EUROPEAN PARLIAMENT 2014 - 2019

Committee on Agriculture and Rural Development

2014/0257(COD)

7.5.2015

AMENDMENTS
34 - 356

Draft opinion
Marit Paulsen
(PE552.056v01-00)

on the proposal for a regulation of the European Parliament and of the Council on veterinary medicinal products

Proposal for a regulation
(COM(2014)0558 – C8-0164/2014 – 2014/0257(COD))

AM_Com_LegOpinion

Amendment 34
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(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.	(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 ***need for the*** legal framework for veterinary medicinal products ***to*** be adapted to scientific progress, the current market conditions and economic reality ***cannot be said to have been proven***.

Or. fr

Amendment 35
Aldo Patriciello

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(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	(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. ***Because of the great number of*** animal species, ***the veterinary sector is fragmented and requires*** 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

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 considered appropriate to develop a regulatory framework addressing the characteristics and specificities of the veterinary sector, which cannot be considered as a model for the human medicines market.

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 considered appropriate to develop a regulatory framework addressing the characteristics and specificities of the veterinary sector, which cannot be considered as a model for the human medicines market.

Or. it

Amendment 36
Bas Belder, James Nicholson

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(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 of the agriculture and aquaculture sectors.	(6) ***Despite the measures that farmers take on good hygiene, feed, management and biosecurity,*** animals may suffer from a broad range of diseases which ***need to*** be prevented or treated ***by veterinary medicinal products for both animal health and welfare reasons.*** The impact of animal diseases and the measures necessary to control them can be devastating for individual animals, animal populations, animal keepers and the economy. Animal diseases transmissible to humans may also have a significant impact on public health. Therefore sufficient and effective veterinary medicinal products should be available in the Union in order to ensure high standards of animal and public health, and for the development of the agriculture and aquaculture sectors.

Or. en

Amendment 37
Momchil Nekov

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(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 of the agriculture and aquaculture sectors.	*(Does not affect the English version.)*

Or. bg

Amendment 38
Momchil Nekov

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(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.	*(Does not affect the English version.)*

Or. bg

Amendment 39
Giulia Moi

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) This regulation aims at ensuring a high level of protection of both animal and human health while securing the protection of the environment. The precautionary principle should be applied and 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 any unacceptable effects on the environment.

Or. en

Amendment 40
Molly Scott Cato
on behalf of the Verts/ALE Group
Martin Häusling

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) This regulation aims at ensuring a high level of protection of both animal and human health while securing the protection of the environment. The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that pharmaceutical substances or veterinary medicinal products produced or placed on the market have no unacceptably harmful effects on human or animal health or any unacceptable effects on the environment.

Or. en

Amendment 41
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(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.	(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, ***the scientific evaluation carried out by the applicant's Member State should be compared with*** a scientific evaluation of the product 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.

Or. fr

Amendment 42
Daniel Buda

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(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	(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.	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 bureaucratic procedures that might hamper the development of research and innovation for the purpose of identifying new medicines.***

Or. ro

Justification

Development and innovation with regard to new medicines is sometimes hampered by the risk of the product not being authorised.

Amendment 43
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) In the event of disagreement, the Member State should be free to ban a substance it regards as dangerous (including in food derived from imported animals).

Or. fr

Amendment 44
Peter Jahr, Norbert Lins, Elisabeth Köstinger, Peter Liese

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) However, there may be situations where no suitable authorised veterinary	(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.	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***, whereby antimicrobial medicinal products for human use may be employed only subject to the issuing of a prescription by a vet and authorisation by the veterinary authority responsible for monitoring the work of the vet 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.

Or. de

Justification

With a view to protecting health and the environment, authorised veterinary medicinal products should be used as a matter of priority. Strict conditions should be laid down to govern the use of medicinal products for human use.

Amendment 45
Aldo Patriciello

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) Directive 2010/63/EU of the European Parliament and of the Council[15] 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	(20) Directive 2010/63/EU of the European Parliament and of the Council[15] 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.	information on the safety and efficacy of a veterinary medicinal product, should be ***optimised in order*** to provide the most satisfactory results whilst using the minimum number of animals, the procedures should be the least likely to cause pain, suffering or distress to animals and should take into account the principles established by Directive 2010/63/EU.
[15] 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).	[15] 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).

Or. it

Amendment 46
Bas Belder, James Nicholson

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(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.	(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.

Or. en

Amendment 47
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(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.	(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 system as it stood until now has led to duplicate testing, wasting resources, and lack of harmonisation of environmental risk assessments. The Pharmacovigilance system has to date not been able to compensate for the effects of this poor harmonisation. This particularly applies to veterinary medicinal products authorised before the environmental risk assessment requirement came into force. Therefore, the Commission should establish a substance-based review system for the environmental risk assessment of these veterinary medicinal products. The results of the review system would be published in so-called 'monographs'.***

Or. en

Amendment 48
Aldo Patriciello

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) The protection of technical documentation should be applied to new veterinary medicinal products***, as well as*** to data developed for supporting innovations of products with or referring to an existing marketing authorisation, for example in the case of extending use of an existing product to an additional animal species. In this case the variation or marketing authorisation application may refer partly to data submitted in a former marketing authorisation or variation applications, and should include new data specifically developed to support the required innovation of the existing product.	(28) The protection of technical documentation should be applied ***both*** to new veterinary medicinal products ***and*** 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.

Or. it

Amendment 49
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Conditions for renewing the approval of a marketing authorisation should be imposed only exceptionally and should be duly justified.

Or. en

Amendment 50
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 30 a (new)

Text proposed by the Commission	*Amendment*
	(30a) In the interest of safety and public, animal and environmental health, the approval period for pharmaceutical substances and veterinary medicinal products should be limited in time. At the time of subsequent approvals, any developments in science and technology should be taken into account when any decision regarding the renewal of an approval is taken. The renewal of the approval should be for a period not exceeding 15 years.

Or. en

Justification

The current use of veterinary medicinal products and the substances therein suggests that a precautionary approach should be taken, especially given the vested self-interest inherent in the system. Renewal allows for adapting approvals to account for possible incidence of initial data gaps, skewing of data, biases in the methodologies, the non-independence of the data and studies and trials, self-policing by producers, development of resistance, or previously unforeseen or hidden effects.

Amendment 51
Annie Schreijer-Pierik

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) Antimicrobial resistance to human and veterinary medicinal products is a growing health problem in the Union and worldwide. Many of the antimicrobials used in animals are also used in humans. Some of those antimicrobials are critical for preventing or treating life-threatening infections in humans. In order to fight antimicrobial resistance a number of measures should be taken. It needs to be ensured that appropriate warnings and guidance are included on the labels of ***veterinary*** antimicrobials. Use not covered by the terms of the marketing authorisation of certain new or critically important antimicrobials for humans should be restricted in the veterinary sector. The rules for advertising veterinary antimicrobials should be tightened, and the authorisation requirements should sufficiently address the risks and benefits of antimicrobial veterinary medicinal products.	(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 ***measures are proportionally applied in both the humane and animal sector. And*** appropriate warnings and guidance are included on the labels of 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.

Or. en

Amendment 52
Momchil Nekov

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(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	*(Does not affect the English version.)*

for preventing or treating life-threatening infections in humans. In order to fight antimicrobial resistance a number of measures should be taken. It needs to be ensured that appropriate warnings and guidance are included on the labels of veterinary antimicrobials. Use not covered by the terms of the marketing authorisation of certain new or critically important antimicrobials for humans should be restricted in the veterinary sector. The rules for advertising veterinary antimicrobials should be tightened, and the authorisation requirements should sufficiently address the risks and benefits of antimicrobial veterinary medicinal products.

Or. bg

Amendment 53
Bas Belder, James Nicholson

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) Antimicrobial resistance to human and veterinary medicinal products is a growing health problem in the Union and worldwide**.** Many of the antimicrobials used in animals are also used in humans. Some of those antimicrobials are critical for preventing or treating life-threatening infections in humans. In order to fight antimicrobial resistance a number of measures should be taken. It needs to be ensured that appropriate warnings and guidance are included on the labels of veterinary antimicrobials. Use not covered by the terms of the marketing authorisation of certain new or critically important antimicrobials for humans should be restricted in the veterinary sector. The rules for advertising veterinary antimicrobials should be tightened, and the authorisation	(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 Member States and all relevant actors.*** 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

requirements should sufficiently address the risks and benefits of antimicrobial veterinary medicinal products.	for advertising veterinary antimicrobials should be tightened, and the authorisation requirements should sufficiently address the risks and benefits of antimicrobial veterinary medicinal products.

Or. en

Amendment 54
Daniel Buda

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) Antimicrobial resistance to human and veterinary medicinal products is a growing health problem in the Union and worldwide. Many of the antimicrobials used in animals are also used in humans. Some of those antimicrobials are critical for preventing or treating life-threatening infections in humans. In order to fight antimicrobial resistance a number of measures should be taken. It needs to be ensured that appropriate warnings and guidance are included on the labels of veterinary antimicrobials. Use not covered by the terms of the marketing authorisation of certain new or critically important antimicrobials for humans should be restricted in the veterinary sector. The rules for advertising veterinary antimicrobials should be tightened, and the authorisation requirements should sufficiently address the risks and benefits of antimicrobial veterinary medicinal products.	(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. ***Better information is necessary regarding the utilisation and effects of antimicrobial medicines.*** It needs to be ensured that appropriate warnings and guidance are included on the labels of veterinary antimicrobials. Use not covered by the terms of the marketing authorisation of certain new or critically important antimicrobials for humans should be restricted in the veterinary sector. The rules for advertising veterinary antimicrobials should be tightened, and the authorisation requirements should sufficiently address the risks and benefits of antimicrobial veterinary medicinal products.

Or. ro

Amendment 55
Momchil Nekov

Proposal for a regulation
Recital 34

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

Or. bg

Amendment 56
Momchil Nekov

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) The combined use of several antimicrobial active substances may represent a particular risk with respect to the development of antimicrobial	*(Does not affect the English version.)*

resistance. Combinations of antimicrobial substances should therefore only be authorised where evidence is provided that the benefit-risk balance of the combination is favourable.

Or. bg

Amendment 57
Momchil Nekov

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(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.	*(Does not affect the English version.)*

Or. bg

Amendment 58
Daniel Buda

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) The development of new	(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.

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.***

Or. ro

Amendment 59
Momchil Nekov

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(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.	*(Does not affect the English version.)*

Or. bg

Amendment 60
Daniel Buda

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(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.	(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. ***In order to maintain animal health and welfare, a list of preventive treatments for use in various seasonal and climatic conditions should be drawn up to deal with seasonal disorders affecting different animal species.***

Or. ro

Amendment 61
Annie Schreijer-Pierik

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(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	(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***. Veterinarians have a legal obligation which is part of their professional code of conduct.*** They should not be influenced,

those products. Therefore the supply of veterinary antimicrobials by those health professionals should be restricted to the amount required for treatment of the animals under their care.	directly or indirectly, by economic incentives when prescribing those products. ***The animal health industry and the veterinarians should together promote responsible use.*** Therefore the supply of veterinary antimicrobials by those health professionals should be restricted to the amount required for treatment of the animals under their care.

Or. en

Amendment 62
Momchil Nekov

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) If an antimicrobial is administered and used incorrectly, this presents a risk to public or animal health. Therefore antimicrobial veterinary medicinal products should only be available on veterinary prescription. Persons having the right to prescribe have a key role in ensuring prudent use of antimicrobials and consequently they should not be influenced, directly or indirectly, by economic incentives when prescribing those products. Therefore the supply of veterinary antimicrobials by those health professionals should be restricted to the amount required for treatment of the animals under their care.	*(Does not affect the English version.)*

Or. bg

Amendment 63
Norbert Lins, Annie Schreijer-Pierik, Peter Jahr

Proposal for a regulation
Recital 38 a (new)

Text proposed by the Commission	*Amendment*
	(38a) Prudent use of antimicrobials is a cornerstone in addressing antimicrobial resistance. The Guidelines for prudent use, drafted by the Commission, need to be considered by Member States.

Or. en

Amendment 64
Annie Schreijer-Pierik, Norbert Lins

Proposal for a regulation
Recital 38 a (new)

Text proposed by the Commission	*Amendment*
	(38a) In order to facilitate prudent use, there is an imperative need for rapid, reliable and efficacious veterinary diagnostics both to identify the cause of disease as to perform antibiotic sensitivity testing. This will facilitate correct diagnosis, allow for a targeted use of antibiotics, avoiding the use of critically important antibiotics, and therefore restrain from the development of antibiotic resistance. There is clear need for future innovation specifically for on-site diagnostics, and a need to reflect whether more harmonisation or EU regulation in this sector is needed.

Or. en

Amendment 65
Momchil Nekov

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) It is important to consider the international dimension of the development of antimicrobial resistance when assessing the benefit-risk balance of certain veterinary antimicrobials in the Union. Any measure restricting the use of those products may affect the trade of products of animal origin or the competitiveness of certain animal production sectors in the Union. Moreover, antimicrobial resistant organisms can spread to humans and animals in the Union through consumption of products of animal origin imported from third countries, from direct contact with animals or humans in third countries or by other means. Therefore, measures restricting the use of veterinary antimicrobials in the Union should be based on scientific advice and should be considered in the context of cooperation with third countries and international organisations addressing antimicrobial resistance in order the ensure consistency with their activities and policies.	*(Does not affect the English version.)*

Or. bg

Amendment 66
Clara Eugenia Aguilera García

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(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	(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 of the Agency.

collect data on the sales and ***consumption*** of antimicrobials in animals, data on the ***consumption*** of antimicrobials in humans and data on antimicrobial resistant organisms found in animals, humans and food***. In particular, better data is needed on how, when, where and why antibiotics are being used***. To ensure that the information collected can be used effectively, appropriate rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data on the use of antimicrobials under the coordination of the Agency.

Or. en

Amendment 67
Momchil Nekov

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(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	*(Does not affect the English version.)*

coordination of the Agency.

Or. bg

Amendment 68
Beata Gosiewska

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(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 of the Agency.	(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. ***In particular, better data are needed on how, when, where and why antimicrobials are being used, as well as data on adverse events (reactions) resulting from the use of antimicrobials.*** To ensure that the information collected can be used effectively, appropriate rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data on the use of antimicrobials under the coordination of the Agency.

Or. pl

Amendment 69
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 49

Text proposed by the Commission	*Amendment*
(49) ***It is necessary,*** in specific cases***, or*** from a public health ***and*** animal health perspective, to complement the safety and efficacy data available at the time of authorisation with additional information following the placing of the product on the market. Therefore the obligation to conduct post-authorisation studies should be imposed on the marketing authorisation holder.	(49) In specific cases ***it is necessary,*** from a public health***,*** animal health ***or environmental*** perspective, to complement the safety and efficacy data available at the time of authorisation with additional information following the placing of the product on the market. Therefore the obligation to conduct post-authorisation studies should be imposed on the marketing authorisation holder.

Or. en

Amendment 70
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 56

Text proposed by the Commission	*Amendment*
(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.	(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 ***not*** be allowed to sell prescription and non-prescription veterinary medicinal products via the Internet to buyers in other Member States.

Or. fr

Amendment 71
Marc Tarabella, Michel Dantin, Angélique Delahaye

Proposal for a regulation
Recital 56

Text proposed by the Commission	*Amendment*
(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.	(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 ***- where appropriate, veterinarians - who are*** 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.

Or. fr

Amendment 72
Marc Tarabella, Michel Dantin, Angélique Delahaye

Proposal for a regulation
Recital 56 a (new)

Text proposed by the Commission	*Amendment*
	(56a) 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.

Or. fr

Amendment 73
Marc Tarabella, Michel Dantin, Angélique Delahaye

Proposal for a regulation
Recital 56 b (new)

Text proposed by the Commission	*Amendment*
	(56b) Decoupling prescription from supply does not lower the consumption of antibiotics. This is borne out by the fact that the Member States in which antibiotics consumption is highest have already decoupled prescription from supply, while the Member States that have reduced consumption the most are those in which the two are still coupled.

Or. fr

Justification

European Medicines Agency, 'Sales of veterinary antimicrobial agents in 26 EU/EEA countries in 2012'
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2014/10/WC500175671.pdf

Amendment 74
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*
	(57a) The online sale of medicinal products should be prohibited.

Or. fr

Amendment 75
Norbert Erdős

Proposal for a regulation
Recital 58

Text proposed by the Commission	*Amendment*
(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 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.	(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 to ***stricter*** conditions ***than required by this regulation to the extent that this is*** justified by the protection of public health. Such conditions should not unduly restrict the functioning of the internal market.

Or. hu

Justification

From a human and animal health point of view, it is very important that Member States be permitted to keep or introduce stricter requirements on the use and supply of veterinary medicines within their territory.

Amendment 76
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 58

Text proposed by the Commission	*Amendment*
(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 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***.	(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***, the online sale of medicinal products should be prohibited***.

Or. fr

Amendment 77
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 59

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Or. fr

Amendment 78
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 61

Text proposed by the Commission	*Amendment*
(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	(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.	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 ***leads*** to medicine misuse or overconsumption which is liable to harm public or animal health, or the environment***, and should be prohibited***.

Or. fr

Amendment 79
Miguel Viegas

Proposal for a regulation
Recital 62

Text proposed by the Commission	*Amendment*
(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.	(62) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a ***veterinarian, or an equivalent professional as defined in the laws of Member States,*** 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.

Or. pt

Amendment 80
Norbert Lins, Annie Schreijer-Pierik, Peter Jahr

Proposal for a regulation
Recital 62

Text proposed by the Commission	*Amendment*
(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.	(62) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a ***veterinarian*** for an individual animal or group of animals, it should in principle be possible for that veterinary prescription to be recognised and for the medicinal product to be dispensed in another Member State. 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.

Or. en

Amendment 81
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 62

Text proposed by the Commission	*Amendment*
(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.	(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 ***must*** not affect any professional or ethical duty for dispensing professionals to refuse to dispense the medicine stated in the prescription.

Or. fr

Amendment 82
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 65

Text proposed by the Commission	*Amendment*
(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 control reports***. In order to preserve the effectiveness of the inspections, authorities should ***perform a certain percentage of*** unannounced inspections***, to be determined by a delegated act***.

Or. en

Amendment 83
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 67

Text proposed by the Commission	*Amendment*
(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	(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.	health and the environment. ***The Commission should*** ensure a harmonised approach to inspections throughout the Union, ***and*** should be able to carry out audits in the Member States to verify the functioning of national control systems.

Or. en

Amendment 84
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 70

Text proposed by the Commission	*Amendment*
(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 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.***	(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 definition of a veterinary medicinal product.

Or. fr

Amendment 85
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 72

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Or. fr

Amendment 86
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 73

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Or. fr

Amendment 87
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 74

Text proposed by the Commission	*Amendment*
(74) In order to ensure that annexes to	***deleted***

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.

Or. fr

Amendment 88
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 75

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Or. fr

Amendment 89
Momchil Nekov

Proposal for a regulation
Recital 75

Text proposed by the Commission	*Amendment*
(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	*(Does not affect the English version.)*

the granted marketing authorisation, in particular regarding establishing a list of antimicrobial veterinary medicinal products for which such use should be prohibited.

Or. bg

Amendment 90
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 76

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Or. fr

Amendment 91
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 77

Text proposed by the Commission	*Amendment*
(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	***deleted***

veterinary medicinal products, in particular with a view to preserving the efficacy of certain active substances in treating infections in humans.

Or. fr

Amendment 92
Momchil Nekov

Proposal for a regulation
Recital 77

Text proposed by the Commission	*Amendment*
(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.	*(Does not affect the English version.)*

Or. bg

Amendment 93
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 78

Text proposed by the Commission	*Amendment*
(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	***deleted***

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.

Or. fr

Amendment 94
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 79

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Or. fr

Amendment 95
Momchil Nekov

Proposal for a regulation
Recital 79

Text proposed by the Commission	*Amendment*
(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	*(Does not affect the English version.)*

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.

Or. bg

Amendment 96
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Recital 80

Text proposed by the Commission	*Amendment*
(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[19].	***deleted***
[19] 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).	

Or. fr

Amendment 97
Giulia Moi

Proposal for a regulation
Article 2 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In addition to the products referred to in paragraph 1, Chapter VI shall also apply to ***active substances,*** intermediate products and ***excipients*** used as starting materials in veterinary medicinal products.	2. In addition to the products referred to in paragraph 1, Chapter VI shall also apply to intermediate products and ***active substances*** used as starting materials in veterinary medicinal products.

Or. en

Amendment 98
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 2 – paragraph 4 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) substances used to raise animal productivity levels.

Or. fr

Amendment 99
Stanislav Polčák

Proposal for a regulation
Article 4 – paragraph 1 – point 1 – point b

Text proposed by the Commission	*Amendment*
(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;	(b) ***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;

Or. en

Amendment 100
Stanislav Polčák

Proposal for a regulation
Article 4 – paragraph 1 – point 1 – point c

Text proposed by the Commission	*Amendment*
(c) ***its purpose is to*** be used for euthanasia of animals;	(c) ***it may*** be used for euthanasia of animals;

Or. en

Justification

The definition of a veterinary medicinal product should be clear, in particular in terms of classification of the existing products. There is a body of European Court of Justice rulings which is based on two 'limbs', the first being 'medicinal product by presentation', and the second, 'medicinal product by function'. The Commission proposal may lead to different interpretation and, as a result, to unexpected consequences, e.g. re-classification of existing products.

Amendment 101
Momchil Nekov

Proposal for a regulation
Article 4 – paragraph 1 – point 8

Text proposed by the Commission	*Amendment*
(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;	(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 ***halt the growth of*** or kill microorganisms of the same species;

Or. bg

Amendment 102
Daniel Buda

Proposal for a regulation
Article 4 – paragraph 1 – point 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) Antiparasitic — a medicinal product/ substance used in the treatment of parasitic diseases attributable to various causes;

Or. ro

Justification

Antiparasitic medicines account for over 60% of the total quantity of veterinary medicines sold worldwide.

Amendment 103
James Nicholson, Bas Belder

Proposal for a regulation
Article 4 – paragraph 1 – point 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) 'antimicrobial': an active substance of synthetic or natural origin which destroys microorganisms, suppresses their growth or their ability to reproduce in animals or humans;

Or. en

Justification

The introduced definition is used by the European Medicines Agency in their paper entitled 'Answers to the requests for scientific advice on the impact on public health and animal health of the use of antibiotics in animals' (reference number EMA/381884/2014).

Amendment 104
Albert Deß

Proposal for a regulation
Article 4 – paragraph 1 – point 8 b (new)

Text proposed by the Commission	*Amendment*
	(8b) 'antimicrobial substance' means a compound with a direct action on microorganisms used for treatment or prevention of infections. Antimicrobial substances include antibacterials, antivirals, antifungals and antiprotozoals; in the context of this Regulation, antimicrobial substance refers to an antibacterial.

Or. de

Justification

It is important to give a precise definition of the concepts used and the scope of this Regulation. It should specifically address antibacterials and the need to tackle antibiotic resistance in bacteria originating in animals. The proposed definition is in line with the definition used by EPRUMA, a broad platform for stakeholders that campaigns for the responsible use of antibacterial substances.

Amendment 105
Ulrike Müller

Proposal for a regulation
Article 4 – paragraph 1 – point 11 – introductory part

Text proposed by the Commission	*Amendment*
(11) 'benefit-risk balance' means an evaluation of the ***positive effects of the veterinary medicinal*** product in relation to the following risks relating to the use of that product:	(11) 'benefit-risk balance' means an evaluation of the ***risk of damage to animal health caused by the absence of the*** product in relation to the following risks relating to the use of that product:

Or. de

Justification

Benefits and risks vary in scale, and risks can only be compared with other risks.

Amendment 106
Stanislav Polčák

Proposal for a regulation
Article 4 – paragraph 1 – point 11 – introductory part

Text proposed by the Commission	*Amendment*
(11) 'benefit-risk balance' means an evaluation of the positive effects of the veterinary medicinal product in relation to the following risks relating to the use of that product:	(11) 'benefit-risk balance' means an evaluation of the positive ***therapeutic*** effects of the veterinary medicinal product in relation to the following risks relating to the use of that product:

Or. en

Justification

The Commission proposal introduces a broader interpretation of benefits, which may bring problems in interpretation of benefit-risk for certain products, for example antimicrobials, where the benefits may also include positive effects on zootechnical parameters, like improved yield, which is contrary to the ambitions of the Commission proposal in terms of antimicrobial resistance. It is therefore proposed to define benefits as 'therapeutic benefits'.

Amendment 107
Momchil Nekov

Proposal for a regulation
Article 4 – paragraph 1 – point 11 – point c

Text proposed by the Commission	*Amendment*
(c) any risk relating to the development of antimicrobial resistance;	*(Does not affect the English version.)*

Or. bg

Amendment 108
Stanislav Polčák

Proposal for a regulation
Article 4 – paragraph 1 – point 12

Text proposed by the Commission	*Amendment*
(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***;	(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***;

Or. en

Justification

The aim of this amendment is to correct an apparent mistake in the Commission draft. Common names are not used to identify the veterinary medicinal product, but the constituents of the veterinary medicinal products.

Amendment 109
Michel Dantin, Marc Tarabella, Angélique Delahaye

Proposal for a regulation
Article 4 – paragraph 1 – point 20 – point b

Text proposed by the Commission	*Amendment*
(b) veterinary medicinal products for animal species other than cattle, ***sheep,*** pigs, chickens, dogs and cats;	(b) veterinary medicinal products for animal species other than cattle, pigs, chickens, dogs and cats;

Or. fr

Justification

Sheep should be regarded as a limited market.

Amendment 110
Eric Andrieu, Jean-Paul Denanot

Proposal for a regulation
Article 4 – paragraph 1 – point 20 – point b

Text proposed by the Commission	*Amendment*
(b) veterinary medicinal products for animal species other than cattle, ***sheep,*** pigs, chickens, dogs and cats;	(b) veterinary medicinal products for animal species other than cattle, pigs, chickens, dogs and cats;

Or. fr

Justification

In terms of veterinary medicine, sheep are a limited market as they are reared extensively and have only a low economic value. The market in medicines for sheep is therefore more restricted than that for horses, for example.

Amendment 111
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 4 – paragraph 1 – point 20 – point b

Text proposed by the Commission	*Amendment*
(b) veterinary medicinal products for animal species other than cattle, sheep, pigs, chickens, dogs and cats;	(b) veterinary medicinal products for animal species other than cattle, sheep ***(only meat obtained from sheep)***, pigs, chickens, dogs and cats;

Or. en

Justification

Milk produced by sheep should be considered as a 'minor production' and in consequence a limited market.

Amendment 112
Michel Dantin, Marc Tarabella, Angélique Delahaye

Proposal for a regulation
Article 4 – paragraph 1 – point 20 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) veterinary medicinal products for animal species the national population of which is not large enough for research and development costs to be amortised during the data protection period specified in Article 34.

Or. fr

Justification

Livestock numbers can vary from Member State to Member State.

Amendment 113
Stanislav Polčák

Proposal for a regulation
Article 4 – paragraph 1 – point 21

Text proposed by the Commission	*Amendment*
(21) **'**pharmacovigilance' means the process of monitoring and investigating adverse events;	(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 benefit-risk balance of veterinary medicinal products***;

Or. en

Justification

The proposal of definition only focuses on the process of monitoring and investigating of adverse events. Pharmacovigilance has to be defined in a wider sense, as the monitoring and investigating of adverse events has to translate to measures to ensure that the benefit-risk balance remains positive throughout a product's lifecycle. This is of particular importance for products the benefit-risk balance of which is prone to change over time, like antimicrobial or anti-parasitic medicines.

Amendment 114
Annie Schreijer-Pierik

Proposal for a regulation
Article 4 – paragraph 1 – point 24

Text proposed by the Commission	*Amendment*
(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;***	(24) **'**veterinary prescription' means any prescription for a veterinary medicinal product***, provided or dispensed by a veterinarian, to the owner or the*** person ***taking care of the animal(s) only if he/she has examined the animals and made a diagnosis before the prescription or has personal knowledge of the condition of the animals in order to prescribe the correct medicine. A written or electronic prescription is always required when the medicine is not dispensed by the prescriber.***

Or. en

Amendment 115
Stanislav Polčák

Proposal for a regulation
Article 4 – paragraph 1 – point 27 a (new)

Text proposed by the Commission	*Amendment*
	(27a) '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;

Or. en

Justification

The name of the medicinal product plays a key part in the regulation of such products and it is not only important for the identification of the product concerned but also plays a role in its safe and effective use and especially in a competition between veterinary medicinal products. The legislation should clearly stipulate that the invented names of products shall be such that they cannot be confused with the common names which are used for naming the constituents of the products.

Amendment 116
Stanislav Polčák

Proposal for a regulation
Article 4 – paragraph 1 – point 27 b (new)

Text proposed by the Commission	*Amendment*
	(27b) '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 authorized or entitled to supply medicinal products to the public in accordance with applicable national law;

Or. en

Justification

For the sake of clarity and predictability, it is essential that the new Regulation clearly defines what wholesale distribution means. Without a definition of the wholesale distribution, it would be extremely difficult for the Member State to perform any control activities and to act against illegal activities in the field of veterinary medicinal products.

Amendment 117
Stanislav Polčák

Proposal for a regulation
Article 4 – paragraph 1 – point 27 c (new)

Text proposed by the Commission	*Amendment*
	(27c) 'pre-mix for medicated feedingstuffs' means any veterinary medicinal product prepared in advance with a view to the subsequent manufacture of medicated feedingstuffs according to the Regulation (...Regulation on medicated feedingstuffs...).

Or. en

Justification

The provisions on veterinary medicinal products and on medicated feedingstuffs should be properly interconnected. Antimicrobials are the most important class of drugs used by means of medicated feedingstuffs. The legislation on veterinary medicinal products should clearly require that only medicated pre-mixes can be authorised for use for subsequent manufacture of medicated feedingstuffs.

Amendment 118
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
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***.	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. fr

Amendment 119
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. A marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period ***of time***.	2. A marketing authorisation for a veterinary medicinal product shall be valid for ***five years. The authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance. Once renewed, the marketing authorisation shall be valid for*** an unlimited period***, unless the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal***.

Or. en

Justification

It is important to maintain a renewal at 5 years in order to carry out an analysis of the pharmacovigilance data accumulated during commercialisation of the product and decided if there is a change in the benefit / risk balance.

Amendment 120
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. ***A*** marketing authorisation for a veterinary medicinal product shall be valid for ***an unlimited period of time***.	2. ***An initial*** marketing authorisation for a veterinary medicinal product shall be valid for ***five years***.

Or. en

Amendment 121
Miguel Viegas

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. A marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period of time.	2. A marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period of time***, except where new scientific knowledge gives grounds for reassessment***.

Or. pt

Amendment 122
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 5 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. After the first period of five years the marketing authorisation shall be limited to a period not exceeding 15 years. After that period the applicant may apply for another 15 years authorisation. The renewal assessment shall be based on the current state of scientific knowledge and techniques and must take into account adverse effects reported under Article 76.

Or. en

Amendment 123
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 5 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. When a previously authorised veterinary medicinal product has not been

	present on the market in a Member State for a period of three consecutive years, the authorisation granted for that veterinary medicinal product shall cease to be valid.
	The competent authority may, in exceptional circumstances, and on human or animal health grounds, grant exemptions from the previous paragraph. Such exemptions shall be duly justified.

Or. en

Justification

This clause has existed in legislation for many years. If it is not maintained in future regulation it will be impossible for competent authorities to manage adequately the register of veterinary medicinal products in each Member State.

Amendment 124
Clara Eugenia Aguilera García

Proposal for a regulation
Article 6 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. Applications shall be submitted electronically ***via a single electronic portal. For all types of*** applications submitted in accordance with ***this Regulation***, the formats made available by the Agency shall be used.

Or. en

Justification

To maximise the reduction of administrative burden, the use of multiple different formats and systems must be avoided.

Amendment 125
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 7 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) documentation on the direct or indirect risks to public or animal health of use of the antimicrobial veterinary medicinal product in animals,	(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,

Or. en

Justification

Antimicrobials kill soil bacteria, which destroys soil ecosystems, so depressing natural fertility, nutrient cycling, weed and pest suppression by beneficial micro-organisms. Antimicrobial-resistant bacteria can also spread to humans via environmental routes.

Amendment 126
Momchil Nekov

Proposal for a regulation
Article 7 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) documentation on the direct or indirect risks to public or animal health of use of the antimicrobial veterinary medicinal product in animals,	*(Does not affect the English version.)*

Or. bg

Amendment 127
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 7 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) information about risk mitigation measures to limit antimicrobial resistance development related to the use of veterinary medicinal product.	(b) information about risk mitigation measures to limit antimicrobial resistance development related to the use of veterinary medicinal product***, 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***.

Or. en

Amendment 128
Giulia Moi

Proposal for a regulation
Article 7 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) information about risk mitigation measures to limit antimicrobial resistance development related to the use of veterinary medicinal product.	(b) information about risk mitigation measures to limit antimicrobial resistance development related to the use of veterinary medicinal product***, including that the product is not to be used as a routine prophylactic measure in food producing animals, unless specifically authorised by CVMP***.

Or. en

Amendment 129
Momchil Nekov

Proposal for a regulation
Article 7 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) information about risk mitigation	*(Does not affect the English version.)*

measures to limit antimicrobial resistance development related to the use of veterinary medicinal product.

Or. bg

Amendment 130
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 7 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. When applying for renewal, publicly available, peer-reviewed scientific literature on the active pharmaceutical substance and its relevant metabolites dealing with side-effects on human health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier.

Or. en

Amendment 131
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 8 – paragraph 2 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) the tested product is an unauthorised veterinary medicinal product, all the pharmacological active substances have a maximum residues limit, and the withdrawal period set by the veterinarian in accordance with Article 117 is respected, or

Or. en

Justification

All pharmacological active substances of the product must have a maximum residues level in order to allow the veterinarian to establish a withdrawal period that avoids any health risk for consumers.

Amendment 132
Ulrike Müller

Proposal for a regulation
Article 8 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) a provisional maximum residue limit has been established for the tested product.

Or. de

Justification

Currently, animals and animal products can be marketed after tests have been carried out provided that they comply with provisional maximum residue limits. This should remain possible.

Amendment 133
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 8 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. The holder of the clinical trial authorization shall notify the competent authority of every serious adverse events and all human adverse reactions shall be notified promptly and in any case not later than 15 days following receipt of the information.

Or. en

Justification

It is important that competent authorities are properly and promptly informed of serious adverse events and human adverse reactions in order to consider whether an additional precaution should be taken or if it is necessary to suspend the clinical trial.

Amendment 134
Nicola Caputo

Proposal for a regulation
Article 9 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The immediate packaging of a veterinary medicinal product shall contain ***only*** the following information:	1. The immediate packaging of a veterinary medicinal product shall contain ***at least*** the following information:

Or. en

Justification

The pack sizes of veterinary medicinal products cover a very wide range, for example from small 10ml vials to large 10 or 25 kg bags. Some labels have much more space than others, and can accommodate more information. For some categories of products that can be sold directly to the public without prescription it may be important to include additional information on the immediate packaging.

Amendment 135
Giulia Moi

Proposal for a regulation
Article 9 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The immediate packaging of a veterinary medicinal product shall contain ***only the following*** information***:***	1. The immediate packaging of a veterinary medicinal product shall ***only be required to*** contain ***the information set out below. Additional*** information ***consistent with Article 30 may be included where space***

allows.

Or. en

Amendment 136
Momchil Nekov

Proposal for a regulation
Article 9 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) an indication of the presence of genetically modified organisms where the product contains or consists of such organisms;

Or. bg

Amendment 137
Momchil Nekov

Proposal for a regulation
Article 9 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) the expiry date, in the format: "mm/yyyy , preceded by the abbreviation "Exp." ;	*(Does not affect the English version.)*

Or. bg

Amendment 138
Ulrike Müller

Proposal for a regulation
Article 9 – paragraph 1 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) a barcode containing all the

information listed in paragraph 1, points (a) to (g), and enabling this information and the information contained in the package leaflet to be provided electronically in a readable form and in all languages at the place of treatment, and making the data available for other documentation systems through standard interfaces.

Or. de

Justification

The regulation should make use of all the electronic possibilities available in order to provide information on medicinal products in a user-friendly way in the reader's mother tongue. This can only be achieved by the barcode on the immediate packaging.

Amendment 139
Nicola Caputo

Proposal for a regulation
Article 10 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The outer packaging of a veterinary medicinal product shall contain ***only*** the following information:	1. The outer packaging of a veterinary medicinal product shall contain ***at least*** the following information:

Or. en

Justification

The minimum mandatory information that must be included on the outer packaging of a veterinary medicinal product needs to be defined by legislation. The size of veterinary medicinal products can range from small 10ml vials to large 5, 10 or 25 kg bags. Some products have much more space on the outer packaging than others, and can accommodate more information. For products sold direct to the public without prescription it may be important to include additional information on the outer packaging.

Amendment 140
Miguel Viegas

Proposal for a regulation
Article 10 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) warning that the veterinary medicinal product is for animal treatment only;	***deleted***

Or. pt

Amendment 141
Giulia Moi

Proposal for a regulation
Article 10 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(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***;	(f) ***specific precautions relating to*** the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, ***a reference to any appropriate collection system in place***;

Or. en

Amendment 142
Miguel Viegas

Proposal for a regulation
Article 10 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) requirement to use take-back schemes for veterinary medicinal products for the disposal of ***unused*** veterinary medicinal products ***or waste materials derived from***	(f) requirement to use take-back schemes for veterinary medicinal products for the disposal of veterinary medicinal products ***in accordance with the law in force***;

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;

Or. pt

Amendment 143
Ulrike Müller

Proposal for a regulation
Article 10 – paragraph 1 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) waiting times.

Or. de

Justification

Where waiting times are prescribed, they should be stated on the outer packaging; where there is no outer packaging, they should be indicated on the immediate packaging (and not just in the package leaflet). This is particularly necessary in the case of retail sales at a distance.

Amendment 144
Momchil Nekov

Proposal for a regulation
Article 11 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) an indication of the presence of genetically modified organisms where the product contains or consists of such organisms;

Or. bg

Amendment 145
Momchil Nekov

Proposal for a regulation
Article 11 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the expiry date, in the format: "mm/yyyy , preceded by the abbreviation "Exp." .	*(Does not affect the English version.)*

Or. bg

Amendment 146
Momchil Nekov

Proposal for a regulation
Article 12 – paragraph 1 – point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) in the case of veterinary medicinal products which include or consist of genetically modified organisms, information to that effect;

Or. bg

Amendment 147
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 12 – paragraph 1 – point m a (new)

Text proposed by the Commission	*Amendment*
	(ma) Qualitative and quantitative composition.

Or. en

Justification

The composition of the product is absolutely necessary. It is not understandable why the composition of veterinary medicinal products is not included as for many other health products, food products, etc.

Amendment 148
Ulrike Müller

Proposal for a regulation
Article 12 – paragraph 1 a – point m a (new)

Text proposed by the Commission	*Amendment*
	(ma) the barcode referred to in Article 9(1)(ga).

Or. de

Amendment 149
Ulrike Müller

Proposal for a regulation
Article 12 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The package leaflet shall be written and designed to be clear and understandable, in terms that are comprehensible to the general public.	3. The package leaflet shall be written and designed to be clear***, readable*** and understandable, in terms that are comprehensible to the general public.

Or. de

Justification

The package leaflet should be readable even in poor light in sheds and barns.

Amendment 150
Momchil Nekov

Proposal for a regulation
Article 13 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the expiry date, in the format: " mm/yyyy " , preceded by the abbreviation " ***Exp.*** " ;	(d) the expiry date, in the format: " mm/yyyy " , preceded by the abbreviation " ***Expiry date*** " ;

Or. bg

Amendment 151
Momchil Nekov

Proposal for a regulation
Article 13 – paragraph 1 – point h

Text proposed by the Commission	*Amendment*
(h) a special warning if necessary for the medicinal product;	(h) a special warning if necessary for the medicinal product ***(e.g. presence of genetically modified organisms)***;

Or. bg

Amendment 152
Miguel Viegas

Proposal for a regulation
Article 14 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The information on the labelling shall be provided in the national language of every Member State where the veterinary medicinal product is made available on the market.

Or. pt

Amendment 153
Ulrike Müller

Proposal for a regulation
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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***,*** efficacy ***and residue behaviour***. 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.

Or. de

Justification

Residue behaviour is of crucial importance for food safety. Unexpected residues can give rise to considerable compensation claims against animal holders and other food business operators.

Amendment 154
Giulia Moi

Proposal for a regulation
Article 16 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The summary of the product characteristics of the generic veterinary	5. ***The clinical information of*** the summary of the product characteristics ***(as***

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.	***defined in Article 30(1)(c), excluding point (vi))*** of the generic veterinary medicinal product shall be identical to that of the reference veterinary medicinal product. However, ***this*** requirement shall not apply to***:***
	(a) 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 ***or protection of technical documentation (Articles 33 to 36)*** at the time when the generic veterinary medicinal product is authorised ***or***
	(b) a subsequent amendment of the reference medicinal product.

Or. en

Amendment 155
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 16 – paragraph 6

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. en

Justification

If a generic product had demonstrated the bioequivalence with a reference product the application shall not contain the documentation on safety and efficacy. This should cover also the documentation on safety for environment like other parts on safety (safety for the animals, withdrawal periods, etc.).

Amendment 156
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 16 – paragraph 6

Text proposed by the Commission	*Amendment*
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.	6. ***The applicant shall submit to the competent authority or the Agency*** 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.

Or. en

Amendment 157
Albert Deß

Proposal for a regulation
Article 16 – paragraph 6

Text proposed by the Commission	*Amendment*
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***	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 ***if a potential environmental risk has been identified for***

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.	***that*** product.

Or. de

Justification

A fresh comprehensive assessment of environmental data is required only where a potential environmental risk has been identified for a veterinary medicinal product. It would be hard to justify requiring fresh environmental data for generics without making any distinction, since such products have already undergone a detailed and comprehensive second phase environmental risk assessment as part of the authorisation procedure for the reference veterinary medicinal product.

Amendment 158
Nicola Caputo

Proposal for a regulation
Article 16 – paragraph 6

Text proposed by the Commission	*Amendment*
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***.	6. ***If there is evidence that a constituent of a*** medicinal product ***is a hazard*** for the ***environment, a competent authority or the Agency shall require the safety data concerning the potential risks simultaneously from all the marketing authorisation holders concerned***.

Or. en

Justification

If there is evidence that a constituent of a medicinal product is a hazard for the environment, all the marketing authorisation holders should be concerned, not just generics. The Commission's proposal poses a risk of dis-harmonisation between generics and reference

products.

Amendment 159
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 16 – paragraph 7

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. fr

Amendment 160
Giulia Moi

Proposal for a regulation
Article 17 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
By way of derogation from Article 7(1)(b) an application for a marketing authorisation for a veterinary medicinal product containing a combination of active substances ***that have each*** already been used in authorised veterinary medicinal products, but have not hitherto been authorised in that combination (**'**combination veterinary medicinal product') shall satisfy the following criteria:	By way of derogation from Article 7(1)(b) an application for a marketing authorisation for a veterinary medicinal product containing a combination of active substances ***where one or more have*** 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:

Or. en

Amendment 161
Giulia Moi

Proposal for a regulation
Article 17 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the applicant can demonstrate that the veterinary medicinal product ***is*** a combination ***of*** reference veterinary medicinal products as referred to in Article 16(1)(b);	(b) the applicant can demonstrate that the veterinary medicinal product ***contains*** a combination ***with at least one*** reference veterinary medicinal products as referred to in Article 16(1)(b);

Or. en

Amendment 162
Giulia Moi

Proposal for a regulation
Article 17 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) documentation on the safety of that combination is provided.	(d) ***where needed, appropriate*** documentation on the safety of that combination is provided.

Or. en

Amendment 163
Giulia Moi

Proposal for a regulation
Article 19 – paragraph 1

Text proposed by the Commission	*Amendment*
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***	By way of derogation from Article 16(1)(b), an applicant for a marketing authorisation for a veterinary medicinal product shall not be required to provide the documentation ***for which he has a relevant*** letter of access ***to*** the documentation ***of*** the reference veterinary medicinal product.

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

Or. en

Amendment 164
Momchil Nekov

Proposal for a regulation
Article 21 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the benefit of the immediate availability on the market of the veterinary medicinal product to ***the*** animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided;	(a) the benefit of the immediate availability on the market of the veterinary medicinal product to animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided;

Or. bg

Amendment 165
Paul Brannen

Proposal for a regulation
Article 21 – paragraph 2

Text proposed by the Commission	*Amendment*
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***.	2. By way of derogation from Article 5(2), a marketing authorisation for a limited market shall be ***valid for an unlimited*** period of ***time, unless risks to animal health, public health and protection of the environment ('signal management process') are detected***.

Or. en

Justification

Making an authorisation valid for unlimited period of time would provide the industry with incentives to develop new effective VMPs or their feasible alternatives.

Amendment 166
Michel Dantin, Marc Tarabella, Angélique Delahaye

Proposal for a regulation
Article 21 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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. ***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.***

Or. fr

Amendment 167
Momchil Nekov

Proposal for a regulation
Article 22 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
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:	*(Does not affect the English version)*

Or. bg

Amendment 168
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 25

Text proposed by the Commission	*Amendment*
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).	The competent authority shall ascertain that the manufacturers of veterinary medicinal products from third countries ***comply with EU legislation applicable and*** 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).

Or. en

Justification

It should be clearly stated that manufacturers shall comply with EU legislation and not only that they are able to manufacture and control the product in accordance with the application for marketing authorisation.

Amendment 169
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 28 – paragraph 3

Text proposed by the Commission	*Amendment*
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-	3. Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission ***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.	risk balance remains positive with a view to the possible development of antimicrobial resistance.

Or. en

Justification

This means granting marketing authorisation would always result in monitoring of antimicrobial use, which allows continuous risk assessment.

Amendment 170
Momchil Nekov

Proposal for a regulation
Article 28 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	*(Does not affect the English version)*

Or. bg

Amendment 171
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 29 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. A competent authority ***or the Commission*** shall classify the following veterinary medicinal products as subject to veterinary prescription:	1. A competent authority shall classify the following veterinary medicinal products as subject to veterinary prescription:

Or. fr

Amendment 172
Momchil Nekov

Proposal for a regulation
Article 29 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) antimicrobial veterinary medicinal products;	*(Does not affect the English version)*

Or. bg

Amendment 173
Miguel Viegas

Proposal for a regulation
Article 29 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
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:	3. ***Notwithstanding*** 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:

Or. pt

Amendment 174
Momchil Nekov

Proposal for a regulation
Article 29 – paragraph 3 – point h

Text proposed by the Commission	*Amendment*
(g) there is no risk to public or animal health as regards the development of	*(Does not affect the English version)*

resistance to anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly.

Or. bg

Amendment 175
Giulia Moi

Proposal for a regulation
Article 30 – paragraph 1 – point c – point vi

Text proposed by the Commission	*Amendment*
(vi) frequency and seriousness of adverse events,	(vi) frequency and seriousness of adverse events ***or reactions***,

Or. en

Amendment 176
Giulia Moi

Proposal for a regulation
Article 30 – paragraph 1 – point c – point viii

Text proposed by the Commission	*Amendment*
(viii) interaction with other medicinal products and other forms of interaction**,**	(viii) ***known*** interaction with other medicinal products and other ***known*** forms of interaction**.**

Or. en

Amendment 177
Momchil Nekov

Proposal for a regulation
Article 30 – paragraph 1 – point c – point xii

Text proposed by the Commission	*Amendment*
(xii) where appropriate, an indication of classification of an antimicrobial regarding its strategic use,	*(Does not affect the English version)*

Or. bg

Amendment 178
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 30 – paragraph 1 – point c – point xiii

Text proposed by the Commission	*Amendment*
(xiii) special conditions for use, including restrictions on the use of antimicrobials in order to limit the risk of development of antimicrobial resistance,	(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 to be used as a routine preventative measure in food producing animals, or in prophylactic group treatments where there has been no diagnosis of disease,***

Or. en

Amendment 179
Giulia Moi

Proposal for a regulation
Article 30 – paragraph 1 – point c – point xiii

Text proposed by the Commission	*Amendment*
(xiii) special conditions for use, including restrictions on the use of antimicrobials in order to limit the risk of development of antimicrobial resistance,	(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 to be used as a routine preventative measure in food***

producing animals,

Or. en

Amendment 180
Momchil Nekov

Proposal for a regulation
Article 30 – paragraph 1 – point c – point xiii

Text proposed by the Commission	*Amendment*
(xiii) special conditions for use, including restrictions on the use of antimicrobials in order to limit the risk of development of antimicrobial resistance,	*(Does not affect the English version)*

Or. bg

Amendment 181
Giulia Moi

Proposal for a regulation
Article 30 – paragraph 1 – point e – point viii

Text proposed by the Commission	*Amendment*
(viii) ***requirement to use take-back schemes for veterinary medicinal products for*** the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, ***additional precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products***;	(viii) ***specific precautions relating to*** the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, ***a reference to any appropriate collection system in place***;

Or. en

Amendment 182
Clara Eugenia Aguilera García

Proposal for a regulation
Article 30 – paragraph 1 – point e – point viii a (new)

Text proposed by the Commission	*Amendment*
	(viiia) when the veterinary medicinal product is authorised to be administered via medicated feed, information on known incompatibilities between the veterinary medicinal product and the feed ingredients impairing the safety or the efficacy of the medicated feed.

Or. en

Justification

The Summary of Product Characteristics of the VMP has to provide this information to the manufacturer of medicated feed.

Amendment 183
Tibor Szanyi

Proposal for a regulation
Article 30 – paragraph 1 – point j a (new)

Text proposed by the Commission	*Amendment*
	(ja) When the veterinary medical product is authorised to be administered via medicated feed, information on the possibility to have interaction between the VMP and the feed impairing the safety or the efficacy of the medicated feed shall be provided through a list of incompatibilities.

Or. en

Amendment 184
Molly Scott Cato
on behalf of the Verts/ALE Group

Martin Häusling

Proposal for a regulation
Article 30 – paragraph 1 – point j a (new)

Text proposed by the Commission	*Amendment*
	(ja) 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.

Or. en

Amendment 185
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 30 – paragraph 1 – point j b (new)

Text proposed by the Commission	*Amendment*
	(jb) ecotoxicological information including effects on non-target species and persistence of active substances and active metabolites in soil and water.

Or. en

Amendment 186
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 31 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The competent authority ***or the Commission*** shall make the decision	2. The competent authority shall make the decision granting the marketing

granting the marketing authorisation publicly available and record it in the database referred to in Article 51.	authorisation publicly available and record it in the database referred to in Article 51.

Or. fr

Amendment 187
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 31 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Where two products have the same therapeutic effect, comparative assessments may be carried out. Products that are hazardous to the environment or to the treated animals shall be substituted by less hazardous products.

Or. en

Justification

This introduces the possibility of comparative assessment to allow substitution of a hazardous product with another one with the similar/the same therapeutic effect but less detrimental effects on the animals being treated or on the environment / non-target species.

Amendment 188
Michel Dantin, Marc Tarabella, Angélique Delahaye

Proposal for a regulation
Article 32

Text proposed by the Commission	*Amendment*
[...]	***deleted***

Or. fr

Justification

Almost all antimicrobial veterinary medicines are by-products of research and development on medicines for human use. Resistance to antibiotics must be combated by means of preventive measures and by setting conditions for the prescription and use of antimicrobials.

Amendment 189
Ulrike Müller

Proposal for a regulation
Article 32 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the product is a ***zootechnical veterinary medicinal product or a*** performance enhancer, and the applicant has not sufficiently demonstrated the benefits of the product to the animal health and welfare or public health;	(c) the product is a performance enhancer, and the applicant has not sufficiently demonstrated the benefits of the product to the animal health and welfare or public health;

Or. de

Justification

The regulation should take account of the possibilities of modern livestock farming and modern animal health management. The wording in the proposal may correspond to the current legal situation, but it is out of touch with the actual circumstances. The most lasting way of removing diseases from the animal population is to identify carriers and use biotechnical measures to breed carriers of desirable traits.

Amendment 190
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 32 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(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	(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

increase yields from treated animals;	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*** ;

Or. en

Amendment 191
Ulrike Müller

Proposal for a regulation
Article 32 – paragraph 1 – point g

Text proposed by the Commission	*Amendment*
(g) risk for public health ***in case of development of antimicrobial resistance*** outweighs the ***benefits of the product*** to animal health;	(g) risk for public health outweighs the ***risk of damage*** to animal health ***caused by the absence of a product***;

Or. de

Justification

The Commission's proposed text is attempting to compare apples and oranges. Risks can only be compared with other risks.

Amendment 192
Momchil Nekov

Proposal for a regulation
Article 32 – paragraph 1 – point g

Text proposed by the Commission	*Amendment*
(g) risk for public health in case of development of antimicrobial resistance outweighs the benefits of the product to animal health;	*(Does not affect the English version)*

Or. bg

Amendment 193
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 32 – paragraph 1 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) the product is a substance of high concern;

Or. en

Justification

These would include substances which are persistent, biocidal and toxic (PBT), very persistent and very toxic (vPvP) or are endocrine disruptors. It follows the terminology of the REACH directive.

Amendment 194
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 32 – paragraph 1 – point g b (new)

Text proposed by the Commission	*Amendment*
	(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;

Or. en

Justification

This approach mirrors biocide and pesticide legislations. EMA guidelines EMA/CVMP/ERA/52740/2012 for assessment of PBTs and vPvBs substances are currently being reviewed (see http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/07/WC500130368.pdf)

Amendment 195
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 32 – paragraph 1 – point h a (new)

Text proposed by the Commission	*Amendment*
	(ha) unacceptable side effects or secondary effects on the treated animal;

Or. en

Amendment 196
Ulrike Müller

Proposal for a regulation
Article 32 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. de

Justification

This provision would virtually exclude research and development into antimicrobial substances and veterinary medicinal products. 95% of antimicrobial veterinary medicinal products are by-products of research and development into human medicinal products. The market for veterinary medicinal products, which is already small, would be unnecessarily

restricted.

Amendment 197
Momchil Nekov

Proposal for a regulation
Article 32 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	*(Does not affect the English version)*

Or. bg

Amendment 198
Ulrike Müller

Proposal for a regulation
Article 32 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. de

Justification

This provision would virtually exclude research and development into antimicrobial substances and veterinary medicinal products. 95% of antimicrobial veterinary medicinal products are by-products of research and development into human medicinal products. The market for veterinary medicinal products, which is already small, would be unnecessarily

restricted.

Amendment 199
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 32 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. fr

Amendment 200
Momchil Nekov

Proposal for a regulation
Article 32 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	*(Does not affect the English version)*

Or. bg

Amendment 201
Nicola Caputo

Proposal for a regulation
Article 32 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to establish rules for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of certain active substances in humans.	3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 ***and taking into consideration the scientific advice of the Agency*** in order to establish rules for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of certain active substances in humans. ***The Commission, when establishing these rules, will make decisions on appropriate risk management measures at the class, substance or even the indication level and will consider also the route of administration.***

Or. en

Justification

In order for the rules to successfully achieve their intended purpose they need to be based on science. This methodology for classifying antimicrobials is the one recommended by the Agency in its report on antimicrobials dated 18 December 2014 (European Medicines Agency, 'Answers to the requests for scientific advice on the impact on public health and animal health of the use of antibiotics in animals', 18 December 2014, pp. 6 & 16).

Amendment 202
Bas Belder, James Nicholson

Proposal for a regulation
Article 32 – paragraph 3

Text proposed by the Commission	*Amendment*
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	3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 ***and based on the latest scientific advice*** in order to establish rules for the designation of the antimicrobials

infections in humans in order to preserve the efficacy of certain active substances in humans.	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 Commission, when establishing these rules, will make decisions on appropriate risk management measures at the class, substance or even the indication level and will consider also the route of administration.***

Or. en

Justification

Decisions will be based on scientific advice and in particular the European Medicines Agency methodology for classifying antimicrobials.

Amendment 203
Ulrike Müller

Proposal for a regulation
Article 32 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	***deleted***

Or. de

Justification

This provision would virtually exclude research and development into antimicrobial substances and veterinary medicinal products. 95% of antimicrobial veterinary medicinal products are by-products of research and development into human medicinal products. The market for veterinary medicinal products, which is already small, would be unnecessarily restricted.

Amendment 204
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 32 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	***deleted***

Or. fr

Amendment 205
Momchil Nekov

Proposal for a regulation
Article 32 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	*(Does not affect the English version)*

Or. bg

Amendment 206
Nicola Caputo

Proposal for a regulation
Article 32 – paragraph 4

Text proposed by the Commission	*Amendment*
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).	4. The Commission shall, by means of implementing acts ***and taking into consideration the scientific advice of the Agency***, 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). ***The Commission, when establishing these rules, will make decisions on appropriate risk management measures at the class, substance or even the indication level and will consider also the route of administration.***

Or. en

Justification

In order for the rules to successfully achieve their intended purpose they need to be based on science. This methodology for classifying antimicrobials is the one recommended by the Agency in its report on antimicrobials dated 18 December 2014 (European Medicines Agency, 'Answers to the requests for scientific advice on the impact on public health and animal health of the use of antibiotics in animals', 18 December 2014, pp. 6 & 16).

Amendment 207
Bas Belder, James Nicholson

Proposal for a regulation
Article 32 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials	4. The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials

reserved for treatment of certain infections in humans. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	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). ***The Commission, when establishing these rules, will make decisions on appropriate risk management measures at the class, substance or even the indication level and will consider also the route of administration.***

Or. en

Amendment 208
Ulrike Müller

Proposal for a regulation
Article 33 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Any marketing authorisation or variation to the terms of a marketing authorisation differing from the previously granted marketing authorisation only with regard to strengths***, pharmaceutical forms, administration routes*** or presentations shall be regarded as the same marketing authorisation as the one previously granted for the purpose of applying the rules of the protection of technical documentation.	3. Any marketing authorisation or variation to the terms of a marketing authorisation differing from the previously granted marketing authorisation only with regard to strengths 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.

Or. de

Justification

From a veterinary point of view, pharmaceutical forms and administration routes require significant development to ensure that medicinal products can be applied to animals in an appropriate way, particularly bearing in mind that this may differ from one species to another. For example, a medicinal product or capsule may pass through the stomachs of ruminants but be broken down by gastric acid when administered to pigs.

Amendment 209
Michel Dantin, Marc Tarabella, Angélique Delahaye

Proposal for a regulation
Article 34 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) 10 years for the veterinary medicinal products for cattle, ***sheep,*** pigs, chickens, dogs and cats;	(a) 10 years for the veterinary medicinal products for cattle, pigs, chickens, dogs and cats;

Or. fr

Justification

Sheep should be regarded as a limited market.

Amendment 210
Eric Andrieu, Jean-Paul Denanot

Proposal for a regulation
Article 34 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) 10 years for the veterinary medicinal products for cattle, ***sheep,*** pigs, chickens, dogs and cats;	(a) 10 years for the veterinary medicinal products for cattle, pigs, chickens, dogs and cats;

Or. fr

Justification

In terms of veterinary medicine, sheep are a limited market as they are reared extensively and have only a low economic value. The market in medicines for sheep is therefore more restricted than that for horses, for example.

Amendment 211
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 34 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) 10 years for the veterinary medicinal products for cattle, sheep, pigs, chickens, dogs and cats***;***	(a) 10 years for the veterinary medicinal products for cattle, sheep ***(only for meat)***, pigs, chickens, dogs and cats***.***

Or. en

Justification

Nowadays sheep producing milk is considered a "minor use" and products indicated for that animals should have higher protection than products indicated for meat sheep.

Amendment 212
Bas Belder, James Nicholson

Proposal for a regulation
Article 34 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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;	(b) ***18*** 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;

Or. en

Amendment 213
Miguel Viegas

Proposal for a regulation
Article 34 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) ***14*** years for antimicrobial veterinary medicinal products for cattle, sheep, pigs, chickens, dogs and cats containing an	(b) ***10*** 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;	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;

Or. pt

Amendment 214
Michel Dantin, Marc Tarabella, Angélique Delahaye

Proposal for a regulation
Article 34 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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;	(b) 14 years for antimicrobial veterinary medicinal products for cattle, 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;

Or. fr

Justification

Sheep should be regarded as a limited market.

Amendment 215
Eric Andrieu, Jean-Paul Denanot

Proposal for a regulation
Article 34 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) 14 years for antimicrobial veterinary medicinal products for cattle, ***sheep,*** pigs, chickens, dogs and cats containing an antimicrobial active substance which has	(b) 14 years for antimicrobial veterinary medicinal products for cattle, 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;	not been an active substance in a veterinary medicinal product authorised within the Union on the date of the submission of the application;

Or. fr

Justification

In terms of veterinary medicine, sheep are a limited market as they are reared extensively and have only a low economic value. The market in medicines for sheep is therefore more restricted than that for horses, for example.

Amendment 216
Momchil Nekov

Proposal for a regulation
Article 34 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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;	*(Does not affect the English version)*

Or. bg

Amendment 217
Giulia Moi

Proposal for a regulation
Article 34 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) ***18*** years for veterinary medicinal products for bees;	(c) ***20*** years for veterinary medicinal products for bees;

Or. it

Amendment 218
Miguel Viegas

Proposal for a regulation
Article 34 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) ***18*** years for veterinary medicinal products for bees;	(c) ***10*** years for veterinary medicinal products for bees;

Or. pt

Amendment 219
Giulia Moi

Proposal for a regulation
Article 34 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) ***14*** years for veterinary medicinal products for animal species other than listed in paragraph 1(a) and (c).	(d) ***16*** years for veterinary medicinal products for animal species other than listed in paragraph 1(a) and (c).

Or. it

Amendment 220
Miguel Viegas

Proposal for a regulation
Article 34 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) ***14*** years for veterinary medicinal products for animal species other than listed in paragraph 1(a) and (c).	(d) ***10*** years for veterinary medicinal products for animal species other than listed in paragraph 1(a) and (c).

Or. pt

Amendment 221
Ulrike Müller

Proposal for a regulation
Article 34 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The period shall be extended in line with the prolongation periods provided for in Article 35 where the veterinary medicinal product has been authorised for more than one species.

Or. de

Justification

The period of the protection of technical documentation may not provide sufficient incentive for the development of new veterinary medicinal products. The prolongation possibilities under Article 35 should be granted at the same time as the initial marketing authorisation.

Amendment 222
Nicola Caputo

Proposal for a regulation
Article 35 – title

Text proposed by the Commission	*Amendment*
Prolongation of the periods of ***the*** protection of technical documentation	***Grant of*** periods of protection of technical documentation

Or. en

Justification

The strategy proposed by the Commission will obstruct the generic development and competition - i.e. competitor market blocked - resulting in non-availability and non-affordability of medicines, with consequent higher prices of treatments and negative spill-over effect for the food chain. Therefore, PTD should be 'granted', not 'prolonged'.

Amendment 223
Bas Belder

Proposal for a regulation
Article 35 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to another species ***listed in Article 34(1)(a), the period*** of the protection provided for in ***that Article*** shall be prolonged by ***1 year*** for each additional target species, provided that the variation has been submitted at least 3 years before the expiration of the protection ***period*** laid down in Article 34***(1)(a)***.	1. Where ***the first marketing authorisation is granted for more than one species or*** a variation is approved in accordance with Article 65 extending the marketing authorisation to another species***, the periods*** of the protection provided for in ***Article 34*** shall be prolonged by ***2 years*** for each additional target species ***listed in Article 34(1)(a)***, provided that the variation has been submitted at least 3 years before the expiration of the protection ***periods*** laid down in Article 34.

Or. en

Amendment 224
Nicola Caputo

Proposal for a regulation
Article 35 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to another species listed in Article 34(1)(a), the period of the protection provided for in that Article shall be ***prolonged by*** 1 year for each additional target species***, provided that the variation has been submitted at least 3 years before the expiration of the protection period laid down in Article 34(1)(a)***.	1. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to another species listed in Article 34(1)(a), the ***granted*** period of the protection provided for in that Article shall be 1 year for each additional target species.

Or. en

Justification

The strategy proposed by the Commission will obstruct the generic development and competition - i.e. competitor market blocked - resulting in non-availability and non-affordability of medicines, with consequent higher prices of treatments and negative spill-over effect for the food chain. Therefore, PTD should be 'granted', not 'prolonged'.

Amendment 225
Ulrike Müller

Proposal for a regulation
Article 35 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to another species listed in Article 34(1)(a), the period of the protection provided for in that Article shall be prolonged by ***1 year*** for each additional target species, provided that the variation has been submitted at least 3 years before the expiration of the protection period laid down in Article 34(1)(a).	1. Where 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 ***2 years*** 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).

Or. de

Justification

The specific veterinary factors that have to be taken into account when developing veterinary medicinal products are considered to be so significant that a prolongation of only one year may not provide a sufficient incentive for further development.

Amendment 226
Michel Dantin, Marc Tarabella, Angélique Delahaye

Proposal for a regulation
Article 35 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to another species	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).	listed in Article 34(1)(a), the period of the protection provided for in that Article shall be prolonged by ***two years*** 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).

Or. fr

Amendment 227
Eric Andrieu, Jean-Paul Denanot

Proposal for a regulation
Article 35 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to another species listed in Article 34(1)(a), the period of the protection provided for in that Article shall be prolonged by ***1 year*** for each additional target species, provided that the variation has been submitted at least 3 years before the expiration of the protection period laid down in Article 34(1)(a).	1. Where 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 ***two years*** 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).

Or. fr

Justification

To increase the availability of veterinary medicines, applications for extension should be encouraged by increasing the prolongation of the data protection period to two years.

Amendment 228
Nicola Caputo

Proposal for a regulation
Article 35 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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 4 years.

Or. en

Justification

The strategy proposed by the Commission will obstruct the generic development and competition - i.e. competitor market blocked - resulting in non-availability and non-affordability of medicines, with consequent higher prices of treatments and negative spill-over effect for the food chain. Therefore, PTD should be 'granted', not 'prolonged'.

Amendment 229
Miguel Viegas

Proposal for a regulation
Article 35 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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 ***2*** years.

Or. pt

Amendment 230
Giulia Moi

Proposal for a regulation
Article 35 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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 ***6*** years.

Or. it

Amendment 231
Bas Belder

Proposal for a regulation
Article 35 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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 another species***, the periods*** of the protection provided for in Article 34 shall be prolonged by 4 years ***for each additional target species not listed in Article 34(1)(a)***.

Or. en

Amendment 232
Nicola Caputo

Proposal for a regulation
Article 35 – paragraph 3

Text proposed by the Commission	*Amendment*
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	***deleted***

belonging to the same marketing authorisation ('overall period of the protection of technical documentation') shall not exceed 18 years.

Or. en

Justification

The strategy proposed by the Commission will obstruct the generic development and competition - i.e. competitor market blocked - resulting in non-availability and non-affordability of medicines, with consequent higher prices of treatments and negative spill-over effect for the food chain. Therefore, PTD should be 'granted', not 'prolonged'.

Amendment 233
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 35 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The period of the protection of the first marketing authorisation prolonged by any additional periods ***of protection*** due to any variations or new authorisations belonging to the same marketing authorisation ***('overall*** period of ***the*** protection ***of technical documentation') shall not exceed 18 years***.	3. The period of the protection of the first marketing authorisation ***shall not be*** prolonged by any additional periods due to any variations or new authorisations belonging to the same marketing authorisation***.***
	The variations or new authorisation should have their own period of ***protection. This*** protection ***shall be three years for each variation or new authorisation***.

Or. en

Justification

We consider that variation or new product should have their own period of protection (to be established in that Regulation) and should not prolong the period of protection of the "initial product". It is necessary to protect innovation but respecting the competence. With this proposal both objectives are met.

Amendment 234
Miguel Viegas

Proposal for a regulation
Article 35 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The period of the protection of the first marketing authorisation prolonged by any additional periods of protection due to any variations or new authorisations belonging to the same marketing authorisation (‘overall period of the protection of technical documentation’) shall not exceed ***18*** years.	3. The period of the protection of the first marketing authorisation prolonged by any additional periods of protection due to any variations or new authorisations belonging to the same marketing authorisation (‘overall period of the protection of technical documentation’) shall not exceed ***15*** years.

Or. pt

Amendment 235
Giulia Moi

Proposal for a regulation
Article 35 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The period of the protection of the first marketing authorisation prolonged by any additional periods of protection due to any variations or new authorisations belonging to the same marketing authorisation (' overall period of the protection of technical documentation ') shall not exceed ***18*** years.	3. The period of the protection of the first marketing authorisation prolonged by any additional periods of protection due to any variations or new authorisations belonging to the same marketing authorisation ('overall period of the protection of technical documentation') shall not exceed ***20*** years.

Or. it

Amendment 236
Nicola Caputo

Proposal for a regulation
Article 35 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Any grant of periods for protection of technical documentation should also be equally applied to innovation performed to generic veterinary medicines, and not only to originators.

Or. en

Justification

All type of marketing authorisations (originators, generics, etc.) should be eligible to obtain Protection of Technical Documentation (PTD, also known as 'data protection') when they submit a new data package according to Article 35(1).

Amendment 237
Bas Belder

Proposal for a regulation
Article 35 a (new)

Text proposed by the Commission	*Amendment*
	Article 35 a
	Data protection for redevelopment of veterinary medicinal products
	Where the data protection period as set out in Articles 34 and 35 has elapsed, any applicant may apply for a data protection period for additional innovations to existing veterinary medicinal products, which shall amount to two years for an additional species and one year for an additional indication, additional pharmaceutical form or new withdrawal period.

Or. en

Justification

Incentive for further development of existing veterinary medicines, which can be done by any

company including generic companies. A limited data protection period will be granted for the additional innovation only (the elapsed protection period of the initial marketing authorisation will not be prolonged).

Amendment 238
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 38

Text proposed by the Commission	*Amendment*
[...]	***deleted***

Or. fr

Amendment 239
Miguel Viegas

Proposal for a regulation
Article 38 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Centralised marketing authorisations shall be granted by the Commission in accordance with this Section. They shall be valid throughout the Union.	1. Centralised marketing authorisations shall be granted by the Commission in accordance with this Section. They shall be valid throughout the Union ***and considered the priority procedure***.

Or. pt

Amendment 240
Stanislav Polčák

Proposal for a regulation
Article 38 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) veterinary medicinal products containing an active substance which has	***deleted***

not been authorised as a veterinary medicinal product within the Union at the date of the submission of the application;

Or. en

Amendment 241
Stanislav Polčák

Proposal for a regulation
Article 38 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) generic veterinary medicinal products of reference veterinary medicinal products authorised under the centralised authorisation procedure.	***deleted***

Or. en

Justification

One of the major motivations of the revision of the veterinary pharmaceutical legislation should be the improvement of availability of veterinary medicinal products and support of innovations. The proposed measure does not fit with the declared goals, as it is extending obligation to authorise certain veterinary medicinal products by means of centralised marketing authorisation procedure.

Amendment 242
Norbert Erdős

Proposal for a regulation
Article 38 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) generic veterinary medicinal products of reference veterinary medicinal products authorised under the centralised authorisation procedure.	***deleted***

Or. hu

Justification

Extending the power of centralised authorisation, primarily in the case of generic products, may be unequivocally damaging to SMEs, as they do not have the requisite resources for it. This may damage innovation, the budgets of SMEs and employment rates.

Amendment 243
Bas Belder, James Nicholson

Proposal for a regulation
Article 38 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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 ***or if the application concerns a conversion of a marketing authorisation as referred to in Article 57a***.

Or. en

Justification

It should be possible to easily convert existing marketing authorisations into a centralised marketing authorisation. This will reduce the administrative burden (see related amendment on new Article 57a).

Amendment 244
Stanislav Polčák

Proposal for a regulation
Article 38 – paragraph 4

Text proposed by the Commission	*Amendment*
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	***deleted***

146 in order to amend the list set out in paragraph 2.

Or. en

Justification

The scope of the centralised procedure is essential for the entire EU regulatory system, animal health, public health, as well as development of the national veterinary pharmaceutical industry.

Amendment 245
Momchil Nekov

Proposal for a regulation
Article 38 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	*(Does not affect the English version).*

Or. bg

Amendment 246
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 40

Text proposed by the Commission	*Amendment*
[...]	***deleted***

Or. fr

Amendment 247
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 41

Text proposed by the Commission	*Amendment*
Article 41	***deleted***
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.	
3. Within 15 days after its adoption, the Agency shall forward its opinion to the Commission and the applicant.	

Or. fr

Amendment 248
Norbert Erdős

Proposal for a regulation
Article 46 – paragraph 1

Text proposed by the Commission	*Amendment*
(1) Applications for decentralised marketing authorisation shall be submitted to the Member State chosen by the applicant (‘reference Member State’).	(1) Applications for decentralised marketing authorisation shall be submitted to the Member State chosen by the applicant (‘reference Member State’). ***It shall also forward the applications to all Member States for information.***

Or. hu

Justification

In the case of decentralised authorisation procedures based on mutual recognition, it is important that access to the full documentation on medicines should not be confined only to the reference Member State. All Member States participating in the procedure should have the opportunity to inspect it.

Amendment 249
Stanislav Polčák

Proposal for a regulation
Article 46 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The application shall list Member States where the applicant seeks to obtain a marketing authorisation ('Member States concerned').	2. The application shall list Member States where the applicant seeks to obtain a marketing authorisation ('Member States concerned'). ***The applicant shall send an application identical to that submitted to the reference Member State, including an identical dossier as provided under Article 7, to all Member States concerned.***

Or. en

Justification

The legislation must make it clear that all Member States where the marketing authorisation is sought have available data on the base of which the decision shall be granted. This is extremely important not only for the initial marketing authorisation, but also for the entire post-marketing period (pharmacovigilance, variations to the marketing authorisation) and for any market surveillance/control activities where the Member States shall execute their responsibilities.

Amendment 250
Norbert Erdős

Proposal for a regulation
Article 48 – paragraph 1

Text proposed by the Commission	*Amendment*
(1) Applications for mutual recognition of	(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 ").	marketing authorisations shall be submitted to the Member State that granted the first national marketing authorisation ("reference Member State"). ***It shall also forward the applications to all Member States for information.***

Or. hu

Justification

In the case of decentralised authorisation procedures based on mutual recognition, it is important that access to the full documentation on medicines should not be confined only to the reference Member State. All Member States participating in the procedure should have the opportunity to inspect it.

Amendment 251
Stanislav Polčák

Proposal for a regulation
Article 48 – paragraph 1

Text proposed by the Commission	*Amendment*
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').	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’) ***and the Member States where the applicant seeks to obtain recognition of the marketing authorisation (‘concerned Member States’)***.

Or. en

Justification

The legislation must make it clear that all Member States where the marketing authorisation is sought have available data on the base of which the decision shall be granted. This is extremely important not only for the initial marketing authorisation, but also for the entire post-marketing period (pharmacovigilance, variations to the marketing authorisation) and for any market surveillance/control activities where the Member States shall execute their responsibilities.

Amendment 252
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 48 – paragraph 1

Text proposed by the Commission	*Amendment*
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**'**).	1. Applications ***and the dossier*** for mutual recognition of marketing authorisations shall be submitted to ***all*** the Member ***States. The Member State*** that granted the first national marketing authorisation ***is the*** ('reference Member State').

Or. en

Justification

It should be clear that the applicant should send the application and the dossier to all Member States and not only to the Reference Member State.

Amendment 253
Nicola Caputo

Proposal for a regulation
Article 48 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. en

Justification

The introduction of a requirement that companies must wait 6 months between a national procedure and a mutual recognition procedure is unnecessary and could even cause problems

if a serious animal health or public health situation arises necessitating the quick authorisation of the product in additional Member States.

Amendment 254
Miguel Viegas

Proposal for a regulation
Article 48 – paragraph 2

Text proposed by the Commission	*Amendment*
2. A minimum of ***6*** months shall elapse between the decision granting the first national marketing authorisation and the submission of the application for mutual recognition of the national marketing authorisation.	2. A minimum of ***4*** 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.

Or. pt

Amendment 255
Stanislav Polčák

Proposal for a regulation
Article 48 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(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;	***deleted***

Or. en

Justification

In line with current legislation and the draft Regulation, applications must be dealt with by using the mutual recognition procedure. It is proposed to replace this requirement by a requirement for a consolidated marketing authorisation dossier which must be available to the concerned Member State in order that Member States can make evidence based decisions on the initial marketing authorisation and perform any post-authorisation responsibilities.

Amendment 256
Miguel Viegas

Proposal for a regulation
Article 48 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Within ***90*** days of receipt of a valid application, the reference Member State shall prepare an updated assessment report for the veterinary medicinal product. The updated assessment report together with the approved summary of the product characteristics and the text to appear in the labelling and package leaflet shall be forwarded to all Member States and the applicant, together with the list of Member States where the applicant seeks to obtain recognition of the marketing authorisation ('concerned Member States').	4. Within ***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 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').

Or. pt

Amendment 257
Stanislav Polčák

Proposal for a regulation
Article 48 – paragraph 4

Text proposed by the Commission	*Amendment*
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	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 ***concerned*** Member States and the applicant**.** , together with the list of Member States where the applicant seeks to obtain recognition of the marketing

(**'**concerned Member States').	authorisation (‘concerned Member States’).

Or. en

Justification

The amendment seeks to adapt the provision to the previous amendments to Article 48.

Amendment 258
Bas Belder, James Nicholson

Proposal for a regulation
Article 49 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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.***

Or. en

Amendment 259
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 49 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Within the coordination group, a rapporteur shall be appointed in order to prepare a second assessment report for the veterinary medicinal product.	***deleted***

Or. en

Justification

It is proposed to delete this paragraph because it would unnecessarily increase the workload for competent authorities. The objection should be discussed between the States involved in the procedure. If there is no agreement, then it is acceptable that the issue is discussed at the Coordination group.

Amendment 260
Bas Belder, James Nicholson

Proposal for a regulation
Article 49 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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.

Or. en

Justification

As Article 66 (variation) and Article 69 (harmonisation) could also give rise to a coordination group review resulting in amendment, this word should be added throughout the Article.

Amendment 261
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 50 – paragraph 1

Text proposed by the Commission	*Amendment*
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**.**	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 ***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

Or. en

Justification

We consider that a request sent to the Agency will increase the workload and the administrative burden of the Agency and it would be more simple if the request is made to the Coordination group.

Amendment 262
Norbert Erdős

Proposal for a regulation
Article 51 – paragraph 4

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Or. hu

Justification

Inputting information to the EU database of medicines would be a heavy burden on national

authorities. In the human medicine sector, this is done by permit-holders. In addition, the technological realisation is also uncertain (e.g. format, language regime).

Amendment 263
Norbert Erdős

Proposal for a regulation
Article 51 – paragraph 6

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Or. hu

Justification

Inputting information to the EU database of medicines would be a heavy burden on national authorities. In the human medicine sector, this is done by permit-holders. In addition, the technological realisation is also uncertain (e.g. format, language regime).

Amendment 264
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 51 a (new)

Text proposed by the Commission	*Amendment*
	Article 51a
	Feasibility study for monograph review system
	By the 1st June 2018, the Commission shall present a report to the European

Parliament and the Council on establishing a substance-based review system (monographs) for the environmental risk assessment of veterinary medicinal products, to be accompanied by a legislative proposal if appropriate.

Or. en

Justification

The monograph approach is already successfully used in pesticide and biocide assessment and would save resources and allows effective comparison of datasets.

Amendment 265
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 52 – paragraph 3

Text proposed by the Commission	*Amendment*
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***.	3. The general public shall have access to information in the product database .

Or. en

Justification

Products, and residues and metabolites of their active ingredients, are found in the public sphere, far beyond the treated animal, in the wider environment and in the bodies of non-target species (including humans, and whether we like it or not). Therefore the data on what those substances are and their characteristics shall be also in the public sphere.

Amendment 266
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 52 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Commercial sensitivity must not be used as an excuse to deny citizens access to information about chemicals affecting their bodies and those of other non-target species in the wider environment. Maximal transparency shall be ensured while protecting the most commercially sensitive information.

Or. en

Justification

A balance can be found between the two objectives.

Amendment 267
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 54 – title

Text proposed by the Commission	*Amendment*
Collection of data on the sales and use of ***antimicrobial*** veterinary medicinal products	Collection of data on the sales and use of veterinary medicinal products

Or. en

Amendment 268
Momchil Nekov

Proposal for a regulation
Article 54 – title

Text proposed by the Commission	*Amendment*
Collection of data on the sales and use of antimicrobial veterinary medicinal products	*(Does not affect the English version)*

Or. bg

Amendment 269
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 54 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall collect relevant and comparable data on the volume of sales and the use of veterinary antimicrobial medicinal products.	1. Member States shall collect relevant and comparable data on the volume of sales and the use of veterinary antimicrobial medicinal products. ***These data shall include:***
	(a) volume of sales in terms of weight and monetary value for each antimicrobial type;
	(b) use of antimicrobials including species treated, disease or infection being treated, and method of treatment.

Or. en

Justification

Specific and rigorous data are needed to ensure the dataset upon which effective action against antimicrobial resistance will be based is relevant, comparable and useful. Without data of this kind available the monitoring of antimicrobial use is not possible.

Amendment 270
Bas Belder

Proposal for a regulation
Article 54 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall collect relevant and comparable data on the volume of sales ***and*** the use of veterinary antimicrobial medicinal products.	1. Member States shall collect relevant and comparable data on the volume of sales**,** the use of veterinary antimicrobial medicinal products ***and data on antimicrobial resistant organisms in animals***.

Or. en

Amendment 271
Momchil Nekov

Proposal for a regulation
Article 54 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall collect relevant and comparable data on the volume of sales and the use of veterinary antimicrobial medicinal products.	*(Does not affect the English version)*

Or. bg

Amendment 272
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 54 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. These data should provide detail at least by species and by antibiotic class and on a per-farm level.

Or. en

Justification

Specific and rigorous data are needed to ensure the dataset upon which effective action against AB resistance will be based is relevant, comparable and useful. Without data of this kind available the monitoring of antimicrobial use is not possible.

Amendment 273
Nicola Caputo

Proposal for a regulation
Article 54 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. Member States shall send ***to the Agency*** data on the volume of sales of veterinary antimicrobial medicinal products ***as well as data on how, when, where and why antimicrobials are being used***. The Agency shall analyse the data and publish an annual report.

Or. en

Amendment 274
Momchil Nekov

Proposal for a regulation
Article 54 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	*(Does not affect the English version)*

Or. bg

Amendment 275
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 54 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. fr

Amendment 276
Momchil Nekov

Proposal for a regulation
Article 54 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	*(Does not affect the English version)*

Or. bg

Amendment 277
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 54 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	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.

Or. en

Justification

The idea is to extend the concept outlined for antibiotics to other types of vet medicine with biological effects on non-target species in the wider ecosystem, i.e. hormonal products (which can effect sex of non-target species especially in aquatic habitats) and anti-parasitic products (which can be highly toxic to bees, for example).

Amendment 278
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 54 – paragraph 4

Text proposed by the Commission	*Amendment*
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. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	***deleted***

Or. fr

Amendment 279
Norbert Erdős

Proposal for a regulation
Article 56

Text proposed by the Commission	*Amendment*
Article 56	***deleted***
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.

(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.

Or. hu

Justification

Establishing the proposed national information services would impose a heavy burden on Member States' authorities, for which in many Member States the requisite funding is not available. At present the authorities are already fully required to inform the industry, including SMEs, about regulations. They are entirely responsible for keeping information up to date.

Amendment 280
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 57 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) a ***summary report on pharmacovigilance data***.	(c) A ***bridging PSUR***.

Or. en

Justification

The documentation required ('a summary report on pharmacovigilance data') is not defined in any part of the Regulation or in any guideline. It is proposed to substitute by a Bridging PSUR that is define in proper guidelines for several years and the Marketing authorisation holders are familiarized with them.

Amendment 281
Bas Belder

Proposal for a regulation
Article 57 a (new)

Text proposed by the Commission	*Amendment*
	Article 57a
	Subsequent conversion into centralised marketing authorisation
	1. After completion of a decentralised procedure laid down in Article 46, a mutual recognition procedure laid down in Article 48, or a marketing authorisation harmonisation procedure laid down in Article 69, the marketing authorisation holder may submit an application to convert the existing marketing authorisations for the veterinary medicinal product into a centralised marketing authorisation granted by the Commission and 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, summary of the product

characteristics, labelling and package leaflet.

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, decentralised procedure or marketing authorisation harmonisation procedure after the date of the application of this Regulation.

Or. en

Justification

It should be possible for marketing authorisation holders to 'upgrade' existing marketing authorisations into a centralised marketing authorisation. This will reduce the administrative burden, e.g. in case of filing future variations to the veterinary medicinal product.

Amendment 282
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 58

Text proposed by the Commission	*Amendment*
Article 58	***deleted***
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').	
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'). These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

3. When adopting those implementing acts, the Commission shall take account of the following criteria:

(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.

Or. fr

Amendment 283
Stanislav Polčák

Proposal for a regulation
Article 58 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Variation to the terms of a marketing authorisation means ***a change*** to the ***terms*** of the ***marketing authorisation for a veterinary medicinal product as*** referred to in ***Article 31*** (***'variation'***).	1. Variation to the terms of a marketing authorisation ***('variation')*** means ***an amendment*** to the ***contents*** of the ***particulars and documents and/or conditions*** referred to in ***Articles 7***(***1***) ***and 16***.

Or. en

Amendment 284
Stanislav Polčák

Proposal for a regulation
Article 58 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission shall***, by means of implementing acts, establish a list*** of variations to the terms of ***a marketing authorisation for a veterinary medicinal product requiring assessment ('variations requiring assessment'). Those*** implementing ***acts*** shall be adopted in accordance with the examination procedure referred to in Article 145(2).	2. The Commission shall ***adopt appropriate arrangements for the examination*** of variations to the terms of ***marketing authorisations granted in accordance with this Regulation.***
	The Commission shall adopt these arrangements in the form of an implementing Regulation. That implementing ***act,*** shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Or. en

Amendment 285
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 58 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall take account of the following criteria when adopting those implementing acts:	***deleted***
(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.	

Or. en

Justification

The criteria are too ambiguous and should be detailed more precisely by the Commission.

Amendment 286
Stanislav Polčák

Proposal for a regulation
Article 58 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. The Commission shall ***take account of the following criteria when adopting those implementing acts:***	3. ***By (...insert date 12 months after this Regulation comes into force...),*** the Commission shall ***submit a report to the European Parliament and to the Council to review experience gained from the application of Regulation 1234/2008.*** ***The report shall, if appropriate, be accompanied by relevant proposals to amend Regulation 1234/2008.***

Or. en

Amendment 287
Stanislav Polčák

Proposal for a regulation
Article 58 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) the need for a scientific assessment of changes in order to determine the risk to public health, animal health or the environment;	***deleted***

Or. en

Amendment 288
Momchil Nekov

Proposal for a regulation
Article 58 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) the need for a scientific assessment of changes in order to determine the risk to public health, animal health or the environment;	*(Does not affect the English version)*

Or. bg

Amendment 289
Stanislav Polčák

Proposal for a regulation
Article 58 – paragraph 3 – point b

Text proposed by the Commission	*Amendment*
(b) whether changes have an impact on the safety and efficacy of the veterinary medicinal product;	***deleted***

Or. en

Amendment 290
Stanislav Polčák

Proposal for a regulation
Article 58 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) whether changes imply a significant alteration to the summary of product characteristics.	***deleted***

Or. en

Amendment 291
Stanislav Polčák

Proposal for a regulation
Article 59

Text proposed by the Commission	*Amendment*
Article 59	***deleted***
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.	

Or. en

Amendment 292
Stanislav Polčák

Proposal for a regulation
Article 60

Text proposed by the Commission	*Amendment*
Article 60	***deleted***
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 amend the decision granting a marketing authorisation in	

accordance with the change.

Or. en

Amendment 293
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 60

Text proposed by the Commission	*Amendment*
Article 60	***deleted***
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 amend the decision granting a marketing authorisation in accordance with the change.	

Or. en

Justification

There is not a system to control if the Marketing authorisation holders comply with this new obligation. On the other hand, the proposal implies a great increase of workload for competent authorities.

Amendment 294
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 60 – paragraph 2

Text proposed by the Commission	*Amendment*
2. If necessary, competent authorities ***or, where the veterinary medicinal product is authorised under the centralised marketing authorisation procedure, the Commission*** shall amend the decision granting a marketing authorisation in accordance with the change.	2. If necessary, competent authorities shall amend the decision granting a marketing authorisation in accordance with the change.

Or. fr

Amendment 295
Stanislav Polčák

Proposal for a regulation
Article 61

Text proposed by the Commission	*Amendment*
Article 61	***deleted***
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;	
(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.

Or. en

Amendment 296
Stanislav Polčák

Proposal for a regulation
Article 62

Text proposed by the Commission	*Amendment*
Article 62	***deleted***
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.	

Or. en

Amendment 297
Stanislav Polčák

Proposal for a regulation
Article 63

Text proposed by the Commission	*Amendment*
Article 63	***deleted***
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 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.

Or. en

Amendment 298
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 63 – paragraph 1

Text proposed by the Commission	*Amendment*
1. When applying for variations to the terms of several marketing authorisations held by the same marketing authorisation holder and granted by different competent authorities ***and/or the Commission***, the marketing authorisation holder shall submit an application to all competent authorities concerned and the Agency.	1. When applying for variations to the terms of several marketing authorisations held by the same marketing authorisation holder and granted by different competent authorities, the marketing authorisation holder shall submit an application to all competent authorities concerned and the Agency.

Or. fr

Amendment 299
Stanislav Polčák

Proposal for a regulation
Article 64

Text proposed by the Commission	*Amendment*
[...]	***deleted***

Or. en

Amendment 300
Stanislav Polčák

Proposal for a regulation
Article 65

Text proposed by the Commission	*Amendment*
Article 65	***deleted***
Measures to close the procedures for variations requiring assessment	
1. Within 30 days of the completion of the procedure laid down in Article 64(6) and (7) a competent authority or the Commission shall amend the marketing authorisation or reject the 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.	
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.	

Or. en

Amendment 301
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 65 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Within 30 days of the completion of the procedure laid down in Article 64(6) and (7) a competent authority ***or the Commission*** shall amend the marketing authorisation or reject the 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).***	1. Within 30 days of the completion of the procedure laid down in Article 64(6) and (7) a competent authority shall amend the marketing authorisation or reject the variation and inform the applicant of the grounds for the rejection.

Or. fr

Amendment 302
Stanislav Polčák

Proposal for a regulation
Article 66

Text proposed by the Commission	*Amendment*
Article 66	***deleted***
Coordination group review	
Where the opinion is prepared by a competent authority assigned in accordance with Article 63(3), each competent authority concerned shall amend the marketing authorisation granted by it or reject the variation in line with the opinion prepared by the competent authority assigned in accordance with Article 63(3).	

However, if a competent authority does not agree with the opinion, the coordination group review procedure laid down in Article 49 shall apply.

Or. en

Amendment 303
Stanislav Polčák

Proposal for a regulation
Article 67

Text proposed by the Commission	*Amendment*
Article 67	***deleted***
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.	

Or. en

Justification

The proposed provisions on variations put in question the marketing authorization procedure itself, as the competent authorities will not be able to check that the benefit-risk balance remains positive in the post-authorisation phase, since the marketing authorization holder will be allowed to introduce variations without informing the authorities.

Amendment 304
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 69 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Harmonised summaries of product characteristics for veterinary medicinal products shall contain all of the following information:	***deleted***
(a) all species mentioned in the marketing authorisations granted by Member States in respect of the similar products in the group;	
(b) all therapeutic indications mentioned in the marketing authorisations granted by Member States in respect of the similar products in the group;	
(c) the shortest withdrawal period of those stated in the summaries of the product characteristics.	

Or. en

Justification

It is not scientifically justified to sum up all indications and species without any technical assessment. Apart from that, it is not reasonable to choose the minor withdrawal period in an administrative way.

Amendment 305
Miguel Viegas

Proposal for a regulation
Article 69 – paragraph 4 – point c

Text proposed by the Commission	*Amendment*
(c) the ***shortest*** withdrawal period of those stated in the summaries of the product characteristics.	(c) the withdrawal period ***deemed appropriate in the light of the most recent scientific studies, out*** of those stated in the summaries of the product characteristics.

Or. pt

Amendment 306
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 70 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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***, or have no environmental risk assessments or incomplete ones,*** shall be reassessed ***in line with Annex II*** before a harmonised summary of the product characteristics is prepared.

Or. en

Justification

This ensures old products are properly assessed in due course, as was originally intended and assumed the legislators.

Amendment 307
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 72 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Competent authorities and the Agency shall supervise the pharmacovigilance	2. Competent authorities and the Agency shall supervise the pharmacovigilance systems of marketing authorisation holders

systems of marketing authorisation holders. ***and authorise them***.

Or. en

Justification

If competent authorities and the Agency are to authorize the pharmacovigilance system of the marketing authorization holders, this authorization can be submitted with the application of another product in accordance with Annex I, (3.2) of this proposal for Regulation, simplifying the control that competent authorities should make.

Amendment 308
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 73 – paragraph 1

Text proposed by the Commission	*Amendment*
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').	1. Member States, the Commission, the Agency and marketing authorisation holders shall collaborate in setting up and maintaining a system to monitor the safety ***and efficacy*** of authorised veterinary medicinal products, enabling them to fulfil their responsibilities as listed in Articles 77 and 79 (‘Union pharmacovigilance system').

Or. en

Justification

Pharmacovigilance is a system that monitors safety and efficacy of the products as is indicated in this Article 73 (2) (b).

Amendment 309
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 73 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(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 signs of antimicrobial resistance, following administration to an animal***;

Or. en

Justification

Competent authorities need to know all cases of suspected lack of efficacy, including cases where the product had not been administered in accordance with the Summary Product Characteristics (pe. products administered in an off label use or following the cascade prescription). All information is important to know the efficacy and the safety of the product independently if it is used or not in accordance with SPC because this information can be used in future in a safer and more efficient way.

Amendment 310
Nicola Caputo

Proposal for a regulation
Article 73 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(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 signs of antimicrobial resistance,*** following administration to an animal in accordance with the summary of product characteristics;

Or. en

Amendment 311
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 73 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) any ***environmental incidents*** observed following administration of a veterinary medicinal product to an animal;	(c) any ***adverse or unintended reaction*** observed ***in non-target species in the wider environment*** following administration of a veterinary medicinal product to an animal;

Or. en

Justification

This could include the high mortality rates in bees after de-worming products are used on livestock, or the death of vultures after feeding on carcasses of bovines treated with the anti-inflammatory Diclofenac.

Amendment 312
Nicola Caputo

Proposal for a regulation
Article 73 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) any environmental incidents observed following administration of a veterinary medicinal product to an animal;	(c) any environmental incidents observed following administration of a veterinary medicinal product to an animal***, including incidents of leakage of antibiotic residues into soil and water***;

Or. en

Amendment 313
Giulia Moi

Proposal for a regulation
Article 73 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) any infringements of withdrawal period following administration to an animal of a veterinary or human	***deleted***

medicinal product;

Or. en

Amendment 314
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 73 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) any noxious ***response*** in humans to a veterinary medicinal product;	(e) any noxious ***reaction*** in humans to a veterinary medicinal product;

Or. en

Justification

It is not expected any 'response' in humans to a veterinary medicine. It is proposed to substitute 'response' by 'reaction' which is a very well-known term in veterinary pharmacovigilance for decades.

Amendment 315
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 73 – paragraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) any suspected transmission via a veterinary medicinal product of any infectious agent.

Or. en

Justification

This situation is currently covered by legislation and should be maintained.

Amendment 316
Nicola Caputo

Proposal for a regulation
Article 73 – paragraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) any relevant documentation and data on the direct or indirect risks to the environment from the use of antimicrobial medicines in animals.

Or. en

Justification

Veterinary medicines like antibiotics are released on fields with the slurry nutrient load where they can accumulate in the soil / sludge / slurry, enter the groundwater via leakage water or run-off directly into waterways. Because of the wide consequences of the occurrence of those residues in the environment, data concerning effects and risks for the environment are necessary.

Amendment 317
Giulia Moi

Proposal for a regulation
Article 74 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Agency shall establish and maintain a Union database on pharmacovigilance of veterinary medicinal products (the ‘pharmacovigilance database’).	1. The Agency shall establish and maintain a Union database on pharmacovigilance of veterinary medicinal products (the ‘***pharmacovigilance database’), linked with the Product database. The Union database shall be the sole point of receipt for adverse events submitted by the MAHs***.

Or. en

Amendment 318
Giulia Moi

Proposal for a regulation
Article 74 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency shall, in ***collaboration*** with the Member States ***and*** the Commission, draw up the functional specifications for the pharmacovigilance database.	2. The Agency shall, in ***consultation*** with the Member States***,*** the Commission, ***and interested parties***, draw up the functional specifications for the pharmacovigilance database.

Or. en

Amendment 319
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 74 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the pharmacovigilance database.	2. The Agency shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the pharmacovigilance database. ***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.***

Or. en

Justification

The idea is to extend the concept of the pharmacovigilance system, which is based on reporting by vets, to include ecotoxicological data by specialists working in the wider environment. Vets don't necessarily see wider ecosystem effects, but e.g. water companies monitoring water bodies, or environmental agencies, would observe any unforeseen or

undesirable effects linked to medicines.

Amendment 320
Giulia Moi

Proposal for a regulation
Article 74 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall ensure that information reported to the pharmacovigilance database is uploaded and made accessible in accordance with Article 75.	3. The Agency shall ensure that information reported to the pharmacovigilance database is uploaded and made ***publicly*** accessible in accordance with Article 75.

Or. en

Amendment 321
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 76 – paragraph 2

Text proposed by the Commission	*Amendment*
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***.	2. Marketing authorisation holders shall ***notify electronically all serious adverse events and human*** events ***relating to the use of veterinary medicinal products that are brought to their attention or*** which ***they can reasonably be expected to have knowledge of to the competent authority of the Member State on whose territory the incident occurred and no later than 15 days following receipt of the information.*** ***The rest of adverse events relating to the use of*** veterinary medicinal products ***that are brought to the attention of the Marketing authorization holders or which they can reasonably be expected to have knowledge of, should be notified electronically to the pharmacovigilance database no later than*** 30 days following

receipt of the ***information***.

Or. en

Justification

It is very important that competent authorities are promptly informed about serious adverse events and human events having occurred in their territory to be ready to assess them and to take the appropriate regulatory actions.

Amendment 322
Giulia Moi

Proposal for a regulation
Article 76 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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. ***Different requirements shall apply for adverse events observed in clinical trials.***

Or. en

Amendment 323
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 76 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Competent authorities ***may***, on their own initiative or on request from the Agency,	3. Competent authorities ***shall***, on their own initiative or on request from the

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.***

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.

Or. en

Amendment 324
Giulia Moi

Proposal for a regulation
Article 76 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. ***In the event of a serious safety concern,*** 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.

Or. en

Amendment 325
Momchil Nekov

Proposal for a regulation
Article 76 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	*(Does not affect the English version)*

Or. bg

Amendment 326
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 76 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. en

Justification

Paragraph 4 should be deleted because it does not give any additional value and increases the administrative burden.

Amendment 327
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 76 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. en

Justification

Paragraph 5 should be deleted because it does not give any additional value and increases the administrative burden.

Amendment 328
Miguel Viegas

Proposal for a regulation
Article 77 – paragraph 2

Text proposed by the Commission	*Amendment*
2. ***Where the*** pharmacovigilance tasks ***have been*** contracted out by the marketing authorisation holder to a third party***, those arrangements shall be set out in details in the pharmacovigilance system master file***.	2. Pharmacovigilance tasks ***may not, under any circumstances, be*** contracted out by the marketing authorisation holder to a third party.

Or. pt

Amendment 329
Miguel Viegas

Proposal for a regulation
Article 77 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. pt

Amendment 330
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 77 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
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.	The marketing authorisation holder shall not communicate information regarding adverse events to the general public in relation to the veterinary medicinal product without ***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.

Or. en

Justification

It is a proposal for clarification of the paragraph. It is not enough 'to give prior notification of his intention'. It is really necessary that competent authorities have a copy of the communication before it is sent to the general public and healthcare professionals.

Amendment 331
Giulia Moi

Proposal for a regulation
Article 77 – paragraph 6

Text proposed by the Commission	*Amendment*
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.	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 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.

Or. en

Amendment 332
Giulia Moi

Proposal for a regulation
Article 78 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) elaborating and maintaining a detailed description of the pharmacovigilance system used by the marketing authorisation holder ***with respect to the veterinary medicinal product for which the authorisation has been granted*** (‘pharmacovigilance system master file’) for all products under their responsibility;	(a) elaborating and maintaining a detailed description of the pharmacovigilance system used by the marketing authorisation holder(‘pharmacovigilance system master file’) for all products under their responsibility;

Or. en

Amendment 333
Giulia Moi

Proposal for a regulation
Article 78 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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;	(b) allocating reference numbers to the pharmacovigilance system master file and communicating the ***relevant*** reference number of the pharmacovigilance master file to the product database ***for each product***;

Or. en

Amendment 334
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 78 – paragraph 1 – point j

Text proposed by the Commission	*Amendment*
(j) ***monitoring*** the pharmacovigilance ***system and ensuring*** that if needed, an appropriate corrective action plan is prepared and implemented***;***	(j) ***carrying out a Signal detection of adverse events included in*** the pharmacovigilance ***database to ensure*** that if needed, an appropriate corrective action plan is prepared and implemented***.*** ***The Signal detection should be made every six months during the first two years of effective commercialization of the product and afterwards yearly and the analysis and results should be sent to competent authorities.***

Or. en

Justification

The Commission proposal is very ambiguous. It should be clearly established that the marketing authorisation holder is obliged to carry out the Signal detection of their products at proper times and inform the competent authorities of the results of the analysis and the conclusions. Marketing authorisation holders are responsible for analysing the efficacy and safety of their products.

Amendment 335
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 78 – paragraph 1 – point l

Text proposed by the Commission	*Amendment*
(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.	(l) communicating any regulatory measure that is taken in a ***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.

Or. en

Justification

It is not understandable why a marketing authorisation holder should inform the competent authorities only about the third country regulatory measures and not about the regulatory measures adopted by a Member State.

Amendment 336
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 78 – paragraph 1 – subparagraph l a (new)

Text proposed by the Commission	*Amendment*
	Unless other requirements have been laid down as a condition for the granting of the marketing authorisation or subsequently established by the competent authority, reports of all adverse reactions shall be submitted to the competent authorities in the form of a periodic safety report, immediately upon request or at least every six months after authorisation until the placing on the market.
	Periodic safety reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the

market, yearly for the following two years and thereafter at three-yearly intervals.

The periodic safety reports shall include a scientific evaluation of the risk-benefit balance of the veterinary medicinal product. Unless other requirements have been laid down as a condition for the granting of the marketing authorisation or subsequently established by competent authority, reports of all adverse reactions shall be submitted to the competent authorities in the form of a periodic safety report, immediately upon request or at least every six months after authorisation until the placing on the market.

Periodic safety reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the market, yearly for the following two years and thereafter at three-yearly intervals.

The periodic safety reports shall include a scientific evaluation of the risk-benefit balance of the veterinary medicinal product.

Or. en

Justification

Since the creation of the PSURs they have been basic for the analysis of the efficacy and safety of the veterinary medicinal products, allowing the marketing authorisation holders and competent authorities to check the benefit-risk balance, to know the sales, treatments administered by species and as a consequence be able to calculate the incidence of each adverse event. This information cannot be substituted by Signal detections activities because they are based on different information.

Amendment 337
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 79 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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.

Or. en

Justification

Consistently with the amendment on Article 76, paragraph 2, competent authorities should assess the cases notified by marketing authorization holders. Evaluation of all information is crucial and no distinction should be made based on the origin of the notifications.

Amendment 338
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 79 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Competent authorities may impose specific requirements on veterinarians and other healthcare professionals in respect of the reporting of adverse events. The Agency and the competent authorities may organise meetings or a network for groups of veterinarians or other healthcare professionals, where there is a specific need for collecting, collating or analysing specific pharmacovigilance data.	3. Competent authorities may impose specific requirements on ***marketing authorisation holders,*** 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.

Or. en

Justification

In certain circumstances it should be necessary to impose specific requirements to marketing

authorisation holders. It is necessary to have this possibility in legislation.

Amendment 339
Annie Schreijer-Pierik

Proposal for a regulation
Article 79 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Competent authorities and the Agency shall ensure that veterinarians receive feedback on adverse events reported and regular feedback on all adverse reactions reported.

Or. en

Amendment 340
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 79 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Agency shall evaluate the adverse events to the centrally authorised veterinary medicinal products, manage risks and recommend measures to the ***Commission***. The ***Commission*** shall take the measures referred to in Articles 130 to 135 concerning marketing authorisations where necessary.	6. The Agency shall evaluate the adverse events to the centrally authorised veterinary medicinal products, manage risks and recommend measures to the ***competent authorities***. The ***competent authorities*** shall take the measures referred to in Articles 130 to 135 concerning marketing authorisations where necessary.

Or. fr

Amendment 341
Miguel Viegas

Proposal for a regulation
Article 80 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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.

Or. pt

Amendment 342
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 81 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. en

Justification

This paragraph is unnecessary in a Regulation. Competent authorities are autonomous to organize the work in the best way.

Amendment 343
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 81 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency and the ***coordination*** group shall agree on sharing of the monitoring of data on groups of veterinary medicinal	3. The Agency and the ***veterinary pharmacovigilance*** group shall agree on sharing of the monitoring of data on groups

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').	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’).

Or. en

Justification

The responsibilities on issues related to pharmacovigilance should be better discussed in the veterinary pharmacovigilance group where experts from competent authorities discuss pharmacovigilance issues and not in the Coordination group.

Amendment 344
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 81 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	4. The results of the signal management process***, except for nationally authorised products,*** shall be agreed upon by the competent authorities and, where appropriate, the Agency. The lead authority shall record the results in the pharmacovigilance database.

Or. en

Justification

The results of signal managements of nationally authorised products it is unnecessary to be agreed at any group and should be discussed and resolved at national level. The Commission proposal would imply an increase of administrative burden.

Amendment 345
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 81 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Where necessary, based on the results of the signal management process referred to in paragraph 4 the competent authorities ***or the Commission*** shall take appropriate measures as referred to in Articles 130 to 135.	5. Where necessary, based on the results of the signal management process referred to in paragraph 4 the competent authorities shall take appropriate measures as referred to in Articles 130 to 135.

Or. fr

Amendment 346
Paul Brannen

Proposal for a regulation
Article 82 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. Marketing authorisations for a limited market granted in accordance with Article 21 shall be re-examined on application from the marketing authorisation holder every 5 years.

Or. en

Amendment 347
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 82 – paragraph 3

Text proposed by the Commission	*Amendment*
3. When an application for re-examination has been submitted, the limited market marketing authorisation shall remain valid	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***.	until a decision on the application has been adopted by the competent authority.

Or. fr

Amendment 348
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 82 – paragraph 5

Text proposed by the Commission	*Amendment*
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).	5. The competent authority 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).

Or. fr

Amendment 349
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 83 – paragraph 3

Text proposed by the Commission	*Amendment*
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***.	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. fr

Amendment 350
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 83 – paragraph 4

Text proposed by the Commission	*Amendment*
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).	4. The competent authority 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).

Or. fr

Amendment 351
Momchil Nekov

Proposal for a regulation
Article 84 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	*(Does not affect the English version)*

Or. bg

Amendment 352
Stanislav Polčák

Proposal for a regulation
Article 98 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(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;

Or. en

Justification

The Commission proposal should be clear in terms of the obligation for the manufacturer to comply with requirements on good manufacturing practice. In addition, in order to ensure the current standards for the quality of active substances used as starting materials, it should be required that only those active substances shall be used for the manufacture of medicinal products which have been manufactured under the system of good manufacturing practice.

Amendment 353
Stanislav Polčák

Proposal for a regulation
Article 98 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) inform the competent authority if the qualified person referred to in Article 100 is replaced;	(d) ***give prior notice to the competent authority of any changes which he may wish to make to any of the particulars supplied pursuant to Article 92 and*** inform the competent authority ***immediately*** if the qualified person referred to in Article 100 is replaced;

Or. en

Justification

Legislation must guarantee that appropriate control over the manufacturing is conducted on

a continuous basis. In order to be able to perform the control activities effectively, manufacturers should inform competent authorities of any change which would affect the conditions under which the manufacturing authorisation has been granted, before such change has been implemented by the concerned manufacturer.

Amendment 354
Stanislav Polčák

Proposal for a regulation
Article 100 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The holder of a manufacturing authorisation shall have permanently and continuously at his disposal the services of at least one qualified person who fulfils the conditions laid down in this Article and is responsible, in particular, for carrying out the duties specified in Article 101.	1. The holder of a manufacturing authorisation shall have permanently 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. ***The holder of the manufacturing authorisation may himself assume the responsibility referred to in this paragraph, if he personally fulfils the conditions for qualified persons provided for by this Regulation.***

Or. en

Amendment 355
Stanislav Polčák

Proposal for a regulation
Article 100 – paragraph 2

Text proposed by the Commission	*Amendment*
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	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.	he personally fulfils those conditions as specified above***. The qualified person shall be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognized as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, medicine, veterinary science, chemistry, pharmaceutical chemistry and technology, biology.*** ***However, the minimum duration of the university course may be three and a half years where the course is followed by a period of theoretical and practical training of at least one year and includes a training period of at least six months in a pharmacy open to the public, corroborated by an examination at university level.*** ***Where two university or recognized equivalent courses coexist in a Member State and where one of these extends over four years and the other over three years, the diploma, certificate or other evidence of formal qualifications awarded on completion of the three-year university course or its recognized equivalent shall be considered to fulfil the condition of duration referred to in the first subparagraph in so far as the diplomas, certificates or other evidence of formal qualifications awarded on completion of both courses are recognized as equivalent by the Member State in question.*** ***The course shall include theoretical and practical tuition bearing upon at least the following basic subjects:*** ***– experimental physics,*** ***– general and inorganic chemistry,*** ***– organic chemistry,***

– analytical chemistry,

– pharmaceutical chemistry, including analysis of medicinal products,

– general and applied biochemistry (medical),

– physiology,

– microbiology,

– pharmacology,

– pharmaceutical technology,

– toxicology,

– pharmacognosy (study of the composition and effects of the active principles of natural substances of plant and animal origin).

Tuition in these subjects should be so balanced as to enable the person concerned to fulfil the obligations specified in this Regulation.

Or. en

Justification

The qualification requirements set out in the Commission proposal are ill-defined and inappropriate in view of the key importance of qualified persons in the manufacturing of veterinary medicinal products. The impact assessment presented by the Commission does not contain any information in this respect and it is therefore not possible to evaluate any impacts which may result from such a significant decrease in terms of qualification requirements.

Amendment 356
Stanislav Polčák

Proposal for a regulation
Article 100 – paragraph 2 a (new)

2a. The qualified person shall have acquired practical experience over at least two years, in one or more undertakings which are authorized manufacturers, in the activities of qualitative analysis of medicinal products, of quantitative

analysis of active substances and of the testing and checking necessary to ensure the quality of veterinary medicinal products.

The duration of practical experience may be reduced by one year where a university course lasts for at least five years and by a year and a half where the course lasts for at least six years.

Or. en

Justification

The qualification requirements set out in the Commission proposal are ill-defined and inappropriate in view of the key importance of qualified persons in the manufacturing of veterinary medicinal products. The impact assessment presented by the Commission does not contain any information in this respect and it is therefore not possible to evaluate any impacts which may result from such a significant decrease in terms of qualification requirements.