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From:	General Secretariat of the Council
To:	Delegations
No. Cion doc.:	13289/14 COM(2014) 558 final
Subject:	Proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products

DOCUMENT PARTIALLY ACCESSIBLE TO THE PUBLIC (30.01.2018)

In the light of the outcome of discussions of Coreper (part 1) on 20 December 2017, delegations will find in Annex to this document a revised table which include the following changes:

- Rewording in Article 122a(1);
- Moving of the reference to 122a(2) from Article 149b(2a) to Article 149b(1);
- Addition of a new Article 111(5);
- Addition of a new paragraph in Recital 7d and deletion of the reference to a report in that same Recital;
- Deletion of Article 149i;
- Rewording in Recital 9a;
- Addition of new footnotes in Article 122a and 135(2)(aa).

ANNEX

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Proposal for a		**DELETED FROM THIS POINT UNTIL THE END OF THE COLUMN**	**DELETED FROM THIS POINT UNTIL THE END OF THE COLUMN**
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL			
on veterinary medicinal products			
(Text with EEA relevance)			
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 proposal from the European Commission,			
After transmission of the draft legislative act to the national Parliaments,			

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Having regard to the opinion of the European Economic and Social Committee[1],			
Having regard to the opinion of the Committee of the Regions[2],			
Acting in accordance with the ordinary legislative procedure,			
Whereas:			
(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.			

1 OJ C , , p. .
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).

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(2) In the light of the experience acquired and following the assessment by the Commission of the functioning of the market for veterinary medicinal products, the legal framework for veterinary medicinal products should be adapted to scientific progress, the current market conditions and economic reality.	**AM 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***.		
(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].			

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

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(4) Experience has shown that the needs of the veterinary sector differ 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			

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specificities of the veterinary sector, which cannot be considered as a model for the human medicines market.			
(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.			
(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 health, and for the development	**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		

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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.***		
(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.		
	AM 4 ***(7a) This Regulation aims at***		

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	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.		

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(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.			
(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	**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		

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for any veterinary medicinal product, including for generics of nationally authorised veterinary medicinal products.	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).***		

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(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.			
(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			

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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.			

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(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.***		

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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.			
(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.			

[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).

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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***		

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	administering antibiotics to food-producing animals.		
(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.	**AM 8** (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.		
(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.			

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(20) Directive 2010/63/EU of the European Parliament and of the Council[7] 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 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.	**AM 9** (20) Directive 2010/63/EU of the European Parliament and of the Council[7] 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 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.		

[7] 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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(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 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[8] 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			

[8] 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.***		
(24) Environmental risk assessments			

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should be mandatory for 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.			

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(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 should be protected against use by other applicants. That protection should, however, be limited in time in order to allow competition.	**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 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.		
	AM 12 ***(25a) Research should be incentivised, not only through the***		

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	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 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.			

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(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 substances' environmental properties. That can lead to divergent decisions being taken on products with similar effects on the***		

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	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.		
	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.***		

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(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.			

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(29) Differences in the 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.			

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(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.	**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 ***also*** be taken into account including societal, economical, ethical, environmental and welfare factors and the feasibility of controls.		
(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[9]. In such circumstances, Member States or the Commission	**AM 16** (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[9]. In such circumstances,		

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

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should seek to obtain additional information necessary for a more objective assessment of the particular concern and should review the measure accordingly within a reasonable period of time.	Member States or the Commission should seek to obtain additional information necessary for a more objective assessment of the particular 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	**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		

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authorisation requirements should sufficiently address the risks and benefits of antimicrobial veterinary medicinal products.	are included on the labels of ***human and*** 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.		
(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			

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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.			
	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-	**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		

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risk balance of the combination is favourable.	evidence is provided that the ***long-term*** benefit-risk balance of the combination is favourable.		
(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 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.	**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 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.***		

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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.		

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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	**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***		

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health professionals should be restricted to the amount required for treatment of the animals under their care.	***medicinal products. T***~~t~~hey should not be influenced, directly or indirectly, by economic incentives 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.***		
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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	**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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
ensure consistency with their activities and policies.	***creation of an international strategy to combat*** antimicrobial resistance***,*** ~~in order the ensure consistency with their activities and policies~~ ***in line with the recent Global Action Plan adopted by the WHO.***		
(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 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	**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 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		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
of the Agency.	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.		
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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 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			

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authorised before 2004.[10].			
(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 safety.			

[10] 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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(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.			
(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 inside the procedural framework			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
(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.			
(47) Holders of marketing authorisations should be responsible for continuously carrying out			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
(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.			
(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	**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		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
imposed on the marketing authorisation holder.	the obligation to conduct post-authorisation studies should 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***.		
(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			

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which apply to products manufactured in the Union, or with requirements which are recognised to be at least equivalent thereto.			
(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 method utilised in third countries for "pregnant mare serum gonadotropin" (PMSG), the Commission should revise Directive 91/412/EEC*** and ***include animal***		

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	welfare standards in the good manufacturing practice for veterinary medicinal products.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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.			

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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(54) Companies should be in possession of an authorisation to be 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.			
(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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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***		

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	antimicrobials, via the Internet to buyers in ***their own or*** other Member States. ***In order to minimise the risk to animal and human health, online sales of antimicrobials should be prohibited***.		

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	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.***		
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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 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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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 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			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.***		

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(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 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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.			
(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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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 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.	**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 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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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.			
(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.			
	AM 295		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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 unannounced 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 ***and should publish annual inspection reports.*** In order to preserve the effectiveness of the inspections, ~~authorities should have the possibility to perform~~ ***all inspections should be*** unannounced inspections.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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 control systems.	**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 functioning of national control		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	systems.		
(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.			

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(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.			
(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 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			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 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.	**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 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***		

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	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.		
	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 for pet animals and exotic species, provided that they notify these rules to the Commission.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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.			
(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		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.			
(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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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[11].			

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

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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.			
(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			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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:			
Chapter I **Subject matter, scope and definitions**			
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.		
	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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	functioning of the internal market.		
	AM 44 ***1b. The Member States shall notify the measures referred to in paragraph 1a to the Commission.***		
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.			
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.			
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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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');			
(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').			
4. This Regulation shall not apply to:			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;			
(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;			
(d) feed additives as defined in Regulation (EC) No 1831/2003 of the European Parliament and of the Council[12];			

[12] 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).

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;***		
	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***[13+]		

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

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

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	AM 47 ***(ec) feedingstuffs as defined in Regulation (EU) No 767/2009 of the European Parliament and of the Council.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 3 *Conflict of laws*			
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[14] 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***		

[14] 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).

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	the definition of a product covered by other Union legislation, the provisions of this Regulation shall prevail.		
2. 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*			
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:			
(a) it is presented as having properties for treating or preventing disease in animals;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;		
(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;		
(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***:		
(a) human,	**AM 52** (a) human***, for example human blood and human blood products;***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(b) animal,	**AM 53** (b) animal***, for example micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;***		
(c) vegetable,	**AM 54** (c) vegetable***, for example micro-organisms, plants, parts of plants, vegetable secretions, extracts;***		
	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;***		
	AM 58 ***(da) mineral.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	AM 59 ***2a. 'active substance' means a substance with a pharmacological activity;***		
(3) 'immunological veterinary medicinal product' means a veterinary medicinal product consisting of vaccines, 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;	**AM 60** 3. 'immunological veterinary medicinal product' means a veterinary medicinal product ~~consisting of~~***, such as*** vaccines, 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;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(4) 'biological veterinary medicinal product' means a veterinary medicinal product an active substance of which 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;			
(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 product;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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 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;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	AM 64 ***8a. 'antimicrobial' means any compound with a direct action on micro-organisms used for treatment or prevention of infections; antimicrobials include anti-bacterials, anti-virals, anti-fungals and anti-protozoals; in the context of this Regulation, an antimicrobial substance refers to an antibacterial;***		
	AM 65 ***8b. 'antiparasitic' means a medicinal product or substance used in the treatment of parasitic diseases attributable to various causes;***		
	AM 66 ***8c. 'antibacterial' means a compound with a direct action on bacteria used for treatment or prevention of infections;***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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~~;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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~~;		
(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:		
(a) any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health;			
(b) any risk of undesirable effects on the environment;			
(c) any risk relating to the development of antimicrobial resistance;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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~~;		
(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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(15) 'labelling' means information on the immediate packaging or the outer packaging;			
(16) 'outer packaging' means packaging in which is placed the immediate packaging;			
(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***;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;			
(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;			
(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***;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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***;		
(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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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***;		
(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 ensure that such foodstuffs do not contain residues in quantities harmful to public health;	**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 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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	of the European Parliament and of the Council[15];		
(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;		
(27) 'placing on the market' means the first making available of a veterinary medicinal product on the Union market.			

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

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	the need to use veterinary pharmaceutical products;		
	AM 80 ***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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	animals treated;		
	AM 83 ***27g. 'curative (therapeutic) treatment' means the treatment of an ill animal or group of animals, when the diagnosis of disease or infection has been made;***		
	AM 84 ***27h. 'control treatment (metaphylaxis)' means the treatment of a group of animals after the diagnosis of clinical disease in part of the group, with the aim of treating the clinically sick animals and controlling the spread of the disease to animals in close contact and at risk which may already be subclinically infected; the presence of such a disease in the group shall be established before the product is used;***		
	AM 85 ***27i. 'preventive treatment (prophylaxis)' means the treatment of an animal or a group of animals before clinical signs of disease emerge, in order to prevent the occurrence of disease or infection;***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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;***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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 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;***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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;***		
	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.***[16]		

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

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Chapter II **Marketing authorisations – general provisions and rules on applications**			
Section 1 **General provisions**			
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***.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 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,***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.***		
3. Decisions to grant, refuse, suspend, withdraw or vary a marketing authorisation shall be made public.			
4. Applicants for marketing authorisations and marketing authorisation holders shall be established in the Union.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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:			
(a) the national procedure laid down in Articles 42, 43 and 44;			
(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***.		
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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***.		
4. The applicant shall be responsible for the accuracy of the documents and data submitted.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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***.		
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Section 2 **Dossier requirements**			
Article 7 *Data to be submitted with the application*			
1. An application for a marketing authorisation shall contain the following information:			
(a) the administrative information set out in Annex I;			
(b) technical documentation satisfying 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
2. Where the application concerns an antimicrobial veterinary medicinal product, the following shall be submitted in addition to the information 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,		
(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***.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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[17] 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[18] ~~shall be~~		

[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).

[18] 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

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	~~submitted in addition to the information listed in paragraph 1~~ ***and that at least six months has elapsed from submission of such application***.		
4. Paragraph 3 shall not apply to 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[19] 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.			

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).

19 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).

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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[20] the application shall in addition to the documents listed in paragraph 1 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;			
(b) the complete technical file supplying the information required under Annexes III and IV to Directive 2001/18/EC;			

[20] 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).

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
Section 3 **Clinical trials**			
Article 8 *Approval of clinical 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.			
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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	withdrawal period. Such period shall either:		
(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***		
(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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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).			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	AM 102 ***6a. The holder of the clinical trial authorisation shall notify the 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**			
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:			
(a) the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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";			
(d) the name or corporate name or logo name of the marketing authorisation holder;			
(e) the target species;			
(f) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp.";			
(g) special storage precautions, if any.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.			
	AM 103 ***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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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:			
(a) the information listed in Article 9(1);			
(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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;		
(e) 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***;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(g) in case of homeopathic veterinary medicinal products, the statement "homeopathic veterinary medicinal product".			
	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.***		
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.		
3. Where there is no outer packaging, all the particulars listed in			

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paragraph 1 shall appear on the immediate packaging.			
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:			
(a) the name of veterinary medicinal product;the name of veterinary medicinal product;			

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(b) the quantitative particulars of the active substances;	**AM 105** (b) the quantitative particulars of the active substances***, unless the product exists in only one concentration or the concentration is reflected in the name***;		
(c) the batch number, preceded by the word "Lot";			
(d) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp.".			
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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:		

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(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 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;			
(c) the strength and pharmaceutical form of the veterinary medicinal product;			
(d) the target species, the dosage for each species, the method and route of administration and advice on correct administration, if necessary;	**AM 106** (d) the target species, the dosage for each species, the method and route of administration and***, if necessary,*** advice on correct administration~~, if necessary~~;		

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(e) the therapeutic indications;			
(f) the contra-indications and adverse events in so far as this information is necessary for the use of the veterinary medicinal product;			
(g) the withdrawal period, even if this is nil, in the event that the target species are food-producing animals;			
(h) special storage precautions, if any;			
(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***;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(k) the marketing authorisation number;	**AM 106** (k) ~~the marketing authorisation number;~~		
(l) in case of generic veterinary medicinal products, the statement 'generic veterinary medicinal product';			
(m) in case of homeopathic veterinary medicinal products, the statement "homeopathic veterinary medicinal product".			
	AM 106 ***(ma) qualitative and quantitative composition.***		

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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.			
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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 13 *Package leaflet of 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:			
(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;	**AM 107** (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;***		
(b) name and address of the marketing authorisation holder and, where appropriate, of the			

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manufacturer;			
(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.";~~		
(e) pharmaceutical form;			
(f) special storage precautions, if any;			
(g) target species;	**AM 107** (g) target species ***as well as dosage levels for the different target species***;		
(h) a special warning if necessary for the medicinal product;			
(i) the batch number, preceded by the word "Lot";	**AM 107** ~~(i) the batch number, preceded by the word "Lot";~~		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(j) registration number;			
(k) withdrawal period, if applicable.			
(l) the statement "homeopathic veterinary medicinal product".			
Article 14 *Languages*			
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 15 *Abbreviations and pictograms common throughout the Union*			
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).			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Section 5 **Dossier 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*			
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:			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(a) the application satisfies the requirements set out in Annex III;			
(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');			
(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.			

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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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
5. The summary of the product 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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:		
(a) the application satisfies the requirements set out in Annex III;			
(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);			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;			
(d) documentation on the safety of that combination is provided.			
Article 18 *Hybrid veterinary medicinal products*			
1. By way of derogation from Article 16(1), the results of appropriate pre-clinical studies and clinical trials shall be required when the product does not meet all the characteristics of a generic veterinary medicinal product because:			
(a) there are changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration of the generic veterinary medicinal product compared to the reference veterinary medicinal product, or			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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.			
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.			

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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 efficacy referred to in Article 7(1)(b) which is available for the reference veterinary medicinal product.			
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			

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documented and that they provide an acceptable level of safety.			
2. The application shall satisfy the requirements set out in Annex III.			
Section 6 **Dossier requirements for applications for limited market and in exceptional circumstances**			
Article 21 *Reduced data requirements for applications 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~~:		

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(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;			
(b) the applicant provides the evidence that the veterinary 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.***		

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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***.		
	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.***		

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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 22 *Data requirements for applications 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:		
(a) a requirement to introduce conditions or restrictions, in particular concerning the safety of the veterinary medicinal product;			
(b) a requirement to notify the	**AM 113** (b) a requirement to notify the		

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competent authorities of any incident relating to the use of the veterinary medicinal product;	competent authorities of any ~~incident~~ ***adverse event*** relating to the use of the veterinary medicinal product;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(c) a requirement to conduct post-authorisation studies.	**AM 113** (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***.		
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***.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Section 7 **Examination of applications and granting of marketing authorisations**			
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:			
(a) verify that the documentation submitted complies with the requirements laid down in Article 7(1) and is satisfactory for granting a marketing authorisation;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(b) assess the veterinary medicinal product regarding the quality, safety and efficacy documentation provided.			
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.			
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:			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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 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[21].			
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.			

[21] 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).

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 25 *Information on manufacturers*			
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 methods described in the documentation submitted in support of the application in accordance with Article 7(1).	**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 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***.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 26 *Information to 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 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.			
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.			
2. If an applicant withdraws his application for marketing authorisation submitted to a competent authority or			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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:			
(a) a summary of the product characteristics containing the information laid down in Article 30;			
(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;			
(c) details of any conditions or restrictions which should be imposed as regards the safe and effective use of the veterinary medicinal product;			

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(d) the approved text of the labelling and package leaflet.			
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 Commission in accordance with Regulation (EC) No 470/2009.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.		
Article 29 *Requirement for a veterinary prescription*			
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:		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;			
(b) veterinary medicinal products for food-producing animals;			
(c) antimicrobial veterinary medicinal products;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;			
(e) officinal formulae intended for food-producing animals;			
(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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	AM 116&298 ***1a. Member States may on their territories provide for additional legal subcategories in accordance with the respective national law.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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:		
(a) the target species,			
(b) the person administering the products to the animal,			
(c) the environment.			
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:		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;			
(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;		
(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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;~~		
(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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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 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*			
1. The summary of the product characteristics referred to in Article 28(1)(a) shall contain the following information:			

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(a) name of the veterinary medicinal product followed by its strength and pharmaceutical form;			
(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;		
(c) clinical information:			
(i) target species,			
(ii) indications for use,			
(iii) contra-indications,			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(iv) special warnings for each target species,			
(v) special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals,			
(vi) frequency and seriousness of adverse events,	**AM 119** (vi) frequency and seriousness of adverse ~~events~~ ***reactions***,		
(vii) use during pregnancy, lactation or lay,			
(viii) interaction with other medicinal products and other forms of interaction,			
(ix) administration route and amounts to be administered,			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(x) overdose symptoms and emergency procedures and antidotes in the event of overdose, where applicable,			
(xi) where appropriate, special indications or restrictions for use in accordance with Articles 107 to 109,			
(xii) where appropriate, an indication of classification of an antimicrobial regarding its strategic use,			
(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,***		
(d) withdrawal periods, including animal species/foodstuffs combinations;			
(e) pharmacological information:			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(i) pharmacodynamics,			
(ii) pharmacokinetics,			
(iii) 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;***		
(iv) 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,			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(vi) special precautions for storage,			
(vii) 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;			
(f) name of the marketing authorisation holder;			
(g) marketing authorisation number(s);			
(h) if applicable, date of the first authorisation;			
(i) the date of the last revision of the summary of the product characteristics;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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'.			
	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 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			

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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*			
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').			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 32 *Decisions refusing marketing authorisations*			
1. The marketing authorisation shall be refused on any of the following grounds:			
(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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;			
(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***;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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***;		
(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;			
(g) risk for public health in case of development of antimicrobial resistance outweighs the benefits of the product to animal health;			
	AM 127 ***(ga) the product is a substance of high concern;***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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;			
	AM 129 ***(ha) the product poses significantly higher risks to the treated animal, public health or the environment compared to the standard reference treatment;***		
	AM 130 **(*hb) unacceptable side effects or secondary effects on the treated animal;***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(i) the qualitative or quantitative composition of the product is not as stated in the application.			
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***.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.	**AM 133** 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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 examination procedure referred to in Article 145(2).	**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 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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Section 8 **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 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:			
(a) the period of the protection of technical documentation as set out in Articles 34 and 35 has elapsed, or			
(b) the applicants have obtained written agreement in the form of a letter of access with regard to that documentation.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	AM 301 ***3a. Safety information with regard to the environmental effects of veterinary medicinal products shall not be protected.***		
Article 34 *Periods of the protection of technical documentation*			
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;		
(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;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(c) 18 years for veterinary medicinal products for bees;	**AM 136** (c) ~~18~~ ***20*** 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).			
2. The protection shall apply from the day when the marketing authorisation for the veterinary medicinal product was granted in accordance with Article 7.			
	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		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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:		
	(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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.		
Article 35 *Prolongation of the 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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	information on the submission for extension of the marketing authorisation shall be made publicly available.		
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 of the protection provided for in Article 34 shall be prolonged by 4 years.	**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 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***.		
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	**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		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
period of the protection of technical documentation') shall not exceed 18 years.	('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.***		
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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
Chapter III **Procedures for granting marketing authorisations**			
Section 1 **Marketing authorisations valid throughout the Union ('centralised marketing authorisations')**			
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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	considered the priority procedure. The Commission and the Agency shall develop and encourage use of the centralised procedure, particularly by facilitating access for SMEs.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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:			
(i) recombinant DNA technology;			
(ii) controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells;			
(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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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***;		
(d) biological veterinary medicinal products which contain or consist of engineered allogeneic tissues or cells;			
(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.~~		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
3. For veterinary medicinal 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.	**AM 143** 3. For veterinary medicinal 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~~.		
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.~~		
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			
Article 40 *Procedure for centralised marketing authorisation*			
1. Centralised marketing authorisations shall be granted by the Commission following an assessment by the Agency.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
6. After the completion of the procedure referred to in paragraph 5 the opinion shall be forwarded without delay to the Commission.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 differences. The draft decision shall be forwarded to Member States and 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).			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
10. The Agency shall disseminate the documents referred to in Article 28 to the applicant.			
11. The Agency shall make the opinion publicly available, after deleting any commercially confidential information.			
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
3. Within 15 days after its adoption, the Agency shall forward its opinion to the Commission and the applicant.			
Section 2 **Marketing authorisations valid in a single Member State ('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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
National marketing authorisations shall only be granted in respect of veterinary medicinal products not falling within the scope of Article 38(2).			
Article 43 *Applications for national marketing authorisations*			
Competent authorities shall verify whether an application for a national marketing authorisation has been submitted or granted for the same veterinary medicinal product in another Member State. Where that is the case, the competent authority of that Member State shall decline to assess the application and inform the applicant of the possibility to submit an application under the mutual recognition procedure or the decentralised authorisation procedure.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
2. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Section 3 **Marketing authorisations valid in several Member States ('decentralised marketing authorisations')**			
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.			
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).			
Article 46 *Procedure for decentralised marketing authorisation*			
1. Applications for decentralised	**AM 145** 1. Applications ***and the dossier***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
marketing authorisation shall be submitted to the Member State chosen by the applicant (‘reference Member State’).	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~~’~~).		
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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
7. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Section 4 **Mutual recognition of marketing authorisations granted by national authorities**			
Article 47 *Scope of mutual recognition marketing authorisation*			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 48 *Procedure for mutual recognition marketing authorisation*			
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~~")~~.		
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.~~		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
3. An application for mutual recognition of a marketing authorisation shall be accompanied by the following:			
(a) an information about the Member States where the applicant seeks to obtain recognition of the marketing authorisation;			
(b) copies of marketing authorisations granted for the veterinary medicinal product in other Member States;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Suggested approach to the EP amendments
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').	**AM 150** 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')~~.		
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			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Suggested approach to the EP amendments
leaflet.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
8. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Section 5 **Coordination group review and scientific re-examination**			
Article 49 *Coordination group review 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 group') by the reference Member State.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 group represented at the meeting.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.		
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 and to the applicant for information purposes.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Chapter IV **Post marketing authorisation measures**			
Section 1 **Union product database**			
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.		
2. The product database shall contain information on:			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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***;		
(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;			
(c) veterinary medicinal products allowed to be used in a Member State in accordance with Articles 119 and 120.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			
7. The Agency shall, in collaboration with Member States and the Commission, draw up the functional specifications for the product database.			
8. The Commission shall ensure that information reported to the product database is collected, collated and made accessible and that the information is shared.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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***.		
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***.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Section 2 **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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 54 *Collection of data on the sales and use of antimicrobial veterinary medicinal products*			
1. Member States shall collect relevant and comparable data on the 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***.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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***.		
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 Agency.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.***		
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).			
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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-producing animals, and in particular the oral routes used through feed and water, and their subsequent impact on antimicrobial resistance.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 55 *Responsibilities of the marketing authorisation holders*			
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 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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[22].			
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.			

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

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 product concerned.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 56 *National helpdesks for small 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 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:		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	(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:		
	(i) the same qualitative and quantitative composition in terms of active substances and excipients, and the same pharmaceutical form;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	(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 Agency shall register the authorisation of parallel importation or parallel distribution***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	AM 169 ***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:***		

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	(a) the name of the veterinary medicinal product, its strength, its pharmaceutical form and its therapeutic indications;		
	(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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	A parallel import authorisation application shall contain at least the following information:		
	(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;		

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	(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 (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;		

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	(b) the name of the qualified person responsible for pharmacovigilance;		
	(c) the Member State of origin and destination.		
	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**			
Article 57 *Subsequent recognition of marketing authorisations by other Member States*			
1. After completion of a mutual recognition procedure laid down in Article 48 or a decentralised procedure laid down in Article 46, the marketing authorisation holder may submit an			

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application for a marketing authorisation for a veterinary medicinal product to additional Member States. The application 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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 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		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	granted by the Commission which shall be valid throughout the Union.		
	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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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**			
Article 58 *Variations to the terms of a marketing authorisation*			
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').			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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).			
3. The Commission shall take account of the following criteria when adopting those implementing acts:			
(a) the need for a scientific assessment of changes in order to determine the risk to public health, animal health or the environment;			
(b) whether changes have an impact on the safety and efficacy of the veterinary medicinal product;			
(c) whether changes imply a significant alteration to the summary of product characteristics.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 59 *Consequential changes to product information*			
Where a variation entails consequential changes to the summary of the product characteristics, the labelling or the package leaflet, those changes shall be considered as part of that variation for the purposes of the examination of the application for a variation.			
Article 60 *Variations to the terms of a marketing authorisation 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.			
2. If necessary, competent authorities or, where the veterinary medicinal product is authorised under the centralised marketing authorisation procedure, the Commission shall			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
amend the decision granting a marketing authorisation in accordance with the change.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
2. The application referred to in paragraph 1 shall contain:			
(a) a description of the variation;			
(b) reference to marketing authorisations affected by the application;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(c) where the variation leads to other 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			
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.			
3. Where none of the marketing authorisations referred to in paragraph 1 is a centralised marketing			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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***.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
5. The opinion shall be forwarded to the applicant.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			
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			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
amend the marketing authorisation or reject the 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).			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
3. The competent authority or the Agency shall notify the marketing authorisation holder of the amended marketing authorisation without delay.			
4. The product database shall be updated accordingly.			
Article 66 *Coordination group review*			
Where the opinion is prepared by a competent authority assigned in accordance with Article 63(3), each competent authority concerned shall amend the marketing authorisation granted by it or reject the variation in line with the opinion prepared by the competent authority assigned in accordance with Article 63(3).			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
However, if a competent authority 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*			
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Section 5 **Harmonisation of the summaries of the product characteristics for nationally authorised products**			
Article 68 *Preparatory phase of the harmonisation exercise*			
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	-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 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	**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		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
and the same pharmaceutical form and for which national marketing authorisations have been granted in different Member States before 1 January 2004 ('similar products').	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***.		
2. For the purposes of determining qualitative and 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 69 *Procedure for harmonisation of summaries of products characteristics*			
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~~.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.		
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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	characteristics.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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:		
(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;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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.***		
	AM 173 ***4a. Further than the conditions of use, other elements of the summary of product characteristics and data quality set, may be harmonised.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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, are*** in conformity with the agreement within 30 days of receipt of the information regarding the agreement from the rapporteur. ***Once an***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 70 *Harmonisation of summary of products characteristics following reassessment*			
1. By way of derogation from Article 69, 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 prepared.	**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 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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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 examination procedure referred to in Article 145(2).	**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 with the examination procedure referred to in Article 145(2).		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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).***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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*			
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		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	products.		
Section 6 Pharmacovigilance			
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		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	listed in Articles 73, 76 and 77 ('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*			
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 Article~~s 77 and~~ 79 ~~('Union pharmacovigilance system')~~. ***Marketing authorisation holders shall set up and maintain a system to monitor the safety, effectiveness***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	and quality of their products, 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'~~:		
(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;***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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~~;		
(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;		
(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;		
(e) any noxious response in humans to a veterinary medicinal product;	(e) any noxious ~~response~~ ***reaction*** in humans to a veterinary medicinal product;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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***;***		
	(fa) any suspected unintended transmission via a veterinary medicinal product of any infectious agent.		
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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 veterinary medicinal products, to be accompanied, if appropriate, by a legislative proposal.***		
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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.		
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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.		
	AM 185 **Article 74 -- paragraph 3 a (new)** ***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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 75 *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 Article 77.			
3. The general public shall have access to the pharmacovigilance database only as regards the following information:			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;		
(b) information on the process and outcome of the signal management referred to in Article 81 for veterinary medicinal products and groups of products.			
	AM 187 **Article 75 -- paragraph " -- point b a (new)** ***(ba) information about incidence of adverse events.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 76 *Adverse events reporting*			
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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	Good Clinical Practice guidelines for clinical trials.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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. 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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			
Article 77 *Pharmacovigilance responsibilities of the marketing authorisation holder*			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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***.		
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.		
	AM 194 **Article 77 -- paragraph 2 a (new)** ***2a. The marketing authorisation holder shall be required to check regularly that the contractor is***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	carrying out the work in accordance with the requirements of the contract.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
3. The marketing authorisation holder shall permanently have at his disposal one or more appropriately qualified persons responsible for pharmacovigilance. Those persons shall reside and operate in the Union. Only one qualified person shall be designated by the marketing authorisation holder per pharmacovigilance system master file.	**AM 195** 3. The marketing authorisation holder shall permanently have at his disposal ~~one or more~~ ***an*** appropriately qualified ~~persons~~ ***person*** responsible for 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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.		
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.		
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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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 which the qualified person designated by the authorisation holder conducts the operations***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.		
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 :***		
(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	**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~~		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
system master file') for all products under their responsibility;	('pharmacovigilance system master file') for all products under their responsibility;		
(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***;		
(c) notifying the competent authorities and the Agency of the place where the qualified person operates and where the pharmacovigilance system master file is accessible in the Union;			
(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;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(e) preparing the adverse event reports referred to in Article 76;			
(f) ensuring that collected adverse event reports are recorded 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 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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(i) evaluating by means of the pharmacovigilance system all information, considering options for risk minimisation and prevention and taking appropriate measures if necessary;			
(j) monitoring the pharmacovigilance system and ensuring that if needed, an appropriate corrective action plan is prepared and implemented;			
(k) ensuring that all personnel involved in the performance of pharmacovigilance activities receives continued training;	**AM 199** (k) ensuring that all personnel 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;***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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; **.**		
	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 review on request from the national competent authority or during the***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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***		
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 Articles 130 to 135 concerning marketing authorisations where necessary.	**AM 200** 1. Competent authorities shall evaluate all adverse events reported to them by ***marketing authorisation holders,*** healthcare professionals and animal holders, manage risks and take the measures referred to in Articles 130 to 135 concerning marketing authorisations where necessary.		
2. Competent authorities shall take all appropriate measures to encourage the reporting of adverse events by			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
healthcare professionals and animal holders.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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***.		
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 Member State subject to the written agreement of the latter.	**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 another 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 81 *Signal management process*			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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').		
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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').		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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*			
1. Before the expiry of the period of validity of 3 years, marketing authorisations for a limited market granted in 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 every 5 years.	**AM 205** 1. Before the expiry of the period of validity of ~~3~~ ***five*** years, marketing authorisations for a limited market granted in 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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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***		
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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
2. The application for re-examination shall be submitted to the competent authority that granted the authorisation or the Agency at least 3 months before the expiry of the marketing authorisation.	**AM 206** ***deleted***		
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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Section 8 **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 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			

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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
2. The draft decision shall be forwarded to Member States.			
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			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
medicinal products subject to the marketing authorisation that contain the active substance 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Chapter V **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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
2. The competent authorities shall record homeopathic veterinary medicinal products registered by them in the database referred to in Article 51.			
	AM 208 **Article 88 -- paragraph 2 a (new)** ***2a. The veterinary homeopathic medicinal products not subject to Article 89(1) shall be authorised in accordance with the general regulations. Where the safety tests, preclinical and clinical trials of veterinary homeopathic medicinal products are not subject to Article 89(1), a Member State may introduce or retain on its territory specific rules in accordance with the principles and characteristics as practised in that Member State.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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:			
(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;			
(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"***;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(c) no specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto.			
2. The Commission shall be 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.			
Article 90 *Requirements 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:			
(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;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;			
	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;			
(d) the manufacturing authorisation for the veterinary medicinal products concerned;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(e) copies of any registrations or authorisations obtained for the same 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;			
(g) data concerning the stability of the medicinal product;			
(h) in the case of veterinary medicinal products intended for food-producing species, proposed withdrawal period together with all requisite justification;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(i) in the case of veterinary medicinal products intended for food-producing species and containing pharmacologically active substances that have not been 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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
4. The procedure of registering a homeopathic veterinary medicinal product shall be completed within 210 days after the submission of a valid application.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Chapter VI **Manufacturing, import and export**			
Article 91 *Manufacturing authorisations*			
1. A manufacturing authorisation shall be required in order to carry out any of the following activities ('manufacturing'):			
(a) to produce or import veterinary medicinal products; or			
(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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
	AM 212 **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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
4. Manufacturing authorisations shall be valid throughout the Union.			
Article 92 *Requirements for obtaining a manufacturing authorisation*			
1. Applications for manufacturing authorisations shall be submitted to a competent authority in the Member State where the manufacturing site is located.			
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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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*;		
(d) statement to the effect that the applicant fulfils the requirements laid down in Article 98.			
Article 93 *Granting 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
2. An authorisation shall apply only to the manufacturing site, the veterinary medicinal products, and the pharmaceutical forms specified in the application.			
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.			
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 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.***		
Article 94 *Database on manufacturing authorisations*			
1. A Union database on manufacturing, import and wholesale distribution shall be set up and maintained by the Agency ('manufacturing and wholesale distribution database').			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
2. The database shall include information on any manufacturing and wholesale distribution authorisations granted by competent authorities within the Union.			
3. The Agency shall make public a format for electronic submissions of data to the database.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
5. The Agency shall, in collaboration with Member States and the Commission, draw up functional specifications 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.			
Article 95 *Access to the database on manufacturing authorisations*			
1. The competent authorities shall have full access to the database set up in accordance with Article 94.			
2. Manufacturers and wholesalers shall have access to the database to the extent necessary for them to comply with their obligations.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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 to 90 days.			
2. The application shall contain description of the requested change and the authorised products affected by this change.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 97 *Manufacturing authorisation for import and export*			
1. The manufacturing authorisation shall also be required for imports from and exports to third countries.			
2. The requirement referred to in paragraph 1 shall not apply to holders of a wholesale distribution authorisation referred to in Article 104.			
Article 98 *Obligations of the manufacturing authorisation holders*			
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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(b) have at his disposal the services of at least one qualified person within the meaning of Article 100;			
(c) enable the qualified person referred to in Article 100 to carry out his duties, particularly by placing at his disposal all the necessary technical equipment and testing facilities;			
	AM 214 **Article 98 -- paragraph 1 -- point c a (new)** ***(ca) comply with the rules on good manufacturing practice for medicinal products established in the Union and use as starting materials only active substances which have been manufactured in accordance with the rules on good manufacturing practice for starting materials established in the Union;***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(d) inform the competent authority if the qualified person referred to in Article 100 is replaced;			
(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;			
(g) keep detailed records of all veterinary medicinal products supplied by him, including samples, in accordance with Article 99.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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:			
(a) date of the transaction,			
(b) name of the veterinary medicinal product,			
(c) quantity supplied,			
(d) name and address of the recipient,			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(e) batch number.			
2. The records mentioned in paragraph 1 shall be available for inspection by competent authorities for a period of 3 years.			
Article 100 *Qualified person for manufacturing*			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
Article 101 *Batch release of veterinary medicinal products*			
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 shall prepare a report to this effect.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
3. The reports signed by the qualified person as referred to in paragraph 1 shall be valid throughout the Union.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
5. Where veterinary medicinal products manufactured in the Union are imported into the Union from a third country, paragraph 1 shall apply.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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[23] and it is demonstrated that the tests referred to in paragraph 1 have been 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.			

[23] 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).

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 102 *Competent authorities' measures*			
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*			
Upon request of the manufacturer or exporter of veterinary medicinal products, or of the authorities of an importing third country, the competent authority shall certify that the manufacturer:			
(a) holds a manufacturing authorisation for the product in question, or			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(b) possesses a certificate of good manufacturing practice as referred to in Article 127.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Chapter VII **Supply and use**			
Section 1 **Wholesale distribution**			
Article 104 *Wholesale distribution of veterinary medicinal products*			
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.			
2. Wholesale distribution authorisations shall be valid throughout the Union.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
3. Supplies of small quantities of veterinary medicinal products from one retailer to another shall not be regarded as wholesale distribution.	**AM 215** **Article 104 -- paragraph 3** 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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
	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.***		
	AM 217 **Article 104 -- paragraph 4 b (new)** ***4b. Wholesalers shall obtain their supplies of medicinal products only***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.			
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 105 *Procedure for granting 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.			
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:			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;***		
(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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(c) has an appropriate record keeping system ensuring compliance with the requirements referred to in Article 106.			
	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;***		
	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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	Member State in accordance with Article 107(1) so that animal health needs in the 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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 106 *Record keeping requirements for wholesale distributors*			
1. The wholesale distributor shall keep detailed records. The following minimum information shall be recorded in respect of each purchase and sale transaction:			
(a) date of the transaction;			
(b) name of the veterinary medicinal product;			
(c) batch number,			
(d) expiry date of the veterinary medicinal product;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(e) quantity received or supplied;			
(f) name and address of the supplier in the event of purchase or of the recipient in the event of sale.			
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.			

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	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 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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Section 2 **Retail**			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 concerned.	**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 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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.***		
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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***:		
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(a) date of the transaction;			
(b) name of the veterinary medicinal product;			
(c) batch number;			
(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;			
(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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

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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[24] 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 products and the prescriptions comply with the law of the***		

[24] 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).

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.*** ***1a. On grounds of public or animal health, animal welfare or environmental protection, Members***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.		

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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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[25], websites offering veterinary medicinal products shall contain at least:	**AM 230** 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***[26], websites offering veterinary medicinal products shall contain at least:		
(a) the contact details of the competent authority of the Member State in which the retailer offering the veterinary medicinal products is established;			

[25] 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).

[26] **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).***

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(b) a hyperlink to the website of the Member State of establishment set up in accordance with 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 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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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).			
5. Each Member State shall set up 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;		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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 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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 bodies which list authorised retailers in Member States.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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***		

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	prescription across the Union, 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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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***		
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,***		

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	ranging from supermarkets, pet stores, to traditional and online (veterinary) 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*			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
1. A veterinary prescription shall contain at least the following elements ('minimum requirements'):			
(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;***		
(b) full name and contact details of the animal owner or keeper;			
(c) issue date;			
(d) full name and contact details, qualifications and professional membership number of the person writing the prescription;			
(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;		
(f) name of the prescribed product;	**AM 235** (f) name of the prescribed product ***and the active substance(s);***		
(g) pharmaceutical form (tablet, solution, etc.);			

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(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;***		
(i) strength;			
(j) dosage regimen;			
(k) withdrawal period if relevant;			
(l) any necessary warnings;	**AM 235** (l) any necessary warnings ***and restrictions, including, where relevant, the risks entailed by imprudent 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.			

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	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***.		
	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.***		

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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.***		
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***		

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	systems issued by any person other than a veterinarian shall immediately notify the Commission, which shall forward such information to all Member States.		
	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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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Section 3 **Use**			
Article 111 *Use of veterinary 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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
2. Member States shall lay down procedures for placing on the market of the medicinal products allowed to be used in their territory in accordance with Articles 115, 116, 119, 120 and 121.			
	AM 238 **Article 111 -- paragraph 2 a (new)** ***2a. Antimicrobial veterinary medicines shall not under any circumstances serve to improve performance or compensate for poor animal husbandry. Routine prophylactic use of antimicrobials is therefore prohibited. Prophylactic use of antimicrobial veterinary medicines shall only be permitted on single animals and when fully justified by a veterinarian in exceptional indications, of which a list shall be drafted by the Agency. Metaphylactic use of antimicrobial veterinary medicines shall be restricted to use in clinicall-ill animals and to those single animals that are identified as being at a high risk of contamination, to prevent***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	further spread of the disease in the group. Where such products are to be 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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	cross compliance under the Common Agricultural Policy's 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))		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	AM 239 **Article 111 a (new)** ***Article 111a*** ***Supply and use of antimicrobials***		

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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	1. Member States may restrict or prohibit the supply or use, or both, of certain antimicrobials in 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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	health. ***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*			
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.		
2. The following information shall be recorded:			
(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***;		

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(b) name of the veterinary medicinal product;			
(c) quantity of the veterinary 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*** ;		
(e) identification of the animals treated;	**AM 243** (e) identification of the animals treated ***and the diagnosis of the disease treated***;		
(f) name and address of the prescribing veterinarian and, if applicable, a copy of the prescription.			

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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.***		
	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, taking into account the type of use.*** ***2. The competent national authority***		

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	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 therapy prevalence, if the biannual therapy***		

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	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 wellbeing of his cattle and***		

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	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			

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Article 113 *Use of immunologicals*			
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:			
(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;			

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(c) the disease to which the product is intended to confer immunity is largely absent from the territory concerned.			
2. The competent authorities shall inform the Commission of all instances in which the provisions of paragraph 1 are applied.			

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Article 114 *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:			
(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;			
(b) the veterinary medicinal products are transported by the veterinarian in the original packaging;			
(c) where intended for administration to food-producing animals, the veterinary medicinal			

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products have the same qualitative and quantitative composition of active substances as the veterinary medicinal products authorised in the host Member State;			

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(d) the veterinarian follows the 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;			
(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;			

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(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 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.			
Article 115 *Use of medicinal products for species or indications 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	**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		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
particular to avoid causing unacceptable suffering, exceptionally treat the animal concerned with the following:	~~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***:		
(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;***		
(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***		

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(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 2001/83/EC of the European Parliament and of the Council[27] or Regulation (EC) No 726/2004;	**AM 247** ***deleted***		

[27] 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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(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 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***		

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	authorised to do so under national law.		

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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.			
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.			
	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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Article 116 *Use of medicinal products for species or indications outside the terms of the marketing authorisation in 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 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***:		

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(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 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***		

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	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 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***		
(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***		

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(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***		
	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 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			

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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 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:			

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(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-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.***		

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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;			
(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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.		
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.			

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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 criteria:			
(a) for meat and offal of food producing mammals and 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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(ii) if the product is not authorised for food producing species, 28 days;			
(b) for animal species 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;			
(ii) if the product is not authorised for any milk producing species, 7 days;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(c) for animal species 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;			
(ii) if the product is not authorised for any eggs producing species, 7 days;			
(d) for aquatic animal species for human consumption and aquatic animal species producing eggs for human consumption not less than:			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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".***		
5. By way of derogation from paragraph 1, the Commission shall 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;			
(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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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).			
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*		
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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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 conditions.	**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 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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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,			
	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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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.***		
	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***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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*			
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 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[28] [*Office of Publications, please insert number and, in a footnote, date, title and the*	**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		

[28] Regulation of the European Parliament and the Council of….. on animal health (OJ L……).

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.	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 suitable medicinal product and after informing the Commission of the detailed conditions of use***.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 120 *Exemption for veterinary medicinal products for certain animals kept exclusively as pets*			
Where veterinary medicinal products are intended solely for aquatic animals, cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits kept exclusively as pets, Member States may permit exemptions, in their territory, from Article 5, provided that such products do not contain substances the use of which requires veterinary controls and that all possible measures are taken to prevent unauthorised use of the products for other animals.			
Article 121 *Use of immunologicals from third countries*			
If an animal is being imported from, or exported to, a third country and is thereby subject to specific binding health rules, a competent authority may permit the use, for the animal in question, of an immunological veterinary medicinal product that is			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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*			
Member States shall ensure that appropriate collection systems are in place for veterinary medicinal products that are unused or expired.			
	AM 267 **Article 122 -- paragraph 1 a (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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Section 4 **Advertising**			
Article 123 *Advertising of veterinary medicinal products*			
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.			

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	AM 268 **Article 123 -- paragraph 1 a (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.***		
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.			

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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 124 *Prohibition of advertising of certain veterinary medicinal products*			
1. The advertising of the following veterinary medicinal products shall be prohibited :			
(a) veterinary medicinal products which are available on veterinary prescription only;			

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(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.			
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.		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Chapter VIII **Inspections and 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.		
	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.***		
	AM 272 **Article 125 -- paragraph 1 b (new)** ***1b. To combat fraud, the competent authorities shall establish a plan for***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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:			
(a) the risk of non-compliance with the legal requirements associated with the activities of the undertakings and the location of the activities,			
(b) the entity's past record as regards the results of inspections performed on them and their compliance with the requirements,			
(c) any information that might indicate non-compliance with the legal requirements,			
(d) the potential impact of non-compliance with the requirements on public health, animal health and the environment.			
3. Inspections may also be carried out upon request of another competent authority, 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:			
(a) inspect manufacturing or supply establishments and any laboratories entrusted by the manufacturing authorisation holder with the task of carrying out control tests;			
(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;			

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(c) examine any documents relating to the object of the inspection;			
(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.			
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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 127 *Certificates of good manufacturing 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 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			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Council Decision 94/358/EC[29] (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 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.			

[29] 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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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
2. The competent authority in the Member State in which the qualified person responsible for pharmacovigilance operates shall 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.			
3. The results of the pharmacovigilance inspections shall be collected in the pharmacovigilance database.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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*			
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 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.			
In such cases, the competent authorities of another Member State shall not apply the provisions of paragraph 4.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
7. The list of tests to be 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
8. The competent authorities shall recognise the results of the tests.			
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.			
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, 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			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
authorities of other Member States in which the veterinary medicinal product is authorised.			
Chapter IX **Restrictions and penalties**			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
2. Member States and the Commission may 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 131 *Suspending, withdrawing or varying 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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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:			
(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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(c) the pharmacovigilance system required in accordance with Article 72 is inadequate;			
(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.			
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 invited to provide oral or written explanations.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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).			
6. Member States shall lay down procedures for application of paragraphs 1 to 3.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

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Article 132 *Suspending and withdrawing 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:			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(a) suspend manufacture of veterinary medicinal products;			
(b) suspend imports of veterinary medicinal products from third countries;			
(c) suspend the manufacturing authorisation for a category of preparations or for all preparations;			
(d) withdraw the manufacturing authorisation for a category of preparations or for all preparations.			
	AM 277 **Article 132 a (new)** **Article 132a** **Suspending and withdrawing wholesale distribution authorisations** ***In cases of non-compliance with the requirements laid down in Articles 104, 105 and 106, the competent authority may:*** ***(a) suspend the wholesale distribution of the veterinary medicinal products;*** ***(b) suspend the authorisation for wholesale distribution of a category***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	of veterinary medicinal products; ***(c) withdraw the authorisation for wholesale distribution of a category, or all categories, of veterinary medicinal products.***		
Article 133 *Prohibiting 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:			
(a) the benefit-risk balance of the veterinary medicinal product is unfavourable;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(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;			
(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 hazard;			
(d) the control tests referred to in Article 129(1) have not been carried out.			
2. The competent authorities or the Commission may confine the prohibition on supply and withdrawal from the market solely to the contested production batches.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 135 *Penalties imposed by the Commission*			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 as well as the conditions and methods for their collection.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Chapter X **Regulatory network**			
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.***		
	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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 ~~136~~ 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.		
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
Article 137 *Information to the Agency and international organisations from the competent authorities*			
1. Each competent authority shall immediately inform the Agency of all decisions granting marketing authorisation and of all decisions refusing or withdrawing marketing authorisation, repealing a decision refusing or withdrawing marketing authorisation, prohibiting supply or withdrawing a product from the market, together with the reasons on which such decisions are based.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
2. The Committee shall establish specific procedural rules for the application of paragraph 1.			
Article 139 *Committee for Medicinal Products for Veterinary Use*			
1. A Committee for Medicinal Products for Veterinary Use ('the Committee') is hereby set up within the Agency.			
2. The Executive Director of the Agency or his representative and 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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).			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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;			
(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 advisory groups;			
(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.			
6. The Secretariat of the Agency shall provide technical, scientific and administrative support for the Committee, and shall ensure			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
consistency and quality of opinions of the Committee and appropriate coordination between this Committee, other committees of the Agency and the coordination group.			
7. The opinions of the Committee shall be publicly accessible.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 140 *Members of the Committee for Medicinal Products for Veterinary Use*			
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.			
	AM 305 **Article 140 -- paragraph 1 a (new)** ***1a. All members, alternate members and accompanying experts shall provide a publicly accessible declaration of interest.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			
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.			

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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.			
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.			
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.***		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
9. The members of the Committee may be accompanied by experts in specific scientific or technical fields.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 141 *Tasks of the Committee for Medicinal Products for Veterinary Use*			
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;			
(b) prepare 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;			
(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;			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
(e) take due account of any request from Member States for opinions;			
(f) formulate opinions whenever there is a request for a scientific re-examination in the course of mutual recognition or decentralised procedures;			
(g) provide guidance on important questions and issues of general scientific or ethical 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
	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 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			

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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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 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*			
1. The coordination group for mutual recognition and decentralised procedures for veterinary medicinal products ("the coordination group") is hereby set up.			

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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.			
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.			
5. The coordination group shall ensure that there is appropriate cooperation and coordination between the group, the competent authorities and the Agency.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 143 *Members of the Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products*			
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.			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
Article 144 *Tasks of the Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products*			
The coordination group shall have the following tasks:			
(a) examine questions concerning mutual recognition and decentralised procedures;			
(b) examine questions concerning pharmacovigilance of veterinary medicinal products authorised in Member States;	**AM 284** ***deleted***		
(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			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
a combination of substances is to be considered a veterinary medicinal product within the scope of this Regulation.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Chapter XI **Final provisions**			
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.			
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011shall apply.			

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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 146 *Exercise of the delegation*			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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), 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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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.			
Article 148 *Repeal*			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 149 *Transitional provisions*			
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.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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.			
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 Regulation shall be completed in accordance with Directive 2001/82/EC.			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments

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Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
Article 150 *Entry into force*			
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.			
This Regulation shall be binding in its entirety and directly applicable in all Member States.			
Done at Brussels,			
For the European Parliament			
The President			
For the Council			
The President			

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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:		

Commission proposal COM(2014) 558 final - 13289/14 - 2014/0257 (COD)	EP amendment	Position in the Council as endorsed by Coreper on 20 December 2017	Position on the EP amendments
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 physical/chemical, pharmacological and/or toxicological properties of the substance(s) concerned, including metabolites, shall be taken into consideration.	**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 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)

ANNEX III

Requirements for abridged and reduced dossiers for marketing authorisation applications

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.

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