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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 Annex 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 **bold and underlined** and ~~strikethrough~~, and the cells including those changes are highlighted.

ANNEX

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 EUROPEAN PARLIAMENT AND OF THE COUNCIL		REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	REGULATION OF THE EUROPEAN PARLIAMENT AND 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 PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168(4)(b) thereof,		Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168(4)(b) thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168(4)(b) thereof,
Having regard to the proposal from the European Commission,		Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,
After transmission of the draft legislative act to the national Parliaments,		After transmission of the draft legislative act to the national Parliaments,	After transmission of the draft legislative act to the national Parliaments,
Having regard to the opinion of the European Economic and Social Committee,		Having regard to the opinion of the European Economic and Social Committee,	Having regard to the opinion of the European Economic and Social Committee[1],

[1] OJ C , , p. .

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Having regard to the opinion of the Committee of the Regions,		Having regard to the opinion of the Committee of the Regions,	Having regard to the opinion of the Committee of the Regions[2],
Acting in accordance with the ordinary legislative procedure,		Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,
Whereas:		Whereas:	Whereas:
(1) 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 constitute the Union regulatory framework for the placing on the market, manufacture, import, export, supply, pharmacovigilance, control and the use of veterinary medicinal products.		(1) 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 constitute the Union regulatory framework for the placing on the market, manufacture, import, export, supply, pharmacovigilance, control and the use of veterinary medicinal products.	(1) Directive 2001/82/EC of the European Parliament and of the Council[3] and Regulation (EC) No 726/2004 of the European Parliament and of the Council[4] constitute the Union regulatory framework for the placing on the market, manufacture, import, export, supply, pharmacovigilance, control and the 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) 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) 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 1** (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 animals, nature and their interaction with man***.	(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 to ensure a high level of animal health and animal welfare and safeguarding public health**.	(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 to ensure a high level of <u>protection of</u> animal health, ~~and~~ animal welfare <u>and environment</u> and safeguarding public health**.
(3) The legal framework should take into account the needs of the businesses in the veterinary pharmaceutical sector and trade in veterinary medicinal products within the Union. It should also integrate the major policy objectives set out in the Communication from the Commission of 3 March 2010 "Europe 2020 A Strategy for smart, sustainable and inclusive growth".		(3) The legal framework should take into account the needs of the businesses in the veterinary pharmaceutical sector and trade in veterinary medicinal products within the Union. It should also integrate the major policy objectives set out in the Communication from the Commission of 3 March 2010 "Europe 2020 A Strategy for smart, sustainable and inclusive growth".	(3) The legal framework should take into account the needs of the businesses in the veterinary pharmaceutical sector and trade in veterinary medicinal products within the Union. It should also integrate the major policy objectives set out in the Communication from the Commission of 3 March 2010 "Europe 2020 A Strategy for smart, sustainable and inclusive growth"[5].
(4) Experience has shown that the needs of the veterinary sector differ		(4) Experience has shown that the needs of the veterinary sector differ	(4) Experience has shown that the needs of the veterinary sector differ

[5] COM(2010) 2020 final, 3.3.2010.

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
substantially from those of the human sector in relation to medicines. In particular, the drivers for investment for the human and the veterinary medicines markets are different. For example, in the veterinary sector there are many different animal species, which creates both a fragmented market and the need for major investments in order to extend the authorisation of medicines existing for one animal species to another. Moreover, the price-setting mechanisms in the veterinary sector follow a completely different logic. Consequently, prices for veterinary medicines are typically substantially lower than for medicinal products for human use. The size of the animal pharmaceutical industry is only a small fraction of the size of the pharmaceutical industry for human medicines.It is therefore appropriate to develop a regulatory framework addressing the characteristics and specificities of the veterinary sector, which cannot be considered as a model for the human medicines market.		substantially from those of the human sector in relation to medicines. In particular, the drivers for investment for the human and the veterinary medicines markets are different. For example, in the veterinary sector there are many different animal species, which creates both a fragmented market and the need for major investments in order to extend the authorisation of medicines existing for one animal species to another. Moreover, the price-setting mechanisms in the veterinary sector follow a completely different logic. Consequently, prices for veterinary medicines are typically substantially lower than for medicinal products for human use. The size of the animal pharmaceutical industry is only a small fraction of the size of the pharmaceutical industry for human medicines.It is therefore appropriate to develop a regulatory framework addressing the characteristics and specificities of the veterinary sector, which cannot be considered as a model for the human medicines market.	substantially from those of the human sector in relation to medicines. In particular, the drivers for investment for the human and the veterinary medicines markets are different. For example, in the veterinary sector there are many different animal species, which creates both a fragmented market and the need for major investments in order to extend the authorisation of medicines existing for one animal species to another. Moreover, the price-setting mechanisms in the veterinary sector follow a completely different logic. Consequently, prices for veterinary medicines are typically substantially lower than for medicinal products for human use. The size of the animal pharmaceutical industry is only a small fraction of the size of the pharmaceutical industry for human medicines.It is therefore appropriate to develop a regulatory framework addressing the characteristics and specificities of the veterinary sector, which cannot be considered as a model for the human medicines 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
(5) The provisions of this act aim to reduce administrative burden, enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection.		(5) The provisions of this act aim to reduce administrative burden, enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection.	(5) The provisions of this act aim to reduce administrative burden, enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection.
		(5a) Identification of packs of veterinary medicinal products via identification codes is common practice in several Member States. These Member States have developed integrated electronic systems at national level for the proper functioning of such codes, linked to national databases. However, the introduction of a harmonised EU-wide system has not been the subject of any assessment as to costs and administrative consequences. Instead, the possibility should be given for Member States to decide at national level on whether or not to adopt a system for identification codes to be added to the information on the outer packaging of the veterinary medicinal products.	**(5a) Identification of packs of veterinary medicinal products via identification codes is common practice in several Member States. These Member States have developed integrated electronic systems at national level for the proper functioning of such codes, linked to national databases. However, the introduction of a harmonised EU-wide system has not been the subject of any assessment as to costs and administrative consequences. Instead, the possibility should be given for Member States to decide at national level on whether or not to adopt a system for identification codes to be added to the information on the outer packaging of the veterinary medicinal products.**

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

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
health, and for the development of the agriculture and aquaculture sectors.	on public health. Therefore sufficient and effective veterinary medicinal products should be available in the Union in order to ensure high standards of animal and public health, and for the development of the agriculture and aquaculture sectors. ***To that end, good husbandry and management practices should be put in place in order to improve animal welfare, limit the spread of diseases, prevent antimicrobial resistance and ensure proper nutrition of livestock.***	have a significant impact on public health. Therefore sufficient and effective veterinary medicinal products should be available in the Union in order to ensure high standards of animal and public health, and for the development of the agriculture and aquaculture sectors.	individual animals, animal populations, animal keepers and the economy. Animal diseases transmissible to humans may also have a significant impact on public health. Therefore sufficient and effective veterinary medicinal products should be available in the Union in order to ensure high standards of animal and public health, and for the development of the agriculture and aquaculture sectors.
(7) This Regulation should set high standards of quality, safety and efficacy for veterinary medicinal products in order to meet common concerns as regards the protection of public and animal health. At the same time, this Regulation should harmonise the rules for the authorisation of veterinary medicinal products and the placing of them on the Union market.	**AM 3** (7) This Regulation should set high standards of quality, safety and efficacy for veterinary medicinal products in order to meet common concerns as regards the protection of public and animal health ***and the environment.*** At the same time, this Regulation should harmonise the rules for the authorisation of veterinary medicinal products and the placing of them on the Union market.	(7) This Regulation should set high standards of quality, safety and efficacy for veterinary medicinal products in order to meet common concerns as regards the protection of public and animal health **and the environment.** At the same time, this Regulation should harmonise the rules for the authorisation of veterinary medicinal products and the placing of them on the Union market.	(7) This Regulation should set high standards of quality, safety and efficacy for veterinary medicinal products in order to meet common concerns as regards the protection of public and animal health **and the environment.** At the same time, this Regulation should harmonise the rules for the authorisation of veterinary medicinal products and the placing of them on the Union 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 shall not apply to veterinary medicinal products which have not undergone an industrial process as, for example non-processed blood.	**(7a) ~~However, t~~<u>This</u> Regulation ~~shall~~ <u>should</u> not apply to veterinary medicinal products which have not undergone an industrial process as, for example non-processed blood.**
			<u>(7aa) Antiparasitics include also substances with repelling activity that are presented for use as veterinary medicinal products.</u>

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

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

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

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(9) The scope of the mandatory use of a centralised authorisation procedure under which the authorisations are valid throughout the Union should cover *inter alia* products containing new active substances and products which contain or consist of engineered tissues or cells. At the same time, in order to ensure the widest possible availability of veterinary medicinal products in the Union, the centralised authorisation procedure should be extended to allow for applications for authorisations under that procedure to be submitted for any veterinary medicinal product, including for generics of nationally authorised veterinary medicinal products.	**AM 5** (9) The scope of the mandatory use of a centralised authorisation procedure under which the authorisations are valid throughout the Union should cover inter alia products containing new active substances and products which contain or consist of engineered tissues or cells. At the same time, in order to ensure the widest possible availability of veterinary medicinal products in the Union, the centralised authorisation procedure should be extended to allow for applications for authorisations under that procedure to be submitted for any veterinary medicinal product, including for generics of nationally authorised veterinary medicinal products. ***The use of the centralised procedure should be encouraged in every way, in particular by facilitating access for small and medium-sized enterprises (SMEs).***	(9) The scope of the mandatory use of a centralised authorisation procedure under which the authorisations are valid throughout the Union should cover *inter alia* products containing new active substances and products which contain or consist of engineered tissues or cells, **including novel therapy veterinary medicinal products with the exclusion of blood components, like plasma, platelet concentrates or red cells.** At the same time, in order to ensure the widest possible availability of veterinary medicinal products in the Union, the centralised authorisation procedure should be extended to allow for applications for authorisations under that procedure to be submitted for any veterinary medicinal product, including for generics of nationally authorised veterinary medicinal products.	(9) The scope of the mandatory use of a centralised authorisation procedure under which the authorisations are valid throughout the Union should cover inter alia products containing new active substances and products which contain or consist of engineered tissues or cells, **including novel therapy veterinary medicinal products with the exclusion of blood components, like plasma, platelet concentrates or red cells.** At the same time, in order to ensure the widest possible availability of veterinary medicinal products in the Union, the **access of small and medium-sized enterprises (SMEs) to the** centralised authorisation procedure should be **facilitated by all appropriate means, and its use should be** extended to allow for applications for authorisations under 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 strain in case of already authorised immunological veterinary medicinal products against e. g. avian influenza, bluetongue, foot and mouth disease or equine influenza should not be considered as adding a new active substance.	**addition of a new antigen or a new strain in case of already authorised immunological veterinary medicinal products against e. g. avian influenza, bluetongue, foot and mouth disease or equine influenza should not be considered as adding a new active substance.**
(10) The national procedure for authorising veterinary medicinal products should be maintained because of varying needs in different geographical areas of the Union as well as the business models of small and medium sized enterprises (SMEs). It should be ensured that marketing authorisations granted in one Member State are recognised in other Member States.		(10) The national procedure for authorising veterinary medicinal products should be maintained because of varying needs in different geographical areas of the Union as well as the business models of small and medium sized enterprises (SMEs). It should be ensured that marketing authorisations granted in one Member State are recognised in other Member States.	(10) The national procedure for authorising veterinary medicinal products should be maintained because of varying needs in different geographical areas of the Union as well as the business models of small and medium sized enterprises (SMEs). It should be ensured that marketing authorisations granted in one Member State are recognised in other Member States.
(11) In order to help applicants, and in particular SMEs, to comply with the requirements of this Regulation, Member States should provide advice to the applicants, for example by establishing helpdesks. This advice should be provided in addition to the operational guidance documents and other advice and assistance provided by the European Medicines Agency.		(11) In order to help applicants, and in particular SMEs, to comply with the requirements of this Regulation, Member States should provide advice to the applicants […]. This advice should be provided in addition to the operational guidance documents and other advice and assistance provided by the European Medicines Agency.	(11) In order to help applicants, and in particular SMEs, to comply with the requirements of this Regulation, Member States should provide advice to the applicants […]. This advice should be provided in addition to the operational guidance documents and other advice and assistance provided by the European Medicines Agency.

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

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		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. ***The authorisation procedure for veterinary medicinal products should be adjusted so as to eliminate other administrative procedures that might hamper the development of research and innovation for the purpose of identifying new medicines.***	(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 product should be allowed to be placed on the market or used in the Union unless it has been authorised, and its quality, safety and efficacy have been demonstrated.		(15) No veterinary medicinal product should be allowed to be placed on the market […] in the Union unless it has been authorised, and its quality, safety and efficacy have been demonstrated.	(15) No veterinary medicinal product should be allowed to be placed on the market […] in the Union unless it has been authorised, and its quality, safety and efficacy have been demonstrated.
(16) Where a veterinary medicinal product is intended for food-producing animal species, a marketing authorisation should only be granted if the pharmacologically active substances which the product contains are allowed in accordance with Commission Regulation (EU) No 37/2010[6] for the species for which the veterinary medicinal product is intended.		(16) Where a veterinary medicinal product is intended for food-producing animal species, a marketing authorisation should only be granted if the pharmacologically active substances which the product contains are allowed in accordance with **Regulation (EC) No 470/2009 and any acts adopted on the basis thereof** […] for the species for which the veterinary medicinal product is intended.	(16) Where a veterinary medicinal product is intended for food-producing animal species, a marketing authorisation should only be granted if the pharmacologically active substances which the product contains are allowed in accordance with **Regulation (EC) No 470/2009 and any acts adopted on the basis thereof** […][7] for the species for which the veterinary medicinal 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. ***In such cases, antimicrobial medicinal products for human use could be employed only subject to the issuing of a prescription by a veterinarian and the granting of authorisation by the veterinary authority responsible for monitoring the work of the veterinarian in question.*** 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 antibiotics to food-producing animals***.		(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 to allow exceptional use of veterinary medicinal products without a marketing authorisation where it is necessary to respond to Union listed diseases and where the health situation in a Member State so requires.	(18) Member States should be able to allow ***temporary*** exceptional use of veterinary medicinal products without a marketing authorisation where it is necessary to respond to Union listed diseases ***or new diseases*** and where the health situation in a Member State so requires.	(18) Member States should be able to allow exceptional use of veterinary medicinal products without a marketing authorisation where it is necessary to respond to Union listed diseases **or emerging diseases** and where the health situation in a Member State so requires.	(18) Member States should be able to allow exceptional use of veterinary medicinal products without a marketing authorisation where it is necessary to respond to Union listed diseases **or emerging diseases** and where the health situation in a Member State so requires.
(19) Taking into account the need for simple rules on changes to the marketing authorisations of veterinary medicinal products, only changes that may affect animal health, public health or the environment should require a scientific assessment.		(19) Taking into account the need for simple rules on changes to the marketing authorisations of veterinary medicinal products, only changes that may affect animal health, public health or the environment should require a scientific assessment.	(19) Taking into account the need for simple rules on changes to the marketing authorisations of veterinary medicinal products, only changes that may affect animal health, public health or the environment should require a scientific assessment.
(20) Directive 2010/63/EU of the European Parliament and of the Council lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Clinical trials for veterinary medicinal products are exempted from that Directive. The	**AM 9** (20) Directive 2010/63/EU of the European Parliament and of the Council lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Clinical trials for veterinary medicinal products are exempted from that Directive. The	(20) Directive 2010/63/EU of the European Parliament and of the Council lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Clinical trials for veterinary medicinal products are exempted from that Directive. The	(20) Directive 2010/63/EU of the European Parliament and of the Council[8] lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Clinical trials for veterinary medicinal products are 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 trials, which provide essential information on the safety and efficacy of a veterinary medicinal product, should be such as to provide the most satisfactory results whilst using the minimum number of animals, the procedures should be the least likely to cause pain, suffering or distress to animals and should take into account the principles established by Directive 2010/63/EU.	design and performance of clinical trials, which provide essential information on the safety and efficacy of a veterinary medicinal product, should be ~~such as~~ ***optimised in order*** to provide the most satisfactory results whilst using the minimum number of animals, the procedures should be ~~the least likely to cause~~ ***designed to avoid causing*** pain, suffering or distress to animals and should take into account the principles established by Directive 2010/63/EU.	design and performance of clinical trials, which provide essential information on the safety and efficacy of a veterinary medicinal product, should be […] **optimised in order** to provide the most satisfactory results whilst using the minimum number of animals, the procedures should be the […] **designed to avoid causing** pain, suffering or distress to animals and should take into account the principles established by Directive 2010/63/EU **and the guidelines of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products ('VICH')**.	design and performance of clinical trials, which provide essential information on the safety and efficacy of a veterinary medicinal product, should be […] **optimised in order** to provide the most satisfactory results whilst using the minimum number of animals, the procedures should be the […] **designed to avoid causing** pain, suffering or distress to animals and should take into account the principles established by Directive 2010/63/EU, **including the use of alternative test methods wherever possible, and the guidelines of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products ('VICH').**
(21) The principles of replacement, reduction and refinement concerning the care and use of live animals for scientific purposes should therefore be taken into account during the design and performance of clinical trials.		(21) The principles of replacement, reduction and refinement concerning the care and use of live animals for scientific purposes should therefore be taken into account during the design and performance of clinical trials.	(21) The principles of replacement, reduction and refinement concerning the care and use of live animals for scientific purposes should therefore be taken into account during the design and performance of clinical trials.
(22) It is recognised that improved access to information contributes to		(22) It is recognised that improved access to information contributes to	(22) It is recognised that improved access to information contributes to

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public awareness, gives the public the opportunity to express its observations and enables authorities to take due account of those observations. Regulation (EC) No 1049/2001 of the European Parliament and of the Council gives the fullest possible effect to the right of public access to documents and lays down the general principles and limits on such access. The European Medicines Agency should therefore give the widest possible access to the documents carefully balancing the right for information with existing data protection requirements. Certain public and private interests, such as regarding the protection of personal data, or the protection of commercially confidential information, should be protected by way of exceptions in accordance with Regulation (EC) No 1049/2001.		public awareness, gives the public the opportunity to express its observations and enables authorities to take due account of those observations. Regulation (EC) No 1049/2001 of the European Parliament and of the Council gives the fullest possible effect to the right of public access to documents and lays down the general principles and limits on such access. The European Medicines Agency should therefore give the widest possible access to the documents carefully balancing the right for information with existing data protection requirements. Certain public and private interests, such as regarding the protection of personal data, or the protection of commercially confidential information, should be protected by way of exceptions in accordance with Regulation (EC) No 1049/2001.	public awareness, gives the public the opportunity to express its observations and enables authorities to take due account of those observations.**The general public should therefore have access to information in the product database, the pharmacovigilance database and the manufacturing and wholesale distribution database, after the deletion of any commercially confidential information by the competent authority.** Regulation (EC) No 1049/2001 of the European Parliament and of the Council[9] gives the fullest possible effect to the right of public access to documents and lays down the general principles and limits on such access. The European Medicines Agency should therefore give the widest possible access to the documents carefully balancing the 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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			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.	**AM 10** (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 a prescription.***	(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.
(24) Environmental risk assessments should be mandatory for		(24) Environmental risk assessments should be mandatory for	(24) Environmental risk assessments should be mandatory for

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all new applications for a marketing authorisation and should consist of two phases. In the first phase the extent of environmental exposure of the product, its active substances and other constituent should be estimated, while in the second phase the effects of the active residue should be assessed.		all new applications for a marketing authorisation and should consist of two phases. In the first phase the extent of environmental exposure of the product, its active substances and other constituent should be estimated, while in the second phase the effects of the active residue should be assessed.	all new applications for a marketing authorisation and should consist of two phases. In the first phase the extent of environmental exposure of the product, its active substances and other constituent should be estimated, while in the second phase the effects of the active residue 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

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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.
(25) Tests, pre-clinical studies and clinical trials represent a major investment for companies which they need to make in order to submit the necessary data with the application for a marketing authorisation or to establish a maximum residue limit for pharmaceutical active substances in the veterinary medicinal product. That investment should be protected in order to stimulate research and innovation, so that it is ensured the necessary veterinary medicinal products are available in the Union. For that reason data submitted to a competent authority or the Agency	**AM 11** (25) Tests, pre-clinical studies and clinical trials represent a major investment for companies which they need to make in order to submit the necessary data with the application for a marketing authorisation or to establish a maximum residue limit for pharmaceutical active substances in the veterinary medicinal product. That investment should be protected in order to stimulate research and innovation, ***in particular on veterinary medicinal products for minor species and antimicrobials,*** so that it is ensured the necessary veterinary medicinal products are	(25) Tests, pre-clinical studies and clinical trials represent a major investment for companies which they need to make in order to submit the necessary data with the application for a marketing authorisation or to establish a maximum residue limit for […] **pharmacologically** active substances **of** […] the veterinary medicinal product. That investment should be protected in order to stimulate research and innovation, **in particular on veterinary medicinal products for minor species and antimicrobials,** so that it is ensured the necessary veterinary medicinal	(25) Tests, pre-clinical studies and clinical trials represent a major investment for companies which they need to make in order to submit the necessary data with the application for a marketing authorisation or to establish a maximum residue limit for […] **pharmacologically** active substances **of** […] the veterinary medicinal product. That investment should be protected in order to stimulate research and innovation, **in particular on veterinary medicinal products for minor species and antimicrobials,** so that it is ensured 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 marketing authorisation should not be required if a veterinary medicinal product is a generic medicinal product of a veterinary medicinal product that is authorised or has been authorised in the Union.		submitted with an application for a marketing authorisation should not be required if a veterinary medicinal product is a generic medicinal product of a veterinary medicinal product that is authorised or has been authorised in the Union.	submitted with an application for a marketing authorisation should not be required if a veterinary medicinal product is a generic medicinal product of a veterinary medicinal product that is authorised or has been authorised in the Union.
(27) It is recognised that the potential effect of a product on the environment may depend on the volume used and the resulting amount of the pharmaceutical substance that may reach the environment. Therefore, where there is evidence that a constituent of a medicinal product for which a generic application for a marketing authorisation is submitted is a hazard for the environment, it is appropriate to require data on the potential effect on the environment in order to safeguard the environment. In such cases applicants should endeavour to join efforts in generating such data in order to reduce costs and to reduce testing on vertebrate animals.	**AM 13** (27) It is recognised that the potential effect of a product on the environment may depend on the volume used and the resulting amount of the pharmaceutical substance that may reach the environment. Therefore, where there is evidence that a constituent of a medicinal product for which a generic application for a marketing authorisation is submitted is a hazard for the environment, it is appropriate to require data on the potential effect on the environment in order to safeguard the environment. In such cases applicants should endeavour to join efforts in generating such data in order to reduce costs and to reduce testing on vertebrate animals. ***The current impact assessment system results in repetitive and potentially divergent assessments of***	(27) It is recognised that the potential effect of a product on the environment may depend on the volume used and the resulting amount of the pharmaceutical substance that may reach the environment. Therefore, where there is evidence that a constituent of a medicinal product for which a generic application for a marketing authorisation is submitted is a hazard for the environment, it is appropriate to require data on the potential effect on the environment in order to safeguard the environment. In such cases applicants should endeavour to join efforts in generating such data in order to reduce costs and to reduce testing on vertebrate animals. **The establishment of a single European assessment of the environmental properties of active substances for**	(27) It is recognised that the potential effect of a product on the environment may depend on the volume used and the resulting amount of the pharmaceutical substance that may reach the environment. Therefore, where there is evidence that a constituent of a medicinal product for which a generic application for a marketing authorisation is submitted is a hazard for the environment, it is appropriate to require data on the potential effect on the environment in order to safeguard the environment. In such cases applicants should endeavour to join efforts in generating such data in order to reduce costs and to reduce testing on vertebrate animals. **The establishment of a single European assessment of the environmental 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.**

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	AM 14 ***(27a) In accordance with Directive 2010/63/EU, it is necessary to replace, reduce or refine testing on vertebrate 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.***		
(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, 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.		(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.	(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		(29) Differences in the	(29) Differences in the

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manufacturing process of biological products or a change in the excipient used may lead to differences in the generic product characteristics. In an application for generic biological veterinary medicinal product the bioequivalence should be demonstrated in order to ensure, based on the existing knowledge, that quality, safety and efficacy are similar.		manufacturing process of biological products or a change in the excipient used may lead to differences in the generic product characteristics. In an application for generic biological veterinary medicinal product the bioequivalence should be demonstrated in order to ensure, based on the existing knowledge, that quality, safety and efficacy are similar.	manufacturing process of biological products or a change in the excipient used may lead to differences in the generic product characteristics. In an application for generic biological veterinary medicinal product the bioequivalence should be demonstrated in order to ensure, based on the existing knowledge, that quality, safety and efficacy are similar.
(30) In order to avoid unnecessary administrative and financial burdens both for the competent authorities and for the pharmaceutical industry, as a general rule a marketing authorisation for a veterinary medicinal product should be granted for an unlimited period of time. Conditions for renewing the approval of a marketing authorisation should be imposed only exceptionally and should be duly justified.		(30) In order to avoid unnecessary administrative and financial burdens both for the competent authorities and for the pharmaceutical industry, as a general rule a marketing authorisation for a veterinary medicinal product should be granted for an unlimited period of time. Conditions for renewing the approval of a marketing authorisation should be imposed only exceptionally and should be duly justified.	(30) In order to avoid unnecessary administrative and financial burdens both for the competent authorities and for the pharmaceutical industry, as a general rule a marketing authorisation for a veterinary medicinal product should be granted for an unlimited period of time. Conditions for renewing the approval of a marketing authorisation should be imposed only exceptionally and should be duly justified.

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	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 including societal, economical, ethical, environmental and welfare factors and the feasibility of controls.	(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 ***also*** be taken into account including societal, economical, ethical, environmental and welfare factors and the feasibility of controls.	(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 **also** be taken into account including societal, economical, ethical, environmental and welfare factors and the feasibility of controls.	(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 **also** be taken into account 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 concern exists but scientific uncertainty persists, appropriate measures can be adopted taking into account Article 5(7) of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures which has been interpreted for the Union in the Communication from the Commission on the precautionary principle. In such circumstances, Member States or the Commission should seek to obtain additional information necessary for a more objective assessment of the particular	(32) In certain circumstances where a significant animal***, environmental*** or public health concern exists but scientific uncertainty persists, appropriate measures can be adopted taking into account Article 5(7) of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures which has been interpreted for the Union in the Communication from the Commission on the precautionary principle. In such circumstances, Member States or the Commission should seek to obtain additional information necessary for a more	(32) In certain circumstances where a significant animal or public health concern exists but scientific uncertainty persists, appropriate measures can be adopted taking into account Article 5(7) of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures which has been interpreted for the Union in the Communication from the Commission on the precautionary principle. In such circumstances, Member States or the Commission should seek to obtain additional information necessary for a more objective assessment of the particular	(32) In certain circumstances where a significant animal or public health concern exists but scientific uncertainty persists, appropriate measures can be adopted taking into account Article 5(7) of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures which has been interpreted for the Union in the Communication from the Commission on the precautionary principle[10]. In such circumstances, Member States or the Commission should seek to obtain additional information necessary for a more objective assessment of the particular

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

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concern and should review the measure accordingly within a reasonable period of time.	objective assessment of the particular concern and should review the measure accordingly within a reasonable period of time.	concern and should review the measure accordingly within a reasonable period of time.	concern and should review the measure accordingly within a reasonable period of time.
(33) Antimicrobial resistance to human and veterinary medicinal products is a growing health problem in the Union and worldwide. Many of the antimicrobials used in animals are also used in humans. Some of those antimicrobials are critical for preventing or treating life-threatening infections in humans. In order to fight antimicrobial resistance a number of measures should be taken. It 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	**AM 17** (33) Antimicrobial resistance to human and veterinary medicinal products is a growing health problem in the Union and worldwide***, thus involving a common responsibility of all actors concerned***. Many of the antimicrobials used in animals are also used in humans. Some of those antimicrobials are ***highly*** critical for preventing or treating life-threatening infections in humans ***and their use on animals, whether or not covered by the terms of a marketing authorisation, should be prohibited***. In order to fight antimicrobial resistance a number of measures should be taken. It needs to be ensured that ***measures are proportionally applied in both the human and animal sectors and that*** appropriate warnings and guidance are included on the labels of ***human and*** veterinary antimicrobials. ~~Use not covered by the terms of the marketing authorisation of certain~~	(33) Antimicrobial resistance to human and veterinary medicinal products is a growing health problem in the Union and worldwide. Many of the antimicrobials used in animals are also used in humans. Some of those antimicrobials are critical for preventing or treating life-threatening infections in humans. In order to fight antimicrobial resistance a number of measures should be taken. It 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	(33) Antimicrobial resistance to human and veterinary medicinal products is a growing health problem in the Union and worldwide. ~~Many of the antimicrobials used in animals are also used in humans. Some of those antimicrobials are critical for preventing or treating life-threatening infections in humans. In order to fight antimicrobial resistance a number of measures should be taken~~. **Due to the complexity of the problem, its cross-border dimension and the high economic burden, its impact goes beyond its severe consequences for human and animal health and has become a global public health concern that affects the whole of society and requires urgent and coordinated intersectoral action in accordance with the "One Health" approach. Such action includes strengthening of the prudent use of**

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veterinary medicinal products.	~~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.	veterinary medicinal products.	**antimicrobials, avoiding their routine prophylactic and metaphylactic use, actions to restrict the use in animals of antimicrobials that are of critical for preventing or treating life-threatening infections in humans and encouraging and incentivizing the development of new antibiotics.** It **also** 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.

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

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	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 management practices.***		
(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.	**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

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

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			available. Such restrictions should allow the decrease of prophylactic and metaphylactic use in animals towards representing a smaller proportion of total antimicrobial use in animals.
		(36a) In order to strengthen Member States' national policies on prudent use of antimicrobials, especially those antimicrobials which are important for the treatment of infections in humans, but which are also necessary for the use in the veterinary medicine, it may be necessary to restrict or prohibit their use. Therefore the Member States should be permitted following scientific recommendations, to define restrictive conditions for their use, e.g. conditioning their prescription to the realisation of antimicrobial susceptibility testing to ensure that there is no other antimicrobials available sufficiently effective or appropriate to treat diagnosed disease.	**(36a) In order to strengthen Member States' national policies on prudent use of antimicrobials, especially those antimicrobials which are important for the treatment of infections in humans, but which are also necessary for the use in the veterinary medicine, it may be necessary to restrict or prohibit their use. Therefore the Member States should be permitted following scientific recommendations, to define restrictive conditions for their use, e.g. conditioning their prescription to the realisation of antimicrobial susceptibility testing to ensure that there is no other antimicrobials available sufficiently effective or appropriate to treat diagnosed disease.**

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(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, the World Animal 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.**

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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.***		
(38) If an antimicrobial is administered and used incorrectly, this presents a risk to public or animal health. Therefore antimicrobial veterinary medicinal products should only be available on veterinary prescription. Persons having the right to prescribe have a key role in ensuring prudent use of antimicrobials and consequently they should not be influenced, directly or indirectly, by economic incentives when prescribing those products. Therefore the supply of veterinary antimicrobials by those health professionals should be restricted to the amount required for treatment of	**AM 23** (38) If an antimicrobial is administered and used incorrectly, this presents a risk to public or animal health. Therefore antimicrobial veterinary medicinal products should only be available on veterinary prescription. Persons having the right to prescribe have a key role in ensuring prudent use of antimicrobials ~~and consequently~~**.** ***Veterinarians have a legal obligation, which is part of their professional code of conduct, to ensure responsible use of veterinary medicinal products. T***~~t~~hey should not be influenced, directly or indirectly, by economic incentives	(38) If an antimicrobial is administered and used incorrectly, this presents a risk to public or animal health. Therefore antimicrobial veterinary medicinal products should only be available on veterinary prescription. […] **Veterinarians** have a key role in ensuring prudent use of antimicrobials and consequently they should not 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	(38) If an antimicrobial is administered and used incorrectly, this presents a risk to public or animal health. Therefore antimicrobial veterinary medicinal products should only be available on veterinary prescription. […] **Veterinarians** have a key role in ensuring prudent use of antimicrobials and consequently they should ~~not 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~~

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the animals under their care.	when prescribing those products. ***The animal health industry and veterinarians should together promote responsible use.*** Therefore the supply of veterinary antimicrobials by ~~those health professionals~~ ***veterinarians or other persons authorised under national law*** should be restricted to the amount required for treatment of the animals under their care***, and only once a veterinary diagnosis has been established following a clinical examination of the animal, or, in exceptional cases, in the light of continuous health checks on the animal.***	treatment of the animals under their care. **All concerned stakeholders should together promote prudent use of antimicrobials.**	~~treatment of the animals under their care.~~**prescribe such products based on their knowledge of antimicrobial resistance, their epidemiological and clinical knowledge and their understanding of the risk factors for the individual animal or group of animals. In addition, the veterinarians should respect their professional code of conduct. Veterinarians should ensure that they are not in a situation of conflict of interest when prescribing medicines, while recognizing their legitimate 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 their care.** **All concerned stakeholders should together promote prudent use of antimicrobials.**

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	AM 24 ***(38a) Prudent use of antimicrobials is a cornerstone in addressing antimicrobial resistance. The Guidelines for the prudent use of antimicrobials in veterinary medicine, elaborated by the Commission, need to be considered by Member States.***	**(38a) Prudent use of antimicrobials is a cornerstone in addressing antimicrobial resistance. It is therefore important that guidance on prudent use of antimicrobials in veterinary medicine is further elaborated.** **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.**	**(38a) Prudent use of antimicrobials is a cornerstone in addressing antimicrobial resistance. It is therefore important that guidance on prudent use of antimicrobials in veterinary medicine <u>is taken into account and</u> further elaborated.** **<u>The identification of risk factors and the development of criteria for initiation of administration of antimicrobials, as well as the identification of alternative measures, could help in avoiding the unnecessary use of antimicrobial medicinal products, including through metaphylaxis</u>** **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.**

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	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 little as possible critically important 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.***		

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(39) It is important to consider the international dimension of the 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 organisms can spread to humans and animals in the Union through consumption of products of animal origin imported from third countries, from direct contact with animals or humans in third countries or by other means. Therefore, measures restricting the use of veterinary antimicrobials in the Union should be based on scientific advice and should be considered in the context of cooperation with third countries and international organisations addressing antimicrobial resistance in order the ensure consistency with their activities and policies.	**AM 26** (39) It is important to consider the international dimension of the 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,~~ ~~a~~***A***ntimicrobial resistant organisms can spread to humans and animals in the Union through consumption of products of animal origin imported from third countries, from direct contact with animals or humans in third countries or by other means. Therefore, ~~measures restricting the use of veterinary antimicrobials~~ in the Union should be ~~based on scientific advice and should be considered in the context of cooperation with third countries and international organisations addressing~~ ***active in advocating the creation of an international strategy to combat*** antimicrobial resistance***,*** ~~in order the ensure consistency with~~	(39) It is important to consider the international dimension of the 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 organisms can spread to humans and animals in the Union through consumption of products of animal origin imported from third countries, from direct contact with animals or humans in third countries or by other means. Therefore, measures restricting the use of veterinary antimicrobials in the Union should be based on scientific advice and should be considered in the context of cooperation with third countries and international organisations addressing antimicrobial resistance in order the ensure consistency with their activities and policies.	(39) It is important to consider the international dimension of the 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,~~ ~~a~~**A**ntimicrobial resistant organisms can spread to humans and animals in the Union **and third countries** through consumption of products of animal origin **from the Union or** ~~imported~~ from third countries, from direct contact with animals or humans ~~in third countries~~ or by other means. Therefore, measures restricting the use of veterinary antimicrobials in the Union should be based on scientific advice and should be considered in the context of cooperation with third countries and international organisations. ~~addressing~~ **For those reasons it should also be ensured, in a non-discriminatory and**

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	~~their activities and policies~~ ***in line with the recent Global Action Plan adopted by the WHO.***		**proportionate manner, that operators in third countries 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.**
(40) There is still a lack of sufficiently detailed and comparable data at Union level to determine the trends and identify possible risk factors that could lead to the development of measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already introduced. Therefore it is	**AM 27** (40) There is still a lack of sufficiently detailed and comparable data at Union level to determine the trends and identify possible risk factors that could lead to the development of measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already introduced. Therefore it is	(40) There is still a lack of sufficiently detailed and comparable data at Union level to determine the trends and identify possible risk factors that could lead to the development of measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already introduced.	(40) There is still a lack of sufficiently detailed and comparable data at Union level to determine the trends and identify possible risk factors that could lead to the development of measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already introduced.

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important to collect data on the sales and use of antimicrobials in animals, data on the use of antimicrobials in humans and data on antimicrobial resistant organisms found in animals, humans and food. To ensure that the information collected can be used effectively, appropriate rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data on the use of antimicrobials under the coordination of the Agency.	important to collect data on the sales and use of antimicrobials in animals, data on the use of antimicrobials in humans and data on antimicrobial resistant organisms found in animals, humans and food. ***Better data are needed on how, when, where and why antimicrobials are being used. Therefore, the data collected should be broken down by type of antimicrobial, species, disease or infection treated.*** To ensure that the information collected can be used effectively, appropriate rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data on the use of antimicrobials under the coordination of the Agency.	Therefore it is important to […] **continue the collection of data on the sales of antibiotics used in animals and, further develop also the collection of data on the sales and use of all other antimicrobials used in animals. This data, when available, should be analysed with** data on the use of antimicrobials in humans and data on antimicrobial resistant organisms found in animals, humans and food. To ensure that the information collected can be used effectively, appropriate **technical** rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data **on the sales and** use of antimicrobials **used in animals** under the coordination of the Agency. **It should be possible to make further adjustments to the obligations on data collection when the procedures in the Member States for the collection of data on sales and use of antimicrobials are sufficiently reliable.**	Therefore it is important to **continue the collection of <u>such</u> data ~~[…] on the sales of antibiotics used in animals~~ and further develop <u>it in line with a stepwise approach.</u> ~~also the collection of data on the sales and use of all other antimicrobials used in animals.~~ This data, when available, should be analysed with** data on the use of antimicrobials in humans and data on antimicrobial resistant organisms found in animals, humans and food. To ensure that the information collected can be used effectively, appropriate **technical** rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data **on the sales and** use of antimicrobials **used in animals** under the coordination of the Agency. **It should be possible to make further adjustments to the obligations on data collection when the procedures in the Member States for the collection 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 medicinal products on the market have been authorised under national procedures. The lack of harmonisation of summary of product characteristics for veterinary medicinal products authorised nationally in more than one Member State creates additional and unnecessary barriers for the circulation of veterinary medicinal products within the Union. It is necessary to harmonise those summaries of product characteristics. In order to avoid unnecessary costs and burdens for the Member States, the Commission and the pharmaceutical industry, and in order to increase the availability of		(41) The majority of the veterinary medicinal products on the market have been authorised under national procedures. The lack of harmonisation of summary of product characteristics for veterinary medicinal products authorised nationally in more than one Member State creates additional and unnecessary barriers for the circulation of veterinary medicinal products within the Union. It is necessary to harmonise those summaries of product characteristics **at least in regards to dosage, uses and warnings of the veterinary medicinal products**. […].	(41) The majority of the veterinary medicinal products on the market have been authorised under national procedures. The lack of harmonisation of summary of product characteristics for veterinary medicinal products authorised nationally in more than one Member State creates additional and unnecessary barriers for the circulation of veterinary medicinal products within the Union. It is necessary to harmonise those summaries of product characteristics **at least in regards to dosage, uses and warnings of the veterinary medicinal products**. […].

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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 administrative burden and maximise the availability of veterinary medicinal products in the Member States, simplified rules should be laid down as to how their packaging and labelling are to be presented. The textual information provided should be reduced and, if possible, replaced by pictograms and abbreviations. Pictograms and abbreviations should be standardised across the Union. Care should be taken so that those rules do not jeopardise public and animal health and environmental		(42) In order to reduce administrative burden and maximise the availability of veterinary medicinal products in the Member States, simplified rules should be laid down as to how their packaging and labelling are to be presented. The textual information provided should be reduced and, if possible, […] pictograms and abbreviations **might be developed and used as an alternative to such textual information** Pictograms and abbreviations should be standardised across the Union. Care should be	(42) In order to reduce administrative burden and maximise the availability of veterinary medicinal products in the Member States, simplified rules should be laid down as to how their packaging and labelling are to be presented. The textual information provided should be reduced and, if possible, […] pictograms and abbreviations **might be developed and used as an alternative to such textual information** Pictograms and abbreviations should be standardised 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.		taken so that those rules do not jeopardise public and animal health and environmental safety.	taken so that those rules do not jeopardise public and animal health and environmental safety.
(43) In addition, Member States should be empowered to choose the language of the text used in the packaging and labelling of veterinary medicinal products authorised in their territory. The package leaflet, however, should be provided in the official language or languages of the Member State.		(43) In addition, Member States should be empowered to choose the language of the text used in the […] **summary of product characteristics, labelling and package leaflet** of veterinary medicinal products authorised in their territory. […]	(43) In addition, Member States should be empowered to choose the language of the text used in the […] **summary of product characteristics, labelling and package leaflet** of veterinary medicinal products authorised in their territory. […]
(44) With a view to increasing availability of veterinary medicinal products in the Union it should be possible to grant more than one marketing authorisation for a specific veterinary medicinal product to the same marketing authorisation holder in the same Member State. In that case all product-related characteristics of the product and data in support of the applications for the product should be identical. However, multiple applications for a specific product should not be used to circumvent the principles of mutual recognition, and therefore this type of applications in different Member States should take place		(44) With a view to increasing availability of veterinary medicinal products in the Union it should be possible to grant more than one marketing authorisation for a specific veterinary medicinal product to the same marketing authorisation holder in the same Member State. In that case all product-related characteristics of the product and data in support of the applications for the product should be identical. However, multiple applications for a specific product should not be used to circumvent the principles of mutual recognition, and therefore this type of applications in different Member States should take place	(44) With a view to increasing availability of veterinary medicinal products in the Union it should be possible to grant more than one marketing authorisation for a specific veterinary medicinal product to the same marketing authorisation holder in the same Member State. In that case all product-related characteristics of the product and data in support of the applications for the product should be identical. However, multiple applications for a specific product should not be used to circumvent the principles of mutual recognition, and therefore this type of applications in different Member States should take place

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inside the procedural framework for mutual recognition.		inside the procedural framework for mutual recognition.	inside the procedural framework for mutual recognition.
(45) Pharmacovigilance rules are necessary for the protection of public and animal health and the environment. Collection of information on adverse events should contribute to the good usage of veterinary medicinal products.		(45) Pharmacovigilance rules are necessary for the protection of public and animal health and the environment. Collection of information on **suspected** adverse events should contribute to the good usage of veterinary medicinal products.	(45) Pharmacovigilance rules are necessary for the protection of public and animal health and the environment**.** Collection of information on **suspected** adverse events should contribute to the good usage of veterinary medicinal 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, the Agency and marketing authorisation holders should encourage and facilitate the reporting of suspected adverse events in particular by	**(45a) The competent authorities, the Agency and marketing authorisation holders should encourage and facilitate the reporting of suspected adverse events in particular by**

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

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(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.		(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 marketing authorisation.	(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 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 safety and efficacy of the veterinary medicinal products that are on the market.		(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.	(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~~***n specific cases ***it is necessary,*** from a public health***,*** ~~and~~ animal health ***or environmental*** 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) […] **I**n 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) […] **I**n specific cases, **it is necessary** or from a public health**,** ~~and~~ animal health **and environment** 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 competent authorities and the Agency will adopt in order to evaluate the suspected adverse events that they receive should comply with the implementing act on measures on good pharmacovigilance practice adopted by the Commission and, as appropriate, be based on a common standard derived from the current Commission guidelines on pharmacovigilance for veterinary medicinal products. **The evaluation performed by the competent authority or the Agency in this way may be one of the means by which it is determined whether there is any change to the benefit-risk balance of those veterinary medicinal products. It is however emphasised that the 'signal management process' is the 'gold standard' for this purpose and proper attention should be given to it.** **The signal management process**	**(50a) The procedures that competent authorities and the Agency will adopt in order to evaluate the suspected adverse events that they receive should comply with the implementing act on measures on good pharmacovigilance practice adopted by the Commission and, as appropriate, be based on a common standard derived from the current Commission guidelines on pharmacovigilance for veterinary medicinal products.** **The evaluation performed by the competent authority or the Agency in this way may be one of the means by which it is determined whether there is any change to the benefit-risk balance of those veterinary medicinal products. It is however emphasised that the 'signal management process' is the 'gold standard' for this purpose and proper attention should be given to it.** **The signal management process**

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		consists of tasks of signal detection, validation, confirmation, analysis and prioritisation, assessment and recommendation for action.	**consists of tasks of signal detection, validation, confirmation, analysis and prioritisation, assessment and recommendation for action.**
(51) It is necessary to exercise control over the entire chain of distribution of veterinary medicinal products, from manufacture or import into the Union through supply to the end-user. Veterinary medicinal products from third countries should comply with the same requirements which apply to products manufactured in the Union, or with requirements which are recognised to be at least equivalent thereto.		(51) It is necessary to exercise control over the entire chain of distribution of veterinary medicinal products, from manufacture or import into the Union through supply to the end-user. Veterinary medicinal products from third countries should comply with the same requirements which apply to products manufactured in the Union, or with requirements which are recognised to be at least equivalent thereto.	(51) It is necessary to exercise control over the entire chain of distribution of veterinary medicinal products, from manufacture or import into the Union through supply to the end-user. Veterinary medicinal products from third countries should comply with the same requirements which apply to products manufactured in the Union, or with requirements which are recognised to 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 movement of veterinary medicinal products and to prevent checks carried out in one Member State being repeated in others, minimum requirements should be applied to veterinary medicinal products manufactured in or imported from third countries.		(52) In order to facilitate the movement of veterinary medicinal products and to prevent checks carried out in one Member State being repeated in others, minimum requirements should be applied to veterinary medicinal products manufactured in or imported from third countries.	(52) In order to facilitate the movement of veterinary medicinal products and to prevent checks carried out in one Member State being repeated in others, minimum requirements should be applied to veterinary medicinal products manufactured in or imported from third countries.
	AM 314 ***(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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	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 veterinary medicinal products.***		
(53) The quality of veterinary medicinal products manufactured within the Union should be guaranteed by requiring compliance with the principles of good manufacturing practice for medicinal products irrespective of the final destination of the medicinal products.		(53) The quality of veterinary medicinal products manufactured within the Union should be guaranteed by requiring compliance with the principles of good manufacturing practice for medicinal products irrespective of the final destination of the medicinal products.	(53) The quality of veterinary medicinal products manufactured within the Union should be guaranteed by requiring compliance with the principles of good manufacturing practice for medicinal products irrespective of the final destination of the medicinal 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 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 uniform application of principles of good manufacturing practices and good distribution practices, the compilation of Union procedures for inspections and exchange of information should serve as a basis for competent authorities when performing controls on manufacturers and wholesale distributors.	**(53b) In order to ensure the uniform application of principles of good manufacturing practices and good distribution practices, the compilation of Union procedures for inspections and exchange of information should serve as a basis for competent authorities when performing controls on manufacturers and wholesale distributors.**
		(53c) Although inactivated immunological veterinary medicinal products referred to in Article 2(2a) should be manufactured in accordance with the principles of good manufacturing practice, detailed guidelines of good manufacturing practice should specifically be prepared for these products as the way they are manufactured is different from industrially prepared products. This would preserve their quality without hindering their manufacturing and availability.	**(53c) Although inactivated immunological veterinary medicinal products referred to in Article 2(2a) should be manufactured in accordance with the principles of good manufacturing practice, detailed guidelines of good manufacturing practice should specifically be prepared for these products as the way they are manufactured is different from industrially prepared products. This would preserve their quality without hindering their manufacturing and availability.**
(54) Companies should be in possession of an authorisation to be		(54) Companies should be in possession of an authorisation to be	(54) Companies should be in possession of an authorisation to be

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

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

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	to animal and human health, online sales of antimicrobials should be prohibited.	**supply and establish rules on appropriate penalties.**	**consequences of such supply and establish rules on appropriate penalties.**
		(56a) Veterinarians should always issue a veterinary prescription when supplying a prescription only veterinary medicinal product and not administering it themselves. Whenever the veterinarians administers such medicinal products themselves it should be left up to national provisions to specify whether a veterinary prescription needs to be issued. However, veterinarians should always keep records of the medicinal products that they have administered.	**(56a) Veterinarians should always issue a veterinary prescription when supplying a prescription only veterinary medicinal product and not administering it themselves. Whenever the veterinarians administers such medicinal products themselves it should be left up to national provisions to specify whether a veterinary prescription needs to be issued. However, veterinarians should always keep records of the medicinal products that they have 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.***		

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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.***		
(57) The illegal sale of veterinary medicinal products to the public via the Internet may represent a threat to public and animal health, as falsified or substandard medicines may reach the public in this way. It is necessary to address this threat. Account should be taken of the fact that specific conditions for supply of medicinal products to the public have not been harmonised at Union level and, therefore, Member States may impose conditions for supplying medicinal products to the public within the limits of the Treaty.	**AM 34** (57) The illegal sale of veterinary medicinal products to the public via the Internet may represent a threat to public and animal health, as falsified or substandard medicines may reach the public in this way. ~~It is necessary to address this threat.~~ ***A system should be introduced to ensure that such products are properly sold and that controls are placed on the distribution and falsification of substances that are potentially dangerous for human use.*** Account should be taken of the fact that specific conditions for supply of medicinal products to the public have not been harmonised at Union level ~~and, therefore,~~***. To minimise the***	(57) The illegal sale of veterinary medicinal products to the public […] **at a distance** may represent a threat to public and animal health, as falsified or substandard medicines may reach the public in this way. It is necessary to address this threat. Account should be taken of the fact that specific conditions for supply of medicinal products to the public have not been harmonised at Union level and, therefore, Member States may impose conditions for supplying medicinal products to the public within the limits of the Treaty.	(57) The illegal sale of veterinary medicinal products to the public […] **at a distance** may represent a threat to public and animal health, as falsified or substandard medicines may reach the public in this way. It is necessary to address this threat. Account should be taken of the fact that specific conditions for supply of medicinal products to the public have not been harmonised at Union level and, therefore, Member States may impose conditions for supplying medicinal products to the public within the limits of the Treaty.

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

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

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

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

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		(61a) With regard to the advertising of veterinary medicinal products, Member States' experience has shown that it is necessary to put emphasis on the distinction between feed and biocidal products on the one hand and veterinary medicinal products on the other hand, because that distinction is often misrepresented in advertising.	**(61a) With regard to the advertising of veterinary medicinal products, Member States' experience has shown that it is necessary to put emphasis on the distinction between feed and biocidal products on the one hand and veterinary medicinal products on the other hand, because that distinction is often misrepresented in advertising.**
		(61b) The rules of advertisement in this Regulation are to be seen as specific rules that comprise the general rules in Directive 2006/114/EC.	**(61b) The rules of advertisement in this Regulation are to be seen as specific rules that comprise the general rules in Directive 2006/114/EC[12].**
(62) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a member of a regulated animal health profession for an individual animal or group of animals, it should in principle be possible for that veterinary prescription to be recognised and for the medicinal product to be	**AM 36** (62) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a ~~member of a regulated animal health profession~~ ***veterinarian or other persons authorised to do so under national law*** for an individual animal or group of animals, it should in principle be possible for that veterinary	(62) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a **veterinarian** […] for an individual animal or group of animals, it should in principle be possible for that veterinary prescription to be recognised and for the medicinal product to be dispensed in another Member State.	(62) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a **veterinarian** […] for an individual animal or group of animals, it should in principle be possible for that veterinary prescription to be recognised and for the medicinal product to be 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. The removal of 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.	prescription to be recognised and for the medicinal product to be dispensed in another Member State***, provided that the other Member State authorises persons with similar qualifications to issue prescriptions***. The removal of 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.	The removal of regulatory and administrative barriers to such recognition should not affect any professional or ethical duty for **veterinarians** […] to refuse to dispense the medicine stated in the prescription.	The removal of regulatory and administrative barriers to such recognition should not affect any professional or ethical duty for **veterinarians** […] to refuse to dispense the medicine stated in the prescription.
(63) The implementation of the principle of recognition of prescriptions should be facilitated by the adoption of a standard prescription, listing the essential information necessary to ensure the safe and efficacious use of the product. Nothing should prevent Member States from having further elements in their prescriptions, as long as this does not prevent prescriptions from other Member States from being recognised.		(63) The implementation of the principle of recognition of prescriptions should be facilitated by the adoption of a **model format** […] **for veterinary** prescription, listing the essential information necessary to ensure the safe and efficacious use of the product. Nothing should prevent Member States from having further elements in their **veterinary** prescriptions, as long as this does not prevent **veterinary** prescriptions from other Member States from being recognised.	(63) The implementation of the principle of recognition of prescriptions should be facilitated by the adoption of a **model format** […] **for veterinary** prescription, listing the essential information necessary to ensure the safe and efficacious use of the product. Nothing should prevent Member States from having further elements in their **veterinary** prescriptions, as long as this does not prevent **veterinary** prescriptions from other Member States from being recognised.

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

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

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

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			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, 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.	(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 the treatment of such products, to		(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	(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

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

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quality aspect of a homeopathic medicinal product is independent of its use so no specific provisions should apply with regard to the necessary quality requirements and rules.	quality aspect of a homeopathic medicinal product is independent of its use so no specific provisions should apply with regard to the necessary quality requirements and rules. ***Furthermore, it is desirable to generally allow, under specific conditions, the use of homeopathic medicinal products designed for human use, including immunological homeopathic products that have a potency starting from D4, on all animals, including food producing animals.***	requirements and rules.	requirements and rules. **Moreover, while the use of homeopathic veterinary medicinal products authorised under this Regulation is regulated in the same way as other authorised veterinary medicinal products, the use of registered homeopathic veterinary medicinal products is not regulated in this Act. The use of such registered products is therefore subject to national law which is also the case as regards homeopathic medicinal 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***		

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	for pet animals and exotic species, provided that they notify these rules to the Commission.		
(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***, including the establishment of new information technology services with the aim of reducing bureaucracy,*** should be funded through fees charged to enterprises ***and through an increased financial contribution from the Commission***. 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.

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	national level.		
(74) In order to ensure that annexes to this Regulation are adapted to the technical and scientific developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission.		(74) In order to ensure that **the requirements regarding the technical documentation on the quality, safety and efficacy** […] are adapted to the technical and scientific developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission.	(74) In order to ensure that **the requirements regarding the technical documentation on the quality, safety and efficacy** […] are adapted to the technical and scientific developments, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission.
		(74a) It is generally accepted that the existing requirements regarding the technical documentation on the quality, safety and efficacy of veterinary medicinal products presented when applying for a marketing authorisation in Annex I of Directive 2001/82/EC as last amended in 2009 work sufficiently well in practice. Therefore, there is no urgent need to substantially change those requirements. However, there is a need to adjust those requirements in order to respond to the identified discrepancies with the international scientific progress or latest developments, including guidance from VICH, WHO,	**(74a) It is generally accepted that the existing requirements regarding the technical documentation on the quality, safety and efficacy of veterinary medicinal products presented when applying for a marketing authorisation in Annex I of Directive 2001/82/EC as last amended in 2009 work sufficiently well in practice. Therefore, there is no urgent need to substantially change those requirements. However, there is a need to adjust those requirements in order to respond to the identified discrepancies with the international scientific progress or latest developments, including guidance from VICH, WHO,**

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		OECD standards, taking into account also the need to develop specific requirements for novel therapy veterinary medicinal products while avoiding major overhaul of the current provisions, in particular not altering its structure.	**OECD standards, taking into account also the need to develop specific requirements for novel therapy veterinary medicinal products while avoiding major overhaul of the current provisions, in particular not altering its structure.**
(75) In order to adapt this 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 the use of a product outside the terms of the granted marketing authorisation, in particular regarding establishing a list of antimicrobial veterinary medicinal products for which such use should be prohibited.		(75) In order to adapt this 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 the use of a product outside the terms of the granted marketing authorisation, in particular regarding establishing a list of antimicrobial veterinary medicinal products for which such use should be prohibited.	(75) In order to adapt this 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 the use of a product outside the terms of the granted marketing authorisation, in particular regarding establishing a list of antimicrobial veterinary medicinal products for which such use should be prohibited.
(76) In order to adapt this 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		~~(76)~~ […]	~~(76)~~ […]

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authorisation procedure shall be compulsory.			
(77) In order to adapt this 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 establishing detailed rules on the principles for the refusal or restriction of marketing authorisations of antimicrobial veterinary medicinal products, in particular with a view to preserving the efficacy of certain active substances in treating infections in humans.			(77) In order to adapt this 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 establishing detailed rules on the principles for the refusal or restriction of marketing authorisations of antimicrobial veterinary medicinal products, in particular with a view to preserving the efficacy of certain active substances in treating infections in humans.
(78) In order to exercise its supervisory powers effectively, 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 or periodic penalty payments to the holders of marketing authorisations granted under this Regulation, the maximum amounts of these penalties as well as the conditions and			(78) In order to exercise its supervisory powers effectively, 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 or periodic penalty payments to the holders of marketing authorisations granted under this Regulation, the maximum amounts of these penalties as well as the conditions and

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methods for their collection.			methods for their collection.
(79) In order to introduce harmonised standards within the Union for the methods of gathering data on the use of antimicrobials and the methods of transferring of these data to the Commission, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of establishing rules on these methods.			(79) In order to introduce harmonised standards within the Union for the methods of gathering data on the use of antimicrobials and the methods of transferring of these data to the Commission, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of establishing rules on these 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).

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		(80a) When providing services in another Member State veterinarians should follow any national rules present in the host Member State pursuant to Directive 2005/36 EC on Recognition of Professional qualifications and Directive 2006/123 EC on Services in the Internal Market.	**(80a) When providing services in another Member State veterinarians should follow any national rules present in the host Member State pursuant to Directive 2005/36 EC on Recognition of Professional qualifications and Directive 2006/123 EC on Services in the Internal Market.**
(81) Taking into account the main changes that should be made to the existing rules, and aiming to improve the functioning of the internal market, a regulation is the appropriate legal instrument to replace Directive 2001/82/EC in order to lay down clear, detailed and directly applicable rules. Moreover, a regulation ensures that legal requirements are implemented at the same time and in a harmonised manner throughout the Union.		(81) Taking into account the main changes that should be made to the existing rules, and aiming to improve the functioning of the internal market, a regulation is the appropriate legal instrument to replace Directive 2001/82/EC in order to lay down clear, detailed and directly applicable rules. Moreover, a regulation ensures that legal requirements are implemented at the same time and in a harmonised manner throughout the Union.	(81) Taking into account the main changes that should be made to the existing rules, and aiming to improve the functioning of the internal market, a regulation is the appropriate legal instrument to replace Directive 2001/82/EC in order to lay down clear, detailed and directly applicable rules. Moreover, a regulation ensures that legal requirements are implemented at the same time and in a harmonised manner throughout the Union.

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(82) Since the objectives of this Regulation, namely to establish rules on veterinary medicinal products ensuring the protection of human and animal health and the environment as well as the functioning of the internal market, cannot be sufficiently achieved by the Member States, but can rather, by reason of its effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,		(82) Since the objectives of this Regulation, namely to establish rules on veterinary medicinal products ensuring the protection of human and animal health and the environment as well as the functioning of the internal market, cannot be sufficiently achieved by the Member States, but can rather, by reason of its effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,	(82) Since the objectives of this Regulation, namely to establish rules on veterinary medicinal products ensuring the protection of human and animal health and the environment as well as the functioning of the internal market, cannot be sufficiently achieved by the Member States, but can rather, by reason of its effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,
HAVE ADOPTED THIS REGULATION:		HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:

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Chapter I **Subject matter, scope and definitions**		**Chapter I** **Subject matter, scope and definitions**	**Chapter I** **Subject matter, scope and definitions**
Article 1 *Subject matter*		*Article 1* *Subject matter*	*Article 1* *Subject matter*
This Regulation lays down rules for the placing on the market, manufacture, import, export, supply, pharmacovigilance, control and use of veterinary medicinal products.	**AM 42** This Regulation lays down rules for the placing on the market, ***development,*** manufacture, import, export, ***wholesale distribution, retail*** supply, pharmacovigilance, control and use of veterinary medicinal products.	This Regulation lays down rules for the placing on the market, […] manufactur**ing**, import, export, supply, **distribution**, pharmacovigilance, control and use of veterinary medicinal products.	This Regulation lays down rules for the placing on the market, […] manufactur**ing**, import, export, supply, **distribution**, pharmacovigilance, control and use of veterinary medicinal 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 *Scope*		*Article 2* *Scope*	*Article 2* *Scope*
1. This Regulation shall apply to veterinary medicinal products prepared industrially or by a method involving an industrial process and intended to be placed on the market.		1. This Regulation shall apply to veterinary medicinal products prepared industrially or by a method involving an industrial process and intended to be placed on the market.	1. This Regulation shall apply to veterinary medicinal products prepared industrially or by a method involving an industrial process and intended to be placed on the market.
2. In addition to the products referred to in paragraph 1, Chapter VI shall also apply to active substances, intermediate products and excipients used as starting materials in veterinary medicinal products.		2. In addition to the products referred to in paragraph 1, […] **Articles 98a and 98b** shall also apply to active substances~~,~~ […] used as starting materials in veterinary medicinal products.	2. In addition to the products referred to in paragraph 1, […] **Articles 98a and 98b** shall also apply to active substances~~,~~ […] used as starting materials in veterinary medicinal products.
		2a. In addition to the products referred to in paragraph 1, Articles 98a, 110, 112, 122, 124, 125 and 133 shall also apply to inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the	**2a. In addition to the products referred to in paragraph 1, Articles 98a, 110, 112, 122, 124, 125 and 133 shall also apply to inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the**

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

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(b) veterinary medicinal products prepared in a pharmacy in accordance with a veterinary prescription for an individual animal or a small group of animals ('magistral formula');		(b) veterinary medicinal products prepared in a pharmacy **or by a person permitted to do so under national law,** in accordance with a veterinary prescription for an individual animal or a small group of animals ('magistral formula');	(b) veterinary medicinal products prepared in a pharmacy **or by a person permitted to do so under national law,** in accordance with a veterinary prescription for an individual animal or a small group of animals ('magistral formula');
(c) veterinary medicinal products prepared in a pharmacy in accordance with the directions of a pharmacopoeia and intended to be supplied directly to the end-user ('officinal formula').		(c) veterinary medicinal products prepared in a pharmacy in accordance with the directions of a pharmacopoeia and intended to be supplied directly to the end-user ('officinal formula'**). Such officinal formula shall be subject to a veterinary prescription when intended for food producing animals.**	(c) veterinary medicinal products prepared in a pharmacy in accordance with the directions of a pharmacopoeia and intended to be supplied directly to the end-user ('officinal formula'**). Such officinal formula shall be subject to a veterinary prescription when intended for food producing animals.**
4. This Regulation shall not apply to:		4. This Regulation shall not apply to:	4. This Regulation shall not apply 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;		[…]	[…]

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(b) veterinary medicinal products containing autologous or allogeneic cells or tissues that have not been subjected to an industrial process;		(b) veterinary medicinal products containing autologous or allogeneic cells or tissues that have not been subjected to an industrial process;	(b) veterinary medicinal products containing autologous or allogeneic cells or tissues that have not been subjected to an industrial process;
(c) veterinary medicinal products based on radio-active isotopes;		(c) veterinary medicinal products based on radio-active isotopes;	(c) veterinary medicinal products based on radio-active isotopes;
(d) feed additives as defined in Regulation (EC) No 1831/2003 of the European Parliament and of the Council;		(d) feed additives as defined in Regulation (EC) No 1831/2003 of the European Parliament and of the Council;	(d) feed additives as defined in Regulation (EC) No 1831/2003 of the European Parliament and of the Council[14];
(e) veterinary medicinal products intended for research and development.		(e) veterinary medicinal products intended for research and development.	(e) veterinary medicinal products intended for research and 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+]	**(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].**
	AM 47 ***(ec) feedingstuffs as defined in 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 measure it deems appropriate regarding narcotic and psychotropic substances.	**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.**
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.***

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1. Where a veterinary medicinal product referred to in Article 2(1) also falls within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council[16] or Regulation (EC) No 1831/2003 of the European Parliament and of the Council, and there is a conflict between the provisions of this Regulation and the provisions of Regulation (EU) No 528/2012 or Regulation (EC) No 1831/2003, the provisions of this Regulation shall prevail.		1. Where a veterinary medicinal product referred to in Article 2(1) also falls within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council or Regulation (EC) No 1831/2003 of the European Parliament and of the Council, and there is a conflict between the provisions of this Regulation and the provisions of Regulation (EU) No 528/2012 or Regulation (EC) No 1831/2003, the provisions of this Regulation shall prevail.	1. Where a veterinary medicinal product referred to in Article 2(1) also falls within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council or Regulation (EC) No 1831/2003 of the European Parliament and of the Council, and there is a conflict between the provisions of this Regulation and the provisions of Regulation (EU) No 528/2012 or Regulation (EC) No 1831/2003, the provisions of this 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 decisions on whether a specific product or group of products is to be considered as a veterinary medicinal product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).		**paragraph 1, the** Commission may, by means of implementing acts, adopt decisions on whether a specific product or group of products is to be considered as a veterinary medicinal product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	**paragraph 1, the** Commission may, by means of implementing acts, adopt decisions on whether a specific product or group of products is to be considered as a veterinary medicinal product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).
Article 4 *Definitions*		*Article 4* *Definitions*	*Article 4* *Definitions*
For the purposes of this Regulation, the following definitions shall apply:		For the purposes of this Regulation, the following definitions shall apply:	For the purposes of this Regulation, the following definitions shall apply:
(1) 'veterinary medicinal product' means any substance or combination of substances which fulfils at least one of the following conditions:		(1) 'veterinary medicinal product' means any substance or combination of substances which fulfils at least one of the following conditions:	(1) 'veterinary medicinal product' means any substance or combination of substances which fulfils at least one of the following conditions:
(a) it is presented as having properties for treating or preventing disease in animals;		(a) it is presented as having properties for treating or preventing disease in animals;	(a) it is presented as having properties for treating or preventing disease in animals;
(b) its purpose is to be used in or administered to animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;	**AM 49** (b) ~~its purpose is to~~ ***it may*** be used in**,** or administered to**,** animals with a view ***either*** to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;	(b) its purpose is to be used in or administered to animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action;	(b) its purpose is to be used in or administered to animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action;

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

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

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product;			
		(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; ***a homeopathic veterinary medicinal product may contain a number of active ingredients;***	(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;
	AM 62 ***7a. 'herbal medicinal product' means any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more***		

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	such herbal substances in combination with one or more such herbal preparations;		
(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 medicinal product or substance used in the treatment of parasitic diseases attributable to various causes;***		**(8aa) 'antiparasitic' means a substance that kills or interrupts the development of parasites, used for the purpose of treating or preventing an infection, infestation or disease caused or transmitted by parasites, including substances with a repelling activity.**
	AM 66 ***8c. 'antibacterial' means a compound with a direct action on bacteria used for treatment or prevention of infections;***	**(8b) 'antibiotic' means any substance with a direct action on bacteria used for treatment or prevention of infections;**	**(8b) 'antibiotic' means any substance with a direct action on bacteria used for treatment or prevention of infections;**
		(8c) '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;	**(8c) 'metaphylaxis' means the ~~treatment of~~ administration of a medicinal product to a group of animals after the diagnosis of clinical disease in part of the group has been established, 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;**

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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 medicinal product to</u> an animal or 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;		(a) any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health;	(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;		(b) any risk of undesirable effects on the environment;	(b) any risk of undesirable effects on the environment;
(c) any risk relating to the development of antimicrobial resistance;		(c) any risk relating to the development of […] resistance;	(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 ***usual common*** 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 medicinal product' means 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;	**(12a) 'name of the veterinary medicinal product' means 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;**
(13) 'strength' means the content of active substances in a veterinary medicinal product, expressed quantitatively per dosage unit, per unit of volume or per unit of weight according to the pharmaceutical form;		(13) 'strength' means the content of active substances in a veterinary medicinal product, expressed quantitatively per dosage unit, per unit of volume or per unit of weight according to the pharmaceutical form;	(13) 'strength' means the content of active substances in a veterinary medicinal product, expressed quantitatively per dosage unit, per unit of volume or per unit of weight according to the pharmaceutical form;
(14) 'competent authority' means an authority designated by a Member State in accordance with Article 136;		(14) 'competent authority' means an authority designated by a Member State in accordance with Article 136;	(14) 'competent authority' means an authority designated by a Member State in accordance with Article 136;
(15) 'labelling' means information on the immediate packaging or the outer packaging;		(15) 'labelling' means information on the immediate packaging or the outer packaging;	(15) 'labelling' means information on the immediate packaging or the outer packaging;
(16) 'outer packaging' means packaging in which is placed the immediate packaging;		(16) 'outer packaging' means packaging in which is placed the immediate packaging;	(16) 'outer packaging' means packaging in which is placed the immediate packaging;

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(17) 'immediate packaging' means the container or any other form of packaging that is in direct contact with the veterinary medicinal product;		(17) 'immediate packaging' means the container or any other form of packaging that is in direct contact with the veterinary medicinal product;	(17) 'immediate packaging' means the container or any other form of packaging that is in direct contact with 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;	**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 market for one of the following product types:		(20) 'limited market' means a market for one of the following product types:	(20) 'limited market' means a market for one of the following product types:
(a) veterinary medicinal products for the treatment or prevention of diseases that occur infrequently or in limited geographical areas;		(a) veterinary medicinal products for the treatment or prevention of diseases that occur infrequently or in limited geographical areas;	(a) veterinary medicinal products for the treatment or prevention of diseases that occur infrequently or in 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**;

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(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;		(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;	(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 Regulation;		(23) 'control' means any task performed by a competent authority […] for the verification of compliance with this Regulation;	(23) 'control' means any task performed by a competent authority […] for the verification of compliance with this 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 ***veterinarian or another*** professional person qualified to do so in accordance with applicable national law ***once a veterinary diagnosis has been established following a clinical examination of the animal***;	(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 ***necessary*** between the last administration of a veterinary medicinal product to an animal ***under normal conditions of use,*** and the production of foodstuffs from that animal***, for the purpose of***	(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 contain residues in quantities harmful to public health;	***ensuring*** ~~which under normal conditions of use is necessary to ensure~~ that such foodstuffs do not 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];	ensure that such foodstuffs do not contain residues in quantities harmful to public health;	ensure that such foodstuffs do not contain residues in quantities harmful to public health;
(26) 'making available on the market' means any supply of a veterinary medicinal product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	**AM 76** 26. 'making available on the market' means any supply of a veterinary medicinal product for distribution, consumption or use on the ~~Union~~ market ***of a Member State*** in the course of a commercial activity, whether in return for payment or free of charge;	~~(26.)~~ […]	~~(26.)~~ […]
(27) 'placing on the market' means the first making available of a veterinary medicinal product on the Union market.		(27) 'placing on the market' means the first making available of a veterinary medicinal product on the **whole of t**he Union market **or in one or more Member States, as applicable;**	(27) 'placing on the market' means the first making available of a veterinary medicinal product on the **whole of t**he Union market **or in one or more Member States, as 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).***

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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;***		

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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;***		

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	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***		

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	105 which is independent of the holder of the marketing authorisation;		
	AM 88 ***(27l) '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;***		

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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** ***manufacture of medicated feeding stuffs in accordance with Regulation (EU) of the European Parliament and of the Council.***[18]		
		(29) 'aquatic species' means species as defined in Article 4(3) of Regulation (EU) 2016/429;	**(29) 'aquatic species' means species as defined in Article 4(3) of Regulation (EU) 2016/429**[19]**;**
		(30) 'Agency' means the European Medicines Agency as established by Regulation (EC) No 726/2004;	**(30) 'Agency' means the European Medicines Agency as established by Regulation (EC) No 726/2004;**
		(31) 'food producing animals' means food producing animals as defined in Article 2 (b) of Regulation (EC) No 470/2009;	**(31) 'food producing animals' means food producing animals as defined in Article 2 (b) of Regulation (EC) No 470/2009**[20]**;**
		(32) 'variation' means a change to the terms of the marketing	**(32) 'variation' means a change to 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).

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

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

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Chapter II **Marketing authorisations – general provisions and rules on applications**		**Chapter II** **Marketing authorisations – general provisions and rules on applications**	**Chapter II** **Marketing authorisations – general provisions and rules on applications**
Section 1 **General provisions**		**Section 1** **General provisions**	**Section 1** **General provisions**
Article 5 *Marketing authorisations*		*Article 5* *Marketing authorisations*	*Article 5* *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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3. Decisions to grant, refuse, suspend, withdraw or vary a marketing authorisation shall be made public.		3. Decisions to grant, refuse, suspend, […] **revoke** or […] **amend by way of a variation** a marketing authorisation shall be made public.	3. Decisions to grant, refuse, suspend, […] **revoke** or […] **amend by way of a variation** a marketing authorisation shall be made public.
4. Applicants for marketing authorisations and marketing authorisation holders shall be established in the Union.		4. […] **A marketing authorisation for a veterinary medicinal product shall only be granted to an applicant established in the Union. The requirement to be established in the Union shall also apply to marketing authorisation holders.**	4. […] **A marketing authorisation for a veterinary medicinal product shall only be granted to an applicant established in the Union. The requirement to be established in the Union shall also apply to marketing authorisation holders.**
		5. A marketing authorisation for a veterinary medicinal product intended for one or more food producing animals may only be granted if the pharmacologically active substance(s) is allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof for the animal species concerned.	**5. A marketing authorisation for a veterinary medicinal product intended for one or more food producing animals may only be granted if the pharmacologically active substance(s) is allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof for the animal species concerned.**
		6. […] **In the case of veterinary medicinal products** […] intended […] for aqua**rium or pond** animals, **ornamental fish,** cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits **which**	**6[21].** […] **In the case of veterinary medicinal products** […] intended […] for aqua**rium or pond** animals, **ornamental fish,** cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits **which**

[21] Ex Article 120 amended.

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		are exclusively kept […] as pet**s** […], Member States may permit exemptions […] from **this** Article […], provided that such products […] **are not subject to a veterinary prescription** and that all […] **necessary** measures are […] **in place in the Member State** to prevent unauthorised use of the **veterinary medicinal** products for other animals.	**are exclusively** kept […] as pet**s** […], Member States may permit exemptions […] from **this** Article […], provided that such products […] **are not subject to a veterinary prescription** and that all […] **necessary** measures are […] **in place in the Member State** to prevent unauthorised use of the **veterinary medicinal** products for other animals.
Article 6 *Submission of applications for marketing authorisations*		*Article 6* *Submission of applications for marketing authorisations*	*Article 6* *Submission of applications for marketing authorisations*
1. Applications shall be submitted to the competent authority where they concern the granting of marketing authorisations in accordance with any of the following procedures:		1. Applications shall be submitted to the competent authority where they concern the granting of marketing authorisations in accordance with any of the following procedures:	1. Applications shall be submitted to the competent authority where they concern the granting of marketing authorisations in accordance with any of the following procedures:
(a) the national procedure laid down in Articles 42, 43 and 44;		(a) the national procedure laid down in Articles 42[…] and 44;	(a) the national procedure laid down in Articles 42[…] and 44;
(b) the decentralised procedure laid down in Articles 45 and 46;		(b) the decentralised procedure laid down in Articles 45 and 46;	(b) the decentralised procedure laid down in Articles 45 and 46;
(c) the mutual recognition procedure laid down in Articles 47 and 48.	**AM 93** (c) the mutual recognition procedure laid down in Articles 47**,** ~~and~~ 48 ***and 57***.	(c) the mutual recognition procedure laid down in Articles 47 and 48**;**	(c) the mutual recognition procedure laid down in Articles 47 and 48**;**
		(d) the subsequent recognition procedure laid down in Article	**(d) the subsequent recognition 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.		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 considered to have been withdrawn.	**limit set, the application shall be considered to have been withdrawn.**
		7. If the applicant fails to provide a complete translation of the required documentation within a period of six months from having received the information referred to in Article 46(5), 48(5b) and Article 48a(2), the application shall be considered to have been withdrawn.	**7. If the applicant fails to provide a complete translation of the required documentation within a period of six months from having received the information referred to in Article 46(5), 48(5b) and Article 48a(2), the application shall be considered to have been withdrawn.**
		Article 6a ***Languages***[22]	***Article 6a*** ***Languages***
		1. The language or languages of **the summary of the product characteristics and the** information on the labelling **and on the package leaflet** shall, **unless the Member State** […] determine**s**[…] **otherwise, be the official language or languages of the** […] Member State where the veterinary medicinal product is made available on the market.	1. The language or languages of **the summary of the product characteristics and the** information on the labelling **and on the package leaflet** shall, **unless the Member State** […] determine**s**[…] **otherwise, be the official language or languages of the** […] Member State where the veterinary medicinal product is made available on the market.

[22] Ex Article 14

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

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2. Where the application concerns an antimicrobial veterinary medicinal product, the following shall be submitted in addition to the information listed in paragraph 1:		2. Where the application concerns an antimicrobial veterinary medicinal product, the following shall be submitted in addition to the information **and technical documentation** listed in paragraph 1:	2. Where the application concerns an antimicrobial veterinary medicinal product, the following shall be submitted in addition to the information **and technical documentation** listed in paragraph 1:
(a) documentation on the direct or indirect risks to public or animal health of use of the antimicrobial veterinary medicinal product in animals,	**AM 96** (a) documentation on the direct or indirect risks to public or animal health ***or the environment*** of use of the antimicrobial veterinary medicinal product in animals,	(a) documentation on […] the direct or indirect risks, to public or animal health **or to the environment** of use of the antimicrobial veterinary medicinal product in animals,	(a) documentation on […] the direct or indirect risks, to public or animal health **or to the environment** of use of the antimicrobial veterinary medicinal product in animals,
(b) information about risk mitigation measures to limit antimicrobial resistance development related to the use of veterinary medicinal product.	**AM 97** (b) information about risk mitigation measures to limit antimicrobial resistance development related to the use of veterinary medicinal product, ***including 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***.	(b) information about risk mitigation measures to limit antimicrobial resistance development related to the use of veterinary medicinal product.	(b) information about risk mitigation measures to limit antimicrobial resistance development related to the use of veterinary medicinal product.

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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 Council[23] 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 ***shall be submitted in addition to the information listed in paragraph 1 of this Article*** 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 from submission of such application***.	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.	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.
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).

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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.		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 thereof**.	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 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		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	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[25] 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 the competent authorities to the deliberate release into the environment of the genetically modified organisms for research and development purposes, as provided for in Part B of Directive 2001/18/EC;		(a) a copy of the written consent of the competent authorities to the deliberate release into the environment of the genetically modified organisms for research and development purposes, as provided for in Part B of Directive 2001/18/EC;	(a) a copy of the written consent of the competent authorities to the deliberate release into the environment of the genetically modified organisms for research and development purposes, as provided for in Part B of Directive 2001/18/EC;
(b) the complete technical file supplying the information required under Annexes III and IV to Directive 2001/18/EC;		(b) the complete technical file supplying the information required under Annexes III and IV to Directive 2001/18/EC;	(b) the complete technical file supplying the information required under Annexes III and IV to Directive 2001/18/EC;
(c) the environmental risk assessment in accordance with the principles set out in Annex II to Directive 2001/18/EC; and		(c) the environmental risk assessment in accordance with the principles set out in Annex II to Directive 2001/18/EC; and	(c) the environmental risk assessment in accordance with the principles set out in Annex II to Directive 2001/18/EC; and
(d) the results of any investigations performed for the purposes of research or development.		(d) the results of any investigations performed for the purposes of research or development.	(d) the results of any investigations performed for the purposes of 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 in the Union**.	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 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* *[…]**C**linical trials*	*Article 8* *[…]**C**linical trials*
1. An application for the approval of a clinical trial shall be submitted to a competent authority of the Member State in which the clinical trial is to take place.		1. An application for the approval of a clinical trial shall be submitted **in accordance with national law** to a competent authority of the Member State in which the clinical trial is to	1. An application for the approval of a clinical trial shall be submitted **in accordance with national law** to a competent authority of the Member State in which the clinical trial is to

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		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 paragraph 1 shall be carried out taking due account of the standards set by the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.		4. The clinical trials referred to in paragraph 1 shall be carried out taking due account of […] the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.	4. The clinical trials referred to in paragraph 1 shall be carried out taking due account of […] the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal 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 be submitted with the application for a marketing authorisation for the purposes of providing the documentation referred to in Article 7(1)(b).		5. **Data stemming from** […] clinical trials shall be submitted with the application for a marketing authorisation for the purposes of providing the documentation referred to in Article 7(1)(b).	5. **Data stemming from** […] clinical trials shall be submitted with the application for a marketing authorisation for the purposes of providing the documentation referred to in Article 7(1)(b).
6. Data stemming from clinical trials conducted outside the Union may be taken into consideration for the assessment of an application for a marketing authorisation only if those trials were designed, implemented and reported in accordance with the standards set by the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.		6. Data stemming from clinical trials conducted outside the Union may be taken into consideration for the assessment of an application for a marketing authorisation only if those trials were designed, implemented and reported in accordance with […] the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.	6. Data stemming from clinical trials conducted outside the Union may be taken into consideration for the assessment of an application for a marketing authorisation only if those trials were designed, implemented and reported in accordance with […] the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal 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 **Labelling and package leaflet**		**Section 4** **Labelling and package leaflet**	**Section 4** **Labelling and package leaflet**
Article 9 *Labelling of the immediate packaging of veterinary medicinal products*		*Article 9* *Labelling of the immediate packaging of veterinary medicinal products*	*Article 9* *Labelling of the immediate packaging of veterinary medicinal products*
1. The immediate packaging of a veterinary medicinal product shall contain only the following information:		1. The immediate packaging of a veterinary medicinal product shall contain […] the following information **and shall, subject to Article 10(3), contain no other information**:	1. The immediate packaging of a veterinary medicinal product shall contain […] the following information **and shall, subject to Article 10(3), contain no other information**:
(a) the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;		(a) the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;	(a) the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;
(b) a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using their common names;		(b) a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using their common names;	(b) a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using their common names;
(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";

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(d) the name or corporate name or logo name of the marketing authorisation holder;		(d) the name or corporate name or logo name of the marketing authorisation holder;	(d) the name or corporate name or logo name of the marketing authorisation holder;
(e) the target species;		(e) the target species;	(e) the target species;
(f) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp.";		(f) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp.";	(f) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp.";
(g) special storage precautions, if any.		(g) special storage precautions, if any**;**	(g) special storage precautions, if any**;**
		~~(h)~~	**~~(h)~~**
		(i) route of administration	**(i) route of administration**
		(j) if applicable, the withdrawal period, even if it is zero.	**(j) if applicable, the withdrawal 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 paragraph 1 shall appear in easily legible and clearly comprehensible characters, 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)**.
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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 1, a Member State may decide that, on the immediate packaging of a veterinary medicinal product made available in its territory, an identification code shall be added to the information required under paragraph 1.	**3. Notwithstanding paragraph 1, a Member State may decide that, on the immediate packaging of a veterinary medicinal product made available in its territory, an identification code shall be added to the information required under paragraph 1.**
Article 10 *Labelling of the outer packaging of veterinary medicinal products*		*Article 10* *Labelling of the outer packaging of veterinary medicinal products*	*Article 10* *Labelling of the outer packaging of veterinary medicinal products*
1. The outer packaging of a veterinary medicinal product shall contain only the following information:		1. The outer packaging of a veterinary medicinal product shall contain […] the following information **and shall contain no other information**:	1. The outer packaging of a veterinary medicinal product shall contain […] the following information **and shall contain no other information**:
(a) the information listed in Article 9(1);		(a) the information listed in Article 9(1);	(a) the information listed in Article 9(1);

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(b) the contents by weight, volume or number of immediate packaging units of the veterinary medicinal product;		(b) the contents by weight, volume or number of immediate packaging units of the veterinary medicinal product;	(b) the contents by weight, volume or number of immediate packaging units of the veterinary medicinal product;
(c) warning that the veterinary medicinal product must be kept out of the sight and reach of children;		(c) warning that the veterinary medicinal product must be kept out of the sight and reach of children;	(c) warning that the veterinary medicinal product must be kept out of the sight and reach of children;
(d) warning that the veterinary medicinal product is for animal treatment only;	**AM 104** (d) ***a common pictogram*** warning that the veterinary medicinal product is for animal treatment only;	(d) warning that the veterinary medicinal product is **"**for animal treatment only**"**;	(d) warning that the veterinary medicinal product is **"**for animal treatment only**"**;
(e) recommendation to read the package leaflet;		(e) **without prejudice to Article 12(4),** recommendation to read the package leaflet;	(e) **without prejudice to Article 12(4),** recommendation to read the package leaflet;
(f) 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 as regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products;	**AM 104** (f) 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 as 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***;	~~(f)~~ […]	~~(f)~~ […]

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(g) in case of homeopathic veterinary medicinal products, the statement "homeopathic veterinary medicinal product".		(g) in case of homeopathic veterinary medicinal products, the statement "homeopathic veterinary medicinal product"**;**	(g) in case of homeopathic veterinary medicinal products, the statement "homeopathic veterinary medicinal product"**;**
		(h) in case of veterinary medicinal products not subject to a veterinary prescription, the indication(s);	**(h) in case of veterinary medicinal products not subject to a veterinary prescription, the indication(s);**
		(i) the marketing authorisation number.	**(i) the marketing authorisation 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 1, a Member State may decide that, on the outer packaging of a veterinary medicinal product made available in its territory, an identification code shall be added to the information required under paragraph 1. Such a code may be used to replace the marketing authorisation number referred to in paragraph (1)(i).	**1a. Notwithstanding paragraph 1, a Member State may decide that, on the outer packaging of a veterinary medicinal product made available in its territory, an identification code shall be added to the information required under paragraph 1. Such a code may be used to replace the marketing authorisation number referred to 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, ***as well as in machine-readable format***, 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.		3. Where there is no outer packaging, all the particulars listed in paragraph**s** 1 **and 1a** shall appear on the immediate packaging.	3. Where there is no outer packaging, all the particulars listed in paragraph**s** 1 **and 1a** shall appear on the immediate packaging.
Article 11 *Labelling of small immediate packaging units of veterinary medicinal products*		*Article 11* *Labelling of small immediate packaging units of veterinary medicinal products*	*Article 11* *Labelling of small immediate packaging units of veterinary medicinal products*
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;		(a) the name of veterinary medicinal product;	(a) the name of veterinary medicinal product;
(b) the quantitative particulars of	**AM 105** (b) the quantitative particulars of	(b) the quantitative particulars of	(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 **By way of derogation from Articles 9(1), 10(1) and 11(1), Member States may, within their territory, on request of the applicant, allow him to include on the immediate package or outer packaging of a veterinary medicinal product additional useful information which is compatible with the summary of the product characteristics, to the exclusion of any advertising of a veterinary medicinal product.**	***Article 11a*** **By way of derogation from Articles 9(1), 10(1) and 11(1), Member States may, within their territory, on request of the applicant, allow him to include on the immediate package or outer packaging of a veterinary medicinal product additional useful information which is compatible with the summary of the product characteristics, to the exclusion of any advertising of a veterinary medicinal product.**
Article 12 *Package leaflet of veterinary medicinal products*		*Article 12* *Package leaflet of veterinary medicinal products*	*Article 12* *Package leaflet of veterinary medicinal products*
1. The package leaflet shall be available for each veterinary medicinal product and shall contain at least the following information:	**AM 106** 1. The package leaflet shall be ***directly*** available ~~for~~ ***with*** each veterinary medicinal product and shall contain at least the following information:	1. The package leaflet shall be **made readily available by the marketing authorisation holder** […] for each veterinary medicinal product and shall contain at least the following information:	1. The package leaflet shall be **made readily available by the marketing authorisation holder** […] for each veterinary medicinal product and shall contain at least the following information:
(a) the name or corporate name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer and, where applicable, of the representative of the marketing		(a) the name or corporate name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer and, where applicable, of the representative of the marketing	(a) the name or corporate name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer and, where applicable, of the representative of the marketing

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authorisation holder;		authorisation holder;	authorisation holder;
(b) the name of the veterinary medicinal product or, where applicable, a list of the names of the veterinary medicinal product, as authorised in different Member States;		(b) the name of the veterinary medicinal product **followed by its strength and pharmaceutical form** […];	(b) the name of the veterinary medicinal product **followed by its strength and pharmaceutical form** […];
		(ba) qualitative and quantitative composition of the active substance(s);	**(ba) qualitative and quantitative composition of the active substance(s);**
(c) the strength and pharmaceutical form of the veterinary medicinal product;		~~(c)~~ […]	~~(c)~~ […]
(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***, if necessary,*** advice on correct administration~~, if 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 adverse events in so far as this information is necessary for the use of the veterinary medicinal product;		(f) the contra-indications and adverse events […];	(f) the contra-indications and adverse events […];
(g) the withdrawal period, even if this is nil, in the event that the target species are food-producing animals;		(g) **if applicable**, the withdrawal period, even if this is […] **zero**;	(g) **if applicable**, the withdrawal period, even if this is […] **zero**;
(h) special storage precautions, if any;		(h) special storage precautions, if any;	(h) special storage precautions, if 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;	**AM 106** (k) ~~the marketing authorisation number;~~	(k) the marketing authorisation number;	(k) the marketing authorisation number;
(l) in case of generic veterinary medicinal products, the statement 'generic veterinary medicinal product';		~~(l)~~ […]	~~(l)~~ […]
(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;	**(l) 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. Th**at** 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**,** ***readable*** 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 1, the information required in accordance with this Article may, alternatively, be provided on the packaging of the veterinary medicinal product.	**4. By derogation from paragraph 1, the information required in accordance with this Article may, alternatively, be provided on the packaging of the veterinary medicinal product.**
		Article 12a	***Article 12a***
		The information listed in Articles 9 to 12 shall comply with the summary of the product characteristics as set out in Article 30.	**The information listed in Articles 9 to 12 shall comply with the summary of the product characteristics as set out in Article 30.**
Article 13 *Package leaflet of homeopathic veterinary medicinal products*		*Article 13* *Package leaflet of* ***registered*** *homeopathic veterinary medicinal products*	*Article 13* *Package leaflet of* ***registered*** *homeopathic veterinary medicinal products*
By way of derogation from Article 12(1), the package leaflet for homeopathic veterinary medicinal products registered in accordance with Articles 89 to 90 shall contain only the following information:		By way of derogation from Article 12(1), the package leaflet for homeopathic veterinary medicinal products registered in accordance with Article~~s~~ 89 […] shall contain […]**, at least**, the following information:	By way of derogation from Article 12(1), the package leaflet for homeopathic veterinary medicinal products registered in accordance with Article~~s~~ 89 […] shall contain […]**, at least**, the following information:
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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; ***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;***	(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;		(e) pharmaceutical form;	(e) pharmaceutical form;
(f) special storage precautions, if any;		(f) special storage precautions, if any;	(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;		(j) registration number;	(j) registration number;
(k) withdrawal period, if applicable.		(k) withdrawal period, if applicable.	(k) withdrawal period, if applicable.
(l) the statement "homeopathic veterinary medicinal product".		(l) the statement "homeopathic veterinary medicinal product".	(l) the statement "homeopathic veterinary medicinal product".
Article 14 *Languages*		~~*Article 14*~~ ~~*Languages*~~	~~*Article 14*~~ ~~*Languages*~~[26]
1. The language or languages of the information on the labelling shall be determined by Member State where the veterinary medicinal product is made available on the market.		[…]	[…]

[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 *Abbreviations and pictograms common throughout the Union*		*Article 15* *[…] **Implementing powers with respect to section 4***	*Article 15* *[…] **Implementing powers with respect to section 4***
		0. The Commission may, by means of implementing acts, provide uniform rules on the identification code referred to in Articles 9(3) and 10(1a). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	**0. The Commission ~~may~~ shall, when appropriate, by means of implementing acts, provide uniform rules on the identification code referred to in Articles 9(3) and 10(1a). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**
The Commission shall, by means of implementing acts, adopt a list of the abbreviations and pictograms common throughout the Union to be used for the purposes of Article 9(2) and Article 10(2). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).		**1.** The Commission shall, by means of implementing acts, adopt a list of the abbreviations and pictograms common throughout the Union to be used for the purposes of Article 9(2) and Article 10(2). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	**1.** The Commission shall, by means of implementing acts, adopt a list of the abbreviations and pictograms common throughout the Union to be used for the purposes of Article 9(2) and Article 10(2). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

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		2. The Commission shall, by means of implementing acts, provide uniform rules on the size of packaging units referred to in Article 11. 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, provide uniform rules on the size of packaging units referred to in Article 11. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**
Section 5 **Dossier requirements for generic, combination and hybrid veterinary medicinal products and for applications based on informed consent and bibliographic data**		**Section 5** **Specific requirements for generic, combination and hybrid veterinary medicinal products and for applications based on informed consent and bibliographic data**	**Section 5** **Specific requirements for generic, combination and hybrid veterinary medicinal products and for applications based on informed consent and bibliographic data**
Article 16 *Generic veterinary medicinal products*		*Article 16* *Generic veterinary medicinal products*	*Article 16* *Generic veterinary medicinal products*
1. By way of derogation from Article 7(1)(b), an application for a marketing authorisation for a generic veterinary medicinal products shall not contain the documentation on safety and efficacy if all the following conditions are fulfilled:		1. By way of derogation from Article 7(1)(b), **it shall not be required that** an application for a marketing authorisation for a generic veterinary medicinal product […] contain**s** the documentation on safety and efficacy if all the following conditions are fulfilled:	1. By way of derogation from Article 7(1)(b), **it shall not be required that** an application for a marketing authorisation for a generic veterinary medicinal product […] contain**s** the documentation on safety and efficacy if all the following 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 were not performed;	**(aa) bioavailability studies have demonstrated its bioequivalence with the reference veterinary medicinal product or a justification is provided as to why 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 […] demonstrate**s** 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 […] demonstrate**s** 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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2. For the purpose of this Section, where the active substance consists of salts, esters, ethers, isomers and mixtures of isomers, complexes or derivatives differing from the active substance used in the reference veterinary medicinal product, it shall be considered to be the same active substance as that used in the reference veterinary medicinal product, unless it differs significantly in respect of properties with regard to safety or efficacy. Where it differs significantly in respect of those properties, the applicant shall submit additional information in order to prove the safety and/or efficacy of the various salts, esters or derivatives of the authorised active substance of the reference veterinary medicinal product.	**AM 108** 2. For the purpose of this Section, where the active substance consists of salts, esters, ethers, isomers and mixtures of isomers, complexes or derivatives differing from the active substance used in the reference veterinary medicinal product, it shall be considered to be the same active substance as that used in the reference veterinary medicinal product, unless it differs significantly in respect of properties with regard to safety**,** ~~or~~ efficacy ***and behaviour of residues***.. Where it differs significantly in respect of those properties, the applicant shall submit additional information in order to prove the safety and/or efficacy of the various salts, esters or derivatives of the authorised active substance of the reference veterinary medicinal product.	2. […] **W**here the active substance **of a generic veterinary medicinal product** consists of salts, esters, ethers, isomers and mixtures of isomers, complexes or derivatives differing from the active substance used in the reference veterinary medicinal product, it shall be considered to be the same active substance as that used in the reference veterinary medicinal product, unless it differs significantly in respect of properties with regard to safety or efficacy. Where it differs significantly in respect of those properties, the applicant shall submit additional information in order to prove the safety and/or efficacy of the various salts, esters or derivatives of the authorised active substance of the reference veterinary medicinal product.	2. […] **W**here the active substance **of a generic veterinary medicinal product** consists of salts, esters, ethers, isomers and mixtures of isomers, complexes or derivatives differing from the active substance used in the reference veterinary medicinal product, it shall be considered to be the same active substance as that used in the reference veterinary medicinal product, unless it differs significantly in respect of properties with regard to safety or efficacy. Where it differs significantly in respect of those properties, the applicant shall submit additional information in order to prove the safety and/or efficacy of the various salts, esters or derivatives of the authorised active substance of the reference veterinary medicinal product.

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		2a. Where several immediate-release oral pharmaceutical forms of a generic veterinary medicinal product are presented, they shall be considered to be the same pharmaceutical form.	**2a. Where several immediate-release oral pharmaceutical forms of a generic veterinary medicinal product are presented, they shall be considered to be the same pharmaceutical form.**
3. Where the reference veterinary medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted, or the application is submitted in accordance with Article 38(3) where the reference medicinal product was authorised in a Member State, the applicant shall indicate in its application the Member State in which the reference veterinary medicinal product has been authorised.		3. Where the reference veterinary medicinal product […] **is** not authorised in the Member State in which the application for the generic medicinal product is submitted, or the application is submitted in accordance with Article 38(3) where the reference medicinal product […] **is** authorised in a Member State, the applicant shall indicate in its application the Member State in which the reference veterinary medicinal product has been authorised.	3. Where the reference veterinary medicinal product […] **is** not authorised in the Member State in which the application for the generic medicinal product is submitted, or the application is submitted in accordance with Article 38(3) where the reference medicinal product […] **is** authorised in a Member State, the applicant shall indicate in its application the Member State in which the reference veterinary medicinal product has been authorised.
4. The competent authority or the Agency may request information on the reference veterinary medicinal product from the competent authority of the Member State where it was authorised. Such information shall be transmitted to the requestor within 30 days of receipt of the request.		4. The competent authority or the Agency**, as applicable,** may request information on the reference veterinary medicinal product from the competent authority of the Member State where it […] **is** authorised. Such information shall be transmitted to the requestor within 30 days of receipt of the request.	4. The competent authority or the Agency**, as applicable,** may request information on the reference veterinary medicinal product from the competent authority of the Member State where it […] **is** authorised. Such information shall be transmitted to the requestor within 30 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 veterinary medicinal product shall be identical to that of the reference veterinary medicinal product. However, that requirement shall not apply to those parts of the summary of the product characteristics of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are still covered by patent law at the time when the generic veterinary medicinal product is authorised.		characteristics of the generic veterinary medicinal product shall be […] **essentially similar** to that of the reference veterinary medicinal product. However, that requirement shall not apply to those parts of the summary of the product characteristics of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are still covered by patent law at the time when the generic veterinary medicinal product is authorised.	characteristics of the generic veterinary medicinal product shall be […] **essentially similar** to that of the reference veterinary medicinal product. However, that requirement shall not apply to those parts of the summary of the product characteristics of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are still covered by patent law at the time when the generic veterinary medicinal product is authorised.
6. A competent authority or the Agency may require the applicant to provide safety data concerning the potential risks posed by the generic veterinary medicinal product to the environment in case the marketing authorisation for the reference veterinary medicinal product was granted before 20 July 2000 or in case the second phase environmental risk assessment was required for the reference veterinary medicinal product.	**AM 109** 6. ~~A~~ ***The applicant shall submit to the*** competent authority or the Agency***, on their request,*** ~~may require the applicant to provide~~ safety data concerning the potential risks posed by the generic veterinary medicinal product to the environment ~~in case the marketing authorisation for the reference veterinary medicinal product was granted before 20 July 2000 or in case the second phase environmental risk assessment was required for the~~	6. A competent authority or the Agency**, as applicable,** may require the applicant to provide safety data concerning the potential risks posed by the generic veterinary medicinal product to the environment in case the marketing authorisation for the reference veterinary medicinal product was granted before […] **7 October 2005** […].	6. A competent authority or the Agency**, as applicable,** may require the applicant to provide safety data concerning the potential risks posed by the generic veterinary medicinal product to the environment in case the marketing authorisation for the reference veterinary medicinal product was granted before […] ~~7~~ ***1*** **October 2005**[27] […].

[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 reference*** product.		
7. The Commission shall be 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.		~~7.~~ […]	~~7.~~ […]
		Article 16a[28] ***Hybrid veterinary medicinal products***	***Article 16a*** ***Hybrid veterinary medicinal products***
		1. By way of derogation from Article 16(1), the results of appropriate pre-clinical studies and **/or** clinical trials shall be required when the product does not meet all the characteristics of a generic veterinary medicinal product because:	1. By way of derogation from Article 16(1), the results of appropriate pre-clinical studies and **/or** 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), […]indications **for use**, strength, pharmaceutical form or route of administration of the generic	(a) there are changes in the active substance(s), […]indications **for use**, strength, pharmaceutical form or route of administration of the generic

[28] Ex Article 18

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		veterinary medicinal product compared to the reference veterinary medicinal product, or	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	(b) bioavailability studies cannot be used to demonstrate bioequivalence with the reference veterinary medicinal product, or
		(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.	(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 for a hybrid veterinary medicinal product** may be conducted with batches of the reference product […] **authorised** in the Union or in third countries. […] **T**he applicant shall demonstrate […] that the […] reference product **in third countries has been authorised in accordance with requirements equivalent to those established for the reference veterinary medicinal product and** are so highly similar that they can substitute […] each other in the clinical trials.	2. The pre-clinical studies or clinical **trials for a hybrid veterinary medicinal product** may be conducted with batches of the reference product […] **authorised** in the Union or in third countries. […] **T**he applicant shall demonstrate […] that the […] reference product **in third countries has been authorised in accordance with requirements equivalent to those established for the reference veterinary medicinal product and** are so highly similar that they can substitute […] each other in the clinical trials.

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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;		~~(a)~~ […]	~~(a)~~ […]
(b) the applicant can demonstrate that the veterinary medicinal product is a combination of reference veterinary medicinal products as referred to in Article 16(1)(b);		~~(b)~~ […]	~~(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;		~~(c)~~ […]	~~(c)~~ […]
(d) documentation on the safety of		~~(d)~~ […]	~~(d)~~ […]

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that combination is provided.			
Article 18 *Hybrid veterinary medicinal products*		~~*Article 18*~~[29] […]	~~*Article 18*~~ […]
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.

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(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 *Application based on informed consent*		*Article 19* *Application based on informed consent*	*Article 19* *Application based on informed consent*
By way of derogation from Article 16(1)(b), an applicant for a marketing authorisation for a generic veterinary medicinal product shall not be required to provide the documentation on safety and efficacy if he demonstrates in the form of a letter of access that he is allowed to use the documentation on safety and		By way of derogation from Article […] **7**(1)(b), an applicant for a marketing authorisation for a […] veterinary medicinal product shall not be required to provide the **technical** documentation on **quality,** safety and efficacy if he demonstrates in the form of a letter of access that he is allowed to use […] **that** documentation […]	By way of derogation from Article […] **7**(1)(b), an applicant for a marketing authorisation for a […] veterinary medicinal product shall not be required to provide the **technical** documentation on **quality,** safety and efficacy if he demonstrates in the form of a letter of access that he is allowed to use

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

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Section 6 **Dossier requirements for applications for limited market and in exceptional circumstances**		**Section 6** **Marketing authorisations** for […] limited market**s** and in exceptional circumstances	**Section 6** **Marketing authorisations** for […] limited market**s** and in exceptional circumstances
Article 21 *Reduced data requirements for applications for limited markets*		*Article 21* *[…] **A**pplications for limited markets*	*Article 21* *[…] **A**pplications for limited markets*
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:	**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~~ ***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

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medicinal product is intended for a limited market.		product is intended for a limited market.	medicinal product is intended for a 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~~ ***five*** 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~~ ***information on its*** 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 ***3a. 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.***		
		Article 21a[30] ***Validity*** *[…] of a marketing authorisation for a limited market* ***and procedure for its re-examination***	***Article 21a*** ***Validity*** *[…] of a marketing authorisation for a limited market* ***and procedure for its re-examination***
		0. By way of derogation from Article 5(2), a marketing authorisation for a limited market shall be valid for a period of 3 years.	**0. By way of derogation from Article 5(2), a marketing authorisation for a limited market shall be valid for a period of ~~3~~ 5 years.**
		1. Before the expiry of the period of validity […] **referred to in paragraph 0**, marketing authorisations for a limited market granted in accordance with Article 21 shall be re-examined on application from the marketing authorisation holder **including an updated benefit-risk assessment**.[…]	1. Before the expiry of the period of validity […] **referred to in paragraph 0**, marketing authorisations for a limited market granted in accordance with Article 21 shall be re-examined on **the basis of an** application from the marketing authorisation holder **including an 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 **be limited to** demonstrat**inge** ~~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**s** for a re-examination **and extend the validity of the marketing authorisation ~~for a~~ by additional period**s **of five years if** the benefit-risk balance […] **remains** positive.

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

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		provided. In such case, the applicant shall be required to demonstrate[…] that for objective **and** verifiable reasons […] the quality, safety and/or efficacy documentation required in accordance with […] Annex II **cannot be provided.**	**provided. In such case, the applicant shall be required to demonstrate**[…] that for objective **and** verifiable reasons […] the quality, safety and/or efficacy documentation required in accordance with […] Annex II **cannot be provided.**
		Article 22a ***Terms of the marketing authorisation in exceptional circumstances***	***Article 22a*** ***Terms of the marketing authorisation in exceptional circumstances***
		1. In exceptional circumstances referred to in Article 22, a marketing authorisation may be granted […] subject to […] **one or more** of the following **requirements for the marketing authorisation holder**:	**1. In exceptional circumstances referred to in Article 22, a marketing authorisation may be granted** […] subject to […] **one or more** of the following **requirements for the marketing authorisation holder**:
(a) a requirement to introduce conditions or restrictions, in particular concerning the safety of the veterinary medicinal product;		(a) a requirement to introduce conditions or restrictions, in particular concerning the safety of the veterinary medicinal product;	(a) a requirement to introduce conditions or restrictions, in particular concerning the safety of the veterinary medicinal product;
(b) a requirement to notify the competent authorities of any incident relating to the use of the veterinary medicinal product;	**AM 113** (b) a requirement to notify the competent authorities of any ~~incident~~ ***adverse event*** relating to the use of the veterinary medicinal product;	(b) a requirement to notify **to** the competent authorities **or the Agency, as applicable,** of any […] **adverse event** relating to the use of the veterinary medicinal product;	(b) a requirement to notify **to** the competent authorities **or the Agency, as applicable,** of any […] **adverse event** relating to the use of the veterinary medicinal product;
	AM 113		

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(c) a requirement to conduct post-authorisation studies.	(c) a requirement to ~~conduct~~ ***provide further data based on either*** 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***.	(c) a requirement to conduct post-authorisation studies.	(c) a requirement to conduct post-authorisation studies.
2. By way of derogation from Article 5(2), a marketing authorisation in exceptional circumstances shall be granted for a period of 1 year.	**AM 113** 2. ~~By way of derogation from Article 5(2),~~ ***The continuation of*** a marketing authorisation ~~in exceptional circumstances~~ ***granted in 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***.	~~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, safety and/or efficacy has been conducted due to the lack of comprehensive quality, safety and/or efficacy data.	**AM 113** 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, safety and/or efficacy has been conducted due to the lack of comprehensive quality, safety and/or efficacy data. ***The packaging shall***	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 quality, safety and/or efficacy has been conducted due to the lack of comprehensive quality, 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 quality, safety and/or efficacy has been conducted due to the lack of comprehensive quality, safety and/or 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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		Article 22b[31] ***Validity of a marketing authorisation in exceptional circumstances and procedure for its re-examination***	***Article 22b*** ***Validity of a marketing authorisation in exceptional circumstances and procedure for its re-examination***
		0. By way of derogation from Article 5(2), a marketing authorisation in exceptional circumstances shall be valid for a period of 1 year.	**0. By way of derogation from Article 5(2), a marketing authorisation in exceptional circumstances shall be valid for a period of 1 year.**
		1. Before the expiry of the period of validity […] **referred to in paragraph 0**, marketing authorisations granted in accordance with Article 22 **and 22a** shall be re-examined on application from the marketing authorisation holder **including an updated benefit-risk assessment.**	1. Before the expiry of the period of validity […] **referred to in paragraph 0**, marketing authorisations granted in accordance with Article 22 **and 22a** shall be re-examined on application from the marketing authorisation holder **including an updated benefit-risk assessment.**
		2. **The** […] application for re-examination shall be submitted to the competent authority that granted the authorisation or the Agency**, as applicable,** at least 3 months before the expiry of the […] **period of validity referred to in paragraph 0, and shall demonstrate that the exceptional circumstances related**	2. **The** […] application for re-examination shall be submitted to the competent authority that granted the authorisation or the Agency**, as applicable,** at least 3 months before the expiry of the […] **period of validity referred to in paragraph 0, and shall demonstrate that the exceptional circumstances related**

[31] ex Article 83

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

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authorisations		**authorisations**	**authorisations**
Article 23 *Examination of applications*		*Article 23* *Examination of applications*	*Article 23* *Examination of applications*
1. The competent authority or the Agency to which the application has been submitted in accordance with Article 6 shall:		1. The competent authority or the Agency**, as applicable,** to which the application has been submitted in accordance with Article 6 shall:	1. The competent authority or the Agency**, as applicable,** to which the application has been submitted in accordance with Article 6 shall:
(a) verify that the documentation submitted complies with the requirements laid down in Article 7(1) and is satisfactory for granting a marketing authorisation;		(a) verify that the **data** […] submitted complies with the requirements laid down in Article 7[…];	(a) verify that the **data** […] submitted complies with the requirements laid down in Article 7[…];
(b) assess the veterinary medicinal product regarding the quality, safety and efficacy documentation provided.		(b) assess the veterinary medicinal product regarding the quality, safety and efficacy documentation provided.	(b) assess the veterinary medicinal product regarding the quality, safety and efficacy documentation provided.
		(c) draw up a conclusion on the benefit-risk balance for the veterinary medicinal product.	**(c) draw up a conclusion on the benefit-risk balance for the veterinary medicinal product.**
2. During the process of assessing applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms as referred to in Article 7(5), the necessary consultations shall be held by the Agency with the bodies set up by the Union or Member States in accordance with Directive 2001/18/EC.		2. During the process of assessing applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms as referred to in Article 7(5), the necessary consultations shall be held by the Agency with the bodies set up by the Union or Member States in accordance with Directive 2001/18/EC.	2. During the process of assessing applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms as referred to in Article 7(5), the necessary consultations shall be held by the Agency with the bodies set up by the Union or Member States in accordance with Directive 2001/18/EC.

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

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maximum residue level of the pharmacologically active substance established by the Commission in accordance with Regulation (EC) No 470/2009 and Commission Decision 2002/657/EC[32].		of residue levels, particularly those exceeding the maximum residue level of the pharmacologically active substance established by the Commission in accordance with Regulation (EC) No 470/2009 **and for official controls of animals and products of animal origin in accordance with Regulation (EU) No 2017/625** […].	presence of residue levels, particularly those exceeding the maximum residue level of the pharmacologically active substance established by the Commission in accordance with Regulation (EC) No 470/2009 **and for official controls of animals and products of animal origin in accordance with Regulation (EU) No 2017/625** […].
2. The time limits laid down in Articles 40, 44, 46 and 48 shall be suspended until the samples requested in accordance with paragraph 1 have been provided.		2. The time limits laid down in Articles 40, 44, 46**,** […] 48 **and 48a** shall be suspended until the samples requested in accordance with paragraph 1 **of this Article** have been provided.	2. The time limits laid down in Articles 40, 44, 46**,** […] 48 **and 48a** shall be suspended until the samples requested in accordance with paragraph 1 **of this Article** have been provided.
Article 25 *Information on manufacturers*		*Article 25* *Information on manufacturers*	*Article 25* *Information on manufacturers* ***in third countries***
The competent authority shall ascertain that the manufacturers of veterinary medicinal products from third countries are able to manufacture the veterinary medicinal product concerned and/or carry out control tests in accordance with the	**AM 114** The competent authority shall ascertain that the manufacturers of veterinary medicinal products from third countries ***comply with applicable Union law,*** are able to manufacture the veterinary medicinal product concerned and/or carry out	The competent authority […] **or the Agency, as applicable, to which the application has been submitted in accordance with Article 6, may request the relevant competent authority to forward to it the information ascertaining that the**	The competent authority […] **or the Agency, as applicable, to which the application has been submitted in accordance with Article 6,** ~~**may request the relevant competent authority to forward to it 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 documentation submitted in support of the application in accordance with 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) ***and that they minimise environmental pollution***.	**manufacturers of veterinary medicinal products** are able to manufacture the veterinary medicinal product concerned and/or carry out control tests in accordance with the methods described in the documentation submitted in support of the application in accordance with Article 7(1).	~~**manufacturers of veterinary medicinal products**~~ **shall ascertain, through the procedure in Articles 91 to 93, that the manufacturers of veterinary medicinal products from third countries** are able to manufacture the veterinary medicinal product concerned and/or carry out control tests in accordance with the methods described in the documentation submitted in support of the application in accordance with Article 7(1). **A competent authority or the Agency, as applicable, may request the relevant competent authority to present information ascertaining that the manufacturers of veterinary medicinal products are able to carry out the activities referred to in this Article.**
Article 26 *Information to the applicant*		*Article 26* ***Additional i**nformation […] **from** the applicant*	*Article 26* ***Additional i**nformation […] **from** the applicant*
The competent authority or the Agency to which the application has been submitted in accordance with Article 6 shall inform the applicant if the documentation submitted in support of the application is		The competent authority or the Agency**, as applicable,** to which the application has been submitted in accordance with Article 6 shall inform the applicant if the documentation submitted in support	The competent authority or the Agency**, as applicable,** to which the application has been submitted in accordance with Article 6 shall inform the applicant if the documentation submitted in support

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

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accordance with Article 6.		application was submitted in accordance with Article 6.	application was submitted in accordance with Article 6.
3. If an assessment report or, in case of the centralised authorisation procedure, the opinion, has been drawn up, it shall be made public by the competent authorities or the Agency, after deletion of any commercially confidential information.		3. […] **In case of a centralised authorisation procedure, the Agency shall make publicly available the information that the application has been withdrawn together with** […] the opinion, […] **already** drawn up, […] after deletion of any commercially confidential information.	3. ~~[…] In case of a centralised authorisation procedure,~~ **The competent authorities or the Agency, as applicable, shall make publicly available the information that the application has been withdrawn together with** […] the opinion, […] **already** drawn up, […] after deletion of any commercially confidential information.
Article 28 *Outcome of the assessment*		*Article 28* *Outcome of the assessment*	*Article 28* *Outcome of the assessment*
1. In case of favourable assessment to grant a marketing authorisation, the competent authority or the Agency examining the application shall prepare an opinion including the following documents:		1. **The competent authority or the Agency, as applicable, examining the application in accordance with Article 23, shall prepare, respectively, an assessment report or an opinion.** In case of **a** favourable assessment […], **that assessment report or opinion shall include** the following […]:	1. **The competent authority or the Agency, as applicable, examining the application in accordance with Article 23, shall prepare, respectively, an assessment report or an opinion.** In case of **a** favourable assessment […], **that assessment report or opinion shall include** the following […]:
(a) a summary of the product characteristics containing the information laid down in Article 30;		(a) a summary of the product characteristics containing the information laid down in Article 30;	(a) a summary of the product characteristics containing the 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 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 Article 29;
(c) details of any conditions or restrictions which should be imposed as regards the safe and effective use of the veterinary medicinal product;		(c) […]	(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 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 antimicrobial resistance.	**AM 115** 3. Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission ~~may~~ ***shall*** 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 antimicrobial resistance.	~~3.~~ […][33]	~~3.~~ […]
Article 29 *Requirement for a veterinary prescription*		*Article 29* *[…]* ***Classification of veterinary medicinal products***	*Article 29* *[…]* ***Classification of veterinary 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~~***T***he following veterinary medicinal products ~~as~~ ***shall be*** subject to ***mandatory*** 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:

[33] Moved to Article 31.

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(a) veterinary medicinal products 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;		(a) veterinary medicinal products which contain […] narcotic drugs **or psychotropic substances, or substances frequently used in the illicit manufacture of these drugs or substances** 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 **and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 or by Union legislation on drug precursors**;	(a) veterinary medicinal products which contain […] narcotic drugs **or psychotropic substances, or substances frequently used in the illicit manufacture of these drugs or substances** 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 **and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 or by Union legislation on drug precursors**;
(b) veterinary medicinal products for food-producing animals;		(b) veterinary medicinal products for food-producing animals;	(b) veterinary medicinal products for food-producing animals;
(c) antimicrobial veterinary medicinal products;		(c) antimicrobial veterinary medicinal products;	(c) antimicrobial veterinary medicinal products;
(d) products intended for treatments of pathological processes which require a precise prior diagnosis or the use of which may have effects which impede or interfere with subsequent diagnostic or therapeutic measures;		(d) **veterinary medicinal** products intended for treatments of pathological processes which require a precise prior diagnosis or the use of which may have effects which impede or interfere with subsequent diagnostic or therapeutic measures;	(d) **veterinary medicinal** products intended for treatments of pathological processes which require a precise prior diagnosis or the use of which may have effects which impede or interfere with subsequent diagnostic or therapeutic measures;
		(dd) veterinary medicinal products used for euthanasia of	**(dd) veterinary medicinal 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 medicinal products containing an active substances having a hormonal or thyrostatic action and beta-agonists.	**(h) without prejudice to Council Directive 96/22/EC[35], veterinary medicinal products containing an active substances having a 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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	AM 116&298 ***1a. Member States may on their territories provide for additional legal subcategories in accordance with the respective national law.***		
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:	**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**.** […]	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) the target species,		~~(a)~~	~~(a)~~
(b) the person administering the products to the animal,		~~(b)~~	~~(b)~~
(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** 3. By the way of derogation from paragraph 1, a competent authority or the ~~Agency~~ ***Commission*** may ~~not classify~~ ***exempt*** a veterinary medicinal product ~~as subject to~~ ***from a mandatory*** veterinary prescription if all of the following conditions are fulfilled:	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	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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		all of the following conditions are fulfilled:	all of the following conditions are fulfilled:
(a) the administration of the veterinary medicinal product is restricted to pharmaceutical forms requiring no particular knowledge or skill in using the products;		(a) the administration of the veterinary medicinal product is restricted to pharmaceutical forms requiring no particular knowledge or skill in using the products;	(a) the administration of the veterinary medicinal product is restricted to pharmaceutical forms requiring no particular knowledge or skill in using the products;
(b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal(s) treated, to the person administering the product or to the environment;		(b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal(s) treated **or to other animals**, to the person administering the product or to the environment;	(b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal(s) treated **or to other animals**, to the person administering the product or to the environment;
(c) the summary of the product characteristics of the veterinary medicinal product does not contain any warnings of potential serious side effects deriving from its correct use;	**AM 116&298** (c) the summary of the product characteristics of the veterinary medicinal product does not contain any warnings of potential serious ~~side effects~~ ***adverse events*** deriving from its correct use;	(c) the summary of the product characteristics of the veterinary medicinal product does not contain any warnings of potential serious **adverse events** […] deriving from its correct use;	(c) the summary of the product characteristics of the veterinary medicinal product does not contain any warnings of potential serious **adverse events** […] deriving from its correct use;
(d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent adverse event reporting;		(d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent adverse event reporting;	(d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent adverse event reporting;

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(e) the summary of the product characteristics does not refer to contraindications related to other veterinary medicinal products commonly used without prescription;		(e) the summary of the product characteristics does not refer to contraindications related to other veterinary medicinal products commonly used without prescription;	(e) the summary of the product characteristics does not refer to contraindications related to other veterinary medicinal products commonly used without prescription;
(f) the veterinary medicinal product is not subject to special storage conditions;	**AM 116&298** (f) ~~the veterinary medicinal product is not subject to special storage conditions;~~	(f) the veterinary medicinal product is not subject to special storage conditions;	~~(f) the veterinary medicinal product is not subject to special storage conditions;~~
(g) there is no risk for public health as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly;		(g) there is no risk for public health as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly;	(g) there is no risk for public health as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly;
(h) there is no risk to public or animal health as regards the development of resistance to anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly.	**AM 116&298** h) there is no risk to public or animal health as regards the development of ***antiparasic*** resistance ~~to anthelmintic substances~~ even where the veterinary medicinal products containing those substances are used incorrectly.	(h) there is no risk to public or animal health as regards the development of resistance to […] substances even where the veterinary medicinal products containing those substances are used incorrectly.	(h) there is no risk to public or animal health as regards the development of resistance to […] substances even where the veterinary medicinal products containing those substances are used incorrectly.
	AM 117 ***3a. Notwithstanding paragraph 1, 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 States**[36];	(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] This wording is moved here from Article 12(1)(b).
[37] 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 or lay,		(vii) use during pregnancy, lactation or lay,	(vii) use during pregnancy, lactation or lay,
(viii) interaction with other medicinal products and other forms of interaction,		(viii) interaction with other medicinal products and other forms of interaction,	(viii) interaction with other medicinal products and other forms of interaction,
(ix) administration route and amounts to be administered,		(ix) administration route and **dosage** […],	(ix) administration route and **dosage** […],
(x) overdose symptoms and emergency procedures and antidotes in the event of overdose, where applicable,		(x) […] symptoms **of overdose** and**, where applicable,** emergency procedures and antidotes in the event of overdose, […],	(x) […] symptoms **of overdose** and**, where applicable,** emergency procedures and antidotes in the event of overdose, […],
(xi) where appropriate, special indications or restrictions for use in accordance with Articles 107 to 109,		(xi) […] special […] restrictions for use,	(xi) […] special […] restrictions for use,
(xii) where appropriate, an indication of classification of an antimicrobial regarding its strategic use,		~~(xii)~~ [….]	~~(xii)~~ [….]
(xiii) special conditions for use, including restrictions on the use of antimicrobials in order to limit the risk of development of antimicrobial resistance,	**AM 120** (xiii) special conditions for use, including restrictions on the use of antimicrobials in order to limit the risk of development of antimicrobial resistance, ***and specifying that the product is not allowed to be used as a routine preventive measure,***	(xiii) special conditions for use, including restrictions on the use of antimicrobial **and antiparasitic veterinary medicinal products** in order to limit the risk of development of […] resistance,	(xiii) special conditions for use, including restrictions on the use of antimicrobial **and antiparasitic veterinary medicinal products** in order to limit the risk of development of […] resistance,
(d) withdrawal periods, including animal species/foodstuffs combinations;		~~(d)~~ **(xiii) if applicable**, withdrawal periods[…] **including when it is zero** […]**,**	~~(d)~~ **(xiii) if applicable**, withdrawal periods[…] **including when it is zero** […]**,**

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(e) pharmacological information:		(e) pharmacological information:	(e) pharmacological information:
		(oi) Anatomical Therapeutic Chemical Veterinary Code (ATC Vet Code);	**(oi) Anatomical Therapeutic Chemical Veterinary Code (ATC Vet Code);**
(i) pharmacodynamics,		(i) pharmacodynamics,	(i) pharmacodynamics,
(ii) pharmacokinetics,		(ii) pharmacokinetics,	(ii) pharmacokinetics,
		In case of an immunological veterinary medicinal product, instead of points (0i), (i) and (ii) immunological information;	**In case of an immunological veterinary medicinal product, instead of points (0i), (i) and (ii) immunological information;**
(iii) pharmaceutical particulars,		**(eb)**[…] pharmaceutical particulars**:**	**(eb)**[…] pharmaceutical 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 after reconstitution of the medicinal product or after the immediate packaging has been opened for the first time,		([…]**ii**) shelf life, where applicable after reconstitution of the medicinal product or after the immediate packaging has been opened for the first time,	([…]**ii**) shelf life, where applicable after reconstitution of the medicinal product or after the immediate packaging has been opened for the first time,
(vi) special precautions for storage,		([…]**iii**) special precautions for storage,	([…]**iii**) special precautions for storage,
(vii) nature and composition of immediate packaging,		(**iv**[…]) nature and composition of immediate packaging,	(**iv**[…]) nature and composition of immediate packaging,
(viii) 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;		(viii) 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;	(viii) 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;
(f) name of the marketing authorisation holder;		(f) name of the marketing authorisation holder;	(f) name of the marketing authorisation holder;
(g) marketing authorisation number(s);		(g) marketing authorisation number(s);	(g) marketing authorisation number(s);
(h) if applicable, date of the first authorisation;		(h) […] date of the first **marketing** authorisation;	(h) […] date of the first **marketing** authorisation;

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(i) the date of the last revision of the summary of the product characteristics;		(i) […] date of the last revision of the summary of the product characteristics;	(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 'market authorisation granted for a limited market/exceptional circumstances and therefore assessment based on customised requirements for documentation'.		(j) if applicable, for products […] **referred to in** Article 21 or Article 22**a**, the statement 'market**ing** authorisation granted for a limited market/exceptional circumstances and therefore assessment based on customised requirements for documentation'.	(j) if applicable, for products […] **referred to in** Article 21 or Article 22**a**, the statement 'market**ing** 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 medicinal products, the parts of the summary of the product characteristics of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are protected by patent law in a Member State at the time of placing the generic veterinary medicinal product on the market may be omitted.		2. In case of generic veterinary medicinal products, the parts of the summary of the product characteristics of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are protected by patent law in a Member State at the time of placing the generic veterinary medicinal product on the market may be omitted.	2. In case of generic veterinary medicinal products, the parts of the summary of the product characteristics of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are protected by patent law in a Member State at the time of placing the generic veterinary medicinal product on the market may be omitted.
Article 31 *Decisions granting marketing authorisations*		*Article 31* *Decisions granting marketing authorisations*	*Article 31* *Decisions granting marketing authorisations*
1. Decisions granting marketing authorisations shall be taken on the basis of the documents prepared in accordance with Article 28 and shall set out the conditions attached to the placing on the market of the veterinary medicinal product and the summary of the product characteristics ('terms of the marketing authorisation').		1. Decisions granting marketing authorisations referred to in Article 5(1) shall be taken on the basis of the documents prepared in accordance with Article 28(1) and shall set out […] any conditions attached to the placing on the market of the veterinary medicinal product and the summary of the product characteristics ('terms of the marketing authorisation').	1. Decisions granting marketing authorisations referred to in Article 5(1) shall be taken on the basis of the documents prepared in accordance with Article 28(1) and shall set out […] any conditions attached to the placing on the market of the veterinary medicinal product and the summary of the product characteristics ('terms of the marketing authorisation').

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2. 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*		*Article 32* *Decisions refusing marketing*	*Article 32* *Decisions refusing marketing*

[38] ex Article 28(3)

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authorisations		*authorisations*	*authorisations*
		0. Decisions refusing marketing authorisations referred to in Article 5(1) shall be taken on the basis of the documents prepared in accordance with Article 28(1a) and shall be duly justified and include the reasons for refusal.	**0. Decisions refusing marketing authorisations referred to in Article 5(1) shall be taken on the basis of the documents prepared in accordance with Article 28(1a) and shall be duly justified and include the reasons for refusal.**
1. The marketing authorisation shall be refused on any of the following grounds:		1. **A** marketing authorisation shall be refused **on any of the following grounds**:	1. **A** marketing authorisation shall be refused **on any of the following 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** 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 ***within the meaning of 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.**	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.**
	AM 133		

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3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to establish rules for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of certain active substances in humans.	3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 ***and taking into consideration the scientific advice of the Agency*** in order to establish rules for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of certain active substances 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.***	3. The Commission shall […] adopt delegated acts in accordance with Article 146 **supplementing the rules of this Regulation concerning the** establish**ment of criteria** […] for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of […] **those antimicrobials**.	3. The Commission shall […] adopt delegated acts in accordance with Article 146 **supplementing the rules of this Regulation concerning the** establish**ment of criteria** […] for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of […] **those antimicrobials**.
4. The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. Those implementing acts shall be adopted in accordance with the	**AM 134** 4. The Commission shall, by means of implementing acts ***and taking into consideration the scientific advice of the Agency as well as the work already carried out by the WHO***, designate antimicrobials or groups of	4. The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. Those implementing acts shall be adopted in accordance with the	4. The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. Those implementing acts shall be 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 shall consider also the route of administration.***	examination procedure referred to in Article 145(2).	examination procedure referred to in Article 145(2).
		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.	**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.**
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, safety and efficacy originally		1. Without prejudice to the requirements and obligations laid down in Directive 2010/63/EU, technical documentation on quality, safety and efficacy originally	1. Without prejudice to the requirements and obligations laid down in Directive 2010/63/EU, technical documentation on quality, safety and efficacy originally

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

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

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

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authorisation for the veterinary medicinal product was granted in accordance with Article 7.		authorisation for the veterinary medicinal product was granted in accordance with **the provisions referred to in** Article […] **5(1)**.	authorisation for the veterinary medicinal product was granted in accordance with **the provisions 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:		

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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.		

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Article 35 *Prolongation of the periods of the protection of technical documentation*		*Article 35* *Prolongation of the periods of the protection of technical documentation*	*Article 35* *Prolongation ~~of the~~ **and additional** periods of the protection of technical documentation*
1. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to another species listed in Article 34(1)(a), the period of the protection provided for in that Article shall be prolonged by 1 year for each additional target species, 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).	**AM 138** 1. Where ***the first marketing authorisation is granted for more than one species or*** a variation is approved in accordance with Article 65 extending the marketing authorisation to another species listed in Article 34(1)(a), the period of the protection provided for in that Article ***34*** shall be prolonged by ~~1~~ ***two*** year***s*** for each additional target species ***in the original dossiers***, 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 information on the submission for extension of the marketing authorisation shall be made publicly available.***	1. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to another species listed in Article 34(1)(a), the period of the protection provided for in that Article shall be prolonged by 1 year for each additional target species, 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).	1. Where **the first marketing authorisation is granted for more than one species listed in Article 34(1)(a) or (b), or** a variation is approved in accordance with Article 65 extending the marketing authorisation to another species listed in Article 34(1)(a) **or (b),** the period of the protection provided for in that Article shall be prolonged by 1 year for each additional target species, provided that**, in case of a** ~~th~~e variation**, the application** has been submitted at least 3 years before the expiration of the protection period laid down in Article 34(1)(a) **or (b).**
2. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to a another species not listed in Article 34(1)(a), the period	**AM 138** 2. Where ***the first marketing authorisation is granted for more than one species or*** a variation is approved in accordance with Article 65 extending the marketing	2. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to a another species not listed in Article 34(1)(a), the period	2. Where **the first marketing authorisation is granted for more than one species listed in Article 34(1)(d) or** a variation is approved in accordance with Article 65 extending

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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~~ **referred to** 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.

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

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		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.	**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 *Patent-related rights*		*Article 36* *Patent-related rights*	*Article 36* *Patent-related rights*
Conducting the necessary studies, tests and trials with a view to applying for a marketing authorisation in accordance with Article 16 and the consequential practical requirements shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for medicinal products.		Conducting the necessary studies, tests and trials with a view to applying for a marketing authorisation in accordance with Article 16 and the […] requirements **set out there in** shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for medicinal products **as**	Conducting the necessary studies, tests and trials with a view to applying for a marketing authorisation in accordance with Article 16 and the […] requirements **set out there in** shall not be regarded as contrary to patent-related rights or to supplementary-protection 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 **Procedures for granting marketing authorisations**		**Chapter III** **Procedures for** […] **marketing authorisations**	**Chapter III** **Procedures for** […] **marketing authorisations**
Section 1 **Marketing authorisations valid throughout the Union ('centralised marketing authorisations')**		**Section 1** **Marketing authorisations valid throughout the Union ('centralised marketing authorisations')**	**Section 1** **Marketing authorisations valid throughout the Union ('centralised marketing authorisations')**
Article 38 *Scope of the centralised marketing authorisation procedure*		*Article 38* *Scope of the centralised marketing authorisation procedure*	*Article 38* *Scope of the centralised marketing 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 authorisation procedure shall apply in respect of the following veterinary medicinal products:		2. Centralised marketing authorisation procedure shall apply in respect of the following veterinary medicinal products:	2. Centralised marketing authorisation procedure shall apply in respect of the following veterinary medicinal products:
(a) veterinary medicinal products developed by means of one of the following biotechnological processes:		(a) veterinary medicinal products developed by means of one of the following biotechnological processes:	(a) veterinary medicinal products developed by means of one of the following biotechnological processes:
(i) recombinant DNA technology;		(i) recombinant DNA technology;	(i) recombinant DNA technology;
(ii) controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells;		(ii) controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells;	(ii) controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells;
(iii) hybridoma and monoclonal antibody methods;		(iii) hybridoma and monoclonal antibody methods;	(iii) hybridoma and monoclonal antibody methods;
(b) veterinary medicinal products intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals;		(b) veterinary medicinal products intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals;	(b) veterinary medicinal products intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from 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)~~ […]
		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	**AM 143** 3. For veterinary medicinal	3. For veterinary medicinal	3. For veterinary medicinal

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

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

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

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7. The Commission may request clarifications from the Agency as regards the content of the opinion, in which case the Agency shall provide a response to this request within 90 days.		7. The Commission may request clarifications from the Agency as regards the content of the opinion, in which case the Agency shall provide a response to this request within 90 days.	7. The Commission may request clarifications from the Agency as regards the content of the opinion, in which case the Agency shall provide a response to this request within 90 days.
		7a. The applicant shall submit to the Agency the necessary translations of the summary of product characteristics, package leaflet and labelling in accordance with Article 6a, within the time limit set by the Agency, but at the latest on the date the draft decision is forwarded to the competent authorities in accordance with paragraph 8.	**7a. The applicant shall submit to the Agency the necessary translations of the summary of product characteristics, package leaflet and labelling in accordance with Article 6a, within the time limit set by the Agency, but at the latest on the date the draft decision is forwarded to the competent authorities in accordance with paragraph 8.**
8. Within 15 days of receipt of the opinion, the Commission shall prepare a draft of the decision to be taken in respect of the application. Where a draft decision envisages granting of a marketing authorisation, it shall include or make reference to the documents listed in Article 28. Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall annex a detailed explanation of the reasons for the		8. Within 15 days of receipt of the opinion, the Commission shall prepare a draft […] decision to be taken in respect of the application. Where a draft decision envisages granting of a marketing authorisation, it shall include […] **the opinion prepared in accordance with paragraph 1**. Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall annex a detailed explanation of the reasons	8. Within 15 days of receipt of the opinion, the Commission shall prepare a draft […] decision to be taken in respect of the application. Where a draft decision envisages granting of a marketing authorisation, it shall include […] **the opinion prepared in accordance with paragraph 2**. Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall annex a detailed explanation of the reasons

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

[40] The original paragraph 11 is reinstated.

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

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Section 2 **Marketing authorisations valid in a single Member State ('national marketing authorisation')**		**Section 2** **Marketing authorisations valid in a single Member State ('national marketing authorisation')**	**Section 2** **Marketing authorisations valid in a single Member State ('national marketing authorisation')**
Article 42 *Scope of national marketing authorisation*		*Article 42* *Scope of national marketing authorisation*	*Article 42* *Scope of national marketing authorisation*
National marketing authorisations shall be granted by the competent authorities in accordance with this Section and applicable national provisions. A national marketing authorisation shall be valid in the Member State which granted it.		**1.** National marketing authorisations shall be granted by the competent authorities in accordance with this Section and applicable national provisions. A national marketing authorisation shall be valid **only** in the Member State **of the competent authority** which granted it.	**1.** National marketing authorisations shall be granted by the competent authorities in accordance with this Section and applicable national provisions. A national marketing authorisation shall be valid **only** in the Member State **of the competent authority** which granted it.
National marketing authorisations shall only be granted in respect of veterinary medicinal products not falling within the scope of Article 38(2).		**2.** National marketing authorisations shall **not** […] be granted in respect of veterinary medicinal products […] falling within the scope of Article 38(2) **or for which a national marketing authorisation has been granted or an application in accordance with this Section is pending in another Member State or in the Union.**	**2.** National marketing authorisations shall **not** […] be granted in respect of veterinary medicinal products […] falling within the scope of Article 38(2) **or for which a national marketing authorisation has been granted or an application in accordance with this Section is pending in another Member State or in the Union.**

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Article 43 *Applications for national marketing authorisations*		~~*Article 43*~~ […]	~~*Article 43*~~ […]
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 *Procedure for national marketing authorisation*		*Article 44* *Procedure for national marketing authorisation*	*Article 44* *Procedure for national marketing authorisation*
1. The procedure for granting a national marketing authorisation for a veterinary medicinal product shall be completed within a maximum of 210 days after the submission of the complete application.		1. The procedure for granting **or refusing** a national marketing authorisation for a veterinary medicinal product shall be completed within a maximum of 210 days after the submission of the **valid** […] application.	1. The procedure for granting **or refusing** a national marketing authorisation for a veterinary medicinal product shall be completed within a maximum of 210 days after the submission of the **valid** […] application.

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		1a. The competent authority shall prepare an assessment report containing the information referred to in Article 28.	**1a. The competent authority shall prepare an assessment report containing the information referred to in Article 28.**
2. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.		2. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.	2. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.
Section 3 **Marketing authorisations valid in several Member States ('decentralised marketing authorisations')**		**Section 3** **Marketing authorisations valid in several Member States ('decentralised marketing authorisations')**	**Section 3** **Marketing authorisations valid in several Member States ('decentralised marketing authorisations')**
Article 45 *Scope of decentralised marketing authorisation*		*Article 45* *Scope of decentralised marketing authorisation*	*Article 45* *Scope of decentralised marketing authorisation*
1. Decentralised marketing authorisations shall be granted by the competent authorities in accordance with this Section. They shall be valid in the Member States stated therein.		1. Decentralised marketing authorisations shall be granted by the competent authorities in **the Member States where the applicant seeks to obtain a marketing authorisation ('concerned Member States') in** accordance with this Section. They shall be valid in th**os**e Member States […].	1. Decentralised marketing authorisations shall be granted by the competent authorities in **the Member States where the applicant seeks to obtain a marketing authorisation ('concerned Member States') in** accordance with this Section. They shall be valid in th**os**e 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
2. Decentralised marketing authorisations shall only be granted in respect of veterinary medicinal products for which no national marketing authorisation has been granted at the time of application for a decentralised marketing authorisation and which does not fall within the scope of Article 38(2).		2. Decentralised marketing authorisations shall **not** […] be granted in respect of veterinary medicinal products for which **a** […] national marketing authorisation has been granted **or for which an application for a marketing authorisation is pending** at the time of **the** application for a decentralised marketing authorisation […] **or** which […] fall within the scope of Article 38(2).	2. Decentralised marketing authorisations shall **not** […] be granted in respect of veterinary medicinal products for which **a** […] national marketing authorisation has been granted **or for which an application for a marketing authorisation is pending** at the time of **the** application for a decentralised marketing authorisation […] **or** which […] fall within the scope of Article 38(2).
Article 46 *Procedure for decentralised marketing authorisation*		*Article 46* *Procedure for decentralised marketing authorisation*	*Article 46* *Procedure for decentralised marketing authorisation*
1. Applications for decentralised marketing authorisation shall be submitted to the Member State chosen by the applicant (‘reference Member State’).	**AM 145** 1. Applications ***and the dossier*** for decentralised marketing authorisation shall be submitted to ***all the Member States.*** ~~‘~~***T***he Member State chosen by the applicant ***shall be the*** ~~(‘~~reference Member State~~’)~~.	1. A**n a**pplication for decentralised marketing authorisation shall be submitted to the **competent authority in the** Member State chosen by the applicant **to prepare an assessment report and to act in accordance with the provisions in this Section** (‘reference Member State’) **and to the competent authorities in the other concerned Member States**.	1. A**n a**pplication for decentralised marketing authorisation shall be submitted to the **competent authority in the** Member State chosen by the applicant **to prepare an assessment report and to act in accordance with the provisions in this Section** (‘reference Member State’) **and to the competent authorities in the other concerned Member States**.

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2. The application shall list Member States where the applicant seeks to obtain a marketing authorisation ('Member States concerned').	**AM 146** 2. The application shall list Member States where the applicant seeks to obtain a marketing authorisation ('Member States 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. The application shall list **the concerned** Member States […].	2. The application shall list **the concerned** Member States […].
		2a. If the applicant indicates that one or more of the concerned Member States shall no longer be considered as such, the competent authorities in those Member States shall provide to the competent authority in the reference Member State and to the competent authorities in the other concerned Member States any information they consider relevant relating to the withdrawal of the application.	**2a. If the applicant indicates that one or more of the concerned Member States shall no longer be considered as such, the competent authorities in those Member States shall provide to the competent authority in the reference Member State and to the competent authorities in the other concerned Member States any information they consider relevant relating to the withdrawal of the application.**
3. Within 120 days of receipt of a valid application, the reference Member State shall prepare an assessment report. The assessment report together with the approved summary of the product		3. Within 120 days of receipt of a valid application, the **competent authority in the** reference Member State shall prepare an assessment report **containing the information referred to in Article 28 and shall**	3. Within 120 days of receipt of a valid application, the **competent authority in the** reference Member State shall prepare an assessment report **containing the information 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 the labelling and package leaflet shall be forwarded to all Member States and the applicant, together with the list of the Member States concerned.		**forward it to the competent authorities in the other concerned** Member States and **to** the applicant […].	**forward it to the competent authorities in the other concerned** Member States and **to** the applicant […].
4. 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 they have no objections to the assessment report, summary of product characteristics, labelling and package leaflet.		**4.** Within 90 days after receipt of the **assessment report** […] referred to in paragraph 3, **the competent authorities in the other concerned** Member States **[…]** shall examine **it** […] and inform the **competent authority in the** reference Member State of whether they have […] **any** objection to […] **it on the ground that it would pose a potential serious risk to human or animal health or for the environment**. **The assessment report resulting from this examination shall be forwarded by the competent authority in the reference Member State to the competent authorities in the other concerned Member States and to the applicant.**	**4.** Within 90 days after receipt of the **assessment report** […] referred to in paragraph 3, **the competent authorities in the other concerned** Member States **[…]** shall examine **it** […] and inform the **competent authority in the** reference Member State of whether they have […] **any** objection to […] **it on the ground that it would pose a potential serious risk to human or animal health or for the environment**. **The assessment report resulting from this examination shall be forwarded by the competent authority in the reference Member State to the competent authorities in the other concerned Member States and to the applicant.**

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		4a. If requested by the competent authorities in the reference Member State or in another concerned Member State, the coordination group shall be convened to examine the assessment report within the period referred to in paragraph 4.	**4a. If requested by the competent authorities in the reference Member State or in another concerned Member State, the coordination group shall be convened to examine the assessment report within the period referred to in paragraph 4.**
5. Where all Member States agree, the reference Member State shall record the agreement, close the procedure and inform the applicant and the Member States accordingly. Each Member State from the list referred to in paragraph 2 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 the receipt of the information regarding the agreement from the reference Member State.		**5.** Where […] **the assessment report is favourable and where no competent authority has informed the competent authority in** the reference Member State **of an objection thereto, as set out in paragraph 4, the latter** shall record […] **that there is an** agreement, close the procedure and inform the applicant and the **competent authorities in all** Member States accordingly**, without undue delay**. […] **The competent authorities in the concerned Member States shall grant a marketing authorisation in conformity with the assessment report within 30 days of the receipt of both the information on the agreement from the competent authority in the reference Member State and also the complete translations of the summary of**	**5.** Where […] **the assessment report is favourable and where no competent authority has informed the competent authority in** the reference Member State **of an objection thereto, as set out in paragraph 4, the latter** shall record […] **that there is an** agreement, close the procedure and inform the applicant and the **competent authorities in all** Member States accordingly**, without undue delay**. […] **The competent authorities in the concerned Member States shall grant a marketing authorisation in conformity with the assessment report within 30 days of the receipt of both the information on the agreement from the competent authority in the reference Member State and also the complete translations of the summary of**

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		product characteristics, labelling and package leaflet from the applicant, whichever is submitted **the latest.**	**product characteristics, labelling and package leaflet from the applicant, whichever is submitted the latest.**
		5a. Where the assessment report is unfavourable and where none of the concerned competent authorities has informed the competent authority in the reference Member State of an objection thereto, as set out in paragraph 4, the competent authority in the reference Member State shall record that there is a refusal to grant the marketing authorisation, close the procedure and inform the applicant and the competent authorities in all Member States accordingly, without undue delay.	**5a. Where the assessment report is unfavourable and where none of the concerned competent authorities has informed the competent authority in the reference Member State of an objection thereto, as set out in paragraph 4, the competent authority in the reference Member State shall record that there is a refusal to grant the marketing authorisation, close the procedure and inform the applicant and the competent authorities in all Member States accordingly, without undue delay.**
		5b. Where a competent authority informs the competent authority in the reference Member State of an objection in accordance with paragraph 4, the procedure set out in Article 49 shall apply.	**5b. Where a competent authority informs the competent authority in the reference Member State of an objection in accordance with paragraph 4, the procedure set out in Article 49 shall apply.**

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6. If at any stage of the procedure a Member State concerned 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.		6. 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. […]	6. 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. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.		7. **The c**ompetent authorit**y in the reference Member State** shall make the assessment report publicly available, after deleting any commercially confidential information.	7. **The c**ompetent authorit**y in the reference Member State** shall make the assessment report publicly available, after deleting any commercially confidential information.
		Article 46a ***Request by the applicant for re-examination of the assessment report***	***Article 46a*** ***Request by the applicant for re-examination of the assessment report***
		1. Within 15 days after receipt of the assessment report referred to in Article 46(4) the applicant may provide written notice to the competent authority in the reference Member State requesting a re-examination of the assessment report. In that case, the	**1. Within 15 days after receipt of the assessment report referred to in Article 46(4) the applicant may provide written notice to the competent authority in the reference Member State requesting a re-examination of the assessment report. In that case, the**

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		applicant shall forward to the competent authority in the reference Member State detailed grounds for the request within 60 days after receipt of that assessment report. The competent authority in the reference Member State shall without delay forward this request and the detailed grounds to the coordination group.	**applicant shall forward to the competent authority in the reference Member State detailed grounds for the request within 60 days after receipt of that assessment report. The competent authority in the reference Member State shall without delay forward this request and the detailed grounds to the coordination group.**
		2. Within 60 days after receipt of the detailed grounds for the request for re-examination of the assessment report, the coordination group shall re-examine the assessment report. The conclusions reached and the reasons for the conclusions shall be annexed to the assessment report and shall form an integral part thereof.	**2. Within 60 days after receipt of the detailed grounds for the request for re-examination of the assessment report, the coordination group shall re-examine the assessment report. The conclusions reached and the reasons for the conclusions shall be annexed to the assessment report and shall form an integral part thereof.**
		3. Within 15 days after the re-examination of the assessment report, the competent authority in the reference Member State shall forward the assessment report to the applicant.	**3. Within 15 days after the re-examination of the assessment report, the competent authority in the reference Member State shall forward the assessment report to the applicant.**

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		4. Subsequent to the procedure set out in paragraph 3 of this Article, paragraphs (5), (5a), (6) and (7) of Article 46 shall apply.	**4. Subsequent to the procedure set out in paragraph 3 of this Article, paragraphs (5), (5a), (6) and (7) of Article 46 shall apply.**
Section 4 **Mutual recognition of marketing authorisations granted by national authorities**		**Section 4** **Mutual recognition of marketing authorisations granted by national authorities**	**Section 4** **Mutual recognition of marketing authorisations granted by national authorities**
Article 47 *Scope of mutual recognition marketing authorisation*		*Article 47* *Scope of mutual recognition **of** marketing authorisation**s***	*Article 47* *Scope of mutual recognition **of** marketing authorisation**s***
A national marketing authorisation for a veterinary medicinal product shall be recognised by other Member States in accordance with the procedure laid down in Article 48.		A national marketing authorisation for a veterinary medicinal product**, granted in accordance with Article 44,** shall be recognised […] **in** other Member States in accordance with the procedure laid down in Article 48 […].	A national marketing authorisation for a veterinary medicinal product**, granted in accordance with Article 44,** shall be recognised […] **in** other Member States in accordance with the procedure laid down in Article 48 […].
Article 48 *Procedure for mutual recognition marketing authorisation*		*Article 48* *Procedure for mutual recognition **of** marketing authorisation**s***	*Article 48* *Procedure for mutual recognition **of** marketing authorisation**s***
1. Applications for mutual recognition of marketing authorisations shall be submitted to the Member State that granted the first national marketing authorisation ("reference Member State").	**AM 147** 1. Applications ***and the dossier*** for mutual recognition of marketing authorisations shall be submitted to ***all the Member States.*** ~~t~~***T***he Member State that granted the first national marketing authorisation ***shall be the*** ~~("~~reference Member State~~")~~.	1. A**n a**pplication for mutual recognition of **a** marketing authorisatio**n** shall be submitted to the **competent authority in the** Member State that granted the […] national marketing authorisation **in accordance with Article 44** ('reference Member State') **and to**	1. A**n a**pplication for mutual recognition of **a** marketing authorisatio**n** shall be submitted to the **competent authority in the** Member State that granted the […] national marketing authorisation **in accordance with Article 44** ('reference Member State') **and to**

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

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3. An application for mutual recognition of a marketing authorisation shall be accompanied by the following:		~~3~~. […]	~~3~~. […]
(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;		[…]	[…]
(c) an information about the Member States in which an application for a marketing authorisation submitted by the applicant for the same veterinary medicinal product is under examination;	**AM 149** ~~(c) an information about the Member States in which an application for a marketing authorisation submitted by the applicant for the same veterinary medicinal product is under examination;~~	[…]	[…]
(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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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 ***concerned*** 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 a**n** 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 a**n** 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) 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
		report resulting from this examination shall be forwarded by the competent authority in the reference Member State to the competent authorities in the other concerned Member States and to the applicant.	**report resulting from this examination shall be forwarded by the competent authority in the reference Member State to the competent authorities in the other concerned Member States and to the applicant.**
		5a. If requested by the competent authorities in the reference Member States or in another concerned Member State, the coordination group shall be convened to examine the updated assessment report within the period referred to in paragraph 5.	**5a. If requested by the competent authorities in the reference Member States or in another concerned Member State, the coordination group shall be convened to examine the updated assessment report within the period referred to in paragraph 5.**
		5b. Where no competent authority of any concerned Member State has informed the competent authority in the reference Member State of an objection to the updated assessment report, as set out in paragraph 5, the latter shall record that there is an agreement, close the procedure and inform the applicant and the competent authorities in all Member States accordingly, without undue delay. The competent authorities in the concerned Member States shall	**5b. Where no competent authority of any concerned Member State has informed the competent authority in the reference Member State of an objection to the updated assessment report, as set out in paragraph 5, the latter shall record that there is an agreement, close the procedure and inform the applicant and the competent authorities in all Member States accordingly, without undue delay. The competent authorities in the concerned Member States shall**

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

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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** […] **c**ompetent authorit**y** […] **in the reference Member State** shall make the assessment report publicly available, after deleting any commercially confidential information.	8. **The** […] **c**ompetent authorit**y** […] **in the reference Member State** shall make the assessment report publicly available, after deleting any commercially confidential information.

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		Section 4a **Subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures**	**Section 4a** **Subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures**
		*Article **48a**[41]* *Subsequent recognition of marketing authorisations by […] **additional concerned** Member States*	*Article **48a*** *Subsequent recognition of marketing authorisations by […] **additional concerned** Member States*
		1. After completion of **a decentralised procedure laid down in Article 46 or** a mutual recognition procedure laid down in Article 48 **granting a marketing authorisation** […], the marketing authorisation holder may submit an application for a marketing authorisation for […] **the** veterinary medicinal product to **the competent authorities in** additional **concerned** Member States **and to the competent authority in the reference Member State referred to in Article 46 or 48, as applicable, in accordance with the procedure laid down in this Article**. The application shall include	1. After completion of **a decentralised procedure laid down in Article 46 or** a mutual recognition procedure laid down in Article 48 **granting a marketing authorisation** […], the marketing authorisation holder may submit an application for a marketing authorisation for […] **the** veterinary medicinal product to **the competent authorities in** additional **concerned** Member States **and to the competent authority in the reference Member State referred to in Article 46 or 48, as applicable, in accordance with the procedure laid down in this Article**. The application shall include

[41] Ex Article 57

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

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

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		State referred to in Article 46 or 48, as applicable, and to the competent authorities in the concerned Member States, referred to in those Articles, and to the applicant.	**State referred to in Article 46 or 48, as applicable, and to the competent authorities in the concerned Member States, referred to in those Articles, and to the applicant.**
		3.&4.[…] [42]	3.&4.[…]
		5. In case of objections in accordance with paragraph 2a, the competent authority in the reference Member State shall take any appropriate initiatives, in order to seek an agreement as regards the objections made. The competent authorities shall use their best endeavours to reach an agreement on the action to be taken.	**5. In case of objections in accordance with paragraph 2a, the competent authority in the reference Member State shall take any appropriate initiatives, in order to seek an agreement as regards the objections made. The competent authorities shall use their best endeavours to reach an agreement on the action to be 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.

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

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		competent authorities in the additional concerned Member State to the coordination group in accordance with the review procedure set out in Article 49.	**competent authorities in the additional concerned Member State to the coordination group in accordance with the review procedure set out in Article 49.**
Section 5 **Coordination group review and scientific re-examination**		**Section 5** […] **Review procedure […]**	**Section 5** […] **Review procedure […]**
Article 49 *Coordination group review procedure*		*Article 49* *[...]**R**eview procedure*	*Article 49* *[...]**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 Article 142('the coordination	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 without delay by the competent	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 without delay by the competent

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	group') by the reference Member State.	authority […] **in** the reference Member State to the coordination group.	authority […] **in** the reference Member State to the coordination group.
		1a. The competent authority in the reference Member State shall take any appropriate initiatives in order to seek an agreement within the period of 90 days as regards the objection made.	**1a. The competent authority in the reference Member State shall take any appropriate initiatives in order to seek an agreement within the period of 90 days as regards the objection made.**
		1b. The competent authority in the reference Member State shall provide the applicant or the marketing authorisation holder with the opportunity to make his point of view known orally or in writing.	**1b. The competent authority in the reference Member State shall provide the applicant or the marketing authorisation holder with the opportunity to make his point of view known orally or in writing.**
2. Within the coordination group, a rapporteur shall be appointed in order to prepare a second assessment report for the veterinary medicinal product.	**AM 152** ~~2. Within the coordination group, a rapporteur shall be appointed in order to prepare a second assessment report for the veterinary medicinal product.~~	[…]	[…]
3. The second assessment report shall be presented by the rapporteur to 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 ***or amending*** 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 opinion, the marketing authorisation shall be refused by each Member State concerned within 30 days of acknowledgement of the agreement. The scientific conclusions and grounds for revocation of the marketing authorisation shall be annexed to the unfavourable opinion.		6 […]. **When the competent authorities referred to in Articles 46(1), 48(1), 48a(1) and 64(1) reach an agreement by consensus to refuse the marketing authorisation or to reject the variation, the competent authority in the reference Member State close the procedure and inform the applicant or the marketing authorisation holder providing the grounds for the refusal or the rejection. The competent authorities in the concerned Member State shall refuse the marketing authorisation or reject the variation.**	6 […]. **When the competent authorities referred to in Articles 46(1), 48(1), 48a(1) and 64(1) reach an agreement by consensus to refuse the marketing authorisation or to reject the variation, the competent authority in the reference Member State close the procedure and inform the applicant or the marketing authorisation holder providing the grounds for the refusal or the rejection. The competent authorities in the concerned Member State shall refuse the marketing authorisation or reject the variation.**
		6a. If an agreement between the competent authorities cannot be reached by consensus, the coordination group shall provide the Commission with the assessment report referred to in Articles 46(4), 48(5), 48a(2a) or 64(3), together with information on the points of disagreement at the latest within a period of 90 days from when the objection referred to in paragraph 1 was raised.	**6a. If an agreement between the competent authorities cannot be reached by consensus, the coordination group shall provide the Commission with the assessment report referred to in Articles 46(4), 48(5), 48a(2a) or 64(3), together with information on the points of disagreement at the latest within a period of 90 days from when the objection referred to in paragraph 1 was raised.**

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

[43] Same deadline as in Article 40(8).

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		Member States as references to relevant Member States.	**Member States as references to relevant Member States.**
		9. The Commission shall, by means of implementing acts, take a decision on the granting, changing, ~~or~~ refusing or revoking of a marketing authorisation or rejecting the variation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	**9. The Commission shall, by means of implementing acts, take a decision on the granting, changing, ~~or~~ refusing or revoking of a marketing authorisation or rejecting the variation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**
Article 50 *Request for scientific re-examination*		~~*Article 50*~~ ~~*Request for scientific re-examination*~~	~~*Article 50*~~ ~~*Request for scientific re-examination*~~
1. Within 15 days after receipt of the assessment report referred to in Article 46(3) or in Article 48(4) the applicant may provide written notice to the Agency requesting a re-examination of the assessment report. In that case the applicant shall forward to the Agency detailed grounds for the request within 60 days of receipt of the assessment report. The application shall be accompanied by proof of payment of the fee payable to the Agency for the re-examination.	**AM 154** 1. Within 15 days after receipt of the assessment report referred to in Article 46(3) or in Article 48(4) the applicant may provide written notice to the ~~Agency~~ ***Coordination group*** requesting a re-examination of the assessment report. In that case the applicant shall forward to the Agency detailed grounds for the request within 60 days of receipt of the assessment report. The application shall be accompanied 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.		[…]	[…]
3. The re-examination procedure shall deal only with the points of the assessment report identified by the applicant in the written notice.	**AM 155** 3. ~~The re-examination procedure shall deal only with the points of the assessment report identified by the applicant in the written notice.~~ ***The Committee shall define the scope of the examination, taking into account the information supplied by the applicant.***	[…]	[…]
4. Within 15 days of its adoption, the Agency shall forward the opinion of the Committee to the coordination group, together with a report describing the assessment of the veterinary medicinal product by the Committee and stating the reasons for its conclusions. Those documents shall be forwarded to the Commission, to Member States and to the applicant for information purposes.	**AM 156** 4. Within 15 days of its adoption, the Agency shall forward the opinion of the Committee to the ~~coordination group~~ ***Commission***, together with a report describing the assessment of the veterinary medicinal product by the Committee and stating the reasons for its conclusions. Those documents shall be forwarded ~~to 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. ***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 **Post marketing authorisation measures**		**Chapter IV** **Post marketing authorisation measures**	**Chapter IV** **Post marketing authorisation measures**
Section 1 **Union product database**		**Section 1** **Union product database**	**Section 1** **Union product database**
Article 51 *Union database on veterinary medicinal products*		*Article 51* *Union database on veterinary medicinal products*	*Article 51* *Union database on veterinary medicinal products*
1. A Union database on veterinary medicinal products ('product database') shall be set up and maintained by the Agency.	**AM 158** 1. A Union-***wide*** database on veterinary medicinal products ('product database') shall be set up and maintained by the Agency.	1. A Union database on veterinary medicinal products ('product database') shall be set up and maintained by the Agency **in collaboration with the Member States in accordance with the provisions in this Section**.	1. A Union database on veterinary medicinal products ('product database') shall be set up and maintained by the Agency **in collaboration with the Member States in accordance with the provisions in this Section**.
2. The product database shall contain information on:		2. The product database shall contain […] **at least the following** information […]:	2. The product database shall contain […] **at least the following** information […]:
(a) veterinary medicinal products authorised within the Union by the Commission and by the competent authorities, together with their summaries of product characteristics, package leaflets and lists of sites where each product is manufactured;	**AM 159** (a) veterinary medicinal products authorised within the Union by the Commission and by the competent authorities, together with their summaries of product characteristics, package leaflets and lists of sites where each product is manufactured ***and reference numbers to the pharmacovigilance system master file***;	(a) **for** veterinary medicinal products authorised within the Union by the Commission and by the competent authorities**:** […] **name of the veterinary medicinal product, its active substance(s) and its strength,** summary of product characteristics, package leaflet**, the assessment report,**[…] list of sites where […]**the** product is manufactured **and the dates of its**	(a) **for** veterinary medicinal products authorised within the Union by the Commission and by the competent authorities**:** […] **name of the veterinary medicinal product, its active substance(s) and its strength,** summary of product characteristics, package leaflet**, the assessment report,**[…] list of sites where […]**the** product is manufactured **and the dates of its**

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		placing on the market in a Member State;	**placing on the market in a Member State**;
(b) homeopathic veterinary medicinal products registered within the Union by the Commission and by the competent authorities, together with their package leaflet and lists of sites where each product is manufactured;		(b) **for** […] homeopathic veterinary medicinal products registered **in accordance with Chapter V** within the Union […] by the competent authorities**: name of the registered homeopathic veterinary medicinal product,** […] package leaflet and lists of sites where […] **the** product is manufactured;	(b) **for** […] homeopathic veterinary medicinal products registered **in accordance with Chapter V** within the Union […] by the competent authorities**: name of the registered homeopathic veterinary medicinal product,** […] package leaflet and lists of sites where […] **the** product is manufactured;
(c) veterinary medicinal products allowed to be used in a Member State in accordance with Articles 119 and 120.		(c) veterinary medicinal products allowed to be used in a Member State in accordance with Article […] **5(6);**	(c) veterinary medicinal products allowed to be used in a Member State in accordance with Article […] **5(6);**
		(d) the annual volume of sales and information on the availability for each veterinary medicinal product.	**(d) the annual volume of sales and information on the availability for each veterinary medicinal product.**
3. Within 12 months from the date 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.		~~3.~~ […]	~~3.~~ […]

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		3a. The Commission shall, by means of implementing acts, adopt the necessary measures and practical arrangements laying down:	**3a. The Commission shall, by means of implementing acts, adopt the necessary measures and practical arrangements laying down:**
		(a) the technical specifications of the product database including the electronic data exchange mechanism for exchanging with the existing national systems and the format for electronic submission;	**(a) the technical specifications of the product database including the electronic data exchange mechanism for exchanging with the existing national systems and the format for electronic submission;**
		(b) the practical arrangements for the functioning of the product database, in particular to ensure protection of commercially confidential information and security of exchange of information;	**(b) the practical arrangements for the functioning of the product database, in particular to ensure protection of commercially confidential information and security of exchange of information;**
		(c) detailed specifications of the information to be included, updated and shared and by whom;	**(c) detailed specifications of the information to be included, updated and shared and by whom;**
		(d) contingency arrangements to be applied in case of unavailability of any of the functionalities of the product database;	**(d) contingency arrangements to be applied in case of unavailability of any of the functionalities of the product database;**

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		(e) where appropriate, data to be included in addition to the information of the product database as referred to in paragraph 2.	**(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).	**Those implementing acts shall be adopted in accordance with the 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~~

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7. The Agency shall, in collaboration with Member States and the Commission, draw up the functional specifications for the product database.		~~7~~	~~7~~
8. The Commission shall ensure that information reported to the product database is collected, collated and made accessible and that the information is shared.		~~8~~	~~8.~~
Article 52 *Access to the product database*		*Article 52* *Access to the product database*	*Article 52* *Access to the product database*
1. The competent authorities, the Agency and the Commission shall have full access to the information in the product database.		1. The competent authorities, the Agency and the Commission shall have full access to the information in the product database.	1. The competent authorities, the Agency and the Commission shall have full access to the information in the product database.
2. Marketing authorisation holders shall have full access to the information in the product database concerning their own marketing authorisations.	**AM 160** 2. Marketing authorisation holders shall have full access to the information in the product database concerning their own marketing authorisations ***and limited access to other products***.	2. Marketing authorisation holders shall have full access to the information in the product database concerning their own marketing authorisations.	2. Marketing authorisation holders shall have full access to the information in the product database concerning their own marketing authorisations.

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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 **Placing on the market**		**Section 2** […] **Collection of data by Member States and responsabilities of marketing authorisation holders**	**Section 2** […] **Collection of data by Member States and responsabilities of marketing authorisation holders**
Article 53 *Placing on the market*		~~*Article 53*~~ ~~*Placing on the market*~~	~~*Article 53*~~ ~~*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.		[…]	[…]

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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*		*Article 54* *Collection of data on […] antimicrobial […]medicinal products* ***used in animals***	*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.	**AM 162** 1. Member States shall collect relevant ~~and~~ comparable ***and 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***.	1. Member States shall collect relevant and comparable data on the 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**.	1. Member States shall collect relevant and comparable data on the 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**.
		1a. Member States shall take measures aiming to ensure the	*If the EP accepts the compromise text in paragraphs 2 to 4a,*

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		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.	*paragraphs 1a, 5 and 6 will be deleted.*
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 ***cooperate with other European agencies to*** analyse the data and publish an annual report ***which shall also include the corresponding data for human use of antimicrobials as well as the current situation on antimicrobial resistance in the Union and, where appropriate, issue guidelines and recommendations***.	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 **collated** data ~~**referred to in paragraph 1** […]~~ **on the volume of sales and the use per animal species** to the Agency **in accordance with paragraph 4aa and within the time limits set therein**. The Agency shall **cooperate with Member States and with other Union agencies to** analyse […] **these** data and publish an annual report. **The Agency shall take into account these data when adopting any relevant guidelines and recommendations.**
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to establish detailed rules on the methods of gathering data on the use of antimicrobials and the method of transfer of these data to the		3. The Commission shall […] adopt delegated acts in accordance with Article 146 […] **supplementing the provisions of this Article concerning the** establish**ment of** detailed rules on the methods of gathering data on the use of **the**	3. The Commission shall […] adopt delegated acts in accordance with Article 146 […] **supplementing the provisions of this Article concerning the** establish**ment of the requirements as regards:** **(a) the types of antimicrobials**

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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.***		

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4. The Commission may, by means of implementing acts, set up the format and the requirements for the data to be collected in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).		4. The Commission **shall** […], by means of implementing acts, set up the format and the requirements for the data to be collected in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	4. The Commission **shall** […], by means of implementing acts, set up the format ~~and the requirements~~ for the data to be collected in accordance with this Article.Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 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**

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			in Article 150, data shall be collected for other animals which are bred or kept.
			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-***		

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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 to the European Parliament and to the Council within five years after the date of application of this 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.	*If the EP accepts the compromise text in paragraphs 2 to 4a , paragraphs 1a, 5 and 6 will be deleted.*
		6. As of 5 years after the date of application in accordance with Article 150 the Commission is empowered to adopt delegated acts 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	*If the EP accepts the compromise text in paragraphs 2 to 4a, paragraphs 1a, 5 and 6 will be deleted.*

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		the use of antimicrobial medicinal products, are sufficiently reliable and that the data is available.	
Article 55 *Responsibilities of the marketing authorisation holders*		*Article 55* *Responsibilities of the marketing authorisation holders*	*Article 55* *Responsibilities of the marketing authorisation holders*
		0a. The marketing authorisation holder shall be responsible for the marketing of his veterinary medicinal products. The designation of a representative shall not relieve the marketing authorisation holder of his legal responsibility.	**0a. The marketing authorisation holder shall be responsible for the marketing of his veterinary medicinal products. The designation of a representative shall not relieve the marketing authorisation holder of his legal responsibility.**
		0b. The marketing authorisation holder shall, within the limits of his responsibilities, ensure appropriate and continued supplies of his veterinary medicinal products.	**0b. The marketing authorisation holder shall, within the limits of his responsibilities, ensure appropriate and continued supplies of his veterinary medicinal products.**
1. In respect of the manufacturing process and control methods stated in the application for a marketing authorisation for the veterinary medicinal product and in order to take account of scientific and technical progress, the marketing authorisation holders shall ensure that any changes that may be required to enable that veterinary		1. **After a marketing authorisation has been granted, the marketing authorisation holder shall, i**n respect of the **methods of** manufacture and control […] stated in the application for a marketing authorisation**,** […] take account of scientific and technical progress, **and introduce** […] any changes that may be required to enable […] **the**	1. **After a marketing authorisation has been granted, the marketing authorisation holder shall, i**n respect of the **methods of** manufacture and control […] stated in the application for a marketing authorisation**,** […] take account of scientific and technical progress, **and introduce** […] any changes that may be required to enable […] **the**

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medicinal product to be manufactured and verified by means of generally accepted scientific methods are introduced. The introduction of such changes shall be subject to the procedures laid down in Section 4 of this Chapter.		veterinary medicinal product to be manufactured and […] **controlled** by means of generally accepted scientific methods […]. The introduction of such changes shall be subject to the procedures laid down in Section 4 of this Chapter.	veterinary medicinal product to be manufactured and […] **controlled** by means of generally accepted scientific methods […]. The introduction of such changes shall be subject to the procedures laid down in Section 4 of this Chapter.
		1aa. The marketing authorisation holder shall ensure that the summary of product characteristics, package leaflet and labelling is kept up to date with the current scientific knowledge.	**1aa. The marketing authorisation holder shall ensure that the summary of product characteristics, package leaflet and labelling is kept up to date with the current scientific knowledge.**
		1a. As regards generic veterinary medicinal products and hybrid veterinary medicinal products the marketing authorisation holder shall not place such products on the Union 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.[44]	**1a. As regards generic veterinary medicinal products and hybrid veterinary medicinal products the marketing authorisation holder shall not place such products on the Union 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.**
		1b. The marketing authorisation holder shall record in the product database the dates when its	**1b. The marketing authorisation holder shall record in the product database the dates when its**

[44] Moved from Article 53(2).

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		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 c**ompetent 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 c**ompetent 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**.

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

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product concerned.		information which might influence the assessment of the benefits and risks of the veterinary medicinal product concerned**, including from the outcome of the signal management process carried out in accordance with Article 81**.	information which might influence the assessment of the benefits and risks of the veterinary medicinal product concerned**, including from the outcome of the signal management process carried out in accordance with Article 81**.
6. Upon request from a competent authority, the Commission or the Agency, the marketing authorisation holder shall provide the competent authority, the Commission or the Agency with all data in his possession relating to the volume of sales.		6. […] **T**he marketing authorisation holder shall provide the competent authority, the Commission or the Agency**, as applicable, within the time limit set,** with all data in his possession relating to the volume of sales **of the veterinary medicinal product concerned**.	6. […] **T**he marketing authorisation holder shall provide the competent authority, the Commission or the Agency**, as applicable, within the time limit set,** with all data in his possession relating to the volume of sales **of the veterinary medicinal product concerned**.
		6a. The marketing authorisation holder shall record in the product database the annual volume of sales for each veterinary medicinal product.	**6a. The marketing authorisation holder shall record in the product database the annual volume of sales for each veterinary medicinal product.**

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		7. 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.	**7. 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.**
Article 56 *National helpdesks for small and medium-sized enterprises*		*Article 56* *[…]**S**mall and medium-sized enterprises*	*Article 56* *[…]**S**mall and medium-sized enterprises*
1. In order to help small and medium-sized enterprises to comply with the requirements of this Regulation, Member States shall establish national helpdesks.		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 […].	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.~~ […]

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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) 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;		
	(ii) the same therapeutic effects 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.		
	AM 169		

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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 **Subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures**		~~**Section 3**~~ ~~**Subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures**~~	~~**Section 3**~~ ~~**Subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures**~~
Article 57 *Subsequent recognition of marketing authorisations by other Member States*		~~*Article 57*~~[46]	~~*Article 57*~~
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.			
	AM 170 ***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 **Changes to marketing authorisations**		**Section 4** **Changes to the terms of the marketing authorisations**	**Section 4** **Changes to the terms of the marketing authorisations**
Article 58 *Variations to the terms of a marketing authorisation*		*Article 58* *Variations […]*	*Article 58* *Variations […]*
1. Variation to the terms of a marketing authorisation means a change to the terms of the marketing authorisation for a veterinary medicinal product as referred to in Article 31 ('variation').		~~1.~~ […]	~~1.~~ […]

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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 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).	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).
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;		(a) the need for a scientific assessment of changes in order to determine the risk to public health, animal health or the environment;	(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;		(b) whether changes have an impact on the **quality,** safety **or** […] efficacy of the veterinary medicinal product;	(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**;**	(c) whether changes imply […] **no more than a minor** alteration to the summary of product characteristics**;**
		(d) whether changes are of an administrative nature.	**(d) whether changes are of an administrative nature.**

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 59 *Consequential changes to product information*		~~*Article 59*~~[47] […]	~~*Article 59*~~ […]
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 *Variations to the terms of a marketing authorisation that do not require assessment*		*Article 60* *Variations […] that do not require assessment*	*Article 60* *Variations […] that do not require assessment*
1. Where a variation does not appear in the list established in accordance with Article 58(2), the marketing authorisation holder shall record the change in the product database within 12 months following the implementation of the variation.		1. Where a variation […] appear**s** in the list established in accordance with Article 58(2), the marketing authorisation holder shall record **within 30 days** the change**, including as applicable the summary of product characteristics, labelling or package leaflet in accordance with the languages referred to in Article 6a,** in the product database […] following the implementation […] of […] **that** variation.	1. Where a variation […] appear**s** in the list established in accordance with Article 58(2), the marketing authorisation holder shall record **within 30 days** the change**, including as applicable the summary of product characteristics, labelling or package leaflet in accordance with the languages referred to in Article 6a,** in the product database […] following the implementation […] of […] **that** variation.

[47] Moved to a new **Article 61a**

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

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

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 61a ***Consequential changes to product information***	***Article 61a*** ***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.	**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 62 *Groups of variations*		*Article 62* *Groups of variations*	*Article 62* *Groups of variations*
When applying for several variations to the terms of the same marketing authorisation, a marketing authorisation holder may submit one application for all variations.		When **the marketing authorisation holder** applie**s** for several variations […] **not appearing in the list established in accordance with Article 58(2) regarding** the same marketing authorisation **or for one variation not appearing in that list in respect of several different marketing authorisations**, **he** […] may submit one application for all variations.	When **the marketing authorisation holder** applie**s** for several variations […] **not appearing in the list established in accordance with Article 58(2) regarding** the same marketing authorisation **or for one variation not appearing in that list in respect of several different marketing authorisations**, **he** […] may submit one application for all variations.

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 63 *Worksharing procedure*		*Article 63* *Worksharing procedure*	*Article 63* *Worksharing procedure*
1. When applying for variations to the terms of several marketing authorisations held by the same marketing authorisation holder and granted by different competent authorities and/or the Commission, the marketing authorisation holder shall submit an application to all competent authorities concerned and the Agency.		1. When **the marketing authorisation holder** appl**ies** for **one or more** variations **which are identical in all relevant Member States and which do not appear in the list established in accordance with Article 58(2), regarding** […] several marketing authorisations **which are** held by the same marketing authorisation holder and **which have been** granted by different competent authorities and/or the Commission, […] **he** shall submit an **identical** application to […] competent authorities **in all relevant Member States** […] and**, in case a variation to a centrally authorised veterinary medicinal product is included, to** the Agency.	1. When **the marketing authorisation holder** appl**ies** for **one or more** variations **which are identical in all relevant Member States and which do not appear in the list established in accordance with Article 58(2), regarding** […] several marketing authorisations **which are** held by the same marketing authorisation holder and **which have been** granted by different competent authorities and/or the Commission, […] **he** shall submit an **identical** application to […] competent authorities **in all relevant Member States** […] and**, in case a variation to a centrally authorised veterinary medicinal product is included, to** the Agency.
2. Where one of the marketing authorisations referred to in paragraph 1 is a centralised marketing authorisation, the Agency shall assess the application in accordance with the procedure laid down in Article 64.		2. Where […] **any** of the marketing authorisations referred to in paragraph 1 is a centralised marketing authorisation, the Agency shall assess the application in accordance with the procedure laid down in Article 64.	2. Where […] **any** of the marketing authorisations referred to in paragraph 1 is a centralised marketing authorisation, the Agency shall assess the application in accordance with the procedure laid down in Article 64.
3. Where none of the marketing authorisations referred to in		3. Where none of the marketing authorisations referred to in	3. Where none of the marketing authorisations referred to 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
paragraph 1 is a centralised marketing authorisation, the coordination group shall assign a competent authority among those having granted the marketing authorisations to assess the application in accordance with the procedure laid down in Article 64.		paragraph 1 is a centralised marketing authorisation, the coordination group shall **agree upon** […] a competent authority among those having granted the marketing authorisations to assess the application in accordance with the procedure laid down in Article 64.	paragraph 1 is a centralised marketing authorisation, the coordination group shall **agree upon** […] a competent authority among those having granted the marketing authorisations to assess the application in accordance with the procedure laid down in Article 64.
		4. The Commission may, by means of implementing acts, adopt the necessary arrangements regarding the functioning of the worksharing procedure. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	**4. The Commission may, by means of implementing acts, adopt the necessary arrangements regarding the functioning of the worksharing procedure. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**
Article 64 *Procedure for variations requiring assessment*		*Article 64* *Procedure for variations requiring assessment*	*Article 64* *Procedure for variations requiring assessment*
1. If a variation application fulfils the requirements laid down in Article 61, the competent authority or the Agency, or a competent authority assigned in accordance with Article 63(3) shall acknowledge receipt of a complete application.	**AM 171** 1. If a variation application fulfils the requirements laid down in Article 61, the competent authority or the Agency, or a competent authority assigned in accordance with Article 63(3) shall acknowledge receipt of a complete application ***in 15 days***.	1. If a**n** […] application **for a variation** fulfils the requirements laid down in Article 61, the competent authority**,** […] the Agency, […] **the** competent authority […] **agreed upon** in accordance with Article 63(3)**, or the competent authority in the reference Member State, as**	1. If a**n** […] application **for a variation** fulfils the requirements laid down in Article 61, the competent authority**,** […] the Agency, […] **the** competent authority […] **agreed upon** in accordance with Article 63(3)**, or the competent authority in the reference Member State, as**

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

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		assessment of a variation application requires more time due to its complexity, the competent authority or the Agency may extend this time limit to 90 days. In such a case the competent authority or the Agency, as applicable, shall inform the marketing authorisation holder accordingly.	**assessment of a variation application requires more time due to its complexity, the competent authority or the Agency may extend this time limit to 90 days. In such a case the competent authority or the Agency, as applicable, shall inform the marketing authorisation holder accordingly.**
4. Within the period referred to in paragraph 3, the competent authority or the Agency may require the applicant to provide supplementary information within a set time limit. The procedure shall be suspended until the supplementary information has been provided.		4. Within the period referred to in paragraph 3, the competent authority or the Agency, **as applicable,** may require the […] **marketing authorisation holder** to provide supplementary information within a set time limit. The procedure shall be suspended until the supplementary information has been provided.	4. Within the period referred to in paragraph 3, the competent authority or the Agency, **as applicable,** may require the […] **marketing authorisation holder** to provide supplementary information within a set time limit. The procedure shall be suspended until the supplementary information has been provided.
5. The opinion shall be forwarded to the applicant.		~~5.~~ […][48]	~~5.~~ […]

[48] Moved to paragraph 7a.

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6. Where the opinion is prepared by the Agency, the opinion shall be forwarded to the Commission. Where the Agency assesses the application in accordance with Article 63(2), the opinion shall be forwarded to the Commission and all competent authorities concerned.		6. Where the opinion **referred to in paragraph 3** is prepared by the Agency, […] **the Agency** shall […] forward […] **it** to the Commission. […] **and to the marketing authorisation holder.**	6. Where the opinion **referred to in paragraph 3** is prepared by the Agency, […] **the Agency** shall […] forward […] **it** to the Commission. […] **and to the marketing authorisation holder.**
		6a. Where the opinion referred to in paragraph 3 is prepared by the Agency in accordance with Article 63(2), the Agency shall forward it to all competent authorities in the relevant Member States, to the Commission and to the marketing authorisation holder.	**6a. Where the opinion referred to in paragraph 3 is prepared by the Agency in accordance with Article 63(2), the Agency shall forward it to all competent authorities in the relevant Member States, to the Commission and to the marketing authorisation holder.**
7. Where the opinion is prepared by a competent authority assigned in accordance with Article 63(3), the opinion shall be forwarded to all competent authorities concerned.		7. Where the […] **assessment report referred to in paragraph 3** is prepared by **the** […] competent authority […] **agreed upon** in accordance with Article 63(3), **or by the competent authority in the reference Member State,** […] **it** shall be forwarded to […] **the** competent authorities **in all relevant Member States and to the marketing authorisation holder.**	7. Where the […] **assessment report referred to in paragraph 3** is prepared by **the** […] competent authority […] **agreed upon** in accordance with Article 63(3), **or by the competent authority in the reference Member State,** […] **it** shall be forwarded to […] **the** competent authorities **in all relevant Member States and to the marketing authorisation holder.**
		7aa. If a competent authority does not agree with the assessment	**7aa. If a competent authority does not agree with the assessment**

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

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

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variation and inform the applicant of the grounds for the rejection. In case of centralised marketing authorisation, the Commission shall, by means of implementing acts, take a final decision amending the marketing authorisation or rejecting the variation. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).		**package leaflet from the marketing authorisation holder, the** competent authority**,** […] the Commission **or the competent authorities in the Member States listed in accordance with Article 61(2)(d), as applicable,** shall amend the marketing authorisation or reject the variation **in line with the opinion or the assessment report referred to in Article 64** and inform the […] **marketing authorisation holder** of the grounds for the rejection.[…].	**package leaflet from the marketing authorisation holder, the** competent authority**,** […] the Commission **or the competent authorities in the Member States listed in accordance with Article 61(2)(d), as applicable,** shall amend the marketing authorisation or reject the variation **in line with the opinion or the assessment report referred to in Article 64** and inform the […] **marketing authorisation holder** of the grounds for the rejection.[…].
2. Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall annex a detailed explanation of the reasons for not following the opinion of the Agency.		2. **In case of a centralised marketing authorisation, the Commission shall prepare a draft decision to be taken in respect of the variation.** Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall […] **provide** a detailed explanation of the reasons for not following the opinion of the Agency. **The decision amending the marketing authorisation or rejecting the variation shall be adopted by the Commission by means of implementing acts. These implementing acts shall be adopted in accordance with the**	2. **In case of a centralised marketing authorisation, the Commission shall prepare a draft decision to be taken in respect of the variation.** Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall […] **provide** a detailed explanation of the reasons for not following the opinion of the Agency. **The decision amending the marketing authorisation or rejecting the variation shall be adopted by the Commission by means of implementing acts. These implementing acts shall be adopted 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	Draft revised negotiation mandate proposed by the Presidency
		examination procedure referred to in Article 145(2).	**examination procedure referred to 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 *Coordination group review*		~~*Article 66*~~ [49]	~~*Article 66*~~
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).

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does not agree with the opinion, the coordination group review procedure laid down in Article 49 shall apply.			
Article 67 *Implementation of variations requiring assessment*		*Article 67* *Implementation of variations requiring assessment*	*Article 67* *Implementation of variations requiring assessment*
1. A marketing authorisation holder may implement a variation requiring assessment only after a competent authority or the Commission has amended the decision granting the marketing authorisation in accordance with that variation and the holder has been notified thereof.		1. A marketing authorisation holder may implement a variation requiring assessment only after a competent authority or the Commission**, as applicable,** has amended the decision granting the marketing authorisation in accordance with that variation**, has set a deadline for the implementation** and **has notified** the **marketing authorisation** […] thereof **in accordance with Article 65(3)**.	1. A marketing authorisation holder may implement a variation requiring assessment only after a competent authority or the Commission**, as applicable,** has amended the decision granting the marketing authorisation in accordance with that variation**, has set a deadline for the implementation** and **has notified** the **marketing authorisation** […] thereof **in accordance with Article 65(3)**.
2. Where requested by a competent authority or the Agency, a marketing authorisation holder shall supply without delay any information related to a variation to the terms of a marketing authorisation.		2. Where requested by a competent authority or the […] **Commission**, a marketing authorisation holder shall supply**,** without delay**,** any information related to **the implementation of** a variation […].	2. Where requested by a competent authority or the […] **Commission**, a marketing authorisation holder shall supply**,** without delay**,** any information related to **the implementation of** a variation […].

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Section 5 **Harmonisation of the summaries of the product characteristics for nationally authorised products**		**Section 5** **Harmonisation of the summaries of […] product characteristics for nationally authorised products**	**Section 5** **Harmonisation of the summaries of […] product characteristics for nationally authorised products**
Article 68 *Preparatory phase of the harmonisation exercise*		*Article 68* *[…]* ***Scope*** *of the harmonisation […]* ***of summary of product characteristics of veterinary medicinal product***	*Article 68* *[…]* ***Scope*** *of the harmonisation […]* ***of summary of product characteristics of veterinary 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		

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	authorisations may be harmonised with decentralised and/or mutual recognition marketing authorisations if they are for the same product or for essentially similar products.		
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').	**AM 172** 1. ~~A h~~***H***armonised ~~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.			
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[…] ha**s** 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[…] ha**s** 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) 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. The marketing authorisation holder may apply for the procedure of harmonisation of summaries of product characteristics for a reference veterinary medicinal product by submitting to the coordination group the list of different names of this veterinary medicinal product and the different summaries of product characteristics for which marketing authorisation has been granted in accordance with Article 44 in different Member States.	**1a. The marketing authorisation holder may apply for the procedure of harmonisation of summaries of product characteristics for a reference veterinary medicinal product by submitting to the coordination group the list of different names of this veterinary medicinal product and the different summaries of product characteristics for which marketing authorisation has been granted in accordance with Article 44 in different Member States.**
		1aa. The coordination group shall, taking into account the lists provided by the Member States in accordance with paragraph 1 or any application received from a marketing authoristion holder in accordance with paragraph 1a, draw up annually and publish a list of reference veterinary medicinal products which shall be subject to harmonisation of their summaries of product characteristics and shall appoint a reference Member State for each concerned reference veterinary medicinal product.	**1aa. The coordination group shall, taking into account the lists provided by the Member States in accordance with paragraph 1 or any application received from a marketing authoristion holder in accordance with paragraph 1a, draw up annually and publish a list of reference veterinary medicinal products which shall be subject to harmonisation of their summaries of product characteristics and shall appoint a reference Member State for each concerned reference veterinary 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
		1aaa. When drawing up this list, the coordination group may decide on prioritising its work on harmonisation of summaries of product characteristics, taking into account the recommendations of the Agency on class or group of reference veterinary medicinal products that shall be harmonised in order to protect human or animal health or the environment.	**1aaa. When drawing up this list, the coordination group may decide on prioritising its work on harmonisation of summaries of product characteristics, taking into account the recommendations of the Agency on class or group of reference veterinary medicinal products that shall be harmonised in order to protect human or animal health or the environment, including mitigation measures to prevent the risk for the environment.**
		1b. Upon request by the competent authority in the reference Member State referred to in paragraph 1aa, the marketing authorisation holder shall provide the coordination group with a summary detailing the differences between the summaries of product characteristics, his proposal for a harmonised summary of product characteristics, package leaflet and labelling in accordance with Article 6a, supported by the appropriate existing data submitted in accordance with Article 7 relevant to the proposal	**1b. Upon request by the competent authority in the reference Member State referred to in paragraph 1aa, the marketing authorisation holder shall provide the coordination group with a summary detailing the differences between the summaries of product characteristics, his proposal for a harmonised summary of product characteristics, package leaflet and labelling in accordance with Article 6a, supported by the appropriate existing data submitted in accordance with Article 7 relevant to the proposal**

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
		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 ***essentially*** similar products ***as identified in point (b) of Article 68(4)***. For each of the***se*** groups of ***essentially*** 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) 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
		competent authorities in each relevant Member State the necessary translations of the summary of product characteristics, package leaflet and labelling in accordance with Article 6a, within the time limit set by the coordination group.	**competent authorities in each relevant Member State the necessary translations of the summary of product characteristics, package leaflet and labelling in accordance with Article 6a, within the time limit set by the coordination group.**
4. Harmonised summaries of product characteristics for veterinary medicinal products shall contain all of the following information:	**AM 173** 4. Harmonised ~~summaries of product characteristics for veterinary medicinal products~~ ***conditions of use*** shall contain ~~all of~~ ***at least*** the following information:	**4.** […] **Following agreement in accordance with paragraph 3, the competent authorities in each relevant Member State shall vary the marketing authorisation in conformity with the agreement within 30 days of the receipt of the documents referred to in paragraph 3a.**	**4.** […] **Following agreement in accordance with paragraph 3, the competent authorities in each relevant Member State shall vary the marketing authorisation in conformity with the agreement within 30 days of the receipt of the documents referred to in 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 in paragraph 5.

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(a) all species mentioned in the marketing authorisations granted by Member States in respect of the similar products in the group;	**AM 173** (a) all species mentioned in the marketing authorisations granted by Member States in respect of the ***essentially*** similar products in the group;	[…]	[…]
(b) all therapeutic indications mentioned in the marketing authorisations granted by Member States in respect of the similar products in the group;	**AM 173** (b) all therapeutic indications ***and posology*** mentioned in the marketing authorisations granted by Member States in respect of the ***essentially*** similar products in the group;	[…]	[…]
(c) the shortest withdrawal period of those stated in the summaries of the product characteristics.	**AM 173** (c) ~~the shortest~~ ***a*** withdrawal period ~~of those stated in the 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) 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
	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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	are in conformity with the agreement within 30 days of receipt of the information regarding the agreement from the rapporteur. ***Once an opinion in favour of adopting harmonised conditions of use has been issued, marketing authorisations for a particular product shall be eligible to be considered to be mutual recognition marketing authorisations granted under this Regulation.***		
7. In the event of an unfavourable opinion, the procedure referred to in Article 49 shall apply.		[…]	[…]

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

[50] See also Recital 41 as amended.

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		2. By way of derogation from paragraph 1, in case of a marketing authorisation for a hybrid veterinary medicinal product supported by additional pre-clinical studies and/or clinical trials, the relevant sections of the summary of product characteristics referred to in paragraph 1 shall not be considered to be subject to harmonisation.	**2. By way of derogation from paragraph 1, in case of a marketing authorisation for a hybrid veterinary medicinal product supported by additional pre-clinical studies and/or clinical trials, the relevant sections of the summary of product characteristics referred to in paragraph 1 shall not be considered to be subject to harmonisation.**
		3. The marketing authorisation holders of generic and hybrid veterinary medicinal products shall ensure that the summaries of products characteristics shall be essentially similar to that in the reference veterinary medicinal products.	**3. The marketing authorisation holders of generic and hybrid veterinary medicinal products shall ensure that the summaries of products characteristics shall be essentially similar to that in the reference veterinary medicinal products.**
Article 70 *Harmonisation of summary of products characteristics following reassessment*		~~*Article 70*~~ [….]	*Article 70* [….]
1. By way of derogation from Article 69, the Committee may recommend to the Commission groups of similar veterinary medicinal products for which a	**AM 174** 1. By way of derogation from Article 69, ***and where harmonisation of the conditions of use of a group of products is in the interests of public or animal***	[…]	[…]

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
scientific reassessment is necessary before a harmonised summary of the product characteristics is prepared.	***health at Union level,*** the Committee may recommend to the Commission groups of similar veterinary medicinal products for which a scientific reassessment is necessary before ~~a~~ harmonised ~~summary of the product characteristics~~ ~~is~~ ***conditions of use are*** 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.***		
2. The Commission shall, by means of implementing acts, adopt decisions on groups of product for which a reassessment is necessary. Those implementing acts shall be adopted in accordance with the	**AM 174** 2. The Commission shall, by means of implementing acts, adopt decisions on groups of ***similar*** product***s*** for which a reassessment is necessary. Those implementing acts shall be adopted in accordance	[…]	[…]

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

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	AM 174 ***3a. 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.***		
4. For the purposes of paragraphs 1 and 3, the procedure for a Union interest referral in accordance with Articles 84 to 87 shall apply accordingly.	**AM 174** 4. For the purposes of paragraphs 1***, 3*** and 3***a***, the procedure for a Union interest referral in accordance with Articles 84 to 87 shall apply accordingly.		
Article 71 *Position of marketing authorisation holder*		~~*Article 71*~~ […]	~~*Article 71*~~ […]
Upon request from the coordination group or the Agency, holders of the marketing authorisations for products included in a group of similar products identified for a harmonisation of the summaries of the product characteristics shall submit information concerning their products.	**AM 175** Upon request from the coordination group or the Agency, holders of the marketing authorisations for products included in a group of similar products identified for a harmonisation of the summaries of the product characteristics ***or the holders of a particular product identified for harmonisation of marketing authorisations*** shall submit information concerning their products.	[…]	[…]
Section 6		**Section 6**	**Section 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
Pharmacovigilance		**Pharmacovigilance**	**Pharmacovigilance**
Article 72 *Pharmacovigilance system of the marketing authorisation holder*		~~*Article 72*~~ ~~*Pharmacovigilance system of the marketing authorisation holder*~~	~~*Article 72*~~ ~~*Pharmacovigilance system of the marketing authorisation holder*~~
1. Marketing authorisation holders shall elaborate and maintain a system for collecting information on the risks of veterinary medicinal products as regards animal health, public health and the environment enabling them to fulfil their pharmacovigilance responsibilities listed in Articles 73, 76 and 77 ('pharmacovigilance system').	**AM 176** 1. Marketing authorisation holders shall ***ensure that risk-benefit balance of authorised veterinary medicinal products is evaluated on a continuous basis and that appropriate measure are taken by the marketing authorisation holders in order to ensure that this balance remains positivefor the authorised veterinary medicinal products. To this end, the marketing authorisation holders shall*** elaborate and maintain a system for collecting***, investigating, 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 measures*** to fulfil the~~ir~~ pharmacovigilance responsibilities listed in Articles 73, 76 and 77	[…]	[…]

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 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 *Union pharmacovigilance system*		*Article 73* *Union pharmacovigilance system*	*Article 73* *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***, environmental authorities of the Member States and other interested parties*** different means of reporting to them the following events ***('adverse events')*** 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~~ the necessary 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***, 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;***	(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***, including potential signs of antimicrobial resistance,*** following ~~administration to~~ ***its use on*** 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 *Union pharmacovigilance database*		*Article 74* *Union pharmacovigilance database*	*Article 74* *Union pharmacovigilance database*
1. The Agency shall establish and maintain a Union database on pharmacovigilance of veterinary medicinal products (the "pharmacovigilance database").	**AM 182** 1. The Agency shall establish and maintain a Union database on pharmacovigilance of veterinary medicinal products (the "pharmacovigilance database")***, linked to the database on veterinary medicinal products***. ***The Union database on veterinary medicinal products shall be the only data entry point for adverse events reported by the holders of marketing authorisations. Maintaining the database shall include electronic archiving of the original reports, related subsequent reports and continuous quality control of the data.***	1. The Agency shall**, in collaboration with Member States,** establish and maintain a Union database on pharmacovigilance **for the reporting and recording of suspected adverse events referred to in paragraph 2 of Article 73** […] (the "pharmacovigilance database")**,** […] **which shall also include the information on qualified person responsible for pharmacovigilance, the reference number(s) of the pharmacovigilance system master file, the results and outcomes of the signal management process and results of pharmacovigilance inspections in accordance with provisions of Article 128**.	1. The Agency shall**, in collaboration with Member States,** establish and maintain a Union database on pharmacovigilance **for the reporting and recording of suspected adverse events referred to in paragraph 2 of Article 73** […] (the "pharmacovigilance database")**,** […] **which shall also include the information on qualified person responsible for pharmacovigilance, the reference number(s) of the pharmacovigilance system master file, the results and outcomes of the signal management process and results of pharmacovigilance inspections in accordance with 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 ***publicity*** 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.	3. The Agency shall ensure that information reported **is uploaded in** […] the pharmacovigilance database […] and made accessible in accordance with Article 75.
	AM 185 **Article 74 -- paragraph 3 a (new)**		

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

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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 ***type of*** product ***and active substance***, 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) **the number and, at the latest within two years from the date of application,** 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 *Adverse events reporting*		*Article 76* ***Reporting and recording of suspected a****dverse events […]*	*Article 76* ***Reporting and recording of suspected a****dverse events […]*
1. Competent authorities shall record in the pharmacovigilance database all adverse events which were reported to them by healthcare professionals and animal holders and that occurred in the territory of their Member State, within 30 days following the receipt of the adverse event report.	**AM 189** 1. Competent authorities shall record ***and assess all adverse events of which they learn under Article 73 and which occur*** in the ***territory of their Member State and shall enter them immediately, but no later than 15 days following the receipt of the information, in the*** 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.	1. Competent authorities shall record in the pharmacovigilance database all **suspected** adverse events which were reported to them […] and that occurred in the territory of their Member State, within 30 days […] **of** receipt of the **suspected** adverse event report.	1. Competent authorities shall record in the pharmacovigilance database all **suspected** adverse events which were reported to them […] and that occurred in the territory of their Member State, within 30 days […] **of** receipt of the **suspected** 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 marketing authorisation holder for centrally authorised products, or for nationally authorised products in case they fall within the scope of a Union interest referral, to collect specific pharmacovigilance data additional to the data listed in Article 73(2) and to carry out post marketing surveillance studies. The Agency shall state in detail the reasons for the request, give an appropriate deadline and inform competent authorities thereof.	**2a. The Agency may request the marketing authorisation holder for centrally authorised products, or for nationally authorised products in case they fall within the scope of a Union interest referral, to collect specific pharmacovigilance data additional to the data listed in Article 73(2) and to carry out post marketing surveillance studies. The Agency shall state in detail the reasons for the request, give an appropriate deadline and inform competent authorities thereof**.
3. Competent authorities may, on their own initiative or on request from the Agency, request the marketing authorisation holder to collect specific pharmacovigilance data, in particular regarding the use of a veterinary medicinal product in specified animal species, in the context of public and animal health, safety of the persons administering the product, and the protection of the environment. The authority shall state in detail the reasons for the request and inform other competent authorities and the Agency thereof.	**AM 191** 3. Competent authorities may, on their own initiative or on ***a*** request from the Agency, request the marketing authorisation holder to ***provide*** specific pharmacovigilance data, ~~in particular~~ ***such as, information relating to ongoing risk-benefit balance evaluations*** regarding the use of a veterinary medicinal product in specified animal species, in the context of public and animal health, safety of the persons administering the product, ~~and~~ ***or*** the protection of the environment.	3. Competent authorities […] **may** request the marketing authorisation holder **for nationally authorised veterinary medicinal products** to collect […] specific pharmacovigilance data, […] **additional to the data** […] **listed in Article 73(2)** […] **and to carry out post marketing surveillance studies.** The **competent** authority shall state in detail the reasons for the request**, give an appropriate deadline** and inform other competent authorities and the Agency thereof.	3. Competent authorities […] **may** request the marketing authorisation holder **for nationally authorised veterinary medicinal products** to collect […] specific pharmacovigilance data, […] **additional to the data** […] **listed in Article 73(2)** […] **and to carry out post marketing surveillance studies.** The **competent** authority shall state in detail the reasons for the request**, give an appropriate deadline** and inform other competent authorities and the Agency thereof.

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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 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.		~~4.~~ […]	~~4.~~ […]
5. Within 60 days following the receipt of the written notice, the competent authority shall re-examine the request and provide the marketing authorisation holder with its decision.		~~5.~~ […]	~~5.~~ […]

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

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

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		master file and its summary. **Those implementing acts shall be adopted in accordance with examination procedure referred to in Article 145(2).**	**master file and its summary.** **Those implementing acts shall be adopted in accordance with examination procedure referred to in Article 145(2).**
2. Where the pharmacovigilance tasks have been contracted out by the marketing authorisation holder to a third party, those arrangements shall be set out in details in the pharmacovigilance system master file.	**AM 193** 2. Where the pharmacovigilance tasks have been contracted out by the marketing authorisation holder to a third party ***(contractor)***, ~~those arrangements~~ ***the responsibilities of both parties*** shall be set out ~~in details~~ ***explicitly in a contract and*** in the pharmacovigilance system master file.	2. Where the pharmacovigilance tasks have been contracted out by the marketing authorisation holder to a third party, those arrangements shall be set out in details in the pharmacovigilance system master file.	2. Where the pharmacovigilance tasks have been contracted out by the marketing authorisation holder to a third party, those arrangements shall be set out in details 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.***		
3. The marketing authorisation holder shall permanently have at his disposal one or more appropriately qualified persons responsible for pharmacovigilance. Those persons	**AM 195** 3. The marketing authorisation holder shall permanently have at his disposal ~~one or more~~ ***an*** appropriately qualified ~~persons~~ ***person*** responsible for	3. The marketing authorisation holder shall **designate** […] one or more […] qualified persons **to carry out the tasks provided for in Article 78** […]. The **qualified**	3. The marketing authorisation holder shall **designate** […] one or more […] qualified persons **to carry out the tasks provided for in 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. […] **T**he 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. […] **T**he 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 ***and potential pharmacovigilance concerns*** to the general public in relation to the veterinary medicinal product without ~~giving prior notification of his intention~~ ***sending in advance a copy of that communication*** 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 product**s** 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 product**s** 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 holder communicates such information to the general public, he shall ensure that it is presented objectively and is not misleading.	Where the marketing authorisation holder communicates such information to the general public, he shall ensure that it is presented objectively and is not misleading.	[…] **T**he marketing authorisation holder **shall ensure that such public announcement** […]-is presented objectively and is not misleading.	[…] **T**he marketing authorisation holder **shall ensure that such public announcement** […] is presented 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 *Qualified person responsible for pharmacovigilance*		*Article 78* *Qualified person responsible for pharmacovigilance*	*Article 78* *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 ~~carry out~~ ***ensure that*** the following tasks ***are carried out :***	**1. The q**ualified perso**n** responsible for pharmacovigilance as referred to in Article 77(3) shall […] **ensure that** the following tasks **are carried out**:	**1. The q**ualified perso**n** 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 ***relevant*** reference number of the pharmacovigilance master file ~~of each~~ to the product 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**;	(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***, including on non-target species and the environment,*** 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 other information relevant to detecting a change to the benefit-risk balance of a veterinary medicinal product, including appropriate information on post-marketing surveillance studies;		(h) providing competent authorities or the Agency**, as applicable,** with any other information relevant to detecting a change to the benefit-risk balance of a veterinary medicinal product, including appropriate information on post-marketing surveillance studies;	(h) providing competent authorities or the Agency**, as applicable,** with any other information relevant to detecting a change to the benefit-risk balance of a veterinary medicinal product, including appropriate information on post-marketing surveillance studies;
(i) evaluating by means of the pharmacovigilance system all information, considering options for risk minimisation and prevention and taking appropriate measures if necessary;		(i) […] **applying the signal management process referred to in Article 81 and ensuring that any arrangements for the fulfilment of responsibilities referred to in paragraph 1 of Article 77 are in place**;	(i) […] **applying the signal management process referred to in Article 81 and ensuring that any arrangements for the fulfilment of responsibilities referred to in paragraph 1 of Article 77 are in place**;
(j) monitoring the pharmacovigilance system and ensuring that if needed, an appropriate corrective action plan is prepared and implemented;		(j) monitoring the pharmacovigilance system and ensuring that if needed, an appropriate **preventive or** corrective action plan is prepared**,** […] implemented **and, where necessary, ensuring changes to the pharmacovigilance system master file**;	(j) monitoring the pharmacovigilance system and ensuring that if needed, an appropriate **preventive or** corrective action plan is prepared**,** […] implemented **and, where necessary, ensuring changes to the pharmacovigilance system master file**;
(k) ensuring that all personnel	**AM 199** (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 ***tailored to their duties, on an ongoing basis; training courses are documented and their effectiveness reviewed;***	**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;
(l) 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** (l) 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;	(l) 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.	(l) 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 **21** ~~**30**~~ […] 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***		

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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 responsible for pharmacovigilance referred to in Article 77(3) shall be the contact point for the marketing authorisation holder regarding pharmacovigilance inspections.	**2. The qualified person responsible for pharmacovigilance referred to in Article 77(3) shall be the contact point for the marketing authorisation holder regarding pharmacovigilance inspections.**
Article 79 *Pharmacovigilance responsibilities of the competent authorities and the Agency*		*Article 79* *Pharmacovigilance responsibilities of the competent authorities and the Agency*	*Article 79* *Pharmacovigilance responsibilities of the competent authorities and the Agency*
1. Competent authorities shall evaluate all adverse events reported to them by healthcare professionals and animal holders, manage risks and take the measures referred to in	**AM 200** 1. Competent authorities shall evaluate all adverse events reported to them by ***marketing authorisation holders,*** healthcare professionals and animal holders,	1. Competent authorities shall **lay down the necessary procedures to** evaluate […] **the results and outcomes of signal management process recorded in the**	1. Competent authorities shall **lay down the necessary procedures to** evaluate […] **the results and outcomes of signal management 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 impose specific requirements on veterinarians and other healthcare professionals in respect of the reporting of adverse events. The Agency and the competent authorities may organise meetings or a network for groups of veterinarians or other healthcare professionals, where there is a specific need for collecting, collating or analysing specific pharmacovigilance data.		3. Competent authorities may impose specific requirements on veterinarians and other healthcare professionals in respect of the reporting of **suspected** adverse events. The Agency […] may organise meetings or a network for groups of veterinarians or other healthcare professionals, where there is a specific need for collecting, collating or analysing specific pharmacovigilance data.	3. Competent authorities may impose specific requirements on veterinarians and other healthcare professionals in respect of the reporting of **suspected** adverse events. The Agency […] may organise meetings or a network for groups of veterinarians or other healthcare professionals, where there is a specific need for collecting, collating or analysing specific 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 Article**s** 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 Article**s** 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 adverse events to the centrally authorised veterinary medicinal products, manage risks and recommend measures to the Commission. The Commission shall take the measures referred to in Articles 130 to 135 concerning marketing authorisations where necessary.		6. The Agency shall **lay down the necessary procedures to** evaluate […] **suspected** adverse events **reported to it regarding** […] centrally authorised veterinary medicinal products, […] and recommend **risk management** measures to the Commission. The Commission shall take […] **any appropriate** […] measures referred to in Articles 130**, 131, and 133** […] concerning marketing authorisations […].	6. The Agency shall **lay down the necessary procedures to** evaluate […] **suspected** adverse events **reported to it regarding** […] centrally authorised veterinary medicinal products, […] and recommend **risk management** measures to the Commission. The Commission shall take […] **any appropriate** […] measures referred to in Articles 130**, 131, and 133** […] concerning marketing authorisations […].
		7. The competent authority or the Agency, as applicable, may at any time request the marketing authorisation holder to submit a copy of the pharmacovigilance system master file. The marketing authorisation holder shall submit the copy at the latest seven days after receipt of the request.	**7. The competent authority or the Agency, as applicable, may at any time request the marketing authorisation holder to submit a copy of the pharmacovigilance system master file. The marketing authorisation holder shall submit the copy at the latest seven days after receipt of the request.**
Article 80 *Delegation of tasks by competent authority*		*Article 80* *Delegation of tasks by competent authority*	*Article 80* *Delegation of tasks by competent authority*
1. A competent authority may delegate any of the tasks entrusted to it as referred to in Article 79 to a competent authority in another	**AM 203** 1. A competent authority may delegate any of the tasks entrusted to it as referred to in Article 79 to a competent ***public*** authority in	1. A competent authority may delegate any of the tasks entrusted to it as referred to in Article 79 to a competent authority in another	1. A competent authority may delegate any of the tasks entrusted to it as referred to in Article 79 to a 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 Commission, the Agency and other Member States of the delegation in writing. The delegating competent authority and the Agency shall make that information public.		2. The delegating competent authority shall inform the Commission, the Agency and other […] **competent authorities and** make that information public. […]	2. The delegating competent authority shall inform the Commission, the Agency and other […] **competent authorities and** make that information public. […]
Article 81 *Signal management process*		*Article 81* *Signal management process*	*Article 81* *Signal management process*
		0. Marketing authorisation holders shall carry out signal management process for their veterinary medicinal products, if necessary taking into account sales data and other relevant pharmacovigilance data of which they can reasonably be expected to be aware of and which may be useful for the signal management process. This data may include scientific information gathered from scientific literature reviews.	**0. Marketing authorisation holders shall carry out signal management process for their veterinary medicinal products, if necessary taking into account sales data and other relevant pharmacovigilance data of which they can reasonably be expected to be aware of and which may be useful for the signal management process. This data may include scientific information gathered from scientific literature reviews.**

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

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		according to the frequency specified in the marketing authorisation.	**references to relevant scientific literature ~~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 thereof ('lead authority').	3. **For the purpose of paragraph 1, t**he 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 management** ('lead authority').	3. **For the purpose of paragraph 1, t**he 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 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.	**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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	signal management process. 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 ~~3~~ ***five*** 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***, if necessary,*** every ~~5~~ ***five*** 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 *Procedure for re-examination of a marketing authorisation in exceptional circumstances*	**AM 206** ***deleted***	~~*Article 83*~~[52] *[…]*	~~*Article 83*~~ *[…]*
1. Before the expiry of the period of validity of 1 year, marketing authorisations granted in accordance with Article 22 shall be re-examined on application from the marketing authorisation holder.	**AM 206** ***deleted***	[…]	[…]
2. The application for re-examination shall be submitted to the	**AM 206** ***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-examination has been submitted, the marketing authorisation shall remain valid until a decision on the application has been adopted by the competent authority or the Commission.	**AM 206** ***deleted***	[…]	[…]
4. The competent authority or the Commission may at any time grant a 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).	**AM 206** ***deleted***	[…]	[…].
Section 8 **Union interest referral**		**Section 8** **Union interest referral**	**Section 8** **Union interest referral**
Article 84 *Scope of the Union interest referral*		*Article 84* *Scope of the Union interest referral*	*Article 84* *Scope of the Union interest referral*
1. Where the interests of the Union are involved, and in particular the interests of public or animal health or of the environment related to the quality, safety or efficacy of veterinary medicinal products or the free movement of products within		1. Where the interests of the Union are involved, and in particular the interests of public or animal health or of the environment related to the quality, safety or efficacy of veterinary medicinal products […], […] **the marketing authorisation**	1. Where the interests of the Union are involved, and in particular the interests of public or animal health or of the environment related to the quality, safety or efficacy of veterinary medicinal products […], […] **the marketing authorisation**

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

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

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

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

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

[53] Articles 86 and 87 have been merged.

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

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		7. Nationally authorised veterinary medicinal products which have been subject to a referral procedure shall henceforth be transferred to a mutual recognition procedure.	**7. Nationally authorised veterinary medicinal products which have been subject to a referral procedure shall henceforth be transferred to a mutual recognition procedure.**
Chapter V **Homeopathic veterinary medicinal products**		**Chapter V** **Homeopathic veterinary medicinal products**	**Chapter V** **Homeopathic veterinary medicinal products**
Article 88 *Homeopathic veterinary medicinal products*		*Article 88* *Homeopathic veterinary medicinal products*	*Article 88* *Homeopathic veterinary medicinal products*
1. By way of derogation from Article 5, homeopathic veterinary medicinal products that satisfy the requirements set out in Article 89 and are not immunological homeopathic veterinary medicinal products shall be registered in accordance with Article 90.	**AM 207** 1. By way of derogation from Article 5, homeopathic veterinary medicinal products that satisfy the requirements set out in Article 89 and are not immunological homeopathic veterinary medicinal products shall be registered in 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.***	1. […] **H**omeopathic veterinary medicinal products that satisfy the […] **conditions** set out in Article 89 […] shall be registered in accordance with Article 90.	1. […] **H**omeopathic veterinary medicinal products that satisfy the […] **conditions** set out in Article 89 […] shall be registered in accordance with Article 90.

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		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.***		

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Article 89 *Registration of homeopathic veterinary medicinal products*		*Article 89* *Registration of homeopathic veterinary medicinal products*	*Article 89* *Registration of homeopathic veterinary medicinal products*
1. Homeopathic veterinary medicinal products that satisfy all of the following conditions shall be subject to a registration procedure:		1. **A h**omeopathic veterinary medicinal produc**t** that satisf**ies** all of the following conditions shall be subject to a registration procedure:	1. **A h**omeopathic veterinary medicinal produc**t** that satisf**ies** all of the following conditions shall be subject to a registration procedure:
(a) the medicinal product is administered by a route described in the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in Member States;		(a) […] **it** is administered by a route described in the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in Member States;	(a) […] **it** is administered by a route described in the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in Member 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***, unless the ingredients of the medicinal products are included in Table 1 of Regulation (EU) No 37/2010 with the comment "No maximum residue level (MRL) required"***;	(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 indication appears on the labelling of the medicinal product or in any information relating thereto.		**(c) it has** no […] therapeutic indication appear**ing** on **its** the labelling […] or in any information relating thereto.	**(c) it has** no […] therapeutic indication appear**ing** on **its** the labelling […] or in any information relating thereto.
2. The Commission shall be		2. […] **Member States may lay**	2. […] **Member States may lay**

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empowered to adopt delegated acts in accordance with Article 146 in order to adapt paragraph 1(b) and (c) in the light of new scientific evidence.		**down procedures for the registration of homeopathic veterinary medicinal products in addition to those laid down in this Chapter.**	**down procedures for the registration of homeopathic veterinary medicinal products in addition to those laid down in this Chapter.**
Article 90 *Requirements and procedure for registration of homeopathic veterinary medicinal products*		*Article 90* ***Application*** *[…] and procedure for registration of homeopathic veterinary medicinal products*	*Article 90* ***Application*** *[…] and procedure for registration of homeopathic veterinary medicinal products*
1. The following documents shall be included in the application for a registration of a homeopathic veterinary medicinal product:		1. The following documents shall be included in the application for a registration of a homeopathic veterinary medicinal product:	1. The following documents shall be included in the application for a registration of a homeopathic veterinary medicinal product:
(a) scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered;	**AM 210** (a) scientific name or other name given in a pharmacopoeia ***or documented in a monograph*** of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered;	(a) scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the […] rout**e** of administration, pharmaceutical for**m** and degree of dilution to be registered;	(a) scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the […] rout**e** of administration, pharmaceutical for**m** and degree of dilution to be registered;

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(b) a dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate bibliography; in the case of homeopathic veterinary medicinal products containing biological substances, a description of the measures taken to ensure the absence of pathogens;		(b) a dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic […] **use**, on the basis of an adequate bibliography; in the case of homeopathic veterinary medicinal products containing biological substances, a description of the measures taken to ensure the absence of pathogens;	(b) a dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic […] **use**, on the basis of an adequate bibliography; in the case of homeopathic veterinary medicinal products containing biological substances, a description of the measures taken to ensure the absence 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 file for each pharmaceutical form and a description of the method of dilution and potentisation;		(c) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation;	(c) the manufacturing and control file for each pharmaceutical form and a description of the method of 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 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. […] **T**he competent authority […] **may** determine the conditions under which the **registered** homeopathic veterinary medicinal product**s** may be made available […].	3. […] **T**he competent authority […] **may** determine the conditions under which the **registered** homeopathic veterinary medicinal product**s** 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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		5. A registration holder of homeopathic veterinary medicinal products shall be subject to the same obligations as a marketing authorisation holder in so far as the provisions apply to registered homeopathic veterinary medicinal products in accordance with Article 2c.	**5. A registration holder of homeopathic veterinary medicinal products shall be subject to the same obligations as a marketing authorisation holder in so far as the provisions apply to registered homeopathic veterinary medicinal products in accordance with Article 2c.**
		6. A registration for a homeopathic veterinary medicinal product shall only be granted to an applicant established in the Union. The requirement to be established in the Union shall also apply to registration holders.	**6. A registration for a homeopathic veterinary medicinal product shall only be granted to an applicant established in the Union. The requirement to be established in the Union shall also apply to registration holders.**
Chapter VI **Manufacturing, import and export**		**Chapter VI** **Manufacturing, import and export**	**Chapter VI** **Manufacturing, import and export**
Article 91 *Manufacturing authorisations*		*Article 91* *Manufacturing authorisations*	*Article 91* *Manufacturing authorisations*
1. A manufacturing authorisation shall be required in order to carry out any of the following activities ('manufacturing'):		1. A manufacturing authorisation shall be required in order to carry out any of the following activities […]:	1. A manufacturing authorisation shall be required in order to carry out any of the following activities […]:
(a) to produce or import veterinary medicinal products; or		(a) to **manufacture** […] veterinary medicinal products […] **even if intended only for export**;	(a) to **manufacture** […] veterinary medicinal products […] **even if intended only for export**;

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(b) to engage in any part of the process of producing a veterinary medicinal product or of bringing a veterinary medicinal product to its final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing it or any constituent of it for supply as part of that process.		(b) to engage in any part of the process of **manufacturing** […] a veterinary medicinal product or of bringing a veterinary medicinal product to its final state, including engaging in the processing, assembling, packaging **and repackaging**, labelling **and relabelling**, stor**ing** […], sterilising, testing or releasing it […] or supply as part of that process[…]**; or**	(b) to engage in any part of the process of **manufacturing** […] a veterinary medicinal product or of bringing a veterinary medicinal product to its final state, including engaging in the processing, assembling, packaging **and repackaging**, labelling **and relabelling**, stor**ing** […], sterilising, testing or releasing it […] or supply as part of that process[…]**; or**
		(c) to import veterinary medicinal products.	**(c) to import veterinary medicinal products**.
2. Notwithstanding paragraph 1, a manufacturing authorisation shall not be required for preparation, dividing up, changes in packaging or presentation where these processes are carried out solely for retail in accordance with Articles 107 and 108.		2. Notwithstanding paragraph 1, **Member States may decide that** a manufacturing authorisation shall not be required for preparation, dividing up, changes in packaging or presentation **of veterinary medicinal products,** where these processes are carried out solely for retail **directly to the public i**n accordance with Articles 107 and 108.	2. Notwithstanding paragraph 1, **Member States may decide that** a manufacturing authorisation shall not be required for preparation, dividing up, changes in packaging or presentation **of veterinary medicinal products,** where these processes are carried out solely for retail **directly to the public i**n accordance with Articles 107 and 108.
		2a. Where paragraph 2 is applied, the package leaflet shall be given with each divided part and the batch number and expiry date shall be clearly indicated.	**2a. Where paragraph 2 is applied, the package leaflet shall be given with each divided part and the batch number and expiry date shall be clearly indicated.**
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	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.***		
3. The competent authorities shall record the manufacturing authorisations granted by them in the database on manufacturing, import and wholesale distribution set up in accordance with Article 94.		3. The competent authorities shall record the manufacturing authorisations granted by them in the database on manufacturing […] and wholesale distribution set up in accordance with Article 94.	3. The competent authorities shall record the manufacturing authorisations granted by them in the database on manufacturing […] and wholesale distribution set up in accordance with Article 94.
4. Manufacturing authorisations shall be valid throughout the Union.		4. Manufacturing authorisations shall be valid throughout the Union.	4. Manufacturing authorisations shall be valid throughout the Union.
Article 92 *Requirements for obtaining a manufacturing authorisation*		*Article 92* *[…]* ***Application for*** *manufacturing authorisation*	*Article 92* *[…]* ***Application for*** *manufacturing authorisation*
1. Applications for manufacturing authorisations shall be submitted to a competent authority in the Member State where the manufacturing site is located.		1. **An a**pplicatio**n** for **a** manufacturing authorisatio**n** shall be submitted to a competent authority in the Member State where the manufacturing site is located.	1. **An a**pplicatio**n** for **a** manufacturing authorisatio**n** shall be submitted to a competent authority in the Member State where the manufacturing site is located.

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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**,** ***including data about emissions, discharges and losses of the active substance and its precursors to the environment***;	(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 Article**s** 98 **and 100.**	(d) **a** statement to the effect that the applicant fulfils the requirements laid down in Article**s** 98 **and 100.**

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Article 93 *Granting of manufacturing authorisations*		*Article 93* *[…] **Procedure for g**ranting of manufacturing authorisations*	*Article 93* *[…] **Procedure for g**ranting of manufacturing authorisations*
1. Before granting a manufacturing authorisation, the competent authority shall carry out an inspection in accordance with Article 125 of the manufacturing site where the veterinary medicinal products are to be manufactured or tested.		1. Before granting a manufacturing authorisation, the competent authority shall carry out an inspection […] of the manufacturing site […].	1. Before granting a manufacturing authorisation, the competent authority shall carry out an inspection […] of the manufacturing site […].
2. An authorisation shall apply only to the manufacturing site, the veterinary medicinal products, and the pharmaceutical forms specified in the application.		2. […] **A manufacturing** authorisation shall apply only to the manufacturing site […] and the pharmaceutical forms specified in the application **referred to in Article 92**.	2. […] **A manufacturing** authorisation shall apply only to the manufacturing site […] and the pharmaceutical forms specified in the application **referred to in Article 92**.
3. Member States shall lay down procedures for granting manufacturing authorisations. The procedures for granting a manufacturing authorisation shall not exceed 90 days from the day on which the competent authority receives the application.		3. Member States shall lay down procedures for granting **or refusing** manufacturing authorisations. […] **Such procedures shall not exceed 90 days from receipt by the competent authority of a manufacturing authorisation application.**	3. Member States shall lay down procedures for granting **or refusing** manufacturing authorisations. […] **Such procedures shall not exceed 90 days from receipt by the competent authority of a manufacturing authorisation application.**
4. The competent authority may require the applicant to submit further information in addition to that supplied in the application pursuant to Article 92. Where the competent		4. The competent authority may require the applicant to submit further information in addition to that supplied in the application pursuant to Article 92. Where the competent	4. The competent authority may require the applicant to submit further information in addition to that supplied in the application pursuant to Article 92. Where the competent

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authority exercises this right, the time limit referred to in paragraph 3 of this Article shall be suspended until the additional data required has been submitted.		authority exercises this right, the time limit referred to in paragraph 3 of this Article shall be suspended **or revoked** until the additional data required has been submitted.	authority exercises this right, the time limit referred to in paragraph 3 of this Article shall be suspended **or revoked** until the additional data required has been submitted.[54]
5. A manufacturing authorisation may be granted conditionally, subject to a requirement for the applicant to undertake actions or introduce specific procedures within a given time period. The manufacturing authorisation may be suspended if these requirements are not complied with.	**AM 213** **Article 93 -- paragraph 5** 5. A manufacturing authorisation may be granted conditionally ***where minor shortcomings are identified***, subject to a requirement for the applicant to ~~undertake actions or introduce specific procedures~~ ***rectify the shortcomings*** within a given time period. The manufacturing authorisation may be suspended if these requirements are not complied with. ***The manufacturing authorisation shall be refused if manufacturing causes unacceptable risks to the environment.***	5. A manufacturing authorisation may be granted conditionally, subject to a requirement for the applicant to undertake actions or introduce specific procedures within a given time period. The **conditionally granted** manufacturing authorisation […] **shall** be suspended **or revoked** if these requirements are not complied with.	5. A manufacturing authorisation may be granted conditionally, subject to a requirement for the applicant to undertake actions or introduce specific procedures within a given time period. The **conditionally granted** manufacturing authorisation […] **shall** be suspended **or revoked** if these requirements are not complied with.

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

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Article 94 *Database on manufacturing authorisations*		*Article 94* *Database on manufacturing **and wholesale distribution** […]*	*Article 94* *Database on manufacturing **and wholesale distribution** […]*
1. A Union database on manufacturing, import and wholesale distribution shall be set up and maintained by the Agency ('manufacturing and wholesale distribution database').		1. A Union database on manufacturing, import and wholesale distribution shall be set up and maintained by the Agency ('manufacturing and wholesale distribution database').	1. A Union database on manufacturing, import and wholesale distribution shall be set up and maintained by the Agency ('manufacturing and wholesale distribution database').
2. The database shall include information on any manufacturing and wholesale distribution authorisations granted by competent authorities within the Union.		2. The **manufacturing and wholesale distribution** database shall include information **regarding the granting, suspension or revocation by competent authorities of** […] any manufacturing **authorisations,** […] wholesale distribution authorisations**, certificates of good manufacturing practice,** and **registrations of manufacturers, importers and distributors of active substances** […].	2. The **manufacturing and wholesale distribution** database shall include information **regarding the granting, suspension or revocation by competent authorities of** […] any manufacturing **authorisations,** […] wholesale distribution authorisations**, certificates of good manufacturing practice,** and **registrations of manufacturers, importers and distributors of active substances** […].
3. The Agency shall make public a format for electronic submissions of data to the database.		[…]	[…]

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4. Competent authorities shall record in the manufacturing and wholesale distribution database information on authorisations and certificates granted in accordance with Articles 93, 103 and 105 together with information on the veterinary medicinal products covered by the authorisations, using the format referred to in paragraph 3.		4. Competent authorities shall record in the manufacturing and wholesale distribution database information on **manufacturing and wholesale distribution** authorisations and certificates granted in accordance with Articles 93, **98a and** […] 105 […] together with information on[…] **importers, manufacturers and distributors of active substances registered in accordance with Article 98b**.	4. Competent authorities shall record in the manufacturing and wholesale distribution database information on **manufacturing and wholesale distribution** authorisations and certificates granted in accordance with Articles 93, **98a and** […] 105 […] together with information on[…] **importers, manufacturers and distributors of active substances registered in accordance with Article 98b**.
5. The Agency shall, in collaboration with Member States and the Commission, draw up functional specifications for the manufacturing and wholesale distribution database.		5. The Agency shall, in collaboration with Member States and the Commission, draw up functional specifications**, including the format for electronic submissions of data,** for the manufacturing and wholesale distribution database.	5. The Agency shall, in collaboration with Member States and the Commission, draw up functional specifications**, including the format for electronic submissions of data,** for the manufacturing and wholesale distribution database.
6. The Agency shall ensure that information reported to the database is collated and made accessible and that the information is shared.		6. The Agency shall ensure that information reported to the **manufacturing and wholesale distribution** database is collated and made accessible and that the information is shared.	6. The Agency shall ensure that information reported to the **manufacturing and wholesale distribution** database is collated and made accessible and that the information is shared.
Article 95 *Access to the database on*		~~*Article 95*~~[55]	~~*Article 95*~~

[55] Articles 94 and 95 have been merged.

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manufacturing authorisations			
1. The competent authorities shall have full access to the database set up in accordance with Article 94.		~~1.~~7 The competent authorities shall have full access to the **manufacturing and wholesale distribution** database […].	~~1.~~7 The competent authorities shall have full access to the **manufacturing and wholesale 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 access to information in the database specifying the companies that have been granted manufacturing or wholesale distribution authorisations and the manufacturing sites and products concerned by these authorisations.		~~3.~~ **8.** The general public shall have **read only** access to information in the **manufacturing and wholesale distribution** database**.** […]	**8.** The general public shall have ~~**read only**~~ access to information in the **manufacturing and wholesale distribution** database**, without changing the information therein.** […]
Article 96 *Changes to manufacturing authorisations on request*		*Article 96* *Changes to manufacturing authorisations on request*	*Article 96* *Changes to manufacturing authorisations on request*
1. If the holder of a manufacturing authorisation requests a change in that manufacturing authorisation, the procedure for examining such a request shall not exceed 30 days from the day on which the competent authority receives the request. In exceptional cases, this period of time may be extended by the competent authority		1. If the holder of a manufacturing authorisation requests a change in that manufacturing authorisation, the procedure for examining such a request shall not exceed 30 days from the day on which the competent authority receives the request. In […] **justified** cases, **including when an inspection is necessary**, this period of time may	1. If the holder of a manufacturing authorisation requests a change in that manufacturing authorisation, the procedure for examining such a request shall not exceed 30 days from the day on which the competent authority receives the request. In […] **justified** cases, **including when an inspection is necessary**, this period of time may

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

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Article 97 *Manufacturing authorisation for import and export*		~~*Article 97*~~[56]	~~*Article 97*~~
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;		(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;
	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 the Union;***		

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

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

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		which he is established, in accordance with Article 98b;~~.~~	**which he is established, in accordance with Article 98b;~~.~~**
		(l) perform audits based on a risk assessment on the manufacturer, distributor and importers from whom he obtains active substances.	**(l) perform audits based on a risk assessment on the manufacturer, distributor and importers from whom he obtains 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).**
		Article 98a [57] ***Certificates of good manufacturing practice***	***Article 98a*** ***Certificates of good manufacturing practice***
		1. Within 90 days after an inspection […], the competent authority shall issue a certificate of good manufacturing practice of the manufacturer **for the manufacturing site concerned** if	1. Within 90 days after an inspection […], the competent authority shall issue a certificate of good manufacturing practice of the manufacturer **for the manufacturing site concerned** if

[57] ex Article 127amended

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		the inspection establishes […] that the manufacturer in question is […] **in compliance** with the requirements as set out in this Regulation and […] **with the implementing act adopted in accordance with Article 98(2)**.	the inspection establishes […] that the manufacturer in question is […] **in compliance** with the requirements as set out in this Regulation and […] **with the implementing act adopted in accordance with Article 98(2)**.
		2a. If the outcome of the inspection as referred to in paragraph 1 is that the manufacturer does not comply with good manufacturing practice, the information shall be entered into the database for manufacturing and wholesale distribution referred to in Article 94.	**2a. If the outcome of the inspection as referred to in paragraph 1 is that the manufacturer does not comply with good manufacturing practice, the information shall be entered into the database for manufacturing and wholesale distribution referred to in Article 94.**
		3. The conclusions reached following an inspection of a manufacturer shall be valid throughout the Union.	3. The conclusions reached following an inspection of a manufacturer shall be valid throughout the Union.
		~~4.~~ […]	~~4.~~ […]
		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.	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.

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

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

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

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		7. Competent authorities shall enter the information provided in accordance with paragraph 2 of this Article and Article 131(b) in the manufacturing and wholesale distribution database referred to in Article 94.	**7. Competent authorities shall enter the information provided in accordance with paragraph 2 of this Article and Article 131(b) in the manufacturing and wholesale distribution database referred to in Article 94.**
		8. This Article shall be without prejudice to Article 98a.	**8. This Article shall be without prejudice to Article 98a.**
		9. The Commission shall, by means of implementing acts, adopt measures on good distribution practices for active substances used as starting materials in veterinary medicinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	**9. The Commission shall, by means of implementing acts, adopt measures on good distribution practices for active substances used as starting materials in veterinary medicinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**
Article 99 *Record keeping*		*Article 99* *Record keeping*	*Article 99* *Record keeping*
1. The following information shall be recorded in respect of all veterinary medicinal products supplied by the holder of a manufacturing authorisation:		1. The **holder of a manufacturing authorisation shall record the** following information […]-in respect of all veterinary medicinal products supplied by **him** […]:	1. The **holder of a manufacturing authorisation shall record the** following information […]-in respect of all veterinary 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 medicinal product,		(b) name of the veterinary medicinal product**, and marketing authorisation number if applicable, as well as pharmaceutical form and strength, as appropriate,**	(b) name of the veterinary medicinal product**, and marketing authorisation number if applicable, as well as pharmaceutical form and strength, as appropriate,**
(c) quantity supplied,		(c) quantity supplied,	(c) quantity supplied,
(d) name and address of the recipient,		(d) name and address of the recipient,	(d) name and address of the recipient,
(e) batch number.		(e) batch number**,**	(e) batch number**,**
		(f) date of expiry.	**(f) date of expiry**.
2. The records mentioned in paragraph 1 shall be available for inspection by competent authorities for a period of 3 years.		2. The records mentioned in paragraph 1 shall be available for inspection by competent authorities for […] **one year after the date of expiry of the batch or at least five years, whichever is the longer**.	2. The records mentioned in paragraph 1 shall be available for inspection by competent authorities for […] **one year after the date of expiry of the batch or at least five years, whichever is the longer**.
Article 100 *Qualified person for manufacturing*		*Article 100* *Qualified person **responsible** for manufacturing **and batch release***	*Article 100* *Qualified person **responsible** for manufacturing **and batch release***
1. The holder of a manufacturing authorisation shall have permanently and continuously at his disposal the services of at least one qualified person who fulfils the conditions laid down in this Article and is responsible, in particular, for carrying out the duties specified in Article 101.		1. The holder of a manufacturing authorisation shall have permanently […] at his disposal the services of at least one qualified person who fulfils the conditions laid down in this Article and is responsible, in particular, for carrying out the duties specified in **this** Article […].	1. The holder of a manufacturing authorisation shall have permanently […] at his disposal the services of at least one qualified person who fulfils the conditions laid down in this Article and is responsible, in particular, for carrying out the duties specified in **this** Article […].

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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.** **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.**	**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.**

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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** […].	**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 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**. […] **T**he 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**. […] **T**he 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 manufacturing shall keep records in respect of each released production batch. These records shall be kept up to date as operations are carried out and shall remain at the disposal of the competent authority for a period of 5 years.		[…] **8**. The qualified person **responsible** for manufacturing shall keep records in respect of each released production batch. These records shall be kept up to date as operations are carried out and shall remain at the disposal of the competent authority for […] **one year after the date of expiry of the batch or at least five years, whichever is the longer**.	[…] **8**. The qualified person **responsible** for manufacturing shall keep records in respect of each released production batch. These records shall be kept up to date as operations are carried out and shall remain at the disposal of the competent authority for […] **one year after the date of expiry of the batch or at least five years, whichever is the longer**.
5. Where veterinary medicinal products manufactured in the Union are imported into the Union from a third country, paragraph 1 shall apply.		[…] **9**. Where veterinary medicinal products manufactured in the Union are **exported and subsequently** imported **back** into the Union from a third country, paragraph […] **6** shall apply.	[…] **9**. Where veterinary medicinal products manufactured in the Union are **exported and subsequently** imported **back** into the Union from a third country, paragraph […] **6** shall apply.
6. Where veterinary medicinal products are imported from third countries with which the Union has made arrangements regarding application of standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/412/EEC[60] and it is demonstrated that the tests referred to in paragraph 1 have been		[…] **10**. Where veterinary medicinal products are imported from third countries with which the Union has made arrangements regarding application of standards of good manufacturing practice at least equivalent to those laid down **in accordance with Article 98(2)** […] and it is demonstrated that the tests referred to in paragraph […] **6** have	[…] **10**. Where veterinary medicinal products are imported from third countries with which the Union has made arrangements regarding application of standards of good manufacturing practice at least equivalent to those laid down **in accordance with Article 98(2)** […] and it is demonstrated that the tests 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 responsibility for carrying out the tests referred to in paragraph 2.		been carried out in the exporting country, the […] **qualified person may draw up the control report referred to in paragraph 6 without the necessary tests referred to in paragraph 7 being carried out** […]**, unless the competent authority of the Member State of importation decides otherwise**.	been carried out in the exporting country, the […] **qualified person may draw up the control report referred to in paragraph 6 without 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 *Competent authorities' measures*		~~*Article 102*~~	~~*Article 102*~~
1. The competent authority shall ensure that the obligations of qualified persons referred to in Article 100 are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct.		[…]	[…]
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.		[…]	[…]
Article 103 *Certificates of manufacturing authorisations*		*Article 103* *Certificates of* ***veterinary medicinal product*** *[…]*	*Article 103* *Certificates of* ***veterinary medicinal product*** *[…]*
Upon request of the manufacturer or exporter of veterinary medicinal		**1.** Upon request of […] **a** manufacturer or **an** exporter of	**1.** Upon request of […] **a** 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 competent authority shall attach the approved summary of the product characteristics or, in the absence thereof, an equivalent document, in case of veterinary medicinal products intended for export which are already authorised in their territory.		**2.** When issuing such certificates, the competent authority **or the Agency** shall […] **take into account the relevant prevailing administrative arrangements with regard to the content and format of such certificates.**	**2.** When issuing such certificates, the competent authority **or the Agency** shall […] **take into account the relevant prevailing administrative arrangements with regard to the content and format of such certificates.**
Chapter VII **Supply and use**		**Chapter VII** **Supply and use**	**Chapter VII** **Supply and use**
Section 1 **Wholesale distribution**		**Section 1** **Wholesale distribution**	**Section 1** **Wholesale distribution**
Article 104 *Wholesale distribution of veterinary medicinal products*		*Article 104* *Wholesale distribution* ***authorisations** […]*	*Article 104* *Wholesale distribution* ***authorisations** […]*
1. The wholesale distribution of veterinary medicinal products shall be subject to the holding of a wholesale distribution authorisation. Member States shall lay down procedures for granting a wholesale distribution authorisation.		1. The wholesale distribution of veterinary medicinal products shall be subject to the holding of a wholesale distribution authorisation. […]	1. The wholesale distribution of veterinary medicinal products shall be subject to the holding of a wholesale distribution authorisation. […]
		1a. The holders of a wholesale distribution authorisation shall be established in the Union.	**1a. The holders of a wholesale distribution authorisation shall be established in the Union.**
2. Wholesale distribution authorisations shall be valid throughout the Union.		2. Wholesale distribution authorisations shall be valid throughout the Union.	2. Wholesale distribution authorisations shall be valid throughout the Union.
3. Supplies of small quantities of	**AM 215** **Article 104 -- paragraph 3**	3. **Member States may decide**	3. **Member States may decide**

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veterinary medicinal products from one retailer to another shall not be regarded as wholesale distribution.	3. ~~Supplies of small quantities of veterinary medicinal products from one retailer to another shall not be regarded as wholesale distribution.~~ ***The purchase, sale, import or export of veterinary medicinal products or any other 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.***	**that s**upplies of small quantities of veterinary medicinal products from one retailer to another **in the same Member State**, shall not be **subject to the requirement of holding a** […] wholesale distribution **authorisation**.	**that s**upplies of small quantities of veterinary medicinal products from one retailer to another **in the same Member State**, shall not be **subject to the requirement of holding a** […] wholesale distribution **authorisation**.
		3a. By derogation from paragraph 1, a holder of a manufacturing authorisation shall not be required to hold a wholesale distribution authorisation for the veterinary medicinal products covered by the manufacturing	**3a. By derogation from paragraph 1, a holder of a manufacturing authorisation shall not be required to hold a wholesale distribution authorisation for the veterinary medicinal products covered by the manufacturing**

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		authorisation.	**authorisation.**
4. The wholesale distributor shall 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.		~~4.~~ […][61]	~~4.~~ […]
	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 means of implementing acts, adopt measures on good distribution practices for veterinary medicinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	**6. The Commission shall, by means of implementing acts, adopt measures on good distribution practices for veterinary medicinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**
Article 105 *Procedure for granting wholesale distribution authorisations*		*Article 105* ***Application and p****rocedures for […] wholesale distribution authorisations*	*Article 105* ***Application and p****rocedures for […] wholesale distribution authorisations*
1. An application for a wholesale distribution authorisation shall be submitted to the competent authority of the Member State in which the wholesale distributor is established.		1. An application for a wholesale distribution authorisation shall be submitted to the competent authority […] **in** the Member State **where the site(s) of** […] the wholesale distributor is/**are located**.	1. An application for a wholesale distribution authorisation shall be submitted to the competent authority […] **in** the Member State **where the site(s) of** […] the wholesale distributor is/**are located**.
2. The procedure for granting a wholesale distribution authorisation shall not exceed 90 days from the date on which the competent authority receives an application.		2. The procedure for granting a wholesale distribution authorisation shall not exceed 90 days from the date on which the competent authority receives an application.	2. The procedure for granting a wholesale distribution authorisation shall not exceed 90 days from the date on which the competent authority receives an application.
3. An applicant shall demonstrate in the application that he fulfils the following requirements:		[…] **1a**. An applicant shall demonstrate in the application that he fulfils the following requirements:	[…] **1a**. An applicant shall demonstrate in the application that he fulfils the following 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 guaranteeing 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;		(b) has […] **a** plan guaranteeing effective implementation of any withdrawal **or recall** ordered by the competent authorities or the Commission or undertaken in cooperation with the manufacturer […] or marketing authorisation holder **of the veterinary medicinal product in question**;	(b) has […] **a** plan guaranteeing effective implementation of any withdrawal **or recall** ordered by the competent authorities or the Commission or undertaken in cooperation with the manufacturer […] or marketing authorisation holder **of the veterinary medicinal product in question**;

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(c) has an appropriate record keeping system ensuring compliance with the requirements referred to in Article 106.		(c) has an appropriate record keeping system ensuring compliance with the requirements referred to in Article 10**5a;**	(c) has an appropriate record keeping system ensuring compliance with the requirements referred to in Article 10**5a;**
	AM 220 **Article 105 -- paragraph 3 -- point ca (new)** ***(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;***	**(d) has a statement to the effect that he fulfils the requirements laid down in Article 105a.**	**(d) has a statement to the effect that he fulfils the requirements laid down in Article 105a.**
	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 down procedures for granting, refusing, suspending, revoking or changing a wholesale distribution authorisation.	**1b. Member States shall lay down procedures for granting, refusing, suspending, revoking or changing a wholesale distribution authorisation.**
		2. The procedure for granting, **refusing, suspending, revoking or changing** […] wholesale distribution authorisation shall not exceed 90 days from the date on which the competent authority receives […] application **in accordance to national law**.	2. The procedure for granting, **refusing, suspending, revoking or changing** […] wholesale distribution authorisation shall not exceed 90 days from the date on which the competent authority receives […] application **in accordance to national law**.

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

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

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

[62] Articles 105a and 106 have been merged.

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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.		[…]**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 […] **five** years.	[…]**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 […] **five** years.
	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 form of proof serving to demonstrate that they are***		

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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 ***Parallel trade in veterinary medicinal products***[63]	***Article 106a*** ***Parallel trade in veterinary medicinal products***
		1. For the purpose of parallel trade in veterinary medicinal products, the wholesale distributor shall ensure that the veterinary medicinal product he intends to source from a Member State ('source Member State') and distribute in another ('destination Member State') share a common origin with the veterinary medicinal product already authorised in the destination Member State. The veterinary medicinal products are ~~is~~ considered as sharing a common origin if they fulfill the following conditions:	**1. For the purpose of parallel trade in veterinary medicinal products, the wholesale distributor shall ensure that the veterinary medicinal product he intends to source from a Member State ('source Member State') and distribute in another ('destination Member State') share a common origin with the veterinary medicinal product already authorised in the destination Member State. The veterinary medicinal products are ~~is~~ considered as sharing a common origin if they fulfill the following conditions:**
		(a) they have the same qualitative and quantitative composition in terms of active substances and excipients, and;	**(a) they have the same qualitative and quantitative composition in terms of active substances and excipients, and;**
		(aa) they have the same pharmaceutical form, and;	**(aa) they have the same 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, withdrawal period; and,	**information and, if applicable, withdrawal period; and,**
		(bb) they have been manufactured by the same manufacturer or by a manufacturer working under licence according to the same formulation;	**(bb) they have been manufactured by the same manufacturer or by a manufacturer working under licence according to the same formulation;**
		1a. The veterinary medicinal product obtained from a source Member State shall comply with the labelling and language requirements of the destination Member State.	**1a. The veterinary medicinal product obtained from a source Member State shall comply with the labelling and language requirements of the destination Member State.**
		2. Competent authorities shall lay down administrative procedures for the parallel trade in veterinary medicinal products and administrative procedure for the approval of the application for paralell trade in such products.	**2. Competent authorities shall lay down administrative procedures for the parallel trade in veterinary medicinal products and administrative procedure for the approval of the application for paralell trade in such products.**
		3. Competent authorities of the destination Member State shall make public the list of veterinary medicinal products that are parallel traded in that Member State, in the product database as referred to in Article 51.	**3. Competent authorities of the destination Member State shall make public the list of veterinary medicinal products that are parallel traded in that Member State, in the product database as referred to in Article 51.**
		4. A wholesale distributor who is not the marketing authorisation holder shall notify the marketing	**4. A wholesale distributor who is not the marketing authorisation holder shall notify the marketing**

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		authorisation holder and the competent authority of the source Member State of his intention to parallel trade the veterinary medicinal product to a destination Member State.[64]	**authorisation holder and the competent authority of the source Member State of his intention to parallel trade the veterinary medicinal product to a destination Member State.**
		5. A wholesale distributor intending to parallel trade a veterinary medicinal product to a destination Member State shall comply with at least the following obligations:	**5. A wholesale distributor intending to parallel trade a veterinary medicinal product to a destination Member State shall comply with at least the following obligations:**
		(a) submit a declaration to the competent authority in the destination Member State and take appropriate measures to ensure that the wholesale distributor in the source Member State will keep him informed of any pharmacovigilance issues;	**(a) submit a declaration to the competent authority in the destination Member State and take appropriate measures to ensure that the wholesale distributor in the source Member State will keep him informed of any pharmacovigilance issues;**
		(b) notify the marketing authorisation holder in the destination Member State about the veterinary medicinal product to be procured from the source Member State and intended to be placed on the market in the destination Member State at	**(b) notify the marketing authorisation holder in the destination Member State about the veterinary medicinal product to be procured from the source Member State and intended to be placed on the market in the 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;**
		(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;	**(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.	**(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.	**(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 shall be attached to the list referred to in paragraph 3 in respect of all veterinary medicinal products:	**6. The following information shall be attached to the list referred to in paragraph 3 in respect of all veterinary medicinal products:**
		(a) name of the veterinary medicinal product(s);	**(a) name of the veterinary medicinal product(s);**
		(b) active substance(s);	**(b) active substance(s);**
		(c) pharmaceutical form(s);	**(c) pharmaceutical form(s);**
		(d) classification of the veterinary medicinal product(s) in the destination Member State;	**(d) classification of the veterinary medicinal product(s) in the destination Member State;**
		(e) marketing authorisation number of the veterinary medicinal product(s) in the Member State from where it is sourced;	**(e) marketing authorisation number of the veterinary medicinal product(s) in the Member State from where it is sourced;**
		(f) marketing authorisation number of the veterinary medicinal product(s) in the Member State of destination;	**(f) marketing authorisation number of the veterinary medicinal product(s) in the Member State of destination;**
		(g) name and address of the wholesale distributor in the source Member State and of the wholesale distributor in the destination Member State.	**(g) name and address of the wholesale distributor in the source Member State and of the wholesale distributor in the 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 Retail		**Section 2 Retail**	**Section 2 Retail**
Article 107 Retail of veterinary medicinal products and record keeping		*Article 107 Retail of veterinary medicinal products and record keeping*	*Article 107 Retail of veterinary medicinal products and record keeping*
1. The retail of veterinary medicinal products shall be conducted only by persons who are permitted to carry out such operations under national law.		1. **The rules on** […] retail of veterinary medicinal products shall be **determined** […] by […] national law**, unless otherwise provided in this Regulation**.	1. **The rules on** […] retail of veterinary medicinal products shall be **determined** […] by […] national law**, unless otherwise provided in 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 ***immediate*** care, ***subject to an appropriate veterinary***	~~2.~~ […]	~~2.~~ […]

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concerned.	***diagnosis and examination of the animal(s) concerned,*** 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.***		

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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.***		
3. Retailers of veterinary medicinal products shall keep detailed records of the following information in respect of each purchase and sale of veterinary medicinal products:	**AM 228** 3. Retailers of veterinary medicinal products shall keep detailed records of the following information in respect of each purchase and sale of veterinary medicinal products ***obtainable only on prescription***:	3. Retailers of veterinary medicinal products shall keep detailed records of the following information in respect of each **transaction** […] of veterinary medicinal products **requiring a veterinary prescription under Article 29**:	3. Retailers of veterinary medicinal products shall keep detailed records of the following information in respect of each **transaction** […] of veterinary medicinal products **requiring a veterinary prescription under Article 29**:

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	AM 229 **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 medicinal product;		(b) name of the veterinary medicinal product **including pharmaceutical form and strength, as appropriate**;	(b) name of the veterinary medicinal product **including pharmaceutical form and strength, 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 supplier in the event of purchase, or of the recipient in the event of sale;		(e) name and address of the supplier in the event of purchase, or of the recipient in the event of sale;	(e) name and address of the supplier in the event of purchase, or of the recipient in the event of sale;
(f) name and address of the prescribing veterinarian and a copy of the prescription in case of veterinary medicinal products requiring a prescription in accordance with Article 29.		(f) name and […] **contact details** of the prescribing veterinarian and a copy of the **veterinary** prescription, **where appropriate** […].	(f) name and […] **contact details** of the prescribing veterinarian and a copy of the **veterinary** prescription, **where appropriate** […].

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

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		proportional and non-discriminatory.	**conditions comply with Union law, are ~~proportional~~ proportionate and non-discriminatory.**
Article 108 *Retail of veterinary medicinal products at a distance*		*Article 108* *Retail of veterinary medicinal products at a distance*	*Article 108* *Retail of veterinary medicinal 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.	**AM 230** 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 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.~~***:*** ***(a) the veterinary medicinal***	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.***		

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	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 has provided a secure system for 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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		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 rules on the withdrawal of such permissions.	**1aa. <u>That</u> Member State <u>shall ensure that adapted measures are in place in order to guarantee that the requirements relating to a veterinary prescription are respected as regards supply by means of information society services and</u> ~~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 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.**
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2. In addition to the information requirements set out in Article 6 of the Directive 2000/31/EC of the European Parliament and of the Council[66], websites offering veterinary medicinal products shall contain at least:	2. In addition to the information requirements set out in Article 6 of the Directive 2000/31/EC of the European Parliament and of the Council ***and Article 6 of Directive 2011/83/EU of the European Parliament and of the Council***[67], websites offering veterinary medicinal products shall contain at least:	2. In addition to the information requirements set out in Article 6 of the Directive 2000/31/EC of the European Parliament and of the Council, **retailers** […] offering veterinary medicinal products **by means of information society services** shall **provide** […] at least **the following information**:	2. In addition to the information requirements set out in Article 6 of the Directive 2000/31/EC of the European Parliament and of the Council[68], **retailers** […] offering veterinary medicinal products **by means of information society services** shall **provide** […] at least **the following information**:
(a) the contact details of the competent authority of the Member State in which the retailer offering the veterinary medicinal products is established;		(a) the contact details of the competent authority of the Member State in which the retailer offering the veterinary medicinal products is established;	(a) the contact details of the competent authority of the Member State in which the retailer offering the veterinary medicinal products is established;
(b) a hyperlink to the website of the Member State of establishment set up in accordance with paragraph 5;		(b) a hyperlink to the website of the Member State of establishment set up in accordance with paragraph 5;	(b) a hyperlink to the website of the Member State of establishment set up in accordance with paragraph 5;

[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 in accordance with paragraph 3 clearly displayed on every page of the website that relates to the offer for sale at a distance to the public of veterinary medicinal products and containing a hyperlink to the entry of the retailer in the list of authorised retailers referred to in point (c) of paragraph 5.		(c) the common logo established in accordance with paragraph 3 clearly displayed on every page of the website that relates to the offer for sale at a distance […] of veterinary medicinal products and containing a hyperlink to the entry of the retailer in the list of […] **permitted** retailers referred to in point (c) of paragraph 5.	(c) the common logo established in accordance with paragraph 3 clearly displayed on every page of the website that relates to the offer for sale at a distance […] of veterinary medicinal products and containing a hyperlink to the entry of the retailer in the list of […] **permitted** retailers referred to in point (c) of paragraph 5.
3. A common logo shall be established that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering veterinary medicinal products for sale at a distance to the public is established. The logo shall be clearly displayed on websites offering veterinary medicinal products for sale at a distance.		3. A common logo shall be established that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering veterinary medicinal products for sale at a distance […] is established. The logo shall be clearly displayed on websites offering veterinary medicinal products for sale at a distance.	3. A common logo shall be established that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering veterinary medicinal products for sale at a distance […] is established. The logo shall be clearly displayed on websites offering veterinary medicinal products for sale at a distance.
4. The Commission shall adopt the design of the common logo by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).		4. The Commission shall adopt the design of the common logo **referred to in paragraph 3** by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	4. The Commission shall adopt the design of the common logo **referred to in paragraph 3** by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 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 medicinal products at a distance, providing at least the following information:		a website regarding sale of veterinary medicinal products at a distance, providing at least the following information:	a website regarding sale of veterinary medicinal products at a distance, providing at least the following information:
(a) information on its national legislation applicable to the offering of veterinary medicinal products for sale at a distance to the public by means of information society services, including information on the fact that there may be differences between Member States regarding the classification of the supply of the veterinary medicinal products;	**AM 230** (a) information on its national legislation applicable to the offering of veterinary medicinal products for sale at a distance ~~to the public by means of information society services,~~ ***on the internet***, including information on the fact that there may be differences between Member States regarding the classification of the supply of the veterinary medicinal products;	(a) information on its national legislation applicable to the offering of veterinary medicinal products for sale at a distance […] by means of information society services, **in accordance with paragraphs 1 and 1a,** including information on the fact that there may be differences between Member States regarding the classification of the supply of the veterinary medicinal products;	(a) information on its national legislation applicable to the offering of veterinary medicinal products for sale at a distance […] by means of information society services, **in accordance with paragraphs 1 and 1a,** including information on the fact that there may be differences between Member States regarding the classification of the supply of the veterinary medicinal products;
(b) information on the common logo;		(b) information on the common logo;	(b) information on the common logo;
(c) a list of retailers established in the Member State authorised to offer veterinary medicinal products for sale at a distance to the public by means of information society services in accordance with paragraph 1 as well as the website addresses of those retailers.	**AM 230** (c) a list of retailers established in the Member State authorised to offer veterinary medicinal products for sale at a distance to the public ***on the internet*** in accordance with paragraph 1 as well as the website addresses of those retailers***; and also a hyperlink to the website of the Agency set up in accordance with paragraph 6;*** ***(ca) information on applicable***	(c) a list of retailers established in the Member State […] **permitted** to offer veterinary medicinal products for sale at a distance […] by means of information society services in accordance with paragraph**s** 1 **and 1a** as well as the website addresses of those retailers.	(c) a list of retailers established in the Member State […] **permitted** to offer veterinary medicinal products for sale at a distance […] by means of information society services in accordance with paragraph**s** 1 **and 1a** as well as the website addresses of those retailers.

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	procedures for the safe disposal of medicinal products, specifying the public or private body responsible at national or local level for the disposal of veterinary medicine residues and the collection points for disposal free of charge; ***(cb) hyperlinks to the web pages of the bodies responsible in Member States for listing authorised national retailers.***		
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 retailers in Member States.		
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.	**AM 230** 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.~~ ***7a. Member States shall take the measures necessary to ensure that persons other than those referred to in paragraph 1 offering veterinary medicinal products for sale at a distance to the public on the internet and operating on their territory are subject to effective, proportionate, and dissuasive penalties in case of abuse or illegal practice, or the failure to act according to their professional 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,***	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.

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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 Member States shall contain a hyperlink to the website of the Agency set up in accordance with paragraph 6.	**8. The websites set up by Member States shall contain a hyperlink to the website of the Agency set up in accordance with paragraph 6.**

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Article 109 *Retail of anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic veterinary medicinal products*	**AM 231** **Article 109 title** Retail ***only*** of ***medicinal products which are subject to prescription, or active substances, with*** anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal, ***immunological*** or psychotropic ~~veterinary medicinal products~~ ***properties***	~~*Article 109*~~ […]	~~*Article 109*~~ […]
1. Only manufacturers, wholesale distributors and retailers authorised specifically to do so in accordance with applicable national law shall be allowed to supply and purchase veterinary medicinal products which have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties or substances which may be used as veterinary medicinal products having those properties.	**AM 232** 1. Only manufacturers, wholesale distributors and retailers authorised ~~specifically~~ to do so in accordance with applicable national law shall be allowed to supply and purchase ***prescription only*** veterinary medicinal products which have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal***,*** ***immunological*** or psychotropic 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)***	[…]	[…]

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	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 ***of prescription for veterinary medicinal products***:	[…]	[…]
(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 supplier in the event of purchase, or of the recipient in the event of sale.	**AM 234** (d) name and address of the supplier in the event of purchase ~~, or of the recipient in the event of sale~~.	[…]	[…]

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These records shall be available for inspection by the competent authorities in accordance with Article 125 for a period of 3 years.		[…]	[…]
Article 110 *Veterinary prescriptions*		*Article 110* *Veterinary prescriptions*	*Article 110* *Veterinary prescriptions*
			00. A veterinary prescription for an antimicrobial medicinal product for metaphylaxis shall only be issued after a diagnosis of the infectious disease by a veterinarian. **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 shall be issued only after a clinical examination or any other proper assessment of the health status of the animal or group of animals by a veterinarian.	**0. A veterinary prescription shall be issued only after a clinical examination or any other proper assessment of the health status of the animal or group of animals by a veterinarian.**
		1a. By way of derogation from paragraph 0, a Member State may allow that a veterinary prescription is issued by a professional person qualified to do	**1a. By way of derogation from Article 4(24) and paragraph 0 of this Article, a Member State may allow that a veterinary prescription is issued by a**

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		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.	**professional 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;

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(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~~ ***issuing*** 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).

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(k) withdrawal period if relevant;		(k) **for food producing species**,withdrawal period **even if zero days** […];	(k) **for food producing species**,withdrawal period **even if zero days** […];
(l) any necessary warnings;	**AM 235** (l) any necessary warnings ***and restrictions, including, where relevant, the risks entailed by imprudent use of antimicrobials;***	(l) any […] warnings **necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials**;	(l) 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 marketing authorisation for that product, a statement to that effect.		(m) if a product is prescribed […] **under the provisions of Articles 115, 116 and 116a**, a statement to that effect;	(m) if a product is prescribed […] **under the provisions of Articles 115, 116 and 116a**, a statement to that effect;
		(n) if a product is prescribed under the provisions of Article 111a paragraphs 2, 2aa and 3, a statement to that effect.	**(n) if a product is prescribed under the provisions of Article 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 ***veterinarian or other*** person qualified to do so in accordance with applicable national law***, following a proper assessment of the health status of the animal concerned***.	2. […]	2. […]

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	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.***		
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** 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. […]**T**he quantity prescribed […] shall be **limited** […] to the amount required for the treatment or therapy concerned.	3. […]**T**he quantity prescribed […] shall be **limited** […] to the amount required for the treatment or therapy concerned. **As regards antimicrobial medicinal products for metaphylaxis or prophylaxis such products shall be prescribed only for a limited duration to cover the period of risk.**

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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 ***issued by a veterinarian*** 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.***		

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		5. The Commission may, by means of implementing acts, set a model format for the requirements set in paragraph 1, which model format shall also be made available in electronic version. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	**5. The Commission may, by means of implementing acts, set a model format for the requirements set in paragraph 1, which model format shall also be made available in electronic version. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**
		6. The medicinal product prescribed shall be supplied in accordance with applicable national law.	**6. The medicinal product prescribed shall be supplied in accordance with applicable national law.**
		7. A veterinary prescription for antimicriobial medicinal products shall be valid for 5 days from the date of issuing.	**7. A veterinary prescription for antimicriobial medicinal products shall be valid for 5 days from the date of issuing.**
		8. In addition to the requirements set out in this Article, Member States may lay down rules on record keeping for veterinarians when issuing veterinary prescriptions.	**8. In addition to the requirements set out in this Article, Member States may lay down rules on record keeping for veterinarians when issuing veterinary prescriptions.**
		9. Notwithstanding Article 29, a veterinary medicinal product classified as subject to veterinary prescription under that Article may be administered by a veterinarian himself without a	**9. Notwithstanding Article 29, a veterinary medicinal product classified as subject to veterinary prescription under that Article may be administered by a veterinarian himself without a**

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		veterinary prescription, unless otherwise provided for under applicable national law. The veterinarian shall keep records in accordance with applicable national law.	**veterinary prescription, unless otherwise provided for under applicable national law. The veterinarian shall keep records in accordance with applicable national law.**
Section 3 **Use**		**Section 3** **Use**	**Section 3** **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 ***responsibly*** in accordance ***with the principle of good animal husbandry and*** with the terms of the marketing authorisation ***or registration when no marketing authorisation is required.***	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.
		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.	**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[70].**
2. Member States shall lay down procedures for placing on the market		2. Member States […] **may** lay down […] **any** procedures **they**	2. Member States […] **may** lay 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).

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of the medicinal products allowed to be used in their territory in accordance with Articles 115, 116, 119, 120 and 121.		**deem necessary** for **the** […] **implementation** […] **of** Articles **113, 114,** 115, 116, **116a and** 119 […].	**deem necessary** for **the** […] **implementation** […] **of** Articles **113, 114,** 115, 116, **116a and** 119 […].
	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***		

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	used for non-routine metaphylaxis, owners and keepers of food-producing animals shall ensure that they have a health plan specifying appropriate non-medical measures to reduce the need to resort to metaphylactic use in the future. Moreover, they shall be required to comply with the following measures: ***(i) using good healthy breeding stock with suitable genetic diversity;*** ***(ii) conditions that respect the behavioural needs of the species, including social interactions/hierarchies;*** ***(iii) stocking densities that do not increase risk of disease transmission;*** ***(iv) isolation of sick animals away from the rest of the group;*** ***(v)for chickens and smaller animals, subdivision of flocks into smaller, physically separated groups;*** ***(vi) implementation of existing animal welfare rules already in cross compliance under the Common Agricultural Policy's***		

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	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 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**

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		for the target animal species and the indication.	**for the target animal species and the indication.**
		5. The Commission may, by means of implementing acts, establish rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via other routes than medicated feed, such as mixing of water for drinking with a veterinary medicinal product or as manual mixing of a veterinary medicinal product into feed and administered by the animal keeper to food producing animals. The Commission shall take into account the scientific advice of the Agency, when adopting those implementing acts. **Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**	**5. The Commission ~~may, by means of implementing~~ shall adopt delegated acts, in accordance with Article 146, supplementing the provisions of this Article, as necessary, concerning the establishment of rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via other routes than medicated feed, such as mixing of water for drinking with a veterinary medicinal product or as manual mixing of a veterinary medicinal product into feed and administered by the animal keeper to food producing animals. The Commission shall take into account the scientific advice of the Agency, when adopting those ~~implementing~~ delegated acts. ~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).~~**
	AM 239		

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	Article 111 a (new) ***Article 111a*** ***Supply and use of antimicrobials***	***Article 111a*** ***Use of antimicrobial medicinal products*** **1. Antimicrobial medicinal products shall not be applied routinely nor used to compensate for poor hygiene, or inadequate animal husbandry or lack of care or to compensate for poor farm management.** **1a. Antimicrobial medicinal products shall not be used in animals for the purpose of promoting growth or increase yield.**	***Article 111a*** ***Use of antimicrobial medicinal products*** **1. Antimicrobial medicinal products shall not be applied routinely nor used to compensate for poor hygiene, or inadequate animal husbandry or lack of care or to compensate for poor farm management.** **1a. Antimicrobial medicinal products shall not be used in animals for the purpose of promoting growth or increase yield.**
		2. Antimicrobial medicinal products shall not be used for prophylaxis unless, in exceptional cases for the treatment of a restricted number of animals when the risk for infection is very high and the consequences of the infection are likely to be severe.	**2. Antimicrobial medicinal products shall not be used for prophylaxis unless, in exceptional cases for the ~~treatment of~~ administration to an individual animal or a restricted number of animals when the risk ~~for~~ of an infection or of an infectious disease 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**

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			administration to individual animal only, under the conditions laid down in the first sentence.
		2aa. Antibiotics shall not be used for prophylaxis unless in exceptional cases for the treatment of an individual animal when the risk of development or spread of infectious disease is very high or the consequences of the infection are likely to be severe.	**~~2aa. Antibiotics shall not be used for prophylaxis unless in exceptional cases for the treatment of an individual animal when the risk of development or spread of infectious disease is very high or the consequences of the infection are likely to be severe.~~**
		3. Antimicrobial medicinal products shall be used for metaphylaxis only when the risk of spread of infection in a group of animals is high.	**3. Antimicrobial medicinal products shall be used for metaphylaxis only when the risk of spread of an infection or of an infectious disease in ~~a~~ the group of animals is high and where no other 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 referred to in Article 32(4) shall not be used in accordance with	**4. The designated antimicrobials referred to in Article 32(4) shall not be used in accordance with**

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		Articles 115, 116 and 116a. **5. The Commission may, by means of implementing acts, and taking into consideration scientific advice of the Agency, establish a list of antimicrobials which:** **(a) shall not be used in accordance with Articles 115, 116 and 116a, or** **(b) shall only be used in accordance with Articles 115, 116 and 116a subject to certain conditions.** **When adopting those implementing acts, the Commission shall take account of the following criteria:** **(a) risks to animal or public health if the antimicrobials is used in accordance with Articles 115, 116 and 116a;** **(b) risk for animal or public health in case of development of antimicrobial resistance;** **(c) availability of other treatments for animals,** **(d) availability of other antimicrobial treatments for humans;**	**Articles 115, 116 and 116a.** **5. The Commission may, by means of implementing acts, and taking into consideration scientific advice of the Agency, establish a list of antimicrobials which:** **(a) shall not be used in accordance with Articles 115, 116 and 116a, or** **(b) shall only be used in accordance with Articles 115, 116 and 116a subject to certain conditions.** **When adopting those implementing acts, the Commission shall take account of the following criteria:** **(a) risks to animal or public health if the antimicrobials is used in accordance with Articles 115, 116 and 116a;** **(b) risk for animal or public health in case of development of antimicrobial resistance;** **(c) availability of other treatments for animals,** **(d) availability of other antimicrobial treatments for humans;**

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		(e) impact on aquaculture and farming if the animal affected by the condition receives no treatment. **Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).** **6. A Member State may further restrict or prohibit the use of certain antimicrobials in animals on its territory if the administration of such products to animals is contrary to the implementation of a national policy on prudent use of antimicrobials.**	**(e) impact on aquaculture and farming if the animal affected by the condition receives no treatment.** **Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).** **6. A Member State may further restrict or prohibit the use of certain antimicrobials in animals on its territory if the administration of such products to animals is contrary to the implementation of a national policy on prudent use of antimicrobials.**
	1. Member States may restrict or prohibit the supply or use, or both, of certain antimicrobials in		

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	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 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.*** ***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.***	**7. Measures adopted on the basis of paragraph (6) shall be proportionate and justified.** **8. The Member State shall inform the Commission of any measure it has adopted on the basis of paragraph (6).**	**7. Measures adopted on the basis of paragraph (6) shall be proportionate and justified.** **8. The Member State shall inform the Commission of any measure it has adopted on the basis of paragraph (6).**

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	4. A Member State adopting a measure on the basis of paragraph 1 shall inform the Commission thereof.		
Article 112 *Record keeping by owners and keepers of food-producing animals*		*Article 112* *Record keeping by owners and keepers of food-producing animals*	*Article 112* *Record keeping by owners and keepers of food-producing animals*
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.	**AM 240** 1. Owners or, where the animals are not kept by the owners, keepers of food-producing animals shall keep records of the ***veterinarian-prescribed*** veterinary medicinal products ***and veterinary medicinal products with a withdrawal period higher than nil*** 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 ***and the disease treated***;	(a) date of […] **first administration of** the […] medicinal product to the animal**s**;	(a) date of […] **first administration of** the […] medicinal product to the animal**s**;
(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 ***and, if applicable, a copy of the delivery note*** ;	(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 ***and the diagnosis of the disease treated***;	(e) identification of the animal~~s~~ **or group of animals** treated;	(e) identification of the animal~~s~~ **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 **Article 112 -- paragraph 2 a (new)** ***2a. Particulars already contained in the prescription or in a delivery note shall not need to be recorded again if a clear reference can be made to the corresponding prescription and delivery note.***	**2a. If the information to be recorded in accordance with paragraph 2 is already available on the copy of veterinary prescription, in a record kept on the farm or for equine animals recorded in the single lifetime identification document referred to in Article 114(1)(c) of Regulation (EU) 2016/429, it does not need to be recorded separately.**	**2a. If the information to be recorded in accordance with paragraph 2 is already available on the copy of veterinary prescription, in a record kept on the farm or for equine animals recorded in the single lifetime identification document referred to in Article 114(1)(c) of Regulation (EU) 2016/429, it does not need to be recorded separately.**
		2b. Member States may lay down additional requirements for record-keeping by owners and keepers of food producing animals.	**2b. Member States may lay down additional requirements for record-keeping by owners and 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 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 these records shall be available for inspections by the competent authorities in accordance with Article 125 for a period of at least 3 years		3. The information contained in these records shall be available for inspections by the competent authorities in accordance with Article 125 for a period of at least […] **five** years.	3. The information contained in these records shall be available for inspections by the competent authorities in accordance with Article 125 for a period of at least […] **five** years.
		Article 112b ***Record keeping obligations for equine animals***	***Article 112b*** ***Record keeping obligations for equine animals***
		1. The Commission shall adopt delegated acts in accordance with Article 146 supplementing this Regulation concerning the content and format of the information necessary to apply Articles 115(3) and 117(5) to be contained in the single lifetime identification document referred to in Article 114(1)(c) of Regulation (EU) 2016/429.	**1. The Commission shall adopt delegated acts in accordance with Article 146 supplementing this Regulation concerning the content and format of the information necessary to apply Articles 115(3) and 117(5) to be contained in the single lifetime identification document referred to in Article 114(1)(c) of Regulation (EU) 2016/429.**

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

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

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		veterinary medicinal product not authorised within the Union.[71]	**veterinary medicinal product not authorised within the Union.**
		2a. By way of derogation from Article 111(1), when immunological veterinary medicinal product has been authorised but is no longer available within the Union for a disease which is not referred to in Article 5 or Article 6 of Regulation (EU) No 429/2016 but which is already present in the Union, a competent authority may, in the interest of animal health, welfare and public health, allow the use of an immunological veterinary medicinal product not authorised within the Union on a case by case basis.	**2a. By way of derogation from Article 111(1), when immunological veterinary medicinal product has been authorised but is no longer available within the Union for a disease which is not referred to in Article 5 or Article 6 of Regulation (EU) No 429/2016 but which is already present in the Union, a competent authority may, in the interest of animal health, welfare and public health, allow the use of an immunological veterinary medicinal product not authorised within the Union on a case by case basis.**
		3. The competent authorities shall inform the Commission without delay when the provisions of paragraph 1, 2 and 2a are applied, together with information on the conditions imposed in the implementation of those provisions.	**3. The competent authorities shall inform the Commission without delay when the provisions of paragraph 1, 2 and 2a are applied, together with information on the conditions imposed in the implementation of those provisions.**
		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 thereby subject to specific binding health rules in that third country, a competent authority may permit the use, solely 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 its use is allowed in the third country to where the animal is to be exported.[72]	**exported to a third country and is thereby subject to specific binding health rules in that third country, a competent authority may permit the use, solely 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 its use is allowed in the third country to where the animal is to be exported.**
Article 114 *Veterinarians providing services in other Member States*		*Article 114* *[…]**Use of veterinary medicinal products by veterinarians** providing services **in other Member States***	*Article 114* *[…]**Use of veterinary medicinal products by veterinarians** providing services **in other Member States***
1. A veterinarian providing services in a Member State other than the one where he is established (the 'host Member State') may administer veterinary medicinal products authorised in the host Member State to animals in another Member State which are under his care in the amount required for the treatment of those animals where the following conditions are fulfilled:		1. A veterinarian providing services in a **'host** Member State**' (a Member State** other than the one where he is established**)** […] **shall be allowed to** […] **possess and** […] **treat animals with** veterinary medicinal products **which are not** authorised in th**at**[…] host Member State to animals **or groups of animals** […] which are under his care in the […] **necessary quantity not exceeding the amount** required	1. A veterinarian providing services in a **'host** Member State**' (a Member State** other than the one where he is established**)** […] **shall be allowed to** […] **possess and** […] **treat animals with** veterinary medicinal products **which are not** authorised in th**at**[…] host Member State to animals **or groups of animals** […] which are under his care in the […] **necessary quantity 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 veterinarian provided that the following conditions are fulfilled**:	for the treatment **prescribed by the veterinarian provided that the following conditions are fulfilled**:
(a) the authorisation to place the veterinary medicinal product on the market provided for in Article 5 has been issued by the competent authorities of the host Member State or by the Commission;		(a) **a** […] **marketing** authorisation […] **for** the veterinary medicinal product **to be administered to the animals has been granted** […] by the competent authorities of the […] Member State **in which the veterinarian is established** or by the Commission;	(a) **a** […] **marketing** authorisation […] **for** the veterinary medicinal product **to be administered to the animals has been granted** […] by the competent authorities of the […] Member State **in which the veterinarian is established** or by the Commission;
(b) the veterinary medicinal products are transported by the veterinarian in the original packaging;		(b) the **concerned** veterinary medicinal products are transported by the veterinarian in the**ir** original packaging;	(b) the **concerned** veterinary medicinal products are transported by the veterinarian in the**ir** original packaging;
(c) where intended for administration to food-producing 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;		~~(c)~~ […]	~~(c)~~ […]

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(d) the veterinarian follows the good veterinary practices applied in that Member State and ensures that the withdrawal period specified on the labelling of the veterinary medicinal product is observed;		(d) the veterinarian follows the good veterinary practices applied in that **host** Member State […];	(d) the veterinarian follows the good veterinary practices applied in that **host** Member State […];
		(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 a**n 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 a**n 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***	[…].	[…].

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2001/83/EC of the European Parliament and of the Council[73] or Regulation (EC) No 726/2004;			
(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.	**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).

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	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.***		
		(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 authorised in a third country for the same animal species and same indication.	**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.**

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2. The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility.		~~2.~~ […]	**2. 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.**
3. Paragraph 1 of this Article shall also apply to the treatment by a veterinarian of an animal belonging to the equidae family provided that it has been declared, in accordance with Regulation (EC) No 504/2008, as not being intended for slaughter for human consumption.		3. […] **T**his Article shall also apply to the treatment by a veterinarian of an animal belonging to the […] **equine species** provided that it […] **is** declared […] as not being intended for slaughter for human consumption **in the single lifetime identification document referred to in Article 114(1) of Regulation (EU) No 2016/429**.	3. […] **T**his Article shall also apply to the treatment by a veterinarian of an animal belonging to the […] **equine species** provided that it […] **is** declared […] as not being intended for slaughter for human consumption **in the single lifetime identification document referred to in Article 114(1) of 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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		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 a**n 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 animal**s** 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 a**n 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 animal**s** 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) ~~a~~ ***any*** 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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	~~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 Member State concerned in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004. 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***	**terrestrial species for the same indication, or for another indication;**	**species for the same indication, or for another indication;**

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	national law.		
(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 point**s** (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 point**s** (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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	species for the condition in 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*;*		[…]	[…]
(b) 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.	**AM 252** (b) ***if there is no product as referred to in point (a),*** 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.	[…]	[…]
	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 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 personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat food producing terrestrial animals with a veterinary medicinal product	**4a. 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 personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat food producing terrestrial animals with 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 ***and paragraph 3(b)*** 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 paragraph**s 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 paragraph**s 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 records of the date of examination of the animals, details of the owner, the number of animals treated, the diagnosis, the medicinal products 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.		8. […] **This Article shall apply also when an authorised veterinary medicinal product is not available in the Member State concerned.**	8. […] **This Article shall apply also when an authorised veterinary medicinal product is not available in the Member State concerned.**
		Article 116a ***Use of veterinary medicinal products for food producing aquatic species***	***Article 116a*** ***Use of veterinary medicinal products for food producing aquatic species***
		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 aquatic species, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable	**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 aquatic species, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable**

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

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		with paragraph 3; or,	**with paragraph 3; or,**
		(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.**
		2. By way of derogation from paragraphs 1 (b) and (c), until the list referred to in paragraph 3 is established, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat food-producing aquatic species of a particular holding with:	**2. By way of derogation from paragraphs 1 (b) and (c), until the list referred to in paragraph 3 is established, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat food-producing aquatic species of 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 terrestrial species;	**(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 terrestrial species;**
		(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 or under 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 or under Regulation (EC) No 726/2004.**

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

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

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

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criteria:		criteria:	criteria:
(a) for meat and offal of food producing mammals and birds not less than:		(a) for meat and offal **from** […] food producing mammals and **poultry and farmed game** birds not less than:	(a) for meat and offal **from** […] food producing mammals and **poultry and farmed game** birds not less than:
(i) the longest withdrawal period provided in its summary of the product characteristics for any animal species multiplied by factor 1,5;		(i) the longest withdrawal period provided in its summary of the product characteristics for […] **meat and offal** multiplied by factor 1,5;	(i) the longest withdrawal period provided in its summary of the product characteristics for […] **meat and offal** multiplied by factor 1,5;
(ii) if the product is not authorised for food producing species, 28 days;		(ii) if the product is not authorised for food producing […] **animals**, 28 days;	(ii) if the product is not authorised for food producing […] **animals**, 28 days;
		(iii) one day, if the product has a zero days withdrawal period and it is used in a different animal family than the one authorised.	**(iii) one day, if the product has a zero days withdrawal period and it is used in a different animal family than the one authorised.**
(b) for animal species producing milk for human consumption not less than:		(b) for **milk from** animal**s** […] producing milk for human consumption not less than:	(b) for **milk from** animal**s** […] producing milk for human consumption not less than:
(i) the longest withdrawal period provided in the summary of the product characteristics for any milk producing species multiplied by factor 1.5;		(i) the longest withdrawal period **for milk** provided in the summary of the product characteristics for any **animal** […] multiplied by factor 1.5;	(i) the longest withdrawal period **for milk** provided in the summary of the product characteristics for any **animal** […] multiplied 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 human consumption 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 degree days, but not exceeding 500 degree-days;**	(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;	**(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**

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		rounded up to the nearest number of days.	**rounded up to the nearest number of days.**
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to amend the rules laid down in paragraph 1 in the light of new scientific evidence.		2. The Commission **is** […] empowered to adopt delegated acts in accordance with Article 146 in order to amend the rules laid down in paragraph 1 **and 3** in the light of new scientific evidence.	2. The Commission **is** […] empowered to adopt delegated acts in accordance with Article 146 in order to amend the rules laid down in paragraph 1 **and 3** in the light of new scientific evidence.
3. For bees, the veterinarian shall determine the appropriate withdrawal period by assessing the specific situation of the particular beehive(s) on a case-by-case basis.		3. For bees, the veterinarian shall determine the appropriate withdrawal period […] by assessing the specific situation of the particular beehive(s) on a case-by-case basis **and in particular risk of residue in honey or in any other foodstuffs harvested from beehive(s) intended for human consumption**.	3. For bees, the veterinarian shall determine the appropriate withdrawal period […] by assessing the specific situation of the particular beehive(s) on a case-by-case basis **and in particular risk of residue in honey or in any other foodstuffs harvested from beehive(s) intended for human consumption**.
4. With regard to homeopathic veterinary medicinal products the withdrawal period shall be established at zero days.	**AM 256** 4. ~~With regard to~~ ***The withdrawal period shall be established at zero days for*** 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".***	~~4.~~ […]	~~4.~~ […]
5. By way of derogation from		5. By way of derogation from	5. By way of derogation from

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paragraph 1, the Commission shall establish a list of substances:		paragraph 1 **and paragraph 6 of Article 116**, the Commission shall**, by means of implementing acts,** establish a list of substances […].	paragraph 1 **and paragraph 6 of Article 116**, the Commission shall**, by means of implementing acts,** establish a list of substances […].
(a) which are essential for the treatment of equidae, or which bring added clinical benefit compared to other treatment options available for equidae;		[…] […] which are essential for the treatment of **equine species** […], or which bring added clinical benefit compared to other treatment options available for **equine species** […];	[…] […] which are essential for the treatment of **equine species** […], or which bring added clinical benefit compared to other treatment options available for **equine species** […];
(b) for which the withdrawal period for equidae shall not be less than six months subject to the control mechanisms laid down in Decisions 93/623/EEC and 2000/68/EC.		[…] for which […] the withdrawal period […] for **equine species** […] shall […] be […] six months […].	[…] for which […] the withdrawal period […] for **equine species** […] shall […] be […] six months […].
	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 adopted in accordance with the examination procedure referred to in Article 145(2).		Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	

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Article 118 *Use of antimicrobial veterinary medicinal products for species or indications outside the terms of the marketing authorisation*	**AM 258** *Use of antimicrobial ~~veterinary medicinal products~~* ***substances*** *for species or indications outside the terms of the marketing authorisation*	*~~Article 118~~* […]	*~~Article 118~~* […]
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	[…]	[…]

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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**,** ***including the risks involved in using antimicrobials critical to human health in food producing animals***;		
(b) risk for human health in case of development of antimicrobial resistance;			
(c) availability of other treatments for animals,			

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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.***		

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	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 *Health situation and listed diseases*		*Article 119* *Health situation […]*	*Article 119* *Health situation […]*
1. By way of derogation from Article 111, a competent authority may allow the use in its territory of veterinary medicinal products not authorised in that Member State, where the situation of animal or public health so requires, and the marketing of those veterinary medicinal products is authorised in		~~1.~~ By way of derogation from Article 111**(1),** a competent authority may allow the use in its territory of veterinary medicinal products not authorised in that Member State, where the situation of animal or public health so requires, and the marketing of those veterinary medicinal products	~~1.~~ By way of derogation from Article 111**(1),** a competent authority may allow the use in its territory of veterinary medicinal products not authorised in that Member State, where the situation of animal or public health so requires, and the marketing of those veterinary 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……).

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	suitable medicinal product and after informing the Commission of the detailed conditions of use.		
Article 120 *Exemption for veterinary medicinal products for certain animals kept exclusively as pets*		~~*Article 120*~~ [76] […]	~~*Article 120*~~ […]
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).

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Article 121 *Use of immunologicals from third countries*		~~*Article 121*~~[77] […]	~~*Article 121*~~ […]
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 *Disposal of veterinary medicinal products*		*Article 122* ***Collection and disposal of*** *[…]* ***waste of*** *veterinary medicinal products*	*Article 122* ***Collection and disposal of*** *[…]* ***waste of*** *veterinary medicinal products*
Member States shall ensure that appropriate collection systems are in place for veterinary medicinal products that are unused or expired.		Member States shall ensure that appropriate […] systems are in place for **the collection and disposal of waste of** veterinary medicinal products […].	Member States shall ensure that appropriate […] systems are in place for **the collection and disposal of waste of** veterinary medicinal products […].
	AM 267 **Article 122 -- paragraph 1 a**		

[77] Amended and moved in new paragraph 4 of Article 113.

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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 ***Animals or products of animal origin imported into the Union***	***Article 122a*** ***Animals or products of animal origin imported into the Union***
		1. The provisions of Article 111a(1a) shall apply, *mutatis mutandis,* to operators in third countries and they shall not use the designated antimicrobials referred to in Article 32(4), insofar as relevant in respect of animals or products of animal origin exported from such third countries to the Union, provided that this is compatible with relevant international agreements.	**1. The provisions of Article 111a(1a) shall apply, *mutatis mutandis,* to operators in third countries and they shall not use the designated antimicrobials referred to in Article 32(4), insofar as relevant in respect of animals or products of animal origin exported from such third countries to the Union~~., provided that this is compatible with relevant international agreements~~.**

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

[78] Ex. paragraph 3.

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	(new) ***1a. 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.~~ […]	**~~3.~~ […]**
		4. The suspension of a marketing authorisation shall	**4. The suspension of a marketing authorisation shall**

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		preclude the advertising of the veterinary medicinal product in the Member State where it is suspended during the period of suspension.	**preclude the advertising of the veterinary medicinal product in the Member State where it is suspended during the period of suspension.**
		5. Veterinary medicinal products shall not be distributed for promotional purposes except for small quantities of samples.	**5. Veterinary medicinal products shall not be distributed for promotional purposes except for small quantities of samples.**
		5a. Antimicrobial veterinary medicinal products shall not be distributed for promotional purposes as samples or in any other presentation.	**5a. Antimicrobial veterinary medicinal products shall not be distributed for promotional purposes as samples or in any other presentation.**
		6. The samples referred to in paragraph 5 shall be appropriately labelled indicating that they are samples and given directly to veterinarians or other persons allowed to supply during sponsored events or by sales representatives during their visits.	**6. The samples referred to in paragraph 5 shall be appropriately labelled indicating that they are samples and given directly to veterinarians or other persons allowed to supply during sponsored events or by sales representatives during their visits.**

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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;		(a) […] **veterinarians**;	(a) […] **veterinarians**;
(b) veterinary medicinal products 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.		(b) […] **persons permitted to supply veterinary medicinal products in accordance with the national legislation.**	(b) […] **persons permitted to 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**

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		may be permitted by the Member State provided the following conditions are fulfilled:	**may be permitted by the Member State provided the following conditions are fulfilled:**
		(a) the advertising is limited to immunological veterinary medicinal products;	**(a) the advertising is limited to immunological veterinary medicinal products;**
		(b) the advertising includes an express invitation to the professional keepers of animal to consult the veterinarian about the immunological veterinary medicinal product.	**(b) the advertising includes an express invitation to the professional keepers of animal to consult the veterinarian about the immunological veterinary medicinal product.**
		3. Notwithstanding the provisions of paragraphs 1 and 2 the advertising of inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of animals in a unit having a confirmed epidemiological link shall be prohibited to all persons.	**3. Notwithstanding the provisions of paragraphs 1 and 2 the advertising of inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of animals in a unit having a confirmed epidemiological link shall be prohibited to all persons.**
			Article 124a ***Promotion of medicinal products***

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			used in animals **1. 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.** **2. Persons qualified to prescribe or supply medicinal products as referred to in paragraph 1 shall not solicit or accept any inducement prohibited under that paragraph.** **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 ***Implementation of advertising provisions***	***Article 124~~a~~b*** ***Implementation of advertising provisions***
		Member States may lay down any procedures they deem necessary for the implementation of Articles 123 and 124.	**Member States may lay down any procedures they deem necessary for the implementation of Articles 123, ~~and~~ 124 and 124a.**
Chapter VIII **Inspections and controls**		**Chapter VIII** **Inspections and controls**	**Chapter VIII** **Inspections and controls**
Article 125 *Controls*		*Article 125* *Controls*	*Article 125* *Controls*
1. Competent authorities shall perform controls of manufacturers, importers, marketing authorisation holders, wholesale distributors and suppliers of the veterinary medicinal products regularly, on a risk-basis, in order to verify that the requirements as set out in this Regulation are complied with.	**AM 270** 1. Competent authorities shall perform controls of manufacturers, importers, marketing authorisation holders, wholesale distributors and suppliers of the veterinary medicinal products ***as well as animals and foodstuff*** regularly, on a risk-basis, in order to verify that the requirements as set out in this Regulation are complied with.	1. Competent authorities shall […] **carry out** controls of **the following persons:** – manufacturers **and** importers **of veterinary medicinal products and active substances;** – **distributors of active substances;** – marketing authorisation holders**;** – **holders of a** wholesale […] **distribution authorisation;** – **retailers** […]**;**	1. Competent authorities shall […] **carry out** controls of **the following persons:** – manufacturers **and** importers **of veterinary medicinal products and active substances;** – **distributors of active substances;** – marketing authorisation holders**;** – **holders of a** wholesale […] **distribution authorisation;** – **retailers** […]**;** – **owners and keepers of**

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		– **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.**	**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.**
	AM 271 **Article 125 -- paragraph 1 a (new)** ***1a. The Commission shall ensure a harmonised approach to inspections and controls of veterinary medicines throughout the Union.***	**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 […].	**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 […].
	AM 272 **Article 125 -- paragraph 1 b (new)** ***1b. 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.***		

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2. The risk-based controls referred to in paragraph 1 shall be carried out by the competent authorities taking account of:		2. The risk-based controls referred to in paragraph 1**a** shall be carried out by the competent authorities taking account of **at least:**	2. The risk-based controls referred to in paragraph 1**a** shall be carried out by the competent authorities taking account of **at least:**
(a) the risk of non-compliance with the legal requirements associated with the activities of the undertakings and the location of the activities,		(a) the **intrinsic** risk**s** […] associated with the activities of the […] **persons referred to in paragraph 1** and the location of the**ir** activities,	(a) the **intrinsic** risk**s** […] associated with the activities of the […] **persons referred to in paragraph 1** and the location of the**ir** activities,
(b) the entity's past record as regards the results of inspections performed on them and their compliance with the requirements,		(b) the […] **past record of the persons referred to paragraph 1** […] as regards the results of […] **controls** performed on them and their **previous** compliance […],	(b) the […] **past record of the persons referred to paragraph 1** […] as regards the results of […] **controls** performed on them and their **previous** compliance […],
(c) any information that might indicate non-compliance with the legal requirements,		(c) any information that might indicate non-compliance […],	(c) any information that might indicate non-compliance […],
(d) the potential impact of non-compliance with the requirements on public health, animal health and the environment.		(d) the potential impact of non-compliance […] on public health, animal health**, animal welfare** and the environment.	(d) the potential impact of non-compliance […] on public health, animal health**, animal welfare** and the environment.
3. Inspections may also be carried out upon request of another competent authority, the Commission or the Agency.		3. […] **Controls** may also be carried out upon request of […] **a** competent authority **of another Member State**, the Commission or the Agency.	3. […] **Controls** may also be carried out upon request of […] **a** competent authority **of another Member State**, the Commission or the Agency.

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4. The inspections shall be carried out by authorised representatives of the competent authority who shall be empowered to:		4. […] **Controls** shall be carried out by […] representatives of the competent authority**.** […]	4. […] **Controls** shall be carried out by […] representatives of the competent authority**.** […]
		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 inspection;		(c) […] **document any evidence deemed necessary by the representatives**;	(c) […] **document any evidence deemed necessary by the 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 on behalf of a marketing authorisation holder.		(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** […].	(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** […].
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)** ***4a. Inspections may also be carried out on the premises of manufacturers of active 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 authority shall draft a report on compliance with the requirements set out in this Regulation. Before adopting a report, the inspected entity shall have the opportunity to submit comments.		5. […] **The representatives of the competent authorities shall keep record~~s~~ of every control that they carry out and where necessary shall draw up a report. The person referred to in paragraph 1 shall be promptly informed in writing by the competent authority of any case of non-compliance identified through the controls and shall have the opportunity to submit comments within a time set by the competent authority.**	5. […] **The representatives of the competent authorities shall keep record~~s~~ of every control that they carry out and where necessary shall draw up a report. The person referred to in paragraph 1 shall be promptly informed in writing by the competent authority of any case of non-compliance identified through the controls and shall have the opportunity to submit comments within a time set by the competent 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.
6. Inspection reports shall be uploaded to the appropriate database, with continuous access for all competent authorities.	**AM 275** 6. Inspection reports shall be uploaded to the appropriate database, with continuous access for all competent authorities. ***A summary of the inspection results shall be made publicly available.***	~~6.~~ […]	~~6.~~ […]

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

[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 ***Certificate of suitability***	***Article 127a*** ***Certificate of suitability***
		[…] In order to verify whether the data submitted for obtaining a […] certificate **of suitability** compl**ies** 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 (European Directorate for the Quality of Medicines & Healthcare) may ask the Commission or the Agency to request an inspection **by a competent authority** when the starting material concerned is subject to a European Pharmacopoeia	[…] In order to verify whether the data submitted for obtaining a […] certificate **of suitability** compl**ies** 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[81] (European Directorate for the Quality of Medicines & Healthcare) may ask the Commission or the Agency to request an inspection **by a competent authority** when the starting material concerned is subject 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).

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		monograph. […]	monograph. […]
Article 128 *Specific rules on pharmacovigilance inspections*		*Article 128* *Specific rules on pharmacovigilance inspections*	*Article 128* *Specific rules on pharmacovigilance inspections*
1. The pharmacovigilance inspections shall be coordinated by the Agency together with the competent authorities and shall ensure that all pharmacovigilance system master files in the Union, as identified in the product database, are regularly checked.		1. The **competent authorities and** the […] Agency […] shall ensure that all pharmacovigilance system master files in the Union […] are regularly checked **and that the pharmacovigilance systems are being correctly applied**.	1. The **competent authorities and** the […] Agency […] shall ensure that all pharmacovigilance system master files in the Union […] are regularly checked **and that the pharmacovigilance systems are being correctly applied**.
		1a. Inspections on the pharmacovigilance systems of veterinary medicinal products authorised in accordance with Article 40 shall be coordinated by the Agency and carried out by the competent authorities.	**1a. Inspections on the pharmacovigilance systems of veterinary medicinal products authorised in accordance with Article 40 shall be coordinated by the Agency and carried out by the competent authorities.**
		1b. Inspections on the pharmacovigilance systems of veterinary medicinal products authorised in accordance with Article 44, Article 46 and Article 48 and 48a shall be carried out by the competent authorities.	**1b. Inspections on the pharmacovigilance systems of veterinary medicinal products authorised in accordance with Article 44, Article 46 and Article 48 and 48a shall be carried out by the competent authorities.**
2. The competent authority in the Member State in which the qualified person responsible for pharmacovigilance operates shall		2. **Inspections of the pharmacovigilance systems master files shall be carried out by** […] **t**he competent authorit**ies** […] **of** the	2. **Inspections of the pharmacovigilance systems master files shall be carried out by** […] **t**he competent authorit**ies** […] **of** the

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

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	AM 276 **Article 128 -- paragraph 3 a (new)** ***3a. The Agency and the Commission shall ensure a harmonised approach to veterinary medicine inspections.***		
Article 129 *Proof of the product quality*		*Article 129* *Proof of the product quality* ***for veterinary medicinal products***	*Article 129* *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.		1. 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.	1. 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.
		2. If a competent authority 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	**2. If a competent authority 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 in which the veterinary medicinal product is authorised, and also the Agency in the case the veterinary medicinal product is authorised under the centralised procedure.[82]	**authorities of other Member States in which the veterinary medicinal product is authorised, and also the Agency in the case the veterinary medicinal product is authorised under the centralised procedure.**
		Article 129a ***Proof of the product quality specific for immunological veterinary medicinal products***	***Article 129a*** ***Proof of the product quality specific for immunological veterinary medicinal products***
2. For the purposes of application of paragraph 1, competent authorities may require the marketing authorisation holder for immunological veterinary medicinal products to submit to the competent authorities the copies of all the control reports signed by the qualified person in accordance with Article 101.		[…] **1.** For the purposes of application of paragraph 1 **of Article 129**, competent authorities may require the marketing authorisation holder for immunological veterinary medicinal products to submit to the competent authorities the copies of all the control reports signed by the qualified person in accordance with Article **100** […].	[…] **1.** For the purposes of application of paragraph 1 **of Article 129**, competent authorities may require the marketing authorisation holder for immunological veterinary medicinal products to submit to the competent authorities the copies of all the control reports signed by the qualified person in accordance with Article **100** […].

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

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

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

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if appropriate, the manufacturer, of the results of the tests within the same period of time.		if appropriate, the manufacturer, of the results of the tests within the same period of time.	if appropriate, the manufacturer, of the results of the tests within the same period of time.
11. If a competent authority 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.		[…]**10**. […]	[…]**10**. […]
		11. The competent authority shall verify that the manufacturing processes used in the manufacture of immunological veterinary medicinal products are validated and that batch-to-batch consistency is ensured.	**11. The competent authority shall verify that the manufacturing processes used in the manufacture of immunological veterinary medicinal products are validated and that batch-to-batch consistency is ensured.**

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

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

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the Agency in accordance with Article 84.		**same time as imposing the restriction in accordance with paragraph 1,** refer the issue to the Agency in accordance with Article 84.	**same time as imposing the restriction in accordance with paragraph 1,** refer the issue to the Agency in accordance with Article 84.
3. Where applicable, the marketing authorisation holder shall submit an application for a variation to the terms of the marketing authorisation in accordance with Article 61.		3. Where applicable, the marketing authorisation holder shall submit an application for a variation to the terms of the marketing authorisation in accordance with Article 61.	3. Where applicable, the marketing authorisation holder shall submit an application for a variation to the terms of the marketing authorisation in accordance with Article 61.
Article 131 *Suspending, withdrawing or varying marketing authorisations*		*Article 131* *Suspending, […] **revoking** or varying **the terms of** marketing authorisations*	*Article 131* *Suspending, […] **revoking** or varying **the terms of** marketing authorisations*
1. The competent authority or the Commission shall suspend or withdraw the marketing authorisation if the benefit-risk balance of the veterinary medicinal product is unfavourable.		1. The competent authority or**, in the case of centralised marketing authorisations,** the Commission, shall suspend or […] **revoke or request the marketing authorisation holder to submit an application for a variation to the terms of** the marketing authorisation if the benefit-risk balance of the veterinary medicinal product is **no longer** […]favourable **or is**	1. The competent authority or**, in the case of centralised marketing authorisations,** the Commission, shall suspend or […] **revoke or request the marketing authorisation holder to submit an application for a variation to the terms of** the marketing authorisation if the benefit-risk balance of the veterinary medicinal product is **no 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 following:	of **one or more** […] of the following:
(a) the marketing authorisation holder does not comply with the requirements set out in Article 55;		(a) the marketing authorisation holder does not comply with the requirements set out in Article 55;	(a) the marketing authorisation holder does not comply with the requirements set out in Article 55;
(b) the marketing authorisation holder does not comply with the requirements set out in Article 129;		(b) the marketing authorisation holder does not comply with the requirements set out in Article 129;	(b) the marketing authorisation holder does not comply with the requirements set out in Article 129;
(c) the pharmacovigilance system required in accordance with Article 72 is inadequate;		(c) the pharmacovigilance system **established** […] in accordance with **paragraph 0 of** Article 77[…] is inadequate;	(c) the pharmacovigilance system **established** […] in accordance with **paragraph 0 of** Article 77[…] is inadequate;
(d) the marketing authorisation holder does not fulfil his obligations laid down in Article 77;		(d) the marketing authorisation holder does not fulfil his obligations laid down in Article 77;	(d) the marketing authorisation holder does not fulfil his obligations laid down in Article 77;
(e) the maximum residue limit for the active substance established in accordance with Regulation (EC) No 470/2009 has been amended.		(e) […] **the qualified person responsible for pharmacovigilance does not fulfill his tasks as laid down in Article 78.**	(e) […] **the qualified person responsible for pharmacovigilance does not fulfill his tasks as laid down in Article 78.**
4. For the purpose of paragraphs 1 to 3, before taking action, the Commission shall request, where appropriate, the opinion of the Agency within time-limit which it shall determine in the light of the urgency of the matter, in order to examine the reasons. Whenever practicable, the holder of the marketing authorisation for the veterinary medicinal product shall be		4. For the purpose of paragraphs 1 to 3, **in case of centralised marketing authorisations,** before taking action, the Commission shall request, where appropriate, the opinion of the Agency within time-limit which it shall determine in the light of the urgency of the matter, in order to examine the reasons. […] **T**he holder of the marketing authorisation for the veterinary	4. For the purpose of paragraphs 1 to 3, **in case of centralised marketing authorisations,** before taking action, the Commission shall request, where appropriate, the opinion of the Agency within time-limit which it shall determine in the light of the urgency of the matter, in order to examine the reasons. […] **T**he holder of the marketing authorisation for the veterinary

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

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

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

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

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

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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 those provisions to the Commission by *[Publications Office: insert date counting 36 months from the date of entry into force of this Regulation]* and shall notify it without delay of any subsequent amendments affecting them.		[…] Member States shall notify those provisions to the Commission by *[Publications Office: insert date counting 36 months from the date of entry into force of this Regulation]* and shall notify it without delay of any subsequent amendments affecting them.	[…] Member States shall notify those provisions to the Commission by *[Publications Office: insert date counting 36 months from the date of entry into force of this Regulation]* and shall notify it without delay of any subsequent amendments affecting them.
4. Where the Member State imposes a financial penalty, it shall publish a concise summary of the case, including the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed, having regard to the legitimate interest of the marketing authorisation holders in the protection of their business secrets.		~~4.~~ […]	**1a. The competent authorities shall ensure the publication of information on the type and number of cases where financial penalties were imposed, having regard to the legitimate interest of the concerned parties 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 any litigation against marketing authorisation holders of centrally authorised veterinary medicinal products instituted for infringement of this Regulation.	**the Commission immediately of any litigation against marketing authorisation holders of centrally authorised veterinary medicinal products instituted for infringement of this Regulation.**
Article 135 *Penalties imposed by the Commission*		*Article 135* ***Financial p****enalties imposed by the Commission* ***on marketing authorisation holders of centrally authorised veterinary medicinal products***[83]	*Article 135* ***Financial penalties imposed by the Commission on marketing authorisation holders of centrally authorised veterinary medicinal products***
1. The Commission may impose financial penalties on the holders of marketing authorisations granted under this Regulation if they fail to observe their obligations in accordance with this Regulation.		1. The Commission may impose financial penalties on the [….] marketing authorisation[…] **holders of centrally authorised veterinary medicinal products** granted under this Regulation if they fail to observe **any of** their obligations in accordance with this Regulation **in connection with those marketing authorisations**.	1. The Commission may impose financial penalties on the [….] marketing authorisation **holders of centrally authorised veterinary medicinal products** granted under this Regulation if they fail to observe any of their obligations ~~in accordance with this Regulation~~ **laid down in Annex III in connection 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, insofar as specifically provided for in the delegated acts referred to in paragraph 1e(bb), impose the financial penalties referred to in paragraph 1 also on a different legal entity or entities provided that such entities form part of the same economic entity as the marketing authorisation holder and that such other legal entities: **(i) exerted a decisive influence over the marketing authorisation holder, or** **(ii) were involved in, or could have addressed, the infringement by the marketing authorisation holder.**	**1aa. The Commission may, insofar as specifically provided for in the delegated acts referred to in paragraph ~~1e~~2(bb), impose the financial penalties referred to in paragraph 1 also on a different legal entity or entities provided that such entities form part of the same economic entity as the marketing authorisation holder and that such other legal entities:** **(i) exerted a decisive influence over the marketing authorisation holder, or** **(ii) were involved in, or could have addressed, the infringement by the marketing authorisation holder.**
		1a. Where the Agency or a competent authority of a Member State is of the opinion that a marketing authorisation holder has failed to observe any of the obligations referred to in paragraph 1, it may request the Commission to investigate whether to impose financial penalties pursuant to that paragraph.	**1a. Where the Agency or a competent authority of a Member State is of the opinion that a marketing authorisation holder has failed to observe any of the obligations referred to in paragraph 1, it may request the Commission to investigate whether to impose financial penalties pursuant to that paragraph.**

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

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		decision imposing a fine not exceeding 5 % of the holder's Union turnover in the business year preceding the date of the decision.	**decision imposing a fine not exceeding 5 % of the holder's Union turnover in the business year preceding the date of the decision.**
		Where the marketing authorisation holder has not terminated the infringement, the Commission may, in the decision referred to in paragraph 1, impose periodic penalty payments per day not exceeding 2,5 % of the holder's average daily Union turnover in the business year preceding the date of the decision.	**Where the marketing authorisation holder has not terminated the infringement, the Commission may, in the decision referred to in paragraph 1, impose periodic penalty payments per day not exceeding 2,5 % of the holder's average daily Union turnover in the business year preceding the date of the decision.**
		Periodic penalty payments may be imposed for a period running from the date of notification of that decision until the infringement has been brought to an end.	**Periodic penalty payments may be imposed for a period running from the date of notification of that decision until the infringement has been brought to an end.**
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 laying down 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 under this Regulation, the maximum amounts of these penalties		2. The Commission […] **is** empowered to adopt delegated acts in accordance with Article 146 **supplementing this Regulation by** laying down**:** […]	2. The Commission […] **is** empowered to adopt delegated acts in accordance with Article 146 **supplementing this Regulation by** laying down**:** […]

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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 confidentiality;	**(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;	**(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.**

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		2a. For the conduct of the investigation, the Commission may cooperate with national competent authorities and rely on resources provided by the Agency.	**2a. For the conduct of the investigation, the Commission may cooperate with national competent authorities and rely on resources provided by the Agency.**
3. Where the Commission adopts a decision imposing a financial penalty, it shall publish a concise summary of the case, including the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed, having regard to the legitimate interest of the marketing authorisation holders in the protection of their business secrets.		3. Where the Commission adopts a decision imposing a financial penalty, it shall publish a concise summary of the case, including the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed, having regard to the legitimate interest of the marketing authorisation holders in the protection of their business secrets.	3. Where the Commission adopts a decision imposing a financial penalty, it shall publish a concise summary of the case, including the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed, having regard to the legitimate interest of the marketing authorisation holders in the protection of their business secrets.
4. The Court of Justice shall have unlimited jurisdiction to review decisions whereby the Commission has imposed financial penalties. It may cancel, reduce or increase the fine or periodic penalty payment imposed.		4. The Court of Justice shall have unlimited jurisdiction to review decisions whereby the Commission has imposed financial penalties. It may cancel, reduce or increase the fine or periodic penalty payment imposed.	4. The Court of Justice shall have unlimited jurisdiction to review decisions whereby the Commission has imposed financial penalties. It may cancel, reduce or increase the fine or periodic penalty payment imposed.

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Chapter X **Regulatory network**		**Chapter X** **Regulatory network**	**Chapter X** **Regulatory network**
Article 136 *Competent authorities*		*Article 136* *Competent authorities*	*Article 136* *Competent authorities*
1. Member States shall designate the competent authorities to carry out tasks under this Regulation.	**AM 279** 1. Member States shall designate the competent authorities to carry out tasks under this Regulation. ***The competent authorities shall, inter alia, be responsible for providing the scientific expertise for assessment of all applications under this Regulation.***	1. Member States shall designate the competent authorities to carry out tasks under this Regulation.	1. Member States shall designate the competent authorities to carry out tasks under this Regulation.
	AM 280 **Article 136 -- paragraph 1 a (new)** ***1a. The management of funds intended for activities connected with requirements provided under this Regulation, the operation of communication networks and market surveillance shall be under the permanent control of the competent authorities in order to guarantee the independence of these authorities.***		**1a. Member States shall ensure that adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to carry out the activities required by this Regulation.**

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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 ***and other concerned authorities*** 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 ***and other concerned authorities***, 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.

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4. Member States shall 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.		4. […].	4. […].
Article 137 *Information to the Agency and international organisations from the competent authorities*		~~*Article 137*~~ […]	~~*Article 137*~~ […]
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.		[…]	[…]

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Article 138 *Scientific opinion for international organisations for animal health*		*Article 138* *Scientific opinion for international organisations for animal health*	*Article 138* *Scientific opinion for international organisations for animal health*
1. The Agency may give scientific opinions, in the context of cooperation with international organisations for animal health, for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union. For this purpose, an application shall be submitted to the Agency in accordance with the provisions of Article 7. The Agency may, after consulting the relevant organisation, draw up a scientific opinion.		1. The Agency may give scientific opinions, in the context of cooperation with international organisations for animal health, for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union. For this purpose, an application shall be submitted to the Agency in accordance with the provisions of Article 7. The Agency may, after consulting the relevant organisation, draw up a scientific opinion.	1. The Agency may give scientific opinions, in the context of cooperation with international organisations for animal health, for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union. For this purpose, an application shall be submitted to the Agency in accordance with the provisions of Article 7. The Agency may, after consulting the relevant organisation, draw up a scientific opinion.
2. The Committee shall establish specific procedural rules for the application of paragraph 1.		2. The **Agency** […] shall establish specific procedural rules for the **implementation** […] of paragraph 1.	2. The **Agency** […] shall establish specific procedural rules for the **implementation** […] of paragraph 1.
Article 139 *Committee for Medicinal Products for Veterinary Use*		*Article 139* *Committee for **Veterinary** Medicinal Products […]*	*Article 139* *Committee for **Veterinary** Medicinal Products […]*
1. A Committee for Medicinal Products for Veterinary Use ('the Committee') is hereby set up within the Agency.		1. A Committee for **Veterinary** Medicinal Products […] ('the Committee') is hereby set up within the Agency.	1. A Committee for **Veterinary** Medicinal Products […] ('the Committee') is hereby set up within the Agency.
2. The Executive Director of the Agency or his representative and		2. The Executive Director of the Agency or his representative and	2. The Executive Director of the Agency or his representative and

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representatives of the Commission shall be entitled to attend all meetings of the Committee, working parties and scientific advisory groups and all other meetings convened by the Agency or its committees.		representatives of the Commission shall be entitled to attend all meetings of the Committee, working parties and scientific advisory groups […].	representatives of the Commission shall be entitled to attend all meetings of the Committee, working parties and scientific advisory groups […].
3. The Committee may establish standing and temporary working parties. The Committee may establish scientific advisory groups in connection with the evaluation of specific types of medicinal products or treatments, to which the Committee may delegate certain tasks associated with drawing up the scientific opinions referred to in Article 141(1)(b).		3. The Committee may establish standing and temporary working parties. The Committee may establish scientific advisory groups in connection with the evaluation of specific types of **veterinary** medicinal products […], to which the Committee may delegate certain tasks associated with drawing up the scientific opinions referred to in Article 141(1)(b).	3. The Committee may establish standing and temporary working parties. The Committee may establish scientific advisory groups in connection with the evaluation of specific types of **veterinary** medicinal products […], to which the Committee may delegate certain tasks associated with drawing up the scientific opinions referred to in Article 141(1)(b).
4. The Committee shall establish a standing working party with the sole remit of providing scientific advice to undertakings. The Executive Director, in close consultation with the Committee shall set up the administrative structures and procedures allowing the development of advice for undertakings, as referred to in Article 57(1)(n) of Regulation (EC) No 726/2004, particularly regarding the development of new therapies.		4. The Committee shall establish a standing working party with the sole remit of providing scientific advice to undertakings. The Executive Director, in close consultation with the Committee shall set up the administrative structures and procedures allowing the development of advice for undertakings, as referred to in Article 57(1)(n) of Regulation (EC) No 726/2004, particularly regarding the development of […] **novel** therapy	4. The Committee shall establish a standing working party with the sole remit of providing scientific advice to undertakings. The Executive Director, in close consultation with the Committee shall set up the administrative structures and procedures allowing the development of advice for undertakings, as referred to in Article 57(1)(n) of Regulation (EC) No 726/2004, particularly regarding the development of […] **novel** therapy

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		[…] **veterinary medicinal products**.	[…] **veterinary medicinal products**.
		4a. The Committee shall establish a standing working party for pharmacovigilance with a remit including evaluating potential signals in pharmacovigilance arising from the Union pharmacovigilance system, proposing the options for risk management referred to in Article 79 to the Committee and to the coordination group, and coordinating the communication about pharmacovigilance between the competent authorities and the Agency.	**4a. The Committee shall establish a standing working party for pharmacovigilance with a remit including evaluating potential signals in pharmacovigilance arising from the Union pharmacovigilance system, proposing the options for risk management referred to in Article 79 to the Committee and to the coordination group, and coordinating the communication about pharmacovigilance between the competent authorities and the Agency.**
5. The Committee shall establish its own rules of procedure. Those rules shall, in particular, lay down:		5. The Committee shall establish its own rules of procedure. Those rules shall, in particular, lay down:	5. The Committee shall establish its own rules of procedure. Those rules shall, in particular, lay down:
(a) procedures for appointing and replacing the Chairman;		(a) procedures for appointing and replacing the Chairman;	(a) procedures for appointing and replacing the Chairman;
(b) the appointment of members of any working parties or scientific advisory groups on the basis of the lists of experts referred to in the second subparagraph of Article 62(2) of Regulation (EC) No 726/2004 and procedures for consultation of working parties and scientific		(b) the appointment of members of any working parties or scientific advisory groups on the basis of the lists of **accredited** experts referred to in the second subparagraph of Article 62(2) of Regulation (EC) No 726/2004 and procedures for consultation of working parties and	(b) the appointment of members of any working parties or scientific advisory groups on the basis of the lists of **accredited** experts referred to in the second subparagraph of Article 62(2) of Regulation (EC) No 726/2004 and procedures for consultation of working parties and

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

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Article 140 *Members of the Committee for Medicinal Products for Veterinary Use*		*Article 140* *Members of the Committee […]*	*Article 140* *Members of the Committee […]*
1. Each Member State shall be entitled to appoint a Member and an alternate Member of the Committee. The alternates shall represent and vote for the Members in their absence and may act as rapporteurs.		1. Each Member State shall**, after consultation of the Management Board of the Agency,** […] appoint **for a three-year term which may be renewed, one** […] **m**ember and an alternate **m**ember of the Committee. The alternates shall represent and vote for the **m**embers in their absence and may act as rapporteurs	1. Each Member State shall**, after consultation of the Management Board of the Agency,** […] appoint **for a three-year term which may be renewed, one** […] **m**ember and an alternate **m**ember of the Committee. The alternates shall represent and vote for the **m**embers in their absence and may act as 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 Members of the Committee shall be appointed on the basis of their relevant expertise and experience in the scientific evaluation of medicinal products for veterinary use, in order to guarantee the highest level of qualifications and a broad spectrum of relevant expertise.		2. Members and alternate**s** of the Committee shall be appointed on the basis of their relevant expertise and experience in the scientific […] **assessment** of **veterinary** medicinal products […], in order to guarantee the highest level of qualifications and a broad spectrum of relevant expertise.	2. Members and alternate**s** of the Committee shall be appointed on the basis of their relevant expertise and experience in the scientific […] **assessment** of **veterinary** medicinal products […], in order to guarantee the highest level of qualifications and a broad spectrum of relevant expertise.

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3. Member States shall submit relevant information to the 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.		~~3.~~ […]	~~3.~~ […]
4. The Management Board shall evaluate information on the expert or experts submitted by the Member State and shall communicate its conclusions to the Member State and the Committee.		~~4.~~ […]	~~4.~~ […]
5. Taking into account the 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.		~~5.~~ […]	~~5.~~ […]
6. A Member State may delegate its tasks within the Committee to another Member State. Each Member State may represent no more than one other Member State.		6. A Member State may delegate its tasks within the Committee to another Member State. Each Member State may represent no more than one other Member State.	6. A Member State may delegate its tasks within the Committee to another Member State. Each Member State may represent no more than one other Member State.

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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. ***The co-opted members may act as rapporteurs.***	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.**

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9. The members of the Committee may be accompanied by experts in specific scientific or technical fields.		9. The members of the Committee may be accompanied by experts in specific scientific or technical fields.	9. The members of the Committee may be accompanied by experts in specific scientific or technical fields.
10. Members of the Committee and experts responsible for evaluating veterinary medicinal products shall rely on the scientific evaluation and resources available to competent authorities. Each authority shall monitor and ensure the scientific level and independence of the evaluation carried out and the provision of appropriate contribution to the tasks of the Committee, and facilitate the activities of appointed Committee members and experts. To this end, Member States shall provide adequate scientific and technical resources to the members and experts they have nominated.		10. Members of the Committee and experts responsible for […] **assessing** veterinary medicinal products shall rely on the scientific evaluation and resources available to competent authorities. Each **competent** authority shall monitor and ensure the scientific level and independence of the evaluation carried out and […] **provide** appropriate contribution to the tasks of the Committee, and facilitate the activities of appointed Committee members and experts. To this end, Member States shall provide adequate scientific and technical resources to the members and experts they have nominated.	10. Members of the Committee and experts responsible for […] **assessing** veterinary medicinal products shall rely on the scientific evaluation and resources available to competent authorities. Each **competent** authority shall monitor and ensure the scientific level and independence of the evaluation carried out and […] **provide** appropriate contribution to the tasks of the Committee, and facilitate the activities of appointed Committee members and experts. To this end, Member States shall provide adequate scientific and technical resources to the members and experts they have nominated.
11. Member States shall refrain from giving Committee members and experts instructions incompatible with their own individual tasks, or with the tasks of the Committee and responsibilities of the Agency.		11. Member States shall refrain from giving Committee members and experts instructions incompatible with their own individual tasks, or with the tasks of the Committee and responsibilities of the Agency.	11. Member States shall refrain from giving Committee members and experts instructions incompatible with their own individual tasks, or with the tasks of the Committee and responsibilities of the Agency.

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Article 141 *Tasks of the Committee for Medicinal Products for Veterinary Use*		*Article 141* *Tasks of the Committee […]*	*Article 141* *Tasks of the Committee […]*
1. The Committee shall have the following tasks:		1. The Committee shall have the following tasks:	1. The Committee shall have the following tasks:
(a) carry out the tasks conferred on the Committee under this Regulation and Regulation (EC) No 726/2004;		(a) carry out the tasks conferred on the Committee under this Regulation and Regulation (EC) No 726/2004;	(a) carry out the tasks conferred on the Committee under this Regulation and Regulation (EC) No 726/2004;
(b) prepare opinions of the Agency on questions relating to the evaluation and use of veterinary medicinal products;		(b) prepare **scientific** opinions of the Agency on questions relating to the evaluation and use of veterinary medicinal products;	(b) prepare **scientific** opinions of the Agency on questions relating to the evaluation and use of veterinary medicinal products;
(c) upon request from the Executive Director of the Agency or the Commission draw up opinions on scientific matters concerning the evaluation and use of veterinary medicinal products;		(c) upon request from the Executive Director of the Agency or the Commission […] **prepare** opinions on scientific matters concerning the evaluation and use of veterinary medicinal products;	(c) upon request from the Executive Director of the Agency or the Commission […] **prepare** opinions on scientific matters concerning the evaluation and use of veterinary medicinal products;
(d) draw up opinions of the Agency on questions concerning the admissibility of files submitted in accordance with the centralised procedure, and on granting, varying, suspending or withdrawing a marketing authorisations for centrally authorised veterinary medicinal products;		(d) **prepare** […] opinions of the Agency on questions concerning the admissibility of **applications** […] submitted in accordance with the centralised procedure, and on granting, varying, suspending or […] **revoking** a marketing authorisations for centrally authorised veterinary medicinal products;	(d) **prepare** […] opinions of the Agency on questions concerning the admissibility of **applications** […] submitted in accordance with the centralised procedure, and on granting, varying, suspending or […] **revoking** a marketing authorisations for centrally authorised veterinary medicinal products;
(e) take due account of any request from Member States for opinions;		(e) take due account of any request from Member States for **scientific**	(e) take due account of any request from Member States for **scientific**

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		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 health, concerning the evaluation of certain veterinary medicinal products or active substances intended exclusively for markets outside the Union.		(h) give a scientific opinion, in the context of cooperation with **the World** […] **O**rganisations for […] **A**nimal […] **H**ealth, concerning the evaluation of certain veterinary medicinal products […] intended exclusively for markets outside the Union.	(h) give a scientific opinion, in the context of cooperation with **the World** […] **O**rganisations for […] **A**nimal […] **H**ealth, concerning the evaluation of certain veterinary medicinal products […] intended exclusively for markets outside the Union.
		(i) advise on the maximum limits for residues of veterinary medicinal products and biocidal products used in animal husbandry which may be accepted in foodstuffs of animal origin in accordance with Regulation (EC) No 470/2009;	**(i) advise on the maximum limits for residues of veterinary medicinal products and biocidal products used in animal husbandry which may be accepted in foodstuffs of animal origin in accordance with Regulation (EC) No 470/2009;**

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		(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***		

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

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be based only on the scientific data available when the Committee adopted the opinion. The applicant may request that the Committee consults a scientific advisory group in connection with the re-examination.		be based only on the scientific data available when the Committee adopted the opinion. The applicant may request that the Committee consults a scientific advisory group in connection with the re-examination.	be based only on the scientific data available when the Committee adopted the opinion. The applicant may request that the Committee consults a scientific advisory group in connection with the re-examination.
Article 142 *Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products*		*Article 142* *Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products*	*Article 142* *Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products*
1. The coordination group for mutual recognition and decentralised procedures for veterinary medicinal products ("the coordination group") is hereby set up.		1. The coordination group for mutual recognition and decentralised procedures for veterinary medicinal products ("the coordination group") is hereby set up.	1. The coordination group for mutual recognition and decentralised procedures for veterinary medicinal products ("the coordination group") is hereby set up.
2. The Agency shall provide a secretariat for the coordination group, which shall ensure effective and efficient operation of the procedures of the coordination group and appropriate liaison between this group, the Agency and national competent authorities.		2. The Agency shall provide a secretariat for the coordination group […] **to assist in the operations** of the procedures of the coordination group and **to ensure an** appropriate liaison between this group, the Agency and […] competent authorities.	2. The Agency shall provide a secretariat for the coordination group […] **to assist in the operations** of the procedures of the coordination group and **to ensure an** appropriate liaison between this group, the Agency and […] competent authorities.

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3. The coordination group shall draw up its rules of procedure, which shall enter into force after receiving a favourable opinion from the Commission. These rules of procedure shall be made public.		3. The coordination group shall draw up its rules of procedure, which shall enter into force after receiving a favourable opinion from the Commission. These rules of procedure shall be made public.	3. The coordination group shall draw up its rules of procedure, which shall enter into force after receiving a favourable opinion from the Commission. These rules of procedure shall be made public.
4. The Executive Director of the Agency or his representative and representatives of the Commission shall be entitled to attend all meetings of the coordination group.		4. The Executive Director of the Agency or his representative and representatives of the Commission shall be entitled to attend all meetings of the coordination group.	4. The Executive Director of the Agency or his representative and representatives of the Commission shall be entitled to attend all meetings of the coordination group.
5. The coordination group shall ensure that there is appropriate cooperation and coordination between the group, the competent authorities and the Agency.		5. The coordination group shall […] **cooperate closely with** the competent authorities and the Agency.	5. The coordination group shall […] **cooperate closely with** the competent authorities and the Agency.
Article 143 *Members of the Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products*		*Article 143* *Members of the **c**oordination group […]*	*Article 143* *Members of the **c**oordination group […]*
1. The coordination group shall be composed of one representative per Member State appointed for a renewable period of 3 years. Members of the group may arrange to be accompanied by experts.		1. The coordination group shall be composed of one representative per Member State appointed for a renewable period of 3 years. **Member States may appoint an alternate representative.** Members of the **coordination** group may arrange to be accompanied by experts.	1. The coordination group shall be composed of one representative per Member State appointed for a renewable period of 3 years. **Member States may appoint an alternate representative.** Members of the **coordination** group may arrange to be accompanied by experts.

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2. Members of the coordination group and their experts shall rely on the scientific and regulatory resources available to their competent authorities on relevant scientific assessments and on the recommendations of the Committee for the fulfilment of their tasks. Each national competent authority shall monitor the quality of the evaluations carried out by their representative and facilitate their activities.		2. Members of the coordination group and their experts shall rely on the scientific and regulatory resources available to their competent authorities on relevant scientific assessments and on the recommendations of the Committee for the fulfilment of their tasks. Each […] competent authority shall monitor the quality of the evaluations carried out by their representative and facilitate their activities.	2. Members of the coordination group and their experts shall rely on the scientific and regulatory resources available to their competent authorities on relevant scientific assessments and on the recommendations of the Committee for the fulfilment of their tasks. Each […] competent authority shall monitor the quality of the evaluations carried out by their representative and facilitate their activities.
3. Members of the coordination group shall use their best endeavours to reach consensus on matters under discussion. If such consensus cannot be reached, the position of the simple majority of the members of the coordination group shall prevail.		3. Members of the coordination group shall use their best endeavours to reach consensus on matters under discussion. […]	3. Members of the coordination group shall use their best endeavours to reach consensus on matters under discussion. […]
Article 144 *Tasks of the Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products*		*Article 144* *Tasks of the **c**oordination group […]*	*Article 144* *Tasks of the **c**oordination group […]*
The coordination group shall have the following tasks:		The coordination group shall have the following tasks:	The coordination group shall have the following tasks:
(a) examine questions concerning mutual recognition and decentralised procedures;		(a) examine questions concerning mutual recognition and decentralised procedures;	(a) examine questions concerning mutual recognition and decentralised procedures;
(b) examine questions concerning	**AM 284**	(b) examine […] **advice from the**	(b) examine […] **advice from the**

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pharmacovigilance of veterinary medicinal products authorised in Member States;	***deleted***	**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 authorisation holders as necessary**;	**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 authorisation holders as necessary**;
(c) examine questions concerning variations to the terms of marketing authorisations granted by Member States;		(c) examine questions concerning variations to the terms of marketing authorisations granted by Member States;	(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);**

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		(ea) draw up and publish an annual list of reference veterinary medicinal products which shall be subject to harmonisation of the summaries of product characteristics in accordance with Article 69(1aaa).	**(ea) draw up and publish an annual list of reference veterinary medicinal products which shall be subject to harmonisation of the summaries of product characteristics in accordance with Article 69(1aaa).**
Chapter XI **Final provisions**		**Chapter XI** […] **Common and procedural provisions**	**Chapter XI** […] **Common and procedural provisions**
Article 145 *Standing Committee on Veterinary Medicinal Products*		*Article 145* *Standing Committee on Veterinary Medicinal Products*	*Article 145* *Standing Committee on Veterinary Medicinal Products*
1. The Commission shall be assisted by the Standing Committee on Veterinary Medicinal Products ('the Standing Committee'). The Standing Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.		1. The Commission shall be assisted by the Standing Committee on Veterinary Medicinal Products ('the Standing Committee'). The Standing Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by the Standing Committee on Veterinary Medicinal Products ('the Standing Committee'). The Standing Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011shall apply.		2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

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		Article 145a ***Amendments to Annex II***	***Article 145a*** ***Amendments to Annex II***
		1. The Commission is empowered to adopt delegated acts in accordance with Article 146(2) amending Annex II to adapt the requirements regarding the technical documentation on the quality, safety and efficacy of veterinary medicinal products to technical and scientific progress.	**1. The Commission is empowered to adopt delegated acts in accordance with Article 146(2) amending Annex II to adapt the requirements regarding the technical documentation on the quality, safety and efficacy of veterinary medicinal products to technical and scientific progress.**
		2. The Commission shall adopt delegated acts in accordance with Article 146(2a) amending Annex II to achieve a sufficient level of detail to ensure legal certainty and harmonisation as well as any necessary updating, while avoiding unnecessary disruption with the current Annex II, including as regards the introduction of specific requirements for novel therapy veterinary medicinal products.	**2. The Commission shall adopt delegated acts in accordance with Article 146(2a) amending Annex II to achieve a sufficient level of detail to ensure legal certainty and harmonisation as well as any necessary updating, while avoiding unnecessary disruption with the current Annex II, including as regards the introduction of specific requirements for novel therapy veterinary medicinal products. <u>When adopting those delegated acts, the Commission shall have due regard to animal health, public health and environmental considerations.</u>**
Article 146 *Exercise of the delegation*		*Article 146* *Exercise of the delegation*	*Article 146* *Exercise of the delegation*

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1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Articles 7(7), 16(6), 32(3), 38(4), 54(3), 89(2), 117(2) and 135(2) shall be conferred on the Commission for an indeterminate period of time from the date of the entry into force of this Regulation.		2. The power to adopt delegated acts referred to in Articles […] 32(3), […] 54(3), […] **112b(1),** 117(2)**, 122a(2),** […] 135(**1e**[…])**, and 145a(1)** shall be conferred on the Commission for […] period of […] **five years** from the date of the entry into force of this Regulation.**The Commission shall draw up a report in respect of the delegation of power by not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for the periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**	2. The power to adopt delegated acts referred to in Articles […] 32(3), […] 54(3), […] **112b(1),** 117(2), **122a(2),** […] 135(**2 ~~1e[…]~~**)**, and 145a(1)** shall be conferred on the Commission for […] period of […] **five years** from the date of the entry into force of this Regulation. **The Commission shall draw up a report in respect of the delegation of power by not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for the periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**
		2a. The power to adopt delegated acts referred to in Article 145a (2) shall be conferred on the Commission for a period from the entry into force of this Regulation until the date of application	**2a. The power to adopt delegated acts referred to in Article 145a (2) shall be conferred on the Commission for a period from the entry into force of this Regulation until the date of application**

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

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54(3), 89(2), 117(2) and 135(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.		**paragraph 2 and 2a** […] shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.	**paragraph 2 and 2a** […] shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.
Article 147 *Data protection*		*Article 147* *Data protection*	*Article 147* *Data protection*
1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.		1. Member States shall apply **Regulation (EU) No 2016/679** […] to the processing of personal data carried out in the Member States pursuant to this Regulation.	1. Member States shall apply **Regulation (EU) No 2016/679**[84] […] to the processing of personal data carried out in the Member States 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)

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2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission and the Agency pursuant to this Regulation.		2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission and the Agency pursuant to this Regulation.	2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission and the Agency pursuant to this Regulation.
		Chapter XII **Transitional and final provisions**	**Chapter XII** **Transitional and final provisions**
Article 148 *Repeal*		*Article 148* *Repeal*	*Article 148* *Repeal*
Directive 2001/82/EC is repealed.		Directive 2001/82/EC is repealed.	Directive 2001/82/EC is repealed.
References to the repealed Directive shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in Annex IV.		References to the repealed Directive shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in Annex IV.	References to the repealed Directive shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in Annex IV.
		Article 148a ***Relation with other Union acts***	***Article 148a*** ***Relation with other Union acts***
		1. Nothing in this Regulation shall be understood to affect the provisions laid down in Council Directive 96/22/EC.	**1. Nothing in this Regulation shall be understood to affect the provisions laid down in Council Directive 96/22/EC.**
		2. The provisions of Commission Regulation No 1234/2008 shall not apply to veterinary medicinal products covered by the provisions of this Regulation.	**2. The provisions of Commission Regulation No 1234/2008 shall not apply to veterinary medicinal products covered by the provisions of this 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 Commission Regulation No 658/2007 shall not apply to veterinary medicinal products covered by the provisions of this Regulation.	**3. The provisions of Commission Regulation No 658/2007 shall not apply to veterinary medicinal products covered by the provisions of this Regulation.**
Article 149 *Transitional provisions*		*Article 149* ***Prior applications** […]*	*Article 149* ***Prior applications** […]*
1. Applications for marketing authorisations for veterinary medicinal products submitted in accordance with Regulation (EC) No 726/2004 before the date of application of this Regulation shall be examined in accordance with Regulation (EC) No 726/2004.		1. Applications for marketing authorisations for veterinary medicinal products **or variations thereof** […] **validated** in accordance with Regulation (EC) No 726/2004 before the date of application of this Regulation shall be […] **completed** in accordance with Regulation (EC) No 726/2004.	1. Applications for marketing authorisations for veterinary medicinal products **or variations thereof** […] **validated** in accordance with Regulation (EC) No 726/2004 before the date of application of this Regulation shall be […] **completed** in accordance with Regulation (EC) No 726/2004.
2. Applications for marketing authorisations for veterinary medicinal products submitted in accordance with the requirements of Directive 2001/82/EC before the date of application of this Regulation shall be examined in accordance with Directive 2001/82/EC.		2. Applications for marketing authorisations for veterinary medicinal products […] **validated** in accordance with the requirements of Directive 2001/82/EC before the date of application of this Regulation shall be […] **completed** in accordance with Directive 2001/82/EC.	2. Applications for marketing authorisations for veterinary medicinal products […] **validated** in accordance with the requirements of Directive 2001/82/EC before the date of application of this Regulation shall be […] **completed** in accordance with Directive 2001/82/EC.
3. Procedures initiated on the basis of Articles 33, 34, 35, 39, 40 and 78 of Directive 2001/82/EC before the date of application of this		3. Procedures initiated on the basis of Articles 33, 34, 35, 39, 40 and 78 of Directive 2001/82/EC before the date of application of this	3. Procedures initiated on the basis of Articles 33, 34, 35, 39, 40 and 78 of Directive 2001/82/EC 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 accordance with Directive 2001/82/EC.		Regulation shall be completed in accordance with Directive 2001/82/EC.	Regulation shall be completed in accordance with Directive 2001/82/EC.
		Article 149a ***Existing veterinary medicinal products, marketing authorisations and registrations***	***Article 149a*** ***Existing veterinary medicinal products, marketing authorisations and registrations***
		1. Marketing authorisations of veterinary medicinal products and registrations of homeopathic veterinary medicinal products granted in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 before the date of application of this Regulation shall be deemed to have been issued in accordance with this Regulation, and are, as such, subject to the relevant provisions under this Regulation. The first subparagraph shall not apply to marketing authorisations for antimicrobial veterinary medicinal products which have been reserved for treatment in humans in accordance with implementing acts adopted on the basis of Article 32(4).	**1. Marketing authorisations of veterinary medicinal products and registrations of homeopathic veterinary medicinal products granted in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 before the date of application of this Regulation shall be deemed to have been issued in accordance with this Regulation, and are, as such, subject to the relevant provisions under this Regulation. The first subparagraph shall not apply to marketing authorisations for antimicrobial veterinary medicinal products which have been reserved for treatment in humans in accordance with implementing acts adopted on the basis of Article 32(4).**
		2. Veterinary medicinal products placed on the market in	**2. Veterinary medicinal products placed on the market 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
		accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 may continue to be made available until five years after the date of application of this Regulation, even if they are not in compliance with Articles 9 to 13 or with other provisions of this Regulation.	**accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 may continue to be made available until five years after the date of application of this Regulation, even if they are not in compliance with Articles 9 to 13 or with other provisions of this Regulation.**
		3. By derogation from paragraph 1 of this Article, the periods of protection provided for in Article 34 shall not apply to reference veterinary medicinal products for which an authorisation has been granted before the date of application referred to in Article 150 and, instead, the corresponding provisions in the repealed acts referred to shall continue to apply in that respect.	**3. By derogation from paragraph 1 of this Article, the periods of protection provided for in Article 34 shall not apply to reference veterinary medicinal products for which an authorisation has been granted before the date of application referred to in Article 150 and, instead, the corresponding provisions in the repealed acts referred to shall continue to apply in that respect.**
		Article 149b ***Transitional measures regarding delegated and implementing acts***	***Article 149b*** ***Transitional measures regarding delegated and implementing acts***
		1. The delegated acts referred to in Articles 32(3), 54(3) and 122a(2) and the implementing acts referred to in Articles 32(4), 54(4), 77(1b), 98b(9), 104(6) and 108(4)	**1. The delegated acts referred to in Articles 32(3), 54(3) and 122a(2) and the implementing acts referred to in Articles 32(4), 54(4), 77(1b), 98b(9), 104(6) and 108(4)**

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
		shall apply from the date of application in accordance with Article 150.	**shall apply from the date of application in accordance with Article 150.**
		2. Without prejudice to the date of application referred to in Article 150, the Commission shall adopt the delegated acts referred to in Article 145a(2) and the implementing acts referred to in Articles 51(3a) and 58(2) at the latest on 12 months before the date of application referred to in Article 150. Such acts shall apply from the date of application in accordance with Article 150.	**2. Without prejudice to the date of application referred to in Article 150, the Commission shall adopt the delegated acts referred to in Article 145a(2) and the implementing acts referred to in Articles 51(3a) and 58(2) at the latest on 12 months before the date of application referred to in Article 150. Such acts shall apply from the date of application in accordance with Article 150.**
		3. Without prejudice to the date of application referred to in Article 150, the delegated acts referred to in Article 112b(1) and the implementing acts referred to in Articles 15(1), 15(2), 98(2), 112b(2) and 117(5) shall be adopted at the latest by 36 months from the date of application in accordance with Article 150 and shall start to apply at the earliest on the date of application referred to in Article 150.	**3. Without prejudice to the date of application referred to in Article 150, the delegated acts referred to in Article 112b(1) and the implementing acts referred to in Articles 15(1), 15(2), 98(2), 112b(2) and 117(5) shall be adopted at the latest by 36 months from the date of application in accordance with Article 150 and shall start to apply at the earliest on the date of application referred to in Article 150.**
		4. Without prejudice to the date of application referred to in Article	**4. Without prejudice to the date of application 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
		150, the Commission is empowered to adopt delegated and implementing acts provided for in this Regulation as from [the date of entry into force of this Regulation]. Such acts, unless otherwise provided in this Regulation, shall apply from the date of application in accordance with Article 150.	**150, the Commission is empowered to adopt delegated and implementing acts provided for in this Regulation as from [the date of entry into force of this Regulation]. Such acts, unless otherwise provided in this Regulation, shall apply from the date of application in accordance with Article 150.**
		When adopting the delegated and implementing acts referred to in this Article, the Commission shall allow sufficient time between their adoption and their start of application.	**When adopting the delegated and implementing acts referred to in this Article, the Commission shall allow sufficient time between their adoption and their start of application.**
		Article 149c ***Establishment of the pharmacovigilance database and setting up of the manufacturing and wholesale distribution database***	***Article 149c*** ***Establishment of the pharmacovigilance database and setting up of the manufacturing and wholesale distribution database***
		Without prejudice to the date of application referred to in Article 150, the Agency, in collaboration with the Member States and the Commission, shall, in accordance with Articles 74 and 94 respectively, ensure the establishment of the pharmacovigilance database and	**Without prejudice to the date of application referred to in Article 150, the Agency, in collaboration with the Member States and the Commission, shall, in accordance with Articles 74 and 94 respectively, ensure the establishment of the pharmacovigilance database 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
		the setting up of the manufacturing and wholesale distribution database at the latest by the date of application of this Regulation.	**the setting up of the manufacturing and wholesale distribution database at the latest by the date of application of this Regulation.**
		Article 149d ***Initial input to the product database by competent authorities***	***Article 149d*** ***Initial input to the product database by competent authorities***
		At the latest by the date of application of this Regulation, the competent authorities shall submit, electronically, information on all veterinary medicinal products authorised in their Member State at that time to the Agency, using the format referred to in Article 51(3a)(a).	**At the latest by the date of application of this Regulation, the competent authorities shall submit, electronically, information on all veterinary medicinal products authorised in their Member State at that time to the Agency, using the format referred to in Article 51(3a)(a).**
		Article 149e ***Review of rules for environmental risk assessment***	***Article 149e*** ***Review of rules for environmental risk assessment***
		No later than three years after the date of application of this Regulation, the Commission shall present a report to the European Parliament and to the Council on a feasibility study of an active substance based review system ('monographs') and other potential alternatives for the environmental risk assessment of veterinary	**~~No later than three years after~~ By the date of application of this Regulation, the Commission shall present a report to the European Parliament and to the Council on a feasibility study of an active substance based review system ('monographs') and other potential alternatives for the environmental risk assessment of 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 products, to be accompanied, if appropriate, by a legislative proposal.	**medicinal products, to be accompanied, if appropriate, by a legislative proposal.**
		Article 149f ***Commission report on traditional herbal products used to treat animals***	***Article 149f*** ***Commission report on traditional herbal products used to treat animals***
		The Commission shall report to the European Parliament and to the Council within five years after the date of application of this Regulation, on traditional herbal products used to treat animals in the Union. If appropriate, the Commission shall make a legislative proposal in order to introduce a simplified system for registering traditional herbal products used to treat animals. The Member States shall provide information to the Commission on such traditional herbal products within its territory.	**The Commission shall report to the European Parliament and to the Council within five years after the date of application of this Regulation, on traditional herbal products used to treat animals in the Union. If appropriate, the Commission shall make a legislative proposal in order to introduce a simplified system for registering traditional herbal products used to treat animals. The Member States shall provide information to the Commission on such traditional herbal products within its territory.**

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 149g ***Review of measures regarding animals of the equine species***	***Article 149g*** ***Review of measures regarding animals of the equine species***
		No later than three years after the date of application of this Regulation, the Commission shall present a report to the European Parliament and to the Council on its assessment of the situation as regards the treatment with medicinal products of animals of the equine species and their exclusion from the food chain, including with regard to imports of animals of the equine species from third countries, to be accompanied by any appropriate action by the Commission taking into account in particular ┼public health, animal welfare, the risks for fraud and the level playing field with third countries┼.	**No later than three years after the date of application of this Regulation, the Commission shall present a report to the European Parliament and to the Council on its assessment of the situation as regards the treatment with medicinal products of animals of the equine species and their exclusion from the food chain, including with regard to imports of animals of the equine species from third countries, to be accompanied by any appropriate action by the Commission taking into account in particular ┼public health, animal welfare, the risks for fraud and the level playing field with third countries┼.**
		Article 149h ***Transitional measures regarding certain certificates of good manufacturing practice***	***Article 149h*** ***Transitional measures regarding certain certificates of good manufacturing practice***
		Without prejudice to the date of application referred to in Article 150, the obligations regarding certificates of good manufacturing	**Without prejudice to the date of application referred to in Article 150, the obligations regarding certificates of good manufacturing**

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
		practices for inactivated immunological veterinary medicinal products which are manufactured from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of animals in a unit having a confirmed epidemiological link shall only start to apply at the start of application of the implementing acts laying down specific measures on good manufacturing practices for those products referred to in Article 98(2).	**practices for inactivated immunological veterinary medicinal products which are manufactured from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of animals in a unit having a confirmed epidemiological link shall only start to apply at the start of application of the implementing acts laying down specific measures on good manufacturing practices for those products referred to in 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 *Entry into force*		*Article 150* *Entry into force* ***and application***	*Article 150* *Entry into force* ***and application***
This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.		This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.	This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
It shall apply from *[Office of Publications please insert date counting 24 months from the entry into force]* except for Article 15, 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.		It shall apply from *[Office of Publications please insert date counting* ***36*** *[…] months from the entry into force]*.[…]	It shall apply from *[Office of Publications please insert date counting* ***36*** *[…] months from the entry into force]*.[…]
This Regulation shall be binding in its entirety and directly applicable in all Member States.		This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in 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 -- paragraph 7 Experiments on animals ***other than clinical trials*** shall be conducted in accordance with Directive 2010/63/EU.	**AM 285** ***Member States shall ensure that all*** experiments on animals ~~other than clinical trials~~ shall be conducted in accordance with 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 -- subpoint 1.3.1 -- paragraph 1 -- point e (e) the potential risks relating to the development of antimicrobial resistance.	**AM 286** (e) the potential risks relating to the development of antimicrobial resistance ***during production and use***.		

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 -- subpoint 1.3.1 -- paragraph 7 -- introductory part This assessment shall normally be conducted in two phases. The first phase of the assessment shall always be performed and the second phase shall be performed if necessary. The details of the assessment shall be provided in accordance with accepted guidance. The assessment shall indicate the potential exposure of the environment to the product and the level of risk associated with any such exposure taking into account in particular the following items:	**AM 287** This assessment shall normally be conducted in two phases. ***All available data of sufficient reliability and relevance shall be considered, including information gained during the drug discovery process.*** The first phase of the assessment shall always be performed and the second phase shall be performed if necessary. The details of the assessment shall be provided in accordance with accepted guidance. The assessment shall indicate the potential exposure of the environment to the product 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 -- subpoint 1.3.1 -- paragraph 8 In the second phase, further specific investigation of the fate and effects of the product on particular ecosystems shall be conducted, in accordance with established guidance. The extent of exposure of the product to the environment, and the available information about the	**AM 288** In the second phase, further specific investigation of the fate and effects of the product on particular ecosystems shall be conducted, in accordance with established guidance***, and taking into account the pharmacological effect of the product as well as any relevant side effects***. The extent of exposure		

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
physical/chemical, pharmacological and/or toxicological properties of the substance(s) concerned, including metabolites, shall be taken into consideration.	of the product to the environment, and the available information about the physical/chemical, pharmacological and/or 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. […] **N**ame 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. […] **R**eference 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**.

ANNEX II

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 III[85]

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).
