
(b) name of the veterinary		(b) name of the veterinary	(b) name of the veterinary
medicinal product;		medicinal product including	medicinal product including
1 · · ·		pharmaceutical form and strength,	pharmaceutical form and strength,
		as appropriate;	as appropriate;
(c) batch number;		(c) batch number;	(c) batch number;
(d) quantity received or supplied;		(d) quantity received or supplied;	(d) quantity received or supplied;
(e) name and address of the		(e) name and address of the	(e) name and address of the
supplier in the event of purchase, or		supplier in the event of purchase, or	supplier in the event of purchase, or
of the recipient in the event of sale;		of the recipient in the event of sale;	of the recipient in the event of sale;
(f) name and address of the		(f) name and [] contact details	(f) name and [] contact details
prescribing veterinarian and a copy		of the prescribing veterinarian and a	of the prescribing veterinarian and a
of the prescription in case of		copy of the veterinary prescription,	copy of the veterinary prescription,
veterinary medicinal products		where appropriate [].	where appropriate [].
requiring a prescription in accordance with Article 29.			
accordance with Article 29.			

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		(g) marketing authorisation	(g) marketing authorisation
		number.	number.
		3a. Where Member States	3a. Where Member States
		consider it necessary, they may	consider it necessary, they may
		require retailers to keep detailed	require retailers to keep detailed
		records of any transaction of	records of any transaction of
		veterinary medicinal products not	veterinary medicinal products not
		subject to veterinary	subject to veterinary prescription.
		prescription.	
4. At least once a year a retailer		4. At least once a year a retailer	4. At least once a year a retailer
shall carry out a detailed audit of the		shall carry out a detailed audit of the	shall carry out a detailed audit of the
stock and compare the incoming and		stock and compare the incoming and	stock and compare the incoming and
outgoing veterinary medicinal		outgoing veterinary medicinal	outgoing veterinary medicinal
products recorded with products		products recorded with products	products recorded with products
currently held in stock. Any		currently held in stock. Any	currently held in stock. Any
discrepancies found shall be		discrepancies found shall be	discrepancies found shall be
recorded. The records shall be		recorded. The results of the	recorded. The results of the detailed
available for inspection by the		detailed audit and the records	audit and the records referred to in
competent authorities in accordance		referred to in paragraph 3 shall	paragraph 3 shall be available for
with Article 125 for a period of three		be available for inspection by the	inspection by the competent
years.		competent authorities in accordance	authorities in accordance with
		with Article 125 for a period of	Article 125 for a period of [] five
		[] five years.	years.
		5. Member States may impose	5. Member States may impose
		conditions justified on grounds of	conditions justified on grounds of
		public health protection for the	public health protection <u>of public</u>
		retail on their territory of	<u>health, animal health or of</u>
		veterinary medicinal products	<u>environment</u> for the retail on their
		provided that such conditions	territory of veterinary medicinal
		comply with Union law, are	products provided that such



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536 IIIIai - 2014/0237 (COD)		proportional and non- discriminatory.	conditions comply with Union law, are proportional proportionate and non-discriminatory.
Article 108 Retail of veterinary medicinal		Article 108 Retail of veterinary medicinal	Article 108 Retail of veterinary medicinal
products at a distance	AM 230	products at a distance	products at a distance
1. Persons permitted to supply veterinary medicinal products in accordance with Article 107(1) may offer veterinary medicinal products by means of information society services in the meaning of Directive 98/34/EC of the European Parliament and of the Council to natural or legal persons established in the Union under the condition that those medicinal products comply with the legislation of the destination Member State.	 ANI 230 Persons permitted to supply veterinary medicinal products in accordance with Article 107(1) may offer veterinary medicinal products by means of information society services in the meaning of Directive ç!/34/EC of the European Parliament and of the Council, with the exception of antimicrobials, psychotropic and biological or immunological veterinary medicinal products, on the internet to natural or legal persons established in the Union under the condition that those medicinal products comply with the legislation of the destination Member State.: 	1. Persons permitted to supply veterinary medicinal products in accordance with Article 107(1) may offer veterinary medicinal products by means of information society services in the meaning of Directive 98/34/EC of the European Parliament and of the Council to natural or legal persons established in the Union [] provided that these veterinary medicinal products are not subject to a veterinary prescription pursuant to Article 29 and that they comply with this Regulation and applicable legislation of the Member State where the veterinary products are retailed. []	1. Persons permitted to supply veterinary medicinal products in accordance with Article 107(1) may offer veterinary medicinal products by means of information society services in the meaning of Directive 98/34/EC of the European Parliament and of the Council ⁶⁵ to natural or legal persons established in the Union [] provided that these veterinary medicinal products are not subject to a veterinary prescription pursuant to Article 29 and that they comply with this Regulation and applicable legislation of the Member State where the veterinary products are retailed. []

⁶⁵ Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37). Delegations are invited to note that Directive 98/34 has been repealed and replaced by Directive 2015/1535.

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	products and the prescriptions		
	comply with the law of the		
	destination Member State;		
	(b) the natural or legal person		
	offering veterinary medicinal		
	products is permitted or qualified		
	to supply prescription and non-		
	prescription veterinary medicinal		
	products to the public, including at		
	a distance, in accordance with the		
	national law of the Member State		
	in which that person is		
	established;		
	(c) the person referred to in point		
	(a) has notified at least the		
	following information to the		
	Member State of establishment:		
	(i) the name or corporate name		
	and the permanent address of the		
	place of business from where the		
	veterinary medicinal products are supplied;		
	(ii) the date on which veterinary		
	medicinal products were first		
	offered for sale at a distance to the		
	public on the internet;		
	(iii) the address of the website used		
	for that purpose and all		
	information necessary to identify		
	that website.		
	man moosne.	1	



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
	1a. On grounds of public or animal health, animal welfare or environmental protection, Members States shall be able to limit or condition, or both, the sale at a distance on the internet to the public on their territory of veterinary medicinal products or of other prescription veterinary medicinal products for food producing animals.		
		1a. By way of derogation from paragraph 1, Member States may allow persons permitted to supply veterinary medicinal products in accordance with Article 107(1) to offer veterinary medicinal products subject to a veterinary prescription pursuant to Article 29 by means of information society services. Such permission shall only be granted to persons established in their territory and supply shall only occur within the territory of that Member State.	1a. By way of derogation from paragraph 1, <u>a</u> Member States may allow persons permitted to supply veterinary medicinal products in accordance with Article 107(1) to offer veterinary medicinal products subject to a veterinary prescription pursuant to Article 29 by means of information society services, <u>provided that the Member State</u> <u>has provided a secure system for</u> <u>such supplies</u> . Such permission shall only be granted to persons established in their territory and supply shall only occur within the territory of that Member State.

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558 final - 2014/0257 (COD)		by Coreper on 20 December 2017 1aa. The Member State concerned shall notify the Commission and other Member States if it makes use of the derogation referred to in paragraph 1a and shall, when necessary, cooperate with the Commission and other Member States to avoid any unintended consequences of such supply. The Member States shall establish rules on appropriate penalties to ensure that the national rules adopted are respected, including	proposed by the Presidency1aa. That Member State shallensure that adapted measures arein place in order to guaranteethat the requirements relating to aveterinary prescription arerespected as regards supply bymeans of information societyservices and concerned shall notifythe Commission and otherMember States if it makes use ofthe derogation referred to inparagraph 1a and shall,when necessary, cooperate with the
		rules on the withdrawal of such permissions.	Commission and other Member States to avoid any unintended consequences of such supply. The Member States shall establish rules on appropriate penalties to ensure that the national rules adopted are respected, including rules on the withdrawal of such permissions.
		1b. The persons and activities referred to in paragraph 1 and paragraph 1a shall be subject to the controls referred to in Article 125 by the competent authority of the Member State where the retailer is established.	1b. The persons and activities referred to in paragraph 1 and paragraph 1a shall be subject to the controls referred to in Article 125 by the competent authority of the Member State where the retailer is established.
	AM 230		



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2. In addition to the information	2. In addition to the information	2. In addition to the information	2. In addition to the information
requirements set out in Article 6 of	requirements set out in Article 6 of	requirements set out in Article 6 of	requirements set out in Article 6 of
the Directive 2000/31/EC of the	the Directive 2000/31/EC of the	the Directive 2000/31/EC of the	the Directive 2000/31/EC of the
European Parliament and of the	European Parliament and of the	European Parliament and of the	European Parliament and of the
Council ⁶⁶ , websites offering	Council and Article 6 of Directive	Council, retailers [] offering	Council ⁶⁸ , retailers [] offering
veterinary medicinal products shall	2011/83/EU of the European	veterinary medicinal products by	veterinary medicinal products by
contain at least:	Parliament and of the Council ⁶⁷ ,	means of information society	means of information society
	websites offering veterinary	services shall provide [] at least	services shall provide [] at least
	medicinal products shall contain at	the following information:	the following information:
	least:		
(a) the contact details of the		(a) the contact details of the	(a) the contact details of the
competent authority of the Member		competent authority of the Member	competent authority of the Member
State in which the retailer offering		State in which the retailer offering	State in which the retailer offering
the veterinary medicinal products is		the veterinary medicinal products is	the veterinary medicinal products is
established;		established;	established;
(b) a hyperlink to the website of		(b) a hyperlink to the website of	(b) a hyperlink to the website of
the Member State of establishment		the Member State of establishment	the Member State of establishment
set up in accordance with paragraph		set up in accordance with paragraph	set up in accordance with paragraph
5;		5;	5;

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⁶⁶ Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1).

⁶⁷ AM 230 -- footnote 29a Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council (OJ L 304, 22.11.2011, p. 64).

⁶⁸ Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1).

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(c) the common logo established		(c) the common logo established	(c) the common logo established
in accordance with paragraph 3		in accordance with paragraph 3	in accordance with paragraph 3
clearly displayed on every page of		clearly displayed on every page of	clearly displayed on every page of
the website that relates to the offer		the website that relates to the offer	the website that relates to the offer
for sale at a distance to the public of		for sale at a distance [] of	for sale at a distance [] of
veterinary medicinal products and		veterinary medicinal products and	veterinary medicinal products and
containing a hyperlink to the entry of		containing a hyperlink to the entry of	containing a hyperlink to the entry of
the retailer in the list of authorised		the retailer in the list of []	the retailer in the list of []
retailers referred to in point (c) of		permitted retailers referred to in	permitted retailers referred to in
paragraph 5.		point (c) of paragraph 5.	point (c) of paragraph 5.
3. A common logo shall be		3. A common logo shall be	3. A common logo shall be
established that is recognisable		established that is recognisable	established that is recognisable
throughout the Union, while enabling		throughout the Union, while	throughout the Union, while enabling
the identification of the Member		enabling the identification of the	the identification of the Member
State where the person offering		Member State where the person	State where the person offering
veterinary medicinal products for		offering veterinary medicinal	veterinary medicinal products for
sale at a distance to the public is		products for sale at a distance []	sale at a distance [] is established.
established. The logo shall be clearly		is established. The logo shall be	The logo shall be clearly displayed
displayed on websites offering		clearly displayed on websites	on websites offering veterinary
veterinary medicinal products for		offering veterinary medicinal	medicinal products for sale at a
sale at a distance.		products for sale at a distance.	distance.
4. The Commission shall adopt		4. The Commission shall adopt	4. The Commission shall adopt
the design of the common logo by		the design of the common logo	the design of the common logo
means of implementing acts. Those		referred to in paragraph 3 by	referred to in paragraph 3 by
implementing acts shall be adopted		means of implementing acts. Those	means of implementing acts. Those
in accordance with the examination		implementing acts shall be adopted	implementing acts shall be adopted
procedure referred to in Article		in accordance with the examination	in accordance with the examination
145(2).		procedure referred to in Article	procedure referred to in Article
		145(2).	145(2).
5. Each Member State shall set up		5. Each Member State shall set up	5. Each Member State shall set up

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a website regarding sale of veterinary		a website regarding sale of veterinary	a website regarding sale of veterinary
medicinal products at a distance,		medicinal products at a distance,	medicinal products at a distance,
providing at least the following		providing at least the following	providing at least the following
information:		information:	information:
	AM 230		
(a) information on its national	(a) information on its national	(a) information on its national	(a) information on its national
legislation applicable to the offering	legislation applicable to the	legislation applicable to the offering	legislation applicable to the offering
of veterinary medicinal products for	offering of veterinary medicinal	of veterinary medicinal products for	of veterinary medicinal products for
sale at a distance to the public by	products for sale at a distance to the	sale at a distance [] by means of	sale at a distance [] by means of
means of information society	public by means of information	information society services, in	information society services, in
services, including information on	society services, on the internet,	accordance with paragraphs 1 and	accordance with paragraphs 1 and
the fact that there may be differences	including information on the fact	1a, including information on the fact	1a , including information on the fact
between Member States regarding	that there may be differences	that there may be differences	that there may be differences
the classification of the supply of the	between Member States regarding	between Member States regarding	between Member States regarding
veterinary medicinal products;	the classification of the supply of	the classification of the supply of the	the classification of the supply of the
	the veterinary medicinal products;	veterinary medicinal products;	veterinary medicinal products;
(b) information on the common		(b) information on the common	(b) information on the common
logo;		logo;	logo;
	AM 230		
(c) a list of retailers established in	(c) a list of retailers established	(c) a list of retailers established in	(c) a list of retailers established in
the Member State authorised to offer	in the Member State authorised to	the Member State [] permitted to	the Member State [] permitted to
veterinary medicinal products for	offer veterinary medicinal products	offer veterinary medicinal products	offer veterinary medicinal products
sale at a distance to the public by	for sale at a distance to the public	for sale at a distance [] by means	for sale at a distance [] by means
means of information society services in accordance with	on the internet in accordance with	of information society services in	of information society services in
	paragraph 1 as well as the website	accordance with paragraphs 1 and 1a as well as the website addresses of	accordance with paragraphs 1 and 1a as well as the website addresses of
paragraph 1 as well as the website addresses of those retailers.	addresses of those retailers; and	those retailers.	those retailers.
addresses of mose retailers.	also a hyperlink to the website of	mose retailers.	mose retailers.
	the Agency set up in accordance		
	with paragraph 6;		
	(ca) information on applicable		



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The websites set up by Member States shall contain a hyperlink to the website of the Agency set up in accordance with paragraph 6.	AM 230 deleted	[]	[]
6. The Agency shall set up a website providing information on the common logo. The Agency's website shall explicitly mention that the websites of Member States contain information on persons authorised to offer veterinary medicinal products for sale at a distance to the public by means of information society services in the Member State concerned.	AM 230 6. The Agency shall set up a website providing information on the common logo. The Agency's website shall explicitly mention that the websites of Member States contain information on persons authorised to offer veterinary medicinal products for sale at a distance to the public by means of information society services on the internet in the Member State concerned. The Agency's website shall be linked to the web pages of the appropriate Member State	6. The Agency shall set up a website providing information on the common logo. The Agency's website shall explicitly mention that the websites of Member States contain information on persons [] permitted to offer veterinary medicinal products for sale at a distance [] by means of information society services in the Member State concerned.	6. The Agency shall set up a website providing information on the common logo. The Agency's website shall explicitly mention that the websites of Member States contain information on persons [] permitted to offer veterinary medicinal products for sale at a distance [] by means of information society services in the Member State concerned.



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	bodies which list authorised	✓ ▲	
 7. Members States may impose conditions, justified on grounds of public health protection, for the retail on their territory of medicinal products offered for sale at a distance to the public by means of information society services. 		 by Coreper on 20 December 2017 7. Members States may impose conditions, justified on grounds of public health protection, for the retail on their territory of veterinary medicinal products offered for sale at a distance [] by means of information society services. 	7. Members States may impose conditions, justified on grounds of public health protection, for the retail on their territory of veterinary medicinal products offered for sale at a distance [] by means of information society services.
	code of conduct. 7b. No later than (six) months		
	after the date of application of this Regulation, the Commission shall adopt guidelines supporting the		
	Member States in the development of a harmonized system of digital prescription across the Union,		

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	including measures for controlling		
	cross-border veterinary		
	prescriptions.		
	7c. On the basis of the guidelines		
	referred to in paragraph 7b,		
	Member States shall be		
	encouraged to develop a system of		
	digital prescription at national		
	level, to include measures for the		
	delivery and control of		
	prescriptions. Member States shall		
	also be encouraged to set up a		
	system to facilitate the e-		
	submission of prescriptions by		
	means of a national database,		
	directly linked to all pharmacies		
	(both shop and internet ones),		
	national competent authorities and		
	veterinarians.		
		8. The websites set up by	8. The websites set up by
		Member States shall contain a	Member States shall contain a
		hyperlink to the website of the	hyperlink to the website of the
		Agency set up in accordance with	Agency set up in accordance with
		paragraph 6.	paragraph 6.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Article 109	AM 231	Article 109	Article 109
Retail of anabolic, anti-infectious,	Article 109 title	[]	[]
anti-parasitic, anti-inflammatory,	Retail <i>only</i> of <i>medicinal products</i>		
hormonal or psychotropic veterinary	which are subject to prescription,		
medicinal products	or active substances, with anabolic,		
_	anti-infectious, anti-parasitic, anti-		
	inflammatory, hormonal,		
	immunological or psychotropic		
	veterinary medicinal products		
	properties		
	AM 232		
1. Only manufacturers, wholesale	1. Only manufacturers,	[]	[]
distributors and retailers authorised	wholesale distributors and retailers		
specifically to do so in accordance	authorised specifically to do so in		
with applicable national law shall be	accordance with applicable national		
allowed to supply and purchase	law shall be allowed to supply and		
veterinary medicinal products which	purchase <i>prescription only</i>		
have anabolic, anti-infectious, anti-	veterinary medicinal products		
parasitic, anti-inflammatory,	which have anabolic, anti-		
hormonal or psychotropic properties	infectious, anti-parasitic, anti-		
or substances which may be used as	inflammatory, hormonal,		
veterinary medicinal products having	immunological or psychotropic		
those properties.	properties or substances which may		
	be used as veterinary medicinal		
	products having those properties.		
	In the case of non-food producing		
	animals (i.e. companion and small		
	animals) all retailers, ranging		
	from supermarkets, pet stores, to		
	traditional and online (veterinary)		



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
	pharmacies, shall be allowed to sell anti-parasitic and anti- inflammatory products, without the need to be specifically authorised to do so.		
2. The competent authorities shall maintain a register of manufacturers, wholesale distributors and retailers authorised in accordance with paragraph 1.		[]	[]
3. Those manufacturers and suppliers shall keep detailed records of the following information in respect of each purchase and sale transaction:	AM 233 3. Those manufacturers and suppliers shall keep detailed records of the following information in respect of each purchase and sale transaction <i>of</i> <i>prescription for veterinary</i> <i>medicinal products</i> :	[]	[]
 (a) date of transaction; (b) name and marketing authorisation number of the veterinary medicinal product; 		[] []	[] []
(c) quantity received or supplied;(d) name and address of the	AM 234 (d) name and address of the supplier in the event of purchase 5	[] []	[] []
supplier in the event of purchase, or of the recipient in the event of sale.	or of the recipient in the event of sale.		

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
These records shall be available for		[]	[]
inspection by the competent			
authorities in accordance with			
Article 125 for a period of 3 years.			
Article 110		Article 110	Article 110
Veterinary prescriptions		Veterinary prescriptions	Veterinary prescriptions
			00. A veterinary prescription for
			an antimicrobial medicinal
			product for metaphylaxis
			shall only be issued after a
			diagnosis of the infectious disease
			<u>by a veterinarian.</u>
			000. The veterinarian shall be
			able to provide justification for a
			veterinary prescription of
			antimicrobial medicinal products,
			in particular for metaphylaxis and
			for prophylaxis.
		0. A veterinary prescription	0. A veterinary prescription
		shall be issued only after a clinical	shall be issued only after a clinical
		examination or any other proper	examination or any other proper
		assessment of the health status of	assessment of the health status of
		the animal or group of animals by	the animal or group of animals by
		a veterinarian.	a veterinarian.
		1a. By way of derogation from	1a. By way of derogation from
		paragraph 0, a Member State may	Article 4(24) and paragraph 0 of
		allow that a veterinary	this Article, a Member State may
		prescription is issued by a	allow that a veterinary
		professional person qualified to do	prescription is issued by a

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017 so in accordance with applicable national law at the time of entry into force of this Regulation. Such prescriptions shall exclude prescription of antimicrobial medicinal products and any other veterinary medicinal products where a diagnosis by a veterinarian is necessary and shall be valid only in that Member State.	Draft revised negotiation mandate proposed by the Presidencyprofessional person, other than a veterinarian, qualified to do so in accordance with applicable national law at the time of entry into force of this Regulation. Such prescriptions shall exclude prescription of antimicrobial medicinal products and any other veterinary medicinal products where a diagnosis by a veterinarian is necessary and shall be valid only in that Member State.Paragraphs 1, 3, 5, 6 and 8 shall apply, mutatis mutandis, to such prescriptions.
1. A veterinary prescription shall contain at least the following elements ('minimum requirements'):		1. A veterinary prescription shall contain at least the following elements []:	1. A veterinary prescription shall contain at least the following elements []:
(a) identification of the animal under treatment;	AM 235 (a) identification of the animal or class of animal under treatment and the condition which is being treated;	 (a) identification of the animal or groups of animals to be treated []; 	 (a) identification of the animal or groups of animals to be treated [];
(b) full name and contact details of the animal owner or keeper;		(b) full name and contact details of the animal owner or keeper;	(b) full name and contact details of the animal owner or keeper;
(c) issue date;		(c) issue date;	(c) issue date;



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
(d) full name and contact details, qualifications and professional membership number of the person writing the prescription;		(d) full name and contact details [] of the [] veterinarian [] including, if available, the professional number;	 (d) full name and contact details [] of the [] veterinarian [] including, if available, the professional number;
(e) signature or an equivalent electronic form of identification of the person writing the prescription;	AM 235 (e) signature or an equivalent electronic form of identification of the person writing <i>issuing</i> the prescription;	(e) signature or an equivalent electronic form of identification of the veterinarian [];	(e) signature or an equivalent electronic form of identification of the veterinarian [];
(f) name of the prescribed product;	AM 235 (f) name of the prescribed product and the active substance(s);	 (f) name of the prescribed medicinal product, including its active substance(s); 	 (f) name of the prescribed medicinal product, including its active substance(s);
(g) pharmaceutical form (tablet, solution, etc.);		(g) pharmaceutical form and strength [];	(g) pharmaceutical form and strength [];
(h) quantity;	AM 235 (h) quantity and in cases where the treatment has to be repeated, it shall also contain the number of times it can be repeated;	(h) quantity prescribed, or the number of packs, including pack size;	(h) quantity prescribed, or the number of packs, including pack size;
(i) strength;		(i) [] ⁶⁹	(i) []
(j) dosage regimen;		(j) dosage regimen;	(j) dosage regimen;



⁶⁹ Re-inserted into point (g).

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)(k)withdrawal period if relevant;		by Coreper on 20 December 2017(k)for food producing	proposed by the Presidency (k) for food producing
		<pre>species,withdrawal period even if zero days [];</pre>	<pre>species,withdrawal period even if zero days [];</pre>
(l) any necessary warnings;	AM 235 (1) any necessary warnings and restrictions, including, where relevant, the risks entailed by imprudent use of antimicrobials;	(1) any [] warnings necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials;	(1) any [] warnings necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials;
(m) if a product is prescribed for a condition not mentioned in the		(m) if a product is prescribed [] under the provisions of Articles	(m) if a product is prescribed [] under the provisions of Articles
marketing authorisation for that product, a statement to that effect.		115, 116 and 116a , a statement to that effect;	115, 116 and 116a , a statement to that effect;
		(n) if a product is prescribed under the provisions of Article	(n) if a product is prescribed under the provisions of Article
		111a paragraphs 2, 2aa and 3, a statement to that effect.	111a paragraphs 2 , 2aa and 3, a statement to that effect.
	AM 235 Article 110 paragraph 1 subparagraph m a (new) (ma) period of validity of prescription.		
2. A veterinary prescription shall only be issued by a person qualified to do so in accordance with applicable national law.	AM 235 2. A veterinary prescription shall only be issued by a <i>veterinarian or other</i> person qualified to do so in accordance with applicable national law, <i>following a proper assessment of</i> <i>the health status of the animal</i> <i>concerned</i> .	2. []	2. []

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Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
3. Where a veterinary medicinal product is supplied on prescription, the quantity prescribed and supplied shall be restricted to the amount required for the treatment or therapy concerned.	AM 235 2a. A veterinary prescription of a veterinary medicinal product which has anabolic, anti- inflammatory, anti-infectious (other than anthelmintic), anti- cancer, hormonal or psychotropic properties or substances shall only be issued by a veterinarian after a clinical examination and diagnosis. AM 235 3. Where a veterinary medicinal product is supplied on prescription, the quantity prescribed and supplied shall be restricted to the amount required for the treatment or therapy concerned. The maximum quantity of veterinary medicinal products supplied at one time shall not, however, exceed one month's treatment. For chronic diseases and for periodic treatments the maximum quantity shall not exceed three month's treatment.	3. []The quantity prescribed [] shall be limited [] to the amount required for the treatment or therapy concerned.	3. []The quantity prescribed [] shall be limited [] to the amount required for the treatment or therapy concerned. <u>As regards</u> <u>antimicrobial medicinal products</u> <u>for metaphylaxis or prophylaxis</u> <u>such products shall be prescribed</u> <u>only for a limited duration to cover</u> <u>the period of risk.</u>

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
4. Veterinary prescriptions shall be recognised throughout the Union. A veterinary medicinal product prescribed shall be supplied in accordance with applicable national law.	AM 235 4. Veterinary prescriptions <i>issued by a veterinarian</i> shall be recognised throughout the Union. A veterinary medicinal product prescribed shall be supplied in accordance with applicable national law. Those provisions shall not apply to prescriptions issued under the exceptional circumstances set out in Articles 115 and 116. Those Member States that recognise prescriptions in their national systems issued by any person other than a veterinarian shall immediately notify the Commission, which shall forward such information to all Member States.	4. Veterinary prescriptions issued in accordance with paragraph 0 shall be recognised throughout the Union [].	4. Veterinary prescriptions issued in accordance with paragraph 0 shall be recognised throughout the Union [].
	AM 236 Article 110 paragraph 4 a (new) 4a. The removal of regulatory and administrative barriers to such recognition shall not affect any professional or ethical duty for dispensing professionals to refuse to dispense the medicine stated in the prescription.		



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
<u> </u>		5. The Commission may, by	5. The Commission may, by
		means of implementing acts, set a	means of implementing acts, set a
		model format for the	model format for the requirements
		requirements set in paragraph 1,	set in paragraph 1, which model
		which model format shall also be	format shall also be made available
		made available in electronic	in electronic version. Those
		version. Those implementing acts	implementing acts shall be adopted
		shall be adopted in accordance	in accordance with the
		with the examination procedure	examination procedure referred to
		referred to in Article 145(2).	in Article 145(2).
		6. The medicinal product	6. The medicinal product
		prescribed shall be supplied in	prescribed shall be supplied in
		accordance with applicable	accordance with applicable
		national law.	national law.
		7. A veterinary prescription for	7. A veterinary prescription for
		antimicriobial medicinal products	antimicriobial medicinal products
		shall be valid for 5 days from the	shall be valid for 5 days from the
		date of issuing.	date of issuing.
		8. In addition to the	8. In addition to the
		requirements set out in this	requirements set out in this
		Article, Member States may lay	Article, Member States may lay
		down rules on record keeping for	down rules on record keeping for
		veterinarians when issuing	veterinarians when issuing
		veterinary prescriptions.	veterinary prescriptions.
		9. Notwithstanding Article 29,	9. Notwithstanding Article 29, a
		a veterinary medicinal product	veterinary medicinal product
		classified as subject to veterinary	classified as subject to veterinary
		prescription under that Article	prescription under that Article
		may be administered by a	may be administered by a
		veterinarian himself without a	veterinarian himself without a

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017 veterinary prescription, unless otherwise provided for under applicable national law. The veterinarian shall keep records in accordance with applicable national law.	Draft revised negotiation mandate proposed by the Presidency veterinary prescription, unless otherwise provided for under applicable national law. The veterinarian shall keep records in accordance with applicable national law.
Section 3		Section 3	Section 3
Use		Use	Use
Article 111 Use of veterinary medicinal products		Article 111 Use of [] medicinal products	Article 111 Use of [] medicinal products
1. Veterinary medicinal products shall be used in accordance with the terms of the marketing authorisation.	AM 237 1. Veterinary medicinal products shall be used <i>responsibly</i> in accordance <i>with the principle of</i> <i>good animal husbandry and</i> with the terms of the marketing authorisation <i>or registration when</i> <i>no marketing authorisation is</i> <i>required.</i>	1. Veterinary medicinal products shall be used in accordance with the terms of the marketing authorisation.	1. Veterinary medicinal products shall be used in accordance with the terms of the marketing authorisation.
 Member States shall lay down 		 1a. The use of veterinary medicinal products in accordance with this Section shall be without prejudice to Articles 46 and 47 of Regulation (EU) 2016/429. 2. Member States [] may lay 	 1a. The use of veterinary medicinal products in accordance with this Section shall be without prejudice to Articles 46 and 47 of Regulation (EU) 2016/429⁷⁰. 2. Member States [] may lay
procedures for placing on the market		down [] any procedures they	down [] any procedures they

⁷⁰ Regulation (EU) No 429/2016 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L84, 31.3.2016, p.1).



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
of the medicinal products allowed to		deem necessary for the []	deem necessary for the []
be used in their territory in		implementation [] of Articles	implementation [] of Articles
accordance with Articles 115, 116,		113, 114, 115, 116, 116a and 119	113, 114, 115, 116, 116a and 119
119, 120 and 121.		[].	[].
	AM 238		
	Article 111 paragraph 2 a		
	(new)		
	2a. Antimicrobial veterinary		
	medicines shall not under any		
	circumstances serve to improve		
	performance or compensate for		
	poor animal husbandry. Routine		
	prophylactic use of antimicrobials		
	is therefore prohibited.		
	Prophylactic use of antimicrobial		
	veterinary medicines shall only be		
	permitted on single animals and		
	when fully justified by a		
	veterinarian in exceptional		
	indications, of which a list shall be		
	drafted by the Agency.		
	Metaphylactic use of antimicrobial		
	veterinary medicines shall be restricted to use in clinicall-ill		
	animals and to those single		
	animals that are identified as		
	being at a high risk of		
	contamination, to prevent further		
	spread of the disease in the group.		
	Where such products are to be		

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment <i>used for non-routine</i> <i>metaphylaxis, owners and keepers</i> <i>of food-producing animals shall</i> <i>ensure that they have a health</i> <i>plan specifying appropriate non-</i> <i>medical measures to reduce the</i> <i>need to resort to metaphylactic use</i> <i>in the future. Moreover, they shall</i> <i>be required to comply with the</i> <i>following measures:</i> <i>(i) using good healthy breeding</i> <i>stock with suitable genetic</i> <i>diversity;</i> <i>(ii) conditions that respect the</i> <i>behavioural needs of the species,</i> <i>including social</i> <i>interactions/hierarchies;</i> <i>(iii) stocking densities that do not</i> <i>increase risk of disease</i> <i>transmission;</i> <i>(iv) isolation of sick animals away</i> <i>from the rest of the group;</i> <i>(v)for chickens and smaller</i> <i>animals, subdivision of flocks into</i> <i>smaller, physically separated</i> <i>groups;</i> <i>(vi) implementation of existing</i>	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
	animal welfare rules already in cross compliance under the Common Agricultural Policy's		



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
530 IIIIai - 2014/0237 (COD)	horizontal Regulation 1306/2013, Annex II, SMRs 11, 12, 13. (Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes (OJ L 221, 8.8.1998, p. 23) Council Directive 91/630/EEC of 19 November 1991 laying down minimum standards for the protection of pigs (OJ L 340, 11.12.1991, p. 33), Council Directive 91/629/EEC of 19 November 1991 laying down minimum standards for the	by Coreper on 20 December 2017	proposed by the Tresidency
	protection of calves (OJ L 340, 11.12.1991, p. 28))	3. Member States may, if duly justified, decide that a veterinary medicinal product shall be administered by a veterinarian only.	3. Member States may, if duly justified, decide that a veterinary medicinal product shall be administered by a veterinarian only.
		4. Inactivated immunological veterinary medicinal products referred to in Article 2(2a) shall only be used in those animals in exceptional circumstances, in accordance with a veterinary prescription, and if no immunological veterinary medicinal product is authorised	4. Inactivated immunological veterinary medicinal products referred to in Article 2(2a) shall only be used in those animals in exceptional circumstances, in accordance with a veterinary prescription, and if no immunological veterinary medicinal product is authorised

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		for the target animal species and	for the target animal species and
		the indication.	the indication.
		5. The Commission may, by	5. The Commission may, by
		means of implementing acts,	means of implementing shall adopt
		establish rules on appropriate	delegated acts, in accordance with
		measures to ensure the effective	Article 146, supplementing the
		and safe use of veterinary	provisions of this Article, as
		medicinal products authorised and	necessary, concerning the
		prescribed for oral administration	establish <u>ment of</u> rules on
		via other routes than medicated	appropriate measures to ensure
		feed, such as mixing of water for	the effective and safe use of
		drinking with a veterinary	veterinary medicinal products
		medicinal product or as manual	authorised and prescribed for oral
		mixing of a veterinary medicinal	administration via other routes
		product into feed and	than medicated feed, such as
		administered by the animal keeper	mixing of water for drinking with
		to food producing animals. The	a veterinary medicinal product or
		Commission shall take into	as manual mixing of a veterinary
		account the scientific advice of the	medicinal product into feed and
		Agency, when adopting those	administered by the animal keeper
		implementing acts.	to food producing animals. The
			Commission shall take into
		Those implementing acts shall be	account the scientific advice of the
		adopted in accordance with the	Agency, when adopting those
		examination procedure referred to	implementing <u>delegated</u> acts.
		in Article 145(2).	Those implementing acts shall be
			adopted in accordance with the
			examination procedure referred to
			in Article 145(2).
	AM 239		



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
	Article 111 a (new)	Article 111a	Article 111a
	Article 111a	Use of antimicrobial medicinal	Use of antimicrobial medicinal
	Supply and use of antimicrobials	products	products
		1. Antimicrobial medicinal	1. Antimicrobial medicinal
		products shall not be applied	products shall not be applied
		routinely nor used to compensate	routinely nor used to compensate
		for poor hygiene, or inadequate	for poor hygiene, or inadequate
		animal husbandry or lack of care	animal husbandry or lack of care
		or to compensate for poor farm	or to compensate for poor farm
		management.	management.
		1a. Antimicrobial medicinal	1a. Antimicrobial medicinal
		products shall not be used in	products shall not be used in
		animals for the purpose of	animals for the purpose of
		promoting growth or increase	promoting growth or increase
		yield.	yield.
		2. Antimicrobial medicinal	2. Antimicrobial medicinal
		products shall not be used for	products shall not be used for
		prophylaxis unless, in exceptional	prophylaxis unless, in exceptional
		cases for the treatment of a	cases for the treatment of
		restricted number of animals	administration to an individual
		when the risk for infection is very	<u>animal</u> or a restricted number of
		high and the consequences of the	animals when the risk for <u>of an</u>
		infection are likely to be severe.	infection <u>or of an infectious disease</u> is very high and the consequences
			of the infection are likely to be
			severe. In such cases the use of
			antibiotic medicinal products for
			prophylaxis shall be limited to the



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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			administration to individual
			animal only, under the conditions
			laid down in the first sentence.
		2aa. Antibiotics shall not be used	2aa. Antibiotics shall not be used
		for prophylaxis unless in	for prophylaxis unless in
		exceptional cases for the treatment	exceptional cases for the treatment
		of an individual animal when the	of an individual animal when the
		risk of development or spread of	risk of development or spread of
		infectious disease is very high or	infectious disease is very high or
		the consequences of the infection	the consequences of the infection
		are likely to be severe.	are likely to be severe.
		3. Antimicrobial medicinal	3. Antimicrobial medicinal
		products shall be used for	products shall be used for
		metaphylaxis only when the risk of	metaphylaxis only when the risk of
		spread of infection in a group of	spread of an infection <u>or of an</u>
		animals is high.	<u>infectious disease</u> in a <u>the</u> group of
			animals is high <u>and where no other</u>
			appropriate alternatives are
			available. Member States may
			provide guidance regarding the
			other appropriate alternatives
			referred to in this paragraph and
			shall encourage the development of
			guidelines which promote the
			understanding of risk factors
			associated with metaphylaxis and
			include criteria for its initiation.
		4. The designated antimicrobials	4. The designated antimicrobials
		referred to in Article 32(4) shall	referred to in Article 32(4) shall
		not be used in accordance with	not be used in accordance with

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		Articles 115, 116 and 116a.	Articles 115, 116 and 116a.
		5. The Commission may, by	5. The Commission may, by
		means of implementing acts, and	means of implementing acts, and
		taking into consideration scientific	taking into consideration scientific
		advice of the Agency, establish a	advice of the Agency, establish a
		list of antimicrobials which:	list of antimicrobials which:
		(a) shall not be used in	(a) shall not be used in
		accordance with Articles 115, 116	accordance with Articles 115, 116
		and 116a, or	and 116a, or
		(b) shall only be used in	(b) shall only be used in
		accordance with Articles 115, 116	accordance with Articles 115, 116
		and 116a subject to certain	and 116a subject to certain
		conditions.	conditions.
		When adopting those	When adopting those
		implementing acts, the	implementing acts, the
		Commission shall take account of	Commission shall take account of
		the following criteria:	the following criteria:
		(a) risks to animal or public	(a) risks to animal or public
		health if the antimicrobials is used	health if the antimicrobials is used
		in accordance with Articles 115,	in accordance with Articles 115,
		116 and 116a;	116 and 116a;
		(b) risk for animal or public	(b) risk for animal or public
		health in case of development of	health in case of development of
		antimicrobial resistance;	antimicrobial resistance;
		(c) availability of other	(c) availability of other
		treatments for animals,	treatments for animals,
		(d) availability of other	(d) availability of other
		antimicrobial treatments for	antimicrobial treatments for
		humans;	humans;



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Duaft newiged negatiation mandate
Commission proposal COM(2014)	LF amenument		Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		(e) impact on aquaculture and	(e) impact on aquaculture and
		farming if the animal affected by	farming if the animal affected by
		the condition receives no	the condition receives no
		treatment.	treatment.
		Those implementing acts shall be	Those implementing acts shall be
		adopted in accordance with the	adopted in accordance with the
		examination procedure referred to	examination procedure referred to
		in Article 145(2).	in Article 145(2).
		6. A Member State may further	6. A Member State may further
		restrict or prohibit the use of	restrict or prohibit the use of
		-	-
		certain antimicrobials in animals	certain antimicrobials in animals
		on its territory if the	on its territory if the
		administration of such products to	administration of such products to
		animals is contrary to the	animals is contrary to the
		implementation of a national	implementation of a national
		policy on prudent use of	policy on prudent use of
		antimicrobials.	antimicrobials.
	1. Member States may restrict or		
	•		
	prohibit the supply or use, or both,		
	of certain antimicrobials in		



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
	animals on their territory if either of the following conditions is fulfilled: (a) the antimicrobials are critically important for use in humans; or (b) the administration of antimicrobials to animals is	7. Measures adopted on the basis of paragraph (6) shall be proportionate and justified.	7. Measures adopted on the basis of paragraph (6) shall be proportionate and justified.
	 contradictory to the implementation of a national policy on prudent use of antimicrobials and that the policy is in line with the precautionary principle. 2. Before adopting measures referred to in paragraph 1, the Member State shall ensure that relevant stakeholders have been consulted. 	8. The Member State shall inform the Commission of any measure it has adopted on the basis of paragraph (6).	8. The Member State shall inform the Commission of any measure it has adopted on the basis of paragraph (6).
	3. Measures adopted by Member States on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of protection of animal and public health.		



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
	4. A Member State adopting a		
	measure on the basis of paragraph		
	<i>1 shall inform the Commission thereof.</i>		
Article 112		Article 112	Article 112
Record keeping by owners and		Record keeping by owners and	Record keeping by owners and
keepers of food-producing animals		keepers of food-producing animals	keepers of food-producing animals
	AM 240		
1. Owners or, where the animals are not kept by the owners, keepers of food-producing animals shall keep records of the veterinary medicinal products they use and, if applicable, a copy of the veterinary prescription.	1. Owners or, where the animals are not kept by the owners, keepers of food-producing animals shall keep records of the <i>veterinarian-</i> <i>prescribed</i> veterinary medicinal products <i>and veterinary medicinal</i> <i>products with a withdrawal period</i> <i>higher than nil</i> they use and, if applicable, a copy of the veterinary prescription.	1. Owners or, where the animals are not kept by the owners, keepers of food-producing animals shall keep records of the [] medicinal products they use and, if applicable, a copy of the veterinary prescription.	1. Owners or, where the animals are not kept by the owners, keepers of food-producing animals shall keep records of the [] medicinal products they use and, if applicable, a copy of the veterinary prescription.
2. The following information shall be recorded:		2. [] Records referred to in paragraph 1 shall include:	2. [] Records referred to in paragraph 1 shall include:

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(a) date of administering the veterinary medicinal product to the animal;	AM 241 (a) date of administering the veterinary medicinal product to the animal <i>and the disease treated</i> ;	 (a) date of [] first administration of the [] medicinal product to the animals; 	(a) date of [] first administration of the [] medicinal product to the animals;
(b) name of the veterinary medicinal product;		(b) name of the [] medicinal product;	(b) name of the [] medicinal product;
(c) quantity of the veterinary medicinal product administered;		(c) quantity of the [] medicinal product administered;	(c) quantity of the [] medicinal product administered;
(d) name and address of the supplier;	AM 242 (d) name and address of the supplier <i>and</i> , <i>if applicable</i> , <i>a copy</i> <i>of the delivery note</i> ;	(d) name and address of the supplier;	(d) name and address of the supplier;
		(d0) evidence of acquisition;	(d0) evidence of acquisition;
(e) identification of the animals treated;	AM 243 (e) identification of the animals treated <i>and the diagnosis of the</i> <i>disease treated</i> ;	(e) identification of the animals or group of animals treated;	(e) identification of the animals or group of animals treated;
(f) name and address of the prescribing veterinarian and, if applicable, a copy of the prescription.		(f) name and [] contact details of the prescribing veterinarian, if applicable [];	(f) name and [] contact details of the prescribing veterinarian, if applicable [];
		(g) withdrawal period even if zero days;	(g) withdrawal period even if zero days;
		(h) duration of treatment.	(h) duration of treatment.

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	AM 244	2a. If the information to be	2a. If the information to be
	Article 112 paragraph 2 a	recorded in accordance with	recorded in accordance with
	(new)	paragraph 2 is already available	paragraph 2 is already available
		on the copy of veterinary	on the copy of veterinary
	2a. Particulars already contained	prescription, in a record kept on	prescription, in a record kept on
	in the prescription or in a delivery	the farm or for equine animals	the farm or for equine animals
	note shall not need to be recorded	recorded in the single lifetime	recorded in the single lifetime
	again if a clear reference can be	identification document referred to	identification document referred to
	made to the corresponding	in Article 114(1)(c) of Regulation	in Article 114(1)(c) of Regulation
	prescription and delivery note.	(EU) 2016/429, it does not need to	(EU) 2016/429, it does not need to
		be recorded separately.	be recorded separately.
		2b. Member States may lay down	2b. Member States may lay down
		additional requirements for	additional requirements for
		record-keeping by owners and	record-keeping by owners and
		keepers of food producing animals.	keepers of food producing animals.
	AM 245		
	Article 112 a (new)		
	Article 112a		
	Examination of therapy frequency		
	1. The national competent		
	authority shall identify on the		
	basis of the numbers determined		
	under Article 112, for each half		
	year, the average number of		
	treatments with antibacterial		
	effective substances and the		
	treatment frequency following a		
	standard European key, based on		
	the particular business and the		
	particular type of animals kept,		



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	taking into account the type of use.		
	2. The competent national		
	authority shall inform the farmer		
	in accordance with paragraph 1		
	about the biannual therapy		
	frequency for the particular		
	species of animals held by him in		
	consideration of their type of use.		
	3. The information collected under		
	paragraph 1 by the national		
	competent authority are evaluated		
	by the Commission and compared		
	throughout the Union.		
	4. Member States may request data		
	beyond.		
	AM 246		
	Article 112 b (new)		
	Article 1112b		
	Reduction of therapy approaches		
	based on antibacterial substances		
	1. In order to facilitate the		
	effective reduction regarding the		
	use of pharmaceuticals which		
	contain antibacterial substances,		
	anyone who engages in animal		
	husbandry shall:		
	(a) determine, respectively, two		
	months after the disclosure of the		
	key figures in accordance with		
	paragraph 112b established		



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	therapy prevalence, if the biannual	× •	ž ž ž
	therapy prevalence concerning his		
	reared animal species, and		
	considering the type-of-use during		
	the elapsed time frame, lies above		
	the average therapy prevalence (b) take immediate record of the		
	results of the assessment under		
	point 1.		
	2. In a case where the operational,		
	biannual therapy prevalence of the		
	animal husbandman with respect		
	to his business lies above the		
	biannual average, the animal		
	husbandman under consultation		
	of a veterinarian has to assess the		
	reasons that may have led to		
	exceeding the average, and how		
	the treatment of his cattle with		
	pharmaceuticals containing		
	antibacterial substances may be decreased.		
	If the assessment of the animal		
	husbandman comes to the result		
	that a therapy by means of the		
	concerned pharmaceuticals may		
	be reduced, the husbandman shall		
	take all necessary steps in order to		
	accomplish the reduction. The		
	husbandman shall consider the		



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	wellbeing of his cattle and		
	guarantee the required medical care.		
	3. Member States may determine		
	measures extending beyond the		
	above mentioned requirements.		
3. The information contained in		3. The information contained in	3. The information contained in
these records shall be available for		these records shall be available for	these records shall be available for
inspections by the competent		inspections by the competent	inspections by the competent
authorities in accordance with		authorities in accordance with	authorities in accordance with
Article 125 for a period of at least 3		Article 125 for a period of at least	Article 125 for a period of at least
years		[] five years.	[] five years.
		Article 112b	Article 112b
		Record keeping obligations for	Record keeping obligations for
		equine animals	equine animals
		1. The Commission shall adopt	1. The Commission shall adopt
		delegated acts in accordance with	delegated acts in accordance with
		Article 146 supplementing this	Article 146 supplementing this
		Regulation concerning the	Regulation concerning the content
		content and format of the	and format of the information
		information necessary to apply	necessary to apply Articles 115(3)
		Articles 115(3) and 117(5) to be	and 117(5) to be contained in the
		contained in the single lifetime	single lifetime identification
		identification document referred to	document referred to in Article
		in Article 114(1)(c) of	114(1)(c) of Regulation (EU)
		Regulation (EU) 2016/429.	2016/429.

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		2. The Commission shall adopt	2. The Commission shall adopt
		implementing acts, laying down	implementing acts, laying down
		model forms to enter the	model forms to enter the
		information necessary to apply	information necessary to apply
		Articles 115(3) and 117(5) to be	Articles 115(3) and 117(5) to be
		contained in the single lifetime	contained in the single lifetime
		identification document referred	identification document referred to
		to in Article 114(1)(c) of	in Article 114(1)(c) of Regulation
		Regulation (EU) 2016/429. Those	(EU) 2016/429. Those
		implementing acts shall be	implementing acts shall be adopted
		adopted in accordance with the	in accordance with the
		examination procedure referred to	examination procedure referred to
		in Article 145(2).	in Article 145(2).
Article 113		Article 113	Article 113
Use of immunologicals		Use of immunological[] veterinary	Use of immunological[] veterinary
		medicinal products	medicinal products
1. The competent authorities may,		1. [] The competent authorities	1. [] The competent authorities
in accordance with their national		may, in accordance with the	may, in accordance with the
legislation, prohibit the manufacture,		applicable national law [],	applicable national law [],
import, sale, supply and/or use of		prohibit the manufacture, import,	prohibit the manufacture, import,
immunological veterinary medicinal		distribution, possession, sale,	distribution, possession, sale,
products on the whole of their		supply and/or use of immunological	supply and/or use of immunological
territory or in a part of it if at least		veterinary medicinal products on	veterinary medicinal products on
one of the following conditions is		[] their territory or in a part of it if	[] their territory or in a part of it if
fulfilled:		at least one of the following	at least one of the following
		conditions is fulfilled:	conditions is fulfilled:

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(a) the administration of the		(a) the administration of the	(a) the administration of the
product to animals may interfere		product to animals may interfere	product to animals may interfere
with the implementation of a national		with the implementation of a	with the implementation of a national
programme for the diagnosis, control		national programme for the	programme for the diagnosis, control
or eradication of animal disease;		diagnosis, control or eradication of animal [] disease;	or eradication of animal [] disease;
(b) the administration of the		(b) the administration of the	(b) the administration of the
product to animals may cause		product to animals may cause	product to animals may cause
difficulties in certifying the absence		difficulties in certifying the absence	difficulties in certifying the absence
of contamination in live animals or		of [] disease in live animals or	of [] disease in live animals or
in foodstuffs or other products		contamination of [] foodstuffs or	contamination of [] foodstuffs or
obtained from treated animals;		other products obtained from	other products obtained from treated
		treated animals;	animals;
(c) the disease to which the		(c) the strain(s) of disease	(c) the strain(s) of disease agents
product is intended to confer		agents to which the product is	to which the product is intended to
immunity is largely absent from the		intended to confer immunity is	confer immunity is largely absent in
territory concerned.		largely absent in terms of	terms of geographic spread from
		geographic spread from the	the territory concerned.
		territory concerned.	
2. The competent authorities shall		2. [] By way of derogation	2. [] By way of derogation
inform the Commission of all		from Article 111(1), and in the	from Article 111(1), and in the
instances in which the provisions of		absence of a product as referred to	absence of a product as referred to
paragraph 1 are applied.		in Article 119, in the event of	in Article 119, in the event of an
		an outbreak of a listed diseases as	outbreak of a listed diseases as
		referred to in Article 5 of	referred to in Article 5 of
		Regulation (EU) No 429/2016 or an	Regulation (EU) No 429/2016 or an
		emerging disease as referred to in	emerging disease as referred to in
		Article 6 of that Regulation, a	Article 6 of that Regulation, a
		competent authority may allow,	competent authority may allow,
		the use of an immunological	the use of an immunological



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		veterinary medicinal product not	veterinary medicinal product not
		authorised within the Union. ⁷¹	authorised within the Union.
		2a. By way of derogation from	2a. By way of derogation from
		Article 111(1), when	Article 111(1), when
		immunological veterinary	immunological veterinary
		medicinal product has been	medicinal product has been
		authorised but is no longer	authorised but is no longer
		available within the Union for a	available within the Union for a
		disease which is not referred to in	disease which is not referred to in
		Article 5 or Article 6 of Regulation	Article 5 or Article 6 of Regulation
		(EU) No 429/2016 but which is	(EU) No 429/2016 but which is
		already present in the Union, a	already present in the Union, a
		competent authority may, in the	competent authority may, in the
		interest of animal health, welfare	interest of animal health, welfare
		and public health, allow the use of	and public health, allow the use of
		an immunological veterinary	an immunological veterinary
		medicinal product not authorised	medicinal product not authorised
		within the Union on a case by	within the Union on a case by case
		case basis.	basis.
		3. The competent authorities	3. The competent authorities
		shall inform the Commission	shall inform the Commission
		without delay when the provisions	without delay when the provisions
		of paragraph 1, 2 and 2a are	of paragraph 1, 2 and 2a are
		applied, together with information	applied, together with information
		on the conditions imposed in the	on the conditions imposed in the
		implementation of those	implementation of those
		provisions.	provisions.
	<u> </u>	4. If an animal is being	4. If an animal is being

⁷¹ Moved from Article 119(2).

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		exported to a third country and is	exported to a third country and is
		thereby subject to specific binding	thereby subject to specific binding
		health rules in that third country,	health rules in that third country,
		a competent authority may permit	a competent authority may permit
		the use, solely for the animal in	the use, solely for the animal in
		question, of an immunological	question, of an immunological
		veterinary medicinal product that	veterinary medicinal product that
		is not covered by a marketing	is not covered by a marketing
		authorisation in the Member State	authorisation in the Member State
		in question but its use is allowed in	in question but its use is allowed in
		the third country to where the	the third country to where the
		animal is to be exported. ⁷²	animal is to be exported.
Article 114		Article 114	Article 114
Veterinarians providing services in		[]Use of veterinary medicinal	[]Use of veterinary medicinal
other Member States		products by veterinarians providing	products by veterinarians providing
		services in other Member States	services in other Member States
1. A veterinarian providing		1. A veterinarian providing	1. A veterinarian providing
services in a Member State other		services in a 'host Member State' (a	services in a 'host Member State' (a
than the one where he is established		Member State other than the one	Member State other than the one
(the 'host Member State') may		where he is established) [] shall be	where he is established) [] shall be
administer veterinary medicinal		allowed to [] possess and []	allowed to [] possess and []
products authorised in the host		treat animals with veterinary	treat animals with veterinary
Member State to animals in another		medicinal products which are not	medicinal products which are not
Member State which are under his		authorised in that[] host Member	authorised in that[] host Member
care in the amount required for the		State to animals or groups of	State to animals or groups of
treatment of those animals where the		animals [] which are under his	animals [] which are under his
following conditions are fulfilled:		care in the [] necessary quantity	care in the [] necessary quantity
		not exceeding the amount required	not exceeding the amount required

⁷² Moved from Article 121 as contained in Doc. 5126/17.

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		for the treatment prescribed by the	for the treatment prescribed by the
		veterinarian provided that the	veterinarian provided that the
		following conditions are fulfilled:	following conditions are fulfilled:
(a) the authorisation to place the		(a) a [] marketing	(a) a [] marketing authorisation
veterinary medicinal product on the		authorisation [] for the veterinary	[] for the veterinary medicinal
market provided for in Article 5 has		medicinal product to be	product to be administered to the
been issued by the competent		administered to the animals has	animals has been granted [] by
authorities of the host Member State		been granted [] by the	the competent authorities of the []
or by the Commission;		competent authorities of the []	Member State in which the
		Member State in which the	veterinarian is established or by the
		veterinarian is established or by	Commission;
		the Commission;	
(b) the veterinary medicinal		(b) the concerned veterinary	(b) the concerned veterinary
products are transported by the		medicinal products are transported	medicinal products are transported
veterinarian in the original		by the veterinarian in their original	by the veterinarian in their original
packaging;		packaging;	packaging;
(c) where intended for			
administration to food-producing		(c) []	(c) []
animals, the veterinary medicinal			
products have the same qualitative			
and quantitative composition of			
active substances as the veterinary			
medicinal products authorised in the			
host Member State;			

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(d) the veterinarian follows the		(d) the veterinarian follows the good veterinary practices applied in	(d) the veterinarian follows the
good veterinary practices applied in that Member State and ensures that		that host Member State [];	good veterinary practices applied in that host Member State [];
the withdrawal period specified on			that nost Wember State [],
the labelling of the veterinary			
medicinal product is observed;			
,, _,, _		(dd) the veterinarian sets [] the withdrawal period specified on the labelling or package leaflet of the veterinary medicinal product used [];	(dd) the veterinarian sets [] the withdrawal period specified on the labelling or package leaflet of the veterinary medicinal product used [];
(e) the veterinarian does not retail any veterinary medicinal product to an owner or keeper of animals treated in the host Member State unless this is permissible under the rules of the host Member State, the medicinal product is intended for animals under his care, and only the minimum quantities of veterinary medicinal product necessary to complete the treatment of those animals are retailed;		(e) the veterinarian does not retail any veterinary medicinal product to an owner or keeper of animals treated in the host Member State unless this is permissible under the rules of the host Member State [].	(e) the veterinarian does not retail any veterinary medicinal product to an owner or keeper of animals treated in the host Member State unless this is permissible under the rules of the host Member State [].
(f) the veterinarian keeps detailed records of the animals treated, their diagnosis, the veterinary medicinal products administered, the dose administered, the duration of treatment and the withdrawal period applied, for inspection by the		(f) []	(f) []



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competent authorities of the host Member State for a period of 3 years.			
2. Paragraph 1 shall not apply to immunological veterinary medicinal products which are not authorised for use in the host Member State.		2. Paragraph 1 shall not apply to immunological veterinary medicinal products [] except in case of toxins and sera.	2. Paragraph 1 shall not apply to immunological veterinary medicinal products [] except in case of toxins and sera.
Article 115 Use of medicinal products for species or indications outside the terms of the marketing authorisation in non food-producing species		Article 115 Use of medicinal products [] outside the terms of the marketing authorisation in non food-producing species []	Article 115 Use of medicinal products [] outside the terms of the marketing authorisation in non food-producing species []
1. By way of derogation from Article 111, where there is no authorised veterinary medicinal product in a Member State for a condition affecting a non-food producing animal, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animal concerned with the following:	AM 247 1. By way of derogation from Article 111, where there is no authorised veterinary medicinal product in a Member State for a condition affecting a non-food producing animal, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering the interest of animal health and welfare, exceptionally treat the animal concerned with the following, in descending order of preference:	1. By way of derogation from Article 111(1), where there is no authorised veterinary medicinal product in a Member State for an indication concerning a non-food producing [] species , the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animals concerned with the following:	1. By way of derogation from Article 111(1), where there is no authorised veterinary medicinal product in a Member State for an indication concerning a non-food producing [] species , the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animals concerned with the following:

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(a) a medicinal product:	AM 247 (a) a any veterinary medicinal product authorised under this Regulation with the exception of antimicrobial products used as routine prophylactic measure, unless specifically authorised by the Committee for Medicinal Products for Veterinary Use;	(a) a veterinary medicinal product authorised under this Regulation in the Member State concerned or in another Member State for use in the same species or another species for the same indication or for another indication;	(a) a veterinary medicinal product authorised under this Regulation in the Member State concerned or in another Member State for use in the same species or another species for the same indication or for another indication;
 (i) a veterinary medicinal product authorised under this Regulation in the Member State concerned for use with another animal species, or for another condition in the same species; 	AM 247 deleted	[].	[].
 (ii) a veterinary medicinal product authorised under this Regulation in another Member State for use in the same species or in another species, for the same condition or for another condition; 	AM 247 deleted	[].	[].
(iii) a medicinal product for human use authorised in the Member State concerned in accordance with Directive	AM 247 deleted	[].	[].

mission proposal COM(2014) 58 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
2001/83/EC of the European Parliament and of the Council ⁷³ or Regulation (EC) No 726/2004;			
if there is no product as referred to in point (a), a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription by a person authorised to do so under national legislation.	AM 247 (b) if there is no product as referred to in point (a) ,a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription by a person authorised to do so under national legislation.: (i) a medicinal product for human use authorised in the Member State concerned or another Member State in accordance with Directive 2001/83/EC of the European Parliament and of the Council30 or Regulation (EC) No 726/2004. Antimicrobial medicinal products for human use may only be employed subject to the issuing of a prescription by a veterinarian and the approval by the veterinary authority responsible for	(b) if there is no product as referred to in point (a), a medicinal product for human use authorised in accordance with Directive 2001/83/EC of the European Parliament and of the Council or Regulation (EC) No 726/2004;	(b) if there is no product as referred to in point (a), a medicinal product for human use authorised in accordance with Directive 2001/83/EC of the European Parliament and of the Council ⁷⁴ or Regulation (EC) No 726/2004;

⁷³ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

⁷⁴ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
550 mai - 2014/0257 (COD)	monitoring the work of the veterinarian in question; (ii) a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription by a person authorised to do so under national law.	by coreper on 20 December 2017	proposed by the Tresidency
		(c) if there is no product as referred to in points (a) and (b), a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription.	(c) if there is no product as referred to in points (a) and (b), a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription.
		1a. Except as regards immunological veterinary medicinal products, in case there is no medicinal product available as referred to in paragraph 1 the veterinarian responsible may under his/her direct responsibility and in particular to avoid causing unacceptable suffering exceptionally treat a non-food producing animal with a veterinary medicinal product	1a. Except as regards immunological veterinary medicinal products, in case there is no medicinal product available as referred to in paragraph 1 the veterinarian responsible may under his/her direct responsibility and in particular to avoid causing unacceptable suffering exceptionally treat a non-food producing animal with a veterinary medicinal product
		authorised in a third country for the same animal species and same indication.	authorised in a third country for the same animal species and same indication.



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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2. The veterinarian may		2. []	2. The veterinarian may
administer the medicinal product			administer the medicinal product
personally or allow another person to			personally or allow another person
do so under the veterinarian's			to do so under the veterinarian's
responsibility.			responsibility, in accordance with
			the national provisions.
3. Paragraph 1 of this Article		3. [] This Article shall also	3. [] This Article shall also
shall also apply to the treatment by a		apply to the treatment by a	apply to the treatment by a
veterinarian of an animal belonging		veterinarian of an animal belonging	veterinarian of an animal belonging
to the equidae family provided that it		to the [] equine species provided	to the [] equine species provided
has been declared, in accordance		that it [] is declared [] as not	that it [] is declared [] as not
with Regulation (EC) No 504/2008,		being intended for slaughter for	being intended for slaughter for
as not being intended for slaughter		human consumption in the single	human consumption in the single
for human consumption.		lifetime identification document	lifetime identification document
		referred to in Article 114(1) of	referred to in Article 114(1) of
		Regulation (EU) No 2016/429.	Regulation (EU) No 2016/429.
	AM 303		
	Article 115 paragraph 1 a		
	(new)		
	1a. By way of derogation from		
	paragraph 1, homeopathic		
	medicinal products may be		
	administered to non-food		
	producing animals.		

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<u>330 mai - 2014/0237 (COD)</u>		4. This Article shall apply also when an authorised veterinary medicinal product is not available in the Member State concerned.	4. This Article shall apply also when an authorised veterinary medicinal product is not available in the Member State concerned.
Article 116 Use of medicinal products for species or indications outside the terms of the marketing authorisation in food-producing species		Article 116 Use of medicinal products [] outside the terms of the marketing authorisation in food-producing [] terrestrial species	Article 116 Use of medicinal products [] outside the terms of the marketing authorisation in food-producing [] terrestrial species
1. By way of derogation from Article 111, where there is no authorised veterinary medicinal product in a Member State for a condition affecting a food-producing animal of a non-aquatic species, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animal concerned with any of the following:	AM 249 1. By way of derogation from Article 111, where there is no authorised veterinary medicinal product in a Member State for a condition affecting a food-producing animal of a non-aquatic species, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering the interest of animal health and welfare, exceptionally treat the animal concerned with any of the following, in descending order of preference:	1. By way of derogation from Article 111(1), where there is no authorised veterinary medicinal product in a Member State for an indication [] concerning a food- producing terrestrial [] species, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animals concerned with [] the following:	1. By way of derogation from Article 111(1), where there is no authorised veterinary medicinal product in a Member State for an indication [] concerning a food- producing terrestrial [] species, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animals concerned with [] the following:
(a) a veterinary medicinal product authorised under this Regulation in the Member State concerned for use with another food-producing animal species, or for another condition in the same species;	AM 249 (a) <i>a any</i> veterinary medicinal product authorised under this Regulation in the Member State concerned for use with another food-producing animal species, or for another condition in the same	(a) a veterinary medicinal product authorised under this Regulation in the Member State concerned or in another Member State for use in the same or in another food-producing	(a) a veterinary medicinal product authorised under this Regulation in the Member State concerned or in another Member State for use in the same or in another food-producing terrestrial

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538 IIIIai - 2014/0237 (COD)	species; with the exception of antimicrobial products used prophylactically in an individual or a group where there is no diagnosis of disease in any of the animals;(ba) if there is no product as referred to in point (a):(i) a medicinal product for human use authorised in the MemberState concerned in accordance with Directive 2001/83/EC or under Regulation (EC) No726/2004. Antimicrobial medicinal products for human use may be employed subject to the issuing of a prescription by a veterinarian and the approval by the veterinary authority responsible for monitoring the work of the veterinarian in question and treatment with a veterinary medicinal product as referred to in point (a) or point (ba) is not possible; or(ii) a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription issued by a person authorised to do so under	by Coreper on 20 December 2017 terrestrial species for the same indication, or for another indication;	species for the same indication, or for another indication;



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(b) a veterinary medicinal product authorised under this Regulation in another Member State for use in the same species or in another food- producing species for the same condition or for another condition;	AM 249 deleted	(b) if there is no product as referred to in point (a), a veterinary medicinal product authorised under this Regulation in the Member State concerned for use in a non-food producing species for the same indication; []	(b) if there is no product as referred to in point (a), a veterinary medicinal product authorised under this Regulation in the Member State concerned for use in a non-food producing species for the same indication; []
(c) a medicinal product for human use authorised in the Member State concerned in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004, or	AM 249 deleted	(c) if there is no product as referred to in points (a) or (b)[], a medicinal product for human use authorised [] in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004, or,	(c) if there is no product as referred to in points (a) or (b)[], a medicinal product for human use authorised [] in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004, or,
(d) if there is no product as referred to in point (a), a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription by a person authorised to do so under national legislation.	AM 249 deleted	 (d) if there is no product as referred to in points (a), (b), [] or (c), a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription []. 	 (d) if there is no product as referred to in points (a), (b), [] or (c), a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription [].
	AM 249 Article 116 paragraph 1 subparagraph b a (new) (ba) veterinary medicinal products authorised under this Regulation in another Member State for use in the same aquatic species or in another food-producing aquatic		

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	question or for another condition.		
2. By way of derogation from		[]	[]
Article 111, where there is no			
authorised veterinary medicinal			
product in a Member State for a			
condition affecting a food-producing			
aquatic species, the veterinarian			
responsible may, under his direct			
personal responsibility and in			
particular to avoid causing			
unacceptable suffering, treat the			
animals concerned with any of the			
following medicinal products:			
(a) veterinary medicinal products		[]	[]
authorised under this Regulation in			
the Member State concerned for use			
with another food-producing aquatic			
species, or for another condition in			
the same aquatic species;			
(b) veterinary medicinal products		[]	[]
authorised under this Regulation in			
another Member State for use in the			
same aquatic species or in another			
food-producing aquatic species for			
the condition in question or for			
another condition.			
3. By way of derogation from		[]	[]
paragraph 2, and until an			
implementing act referred to in			

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paragraph 4 is established, if there is			
no product as referred to in			
subparagraphs (a) and (b) of			
paragraph 2, a veterinarian may,			
under his direct personal			
responsibility and in particular to			
avoid causing unacceptable			
suffering, exceptionally treat food-			
producing animals of an aquatic			
species on a particular holding with:			
(a) a veterinary medicinal product		[]	[]
authorised under this Regulation in			
the Member State concerned or in			
another Member State for use with a			
food-producing non-aquatic species;			
	AM 252	[]	[]
(b) a medicinal product for human	(b) <i>if there is no product as</i>		
use authorised in the Member State	referred to in point (a), a medicinal		
concerned in accordance with	product for human use authorised		
Directive 2001/83/EC or under	in the Member State concerned in		
Regulation (EC) No 726/2004.	accordance with Directive		
	2001/83/EC or under Regulation		
	(EC) No 726/2004.		
	AM 304		
	Article 116 paragraph 3 a		
	(new)		
	3a. By way of derogation from		
	paragraphs 1 to 3, homeopathic		
	medicinal products may be		
	administered to treat food-		



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	producing animals under the responsibility of the veterinarian provided that they contain only active ingredients listed in Table 1 of the Annex to Regulation (EU) No 37/2010 as substances for which no maximum limit needs to be set.		
4. The Commission may, by means of implementing acts, establish a list of veterinary medicinal products authorised in the Union for use in terrestrial animals which can be used for treatment of food-producing animals of an aquatic species in accordance with paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).		[]	[]
The Commission shall take account of the following criteria when adopting those implementing acts:		[]	[]
(a) risks to the environment if aquatic animals are treated with these medicinal products;		[]	[]

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(b) impact on animal health and		[]	[]
public health if the aquatic animal			
affected by the condition cannot			
receive treatment with the potential			
listed antimicrobial medicinal			
product;			
(c) impact on the competitiveness of certain sectors in aquaculture in		[]	[]
the Union if the animal affected by			
the condition cannot receive			
treatment with the antimicrobial			
medicinal product concerned;			
(d) availability or lack of		[]	[]
availability of other medicines,			
treatments or measures for			
prevention or treatment of diseases			
or certain conditions in aquatic			
animals.			
		4a. Except as regards	4a. Except as regards
		immunological veterinary	immunological veterinary
		medicinal products, in case there is	medicinal products, in case there is
		no medicinal product available as	no medicinal product available as
		referred to in paragraph 1, the	referred to in paragraph 1, the
		veterinarian responsible may under his/her direct personal	veterinarian responsible may under his/her direct personal
		responsibility and in particular to	responsibility and in particular to
		avoid causing unacceptable	avoid causing unacceptable
		suffering, exceptionally treat food	suffering, exceptionally treat food
		producing terrestrial animals with	producing terrestrial animals with
		a veterinary medicinal product	a veterinary medicinal product

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		authorised in a third country for the same species and same indication.	authorised in a third country for the same species and same indication.
5. For the purpose of treatment in accordance with paragraphs 1 to 3, the veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility.		[]	5. The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility, in accordance with the national provisions.
6. Pharmacologically active substances included in the medicinal product used in accordance with paragraph 1 shall be listed in Table 1 of the Annex to Regulation (EU) No 37/2010. The veterinarian shall specify an appropriate withdrawal period in accordance with Article 117.	AM 255 6. Pharmacologically active substances included in the medicinal product used in accordance with paragraph 1 <i>and paragraph 3(b)</i> shall be listed in Table 1 of the Annex to Regulation (EU) No 37/2010. The veterinarian shall specify an appropriate withdrawal period in accordance with Article 117.	6. Pharmacologically active substances [] included in the medicinal product used in accordance with paragraphs 0, 1 and 4a shall be [] allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof.	6. Pharmacologically active substances [] included in the medicinal product used in accordance with paragraphs 0, 1 and 4a shall be [] allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof.
7. By way of derogation from paragraph 1 and from Article 16(1) of Regulation (EC) No 470/2009 and in case there is no medicinal product available as referred to in paragraph 1, a veterinarian may treat bees, during the period when no honey or other foodstuffs is produced, with a veterinary medicinal product authorised for bees in a third country which is a member or an observer of		[]	[]

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the International Cooperation on			
Harmonisation of Technical			
Requirements for Registration of			
Veterinary Medicinal Products.			
8. The veterinarian shall keep		8. [] This Article shall apply	8. [] This Article shall apply
records of the date of examination of		also when an authorised	also when an authorised veterinary
the animals, details of the owner, the		veterinary medicinal product is	medicinal product is not available
number of animals treated, the		not available in the Member	in the Member State concerned.
diagnosis, the medicinal products		State concerned.	
prescribed, the doses administered,			
the duration of the treatment and the			
withdrawal periods recommended,			
and shall make those records			
available for inspection by the			
competent authorities for a period of			
at least 5 years.			
		Article 116a	Article 116a
		Use of veterinary medicinal	Use of veterinary medicinal
		products for food producing aquatic	products for food producing aquatic
		species	species
		1. By way of derogation from	1. By way of derogation from
		Article 111(1), where there is no	Article 111(1), where there is no
		authorised veterinary medicinal	authorised veterinary medicinal
		product in a Member State for an	product in a Member State for an
		indication concerning a food-	indication concerning a food-
		producing aquatic species, the	producing aquatic species, the
		veterinarian responsible may,	veterinarian responsible may,
		under his direct personal	under his direct personal
		responsibility and in particular to	responsibility and in particular to
		avoid causing unacceptable	avoid causing unacceptable



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		suffering, treat the animals	suffering, treat the animals
		concerned with the following:	concerned with the following:
		(a) veterinary medicinal	(a) veterinary medicinal
		products authorised under this	products authorised under this
		Regulation in the same Member	Regulation in the same Member
		State or in another Member State	State or in another Member State
		for use in the same species or in	for use in the same species or in
		another food-producing aquatic	another food-producing aquatic
		species and for the same	species and for the same indication
		indication or for another	or for another indication; or,
		indication; or,	
		(b) if there is no product as	(b) if there is no product as
		referred to in point (a), a	referred to in point (a), a
		veterinary medicinal product	veterinary medicinal product
		authorised under this Regulation	authorised under this Regulation
		in the Member State concerned	in the Member State concerned or
		or in another Member State for	in another Member State for use
		use with a food-producing	with a food-producing terrestrial
		terrestrial species containing a	species containing a substance
		substance present in the list	present in the list established in
		established in accordance with	accordance with paragraph 3; or,
		paragraph 3; or,	
		(c) if there is no product as	(c) if there is no product as
		referred to in points (a) and (b), a	referred to in points (a) and (b), a
		medicinal product for human use	medicinal product for human use
		authorised in accordance with	authorised in accordance with
		Directive 2001/83/EC or under	Directive 2001/83/EC or under
		Regulation (EC) No 726/2004 and	Regulation (EC) No 726/2004 and
		containing substances present in	containing substances present in
		the list established in accordance	the list established in accordance

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		with paragraph 3; or,	with paragraph 3; or,
		(d) if there is no product as	(d) if there is no product as
		referred to in points (a), (b) or (c),	referred to in points (a), (b) or (c),
		a veterinary medicinal product	a veterinary medicinal product
		prepared extemporaneously in	prepared extemporaneously in
		accordance with the terms of a	accordance with the terms of a
		veterinary prescription.	veterinary prescription.
		2. By way of derogation from	2. By way of derogation from
		paragraphs 1 (b) and (c), until the	paragraphs 1 (b) and (c), until the
		list referred to in paragraph 3 is	list referred to in paragraph 3 is
		established, the veterinarian	established, the veterinarian
		responsible may, under his/her	responsible may, under his/her
		direct personal responsibility and	direct personal responsibility and
		in particular to avoid causing	in particular to avoid causing
		unacceptable suffering,	unacceptable suffering,
		exceptionally treat food-producing	exceptionally treat food-producing
		aquatic species of a particular	aquatic species of a particular
		holding with:	holding with:
		(a) a veterinary medicinal	(a) a veterinary medicinal
		product authorised under this	product authorised under this
		Regulation in the Member State	Regulation in the Member State
		concerned or in another Member	concerned or in another Member
		State for use with a food-	State for use with a food-
		producing terrestrial species;	producing terrestrial species;
		(b) if there is no product as	(b) if there is no product as
		referred to in point (a), a	referred to in point (a), a medicinal
		medicinal product for human use	product for human use authorised
		authorised in accordance with	in accordance with Directive
		Directive 2001/83/EC or under	2001/83/EC or under Regulation
		Regulation (EC) No 726/2004.	(EC) No 726/2004.

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		3. The Commission shall, by	3. The Commission shall, by
		means of implementing acts, at the	means of implementing acts, at the
		latest within five years from the	latest within five years from the
		date referred to in the second	date referred to in the second
		paragraph of Article 150, establish	paragraph of Article 150, establish
		a list of substances used in	a list of substances used in
		veterinary medicinal products	veterinary medicinal products
		authorised in the Union for use in	authorised in the Union for use in
		food-producing terrestrial species	food-producing terrestrial species
		or substances contained in a	or substances contained in a
		medicinal product for human use	medicinal product for human use
		authorised in the Union in	authorised in the Union in
		accordance with Directive	accordance with Directive
		2001/83/EC or under Regulation	2001/83/EC or under Regulation
		(EC) No 726/2004, which may be	(EC) No 726/2004, which may be
		used in food-producing aquatic	used in food-producing aquatic
		species in accordance with	species in accordance with
		paragraph 1. Those	paragraph 1. Those implementing
		implementing acts shall be	acts shall be adopted in accordance
		adopted in accordance with the	with the examination procedure
		examination procedure referred to	referred to in Article 145(2).
		in Article 145(2).	
		The Commission shall take	The Commission shall take
		account of the following criteria	account of the following criteria
		when adopting those implementing	when adopting those implementing
		acts:	acts:

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		(a) risks to the environment if	(a) risks to the environment if
		the food-producing aquatic species	the food-producing aquatic species
		are treated with these substances;	are treated with these substances;
		(b) impact on animal and public	(b) impact on animal and public
		health if the food-producing	health if the food-producing
		aquatic_species affected cannot	aquatic_species affected cannot
		receive an antimicrobial listed in	receive an antimicrobial listed in
		accordance with Article 111a(5);	accordance with Article 111a(5);
		(c) availability or lack of	(c) availability or lack of
		availability of other medicines,	availability of other medicines,
		treatments or measures for	treatments or measures for
		prevention or treatment of diseases	prevention or treatment of diseases
		or certain indications in food-	or certain indications in food-
		producing aquatic species.	producing aquatic species.
		4. Except as regards	4. Except as regards
		immunological veterinary	immunological veterinary
		medicinal products, in case there is	medicinal products, in case there is
		no medicinal product available as	no medicinal product available as
		referred to in paragraph 1 and 2,	referred to in paragraph 1 and 2,
		the veterinarian responsible may,	the veterinarian responsible may,
		under his direct personal	under his direct personal
		responsibility and in particular to	responsibility and in particular to
		avoid causing unacceptable	avoid causing unacceptable
		suffering, exceptionally treat food	suffering, exceptionally treat food
		producing aquatic species with a	producing aquatic species with a
		veterinary medicinal product	veterinary medicinal product
		authorised in a third country for	authorised in a third country for
		the same species and same	the same species and same
		indication.	indication.
			<u>4a. The veterinarian may</u>



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			administer the medicinal product
			personally or allow another person
			to do so under the veterinarian's
			responsibility, in accordance with
	<u></u>		the national provisions.
		5. Pharmacologically active	5. Pharmacologically active
		substances included in the	substances included in the
		medicinal product used in	medicinal product used in
		accordance with paragraphs 0, 1, 2	accordance with paragraphs 0, 1, 2
		and 4 shall be allowed in	and 4 shall be allowed in
		accordance with Regulation (EC)	accordance with Regulation (EC)
		No 470/2009 and any acts adopted	No 470/2009 and any acts adopted
		on the basis thereof.	on the basis thereof.
		6. This Article shall apply also	6. This Article shall apply also
		when an authorised veterinary	when an authorised veterinary
		medicinal product is not available	medicinal product is not available
		in the Member State concerned.	in the Member State concerned.
Article 117		Article 117	Article 117
Withdrawal period for products used		Withdrawal period for products used	Withdrawal period for products used
outside the terms of the marketing		outside the terms of the marketing	outside the terms of the marketing
authorisation in food-producing		authorisation in food-producing	authorisation in food-producing
species		<i>species</i> 1. For the purpose of Article 116	species
1. For the purpose of Article 116, unless a product used has a		1. For the purpose of Article 116 and 116a, unless a product used has	1. For the purpose of Article 116 and 116a, unless a product used has
withdrawal period provided in its		a withdrawal period provided in its	a withdrawal period provided in its
summary of the product		summary of the product	summary of the product
characteristics for the species in		characteristics for the animal species	characteristics for the animal species
question, a withdrawal period shall		in question, a withdrawal period	in question, a withdrawal period
be set by the veterinarian in		shall be set by the veterinarian in	shall be set by the veterinarian in
accordance with the following		accordance with the following	accordance with the following
accordance with the following			accordance with the following



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criteria:		criteria:	criteria:
(a) for meat and offal of food		(a) for meat and offal from []	(a) for meat and offal from []
producing mammals and birds not		food producing mammals and	food producing mammals and
less than:		poultry and farmed game birds not	poultry and farmed game birds not
		less than:	less than:
(i) the longest withdrawal		(i) the longest withdrawal	(i) the longest withdrawal period
period provided in its summary		period provided in its summary	provided in its summary of the
of the product characteristics		of the product characteristics for	product characteristics for [] meat
for any animal species		[] meat and offal multiplied	and offal multiplied by factor 1,5;
multiplied by factor 1,5;		by factor 1,5;	
(ii) if the product is not		(ii) if the product is not	(ii) if the product is not authorised
authorised for food producing		authorised for food producing	for food producing [] animals, 28
species, 28 days;		[] animals , 28 days;	days;
		(iii) one day, if the product	(iii) one day, if the product has a
		has a zero days withdrawal	zero days withdrawal period and it
		period and it is used in a	is used in a different animal family
		different animal family than	than the one authorised.
		the one authorised.	
(b) for animal species producing		(b) for milk from animals []	(b) for milk from animals []
milk for human consumption not less		producing milk for human	producing milk for human
than:		consumption not less than:	consumption not less than:
(i) the longest withdrawal		(i) the longest withdrawal	(i) the longest withdrawal period
period provided in the		period for milk provided in the	for milk provided in the summary of
summary of the product		summary of the product	the product characteristics for any
characteristics for any milk		characteristics for any animal	animal [] multiplied by factor 1.5;
producing species multiplied		[] multiplied by factor 1.5;	
by factor 1.5;			

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(ii) if the product is not authorised for any milk producing species, 7 days;		 (ii) if the product is not authorised for [] animals producing milk for human consumption, 7 days; 	 (ii) if the product is not authorised for [] animals producing milk for human consumption, 7 days;
		(iii) one day, if the product has a zero days withdrawal period.	(iii) one day, if the product has a zero days withdrawal period.
(c) for animal species producing eggs for human consumption not less than:		(c) for eggs from animals [] producing eggs for human consumption not less than:	(c) for eggs from animals []producing eggs for humanconsumption not less than:
 (i) the longest withdrawal period provided in the summary of the product characteristics for eggs multiplied by factor 1.5; 		 (i) the longest withdrawal period for eggs provided in the summary of the product characteristics for any animal [] multiplied by factor 1.5; 	(i) the longest withdrawal period for eggs provided in the summary of the product characteristics for any animal [] multiplied by factor 1.5;
(ii) if the product is not authorised for any eggs producing species, 7 days;		 (ii) if the product is not authorised for [] animals producing eggs for human consumption [] 10 days; 	(ii) if the product is not authorised for [] animals producing eggs for human consumption [] 10 days;
(d) for aquatic animal species for human consumption and aquatic animal species producing eggs for human consumption not less than:		(d) for aquatic species [] producing meat for human consumption [] not less than:	(d) for aquatic species [] producing meat for human consumption [] not less than:
 (i) the longest withdrawal period for any of the aquatic species indicated in the summary of the product characteristics multiplied by factor of 50 and expressed as number of days multiplied by 		(i) the longest withdrawal period for any of the aquatic species indicated in the summary of the product characteristics multiplied by factor of 1.5 [] and expressed as [] ('degree-days'). []	(i) the longest withdrawal period for any of the aquatic species indicated in the summary of the product characteristics multiplied by factor of 1.5 [] and expressed as [] ('degree-days'). []



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the average water temperature ('degree-days'). The withdrawal period shall not be less than 50 degree-days;			
 (ii) if the product is not authorised for food producing aquatic animal species, 500 degree-days. 		(ii) []	(ii) []
		(iii) if the product is authorised for food producing terrestrial animals, the longest withdrawal period for any of the food producing animals indicated in the summary of product characteristics multiplied by a factor of 50 and expressed as	(iii) if the product is authorised for food producing terrestrial animals, the longest withdrawal period for any of the food producing animals indicated in the summary of product characteristics multiplied by a factor of 50 and expressed as
		degree days, but not exceeding 500 degree-days; (iv) if the product is not authorised for food producing species, 500 degree-days;	degree days, but not exceeding 500 degree-days; (iv) if the product is not authorised for food producing species, 500 degree-days;
		(v) 25 degree days if the highest withdrawal period for any animal species is zero days.	(v) 25 degree days if the highest withdrawal period for any animal species is zero days.
		 1a. If, on calculation of the withdrawal period according to paragraph 1 subparagraphs (a)(i), (b)(i), (c)(i),d)(i) and (d)(iii) result in a fraction of days, the withdrawal period shall be 	 1a. If, on calculation of the withdrawal period according to paragraph 1 subparagraphs (a)(i), (b)(i), (c)(i),d)(i) and (d)(iii) result in a fraction of days, the withdrawal period shall be

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		rounded up to the nearest number	rounded up to the nearest number
		of days.	of days.
2. The Commission shall be		2. The Commission is []	2. The Commission is []
empowered to adopt delegated acts		empowered to adopt delegated acts	empowered to adopt delegated acts
in accordance with Article 146 in		in accordance with Article 146 in	in accordance with Article 146 in
order to amend the rules laid down in		order to amend the rules laid down in	order to amend the rules laid down in
paragraph 1 in the light of new scientific evidence.		paragraph 1 and 3 in the light of new scientific evidence.	paragraph 1 and 3 in the light of new scientific evidence.
3. For bees, the veterinarian shall determine the appropriate withdrawal		3. For bees, the veterinarian shall determine the appropriate withdrawal	3. For bees, the veterinarian shall determine the appropriate withdrawal
period by assessing the specific		period [] by assessing the specific	period [] by assessing the specific
situation of the particular beehive(s)		situation of the particular beehive(s)	situation of the particular beehive(s)
on a case-by-case basis.		on a case-by-case basis and in	on a case-by-case basis and in
		particular risk of residue in honey	particular risk of residue in honey
		or in any other foodstuffs	or in any other foodstuffs
		harvested from beehive(s) intended	harvested from beehive(s) intended
		for human consumption.	for human consumption.
	AM 256		
4. With regard to homeopathic	4. With regard to The	4. []	4 . []
veterinary medicinal products the	withdrawal period shall be		
withdrawal period shall be	established at zero days for		
established at zero days.	homeopathic veterinary medicinal		
	products the withdrawal period		
	shall be established at zero days.		
	containing solely active substances		
	listed in Table 1 of Regulation		
	(EU) No 37/2010 with the		
	classification "No maximum		
	residue level (MRL) required''.		
5. By way of derogation from		5. By way of derogation from	5. By way of derogation from



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
paragraph 1, the Commission shall		paragraph 1 and paragraph 6 of	paragraph 1 and paragraph 6 of
establish a list of substances:		Article 116, the Commission shall,	Article 116, the Commission shall,
		by means of implementing acts,	by means of implementing acts,
		establish a list of substances [].	establish a list of substances [].
(a) which are essential for the		[] [] which are essential for the	[] [] which are essential for the
treatment of equidae, or which bring		treatment of equine species [], or	treatment of equine species [], or
added clinical benefit compared to		which bring added clinical benefit	which bring added clinical benefit
other treatment options available for		compared to other treatment options	compared to other treatment options
equidae;		available for equine species [];	available for equine species [];
(b) for which the withdrawal		[] for which [] the withdrawal	[] for which [] the withdrawal
period for equidae shall not be less		period [] for equine species []	period [] for equine species []
than six months subject to the control		shall [] be [] six months [].	shall [] be [] six months [].
mechanisms laid down in Decisions			
93/623/EEC and 2000/68/EC.			
	AM 257		
	Article 117 paragraph 5		
	subparagraph 2 a (new)		
	Data on the use of antibiotics		
	outside the terms of authorisation		
	shall be collected and mandatorily		
	reported to national authorities in		
	accordance with Article 54.		
Those implementing acts shall be		Those implementing acts shall be	
adopted in accordance with the		adopted in accordance with the	
examination procedure referred to in		examination procedure referred to in	
Article 145(2).		Article 145(2).	

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Article 118	AM 258	Article 118	Article 118
Use of antimicrobial veterinary medicinal products for species or indications outside the terms of the marketing authorisation	Use of antimicrobial veterinary medicinal products substances for species or indications outside the terms of the marketing authorisation	[]	[]
1. Antimicrobial medicinal products shall only be used in accordance with Articles 115 and 116 to treat conditions for which there is no other treatment available, and the use of which would not present a risk to public or animal health.	AM 259 1. Antimicrobial medicinal products shall only be used in accordance with Articles 115 and 116 to treat conditions for which there is no other treatment available, and the use of which would not present a risk to public or animal health. Articles 115 and 116 do not apply to critically important antimicrobials as referred to in Article 32(2).	[]	[]
2. The Commission may, by means of implementing acts in accordance with the examination procedure referred to in Article 145(2), and taking into consideration scientific advice of the Agency, establish a list of antimicrobial medicinal products that cannot be used in accordance with paragraph 1, or which can only be used for treatment in accordance with paragraph 1 subject to certain	AM 260 2. The Commission may shall, by means of implementing acts in accordance with the examination procedure referred to in Article 145(2), and taking into consideration scientific advice of the Agency, establish a list of antimicrobial medicinal products substances or groups of substances that cannot be used in accordance with paragraph 1, or which can	[]	[]



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
conditions.	only be used for treatment in accordance with paragraph 1 subject to certain conditions.		
	AM 261 Article 118 paragraph 2 subparagraph 1 a (new) The principles to be used to establish the list of antimicrobials to be restricted in veterinary medicine shall not interfere with or deter Member States from prohibiting the use of certain antimicrobials in some species if they deem it appropriate.		
When adopting those implementing acts, the Commission shall take account of the following criteria:			
(a) risks to public health if the antimicrobial product is used in accordance with paragraph 1;	AM 262 (a) risks to public health if the antimicrobial product is used in accordance with paragraph 1, <i>including the risks involved in</i> <i>using antimicrobials critical to</i> <i>human health in food producing</i> <i>animals</i> ;		
(b) risk for human health in case of development of antimicrobial resistance;			
(c) availability of other treatments for animals,			





Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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	AM 263		
	Article 118 paragraph 2		
	subparagraph 2 point c a (new)		
	(ca) availability of other farming		
	methods that could prevent the		
	outbreak of the disease;		
(d) availability of other			
antimicrobial treatments for humans;			
(e) impact on aquaculture and			
farming if the animal affected by the condition receives no treatment.			
	AM 264		
	Article 118 paragraph 2 a		
	(new)		
	2a. Third countries with laws that		
	authorise the use of antimicrobial		
	medicinal products on the list		
	referred to in paragraph 2 under		
	different conditions from those		
	laid down in that paragraph may		
	not appear on any of the lists of		
	third countries provided for under		
	Union law from which Member		
	States are authorised to import		
	farm or aquaculture animals or		
	meat or products obtained from		
	such animals.		



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
	AM 265 Article 118 paragraph 2 b (new) 2b. Member States shall also prohibit the importation from third countries on any of the lists referred to in paragraph 2a of: (a) farm or aquaculture animals to which substances on the list referred to in paragraph 2 have been administered, unless those substances were administered in compliance with the conditions laid down in paragraph 1; (b) meat or products obtained from animals the importation of which is prohibited under point (a) of this paragraph.		
Article 119		Article 119	Article 119
Health situation and listed diseases		Health situation []	Health situation []
1. By way of derogation from		1. By way of derogation from	1.—By way of derogation from
Article 111, a competent authority		Article 111(1), a competent	Article 111(1), a competent authority
may allow the use in its territory of		authority may allow the use in its	may allow the use in its territory of
veterinary medicinal products not		territory of veterinary medicinal	veterinary medicinal products not
authorised in that Member State,		products not authorised in that	authorised in that Member State,
where the situation of animal or		Member State, where the situation	where the situation of animal or
public health so requires, and the		of animal or public health so	public health so requires, and the
marketing of those veterinary		requires, and the marketing of	marketing of those veterinary
medicinal products is authorised in		those veterinary medicinal products	medicinal products is authorised in



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another Member State.		is authorised in another Member State.	another Member State.
2. By way of derogation from Article 111, in the event of an outbreak of a listed disease as referred to in Article 5 of Regulation (EC) No/ of the European Parliament and the Council ⁷⁵ [Office of Publications, please insert number and, in a footnote, date, title and the OJ reference for the Regulation on animal health] a competent authority may allow, for a limited period of time and under specific restrictions, the use of an immunological veterinary medicinal product authorised in another Member State.	AM 266 2. By way of derogation from Article 111, in the event of an outbreak of a listed disease as referred to in Article 5 of Regulation (EC) No/ of the European Parliament and the Council31 [Office of Publications, please insert number and, in a footnote, date, title and the OJ reference for the Regulation on animal health] or any critical health situation acknowledged by the Chief Veterinary Officer of the Member State a competent authority may allow, for a limited period of time and under specific restrictions, the use of an immunological veterinary medicinal product without a marketing authorisation in the Member State in question but which is authorised either in another Member State or in accordance with the laws of a third country, in the absence of a	2. []	2. []

⁷⁵ Regulation of the European Parliament and the Council of.... on animal health (OJ L.....).



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
	suitable medicinal product and after informing the Commission of the detailed conditions of use.		
Article 120		Article-120-76	Article-120
Exemption for veterinary medicinal		[]	[]
products for certain animals kept			
exclusively as pets			
Where veterinary medicinal products		[]	[]
are intended solely for aquatic			
animals, cage birds, homing pigeons,			
terrarium animals, small rodents,			
ferrets and rabbits kept exclusively			
as pets, Member States may permit			
exemptions, in their territory, from			
Article 5, provided that such products do not contain substances			
the use of which requires veterinary			
controls and that all possible			
measures are taken to prevent			
unauthorised use of the products for			
other animals.			



⁷⁶ Moved in a Article 5(6).

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Article 121		Article 121 ⁷⁷	Article 121
Use of immunologicals from third		[]	[]
countries			
If an animal is being imported from,		[]	[]
or exported to, a third country and is			
thereby subject to specific binding			
health rules, a competent authority			
may permit the use, for the animal in			
question, of an immunological			
veterinary medicinal product that is			
not covered by a marketing			
authorisation in the Member State in			
question but is authorised under the			
legislation of the third country. A			
competent authority shall supervise			
the importation and the use of such			
immunological products.			
Article 122		Article 122	Article 122
Disposal of veterinary medicinal		Collection and disposal of []	Collection and disposal of []
products		waste of veterinary medicinal	waste of veterinary medicinal
		products	products
Member States shall ensure that		Member States shall ensure that	Member States shall ensure that
appropriate collection systems are in		appropriate [] systems are in place	appropriate [] systems are in place
place for veterinary medicinal		for the collection and disposal of	for the collection and disposal of
products that are unused or expired.		waste of veterinary medicinal	waste of veterinary medicinal
		products [].	products [].
	AM 267		
	Article 122 paragraph 1 a		

Amended and moved in new paragraph 4 of Article 113.



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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	(new)		
	Within two years of entry into		
	force of this Regulation, the		
	Commission shall develop,		
	through delegated acts, a		
	harmonised system for collecting		
	these types of products and waste		
	materials at Union level.		
		Article 122a	Article 122a
		Animals or products of animal	Animals or products of animal
		origin imported into the Union	origin imported into the Union
		1. The provisions of Article	1. The provisions of Article
		111a(1a) shall apply, <i>mutatis</i>	111a(1a) shall apply, <i>mutatis</i>
		mutandis, to operators in third	mutandis, to operators in third
		countries and they shall not use	countries and they shall not use the
		the designated antimicrobials	designated antimicrobials referred
		referred to in Article 32(4),	to in Article 32(4), insofar as
		insofar as relevant in respect of	relevant in respect of animals or
		animals or products of animal	products of animal origin exported
		origin exported from such third	from such third countries to the
		countries to the Union, provided	Union. , provided that this is
		that this is compatible with	compatible with relevant
		relevant international	international agreements.
		agreements.	Ŭ

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		2. The Commission shall adopt	2. The Commission shall adopt
		delegated acts in accordance with	delegated acts in accordance with
		Article 146 supplementing this	Article 146 supplementing this
		Article in order to provide the	Article in order to provide the
		necessary detailed rules on the	necessary detailed rules on the
		application of paragraph 1.	application of paragraph 1.
Section 4		Section 4	Section 4
Advertising		Advertising	Advertising
Article 123		Article 123	Article 123
Advertising of veterinary medicinal		Advertising of veterinary medicinal	Advertising of veterinary medicinal
products		products	products
		0. Only veterinary medicinal	0. Only veterinary medicinal
		products that are authorised or	products that are authorised or
		registered in a Member State	registered in a Member State may
		may be advertised in that	be advertised in that Member
		Member State, unless otherwise	State, unless otherwise decided by
		decided by the competent	the competent authority in
		authority in accordance with	accordance with the applicable
		the applicable national law ⁷⁸ .	national law.
1. The advertising of a veterinary		1. The advertising of a	1. The advertising of a veterinary
medicinal product shall make it clear		veterinary medicinal product shall	medicinal product shall make it clear
that it aims at promoting the		make it clear that it aims at	that it aims at promoting the []
prescription, sale or use of the		promoting the [] supply , sale,	supply, sale, prescription,
veterinary medicinal product.		prescription, distribution or use	distribution or use of the veterinary
		of the veterinary medicinal	medicinal product.
		product.	_
	AM 268	1a. The advertising shall not be	
	Article 123 paragraph 1 a	formulated in such a way as to	1a. The advertising shall not be

⁷⁸ Ex. paragraph 3.



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
	(new) Ia. Member States may provide for additional conditions in terms of advertising of veterinary medicinal products to protect public and animal health, animal welfare and the environment including conditions in terms of comparative and misleading advertising or unfair commercial practices.	suggest that the veterinary medicinal product could be a feed or a biocide.	formulated in such a way as to suggest that the veterinary medicinal product could be a feed or a biocide.
2. The advertising shall be coherent with the summary of product characteristics and shall not include information in any form which could be misleading or lead to overconsumption of the veterinary medicinal product.		2. The advertising shall [] comply with the summary of the product characteristics of the advertised veterinary medicinal product [].	2. The advertising shall [] comply with the summary of the product characteristics of the advertised veterinary medicinal product [].
•		2a. [] The advertising shall not include information in any form which could be misleading or lead to [] incorrect use of the veterinary medicinal product.	2a. [] The advertising shall not include information in any form which could be misleading or lead to [] incorrect use of the veterinary medicinal product.
		2b. The advertising shall encourage the responsible use of the veterinary medicinal product, by presenting it objectively and without exaggerating its properties.	2b. The advertising shall encourage the responsible use of the veterinary medicinal product, by presenting it objectively and without exaggerating its properties.
		3.[]4.The suspension of a marketing authorisation shall	3.[]4.The suspension of a marketing authorisation shall



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
		preclude the advertising of the	preclude the advertising of the
		veterinary medicinal product in	veterinary medicinal product in
		the Member State where it is	the Member State where it is
		suspended during the period of	suspended during the period of
		suspension.	suspension.
		5. Veterinary medicinal	5. Veterinary medicinal
		products shall not be distributed	products shall not be distributed
		for promotional purposes except	for promotional purposes except
		for small quantities of samples.	for small quantities of samples.
		5a. Antimicrobial veterinary	5a. Antimicrobial veterinary
		medicinal products shall not be	medicinal products shall not be
		distributed for promotional	distributed for promotional
		purposes as samples or in any	purposes as samples or in any
		other presentation.	other presentation.
		6. The samples referred to in	6. The samples referred to in
		paragraph 5 shall be appropriately	paragraph 5 shall be appropriately
		labelled indicating that they are	labelled indicating that they are
		samples and given directly to	samples and given directly to
		veterinarians or other persons	veterinarians or other persons
		allowed to supply during	allowed to supply during
		sponsored events or by sales	sponsored events or by sales
		representatives during their visits.	representatives during their visits.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Article 124 Prohibition of advertising of certain veterinary medicinal products		Article 124 [] Advertising of veterinary medicinal products subject to veterinary prescription	Article 124 [] Advertising of veterinary medicinal products subject to veterinary prescription
1. The advertising of the following veterinary medicinal products shall be prohibited :		1. The advertising of [] veterinary medicinal products [] that are subject to veterinary prescription in accordance with Article 29 shall be allowed only and when made exclusively to the following persons:	1. The advertising of [] veterinary medicinal products [] that are subject to veterinary prescription in accordance with Article 29 shall be allowed only and when made exclusively to the following persons:
 (a) veterinary medicinal products which are available on veterinary prescription only; (b) veterinary medicinal products 		 (a) [] veterinarians; (b) [] persons permitted to 	 (a) [] veterinarians; (b) [] persons permitted to
which contain psychotropic drugs or narcotics, including those covered by the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the United Nations Convention on Psychotropic Substances of 1971.		supply veterinary medicinal products in accordance with the national legislation.	supply veterinary medicinal products in accordance with the national legislation.
2. The prohibition laid down in paragraph 1 shall not apply to advertising to persons permitted to prescribe or supply veterinary medicinal products.	 AM 269 Article 124 paragraph 2 2. The prohibition laid down set out in paragraph 1 shall not apply to advertising to persons permitted to prescribe or supply veterinary medicinal products. 	2. [] By way of derogation from paragraph 1, advertising of veterinary medicinal products subject to veterinary prescription in accordance with Article 29 to professional keepers of animals	2. [] By way of derogation from paragraph 1, advertising of veterinary medicinal products subject to veterinary prescription in accordance with Article 29 to professional keepers of animals

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		may be permitted by the Member	may be permitted by the Member
		State provided the following	State provided the following
		conditions are fulfilled:	conditions are fulfilled:
		(a) the advertising is limited to	(a) the advertising is limited to
		immunological veterinary	immunological veterinary
		medicinal products;	medicinal products;
		(b) the advertising includes an	(b) the advertising includes an
		express invitation to the	express invitation to the
		professional keepers of animal to	professional keepers of animal to
		consult the veterinarian about the	consult the veterinarian about the
		immunological veterinary	immunological veterinary
		medicinal product.	medicinal product.
		3. Notwithstanding the	3. Notwithstanding the
		provisions of paragraphs 1 and 2	provisions of paragraphs 1 and 2
		the advertising of inactivated	the advertising of inactivated
		immunological veterinary	immunological veterinary
		medicinal products which are	medicinal products which are
		manufactured from pathogens	manufactured from pathogens and
		and antigens obtained from an	antigens obtained from an animal
		animal or animals in an	or animals in an epidemiological
		epidemiological unit and used for	unit and used for the treatment of
		the treatment of that animal or	that animal or those animals in the
		those animals in the same	same epidemiological unit or for
		epidemiological unit or for the	the treatment of animals in a unit
		treatment of animals in a unit	having a confirmed
		having a confirmed	epidemiological link shall be
		epidemiological link shall be	prohibited to all persons.
		prohibited to all persons.	
			<u>Article 124a</u>
	L		Promotion of medicinal products



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<u> </u>		· · ·	<u>used in animals</u>
			<u>1.</u> Where medicinal products
			are being promoted to persons
			qualified to prescribe or supply
			them in accordance with this
			Regulation, no gifts, pecuniary
			advantages or benefit in kind may
			be supplied, offered or promised to
			such persons unless they are
			inexpensive and relevant to the
			practice of prescription or supply
			of medicinal products.
			<u>2.</u> Persons qualified to
			prescribe or supply medicinal
			products as referred to in
			paragraph 1 shall not solicit or
			accept any inducement prohibited
			<u>under that paragraph.</u>
			3. Paragraph 1 shall not
			prevent hospitality being offered,
			directly or indirectly, at events for
			purely professional and scientific
			purposes. Such hospitality shall
			always be strictly limited to those
			main objectives of the event.
			4. Existing measures or trade



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			practices in Member States
			relating to prices, margins and
			discounts shall not be affected by
			paragraphs 1, 2 and 3.
		Article 124a	Article 124 a b
		Implementation of advertising	Implementation of advertising
		provisions	provisions
		Member States may lay down any	Member States may lay down any
		procedures they deem necessary	procedures they deem necessary
		for the implementation of Articles	for the implementation of Articles
		123 and 124.	123 <u>, and 124 and 124a</u> .
Chapter VIII		Chapter VIII	Chapter VIII
Inspections and controls		Inspections and controls	Inspections and controls
Article 125		Article 125	Article 125
Controls		Controls	Controls
	AM 270	1. Competent authorities shall	1. Competent authorities shall
1. Competent authorities shall	1. Competent authorities shall	[] carry out controls of the	[] carry out controls of the
perform controls of manufacturers,	perform controls of manufacturers,	following persons:	following persons:
importers, marketing authorisation	importers, marketing authorisation	 manufacturers and 	 manufacturers and importers
holders, wholesale distributors and	holders, wholesale distributors and	importers of veterinary	of veterinary medicinal
suppliers of the veterinary medicinal	suppliers of the veterinary	medicinal products and	products and active
products regularly, on a risk-basis, in	medicinal products as well as	active substances;	substances;
order to verify that the requirements	animals and foodstuff regularly, on	 distributors of active 	 distributors of active
as set out in this Regulation are	a risk-basis, in order to verify that	substances;	substances;
complied with.	the requirements as set out in this	 marketing authorisation 	 marketing authorisation
	Regulation are complied with.	holders;	holders;
		- holders of a wholesale []	- holders of a wholesale []
		distribution	distribution authorisation;
		authorisation;	– retailers […];
		– retailers [];	 owners and keepers of



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)	AM 271 Article 125 paragraph 1 a (new) Ia. The Commission shall ensure a harmonised approach to inspections and controls of veterinary medicines throughout the Union. AM 272 Article 125 paragraph 1 b (new) Ib. To combat fraud, the competent authorities shall establish a plan for spot checks on veterinary practices and herds to verify that medicinal products held comply with quality standards.	 by Coreper on 20 December 2017 owners and keepers of food-producing animals; veterinarians; holders of a registration for homeopathic veterinary medicinal products; holders of veterinary medicinal products authorised in accordance with Article5(6); and, any other persons having obligations under this Regulation. 1a. The controls referred to in paragraph 1 shall be carried out regularly, on a risk-basis, in order to verify that the persons referred to in paragraph 1 comply with the provisions of [] this Regulation []. 	proposed by the Presidencyfood-producing animals;- veterinarians;- holders of a registration for homeopathic veterinary medicinal products;- holders of veterinary medicinal products authorised in accordance with Article5(6); and,- any other persons having obligations under this Regulation.1a. The controls referred to in paragraph 1 shall be carried out regularly, on a risk-basis, in order to verify that the persons referred to in paragraph 1 comply with the provisions of [] this Regulation



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
2. The risk-based controls		2. The risk-based controls	2. The risk-based controls
referred to in paragraph 1 shall be		referred to in paragraph 1 a shall be	referred to in paragraph 1a shall be
carried out by the competent		carried out by the competent	carried out by the competent
authorities taking account of:		authorities taking account of at least:	authorities taking account of at least:
(a) the risk of non-compliance		(a) the intrinsic risks []	(a) the intrinsic risks []
with the legal requirements		associated with the activities of the	associated with the activities of the
associated with the activities of the		[] persons referred to in	[] persons referred to in
undertakings and the location of the		paragraph 1 and the location of	paragraph 1 and the location of
activities,		the ir activities,	the ir activities,
(b) the entity's past record as		(b) the [] past record of the	(b) the [] past record of the
regards the results of inspections		persons referred to paragraph 1	persons referred to paragraph 1
performed on them and their		[] as regards the results of []	[] as regards the results of []
compliance with the requirements,		controls performed on them and	controls performed on them and
		their previous compliance [],	their previous compliance [],
(c) any information that might		(c) any information that might	(c) any information that might
indicate non-compliance with the		indicate non-compliance [],	indicate non-compliance [],
legal requirements,			
(d) the potential impact of non-		(d) the potential impact of non-	(d) the potential impact of non-
compliance with the requirements on		compliance [] on public health,	compliance [] on public health,
public health, animal health and the		animal health, animal welfare and	animal health, animal welfare and
environment.		the environment.	the environment.
3. Inspections may also be carried		3. [] Controls may also be	3. [] Controls may also be
out upon request of another		carried out upon request of [] a	carried out upon request of [] a
competent authority, the		competent authority of another	competent authority of another
Commission or the Agency.		Member State, the Commission or	Member State, the Commission or
		the Agency.	the Agency.

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4. The inspections shall be carried out by authorised representatives of the competent authority who shall be		4. [] Controls shall be carried out by [] representatives of the competent authority. []	4. [] Controls shall be carried out by [] representatives of the competent authority. []
empowered to:			
		4a. Inspections may be carried out as part of the controls. Such inspection may be made unannounced. During these inspections the representatives of a competent authority shall at least be empowered to:	4a. Inspections may be carried out as part of the controls. Such inspection may be made unannounced. During these inspections the representatives of a competent authority shall at least be empowered to:
(a) inspect manufacturing or supply establishments and any laboratories entrusted by the manufacturing authorisation holder with the task of carrying out control tests;		(a) inspect [] the premises, equipment, means of transport, records, documents and systems, related to the objective of the inspection;	(a) inspect [] the premises, equipment, means of transport, records, documents and systems, related to the objective of the inspection;
(b) take samples of veterinary medicinal products and starting materials, including with a view to submit them for an independent analysis by an Official Medicines Control Laboratory or by a laboratory designated for that purpose by a Member State;		 (b) inspect and take samples [] with a view to submit them for an independent analysis by an Official Medicines Control Laboratory or by a laboratory designated for that purpose by a Member State; 	(b) inspect and take samples [] with a view to submit them for an independent analysis by an Official Medicines Control Laboratory or by a laboratory designated for that purpose by a Member State;

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(c) examine any documents relating to the object of the		(c) [] document any evidence deemed necessary by the	(c) [] document any evidence deemed necessary by the
inspection;		representatives;	representatives;
(d) inspect the premises, records, documents and pharmacovigilance systems of marketing authorisation holders or any parties performing the activities as provided in Chapter IV		(d) carry out the same controls on any parties performing the tasks required under this Regulation with, for or on behalf of the persons referred to in paragraph	(d) carry out the same controls on any parties performing the tasks required under this Regulation with, for or on behalf of the persons referred to in paragraph 1
on behalf of a marketing authorisation holder.		1 [].	[].
If necessary, the inspections may be carried out unannounced.	AM 273 If necessary, the All inspections may shall be carried out unannounced.		
	AM 274 Article 125 paragraph 4 a (new)		
	<i>4a. Inspections may also be carried out on the premises of manufacturers of active</i>		
	substances used as starting materials for veterinary medicinal products where there are grounds		
	for suspecting non-compliance with good manufacturing practices.		

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5. After each control, a competent		5. [] The representatives of	5. [] The representatives of
authority shall draft a report on		the competent authorities shall	the competent authorities shall
compliance with the requirements set		keep record s of every control	keep record s of every control that
out in this Regulation. Before		that they carry out and where	they carry out and where
adopting a report, the inspected		necessary shall draw up a report.	necessary shall draw up a report.
entity shall have the opportunity to		The person referred to in	The person referred to in
submit comments.		paragraph 1 shall be promptly	paragraph 1 shall be promptly
		informed in writing by the	informed in writing by the
		competent authority of any case	competent authority of any case of
		of non-compliance identified	non-compliance identified through
		through the controls and shall	the controls and shall have the
		have the opportunity to submit	opportunity to submit comments
		comments within a time set by	within a time set by the competent
		the competent authority.	authority.
			6a. The competent authorities
			shall have procedures or
			arrangements in place to ensure
			that staff performing controls are
			free of any conflict of interest.
	AM 275	6. []	6. []
6. Inspection reports shall be	6. Inspection reports shall be		
uploaded to the appropriate database,	uploaded to the appropriate		
with continuous access for all	database, with continuous access		
competent authorities.	for all competent authorities. A		
	summary of the inspection results		
	shall be made publicly available.		

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Article 126		Article 126	Article 126
Audits by the Commission		Audits by the Commission	Audits by the Commission
The Commission may carry out		The Commission may carry out	The Commission may carry out
audits in Member States for the		audits in Member States on their	audits in Member States on their
purpose of verifying the controls		competent authorities, for the	competent authorities, for the
carried out by the competent		purpose of [] confirming the	purpose of [] confirming the
authorities. After each audit, the		appropriateness of the controls	appropriateness of the controls
Commission shall draft a report		carried out by [] those	carried out by [] those competent
containing, where appropriate,		competent authorities. Such audits	authorities. Such audits shall be
recommendations to the Member		shall be coordinated with the	coordinated with the Member
State concerned. The audit report		Member State concerned and	State concerned and shall be
may be made public by the		shall be carried out in a manner	carried out in a manner which
Commission.		which avoids unnecessary	avoids unnecessary administrative
		administrative burden.	burden.
		After each audit the Commission	After each audit the Commission
		shall draft a report containing, where	shall draft a report containing, where
		appropriate, recommendations to the	appropriate, recommendations to the
		Member State concerned. The	Member State concerned. The
		Commission shall send the draft	Commission shall send the draft
		report to the competent authority	report to the competent authority
		for comments and shall take into	for comments and shall take into
		account any such comments in	account any such comments in
		drawing up the final report. The	drawing up the final report. The
		[] final report and the comments	[] final report and the comments
		[] shall be made public by the	[] shall be made public by the
		Commission.	Commission.
Article 127		Article 127 ⁷⁹	Article 127
Certificates of good manufacturing		[]	[]

⁷⁹ Moved to new Article 98a



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practice			
1. Within 90 days after an		[]	[]
inspection of a manufacturer, a			
certificate of good manufacturing			
practice shall be issued to the			
manufacturer if the inspection			
established that the manufacturer in			
question is complying with the			
requirements as set out in this			
Regulation and taking due account of			
the principles and guidelines on good			
manufacturing practice.			
2. Competent authorities shall		[]	[]
enter the certificates of good			
manufacturing practice into the			
database for manufacturing			
authorisations.			
3. The conclusions reached		[]	[]
following an inspection of a			
manufacturer shall be valid			
throughout the Union.			
4. The competent authority may		[]	[]
carry out inspections of starting			
material manufacturers at the			
manufacturer's own request. The			
competent authority shall verify that			
the manufacturing processes used in			
the manufacture of immunological			
veterinary medicinal products are			
validated and batch-to-batch			



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consistency is ensured.			
5. Without prejudice to any arrangements which may have been concluded between the Union and a third country, a competent authority, the Commission or the Agency may require a manufacturer established in a third country to undergo an inspection as referred to in paragraph 1.		[]	[]
6. In order to verify whether the data submitted for obtaining a conformity certificate comply with the monographs of the European Pharmacopoeia, the standardisation body for nomenclatures and quality norms within the meaning of the Convention on the elaboration of a European Pharmacopoeia accepted by Council Decision 94/358/EC ⁸⁰ (European Directorate for the Quality of Medicines & Healthcare) may ask the Commission or the Agency to request an inspection when the starting material concerned is subject to a European Pharmacopoeia monograph. In the		[]	[]

⁸⁰ Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).



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event of an inspection carried out			
upon request of the European			
Pharmacopoeia (European			
Directorate for the Quality of			
Medicines & Healthcare), a			
certificate of compliance with the			
monograph shall be issued.		Article 127a	Article 127a
		Certificate of suitability	Certificate of suitability
		[] In order to verify whether the	[] In order to verify whether the
		data submitted for obtaining a []	data submitted for obtaining a []
		certificate of suitability complies	certificate of suitability complies
		with the monographs of the	with the monographs of the
		European Pharmacopoeia the	European Pharmacopoeia the
		standardisation body for	standardisation body for
		nomenclatures and quality norms	nomenclatures and quality norms
		within the meaning of the	within the meaning of the
		Convention on the elaboration of a	Convention on the elaboration of a
		European Pharmacopoeia accepted	European Pharmacopoeia accepted
		by Council Decision 94/358/EC	by Council Decision 94/358/EC ⁸¹
		(European Directorate for the	(European Directorate for the
		Quality of Medicines & Healthcare)	Quality of Medicines & Healthcare)
		may ask the Commission or the	may ask the Commission or the
		Agency to request an inspection by a	Agency to request an inspection by a
		competent authority when the	competent authority when the
		starting material concerned is subject	starting material concerned is subject
		to a European Pharmacopoeia	to a European Pharmacopoeia

⁸¹ Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia (OJ L 158, 25.6.1994, p. 17).

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		monograph. []	monograph. []
Article 128		Article 128	Article 128
Specific rules on pharmacovigilance		Specific rules on pharmacovigilance	Specific rules on pharmacovigilance
inspections		inspections	inspections
1. The pharmacovigilance		1. The competent authorities	1. The competent authorities
inspections shall be coordinated by		and the [] Agency [] shall	and the [] Agency [] shall
the Agency together with the		ensure that all pharmacovigilance	ensure that all pharmacovigilance
competent authorities and shall		system master files in the Union []	system master files in the Union []
ensure that all pharmacovigilance		are regularly checked and that the	are regularly checked and that the
system master files in the Union, as		pharmacovigilance systems are	pharmacovigilance systems are
identified in the product database,		being correctly applied.	being correctly applied.
are regularly checked.			
		1a. Inspections on the	1a. Inspections on the
		pharmacovigilance systems of	pharmacovigilance systems of
		veterinary medicinal products	veterinary medicinal products
		authorised in accordance with	authorised in accordance with
		Article 40 shall be coordinated by	Article 40 shall be coordinated by
		the Agency and carried out by the	the Agency and carried out by the
		competent authorities.1b. Inspections on the	competent authorities. 1b. Inspections on the
		pharmacovigilance systems of	pharmacovigilance systems of
		veterinary medicinal products	veterinary medicinal products
		authorised in accordance with	authorised in accordance with
		Article 44, Article 46 and Article	Article 44, Article 46 and Article
		48 and 48a shall be carried out by	48 and 48a shall be carried out by
		the competent authorities.	the competent authorities.
2. The competent authority in the		2. Inspections of the	2. Inspections of the
Member State in which the qualified		pharmacovigilance systems master	pharmacovigilance systems master
person responsible for		files shall be carried out by [] the	files shall be carried out by [] the
pharmacovigilance operates shall		competent authorities [] of the	competent authorities [] of the

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carry out pharmacovigilance		Member States in which the	Member States in which the
inspections. Any work-sharing		pharmacovigilance system master	pharmacovigilance system master
initiatives and delegation of		files are located. []	files are located. []
responsibilities between competent			
authorities shall ensure that there is			
no duplication of inspections of			
pharmacovigilance system master			
files.			
		2a. Notwithstanding paragraph 2	2a. Notwithstanding paragraph 2
		and pursuant to Article 80, a	and pursuant to Article 80, a
		competent authority may enter	competent authority may enter
		into any work-sharing initiatives and	into any work-sharing initiatives and
		delegation of responsibilities []	delegation of responsibilities []
		with other competent authorities	with other competent authorities
		[] to avoid the duplication of	[] to avoid the duplication of
		inspections of pharmacovigilance	inspections of pharmacovigilance
		systems.[].	system s .[].
3. The results of the		3. The results of the	3. The results of the
pharmacovigilance inspections shall		pharmacovigilance inspections shall	pharmacovigilance inspections shall
be collected in the		be recorded [] in the	be recorded [] in the
pharmacovigilance database.		pharmacovigilance database as	pharmacovigilance database as
		referred to in Article 74.	referred to in Article 74.

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	AM 276 Article 128 paragraph 3 a (new) <i>3a. The Agency and the</i>		
	Commission shall ensure a harmonised approach to veterinary medicine inspections.		
Article 129	meature inspections.	Article 129	Article 129
Proof of the product quality		Proof of the product quality for veterinary medicinal products	Proof of the product quality for veterinary medicinal products
1. The marketing authorisation holder shall provide proof of the control tests carried out on the veterinary medicinal product or on the constituents and intermediate products of the manufacturing process, in accordance with the methods laid down in marketing authorisation.		 The marketing authorisation holder shall have at his disposal the results of the control tests carried out on the veterinary medicinal product or on the constituents and intermediate products of the manufacturing process, in accordance with the methods laid down in marketing authorisation. If a competent authority canceled as that a batch of a 	 The marketing authorisation holder shall have at his disposal the results of the control tests carried out on the veterinary medicinal product or on the constituents and intermediate products of the manufacturing process, in accordance with the methods laid down in marketing authorisation. If a competent authority canaludas that a batab of a
		concludes that a batch of a veterinary medicinal product is not in conformity with the control report of the manufacturer or the specifications provided for in the marketing authorisation, it shall take measures vis-a-vis the marketing authorisation holder and the manufacturer, and shall inform accordingly the competent	concludes that a batch of a veterinary medicinal product is not in conformity with the control report of the manufacturer or the specifications provided for in the marketing authorisation, it shall take measures vis-a-vis the marketing authorisation holder and the manufacturer, and shall inform accordingly the competent

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		authorities of other Member States	authorities of other Member States
		in which the veterinary medicinal	in which the veterinary medicinal
		product is authorised, and also the	product is authorised, and also the
		Agency in the case the veterinary	Agency in the case the veterinary
		medicinal product is authorised	medicinal product is authorised
		under the centralised procedure. ⁸²	under the centralised procedure.
		Article 129a	Article 129a
		Proof of the product quality specific	Proof of the product quality specific
		for immunological veterinary	for immunological veterinary
		medicinal products	medicinal products
2. For the purposes of application		[] 1. For the purposes of	[] 1. For the purposes of
of paragraph 1, competent authorities		application of paragraph 1 of Article	application of paragraph 1 of Article
may require the marketing		129 , competent authorities may	129 , competent authorities may
authorisation holder for		require the marketing authorisation	require the marketing authorisation
immunological veterinary medicinal		holder for immunological veterinary	holder for immunological veterinary
products to submit to the competent		medicinal products to submit to the	medicinal products to submit to the
authorities the copies of all the		competent authorities the copies of	competent authorities the copies of
control reports signed by the		all the control reports signed by the	all the control reports signed by the
qualified person in accordance with		qualified person in accordance with	qualified person in accordance with
Article 101.		Article 100 [].	Article 100 [].

⁸² Ex-paragraph 11 of Article 129 of the Commission proposal.

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3. The marketing authorisation		[] 2 . The marketing	[] 2 . The marketing
holder for immunological veterinary		authorisation holder for	authorisation holder for
medicinal products shall ensure that		immunological veterinary medicinal	immunological veterinary medicinal
an adequate number of representative		products shall ensure that an	products shall ensure that an
samples of each batch of veterinary		adequate number of representative	adequate number of representative
medical products is held in stock at		samples of each batch of veterinary	samples of each batch of veterinary
least up to the expiry date, and		medical products is held in stock at	medical products is held in stock at
provide samples promptly to the		least up to the expiry date, and	least up to the expiry date, and
competent authorities upon request.		provide samples promptly to the	provide samples promptly to the
		competent authorities upon request.	competent authorities upon request.
4. Where necessary for reasons of		[] 3. Where necessary for	[] 3. Where necessary for
human or animal health, a competent		reasons of human or animal health, a	reasons of human or animal health, a
authority may require the marketing		competent authority may require the	competent authority may require the
authorisation holder for an		marketing authorisation holder for an	marketing authorisation holder for an
immunological veterinary medicinal		immunological veterinary medicinal	immunological veterinary medicinal
product to submit samples of batches		product to submit samples of batches	product to submit samples of batches
of the bulk product and/or veterinary		of the bulk product and/or	of the bulk product and/or
medicinal product for control by an		immunological veterinary medicinal	immunological veterinary medicinal
Official Medicines Control		product for control by an Official	product for control by an Official
Laboratory before the product is		Medicines Control Laboratory before	Medicines Control Laboratory before
made available on the market.		the product is [] placed on the	the product is [] placed on the
		market.	market.
5. Upon request by the competent		[] 4 . Upon request by [] a	[] 4 . Upon request by [] a
authority, the marketing		competent authority, the marketing	competent authority, the marketing
authorisation holder shall promptly		authorisation holder shall promptly	authorisation holder shall promptly
supply the samples referred to in		supply the samples referred to in	supply the samples referred to in
paragraph 4, together with the		paragraph [] 2, together with the	paragraph [] 2, together with the
reports of the control referred to in		reports of the control referred to in	reports of the control referred to in
this Chapter. The competent		[] paragraph 1, for control	[] paragraph 1, for control
authority shall inform the competent		testing. The competent authority	testing. The competent authority



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD) authorities in other Member States in which the veterinary medicinal product is authorised as well as the European Directorate for the Quality of Medicines & HealthCare of its intention to control batches or the batch in question.		by Coreper on 20 December 2017 shall inform the competent authorities in other Member States in which the immunological veterinary medicinal product is authorised as well as the European Directorate for the Quality of Medicines & HealthCare and the Agency in the case that immunological veterinary medicinal products is authorised under the centralised procedure, of its intention to control batches of the	proposed by the Presidency shall inform the competent authorities in other Member States in which the immunological veterinary medicinal product is authorised as well as the European Directorate for the Quality of Medicines & HealthCare and the Agency in the case that immunological veterinary medicinal products is authorised under the centralised procedure, of its intention to control batches of the
		immunological veterinary medicinal products.[]	immunological veterinary medicinal products.[]
In such cases, the competent authorities of another Member State shall not apply the provisions of paragraph 4.		[]	[]
6. On the basis of the control reports referred to in this Chapter, the laboratory responsible for the control shall repeat, on the samples provided, all the tests carried out by the manufacturer on the finished product, in accordance with the relevant provisions shown in the dossier for marketing authorisation.		[] 5. On the basis of the control reports referred to in this Chapter, the laboratory responsible for the control [] shall repeat, on the samples provided, all the tests carried out by the manufacturer on the finished immunological veterinary medicinal product, in accordance with the relevant specifications in its dossier provisions shown in the dossier for marketing authorisation.	[] 5. On the basis of the control reports referred to in this Chapter, the laboratory responsible for the control [] shall repeat, on the samples provided, all the tests carried out by the manufacturer on the finished immunological veterinary medicinal product, in accordance with the relevant specifications in its dossier provisions shown in the dossier for marketing authorisation.
7. The list of tests to be repeated		[] 6 . The list of tests to be	[] 6 . The list of tests to be



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by the laboratory responsible for the		repeated by the laboratory	repeated by the laboratory
control shall be restricted to justified		responsible for the control shall be	responsible for the control shall be
tests, provided that all competent		restricted to justified tests, provided	restricted to justified tests, provided
authorities in the Member States		that all competent authorities in the	that all competent authorities in the
concerned, and if appropriate the		Member States concerned, and if	Member States concerned, and if
European Directorate for the Quality		appropriate the European Directorate	appropriate the European Directorate
of Medicines & HealthCare, agree to		for the Quality of Medicines &	for the Quality of Medicines &
this.		HealthCare, agree to this.	HealthCare, agree to this.
For immunological veterinary		For immunological veterinary	For immunological veterinary
medicinal products authorised under		medicinal products authorised under	medicinal products authorised under
the centralised procedure, the list of		the centralised procedure, the list of	the centralised procedure, the list of
tests to be repeated by the control		tests to be repeated by the control	tests to be repeated by the control
laboratory may be reduced only upon		laboratory may be reduced only upon	laboratory may be reduced only upon
agreement of the Agency.		agreement of the Agency.	agreement of the Agency.
8. The competent authorities shall		[] 7. The competent authorities	[] 7. The competent authorities
recognise the results of the tests.		shall recognise the results of the tests	shall recognise the results of the tests
		referred to in paragraph 5.	referred to in paragraph 5.
9. Unless the Commission is		[] 8. Unless the Commission is	[] 8. Unless the Commission is
informed that a longer period is		informed that a longer period is	informed that a longer period is
necessary to conduct the tests, the		necessary to conduct the tests, the	necessary to conduct the tests, the
competent authorities shall ensure		competent authorities shall ensure	competent authorities shall ensure
that this control is completed within		that this control is completed within	that this control is completed within
60 days of receipt of the samples.		60 days of receipt of the samples and	60 days of receipt of the samples and
		control reports.	control reports.
10. The competent authority shall		[] 9. The competent authority shall	[] 9. The competent authority shall
notify the competent authorities of		notify the competent authorities of	notify the competent authorities of
other Member States concerned, the		other Member States concerned, the	other Member States concerned, the
European Directorate for the Quality		European Directorate for the Quality	European Directorate for the Quality
of Medicines & HealthCare, the		of Medicines & HealthCare, the	of Medicines & HealthCare, the
marketing authorisation holder and,		marketing authorisation holder and,	marketing authorisation holder and,



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if appropriate, the manufacturer, of		if appropriate, the manufacturer, of	if appropriate, the manufacturer, of
the results of the tests within the		the results of the tests within the	the results of the tests within the
same period of time.		same period of time.	same period of time.
11. If a competent authority		[] 10 . []	[] 10 . []
concludes that a batch of a veterinary			
medicinal product is not in			
conformity with the control report of			
the manufacturer or the			
specifications provided for in the			
marketing authorisation, it shall take			
measures vis-a-vis the marketing			
authorisation holder and the			
manufacturer, and shall inform			
accordingly the competent			
authorities of other Member States in			
which the veterinary medicinal			
product is authorised.			
		11. The competent authority	11. The competent authority
		shall verify that the manufacturing	shall verify that the manufacturing
		processes used in the manufacture	processes used in the manufacture
		of immunological veterinary	of immunological veterinary
		medicinal products are validated	medicinal products are validated
		and that batch-to-batch	and that batch-to-batch
		consistency is ensured.	consistency is ensured.

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Chapter IX		Chapter IX	Chapter IX
Restrictions and penalties		Restrictions and penalties	Restrictions and penalties
Article 130		Article 130	Article 130
Temporary safety restrictions		Temporary safety restrictions	Temporary safety restrictions
1. In the event of a risk to public		1. In the event of a risk to public	1. In the event of a risk to public
or animal health or to the		or animal health or to the	or animal health or to the
environment that requires urgent		environment that requires urgent	environment that requires urgent
action, the competent authorities or,		action, [] temporary safety	action, [] temporary safety
in the case of centralised marketing		restrictions may be imposed on the	restrictions may be imposed on the
authorisations, the Commission may		marketing authorisation holder and	marketing authorisation holder and
impose temporary safety restrictions		other persons having obligations	other persons having obligations
on the marketing authorisation		under this Regulation by the	under this Regulation by the
holder, including suspending the		competent authority and, in the	competent authority and, in the
marketing authorisation and/or		case of centrally authorised	case of centrally authorised
prohibiting the supply of a veterinary		veterinary medicinal product, also	veterinary medicinal product, also
medicinal product. Other Member		by the Commission. The	by the Commission. The
States and, where the temporary		temporary safety restrictions may	temporary safety restrictions may
safety restriction is imposed by a		include: []	include: []
competent authority, the			
Commission shall be informed of the			
temporary safety restriction imposed			
on the following working day at the			
latest.			
		(a) restriction of supply of the	(a) restriction of supply of the
		veterinary medicinal product at	veterinary medicinal product at
		the request of the competent	the request of the competent
		authority and, in the case of	authority and, in the case of
		centrally authorised veterinary	centrally authorised veterinary
		medicinal product, also at the	medicinal product, also at the
		request of the Commission to the	request of the Commission to the

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		competent authority;	competent authority;
		(b) restriction of the use of the	(b) restriction of the use of the
		veterinary medicinal product at	veterinary medicinal product at
		the request of the competent	the request of the competent
		authority and, in the case of	authority and, in the case of
		centrally authorised veterinary	centrally authorised veterinary
		medicinal product, also at the	medicinal product, also at the
		request of the Commission to the	request of the Commission to the
		competent authority;	competent authority;
		(c) suspension of a marketing	(c) suspension of a marketing
		authorisation by the competent	authorisation by the competent
		authority having granted that	authority having granted that
		marketing authorisation and, in	marketing authorisation and, in
		the case of centrally authorised	the case of centrally authorised
		veterinary medicinal product, by	veterinary medicinal product, by
		the Commission.	the Commission.
		1a. The competent authority	1a. The competent authority
		concerned shall inform the other	concerned shall inform the other
		competent authorities and the	competent authorities and the
		Commission of any temporary	Commission of any temporary
		safety restriction imposed at the	safety restriction imposed at the
		latest on the following working	latest on the following working
		day. In the case of centralised	day. In the case of centralised
		marketing authorisations, the	marketing authorisations, the
		Commission shall inform within	Commission shall inform within
		the same time the competent	the same time the competent
		authorities of any temporary	authorities of any temporary
		safety restriction imposed.	safety restriction imposed.
2. Member States and the		2 [] Competent authorities	2 [] Competent authorities
Commission may refer the issue to		and the Commission may, at the	and the Commission may, at the

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the Agency in accordance with		same time as imposing the	same time as imposing the
Article 84.		restriction in accordance with	restriction in accordance with
		paragraph 1, refer the issue to the	paragraph 1, refer the issue to the
		Agency in accordance with Article	Agency in accordance with Article
		84.	84.
3. Where applicable, the		3. Where applicable, the	3. Where applicable, the
marketing authorisation holder shall		marketing authorisation holder shall	marketing authorisation holder shall
submit an application for a variation		submit an application for a variation	submit an application for a variation
to the terms of the marketing		to the terms of the marketing	to the terms of the marketing
authorisation in accordance with		authorisation in accordance with	authorisation in accordance with
Article 61.		Article 61.	Article 61.
Article 131		Article 131	Article 131
Suspending, withdrawing or varying		Suspending, [] revoking or	Suspending, [] revoking or
marketing authorisations		varying the terms of marketing	varying the terms of marketing
		authorisations	authorisations
1. The competent authority or the		1. The competent authority or, in	1. The competent authority or, in
Commission shall suspend or		the case of centralised marketing	the case of centralised marketing
withdraw the marketing authorisation		authorisations, the Commission,	authorisations, the Commission,
if the benefit-risk balance of the		shall suspend or [] revoke or	shall suspend or [] revoke or
veterinary medicinal product is		request the marketing	request the marketing
unfavourable.		authorisation holder to submit an	authorisation holder to submit an
		application for a variation to the	application for a variation to the
		terms of the marketing authorisation	terms of the marketing authorisation
		if the benefit-risk balance of the	if the benefit-risk balance of the
		veterinary medicinal product is no	veterinary medicinal product is no
		longer []favourable or is	longer []favourable or is

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2. The competent authority or the Commission shall suspend or withdraw the marketing authorisation or request the marketing authorisation holder to submit an application for a variation to the terms of the marketing authorisation where the withdrawal period is inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a public health hazard.		2. [] insufficient to ensure food safety.	2. [] insufficient to ensure food safety.
		2a. The competent authority or, in the case of centralised marketing authorisations, the Commission, shall revoke the marketing authorisation if the marketing authorisation holder no longer fulfils the requirement on establishment in the Union, set out in Article 5(4).	2a. The competent authority or, in the case of centralised marketing authorisations, the Commission, shall revoke the marketing authorisation if the marketing authorisation holder no longer fulfils the requirement on establishment in the Union, set out in Article 5(4).
3. The competent authority or the Commission may suspend or withdraw the marketing authorisation or request the marketing authorisation holder to submit an application for a variation to the terms of the marketing authorisation in case of any of the following:		3. The competent authority or, in the case of centralised marketing authorisations, the Commission may suspend or [] revoke the marketing authorisation or request the marketing authorisation holder to submit an application for a variation to the terms of the marketing authorisation, as applicable, in case	3. The competent authority or, in the case of centralised marketing authorisations, the Commission may suspend or [] revoke the marketing authorisation or request the marketing authorisation holder to submit an application for a variation to the terms of the marketing authorisation, as applicable, in case



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		of one or more [] of the	of one or more [] of the
		following:	following:
(a) the marketing authorisation		(a) the marketing authorisation	(a) the marketing authorisation
holder does not comply with the		holder does not comply with the	holder does not comply with the
requirements set out in Article 55;		requirements set out in Article 55;	requirements set out in Article 55;
(b) the marketing authorisation		(b) the marketing authorisation	(b) the marketing authorisation
holder does not comply with the		holder does not comply with the	holder does not comply with the
requirements set out in Article 129;		requirements set out in Article 129;	requirements set out in Article 129;
(c) the pharmacovigilance system		(c) the pharmacovigilance system	(c) the pharmacovigilance system
required in accordance with Article		established [] in accordance with	established [] in accordance with
72 is inadequate;		paragraph 0 of Article 77[] is	paragraph 0 of Article 77[] is
		inadequate;	inadequate;
(d) the marketing authorisation		(d) the marketing authorisation	(d) the marketing authorisation
holder does not fulfil his obligations		holder does not fulfil his obligations	holder does not fulfil his obligations
laid down in Article 77;		laid down in Article 77;	laid down in Article 77;
(e) the maximum residue limit for		(e) [] the qualified person	(e) [] the qualified person
the active substance established in		responsible for pharmacovigilance	responsible for pharmacovigilance
accordance with Regulation (EC) No		does not fulfill his tasks as laid	does not fulfill his tasks as laid
470/2009 has been amended.		down in Article 78.	down in Article 78.
4. For the purpose of paragraphs		4. For the purpose of paragraphs	4. For the purpose of paragraphs
1 to 3, before taking action, the		1 to 3, in case of centralised	1 to 3, in case of centralised
Commission shall request, where		marketing authorisations, before	marketing authorisations, before
appropriate, the opinion of the		taking action, the Commission shall	taking action, the Commission shall
Agency within time-limit which it		request, where appropriate, the	request, where appropriate, the
shall determine in the light of the		opinion of the Agency within time-	opinion of the Agency within time-
urgency of the matter, in order to		limit which it shall determine in the	limit which it shall determine in the
examine the reasons. Whenever		light of the urgency of the matter, in	light of the urgency of the matter, in
practicable, the holder of the		order to examine the reasons. []	order to examine the reasons. []
marketing authorisation for the		The holder of the marketing	The holder of the marketing
veterinary medicinal product shall be		authorisation for the veterinary	authorisation for the veterinary



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invited to provide oral or written		medicinal product shall be invited to	medicinal product shall be invited to
explanations.		provide oral or written explanations	provide oral or written explanations
explainations.		within a given deadline.	within a given deadline.
5. Following an opinion by the		[] Following an opinion by the	[] Following an opinion by the
Agency, the Commission shall adopt,		Agency, the Commission shall adopt,	Agency, the Commission shall adopt,
where necessary, provisional		where necessary, provisional	where necessary, provisional
measures, which shall be applied		measures, which shall be applied	measures, which shall be applied
immediately. The Commission shall,		immediately. The Commission shall,	immediately. The Commission shall,
by means of implementing acts, take		by means of implementing acts, take	by means of implementing acts, take
a final decision. Those implementing		a final decision. Those implementing	a final decision. Those implementing
acts shall be adopted in accordance		acts shall be adopted in accordance	acts shall be adopted in accordance
with the examination procedure		with the examination procedure	with the examination procedure
referred to in Article 145(2).		referred to in Article 145(2).	referred to in Article 145(2).
6. Member States shall lay down		[] 5 . Member States shall lay	[] 5 . Member States shall lay
procedures for application of		down procedures for application of	down procedures for application of
paragraphs 1 to 3.		paragraphs 1 to 3.	paragraphs 1 to 3.
		Article 131a	Article 131a
		Suspending and revoking a	Suspending and revoking a
		wholesale distribution authorisation	wholesale distribution authorisation
		1. In the event of non-	1. In the event of non-
		compliance with the requirements	compliance with the requirements
		laid down in paragraph 3 of	laid down in paragraph 3 of
		Article 105a the competent	Article 105a the competent
		authority shall suspend or revoke	authority shall suspend or revoke
		the wholesale distribution	the wholesale distribution
		authorisation of veterinary	authorisation of veterinary
		medicinal products.	medicinal products.

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		2. In the event of non-	2. In the event of non-
		compliance with the requirements	compliance with the requirements
		laid down in Article 105a,other	laid down in Article 105a,other
		than paragraph 3 thereof, the	than paragraph 3 thereof, the
		competent authority may, without	competent authority may, without
		prejudice to any other appropriate	prejudice to any other appropriate
		measures according to national	measures according to national
		law, take one or more of the	law, take one or more of the
		following measures:	following measures:
		(a) suspend the wholesale	(a) suspend the wholesale
		distribution authorisation;	distribution authorisation;
		(b) suspend the wholesale	(b) suspend the wholesale
		distribution authorisation for one	distribution authorisation for one
		or more a categories of veterinary	or more a categories of veterinary
		medicinal products;	medicinal products;
		(c) revoke the wholesale	(c) revoke the wholesale
		distribution authorisation for one	distribution authorisation for one
		or more category of veterinary	or more category of veterinary
		medicinal products.	medicinal products.
		Article 131b	Article 131b
		Removal of importers,	Removal of importers,
		manufacturers and distributors of	manufacturers and distributors of
		active substance from the	active substance from the
		manufacturing and wholesale	manufacturing and wholesale
		distribution data base	distribution data base
		In the event of non-compliance of	In the event of non-compliance of
		importers, manufacturers and	importers, manufacturers and
		distributors of active substance	distributors of active substance
		with the requirements laid down in	with the requirements laid down in
		Article 98b, the competent	Article 98b, the competent

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		authority shall, temporarily or	authority shall, temporarily or
		definitively, remove them from the	definitively, remove them from the
		manufacturing and wholesale	manufacturing and wholesale
		distribution data base.	distribution data base.
Article 132		Article 132	Article 132
Suspending and withdrawing		Suspending and [] revoking	Suspending and [] revoking
manufacturing authorisations		manufacturing authorisations	manufacturing authorisations
In the event of non-compliance with		1. In the event of non-compliance	1. In the event of non-compliance
the requirements laid down in Article		with the requirements laid down in	with the requirements laid down in
98, the competent authority shall		Article 98 [], the competent	Article 98 [], the competent
take any of the following measures:		authority shall, without prejudice to	authority shall, without prejudice to
		any other appropriate measures	any other appropriate measures
		according to national law, take one	according to national law, take one
		or more [] of the following	or more [] of the following
		measures:	measures:
(a) suspend manufacture of		(a) suspend the manufacture of	(a) suspend the manufacture of
veterinary medicinal products;		veterinary medicinal products;	veterinary medicinal products;
(b) suspend imports of veterinary		(b) suspend imports of veterinary	(b) suspend imports of veterinary
medicinal products from third		medicinal products from third	medicinal products from third
countries;		countries;	countries;
(c) suspend the manufacturing		(c) suspend or revoke the	(c) suspend or revoke the
authorisation for a category of		manufacturing authorisation for a	manufacturing authorisation for a
preparations or for all preparations;		one or more pharmaceutical forms	one or more pharmaceutical forms
		[];	[];
		(ca) suspend or revoke one or	(ca) suspend or revoke one or
		more activities in one or more	more activities in one or more
		manufacturing sites.	manufacturing sites.



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(d) withdraw the manufacturing		(d) []	(d) []
authorisation for a category of			
preparations or for all preparations.			
	AM 277		
	Article 132 a (new)		
	Article 132a		
	Suspending and withdrawing		
	wholesale distribution		
	authorisations		
	In cases of non-compliance with		
	the requirements laid down in		
	Articles 104, 105 and 106, the		
	competent authority may:		
	(a) suspend the wholesale		
	distribution of the veterinary		
	medicinal products;		
	(b) suspend the authorisation for		
	wholesale distribution of a		
	category of veterinary medicinal		
	products;		
	(c) withdraw the authorisation for		
	wholesale distribution of a		
	category, or all categories, of		
	veterinary medicinal products.		

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Article 133		Article 133	Article 133
Prohibiting supply of veterinary		Prohibiting the supply of veterinary	Prohibiting the supply of veterinary
medicinal products		medicinal products	medicinal products
1. In duly justified cases, the		1. [] In the event of a risk to	1. [] In the event of a risk to
competent authority or the		public or animal health or to the	public or animal health or to the
Commission shall prohibit the supply		environment, the competent	environment, the competent
of a veterinary medicinal product and		authority or, in the case of centrally	authority or, in the case of centrally
require the marketing authorisation		authorised products the	authorised products the
holder to withdraw the veterinary		Commission, shall prohibit the	Commission, shall prohibit the
medicinal product from the market if		supply of a veterinary medicinal	supply of a veterinary medicinal
any of the following apply:		product and require the marketing	product and require the marketing
		authorisation holder and/or	authorisation holder and/or
		suppliers to cease the supply	suppliers to cease the supply
		and/or [] recall the veterinary	and/or [] recall the veterinary
		medicinal product from the market if	medicinal product from the market if
		any of the following apply:	any of the following apply:
(a) the benefit-risk balance of the		(a) the benefit-risk balance of the	(a) the benefit-risk balance of the
veterinary medicinal product is		veterinary medicinal product is no	veterinary medicinal product is no
unfavourable;		longer []favourable;	longer []favourable;
(b) the qualitative and quantitative		(b) the qualitative and/ or	(b) the qualitative and/ or
composition of the veterinary		quantitative composition of the	quantitative composition of the
medicinal product is not as stated in		veterinary medicinal product is not	veterinary medicinal product is not
the summary of the product		as stated in the summary of the	as stated in the summary of the
characteristics referred to in Article		product characteristics referred to in	product characteristics referred to in
30;		Article 30;	Article 30;
(c) the recommended withdrawal		(c) the recommended withdrawal	(c) the recommended withdrawal
period is inadequate to ensure that		period is insufficient to ensure food	period is insufficient to ensure food
foodstuffs obtained from the treated		safety [];	safety [];
animal do not contain residues which			
might constitute a public health			



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hazard;			
(d) the control tests referred to in		(d) the control tests referred to in	(d) the control tests referred to in
Article 129(1) have not been carried		Article 129(1) have not been carried	Article 129(1) have not been carried
out.		out; or	out; or
		(e) the incorrect labelling	(e) the incorrect labelling
		leading to a serious risk for animal	leading to a serious risk for animal
		or public health	or public health
2. The competent authorities or		2. The competent authorities or	2. The competent authorities or
the Commission may confine the		the Commission may confine the	the Commission may confine the
prohibition on supply and		prohibition on supply and [] recall	prohibition on supply and [] recall
withdrawal from the market solely to		from the market solely to the	from the market solely to the
the contested production batches.		contested production batches of the	contested production batches of the
		concerned veterinary medicinal	concerned veterinary medicinal
		product.	product.
Article 134		Article 134	Article 134
Penalties imposed by Member States		Penalties imposed by Member States	Penalties imposed by Member States
1. Member States may impose		1. Member States shall lay	1. Member States shall lay
financial penalties on the holders of		down rules on penalties applicable	down rules on penalties applicable
marketing authorisations granted		to infringements of this Regulation	to infringements of this Regulation
under this Regulation if they fail to		and take all measures necessary to	and take all measures necessary to
observe their obligations in		ensure that they are implemented.	ensure that they are implemented.
accordance with this Regulation.		The penalties provided for must be	The penalties provided for must be
		effective, dissuasive and	effective, dissuasive and
		proportionate.	proportionate.
2. Member States shall lay down		2. []	2. []
rules concerning the initiation,			
duration, time-limits and conduct of			
the imposition of fines or periodic			
penalty payments to the holders of			
marketing authorisations granted			



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under this Regulation, the maximum			
amounts of these penalties as well as			
the conditions and methods for their			
collection. The penalties provided for			
must be effective, dissuasive and			
proportionate to the nature, duration			
and seriousness of the infringement			
as well as to the damage caused to			
public health, animal health and the			
environment.			
3. Member States shall notify		[] Member States shall notify	[] Member States shall notify
those provisions to the Commission		those provisions to the Commission	those provisions to the Commission
by [Publications Office: insert date		by [Publications Office: insert date	by [Publications Office: insert date
counting 36 months from the date of		counting 36 months from the date of	counting 36 months from the date of
entry into force of this Regulation]		entry into force of this Regulation]	entry into force of this Regulation]
and shall notify it without delay of		and shall notify it without delay of	and shall notify it without delay of
any subsequent amendments		any subsequent amendments	any subsequent amendments
affecting them.		affecting them.	affecting them.
4. Where the Member State		4 . []	<u>1a. The competent authorities shall</u>
imposes a financial penalty, it shall			ensure the publication of
publish a concise summary of the			information on the type and
case, including the names of the			number of cases where financial
marketing authorisation holders			penalties were imposed, having
involved and the amounts of and			regard to the legitimate interest of
reasons for the financial penalties			the concerned parties in the
imposed, having regard to the			protection of their business secrets.
legitimate interest of the marketing			
authorisation holders in the			
protection of their business secrets.			
		2. Member States shall inform	2. Member States shall inform



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		the Commission immediately of	the Commission immediately of
		any litigation against marketing	any litigation against marketing
		authorisation holders of centrally	authorisation holders of centrally
		authorised veterinary medicinal	authorised veterinary medicinal
		products instituted for	products instituted for
		infringement of this Regulation.	infringement of this Regulation.
Article 135		Article 135	Article 135
Penalties imposed by the		Financial penalties imposed by the	Financial penalties imposed by the
Commission		Commission on marketing	Commission on marketing
		authorisation holders of centrally	authorisation holders of centrally
		authorised veterinary medicinal	authorised veterinary medicinal
		products ⁸³	products
1. The Commission may impose		1. The Commission may impose	1. The Commission may impose
financial penalties on the holders of		financial penalties on the []	financial penalties on the []
marketing authorisations granted		marketing authorisation[] holders	marketing authorisation holders of
under this Regulation if they fail to		of centrally authorised veterinary	centrally authorised veterinary
observe their obligations in		medicinal products granted under	medicinal products granted under
accordance with this Regulation.		this Regulation if they fail to observe	this Regulation if they fail to observe
		any of their obligations in	any of their obligations in
		accordance with this Regulation in	accordance with this Regulation laid
		connection with those marketing	down in Annex III in connection
		authorisations.	with those marketing
			authorisations.

⁸³ PRES has aligned Article 135 to the equivalent provisions in Article 84a of the Commission proposal amending Regulation (EC) No 726/2004.

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		1aa. The Commission may,	1aa. The Commission may, insofar
		insofar as specifically provided for	as specifically provided for in the
		in the delegated acts referred to in	delegated acts referred to in
		paragraph 1e(bb), impose the	paragraph 1e<u>2(</u>bb), impose the
		financial penalties referred to in	financial penalties referred to in
		paragraph 1 also on a different	paragraph 1 also on a different
		legal entity or entities provided	legal entity or entities provided
		that such entities form part of the	that such entities form part of the
		same economic entity as the	same economic entity as the
		marketing authorisation holder	marketing authorisation holder
		and that such other legal entities:	and that such other legal entities:
		(i) exerted a decisive influence over	(i) exerted a decisive influence over
		the marketing authorisation	the marketing authorisation
		holder, or	holder, or
		(ii) were involved in, or could have	(ii) were involved in, or could have
		addressed, the infringement by the	addressed, the infringement by the
		marketing authorisation holder.	marketing authorisation holder.
		1a. Where the Agency or a	1a. Where the Agency or a
		competent authority of a Member	competent authority of a Member
		State is of the opinion that a	State is of the opinion that a
		marketing authorisation holder	marketing authorisation holder
		has failed to observe any of the	has failed to observe any of the
		obligations referred to in	obligations referred to in
		paragraph 1, it may request the	paragraph 1, it may request the
		Commission to investigate whether	Commission to investigate whether
		to impose financial penalties	to impose financial penalties
		pursuant to that paragraph.	pursuant to that paragraph.

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		1b. In determining whether to	1b. In determining whether to
		impose a financial penalty and in	impose a financial penalty and in
		determining the appropriate	determining the appropriate
		financial penalty, the Commission	financial penalty, the Commission
		shall be guided by the principles of	shall be guided by the principles of
		effectiveness, proportionality and	effectiveness, proportionality and
		dissuasiveness and take into	dissuasiveness and take into
		consideration, where relevant, the	consideration, where relevant, the
		seriousness and the effects of the	seriousness and the effects of the
		infringement.	infringement.
		1c. For the purposes of	1c. For the purposes of
		paragraph 1, the Commission shall	paragraph 1, the Commission shall
		also take into account:	also take into account:
		(a) any infringement procedure	(a) any infringement procedure
		initiated by a Member State	initiated by a Member State
		against the same marketing	against the same marketing
		authorisation holder on the basis	authorisation holder on the basis
		of the same legal grounds and the	of the same legal grounds and the
		same facts, and,	same facts, and,
		(b) any sanctions, including	(b) any sanctions, including
		penalties, already imposed on the	penalties, already imposed on the
		same marketing authorisation	same marketing authorisation
		holder on the basis of the same	holder on the basis of the same
		legal grounds and the same facts.	legal grounds and the same facts.
		1d. Where the Commission finds	1d. Where the Commission finds
		that the marketing authorisation	that the marketing authorisation
		holder has committed,	holder has committed,
		intentionally or negligently, an	intentionally or negligently, an
		infringement as referred to in	infringement as referred to in
		paragraph 1, it may adopt a	paragraph 1, it may adopt a

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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		decision imposing a fine not	decision imposing a fine not
		exceeding 5 % of the holder's	exceeding 5 % of the holder's
		Union turnover in the business	Union turnover in the business
		year preceding the date of the	year preceding the date of the
		decision.	decision.
		Where the marketing	Where the marketing
		authorisation holder has not	authorisation holder has not
		terminated the infringement, the	terminated the infringement, the
		Commission may, in the decision	Commission may, in the decision
		referred to in paragraph 1, impose	referred to in paragraph 1, impose
		periodic penalty payments per day	periodic penalty payments per day
		not exceeding 2,5 % of the holder's	not exceeding 2,5 % of the holder's
		average daily Union turnover in	average daily Union turnover in
		the business year preceding the	the business year preceding the
		date of the decision.	date of the decision.
		Periodic penalty payments may be	Periodic penalty payments may be
		imposed for a period running from	imposed for a period running from
		the date of notification of that	the date of notification of that
		decision until the infringement has	decision until the infringement has
		been brought to an end.	been brought to an end.
2. The Commission shall be		2. The Commission [] is	2. The Commission [] is
empowered to adopt delegated acts		empowered to adopt delegated acts	empowered to adopt delegated acts
in accordance with Article 146		in accordance with Article 146	in accordance with Article 146
laying down rules concerning the		supplementing this Regulation by	supplementing this Regulation by
initiation, duration, time-limits and		laying down: []	laying down: []
conduct of the imposition of fines or			
periodic penalty payments to the			
holders of marketing authorisations			
granted under this Regulation, the			
maximum amounts of these penalties			

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as well as the conditions and methods for their collection.			
		(aa) a list of obligations under this Regulation, the infringement of which may be subject to financial penalties;	(aa) a list of obligations under this Regulation, the infringement of which may be subject to financial penalties;
		(a) procedures to be applied by the Commission when imposing fines or periodic penalty payments, including rules on the initiation of the procedure, measures of inquiry, rights of defence, access to file, legal representation and	(a) procedures to be applied by the Commission when imposing fines or periodic penalty payments, including rules on the initiation of the procedure, measures of inquiry, rights of defence, access to file, legal representation and
		 confidentiality; (bb) further detailed rules on the imposition by the Commission of financial penalties on legal entities other than the marketing authorisation holder; 	 confidentiality; (bb) further detailed rules on the imposition by the Commission of financial penalties on legal entities other than the marketing authorisation holder;
		(b) rules on duration of procedure and limitation periods;	(b) rules on duration of procedure and limitation periods;
		(c) elements to be taken into account by the Commission when setting the level of and imposing fines and periodic penalty payments as well as the conditions and methods for their collection.	(c) elements to be taken into account by the Commission when setting the level of and imposing fines and periodic penalty payments as well as the conditions and methods for their collection.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		2a. For the conduct of the	2a. For the conduct of the
		investigation, the Commission may	investigation, the Commission may
		cooperate with national competent	cooperate with national competent
		authorities and rely on resources	authorities and rely on resources
		provided by the Agency.	provided by the Agency.
3. Where the Commission adopts		3. Where the Commission adopts	3. Where the Commission adopts
a decision imposing a financial		a decision imposing a financial	a decision imposing a financial
penalty, it shall publish a concise		penalty, it shall publish a concise	penalty, it shall publish a concise
summary of the case, including the		summary of the case, including the	summary of the case, including the
names of the marketing authorisation		names of the marketing authorisation	names of the marketing authorisation
holders involved and the amounts of		holders involved and the amounts of	holders involved and the amounts of
and reasons for the financial		and reasons for the financial	and reasons for the financial
penalties imposed, having regard to		penalties imposed, having regard to	penalties imposed, having regard to
the legitimate interest of the		the legitimate interest of the	the legitimate interest of the
marketing authorisation holders in		marketing authorisation holders in	marketing authorisation holders in
the protection of their business		the protection of their business	the protection of their business
secrets.		secrets.	secrets.
4. The Court of Justice shall have		4. The Court of Justice shall have	4. The Court of Justice shall have
unlimited jurisdiction to review		unlimited jurisdiction to review	unlimited jurisdiction to review
decisions whereby the Commission		decisions whereby the Commission	decisions whereby the Commission
has imposed financial penalties. It		has imposed financial penalties. It	has imposed financial penalties. It
may cancel, reduce or increase the		may cancel, reduce or increase the	may cancel, reduce or increase the
fine or periodic penalty payment		fine or periodic penalty payment	fine or periodic penalty payment
imposed.		imposed.	imposed.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Chapter X		Chapter X	Chapter X
Regulatory network		Regulatory network	Regulatory network
Article 136		Article 136	Article 136
Competent authorities		Competent authorities	Competent authorities
	AM 279		
1. Member States shall designate	1. Member States shall	1. Member States shall designate	1. Member States shall designate
the competent authorities to carry out	designate the competent authorities	the competent authorities to carry out	the competent authorities to carry out
tasks under this Regulation.	to carry out tasks under this	tasks under this Regulation.	tasks under this Regulation.
E E	Regulation. <i>The competent</i>	C C	5
	authorities shall, inter alia, be		
	responsible for providing the		
	scientific expertise for assessment		
	of all applications under this		
	Regulation.		
	AM 280		1a. Member States shall ensure
	Article 136 paragraph 1 a		that adequate financial resources
	(new)		are available to provide the staff
	1a. The management of funds		and other resources necessary for
	intended for activities connected		the competent authorities to carry
	with requirements provided under		out the activities required by this
	this Regulation, the operation of		Regulation.
	communication networks and		
	market surveillance shall be under		
	the permanent control of the		
	competent authorities in order to		
	guarantee the independence of		
	these authorities.		



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
2. The competent authorities shall cooperate with each other in the performance of their tasks under this Regulation and shall give the competent authorities of other Member States necessary and useful support to this end. Competent authorities shall communicate the appropriate information to each other, particularly regarding compliance with the requirements for the manufacturing and wholesale distribution authorisations, for the certificates of good manufacturing practice or for marketing authorisations.	AM 281 2. The competent authorities shall cooperate with each other <i>and</i> <i>other concerned authorities</i> in the performance of their tasks under this Regulation and shall give the competent authorities of other Member States necessary and useful support to this end. Competent authorities shall communicate the appropriate information to each other <i>and other</i> <i>concerned authorities</i> , particularly regarding compliance with the requirements for the manufacturing and wholesale distribution authorisations, for the certificates of good manufacturing practice or for marketing authorisations.	2. The competent authorities shall cooperate with each other in the performance of their tasks under this Regulation and shall give the competent authorities of other Member States necessary and useful support to this end. Competent authorities shall communicate the appropriate information to each other [].	2. The competent authorities shall cooperate with each other in the performance of their tasks under this Regulation and shall give the competent authorities of other Member States necessary and useful support to this end. Competent authorities shall communicate the appropriate information to each other [].
3. Upon reasoned request, the competent authorities shall forthwith communicate the reports referred to in Article 125 and Article 129 to the competent authorities of other Member States.		3. Upon reasoned request, the competent authorities shall forthwith communicate the [] written records referred to in Article 125 and control reports referred to in Article 129 to the competent authorities of other Member States.	3. Upon reasoned request, the competent authorities shall forthwith communicate the [] written records referred to in Article 125 and control reports referred to in Article 129 to the competent authorities of other Member States.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
4. Member States shall		4. [].	4. [].
communicate to each other all the			
information necessary to guarantee			
the quality and safety of			
homeopathic veterinary medicinal			
products manufactured and marketed			
within the Union.			
Article 137		Article 137	Article 137
Information to the Agency and		[]	[]
international organisations from the		[]	[]
competent authorities			
1. Each competent authority shall		[]	[]
immediately inform the Agency of			
all decisions granting marketing			
authorisation and of all decisions			
refusing or withdrawing marketing			
authorisation, repealing a decision			
refusing or withdrawing marketing			
authorisation, prohibiting supply or			
withdrawing a product from the			
market, together with the reasons on			
which such decisions are based.			
2. The competent authorities shall		[]	[]
forthwith bring to the attention of the			
relevant international organisations,			
with a copy to the Agency, all			
appropriate information about			
actions taken pursuant to paragraph 1			
which may affect the protection of			
health in third countries.			



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
Article 138		Article 138	Article 138
Scientific opinion for international		Scientific opinion for international	Scientific opinion for international
organisations for animal health		organisations for animal health	organisations for animal health
1. The Agency may give		1. The Agency may give	1. The Agency may give
scientific opinions, in the context of		scientific opinions, in the context of	scientific opinions, in the context of
cooperation with international		cooperation with international	cooperation with international
organisations for animal health, for		organisations for animal health, for	organisations for animal health, for
the evaluation of veterinary		the evaluation of veterinary	the evaluation of veterinary
medicinal products intended		medicinal products intended	medicinal products intended
exclusively for markets outside the		exclusively for markets outside the	exclusively for markets outside the
Union. For this purpose, an		Union. For this purpose, an	Union. For this purpose, an
application shall be submitted to the		application shall be submitted to the	application shall be submitted to the
Agency in accordance with the		Agency in accordance with the	Agency in accordance with the
provisions of Article 7. The Agency		provisions of Article 7. The Agency	provisions of Article 7. The Agency
may, after consulting the relevant		may, after consulting the relevant	may, after consulting the relevant
organisation, draw up a scientific		organisation, draw up a scientific	organisation, draw up a scientific
opinion.		opinion.	opinion.
2. The Committee shall establish		2. The Agency [] shall	2. The Agency [] shall
specific procedural rules for the		establish specific procedural rules for	establish specific procedural rules for
application of paragraph 1.		the implementation [] of	the implementation [] of
		paragraph 1.	paragraph 1.
Article 139		Article 139	Article 139
Committee for Medicinal Products		Committee for Veterinary Medicinal	Committee for Veterinary Medicinal
for Veterinary Use		Products []	Products []
1. A Committee for Medicinal		1. A Committee for Veterinary	1. A Committee for Veterinary
Products for Veterinary Use ('the		Medicinal Products [] ('the	Medicinal Products [] ('the
Committee') is hereby set up within		Committee') is hereby set up within	Committee') is hereby set up within
the Agency.		the Agency.	the Agency.
2. The Executive Director of the		2. The Executive Director of the	2. The Executive Director of the
Agency or his representative and		Agency or his representative and	Agency or his representative and

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
representatives of the Commission		representatives of the Commission	representatives of the Commission
shall be entitled to attend all		shall be entitled to attend all	shall be entitled to attend all
meetings of the Committee, working		meetings of the Committee, working	meetings of the Committee, working
parties and scientific advisory groups		parties and scientific advisory groups	parties and scientific advisory groups
and all other meetings convened by		[].	[].
the Agency or its committees.			
3. The Committee may establish		3. The Committee may establish	3. The Committee may establish
standing and temporary working		standing and temporary working	standing and temporary working
parties. The Committee may		parties. The Committee may	parties. The Committee may
establish scientific advisory groups		establish scientific advisory groups	establish scientific advisory groups
in connection with the evaluation of		in connection with the evaluation of	in connection with the evaluation of
specific types of medicinal products		specific types of veterinary	specific types of veterinary
or treatments, to which the		medicinal products [], to which the	medicinal products [], to which the
Committee may delegate certain		Committee may delegate certain	Committee may delegate certain
tasks associated with drawing up the		tasks associated with drawing up the	tasks associated with drawing up the
scientific opinions referred to in		scientific opinions referred to in	scientific opinions referred to in
Article 141(1)(b).		Article 141(1)(b).	Article 141(1)(b).
4. The Committee shall establish		4. The Committee shall establish	4. The Committee shall establish
a standing working party with the		a standing working party with the	a standing working party with the
sole remit of providing scientific		sole remit of providing scientific	sole remit of providing scientific
advice to undertakings. The		advice to undertakings. The	advice to undertakings. The
Executive Director, in close		Executive Director, in close	Executive Director, in close
consultation with the Committee		consultation with the Committee	consultation with the Committee
shall set up the administrative		shall set up the administrative	shall set up the administrative
structures and procedures allowing		structures and procedures allowing	structures and procedures allowing
the development of advice for		the development of advice for	the development of advice for
undertakings, as referred to in Article		undertakings, as referred to in Article	undertakings, as referred to in Article
57(1)(n) of Regulation (EC) No		57(1)(n) of Regulation (EC) No	57(1)(n) of Regulation (EC) No
726/2004, particularly regarding the		726/2004, particularly regarding the	726/2004, particularly regarding the
development of new therapies.		development of [] novel therapy	development of [] novel therapy

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Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		[] veterinary medicinal	[] veterinary medicinal
		products.	products.
		4a. The Committee shall	4a. The Committee shall
		establish a standing working party	establish a standing working party
		for pharmacovigilance with a	for pharmacovigilance with a
		remit including evaluating	remit including evaluating
		potential signals in	potential signals in
		pharmacovigilance arising from	pharmacovigilance arising from
		the Union pharmacovigilance	the Union pharmacovigilance
		system, proposing the options for	system, proposing the options for
		risk management referred to in	risk management referred to in
		Article 79 to the Committee and to	Article 79 to the Committee and to
		the coordination group, and	the coordination group, and
		coordinating the communication	coordinating the communication
		about pharmacovigilance between	about pharmacovigilance between
		the competent authorities and the	the competent authorities and the
		Agency.	Agency.
5. The Committee shall establish		5. The Committee shall establish	5. The Committee shall establish
its own rules of procedure. Those		its own rules of procedure. Those	its own rules of procedure. Those
rules shall, in particular, lay down:		rules shall, in particular, lay down:	rules shall, in particular, lay down:
(a) procedures for appointing and		(a) procedures for appointing and	(a) procedures for appointing and
replacing the Chairman;		replacing the Chairman;	replacing the Chairman;
(b) the appointment of members of		(b) the appointment of members of	(b) the appointment of members of
any working parties or scientific		any working parties or scientific	any working parties or scientific
advisory groups on the basis of the		advisory groups on the basis of the	advisory groups on the basis of the
lists of experts referred to in the $(2/2)$		lists of accredited experts referred to	lists of accredited experts referred to
second subparagraph of Article $62(2)$		in the second subparagraph of Article $(2(2)) = \int \mathbf{P} \mathbf{P} \mathbf{P} \mathbf{P} \mathbf{P} \mathbf{P} \mathbf{P} \mathbf{P}$	in the second subparagraph of Article $(2(2)) \circ f \mathbf{P}_{2}$ and $(\mathbf{F}_{2}) \mathbf{N}_{2}$
of Regulation (EC) No 726/2004 and		62(2) of Regulation (EC) No	62(2) of Regulation (EC) No
procedures for consultation of		726/2004 and procedures for	726/2004 and procedures for
working parties and scientific		consultation of working parties and	consultation of working parties and



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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advisory groups;		scientific advisory groups;	scientific advisory groups;
(c) a procedure for urgent adoption		(c) a procedure for urgent adoption	(c) a procedure for urgent adoption
of opinions, particularly in relation to		of opinions, particularly in relation to	of opinions, particularly in relation to
the provisions of this Regulation on		the provisions of this Regulation on	the provisions of this Regulation on
market surveillance and		market surveillance and	market surveillance and
pharmacovigilance.		pharmacovigilance.	pharmacovigilance.
The rules of procedure shall enter		The rules of procedure shall enter	The rules of procedure shall enter
into force after receiving a		into force after receiving a	into force after receiving a
favourable opinion from the		favourable opinion from the	favourable opinion from the
Commission and the Management		Commission and the Management	Commission and the Management
Board of the Agency.		Board of the Agency.	Board of the Agency.
6. The Secretariat of the Agency		6. The Secretariat of the Agency	6. The Secretariat of the Agency
shall provide technical, scientific and		shall provide technical, scientific and	shall provide technical, scientific and
administrative support for the		administrative support for the	administrative support for the
Committee, and shall ensure		Committee, and shall ensure	Committee, and shall ensure
consistency and quality of opinions		consistency and quality of opinions	consistency and quality of opinions
of the Committee and appropriate		of the Committee and appropriate	of the Committee and appropriate
coordination between this		coordination between this	coordination between this
Committee, other committees of the		Committee, and other committees of	Committee, and other committees of
Agency and the coordination group.		the Agency referred to in Article 56	the Agency referred to in Article 56
		of Regulation (EC) No 726/2004	of Regulation (EC) No 726/2004
		and the coordination group.	and the coordination group.
7. The opinions of the Committee		7. The opinions of the Committee	7. The opinions of the Committee
shall be publicly accessible.		shall be publicly accessible.	shall be publicly accessible.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Article 140		Article 140	Article 140
Members of the Committee for		Members of the Committee []	Members of the Committee []
Medicinal Products for Veterinary			
Use			
1. Each Member State shall be		1. Each Member State shall, after	1. Each Member State shall, after
entitled to appoint a Member and an		consultation of the Management	consultation of the Management
alternate Member of the Committee.		Board of the Agency, [] appoint	Board of the Agency, [] appoint
The alternates shall represent and		for a three-year term which may	for a three-year term which may
vote for the Members in their		be renewed, one [] member and	be renewed, one [] member and
absence and may act as rapporteurs.		an alternate member of the	an alternate member of the
		Committee. The alternates shall	Committee. The alternates shall
		represent and vote for the members	represent and vote for the members
		in their absence and may act as	in their absence and may act as
		rapporteurs	rapporteurs
	AM 305 Article 140 paragraph 1 a (new) 1a. All members, alternate members and accompanying experts shall provide a publicly accessible declaration of interest.		
2. Members and alternate		2. Members and alternates of the	2. Members and alternates of the
Members of the Committee shall be		Committee shall be appointed on the	Committee shall be appointed on the
appointed on the basis of their		basis of their relevant expertise and	basis of their relevant expertise and
relevant expertise and experience in		experience in the scientific []	experience in the scientific []
the scientific evaluation of medicinal		assessment of veterinary medicinal	assessment of veterinary medicinal
products for veterinary use, in order		products [], in order to guarantee	products [], in order to guarantee
to guarantee the highest level of		the highest level of qualifications and	the highest level of qualifications and
qualifications and a broad spectrum		a broad spectrum of relevant	a broad spectrum of relevant
of relevant expertise.		expertise.	expertise.



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate
3. Member States shall submit			proposed by the Presidency
relevant information to the		3. []	3. []
Management Board of the Agency			
on expertise and experience in			
relation to the scientific profile			
established by the Committee of			
experts that the Member States			
consider for appointment for a			
position in the Committee.			
4. The Management Board shall		4 . []	4 . []
evaluate information on the expert or		4. []	4 . []
experts submitted by the Member			
State and shall communicate its			
conclusions to the Member State and			
the Committee.			
		5. []	5. []
8		5. []	5. []
conclusions referred to in paragraph			
4, each Member State shall appoint one Member and one alternate to the			
Committee for a three-year term			
which may be renewed.			
6. A Member State may delegate		6. A Member State may delegate	6. A Member State may delegate
its tasks within the Committee to		its tasks within the Committee to	its tasks within the Committee to
another Member State. Each Member		another Member State. Each Member	another Member State. Each Member
State may represent no more than		State may represent no more than	State may represent no more than
one other Member State.		one other Member State.	one other Member State.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
7. The Committee may co-opt a maximum of five additional members chosen on the basis of their specific scientific competence. These members shall be appointed for a term of three years, which may be renewed, and shall not have alternates.	AM 282 7. The Committee may co-opt a maximum of five additional members chosen on the basis of their specific scientific competence. These members shall be appointed for a term of three years, which may be renewed, and shall not have alternates. <i>The co-opted members</i> <i>may act as rapporteurs</i> .	7. The Committee may co-opt a maximum of five additional members chosen on the basis of their specific scientific competence. These members shall be appointed for a term of three years, which may be renewed, and shall not have alternates.	7. The Committee may co-opt a maximum of five additional members chosen on the basis of their specific scientific competence. These members shall be appointed for a term of three years, which may be renewed, and shall not have alternates.
8. With a view to the co-opting of such members, the Committee shall identify the specific complementary scientific competence of the additional member(s). Co-opted members shall be chosen among experts nominated by Member States or the Agency.		8. With a view to the co-opting of such members, the Committee shall identify the specific complementary scientific competence of the additional member(s). Co-opted members shall be chosen among experts nominated by Member States or the Agency.	8. With a view to the co-opting of such members, the Committee shall identify the specific complementary scientific competence of the additional member(s). Co-opted members shall be chosen among experts nominated by Member States or the Agency.
		8a. The Committee may appoint for the purpose of performing its tasks listed under Article 141, one of its members to act as rapporteur. The Committee may also appoint a second member to act as co-rapporteur.	8a. The Committee may appoint for the purpose of performing its tasks listed under Article 141, one of its members to act as rapporteur. The Committee may also appoint a second member to act as co-rapporteur.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
9. The members of the		9. The members of the	9. The members of the
Committee may be accompanied by		Committee may be accompanied by	Committee may be accompanied by
experts in specific scientific or		experts in specific scientific or	experts in specific scientific or
technical fields.		technical fields.	technical fields.
10. Members of the Committee		10. Members of the Committee	10. Members of the Committee
and experts responsible for		and experts responsible for []	and experts responsible for []
evaluating veterinary medicinal		assessing veterinary medicinal	assessing veterinary medicinal
products shall rely on the scientific		products shall rely on the scientific	products shall rely on the scientific
evaluation and resources available to		evaluation and resources available to	evaluation and resources available to
competent authorities. Each authority		competent authorities. Each	competent authorities. Each
shall monitor and ensure the		competent authority shall monitor	competent authority shall monitor
scientific level and independence of		and ensure the scientific level and	and ensure the scientific level and
the evaluation carried out and the		independence of the evaluation	independence of the evaluation
provision of appropriate contribution		carried out and [] provide	carried out and [] provide
to the tasks of the Committee, and		appropriate contribution to the tasks	appropriate contribution to the tasks
facilitate the activities of appointed		of the Committee, and facilitate the	of the Committee, and facilitate the
Committee members and experts. To		activities of appointed Committee	activities of appointed Committee
this end, Member States shall		members and experts. To this end,	members and experts. To this end,
provide adequate scientific and		Member States shall provide	Member States shall provide
technical resources to the members		adequate scientific and technical	adequate scientific and technical
and experts they have nominated.		resources to the members and experts	resources to the members and experts
		they have nominated.	they have nominated.
11. Member States shall refrain		11. Member States shall refrain	11. Member States shall refrain
from giving Committee members		from giving Committee members	from giving Committee members
and experts instructions incompatible		and experts instructions incompatible	and experts instructions incompatible
with their own individual tasks, or		with their own individual tasks, or	with their own individual tasks, or
with the tasks of the Committee and		with the tasks of the Committee and	with the tasks of the Committee and
responsibilities of the Agency.		responsibilities of the Agency.	responsibilities of the Agency.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Article 141		Article 141	Article 141
Tasks of the Committee for		Tasks of the Committee []	Tasks of the Committee []
Medicinal Products for Veterinary			
Use			
1. The Committee shall have the		1. The Committee shall have the	1. The Committee shall have the
following tasks:		following tasks:	following tasks:
(a) carry out the tasks conferred on		(a) carry out the tasks conferred on	(a) carry out the tasks conferred on
the Committee under this Regulation		the Committee under this Regulation	the Committee under this Regulation
and Regulation (EC) No 726/2004;		and Regulation (EC) No 726/2004;	and Regulation (EC) No 726/2004;
(b) prepare opinions of the Agency		(b) prepare scientific opinions of	(b) prepare scientific opinions of
on questions relating to the		the Agency on questions relating to	the Agency on questions relating to
evaluation and use of veterinary		the evaluation and use of veterinary	the evaluation and use of veterinary
medicinal products;		medicinal products;	medicinal products;
(c) upon request from the		(c) upon request from the	(c) upon request from the
Executive Director of the Agency or		Executive Director of the Agency or	Executive Director of the Agency or
the Commission draw up opinions on		the Commission [] prepare	the Commission [] prepare
scientific matters concerning the		opinions on scientific matters	opinions on scientific matters
evaluation and use of veterinary		concerning the evaluation and use of	concerning the evaluation and use of
medicinal products;		veterinary medicinal products;	veterinary medicinal products;
(d) draw up opinions of the		(d) prepare [] opinions of the	(d) prepare [] opinions of the
Agency on questions concerning the		Agency on questions concerning the	Agency on questions concerning the
admissibility of files submitted in		admissibility of applications []	admissibility of applications []
accordance with the centralised		submitted in accordance with the	submitted in accordance with the
procedure, and on granting, varying,		centralised procedure, and on	centralised procedure, and on
suspending or withdrawing a		granting, varying, suspending or []	granting, varying, suspending or []
marketing authorisations for		revoking a marketing authorisations	revoking a marketing authorisations
centrally authorised veterinary		for centrally authorised veterinary	for centrally authorised veterinary
medicinal products;		medicinal products;	medicinal products;
(e) take due account of any request		(e) take due account of any request	(e) take due account of any request
from Member States for opinions;		from Member States for scientific	from Member States for scientific

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Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
550 mai - 2014/0257 (COD)		opinions;	opinions;
(f) formulate opinions whenever there is a request for a scientific re- examination in the course of mutual recognition or decentralised procedures;		(f)[]	(f) []
 (g) provide guidance on important questions and issues of general scientific or ethical nature 		(g) provide guidance on important questions and issues of general scientific [] nature;	(g) provide guidance on important questions and issues of general scientific [] nature;
(h) give a scientific opinion, in the context of cooperation with international organisations for animal		 (h) give a scientific opinion, in the context of cooperation with the World [] Organisations for [] 	 (h) give a scientific opinion, in the context of cooperation with the World [] Organisations for []
health, concerning the evaluation of certain veterinary medicinal products		Animal [] Health, concerning the evaluation of certain veterinary	Animal [] Health, concerning the evaluation of certain veterinary
or active substances intended exclusively for markets outside the Union.		medicinal products [] intended exclusively for markets outside the Union.	medicinal products [] intended exclusively for markets outside the Union.
		(i) advise on the maximum	(i) advise on the maximum
		limits for residues of veterinary	limits for residues of veterinary
		medicinal products and biocidal	medicinal products and biocidal
		products used in animal	products used in animal
		husbandry which may be accepted	husbandry which may be accepted
		in foodstuffs of animal origin in	in foodstuffs of animal origin in
		accordance with Regulation (EC) No 470/2009;	accordance with Regulation (EC) No 470/2009;

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
		(j) provide scientific advice on the use of antimicrobials and antiparasitics in animals in order to minimise the occurrence of resistance in the Union; this advice shall be updated when needed;	(j) provide scientific advice on the use of antimicrobials and antiparasitics in animals in order to minimise the occurrence of resistance in the Union; this advice shall be updated when needed;
		(k) provide objective scientific opinions to the Member States on the questions which are referred to them.	(k) provide objective scientific opinions to the Member States on the questions which are referred to them.
	AM 283 Article 141 paragraph 1 point h a (new) (ha) tackle the contribution of farming practices to the development of antimicrobial resistance, by building on the existing action plans of the Commission and Member States, specifically by developing and implementing strategies to: - reduce overall use, - reduce the use of antimicrobials that are critically important for human use, and - end routine prophylactic use. That work shall be laid out in a plan submitted by the Committee to the Commission no later than two years after the adoption of		



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
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	this Regulation. That plan shall contain targets for the reductions in use and a timetable for achieving these reductions.		proposed by the rresidency
2. The members of the		2. The members of the	2. The members of the
Committee shall ensure that there is		Committee shall ensure that there is	Committee shall ensure that there is
appropriate coordination between the		appropriate coordination between the	appropriate coordination between the
tasks of the Agency and the work of		tasks of the Agency and the work of	tasks of the Agency and the work of
competent authorities.		competent authorities.	competent authorities.
3. When preparing opinions the		3. When preparing opinions the	3. When preparing opinions the
Committee shall use its best		Committee shall use its best	Committee shall use its best
endeavours to reach a scientific		endeavours to reach a scientific	endeavours to reach a scientific
consensus. If such consensus cannot		consensus. If such consensus cannot	consensus. If such consensus cannot
be reached, the opinion shall consist		be reached, the opinion shall consist	be reached, the opinion shall consist
of the position of the majority of		of the position of the majority of	of the position of the majority of
members and divergent positions,		members and divergent positions,	members and divergent positions,
with the grounds on which they are		with the grounds on which they are	with the grounds on which they are
based.		based.	based.
4. If there is a request for re-		4. If there is a request for re-	4. If there is a request for re-
examination of an opinion where this		examination of an opinion where this	examination of an opinion where this
possibility is provided for in the		possibility is provided for in the	possibility is provided for in the
Union law, the Committee shall		Union law, the Committee shall	Union law, the Committee shall
appoint a different rapporteur and,		appoint a different rapporteur and,	appoint a different rapporteur and,
where necessary, a different co-		where necessary, a different co-	where necessary, a different co-
rapporteur from those appointed for		rapporteur from those appointed for	rapporteur from those appointed for
the opinion. The re-examination		the opinion. The re-examination	the opinion. The re-examination
procedure may deal only with the		procedure may deal only with the	procedure may deal only with the
points of the opinion initially		points of the opinion initially	points of the opinion initially
identified by the applicant and may		identified by the applicant and may	identified by the applicant and may

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
be based only on the scientific data		be based only on the scientific data	be based only on the scientific data
available when the Committee		available when the Committee	available when the Committee
adopted the opinion. The applicant		adopted the opinion. The applicant	adopted the opinion. The applicant
may request that the Committee		may request that the Committee	may request that the Committee
consults a scientific advisory group		consults a scientific advisory group	consults a scientific advisory group
in connection with the re-		in connection with the re-	in connection with the re-
examination.		examination.	examination.
Article 142		Article 142	Article 142
Coordination group for mutual		Coordination group for mutual	Coordination group for mutual
recognition and decentralised		recognition and decentralised	recognition and decentralised
procedures for veterinary medicinal		procedures for veterinary	procedures for veterinary
products		medicinal products	medicinal products
1. The coordination group for		1. The coordination group for	1. The coordination group for
mutual recognition and decentralised		mutual recognition and decentralised	mutual recognition and decentralised
procedures for veterinary medicinal		procedures for veterinary medicinal	procedures for veterinary medicinal
products ("the coordination group")		products ("the coordination group")	products ("the coordination group")
is hereby set up.		is hereby set up.	is hereby set up.
2. The Agency shall provide a		2. The Agency shall provide a	2. The Agency shall provide a
secretariat for the coordination		secretariat for the coordination group	secretariat for the coordination group
group, which shall ensure effective		[] to assist in the operations of	[] to assist in the operations of
and efficient operation of the		the procedures of the coordination	the procedures of the coordination
procedures of the coordination group		group and to ensure an appropriate	group and to ensure an appropriate
and appropriate liaison between this		liaison between this group, the	liaison between this group, the
group, the Agency and national		Agency and [] competent	Agency and [] competent
competent authorities.		authorities.	authorities.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
3. The coordination group shall		3. The coordination group shall	3. The coordination group shall
draw up its rules of procedure, which		draw up its rules of procedure, which	draw up its rules of procedure, which
shall enter into force after receiving a		shall enter into force after receiving a	shall enter into force after receiving a
favourable opinion from the		favourable opinion from the	favourable opinion from the
Commission. These rules of		Commission. These rules of	Commission. These rules of
procedure shall be made public.		procedure shall be made public.	procedure shall be made public.
4. The Executive Director of the		4. The Executive Director of the	4. The Executive Director of the
Agency or his representative and		Agency or his representative and	Agency or his representative and
representatives of the Commission		representatives of the Commission	representatives of the Commission
shall be entitled to attend all		shall be entitled to attend all	shall be entitled to attend all
meetings of the coordination group.		meetings of the coordination group.	meetings of the coordination group.
5. The coordination group shall		5. The coordination group shall	5. The coordination group shall
ensure that there is appropriate		[] cooperate closely with the	[] cooperate closely with the
cooperation and coordination		competent authorities and the	competent authorities and the
between the group, the competent		Agency.	Agency.
authorities and the Agency.			
Article 143		Article 143	Article 143
Members of the Coordination group		Members of the c oordination group	Members of the c oordination group
for mutual recognition and		[]	[]
decentralised procedures for			
veterinary medicinal products			
1. The coordination group shall		1. The coordination group shall	1. The coordination group shall
be composed of one representative		be composed of one representative	be composed of one representative
per Member State appointed for a		per Member State appointed for a	per Member State appointed for a
renewable period of 3 years.		renewable period of 3 years.	renewable period of 3 years.
Members of the group may arrange		Member States may appoint an	Member States may appoint an
to be accompanied by experts.		alternate representative. Members	alternate representative. Members
		of the coordination group may	of the coordination group may
		arrange to be accompanied by	arrange to be accompanied by
		experts.	experts.



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
2. Members of the coordination		2. Members of the coordination	2. Members of the coordination
group and their experts shall rely on		group and their experts shall rely on	group and their experts shall rely on
the scientific and regulatory		the scientific and regulatory	the scientific and regulatory
resources available to their		resources available to their	resources available to their
competent authorities on relevant		competent authorities on relevant	competent authorities on relevant
scientific assessments and on the		scientific assessments and on the	scientific assessments and on the
recommendations of the Committee		recommendations of the Committee	recommendations of the Committee
for the fulfilment of their tasks. Each		for the fulfilment of their tasks. Each	for the fulfilment of their tasks. Each
national competent authority shall		[] competent authority shall	[] competent authority shall
monitor the quality of the evaluations		monitor the quality of the evaluations	monitor the quality of the evaluations
carried out by their representative		carried out by their representative	carried out by their representative
and facilitate their activities.		and facilitate their activities.	and facilitate their activities.
3. Members of the coordination		3. Members of the coordination	3. Members of the coordination
group shall use their best endeavours		group shall use their best endeavours	group shall use their best endeavours
to reach consensus on matters under		to reach consensus on matters under	to reach consensus on matters under
discussion. If such consensus cannot		discussion. []	discussion. []
be reached, the position of the simple			
majority of the members of the			
coordination group shall prevail.			
Article 144		Article 144	Article 144
Tasks of the Coordination group for		Tasks of the c oordination group []	Tasks of the c oordination group []
mutual recognition and decentralised			
procedures for veterinary medicinal			
products			
The coordination group shall have		The coordination group shall have	The coordination group shall have
the following tasks:		the following tasks:	the following tasks:
(a) examine questions concerning		(a) examine questions concerning	(a) examine questions concerning
mutual recognition and decentralised		mutual recognition and decentralised	mutual recognition and decentralised
procedures;		procedures;	procedures;
(b) examine questions concerning	AM 284	(b) examine [] advice from the	(b) examine [] advice from the



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
558 final - 2014/0257 (COD) pharmacovigilance of veterinary medicinal products authorised in Member States;	deleted	by Coreper on 20 December 2017 pharmacovigilance working party of the Committee concerning risk management measures in pharmacovigilance related to [] veterinary medicinal products authorised in Member States and issue recommendations to the Member States and to the marketing authorized helder as	proposed by the Presidency pharmacovigilance working party of the Committee concerning risk management measures in pharmacovigilance related to [] veterinary medicinal products authorised in Member States and issue recommendations to the Member States and to the
(c) examine questions concerning variations to the terms of marketing authorisations granted by Member States;		marketing authorisation holders as necessary;(c)examine questions concerning variations to the terms of marketing authorisations granted by Member States;	marketing authorisation holders as necessary;(c)examine questions concerning variations to the terms of marketing authorisations granted by Member States;
(d) provide recommendations to Member States whether a substance or a combination of substances is to be considered a veterinary medicinal product within the scope of this Regulation.		 (d) provide recommendations to Member States whether a specific product or a group of products [] is to be considered a veterinary medicinal product within the scope of this Regulation. 	 (d) provide recommendations to Member States whether a specific product or a group of products [] is to be considered a veterinary medicinal product within the scope of this Regulation.
		(e) coordinate the selection of the lead authority responsible for the assessment of the results of the signal management process referred to in Article 81(3);	(e) coordinate the selection of the lead authority responsible for the assessment of the results of the signal management process referred to in Article 81(3);

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
558 mai - 2014/0257 (COD)		(ea) draw up and publish an	(ea) draw up and publish an
		annual list of reference veterinary	annual list of reference veterinary
		medicinal products which shall be	medicinal products which shall be
		subject to harmonisation of the	subject to harmonisation of the
		summaries of product	summaries of product
		characteristics in accordance with	characteristics in accordance with
		Article 69(1aaa).	Article 69(1aaa).
Chapter XI		Chapter XI	Chapter XI
Final provisions		[] Common and procedural	[] Common and procedural
		provisions	provisions
Article 145		Article 145	Article 145
Standing Committee on Veterinary		Standing Committee on Veterinary	Standing Committee on Veterinary
Medicinal Products		Medicinal Products	Medicinal Products
1. The Commission shall be		1. The Commission shall be	1. The Commission shall be
assisted by the Standing Committee		assisted by the Standing Committee	assisted by the Standing Committee
on Veterinary Medicinal Products		on Veterinary Medicinal Products	on Veterinary Medicinal Products
('the Standing Committee'). The		('the Standing Committee'). The	('the Standing Committee'). The
Standing Committee shall be a		Standing Committee shall be a	Standing Committee shall be a
committee within the meaning of		committee within the meaning of	committee within the meaning of
Regulation (EU) No 182/2011.		Regulation (EU) No 182/2011.	Regulation (EU) No 182/2011.
2. Where reference is made to		2. Where reference is made to	2. Where reference is made to
this paragraph, Article 5 of		this paragraph, Article 5 of	this paragraph, Article 5 of
Regulation (EU) No 182/2011shall		Regulation (EU) No 182/2011 shall	Regulation (EU) No 182/2011 shall
apply.		apply.	apply.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		Article 145a	Article 145a
		Amendments to Annex II	Amendments to Annex II
		1. The Commission is	1. The Commission is
		empowered to adopt delegated acts	empowered to adopt delegated acts
		in accordance with Article 146(2)	in accordance with Article 146(2)
		amending Annex II to adapt the	amending Annex II to adapt the
		requirements regarding the	requirements regarding the
		technical documentation on the	technical documentation on the
		quality, safety and efficacy of	quality, safety and efficacy of
		veterinary medicinal products to	veterinary medicinal products to
		technical and scientific progress.	technical and scientific progress.
		2. The Commission shall adopt	2. The Commission shall adopt
		delegated acts in accordance with	delegated acts in accordance with
		Article 146(2a) amending Annex II	Article 146(2a) amending Annex II
		to achieve a sufficient level of	to achieve a sufficient level of
		detail to ensure legal certainty and	detail to ensure legal certainty and
		harmonisation as well as any	harmonisation as well as any
		necessary updating, while avoiding	necessary updating, while avoiding
		unnecessary disruption with the	unnecessary disruption with the
		current Annex II, including as	current Annex II, including as
		regards the introduction of specific	regards the introduction of specific
		requirements for novel therapy	requirements for novel therapy
		veterinary medicinal products.	veterinary medicinal products.
			When adopting those delegated
			acts, the Commission shall have
			due regard to animal health,
			public health and environmental
			considerations.
Article 146		Article 146	Article 146
Exercise of the delegation		Exercise of the delegation	Exercise of the delegation



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
1. The power to adopt delegated		1. The power to adopt delegated	1. The power to adopt delegated
acts is conferred on the Commission		acts is conferred on the Commission	acts is conferred on the Commission
subject to the conditions laid down in		subject to the conditions laid down in	subject to the conditions laid down in
this Article.		this Article.	this Article.
2. The power to adopt delegated		2. The power to adopt delegated	2. The power to adopt delegated acts
acts referred to in Articles 7(7),		acts referred to in Articles [] 32(3),	referred to in Articles [] 32(3),
16(6), 32(3), 38(4), 54(3), 89(2),		[] 54(3), [] 112b(1) , 117(2),	[] 54(3), [] 112b(1) , 117(2),
117(2) and $135(2)$ shall be conferred		122a(2), [] 135(1e[]), and	122a(2), [] 135(21e[]), and
on the Commission for an		145a(1) shall be conferred on the	145a(1) shall be conferred on the
indeterminate period of time from		Commission for [] period of []	Commission for [] period of []
the date of the entry into force of this		five years from the date of the entry	five years from the date of the entry
Regulation.		into force of this Regulation. The	into force of this Regulation. The
		Commission shall draw up a	Commission shall draw up a
		report in respect of the delegation	report in respect of the delegation
		of power by not later than nine	of power by not later than nine
		months before the end of the five	months before the end of the five
		year period. The delegation of	year period. The delegation of
		power shall be tacitly extended for	power shall be tacitly extended for
		the periods of an identical	the periods of an identical
		duration, unless the European	duration, unless the European
		Parliament or the Council opposes	Parliament or the Council opposes
		such extension not later than three	such extension not later than three
		months before the end of each	months before the end of each
		period.	period.
		2a. The power to adopt delegated	2a. The power to adopt delegated
		acts referred to in Article 145a (2)	acts referred to in Article 145a (2)
		shall be conferred on the	shall be conferred on the
		Commission for a period from the	Commission for a period from the
		entry into force of this Regulation	entry into force of this Regulation
		until the date of application	until the date of application

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		referred to in Article 150.	referred to in Article 150.
3. The delegation of power		3. The delegation of power	3. The delegation of power
referred to in Articles 7(7), 16(6),		referred to in paragraph 2 and	referred to in paragraph 2 and
32(3), 38(4), 54(3), 89(2), 117(2) and		2a [] may be revoked at any time	2a [] may be revoked at any time
135(2) may be revoked at any time		by the European Parliament or by the	by the European Parliament or by the
by the European Parliament or by the		Council. A decision to revoke shall	Council. A decision to revoke shall
Council. A decision to revoke shall		put an end to the delegation of the	put an end to the delegation of the
put an end to the delegation of the		power specified in that decision. It	power specified in that decision. It
power specified in that decision. It		shall take effect the day following	shall take effect the day following
shall take effect the day following		the publication of the decision in the	the publication of the decision in the
the publication of the decision in the		Official Journal of the European	Official Journal of the European
Official Journal of the European		Union or at a later date specified	Union or at a later date specified
Union or at a later date specified		therein. It shall not affect the validity	therein. It shall not affect the validity
therein. It shall not affect the validity		of any delegated acts already in	of any delegated acts already in
of any delegated acts already in		force.	force.
force.			
		3a. Before adopting a delegated	3a. Before adopting a delegated
		act, the Commission shall consult	act, the Commission shall consult
		experts designated by each	experts designated by each
		Member State in accordance with	Member State in accordance with
		the principles laid down in the	the principles laid down in the
		Interinstitutional Agreement of 13	Interinstitutional Agreement of 13
		April 2016 on Better Law Making.	April 2016 on Better Law Making.
4. As soon as it adopts a		4. As soon as it adopts a	4. As soon as it adopts a
delegated act, the Commission shall		delegated act, the Commission shall	delegated act, the Commission shall
notify it simultaneously to the		notify it simultaneously to the	notify it simultaneously to the
European Parliament and to the		European Parliament and to the	European Parliament and to the
Council.		Council.	Council.
5. A delegated act adopted pursuant		5. A delegated act adopted	5. A delegated act adopted
to Articles 7(7), 16(6), 32(3), 38(4),		pursuant to provisions listed in	pursuant to provisions listed in

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Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
54(3), 89(2), 117(2) and 135(2) shall		paragraph 2 and 2a [] shall enter	paragraph 2 and 2a [] shall enter
enter into force only if no objection		into force only if no objection has	into force only if no objection has
has been expressed either by the		been expressed either by the	been expressed either by the
European Parliament or the Council		European Parliament or the Council	European Parliament or the Council
within a period of two months of		within a period of two months of	within a period of two months of
notification of that act to the		notification of that act to the	notification of that act to the
European Parliament and the Council		European Parliament and the Council	European Parliament and the Council
or if, before the expiry of that period,		or if, before the expiry of that period,	or if, before the expiry of that period,
the European Parliament and the		the European Parliament and the	the European Parliament and the
Council have both informed the		Council have both informed the	Council have both informed the
Commission that they will not		Commission that they will not	Commission that they will not
object. That period shall be extended		object. That period shall be extended	object. That period shall be extended
by two months at the initiative of the		by two months at the initiative of the	by two months at the initiative of the
European Parliament or of the		European Parliament or of the	European Parliament or of the
Council.		Council.	Council.
Article 147		Article 147	Article 147
Data protection		Data protection	Data protection
1. Member States shall apply		1. Member States shall apply	1. Member States shall apply
Directive 95/46/EC to the processing		Regulation (EU) No 2016/679	Regulation (EU) No 2016/679 ⁸⁴
of personal data carried out in the		[] to the processing of personal	[] to the processing of personal
Member States pursuant to this		data carried out in the Member States	data carried out in the Member States
Regulation.		pursuant to this Regulation.	pursuant to this Regulation.

⁸⁴ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (OJ, L119, 4.5.2016, p.1)

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
2. Regulation (EC) No 45/2001		2. Regulation (EC) No 45/2001	2. Regulation (EC) No 45/2001
shall apply to the processing of		shall apply to the processing of	shall apply to the processing of
personal data carried out by the		personal data carried out by the	personal data carried out by the
Commission and the Agency		Commission and the Agency	Commission and the Agency
pursuant to this Regulation.		pursuant to this Regulation.	pursuant to this Regulation.
		Chapter XII	Chapter XII
		Transitional and final provisions	Transitional and final provisions
Article 148		Article 148	Article 148
Repeal		Repeal	Repeal
Directive 2001/82/EC is repealed.		Directive 2001/82/EC is repealed.	Directive 2001/82/EC is repealed.
References to the repealed Directive		References to the repealed Directive	References to the repealed Directive
shall be construed as references to		shall be construed as references to	shall be construed as references to
this Regulation and shall be read in		this Regulation and shall be read in	this Regulation and shall be read in
accordance with the correlation table		accordance with the correlation table	accordance with the correlation table
set out in Annex IV.		set out in Annex IV.	set out in Annex IV.
		Article 148a	Article 148a
		Relation with other Union acts	Relation with other Union acts
		1. Nothing in this Regulation	1. Nothing in this Regulation
		shall be understood to affect the	shall be understood to affect the
		provisions laid down in Council	provisions laid down in Council
		Directive 96/22/EC.	Directive 96/22/EC.
		2. The provisions of	2. The provisions of
		Commission Regulation No	Commission Regulation No
		1234/2008 shall not apply to	1234/2008 shall not apply to
		veterinary medicinal products	veterinary medicinal products
		covered by the provisions of this	covered by the provisions of this
		Regulation.	Regulation.

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
		3. The provisions of	3. The provisions of
		Commission Regulation No	Commission Regulation No
		658/2007 shall not apply to	658/2007 shall not apply to
		veterinary medicinal products	veterinary medicinal products
		covered by the provisions of this	covered by the provisions of this
		Regulation.	Regulation.
Article 149		Article 149	Article 149
Transitional provisions		Prior applications []	Prior applications []
1. Applications for marketing authorisations for veterinary		1. Applications for marketing authorisations for veterinary	1. Applications for marketing authorisations for veterinary
medicinal products submitted in		medicinal products or variations	medicinal products or variations
accordance with Regulation (EC) No		thereof [] validated in accordance	thereof [] validated in accordance
726/2004 before the date of		with Regulation (EC) No 726/2004	with Regulation (EC) No 726/2004
application of this Regulation shall		before the date of application of this	before the date of application of this
be examined in accordance with		Regulation shall be [] completed	Regulation shall be [] completed
Regulation (EC) No 726/2004.		in accordance with Regulation (EC)	in accordance with Regulation (EC)
		No 726/2004.	No 726/2004.
2. Applications for marketing		2. Applications for marketing	2. Applications for marketing
authorisations for veterinary		authorisations for veterinary	authorisations for veterinary
medicinal products submitted in		medicinal products [] validated in	medicinal products [] validated in
accordance with the requirements of		accordance with the requirements of	accordance with the requirements of
Directive 2001/82/EC before the date		Directive 2001/82/EC before the date	Directive 2001/82/EC before the date
of application of this Regulation		of application of this Regulation	of application of this Regulation
shall be examined in accordance with		shall be [] completed in	shall be [] completed in
Directive 2001/82/EC.		accordance with Directive	accordance with Directive
		2001/82/EC.	2001/82/EC.
3. Procedures initiated on the		3. Procedures initiated on the	3. Procedures initiated on the
basis of Articles 33, 34, 35, 39, 40		basis of Articles 33, 34, 35, 39, 40	basis of Articles 33, 34, 35, 39, 40
and 78 of Directive 2001/82/EC		and 78 of Directive 2001/82/EC	and 78 of Directive 2001/82/EC
before the date of application of this		before the date of application of this	before the date of application of this



Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Regulation shall be completed in		Regulation shall be completed in	Regulation shall be completed in
accordance with Directive		accordance with Directive	accordance with Directive
2001/82/EC.		2001/82/EC.	2001/82/EC.
		Article 149a	Article 149a
		Existing veterinary medicinal	Existing veterinary medicinal
		products, marketing authorisations	products, marketing authorisations
		and registrations	and registrations
		1. Marketing authorisations of	1. Marketing authorisations of
		veterinary medicinal products and	veterinary medicinal products and
		registrations of homeopathic	registrations of homeopathic
		veterinary medicinal products	veterinary medicinal products
		granted in accordance with	granted in accordance with
		Directive 2001/82/EC or	Directive 2001/82/EC or
		Regulation (EC) No 726/2004	Regulation (EC) No 726/2004
		before the date of application of	before the date of application of
		this Regulation shall be deemed to	this Regulation shall be deemed to
		have been issued in accordance	have been issued in accordance
		with this Regulation, and are, as	with this Regulation, and are, as
		such, subject to the relevant	such, subject to the relevant
		provisions under this Regulation.	provisions under this Regulation.
		The first subparagraph shall not	The first subparagraph shall not
		apply to marketing authorisations	apply to marketing authorisations
		for antimicrobial veterinary	for antimicrobial veterinary
		medicinal products which have	medicinal products which have
		been reserved for treatment in	been reserved for treatment in
		humans in accordance with	humans in accordance with
		implementing acts adopted on the	implementing acts adopted on the
		basis of Article 32(4).	basis of Article 32(4).
		2. Veterinary medicinal	2. Veterinary medicinal
		products placed on the market in	products placed on the market in



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		accordance with Directive	accordance with Directive
		2001/82/EC or Regulation (EC) No	2001/82/EC or Regulation (EC) No
		726/2004 may continue to be made	726/2004 may continue to be made
		available until five years after the	available until five years after the
		date of application of this	date of application of this
		Regulation, even if they are not in	Regulation, even if they are not in
		compliance with Articles 9 to 13 or	compliance with Articles 9 to 13 or
		with other provisions of this	with other provisions of this
		Regulation.	Regulation.
		3. By derogation from	3. By derogation from
		paragraph 1 of this Article, the	paragraph 1 of this Article, the
		periods of protection provided for	periods of protection provided for
		in Article 34 shall not apply to	in Article 34 shall not apply to
		reference veterinary medicinal	reference veterinary medicinal
		products for which an	products for which an
		authorisation has been granted	authorisation has been granted
		before the date of application	before the date of application
		referred to in Article 150 and,	referred to in Article 150 and,
		instead, the corresponding	instead, the corresponding
		provisions in the repealed acts	provisions in the repealed acts
		referred to shall continue to apply	referred to shall continue to apply
		in that respect.	in that respect.
		Article 149b	Article 149b
		Transitional measures regarding	Transitional measures regarding
		delegated and implementing acts	delegated and implementing acts
		1. The delegated acts referred	1. The delegated acts referred
		to in Articles 32(3), 54(3) and	to in Articles 32(3), 54(3) and
		122a(2) and the implementing acts	122a(2) and the implementing acts
		referred to in Articles 32(4), 54(4),	referred to in Articles 32(4), 54(4),
		77(1b), 98b(9), 104(6) and 108(4)	77(1b), 98b(9), 104(6) and 108(4)

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		shall apply from the date of	shall apply from the date of
		application in accordance with	application in accordance with
		Article 150.	Article 150.
		2. Without prejudice to the date	2. Without prejudice to the date
		of application referred to in Article	of application referred to in Article
		150, the Commission shall adopt	150, the Commission shall adopt
		the delegated acts referred to in	the delegated acts referred to in
		Article 145a(2) and the	Article 145a(2) and the
		implementing acts referred to in	implementing acts referred to in
		Articles 51(3a) and 58(2) at the	Articles 51(3a) and 58(2) at the
		latest on 12 months before the date	latest on 12 months before the date
		of application referred to in Article	of application referred to in Article
		150. Such acts shall apply from the	150. Such acts shall apply from the
		date of application in accordance	date of application in accordance
		with Article 150.	with Article 150.
		3. Without prejudice to the date	3. Without prejudice to the date
		of application referred to in Article	of application referred to in Article
		150, the delegated acts referred to	150, the delegated acts referred to
		in Article 112b(1) and the	in Article 112b(1) and the
		implementing acts referred to in	implementing acts referred to in
		Articles 15(1), 15(2), 98(2), 112b(2)	Articles 15(1), 15(2), 98(2), 112b(2)
		and 117(5) shall be adopted at the	and 117(5) shall be adopted at the
		latest by 36 months from the date	latest by 36 months from the date
		of application in accordance with	of application in accordance with
		Article 150 and shall start to apply	Article 150 and shall start to apply
		at the earliest on the date of	at the earliest on the date of
		application referred to in Article	application referred to in Article
		150.	150.
		4. Without prejudice to the date	4. Without prejudice to the date
		of application referred to in Article	of application referred to in Article

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		150, the Commission is empowered	150, the Commission is empowered
		to adopt delegated and	to adopt delegated and
		implementing acts provided for in	implementing acts provided for in
		this Regulation as from [the date	this Regulation as from [the date
		of entry into force of this	of entry into force of this
		Regulation]. Such acts, unless	Regulation]. Such acts, unless
		otherwise provided in this	otherwise provided in this
		Regulation, shall apply from the	Regulation, shall apply from the
		date of application in accordance	date of application in accordance
		with Article 150.	with Article 150.
		When adopting the delegated and	When adopting the delegated and
		implementing acts referred to in	implementing acts referred to in
		this Article, the Commission shall	this Article, the Commission shall
		allow sufficient time between their	allow sufficient time between their
		adoption and their start of	adoption and their start of
		application.	application.
		Article 149c	Article 149c
		Establishment of the	Establishment of the
		pharmacovigilance database and	pharmacovigilance database and
		setting up of the manufacturing and	setting up of the manufacturing and
	l	wholesale distribution database	wholesale distribution database
		Without prejudice to the date of	Without prejudice to the date of
		application referred to in Article	application referred to in Article
		150, the Agency, in collaboration	150, the Agency, in collaboration
		with the Member States and the	with the Member States and the
		Commission, shall, in accordance	Commission, shall, in accordance
		with Articles 74 and 94	with Articles 74 and 94
		respectively, ensure the	respectively, ensure the
		establishment of the	establishment of the
	L	pharmacovigilance database and	pharmacovigilance database and

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		the setting up of the	the setting up of the
		manufacturing and wholesale	manufacturing and wholesale
		distribution database at the latest	distribution database at the latest
		by the date of application of this	by the date of application of this
		Regulation.	Regulation.
		Article 149d	Article 149d
		Initial input to the product database	Initial input to the product database
		by competent authorities	by competent authorities
		At the latest by the date of	At the latest by the date of
		application of this Regulation, the	application of this Regulation, the
		competent authorities shall submit,	competent authorities shall submit,
		electronically, information on all	electronically, information on all
		veterinary medicinal products	veterinary medicinal products
		authorised in their Member State	authorised in their Member State
		at that time to the Agency, using	at that time to the Agency, using
		the format referred to in Article	the format referred to in Article
		51(3a)(a).	51(3a)(a).
		Article 149e	Article 149e
		Review of rules for environmental	Review of rules for environmental
		risk assessment	risk assessment
		No later than three years after the	No later than three years after <u>By</u>
		date of application of this	the date of application of this
		Regulation, the Commission shall	Regulation, the Commission shall
		present a report to the European	present a report to the European
		Parliament and to the Council on a	Parliament and to the Council on a
		feasibility study of an active	feasibility study of an active
		substance based review system	substance based review system
		('monographs') and other potential	('monographs') and other potential
		alternatives for the environmental	alternatives for the environmental
		risk assessment of veterinary	risk assessment of veterinary

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		medicinal products, to be	medicinal products, to be
		accompanied, if appropriate, by a	accompanied, if appropriate, by a
		legislative proposal.	legislative proposal.
		Article 149f	Article 149f
		Commission report on traditional	Commission report on traditional
		herbal products used to treat	herbal products used to treat
		animals	animals
		The Commission shall report to	The Commission shall report to
		the European Parliament and to	the European Parliament and to
		the Council within five years after	the Council within five years after
		the date of application of this	the date of application of this
		Regulation, on traditional herbal	Regulation, on traditional herbal
		products used to treat animals in	products used to treat animals in
		the Union. If appropriate, the	the Union. If appropriate, the
		Commission shall make a	Commission shall make a
		legislative proposal in order to	legislative proposal in order to
		introduce a simplified system for	introduce a simplified system for
		registering traditional herbal	registering traditional herbal
		products used to treat animals.	products used to treat animals.
		The Member States shall provide	The Member States shall provide
		information to the Commission on	information to the Commission on
		such traditional herbal products	such traditional herbal products
		within its territory.	within its territory.

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		Article 149g	Article 149g
		Review of measures regarding	Review of measures regarding
		animals of the equine species	animals of the equine species
		No later than three years after the	No later than three years after the
		date of application of this	date of application of this
		Regulation, the Commission shall	Regulation, the Commission shall
		present a report to the European	present a report to the European
		Parliament and to the Council on	Parliament and to the Council on
		its assessment of the situation as	its assessment of the situation as
		regards the treatment with	regards the treatment with
		medicinal products of animals of	medicinal products of animals of
		the equine species and their	the equine species and their
		exclusion from the food chain,	exclusion from the food chain,
		including with regard to imports of	including with regard to imports of
		animals of the equine species from	animals of the equine species from
		third countries, to be accompanied	third countries, to be accompanied
		by any appropriate action by the	by any appropriate action by the
		Commission taking into account in	Commission taking into account in
		particular [public health, animal	particular [public health, animal
		welfare, the risks for fraud and the	welfare, the risks for fraud and the
		level playing field with third	level playing field with third
		countries] .	countries] .
		Article 149h	Article 149h
		Transitional measures regarding	Transitional measures regarding
		certain certificates of good	certain certificates of good
		manufacturing practice	manufacturing practice
		Without prejudice to the date of	Without prejudice to the date of
		application referred to in Article	application referred to in Article
		150, the obligations regarding	150, the obligations regarding
		certificates of good manufacturing	certificates of good manufacturing

Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
		practices for inactivated	practices for inactivated
		immunological veterinary	immunological veterinary
		medicinal products which are	medicinal products which are
		manufactured from an animal or	manufactured from an animal or
		animals in an epidemiological unit	animals in an epidemiological unit
		and used for the treatment of that	and used for the treatment of that
		animal or those animals in the	animal or those animals in the
		same epidemiological unit or for	same epidemiological unit or for
		the treatment of animals in a unit	the treatment of animals in a unit
		having a confirmed	having a confirmed
		epidemiological link shall only	epidemiological link shall only
		start to apply at the start of	start to apply at the start of
		application of the implementing	application of the implementing
		acts laying down specific measures	acts laying down specific measures
		on good manufacturing practices	on good manufacturing practices
		for those products referred to in	for those products referred to in
		Article 98(2).	Article 98(2).

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Article 150		Article 150	Article 150
Entry into force		Entry into force and application	Entry into force and application
This Regulation shall enter into force		This Regulation shall enter into force	This Regulation shall enter into force
on the twentieth day following that		on the twentieth day following that	on the twentieth day following that
of its publication in the Official		of its publication in the Official	of its publication in the Official
Journal of the European Union.		Journal of the European Union.	Journal of the European Union.
It shall apply from [Office of		It shall apply from [Office of	It shall apply from [Office of
Publications please insert date		Publications please insert date	Publications please insert date
counting 24 months from the entry		counting 36 [] months from the	counting 36 [] months from the
into force] except for Article 15,		entry into force].[]	entry into force].[]
Article 54(4), Article 58(2), Article			
108(4) and Article 116(4) which			
shall apply from the date of entry			
into force of this Regulation.			
This Regulation shall be binding in		This Regulation shall be binding in	This Regulation shall be binding in
its entirety and directly applicable in		its entirety and directly applicable in	its entirety and directly applicable in
all Member States.		all Member States.	all Member States.
Done at Brussels,		Done at Brussels,	Done at Brussels,
For the European Parliament		For the European Parliament	For the European Parliament
The President		The President	The President
For the Council		For the Council	For the Council
The President		The President	The President

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Annex 2 part 1 point 1.1	AM 285	· · ·	× × ×
paragraph 7	Member States shall ensure that		
Experiments on animals other than	all experiments on animals other		
clinical trials shall be conducted in	than clinical trials shall be		
accordance with Directive	conducted in accordance with		
2010/63/EU.	Directive 2010/63/EU. As specified		
	in Directive 2010/63/EU, it shall		
	be necessary to replace, reduce or		
	refine testing on vertebrate		
	animals. These methods shall be		
	regularly reviewed and improved		
	with a view to reducing testing on		
	vertebrate animals and the number		
	of animals involved.		
Annex 2 part 1 point 1.3	AM 286		
subpoint 1.3.1 paragraph 1	(e) the potential risks relating to the		
point e	development of antimicrobial		
(e) the potential risks relating to the	resistance <i>during production and</i>		
development of antimicrobial	use.		
resistance.			

Commission proposal COM(2014) 558 final - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Draft revised negotiation mandate proposed by the Presidency
Annex 2 part 1 point 1.3	AM 287	by coreper on 20 December 2017	proposed by the Tresidency
subpoint 1.3.1 paragraph 7	This assessment shall normally be		
introductory part	conducted in two phases. <i>All</i>		
This assessment shall normally be	available data of sufficient		
conducted in two phases. The first	reliability and relevance shall be		
phase of the assessment shall always	considered, including information		
be performed and the second phase	gained during the drug discovery		
shall be performed if necessary. The	process. The first phase of the		
details of the assessment shall be	assessment shall always be		
provided in accordance with	performed and the second phase		
accepted guidance. The assessment	shall be performed if necessary.		
shall indicate the potential exposure	The details of the assessment shall		
of the environment to the product	be provided in accordance with		
and the level of risk associated with	accepted guidance. The assessment		
any such exposure taking into	shall indicate the potential exposure		
account in particular the following	of the environment to the product		
items:	and the level of risk associated with		
	any such exposure taking into		
	account in particular the following		
	items:		
Annex 2 part 1 point 1.3	AM 288		
subpoint 1.3.1 paragraph 8	In the second phase, further specific		
In the second phase, further specific	investigation of the fate and effects		
investigation of the fate and effects	of the product on particular		
of the product on particular	ecosystems shall be conducted, in		
ecosystems shall be conducted, in	accordance with established		
accordance with established	guidance, and taking into account		
guidance. The extent of exposure of	the pharmacological effect of the		
the product to the environment, and the available information about the	product as well as any relevant		
the available information about the	side effects. The extent of exposure		



Commission proposal COM(2014)	EP amendment	Position in the Council as endorsed	Draft revised negotiation mandate
558 final - 2014/0257 (COD)		by Coreper on 20 December 2017	proposed by the Presidency
physical/chemical, pharmacological	of the product to the environment,		
and/or toxicological properties of the	and the available information about		
substance(s) concerned, including	the physical/chemical,		
metabolites, shall be taken into	pharmacological and/or		
consideration.	toxicological properties of the		
	substance(s) concerned, including		
	metabolites, shall be taken into		
	consideration.		
	Annex 2 part 1 point 1.3		
	subpoint 1.3.1 paragraph 8 a		
	(new)		
	The environmental risk		
	assessment shall be updated when		
	new information becomes		
	available that would change the		
	estimation of the risk.		



ANNEX I

Administrative information referred to in Article 7(1)(a)

0. Legal basis for the application for the marketing authorisation.

1. Applicant

1.1. Name [...] and address or registered place of business of the **applicant** [...];

1.2. Name and address of manufacturer (s) or importer(s) of the finished product and name and address of the manufacturer of the active substance(s)

1.3. Name and address of the sites involved in the different stages of the manufacturing, **importing, control and batch release.**

[...]

2. Identification of the veterinary medicinal product

2.1. [...] Name of the veterinary medicinal product and Anatomical Therapeutic Chemical Veterinary code (ATCVet Code)

2.2. Active substance(s) and, if applicable, diluent(s)

2.3. Strength or, in case of immunological veterinary medicinal product, biological activity, potency or titre

2.4. Pharmaceutical form

2.5. Route of administration

2.6 [...]

2.7. Target species

3. Manufacturing and pharmacovigilance information

- 3.1. Proof of a manufacturing authorisation or certificate of good manufacturing practice
- 3.2. [...] Reference number of pharmacovigilance system master file.

4. Product information

- 4.1. [...] Proposed summary of the product characteristics drawn up in accordance with Article 30
- 4.2. Description of the final presentation of the product, including packaging and labelling

4.3. [...] **Proposed** text of the information to be provided **on** the immediate packaging, outer packaging and the package leaflet in accordance with Articles 9-[...] **13** of this Regulation.

5. Other information

5.1. List of countries in which a marketing authorisation has been granted **or revoked** for the veterinary medicinal product

5.2. Copies of all the summaries of product characteristics as included in the terms of marketing authorisations granted by Member States, [...]

5.3. List of countries in which an application has been submitted or refused

5.4. List of **Member States** [...] where the veterinary medicinal product is to be placed on the market, [...]

5.5. Critical expert reports on quality, safety and efficacy of the veterinary medicinal product.

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<u>ANNEX II</u>

Technical requirements referred to in Article 7(1)(b)

Annexes II and III of the above mentionned proposal are merged into one single annex (Annex II), the content of which is replaced by the content of current Annex I of Directive 2001/82/EC at last amended by Commission Directive 2009/9/EC of February 2009.

ANNEX III⁸⁵

List of the obligations referred to in Article 135(1):

- (0) the obligation, as an applicant, to provide accurate information and documentation as referred to in Article 6(4);
- (00) the obligation to provide, in an application submitted in accordance with Article 61, the data referred to in Article 61(2)(aa);
- (1) the obligation to comply with the conditions referred to in Articles 21 and 22;
- (2) the obligation to comply with conditions included in the marketing authorisation of the veterinary medicinal product, as referred to in Article 31(1);
- (3) the obligation to introduce any necessary variation to the terms of the marketing authorisation to take account of technical and scientific progress and enable the veterinary medicinal products to be manufactured and checked by means of generally accepted scientific methods, as provided for in Article 55(1);
- (4) the obligation to keep up to date the summary of product characteristics, package
 leaflet and labelling with the current scientific knowledge, as provided for in Article
 55(1aa);
- (5) the obligation to record in the product database the dates when its authorised veterinary medicinal products are placed on the market and information on the availability for each veterinary medicinal product in each relevant Member State and, as applicable, the dates of any suspension or revocation of the concerned marketing authorisations as well as data relating to the volume of sales of the product, as provided in Article 55(1b) and Article 55(6), respectively;

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⁸⁵ Based on Annex II of the current text of the draft Regulation amending Regulation 726/2004 (Item 135ff. in document 6462/18 ADD 1).

- (6) the obligation to provide within the time limit set, at the request of a competent authority or the Agency, any data demonstrating that the risk-benefit balance remains favourable, as provided for in Articles 55(4);
- (7) the obligation to supply any new information which may entail a variation to the terms of the marketing authorisation, to notify any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is marketed, or to supply any information that may influence the evaluation of the risks and benefits of the product, as provided for in Article 55(5);
- (8) the obligation to place the veterinary medicinal product on the market in accordance with the content of the summary of the product characteristics and the labelling and package leaflet as contained in the marketing authorisation;
- (9) the obligation to record and report suspected adverse events for their veterinary medicinal products, in accordance with Article 76(2);
- (10) the obligation to collect specific pharmacovigilance data additional to the data listed in Article 73(2) and to carry out post marketing surveillance studies in accordance to Article 76(2a);
- (11) the obligation to ensure that public announcements relating to information on pharmacovigilance concerns are presented objectively and are not misleading and to notify them to the Agency, as provided for in Article 77(6);
- (12) the obligation to operate a pharmacovigilance system for the fulfilment of pharmacovigilance tasks, including, maintenance of a pharmacovigilance system master file in accordance with Article 77;
- (13) the obligation to submit, at the request of the Agency, a copy of its pharmacovigilance system master file(s), as provided for in Article 79(7);
- (14) the obligation to carry out signal management process and to record the results and outcomes of that process in accordance with Article 81(0) and (00).
- (15) the obligation to provide to the Agency all available information relating to an Union interest referral, as referred to in Article 84(2).

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