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Committee on the Environment, Public Health and Food Safety

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AMENDMENTS
107 - 393

Draft report
Françoise Grossetête
(PE551.951v01-00)

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_LegReport

Amendment 107
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Proposal for a regulation
Citation 5 a (new)

Text proposed by the Commission	*Amendment*
	– having regard to the European Parliament resolution of 19 May 2015 on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance (A8-0142/2015 - 2014/2207(INI);

Or. it

Amendment 108
Lampros Fountoulis

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 legal framework for veterinary medicinal products should be adapted to scientific progress, the current market conditions and economic reality***, with respect for animals, nature and their interaction with man***.

Or. el

Amendment 109
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) The provisions of this act aim to reduce administrative burden, enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection.	(5) The provisions of this act aim to reduce administrative burden, enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection. ***In line with the precautionary principle the pharmaceuticals industry should be required to demonstrate that veterinary medicines produced or placed on the market have neither a harmful effect on human or animal health nor an unsustainable environmental impact.***

Or. it

Amendment 110
Claudiu Ciprian Tănăsescu, Matthias Groote

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) 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. ***To this end, good husbandry and management practices have to be put place in order to improve animal welfare, limit the spread of diseases, prevent antimicrobial resistance and ensure proper nutrition of livestock.***

Or. en

Amendment 111
Martin Häusling

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.	(7) This Regulation should set high standards of quality, safety and efficacy for veterinary medicinal products in order to meet common concerns as regards the protection of public and animal health ***and the environment***. At the same time, this Regulation should harmonise the rules for the authorisation of veterinary medicinal products and the placing of them on the Union market.

Or. en

Justification

The risk of undesirable effects on the environment is part of the risk-benefit balance for the evaluation of veterinary medicinal products. As such, the Regulation should also meet concerns with regard to the protection of the environment.

Amendment 112
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) With a view to harmonising the internal market for veterinary medicinal products in the Union ***and improving their free movement***, rules should be established concerning the procedures for authorisation of such products that ensure the same conditions for all applications and a transparent framework for all interested	(8) With a view to harmonising the internal market for veterinary medicinal products in the Union, rules should be established concerning the procedures for authorisation of such products that ensure the same conditions for all applications and a transparent framework for all interested

parties.	parties.

Or. fr

Justification

This regulation should seek to maintain a high level of animal health and welfare. Facilitating the free movement of medicinal products is not a public-health objective.

Amendment 113
Lampros Fountoulis

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) The scope of the mandatory use of a centralised authorisation procedure under which the authorisations are valid throughout the Union should cover inter alia products containing new active substances and products which contain or consist of engineered tissues or cells. At the same time, in order to ensure the widest possible availability of veterinary medicinal products in the Union, the centralised authorisation procedure should be extended to allow for applications for authorisations under that procedure to be submitted for any veterinary medicinal product, including for generics of nationally authorised veterinary medicinal products.	(9) The scope of the mandatory use of a centralised authorisation procedure under which the authorisations are valid throughout the Union should cover inter alia products containing new active substances and products which contain or consist of engineered tissues or cells. ***Thought should also be given to medicinal products that may be developed in the future and care should be taken to lay down, in advance, a legal framework to support their development and, at the same time, ensure that they comply with Union regulations.*** At the same time, in order to ensure the widest possible availability of veterinary medicinal products in the Union, the centralised authorisation procedure should be extended to allow for applications for authorisations under that procedure to be submitted for any veterinary medicinal product, including for generics of nationally authorised veterinary medicinal products. ***Particular care must be taken in all cases to control generics, in order to ensure that they meet high quality standards.***

Or. el

Amendment 114
Lampros Fountoulis

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) The national procedure for authorising veterinary medicinal products should be maintained because of varying needs in different geographical areas of the Union as well as the business models of small and medium sized enterprises (SMEs). ***It should be ensured that marketing authorisations granted in one Member State are recognised in other Member States.***	(10) The national procedure for authorising veterinary medicinal products should be maintained because of varying needs in different geographical areas of the Union as well as the business models of small and medium sized enterprises (SMEs).

Or. el

Amendment 115
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) The national procedure for authorising veterinary medicinal products should be maintained because of varying needs in different geographical areas of the Union as well as the business models of small and medium sized enterprises (SMEs). It should be ensured that marketing authorisations granted in one Member State ***are*** recognised in other Member States.	(10) The national procedure for authorising veterinary medicinal products should be maintained because of varying needs in different geographical areas of the Union as well as the business models of small and medium sized enterprises (SMEs). It should be ensured that marketing authorisations granted in one Member State ***can easily be*** recognised in other Member States***, while safeguarding the decision-making independence of each Member State***.

Or. fr

Amendment 116
Lampros Fountoulis

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) In order to avoid unnecessary administrative and financial burdens for applicants and competent authorities, a full in-depth assessment of an application for the authorisation of a veterinary medicinal product should be carried out only once. ***It is appropriate therefore to lay down special procedures for the mutual recognition of national authorisations.***	(12) In order to avoid unnecessary administrative and financial burdens for applicants and competent authorities, a full in-depth assessment of an application for the authorisation of a veterinary medicinal product should be carried out only once.

Or. el

Amendment 117
Lampros Fountoulis

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(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.	(17) However, there may be situations where no suitable authorised veterinary medicinal product is available. In those situations, by way of exception, veterinarians should be allowed to prescribe other medicinal products to the animals under their responsibility in conformity with strict rules and in the interest of animal health or animal welfare only. In case of food-producing animals, veterinarians should ensure that an appropriate withdrawal period is prescribed, so that harmful residues of those medicinal products do not enter the food chain***, and particular care must therefore be taken when administering antibiotics to food-producing animals.***

Or. el

Amendment 118
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(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.	(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***; however, the administration to animals of off-label antimicrobials authorised solely for human use should be prohibited***. 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. it

Amendment 119
Peter Jahr, Norbert Lins, Peter Liese, Elisabeth Köstinger

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(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,	(17) However, there may be situations where no suitable authorised veterinary medicinal product is available. In those situations, by way of exception, veterinarians should be allowed to prescribe other medicinal products to the animals under their responsibility in conformity with strict rules and in the interest of animal health or animal welfare only***; in such cases antimicrobial***

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 products for human use may be employed only subject to the issuing of a prescription by a veterinarian and the granting of authorisation by the veterinary authority responsible for monitoring the work of the veterinarian in question***. In case of food-producing animals, veterinarians should ensure that an appropriate withdrawal period is prescribed, so that harmful residues of those medicinal products do not enter the food chain.

Or. de

Justification

With a view to safeguarding 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 120
Michèle Rivasi, Martin Häusling

Proposal for a regulation
Recital 17

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

Or. en

Justification

This measure can be acceptable in an emergency situation but cannot be an excuse to use dangerous products on a regular basis

Amendment 121
Lampros Fountoulis

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) Member States should be able to allow exceptional use of veterinary medicinal products without a marketing authorisation where it is necessary to respond to Union listed diseases and where the health situation in a Member State so requires.	***deleted***

Or. el

Amendment 122
Ulrike Müller

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) Member States should be able to allow exceptional use of veterinary medicinal products without a marketing authorisation where it is necessary to respond to Union listed diseases and where the health situation in a Member State so requires.	(18) Member States should be able to allow exceptional use of veterinary medicinal products without a marketing authorisation where it is necessary to respond to Union listed diseases ***or new diseases*** and where the health situation in a Member State so requires.

Or. de

Justification

Combating diseases by means of an approach based solely on a positive list is too cumbersome. There must also be scope for dealing with new animal diseases.

Amendment 123
Michèle Rivasi, Martin Häusling

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) Member States should be able to allow exceptional use of veterinary medicinal products without a marketing authorisation where it is necessary to respond to Union listed diseases and where the health situation in a Member State so requires.	(18) Member States should be able to ***temporarily*** allow exceptional use of veterinary medicinal products without a marketing authorisation where it is necessary to respond to Union listed diseases and where the health situation in a Member State so requires.

Or. en

Justification

This measure can be acceptable in an emergency situation but cannot be an excuse to use dangerous products on a regular basis

Amendment 124
Lampros Fountoulis

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) Taking into account the need for simple rules on changes to the marketing authorisations of veterinary medicinal products, ***only*** changes that may affect animal health***, public health or the environment*** should require a scientific assessment.	(19) Taking into account the need for simple rules on changes to the marketing authorisations of veterinary medicinal products, changes that may affect ***public health,*** animal health ***or the environment*** should require a scientific assessment. ***That scientific assessment should be carried out as quickly as possible, in order to prevent problems to the business of undertakings and livestock holdings***.

Or. el

Amendment 125
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) Taking into account the need for simple rules on changes to the marketing authorisations of veterinary medicinal products, only changes that may affect animal health, public health or the environment should require a scientific assessment.	(19) Taking into account the need for simple rules on changes to the marketing authorisations of veterinary medicinal products, only changes that may affect animal health, public health or the environment should require a scientific assessment. ***In any case, such changes may only apply to use within the same species.***

Or. fr

Amendment 126
Piernicola Pedicini, Eleonora Evi, Marco Affronte

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 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.	(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 ***designed to avoid causing*** 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 127
Lampros Fountoulis

Proposal for a regulation
Recital 23

Text proposed by the Commission	*Amendment*
(23) Companies have less interest in developing veterinary medicinal products for markets of a limited size. In order to promote the availability of veterinary medicinal products within the Union for those markets, in some cases it should be possible to grant marketing authorisations without a complete application dossier having been submitted***, on the basis of a benefit-risk assessment of the situation and, where necessary, subject to specific obligations***. In particular, this should be possible in the case of veterinary medicinal products for use in minor species or for the treatment or prevention of diseases that occur infrequently or in limited geographical areas.	(23) Companies have less interest in developing veterinary medicinal products for markets of a limited size. In order to promote the availability of veterinary medicinal products within the Union for those markets, in some cases it should be possible to grant marketing authorisations without a complete application dossier having been submitted. In particular, this should be possible in the case of veterinary medicinal products for use in minor species or for the treatment or prevention of diseases that occur infrequently or in limited geographical areas. ***Any such authorisation should be revoked if a full dossier is not submitted within a short space of time.***

Or. el

Amendment 128
Bolesław G. Piecha

Proposal for a regulation
Recital 23

Text proposed by the Commission	*Amendment*
(23) Companies have less interest in developing veterinary medicinal products for markets of a limited size. In order to promote the availability of veterinary medicinal products within the Union for those markets, in ***some*** cases it should be possible to grant marketing authorisations without a complete application dossier having been submitted, on the basis of a benefit-risk assessment of the situation and, where necessary, subject to specific obligations. In particular, this should be possible in the case of veterinary medicinal products for use in minor species or for the treatment or prevention of diseases that occur infrequently or in limited geographical areas.	(23) Companies have less interest in developing veterinary medicinal products for markets of a limited size. In order to promote the availability of veterinary medicinal products within the Union for those markets, in ***exceptional*** cases it should be possible to grant marketing authorisations without a complete application dossier having been submitted, on the basis of a benefit-risk assessment of the situation and, where necessary, subject to specific obligations. In particular, this should be possible in the case of veterinary medicinal products for use in minor species or for the treatment or prevention of diseases that occur infrequently or in limited geographical areas. ***Such products should only be used on the basis of a prescription.***

Or. pl

Amendment 129
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Recital 23

Text proposed by the Commission	*Amendment*
(23) Companies have less interest in developing veterinary medicinal products for markets of a limited size. In order to promote the availability of veterinary medicinal products within the Union for ***those markets***, in some cases it should be possible to grant marketing authorisations without a complete application dossier having been submitted, on the basis of a benefit-risk assessment of the situation and, where necessary, subject to specific obligations. In particular, this should be possible in the case of veterinary medicinal products for use in minor species or for the	(23) Companies have less interest in developing veterinary medicinal products for markets of a limited size***, which are subject to the same regulatory constraints as those of larger markets***. In order to promote the availability of veterinary medicinal products within the Union for ***species affected by therapeutic gaps***, in some cases it should be possible to grant marketing authorisations without a complete application dossier having been submitted, on the basis of a benefit-risk assessment of the situation and, where necessary, subject to specific obligations.

treatment or prevention of diseases that occur infrequently or in limited geographical areas.	In particular, this should be possible in the case of veterinary medicinal products for use in minor species or for the treatment or prevention of ***non-contagious*** diseases that occur infrequently or in limited geographical areas. ***These provisions shall not apply to antimicrobials. Member States must remain able to ban the use of medicinal products authorised in accordance with such procedures.***

Or. fr

Justification

The rules should not be relaxed for strictly economic reasons. Animal and human health must remain the driving force behind the rules. Member States must therefore be able to ban medicinal products which they do not consider to have been fully assessed.

Amendment 130
Julie Girling, 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 131
Lampros Fountoulis

Proposal for a regulation
Recital 26

Text proposed by the Commission	*Amendment*
(26) Certain particulars and documents that are normally to be submitted with an application for a marketing authorisation ***should*** not be required if a veterinary medicinal product is a generic medicinal product of a veterinary medicinal product that is authorised or has been authorised in the Union.	(26) Certain particulars and documents that are normally to be submitted with an application for a marketing authorisation ***need*** not be required if a veterinary medicinal product is a generic medicinal product of a veterinary medicinal product that is authorised or has been authorised in the Union. ***However, care should be taken to ensure that the medicinal product meets European standards.***

Or. el

Amendment 132
Martin Häusling

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(26a) The potential risk to the environment needs to be assessed for all veterinary medicinal products. Marketing authorisation holders should therefore provide an environmental risk assessment within two years after the entry into force of this Regulation.

Or. en

Justification

Pharmaceuticals are biologically active. Most of them are excreted and thus end up in the environment. It is crucial that all veterinary medicinal products are assessed for their environmental properties, and not just those authorised after 30 October 2005. It is not appropriate not to assess the risks to the environment for most veterinary medicinal products.

Amendment 133
Martin Häusling

Proposal for a regulation
Recital 26 b (new)

Text proposed by the Commission	*Amendment*
	(26b) The establishment of a single decentralised assessment of the environmental properties of active substances for veterinary use by means of a monograph system should be established in the future. The Commission should therefore submit a report to Parliament and the Council as soon as possible, as well as a legislative proposal, if appropriate.

Or. en

Justification

The current system for assessing the environmental risks of veterinary products is unsatisfactory and could be replaced, for example, by a monograph system. Given the technical difficulties involved in implementing such a system, the Commission ought to look into the various options before submitting its proposals to Parliament and the Council.

Amendment 134
Martin Häusling

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	(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.	depend on the volume used and the resulting amount of the pharmaceutical substance that may reach the environment. Therefore, ***for all veterinary*** medicinal ***products*** for which a generic application for a marketing authorisation is submitted, 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.

Or. en

Justification

Generics are used in significant quantities. It is therefore appropriate to require date on the potential effect on the environment for all generic applications. Limiting this to cases where there is evidence of a hazard for the environment is not appropriate..

Amendment 135
Norbert Lins, Peter Jahr, Karl-Heinz Florenz, Renate Sommer, Jens Gieseke

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	(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.	generating such data in order to reduce costs and to reduce testing on vertebrate animals. ***The current impact assessment system results in repetitive and potentially divergent assessments of substances' environmental properties. This can lead to divergent decisions being taken on products with similar effects on the environment, especially in the case of products authorised before the environmental impact assessment was carried out. The establishment of a single centralised assessment of the environmental properties of active substances for veterinary use by means of a monograph system could be a potential alternative. The Commission should therefore submit a report to Parliament and the Council examining the feasibility of monographs and potential alternative options as soon as possible.***

Or. en

Amendment 136
Claudiu Ciprian Tănăsescu, Pavel Poc

Proposal for a regulation
Recital 27 a (new)

Text proposed by the Commission	*Amendment*
	(27a) In accordance with Directive 2010/63/EU, it is necessary to replace, reduce or refine testing on vertebrate animals. Implementation of this Regulation should be based on the use of alternative test methods, suitable for the assessment of health and environmental hazards of products, wherever possible.

Or. en

Amendment 137
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(29) ***Differences in the manufacturing process of biological products or a change in the excipient used may lead to differences in the generic product characteristics.*** In an application for generic biological veterinary medicinal product the bioequivalence should be demonstrated in order to ensure, based on the existing knowledge, that quality, safety and efficacy are similar.	(29) In an application for generic biological veterinary medicinal product the bioequivalence should be demonstrated in order to ensure, based on the existing knowledge, that quality, safety and efficacy are similar.

Or. it

Amendment 138
Martin Häusling

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

Or. en

Justification

Time-limited marketing authorisations are crucial to ensure that authorisations are updated. Unforeseen problems may occur in particular in the first years, so it is inappropriate to immediately grant an unlimited authorisation. It is not appropriate to take risks with the

safety, efficacy and quality of veterinary drugs to save "administrative and financial burden".

Amendment 139
Lampros Fountoulis

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. ***Conditions for renewing the approval of a marketing authorisation*** should ***be imposed only exceptionally and should be duly justified***.	(30) In order to avoid unnecessary administrative and financial burdens both for the competent authorities and for the pharmaceutical industry, as a general rule a marketing authorisation for a veterinary medicinal product should be granted for an ***appropriate*** period of time. ***All authorisations*** should ***be reviewed, especially if new scientific data come to light***.

Or. el

Amendment 140
Martin Häusling

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

Time-limited marketing authorisations are crucial to ensure that authorisations are updated. Unforeseen problems may occur in particular in the first years, so it is inappropriate to immediately grant an unlimited authorisation. The current system of a first approval for five years should be maintained. Thereafter, authorisations should be limited to 15 years (renewable) to ensure that the safety, efficacy and quality of veterinary drugs is adequately reassessed. Renewal is a means to adapt approvals to fill data gaps, to update data, and address previously unforeseen or hidden effects.

Amendment 141
Lampros Fountoulis

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) It is recognised that, in some cases, a scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and other relevant factors should be taken into account including societal, economical, ethical, environmental and welfare factors and the feasibility of controls.	(31) It is recognised that, in some cases, a scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and other relevant factors should ***also*** be taken into account including societal, economical, ethical, environmental and welfare factors and the feasibility of controls.

Or. el

Amendment 142
Martin Häusling

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) In certain circumstances where a significant animal or public health concern exists but scientific uncertainty persists, appropriate measures can be adopted taking into account Article 5(7) of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures which has been interpreted for the Union in	(32) In certain circumstances where a significant animal***, environmental*** or public health concern exists but scientific uncertainty persists, appropriate measures can be adopted taking into account Article 5(7) of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures which has been interpreted for

the Communication from the Commission on the precautionary principle[17] . In such circumstances, Member States or the Commission should seek to obtain additional information necessary for a more objective assessment of the particular concern and should review the measure accordingly within a reasonable period of time.	the Union in the Communication from the Commission on the precautionary principle[17] . In such circumstances, Member States or the Commission should seek to obtain additional information necessary for a more objective assessment of the particular concern and should review the measure accordingly within a reasonable period of time.
[17] Communication from the Commission on the precautionary principle, COM (2000) 1 (final).	[17] Communication from the Commission on the precautionary principle, COM (2000) 1 (final).

Or. en

Justification

Environmental concerns also need to be reflected.

Amendment 143
Piernicola Pedicini, Eleonora Evi, Marco Affronte

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	(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 ***prohibited*** 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.

advertising ***of*** veterinary antimicrobials should be ***geared solely to the provision of scientific information***, and the authorisation requirements should sufficiently address the risks and benefits of antimicrobial veterinary medicinal products.

Or. it

Amendment 144
Martin Häusling

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 appropriate warnings and guidance are included on the labels of veterinary antimicrobials. Use of certain new or critically important antimicrobials for humans should be ***prohibited*** 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

Justification

The use of certain new or critically important antimicrobials for humans should be prohibited in the veterinary sector, and not just off-label use of such antimicrobials.

Amendment 145
Sirpa Pietikäinen

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 appropriate warnings and guidance are included on the labels of veterinary antimicrobials. Use ***of last-line antibiotics in animals should be prohibited. 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 146
Claudiu Ciprian Tănăsescu, Matthias Groote

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 appropriate warnings and guidance are included on the labels of veterinary ***and human*** 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 147
Aldo Patriciello

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	(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. ***Given that the effects on humans are not the same as those on animals, a thorough investigation should be conducted into possible contraindications.*** Some of those antimicrobials are critical for preventing or

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.

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 ***assessed before being allowed, on a*** restricted ***basis,*** in the veterinary sector. The rules for advertising veterinary antimicrobials should be tightened, and the authorisation requirements ***must*** sufficiently address the risks and benefits of antimicrobial veterinary medicinal products.

Or. it

Amendment 148
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	(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 ***any measures to be put in place are proportionately applied to both human and animal sector.*** Appropriate warnings and guidance are included on the labels of ***human and*** veterinary antimicrobials. Use not covered by the terms of the marketing authorisation of certain new or ***the highest priority critical***

should be tightened, and the authorisation requirements should sufficiently address the risks and benefits of antimicrobial veterinary medicinal products.	antimicrobials for humans ***as defined by the WHO*** 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 149
Karin Kadenbach

Proposal for a regulation
Recital 34 a (new)

Text proposed by the Commission	*Amendment*
	(34a) The routine prophylactic and metaphylactic use of antimicrobials in groups of food-producing animals should be brought to an end. Disease should be prevented not by routine recourse to antimicrobials but by good hygiene, husbandry and housing and sound management practices.

Or. en

Justification

In order to reduce antimicrobial resistance, the use of antimicrobials in livestock farming should be restricted as much as possible.

Amendment 150
Martin Häusling

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) The combined use of several	(35) The combined use of several

antimicrobial active substances may represent a particular risk with respect to the development of antimicrobial resistance. Combinations of antimicrobial substances should therefore only be authorised where evidence is provided that the benefit-risk balance of the combination is favourable.	antimicrobial active substances may represent a particular risk with respect to the development of antimicrobial resistance. Combinations of antimicrobial substances should therefore only be authorised ***exceptionally*** where evidence is provided that the ***long-term*** benefit-risk balance of the combination is favourable.

Or. en

Justification

Combinations of antimicrobial substances should only be authorised exceptionally. The benefit-risk balance of the combination needs to be favourable in the long term.

Amendment 151
Annie Schreijer-Pierik, Tom Vandenkendelaere

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.	(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 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.

Or. en

Amendment 152
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Proposal for a regulation
Recital 36 a (new)

Text proposed by the Commission	*Amendment*
	(36a) The use of antimicrobial veterinary medicinal products should be reduced by phasing out their use for prophylactic purposes and minimising their metaphylactic use in treating diseased animals and preventing healthy animals in the same group from becoming infected.

Or. it

Amendment 153
Martin Häusling

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 ***is*** necessary to reserve those antimicrobials for humans only. ***As a baseline, this should apply for the highest priority critically important antimicrobials identified by the WHO. Moreover,*** it should be possible to decide that ***other critically important*** antimicrobials, following the scientific recommendations of the Agency, should not be available on the market in the veterinary sector.

Or. en

Justification

Each year, antibiotic resistance has been estimated to kill more than 700,000 humans worldwide, and 25,000 in Europe. It is unacceptable that critically important antimicrobials for humans continue to be used to in veterinary medicine. A clear baseline needs to be established. Further substances could be added based on the scientific recommendations of the Agency.

Amendment 154
Peter Liese, Merja Kyllönen

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***; the decisive criteria should be that the antibiotic is used in human medicine when other antibiotic therapies are no longer effective and that there is evidence that resistance in human beings cannot be excluded by use in animals***.

Or. en

Amendment 155
Ulrike Müller

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	(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***.	antimicrobials in the treatment of infections in humans, those antimicrobials ***should be used on a tightly restricted basis***. Therefore it should be possible to decide that ***the use of*** certain antimicrobials, following the scientific recommendations of the Agency, should be ***made contingent on the existence of an antibiogram which shows that the antimicrobial in question is essential to the treatment of a given animal disease***.

Or. de

Justification

Banning the use of certain active ingredients makes no sense on animal welfare grounds, since it might be that certain animals could then no longer be treated. What is more, imposing restrictions on active ingredients would exacerbate the problem of antimicrobial resistance, since fewer active ingredients would then be available. Reserving antimicrobials for human use would hamper the vital work of developing new antibiotics for animals.

Amendment 156
Peter Liese, Annie Schreijer-Pierik, Elisabeth Köstinger, Norbert Lins, Ivo Belet, Merja Kyllönen, Cristian-Silviu Buşoi

Proposal for a regulation
Recital 37 a (new)

Text proposed by the Commission	*Amendment*
	(37a) As Antimicrobial resistance to human and veterinary medicinal products is a growing health problem in the Union and worldwide there must soon also action be taken in the field of human medicine for example in the form of an instrument incentivising the development of new antibiotics for human use similar to that already proposed within this regulation.

Or. en

Amendment 157
Iratxe García Pérez, Soledad Cabezón Ruiz

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.	(38) If an antimicrobial is administered and used incorrectly, this presents a risk to public or animal health. Therefore antimicrobial veterinary medicinal products should only be available on veterinary prescription. ***Veterinarians are the only professional authorised*** to prescribe ***medicinal products to animals,*** 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 ***veterinarians*** should be restricted to the amount required ***to continue the treatment until the medicinal product prescribed by the veterinarian is obtained by the farmer or by the owner and only*** for treatment of the animals under their care.

Or. en

Justification

Veterinarian is the only professional capable of prescribe medicinal products for animals. The supply of medicinal products (not only antimicrobials) by the veterinarians should be restricted to the minimum amount of product necessary to continue the treatment until the farmer or the owner of the animals obtain the medicinal products prescribed in a retailer.

Amendment 158
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

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.	(38) If an antimicrobial is administered and used incorrectly, this presents a risk to public or animal health. Therefore antimicrobial veterinary medicinal products should only be available on veterinary prescription. ***Veterinarians*** have a key role in ensuring prudent use of antimicrobials and consequently they should not be influenced, directly or indirectly, by economic incentives when prescribing those products. 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***, after examination of sick animals and those likely to have been contaminated***.

Or. fr

Justification

Only veterinarians properly trained in animal medicine should be authorised to prescribe antimicrobials

Amendment 159
Lampros Fountoulis

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	(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.	economic incentives when prescribing those products. Therefore the supply of veterinary antimicrobials by them should be restricted to the amount required for treatment of the animals under their care.

Or. el

Amendment 160
Biljana Borzan

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.	(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 ***and only once a veterinary diagnosis has been established following a clinical examination of the animals concerned, or in the light of regular health visits of the animal(s) concerned***.

Or. en

Amendment 161
Bolesław G. Piecha

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.	(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 ***veterinarians or other persons authorised under national law*** should be restricted to the amount required for treatment of the animals under their care.

Or. pl

Amendment 162
Piernicola Pedicini, Eleonora Evi, Marco Affronte

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	(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.	amount required for treatment of the animals under their care. ***Veterinarians should not be allowed to sell antimicrobial veterinary medicinal products, as this could result in conflicts of interest that give rise to over-prescription of such products.***

Or. it

Amendment 163
Annie Schreijer-Pierik, Tom Vandenkendelaere

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.	(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 as part of their professional code of conduct*** 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.

Or. en

Amendment 164
Norbert Lins

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 165
Biljana Borzan

Proposal for a regulation
Recital 38 a (new)

Text proposed by the Commission	*Amendment*
	(38a) In order to facilitate responsible 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, support using as little as possible critically important antibiotics and therefore restrain from the development of antibiotic resistance. There is clear need for future innovation specifically for pen-site diagnosis, and a need to consider carefully whether there is a case for more harmonisation and regulation in this sector.

Or. en

Amendment 166
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Recital 38 a (new)

Text proposed by the Commission	*Amendment*
	(38a) One of the main reasons for human and animal resistance to antibiotics is the use of broad-spectrum antibiotics owing to uncertainty about which bacterial strain to treat. Veterinarians should be encouraged to use rapid, on-the-spot diagnostic tests to determine precisely which microbial agent is responsible for the infection and its sensitivity to different antibiotics.

Or. fr

Amendment 167
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

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***	(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, ***as public health should take precedence over any economic consideration, the restrictions applied in the European Union must also be applied in the same way to imported products. For the same reasons, and in order to support its animal production sectors, the Union must take the necessary***

with their activities and policies.	***measures to promote local consumption and self-sufficiency in the internal market.***

Or. fr

Amendment 168
Sirpa Pietikäinen

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***.	(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. 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, ***the EU*** should be ***active advocating the creation of an international strategy to combat*** antimicrobial resistance***, in line with the recent Global Action Plan adopted by the World health Organisation***.

Or. en

Amendment 169
Martin Häusling

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***.	(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. 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 ***take into account*** scientific advice***.*** ***The Union*** should ***actively promote its policies*** in the context of cooperation with third countries and international organisations addressing antimicrobial resistance.

Or. en

Justification

The protection of human health against antimicrobial resistance has to take priority over concerns about trade or competitiveness. Moreover, trade can in fact facilitate the spread of resistant organism. While international cooperation is very important, it must not be a limiting factor for EU action against antimicrobial resistance.

Amendment 170
Claudiu Ciprian Tănăsescu, Matthias Groote

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.	(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. ***To this end, it is necessary to develop an international strategy to combat antimicrobial resistance.***

Or. en

Amendment 171
Peter Jahr

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	(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.	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. ***Veterinarians are already required to meet comprehensive documentation requirements in connection with the use of antibiotics. In keeping with the 'one health' approach, similar documentation requirements should be introduced in the area of human medicine.*** The Member States should be responsible for collecting data on the use of antimicrobials under the coordination of the Agency.

Or. de

Justification

In keeping with the 'one health' approach, the problem of resistance to antibiotics can be addressed only by means of concerted joint action in the areas of animal and human medicine.

Amendment 172
Marit Paulsen, Fredrick Federley, Jan Huitema, Gerben-Jan Gerbrandy, Anneli Jäätteenmäki, Frédérique Ries

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	(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.	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 is needed on how, when, where and why antimicrobials, in particular 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 173
Lampros Fountoulis

Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*
(41) The majority of the veterinary medicinal products on the market have been authorised under national procedures. The lack of harmonisation of summary of product characteristics for veterinary medicinal products authorised nationally in more than one Member State creates ***additional and unnecessary*** barriers for the circulation of veterinary medicinal products within the Union. It is necessary to harmonise those summaries of product characteristics. In order to avoid unnecessary costs and burdens for the Member States, the Commission and the pharmaceutical industry, and in order to increase the availability of veterinary medicinal products as fast as possible, it should be possible to harmonise summaries of the products characteristics for certain veterinary medicinal products in	(41) The majority of the veterinary medicinal products on the market have been authorised under national procedures. The lack of harmonisation of summary of product characteristics for veterinary medicinal products authorised nationally in more than one Member State creates barriers for the circulation of veterinary medicinal products within the Union. It is necessary to harmonise those summaries of product characteristics. In order to avoid unnecessary costs and burdens for the Member States, the Commission and the pharmaceutical industry, and in order to increase the availability of veterinary medicinal products as fast as possible, it should be possible to harmonise summaries of the products characteristics for certain veterinary medicinal products in accordance with an administrative

accordance with an administrative procedure, while taking on board the risk to public and animal health and to the environment. This harmonisation exercise should cover veterinary medicinal products authorised before 2004[18].	procedure, while taking on board the risk to public and animal health and to the environment. This harmonisation exercise should cover veterinary medicinal products authorised before 2004[18].
[18] Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (OJ L 136, 30.4.2004, p. 58).	[18] Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (OJ L 136, 30.4.2004, p. 58).
	Or. el

Amendment 174
Lampros Fountoulis

Proposal for a regulation
Recital 42

Text proposed by the Commission	*Amendment*
(42) In order to reduce administrative burden and maximise the availability of veterinary medicinal products in the Member States, simplified rules should be laid down as to how their packaging and labelling are to be presented. The textual information provided should be reduced and, if possible, replaced by pictograms and abbreviations. Pictograms and abbreviations should be standardised across the Union. Care should be taken so that those rules do not jeopardise public and animal health and environmental safety.	(42) In order to reduce administrative burden and maximise the availability of veterinary medicinal products in the Member States, simplified rules should be laid down as to how their packaging and labelling are to be presented. The textual information provided should be reduced and, if possible, replaced by pictograms and abbreviations. Pictograms and abbreviations should be standardised across the Union. Care should be taken so that those rules do not jeopardise public and animal health and environmental safety. ***Care should also be taken to ensure that the new, simplified presentation does not result in deliberate concealment of important information on the medicinal product.***
	Or. el

Amendment 175
Lampros Fountoulis

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) With a view to increasing availability of veterinary medicinal products in the Union it should be possible to grant more than one marketing authorisation for a specific veterinary medicinal product to the same marketing authorisation holder in the same Member State. In that case all product-related characteristics of the product and data in support of the applications for the product should be identical. However, multiple applications for a specific product should not be used to circumvent the principles of mutual recognition, and therefore this type of applications in different Member States should take place inside the procedural framework for mutual recognition.	***deleted***

Or. el

Amendment 176
Lampros Fountoulis

Proposal for a regulation
Recital 47

Text proposed by the Commission	*Amendment*
(47) Holders of marketing authorisations should be responsible for continuously carrying out pharmacovigilance of the veterinary medicinal products they place on the market. They should collect reports on adverse events relating to their products, including those concerning use outside the terms of the granted marketing authorisation.	(47) Holders of marketing authorisations should be responsible for continuously carrying out pharmacovigilance of the veterinary medicinal products they place on the market. They should collect reports on adverse events relating to their products, including those concerning use outside the terms of the granted marketing authorisation. ***However, final responsibility and competence for pharmacovigilance must rest in all cases***

with the Member States.

Or. el

Amendment 177
Martin Häusling

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

Justification

The environmental dimension needs to be referred to explicitly.

Amendment 178
Lampros Fountoulis

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	(49) It is necessary 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 ***finance the*** conduct ***of*** post-authorisation studies ***under***

imposed on the marketing authorisation holder.	***the supervision of the authorities*** should be imposed on the marketing authorisation holder.

Or. el

Amendment 179
Marit Paulsen, Fredrick Federley, Anneli Jäätteenmäki, Frédérique Ries

Proposal for a regulation
Recital 50

Text proposed by the Commission	*Amendment*
(50) A pharmacovigilance database at Union level should be established to record and integrate information of adverse events for all veterinary medicinal products authorised in the Union. That database should improve detection of adverse events and should allow and facilitate the pharmacovigilance surveillance and work-sharing between the competent authorities.	(50) A pharmacovigilance database at Union level should be established to record and integrate information of adverse events for all veterinary medicinal products authorised in the Union. That database should improve detection of adverse events and should allow and facilitate the pharmacovigilance surveillance and work-sharing between the competent authorities ***and other concerned authorities such as environmental protection agencies and food safety authorities both on national and Union level***.

Or. en

Amendment 180
Lampros Fountoulis

Proposal for a regulation
Recital 51

Text proposed by the Commission	*Amendment*
(51) It is necessary to exercise control over the entire chain of distribution of veterinary medicinal products, from manufacture or import into the Union through supply to the end-user. Veterinary medicinal products from third countries should comply with the same requirements	(51) It is necessary to exercise control over the entire chain of distribution of veterinary medicinal products, from manufacture or import into the Union through supply to the end-user. Veterinary medicinal products from third countries should comply with the same requirements

which apply to products manufactured in the Union***, or with requirements which are recognised to be at least equivalent thereto***.	which apply to products manufactured in the Union.

Or. el

Amendment 181
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Recital 53

Text proposed by the Commission	*Amendment*
(53) The quality of veterinary medicinal products manufactured within the Union should be guaranteed by requiring compliance with the principles of good manufacturing practice for medicinal products irrespective of the final destination of the medicinal products.	(53) The quality of veterinary medicinal products manufactured within the Union should be guaranteed by requiring compliance with the principles of good manufacturing practice for medicinal products irrespective of the final destination of the medicinal products. ***The same requirements must apply to veterinary medicinal products manufactured in third countries and imported into the Union.***

Or. fr

Amendment 182
Claudiu Ciprian Tănăsescu, Matthias Groote

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	(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.

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***, except for antimicrobials,*** via the Internet to buyers in ***their own or*** other Member States.

Or. en

Amendment 183
Biljana Borzan

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 be allowed to sell prescription and non-prescription veterinary medicinal products***, with the exception of antimicrobials,*** via the Internet to buyers in other Member States.

Or. en

Amendment 184
Lampros Fountoulis

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 be allowed to sell prescription and non-prescription veterinary medicinal products, ***depending on the type of medicinal product,*** via the Internet to buyers in other Member States.

Or. el

Amendment 185
Bolesław G. Piecha

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 ***veterinarians or other*** persons authorised to do so by the Member State where they are established***; however, countries which do not allow prescriptions to be issued by persons other than veterinarians may refuse to recognise such prescriptions issued in other countries in accordance with those countries' national laws***. At the same time, in order to improve access to veterinary medicinal products in the Union, retailers that are authorised to supply

	veterinary medicinal products by the competent authority in the Member State where they are established should be allowed to sell prescription and non-prescription veterinary medicinal products via the Internet to buyers in other Member States.

Or. pl

Amendment 186
Piernicola Pedicini, Eleonora Evi, Marco Affronte

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 be allowed to sell prescription and non-prescription veterinary medicinal products via the Internet to buyers in other Member States. ***In order to minimise the risk to animal and human health, online sales of antimicrobials should be prohibited.***

Or. it

Amendment 187
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

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 be allowed to sell non-prescription veterinary medicinal products via the Internet***, after the destination*** Member ***State has obtained a licence***.

Or. fr

Amendment 188
Julie Girling, James Nicholson

Proposal for a regulation
Recital 56 a (new)

Text proposed by the Commission	*Amendment*
	(56a) In order to ensure that the lines of distribution and the supply of veterinary medicines are not restricted, where Member States have a legally defined, professionally qualified animal medicines advisor, they shall continue to prescribe and supply certain veterinary medicines;

Or. en

Justification

The persons authorised to prescribe certain veterinary medicines should be determined by the relevant national authorities. Those with suitable qualifications, recognised by the Member State in which they reside, shall not be prohibited from prescribing and supplying certain veterinary medicines.

Amendment 189
Aldo Patriciello

Proposal for a regulation
Recital 57

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

Or. it

Amendment 190
Lampros Fountoulis

Proposal for a regulation
Recital 57

Text proposed by the Commission	*Amendment*
(57) The illegal sale of veterinary medicinal products to the public via the Internet may represent a threat to public and animal health, as falsified or substandard medicines may reach the public in this way. It is necessary to address this threat. Account should be taken of the fact that specific conditions for supply of medicinal products to the public	(57) The illegal sale of veterinary medicinal products to the public via the Internet may represent a threat to public and animal health, as falsified or substandard medicines may reach the public in this way. It is necessary to address this threat. Account should be taken of the fact that specific conditions for supply of medicinal products to the public

have not been harmonised at Union level and**,** therefore**,** Member States ***may*** impose conditions for supplying medicinal products to the public within the limits of the Treaty.	have not been harmonised at Union level and**,** therefore**,** Member States ***must*** impose conditions for supplying medicinal products to the public within the limits of the Treaty.

Or. el

Amendment 191
Claudiu Ciprian Tănăsescu, Matthias Groote

Proposal for a regulation
Recital 57

Text proposed by the Commission	*Amendment*
(57) The illegal sale of veterinary medicinal products to the public via the Internet may represent a threat to public and animal health, as falsified or substandard medicines may reach the public in this way. It is necessary to address this threat. Account should be taken of the fact that specific conditions for supply of medicinal products to the public have not been harmonised at Union level and, therefore**,** Member States may impose conditions for supplying medicinal products to the public within the limits of the Treaty.	(57) The illegal sale of veterinary medicinal products to the public via the Internet may represent a threat to public and animal health, as falsified or substandard medicines may reach the public in this way. It is necessary to address this threat. Account should be taken of the fact that specific conditions for ***the*** supply of medicinal products to the public have not been harmonised at Union level and, therefore Member States may impose conditions for supplying medicinal products to the public within the limits of the Treaty. ***The online sale of antibiotics should be prohibited.***

Or. en

Amendment 192
Julie Girling

Proposal for a regulation
Recital 57

Text proposed by the Commission	*Amendment*
(57) The illegal sale of veterinary medicinal products to the public via the Internet may represent a threat to public	(57) The illegal sale of veterinary medicinal products to the public via the Internet may represent a threat to public

and animal health, as falsified or substandard medicines may reach the public in this way. It is necessary to address this threat. Account should be taken of the fact that specific conditions for supply of medicinal products to the public have not been harmonised at Union level ***and, therefore,*** Member States may impose conditions for supplying medicinal products to the public within the limits of the Treaty.	and animal health, as falsified or substandard medicines may reach the public in this way. It is necessary to address this threat. Account should be taken of the fact that specific conditions for supply of medicinal products to the public have not been harmonised at Union level***.*** ***To minimise the risks to animal and human health, the online sale of antimicrobials should be prohibited.*** Member States may impose conditions for supplying medicinal products to the public within the limits of the Treaty.

Or. en

Amendment 193
Lampros Fountoulis

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	(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.	for sale at a distance by means of ***online*** services to conditions justified by the protection of public health. Such conditions should not unduly restrict the functioning of the internal market.

Or. el

Amendment 194
Marit Paulsen, Fredrick Federley, Anneli Jäätteenmäki, Frédérique Ries

Proposal for a regulation
Recital 58 a (new)

Text proposed by the Commission	*Amendment*
	(58a) Member States should be able to subject the supply of medicinal products offered for sale to stricter conditions justified by the protection of public health, animal health and the environment.

Or. en

Amendment 195
Piernicola Pedicini, Marco Affronte, Eleonora Evi

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 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	(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 h arm public or animal health, or the environment.	overconsumption which is liable to h arm public or animal health, or the environment. ***Comparative advertising should be allowed only for non-prescription products, in accordance with the rules laid down by Member States.***
	Or. it

Amendment 196
Bolesław G. Piecha

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 other persons authorised to do so under national law*** for an individual animal or group of animals, it should in principle be possible for that veterinary prescription to be recognised and for the medicinal product to be dispensed in another Member State***, provided that that Member State authorises persons with similar qualifications to issue prescriptions***. The removal of regulatory and administrative barriers to such recognition should not affect any professional or ethical duty for dispensing professionals to refuse to dispense the medicine stated in the prescription.
	Or. pl

Amendment 197
Martin Häusling

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 perform inspections at all stages of production, distribution and use of veterinary medicinal products ***and publish annual inspection reports***. In order to preserve the effectiveness of the inspections, ***all inspections should be*** unannounced inspections.

Or. en

Justification

Inspections need to be unannounced to be of any value. Member States should publish annual reports about the inspections carried out.

Amendment 198
Martin Häusling

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 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.	(67) In certain cases failures in Member States' control system can substantially hinder the achievement of the objectives of this Regulation and may lead to the emergence of risks to public and animal health and the environment. ***The Commission should*** 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 199
Martin Häusling

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***. This coordination group should also include an appropriate number of members with comprehensive expertise in complementary and alternative therapies. Members of the coordination group*** should***, among other tasks,*** provide on a case-by-case basis a recommendation whether a product falls within the definition of a veterinary medicinal product ***and whether alternative treatments are available***. In order to ensure legal certainty the Commission may decide whether a specific product is a veterinary medicinal product.

Or. en

Justification

It is important to also include members with comprehensive expertise in complementary and alternative therapies in the coordination group.

Amendment 200
Martin Häusling

Proposal for a regulation
Recital 71

Text proposed by the Commission	*Amendment*
(71) Having regard to the special characteristics of homeopathic veterinary medicinal products, especially the constituents of these products, it is desirable to establish a special, simplified registration procedure and to provide specific provisions for labelling for certain homeopathic veterinary medicinal products which are placed on the market without therapeutic indications. Immunological homeopathic products cannot follow the simplified registration procedure as immunologicals may initiate a response at a high dilution rate. The quality aspect of a homeopathic medicinal product is independent of its use so no specific provisions should apply with regard to the necessary quality requirements and rules.	(71) Having regard to the special characteristics of homeopathic veterinary medicinal products, especially the constituents of these products, it is desirable to establish a special, simplified registration procedure and to provide specific provisions for labelling for certain homeopathic veterinary medicinal products which are placed on the market without therapeutic indications. Immunological homeopathic products cannot follow the simplified registration procedure as immunologicals may initiate a response at a high dilution rate. The quality aspect of a homeopathic medicinal product is independent of its use so no specific provisions should apply with regard to the necessary quality requirements and rules. ***Furthermore, it is desirable to generally allow the use of*** homeopathic medicinal ***products designed for human use, including immunological homeopathic products, that have a potency starting from D4, on all animals, including food producing animals, under certain conditions***.

Or. en

Justification

Homeopathic products used for humans should be allowed to be used also in animals.

Amendment 201
Eleonora Evi

Proposal for a regulation
Recital 71

Text proposed by the Commission	*Amendment*
(71) Having regard to the special characteristics of homeopathic veterinary medicinal products, especially the constituents of these products, it is desirable to establish a special, simplified registration procedure and to provide specific provisions for labelling for certain homeopathic veterinary medicinal products which are placed on the market without therapeutic indications. ***Immunological homeopathic products cannot follow the simplified registration procedure as immunologicals may initiate a response at a high dilution rate.*** The quality aspect of a homeopathic medicinal product is independent of its use so no specific provisions should apply with regard to the necessary quality requirements and rules.	(71) Having regard to the special characteristics of homeopathic veterinary medicinal products, especially the constituents of these products, it is desirable to establish a special, simplified registration procedure and to provide specific provisions for labelling for certain homeopathic veterinary medicinal products which are placed on the market without therapeutic indications. The quality aspect of a homeopathic medicinal product is independent of its use so no specific provisions should apply with regard to the necessary quality requirements and rules.

Or. en

Justification

The meaning of the term "immunological homeopathic products…" is completely unclear and is not found in any other relevant pharmaceutical or legal text. The paragraph should be deleted to avoid confusion

Amendment 202
Martin Häusling

Proposal for a regulation
Recital 71 a (new)

Text proposed by the Commission	*Amendment*
	(71a) The usual rules governing the authorization to market veterinary medicinal products must be applied to homeopathic veterinary medicinal products marketed with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic effect.

Member States should be able to apply particular rules for the evaluation of the results of tests and trials intended to establish the safety and efficacy of these medicinal products for pet animals and exotic species, provided that they notify them to the Commission.

Or. en

Justification

Reinstatement of Recital 19 from Directive 2001/82/EC.

Amendment 203
Eleonora Evi

Proposal for a regulation
Recital 71 a (new)

Text proposed by the Commission	*Amendment*
	(71a) "The usual rules governing the authorisation to market veterinary medicinal products must be applied to homeopathic veterinary medicinal products marketed with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic effect. Member States should be able to apply particular rules for the evaluation of the results of tests and trials intended to establish the safety and efficacy of these medicinal products, provided that they notify them to the Commission."

Or. en

Amendment 204
Pavel Poc

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
This Regulation lays down rules for the placing on the market, manufacture, import, export, supply, pharmacovigilance, control and use of veterinary medicinal products.	This Regulation lays down rules for the placing on the market, ***development,*** manufacture, import, export, ***wholesale distribution, retail*** supply, pharmacovigilance, control and use of veterinary medicinal products.

Or. en

Justification

The provision of Article 1 should be extended to reflect the true scope of the proposal which, for example includes testing of veterinary medicinal products (clinical testing). Considering different requirements conditions, and functions, it is also appropriate to differentiate between wholesale distribution and retail supply of veterinary medicinal products.

Amendment 205
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. it

Amendment 206
Susanne Melior

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

Text proposed by the Commission	*Amendment*
	(ea) substances or preparations which are intended exclusively for external use in

animals, to clean or groom them or to alter their appearance or body odour, provided that no substances or preparations subject to veterinary prescription have been added to them.

Or. de

Justification

This exception is consistent with current EU law.

Amendment 207
Peter Liese, Norbert Lins, Renate Sommer, Jens Gieseke

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

Text proposed by the Commission	*Amendment*
	(ea) substances or preparations which are intended exclusively for external use in animals, to clean or groom them or to alter their appearance or body odour, provided that no substances or preparations subject to veterinary prescription have been added to them.

Or. de

Amendment 208
Pilar Ayuso, Esther Herranz García

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

Text proposed by the Commission	*Amendment*
	(ea) medicated feed and intermediate products as defined in article 2.2 a) and b) of Regulation YYYY/XXX on medicated feed.

Or. en

Justification

To clarify the scope of regulation on veterinary medicinal products it is proposed to exclude feeds (medicated feed and intermediate products) that fall under the proposal for a regulation on medicated feed.

Amendment 209
Peter Liese, Norbert Lins, Renate Sommer, Jens Gieseke

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

Text proposed by the Commission	*Amendment*
	(eb) feedingstuffs as defined in Regulation (EU) No 767/2009 of the European Parliament and of the Council.

Or. de

Amendment 210
Susanne Melior

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

Text proposed by the Commission	*Amendment*
	4a. Feedingstuffs as defined in Regulation (EU) No 767/2009 of the European Parliament and of the Council.

Or. de

Justification

This amendment is consistent with current EU law and makes it clear that feedingstuffs are not medicinal products within the meaning of the regulation.

Amendment 211
Martin Häusling

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

Text proposed by the Commission	*Amendment*
	4a. Substances or preparations of substances that are only intended to be applied externally on the animal for cleaning or care, or for influencing the appearance or body odour, as far as no substances or preparations are added which are excluded from marketing outside pharmacies.

Or. en

Justification

Such substances should be excluded from the scope of this Regulation. This is in line with the German Medicines Act.

Amendment 212
Pavel Poc

Proposal for a regulation
Article 3 – paragraph 1

Text proposed by the Commission	*Amendment*
1. ***Where a veterinary medicinal product referred to in Article 2(1) also falls within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council[21] or Regulation (EC) No 1831/2003 of the European Parliament and of the Council, and there is a conflict between the provisions of this Regulation and the provisions of Regulation (EU) No 528/2012 or Regulation (EC) No 1831/2003***, the provisions of this Regulation shall ***prevail***.	1. ***In cases of doubt, where taking into account all its characteristics, a product may fall within the definition of a "veterinary medicinal product" and within the definition of a product covered by other Union legislation***, the provisions of this Regulation shall ***apply***.
[21] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal	[21] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal

products (OJ L 167, 27.6.2012, p. 1).	products (OJ L 167, 27.6.2012, p. 1).

Or. en

Justification

When deciding on the classification of a product, all its characteristics shall be taken into account. The list of legislation which may be relevant with respect to different types of products, as proposed by the Commission may not be sufficient. As an example, feedingstuffs bearing specific indications may also be classified as veterinary medicinal products. As a result, the Regulation shall be a more generally worded in order to allow any future development.

Amendment 213
Pavel Poc

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

Justification

It is essential, that the definition of the veterinary medicinal product is clear and does not raise any questions, in particular in terms of classification of the existing products on the market. There is a body of European Court of Justice rulings on interpretation of the definition which 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, it may lead to unexpected consequences, e.g. re-classification of existing products on the market. As Commission has not indicated, that the definition of veterinary medicinal product shall be changed, and no impact assessment is available with this regard, it is proposed to keep the definition as stated in the current legislation and which is well interpreted by means of numerous rulings of the European Court of Justice. In terms of product intended for euthanasia, adding this specific criterion is accepted, however, the wording should be used, which is consistent with the „by function"

concept embedded in the definition.

Amendment 214
Pavel Poc

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 ***in*** animals;

Or. en

Justification

It is essential, that the definition of the veterinary medicinal product is clear and does not raise any questions, in particular in terms of classification of the existing products on the market. There is a body of European Court of Justice rulings on interpretation of the definition which 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, it may lead to unexpected consequences, e.g. re-classification of existing products on the market. As Commission has not indicated, that the definition of veterinary medicinal product shall be changed, and no impact assessment is available with this regard, it is proposed to keep the definition as stated in the current legislation and which is well interpreted by means of numerous rulings of the European Court of Justice. In terms of product intended for euthanasia, adding this specific criterion is accepted, however, the wording should be used, which is consistent with the „by function" concept embedded in the definition.

Amendment 215
Eleonora Evi

Proposal for a regulation
Article 4 – paragraph 1 – point 2 – introductory part

Text proposed by the Commission	*Amendment*
(2) ***'substance' means*** any matter ***of the following origin***:	(2) ***Substances:***
	Any matter ***irrespective of origin which may be***:

Or. en

Amendment 216
Eleonora Evi

Proposal for a regulation
Article 4 – paragraph 1 – point 2 – point a

Text proposed by the Commission	*Amendment*
(a) human,	(a) human, ***e.g. human blood and human blood products;***

Or. en

Amendment 217
Eleonora Evi

Proposal for a regulation
Article 4 – paragraph 1 – point 2 – point b

Text proposed by the Commission	*Amendment*
(b) animal,	(b) animal, ***e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;***

Or. en

Amendment 218
Eleonora Evi

Proposal for a regulation
Article 4 – paragraph 1 – point 2 – point c

Text proposed by the Commission	*Amendment*
(c) vegetable,	(c) vegetable, ***e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts;***

Or. en

Amendment 219
Pavel Poc

Proposal for a regulation
Article 4 – paragraph 1 – point 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) fungal

Or. en

Justification

The list of sources of the substances is not complete. It is therefore suggested to include fungal sources as these are widely used substances in veterinary medicinal products.

Amendment 220
Pavel Poc

Proposal for a regulation
Article 4 – paragraph 1 – point 2 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) microbial

Or. en

Justification

The list of sources of the substances is not complete. It is therefore suggested to include microbial sources as these are widely used substances in veterinary medicinal products.

Amendment 221
Eleonora Evi

Proposal for a regulation
Article 4 – paragraph 1 – point 2 – point d

Text proposed by the Commission	*Amendment*
(d) chemical***;***	(d) chemical***, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis***

Or. en

Justification

The explanatory texts on the individual substance groups are missing and should be included from DIR 2001/82/EC. The explanatory text makes it clear that minerals – which play an important role in homeopathy – are also among the substances of chemical origin. The general clause in DIR 2001/82/EC ("Any matter irrespective of origin") is also missing and should be included as well.

Amendment 222
Martin Häusling

Proposal for a regulation
Article 4 – paragraph 1 – point 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) mineral;

Or. en

Amendment 223
Claudiu Ciprian Tănăsescu

Proposal for a regulation
Article 4 – paragraph 1 – point 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) active substance is a substance with a pharmacological activity

Or. en

Amendment 224
Norbert Lins

Proposal for a regulation
Article 4 – paragraph 1 – point 7

Text proposed by the Commission	*Amendment*
(7) 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States;	(7) 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States; ***a homeopathic veterinary medicinal product may contain a number of active ingredients.***

Or. de

Amendment 225
Martin Häusling

Proposal for a regulation
Article 4 – paragraph 1 – point 7

Text proposed by the Commission	*Amendment*
(7) 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States;	(7) 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States; ***A homeopathic veterinary medicinal product may contain a number of principles.***

Or. en

Justification

A homeopathic veterinary medicinal product may contain principles. Most of the preparations used in treatment of animals are combination preparations. The wording added here is identical to the wording in Directive 2001/83 on human medicine.

Amendment 226
Matthias Groote

Proposal for a regulation
Article 4 – paragraph 1 – point 7
Directive 2001/82/EC
Article 4 – paragraph 1 – point 7

Text proposed by the Commission	*Amendment*
(7) 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States***;***	(7) 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States***. A homeopathic veterinary medicinal product may contain a number of active ingredients.***

Or. de

Amendment 227
Eleonora Evi

Proposal for a regulation
Article 4 – paragraph 1 – point 7

Text proposed by the Commission	*Amendment*
(7) 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias	(7) 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias

used officially in Member States***;***	used officially in Member States***.***
	A homeopathic veterinary medicinal product may also contain a number of principles.

Or. en

Amendment 228
Eleonora Evi

Proposal for a regulation
Article 4 – paragraph 1 – point 7

Text proposed by the Commission	*Amendment*
(7) 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared ***from homeopathic stocks*** in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States;	(7) 'homeopathic veterinary medicinal product' means a veterinary medicinal product prepared in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States;

Or. en

Justification

"from homeopathic stocks" is not required for a definition of the term "homeopathic veterinary medicinal product". The term "homeopathic stocks" is misleading, since the original substances (starting materials) are first processed to become homeopathic substances in the further homeopathic process, i.e. the original substance cannot be homeopathic yet. A homeopathic preparation is normally designated by using the Latin name for the concentrated preparation and the degree of dilution. Further the clarifying notice to the effect that a homeopathic veterinary medicinal product may contain several principles is of essential importance in veterinary homeopathy, since most of the preparations used in treatment of animals are combination preparations containing several homeopathic principles. This notice was contained to date in Art. 1 (8) DIR 2001/82/EC and should be included from that source. It was also retained, and is still in effect, in Art. 1 (5) DIR 2001/83/EC in this form.

Amendment 229
Norbert Lins

Proposal for a regulation
Article 4 – paragraph 1 – point 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) 'herbal medicinal product' means any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations;

Or. de

Amendment 230
Eleonora Evi

Proposal for a regulation
Article 4 – paragraph 1 – point 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) Herbal medicinal products are medicinal products containing as the sole active pharmaceutical ingredient one or more vegetable substances or one or more vegetable preparations or one or more such vegetable substances in combination with one or more such vegetable preparations.

Or. en

Amendment 231
Julie Girling, James Nicholson

Proposal for a regulation
Article 4 – paragraph 1 – point 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) 'antimicrobial' means 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

Amendment 232
Norbert Lins

Proposal for a regulation
Article 4 – paragraph 1 – point 7 b (new)

Text proposed by the Commission	*Amendment*
	(b) 'anthroposophic medicinal product' means a medicinal product which has been developed in accordance with the anthroposophic approach to human life and the natural world, using a homeopathic procedure described by the European Pharmacopeia or, in the absence thereof, by the pharmacopoeias used officially in Member States, or using a special anthroposophic procedure, and which are intended to be used in accordance with anthroposophic principles.

Or. de

Amendment 233
Pavel Poc

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 ***bacteria to withstand the effects of*** antimicrobial ***agents that are intended*** to inhibit or kill ***them***;

Or. en

Justification

The definition of antimicrobial resistance is based on the environmental cut off values ("ECOFFS"). This may lead to a number of problems when dealing issue of antimicrobial resistance in veterinary medicine as measures in terms animal health and public health may require a different approach. It is therefore proposed to use a more general definition of antimicrobial resistance which makes it possible to take the most appropriate measures for each respective issue. In addition it is proposed to specifically mention "bacteria" as resistance in this group of microorganisms presents the issue with respect to veterinary medicinal products.

Amendment 234
Claudiu Ciprian Tănăsescu, Pavel Poc, Matthias Groote

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

Text proposed by the Commission	*Amendment*
	(8a) "antimicrobials" mean any compound with a direct action on micro-organisms used for treatment or prevention of infections. Antimicrobials include anti-bacterials, anti-virals, antifungals and anti-protozoals. Antibiotics are synonymous with anti-bacterials.

Or. en

Amendment 235
Pavel Poc

Proposal for a regulation
Article 4 – paragraph 1 – point 9

Text proposed by the Commission	*Amendment*
(9) 'clinical trial' means a study ***which aims to examine*** under ***field conditions the safety or efficacy of a veterinary medicinal product or both*** under ***normal*** conditions ***of animal husbandry or as part of normal*** veterinary ***practice*** for the purpose of obtaining a marketing	(9) 'clinical trial' means a ***scientific*** study ***not falling*** under ***the scope of Directive 2010/63/EU, conducted in a target species in accordance with good clinical practice*** under ***field*** conditions ***to test at least one hypothesis relevant to efficacy claim or to in-use safety in the target animal for a***

authorisation ***or a change thereof***;	veterinary ***medicinal product under investigation*** for the purpose of obtaining a marketing authorisation ***for the veterinary medicinal product concerned or variation thereof; in case of immunological veterinary medicinal product the study is a "field trial"***;

Or. en

Justification

It is important that the regulation on veterinary medicinal products clearly defines the clinical (field) trial and clearly stipulates that it is a study not falling under Directive 2010/63/EU. In this context it is also important to adapt provisions of Section 3 accordingly. In addition, it is important to reflect the specific requirements for immunological veterinary medicinal products whose development is different from pharmaceutical products.

Amendment 236
Martin Häusling

Proposal for a regulation
Article 4 – paragraph 1 – point 9

Text proposed by the Commission	*Amendment*
(9) ‘clinical trial' means a study which aims to examine under field conditions the safety or efficacy of a veterinary medicinal product or both under normal conditions of animal husbandry or as part of normal veterinary practice ***for the purpose of obtaining a marketing authorisation or a change thereof;***	(9) ‘clinical trial' means a study which aims to examine under field conditions the safety or efficacy of a veterinary medicinal product or both under normal conditions of animal husbandry or as part of normal veterinary practice**.**

Or. en

Justification

In the recently revised Regulation on clinical trials on human subjects, the definition of clinical trials is not linked to the purpose of obtaining a marketing authorisation. A clinical trial can also confirm marketing authorization stipulations (e.g. PASS - post-authorisation safety study) or may serve also for to investigate the efficacy in certain indications. It is therefore not appropriate to limit the definition of clinical trials in this legislation to purpose of obtaining a marketing authorisation.

Amendment 237
Eleonora Evi

Proposal for a regulation
Article 4 – paragraph 1 – point 9

Text proposed by the Commission	*Amendment*
(9) ‘clinical trial' means a study which aims to examine under field conditions the safety or efficacy of a veterinary medicinal product or both under normal conditions of animal husbandry or as part of normal veterinary practice ***for the purpose of obtaining a marketing authorisation or a change thereof***;	(9) ‘clinical trial' means a study which aims to examine under field conditions the safety or efficacy of a veterinary medicinal product or both under normal conditions of animal husbandry or as part of normal veterinary practice;

Or. en

Justification

Such a restrictive definition of "clinical trials" with the sole intention of obtaining marketing authorisation is factually incorrect. A clinical trial can also confirm marketing authorization stipulations (e.g. PASS - post-authorisation safety study) or may serve, also for registered homeopathic veterinary medicinal products, e.g. combination preparations, as an investigation of efficacy in certain indications. A restrictive definition such as that used in the Commission Draft is therefore also not used in DIR 2001/82/EC. In order to continue performing clinical trials for all of the purposes listed and to encourage the gaining of knowledge from these trials, the definition should be changed as proposed.

Amendment 238
Martin Häusling

Proposal for a regulation
Article 4 – paragraph 1 – point 10

Text proposed by the Commission	*Amendment*
(10) 'pre-clinical study' means a study not covered by the definition of clinical trial ***which aims to investigate the safety or efficacy of a veterinary medicinal product for the purpose of obtaining a marketing authorisation or a change thereof;***	(10) 'pre-clinical study' means a study not covered by the definition of clinical trial

Or. en

Justification

A preclinical trial can also be carried out to gain knowledge, e.g. to research the mechanisms of action of medicinal products for which market authorisation or registration has already been issued, without attempting to obtain marketing authorisation or a change thereof. In order to be able to continue such trials and not hinder the gaining of knowledge from them, the definition should be changed as proposed.

Amendment 239
Pavel Poc

Proposal for a regulation
Article 4 – paragraph 1 – point 10

Text proposed by the Commission	*Amendment*
(10) 'pre-clinical study' means a study not covered by the definition of clinical trial which aims to investigate the safety or efficacy of a veterinary medicinal product for the purpose of obtaining a marketing authorisation or a change thereof***;**	(10) 'pre-clinical study' means a study not covered by the definition of clinical trial ***conducted in accordance with good laboratory practice [1 a],*** which aims to investigate the safety or efficacy of a veterinary medicinal product for the purpose of obtaining a marketing authorisation or a change ***a variation*** thereof
	[1 a] Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) and Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances

Or. en

Justification

Pre-clinical studies shall be conducted in line with the good laboratory practice. The references shall be added to the directives providing for the Good manufacturing practice (Directive 2004/9/EC and Directive 2004/10/EC. In addition, the terminology should be adapted and the word "variation" shall be used instead of the term "change".

Amendment 240
Eleonora Evi

Proposal for a regulation
Article 4 – paragraph 1 – point 10

Text proposed by the Commission	*Amendment*
(10) 'pre-clinical study' means a study not covered by the definition of clinical trial which aims to investigate the safety or efficacy of a veterinary medicinal product ***for the purpose of obtaining a marketing authorisation or a change thereof***;	(10) 'pre-clinical study' means a study not covered by the definition of clinical trial which aims to investigate the safety or efficacy of a veterinary medicinal product ;

Or. en

Amendment 241
Pavel Poc, Susanne Melior

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

Evaluation of the benefit: risk balance is a key part of scientific assessment veterinary medicinal products in terms of their marketing authorisation, including post-marketing evaluation (e.g. pharmacovigilance). Definition of the benefit: risk is therefore considered

essential. Commission proposal introduces a broader interpretation of benefits, which may bring problems in interpretation of benefit:risk for certain product, 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 242
Pavel Poc

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, or, if one does not exist, the ***usual common name***;

Or. en

Justification

The aim of this amendment is to correct 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 243
Pavel Poc

Proposal for a regulation
Article 4 – paragraph 1 – point 18

Text proposed by the Commission	*Amendment*
(18) 'package leaflet' means ***a documentation leaflet on a*** veterinary medicinal product which contains information to ensure its safe and efficacious use;	(18) 'package leaflet' means ***an information leaflet which attached to a veterinary medicinal product which is intended for a user of the*** veterinary medicinal product ***and*** which contains information to ensure its safe and efficacious use ***which are compliant with***

the information provided for in the summary of product characteristics of the veterinary medicinal product;

Or. en

Justification

The definition of the package leaflet shall be changed in order to clearly stipulate that the package leaflet is a set of information which shall be drafted in compliance with the conditions of marketing authorization of the veterinary medicinal product concerned and which is attached the product concerned. The definition should also make clear that the package leaflet is intended for the user of the veterinary medicinal product

Amendment 244
Pavel Poc

Proposal for a regulation
Article 4 – paragraph 1 – point 20 – introductory part

Text proposed by the Commission	*Amendment*
(20) **'**limited market' means a ***market for one of the following product types:***	(20) ***'veterinary medicinal product for*** limited market' means a ***veterinary medicinal product intended for a target species and/or therapeutic indication where the Union identifies a public interest to improve availability of authorised veterinary medicinal products.***

Or. en

Justification

Despite the improvement of availability of veterinary medicinal products in the "minor" species and "minor" use or indications was the main ambition of the new draft legislation, it can be reasonably expected that the draft legislation will not be able to serve the intention under practical conditions. The draft Regulation shall be thoroughly re-drafted and it is proposed that the Regulation only provides for the high-level principles while the technical details should be further specified in the implementing legislation.

Amendment 245
Pavel Poc

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

Text proposed by the Commission	*Amendment*
(a) veterinary medicinal products for the treatment or prevention of diseases that occur infrequently or in limited geographical areas;	***deleted***

Or. en

Amendment 246
Pavel Poc

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;	***deleted***

Or. en

Amendment 247
Susanne Melior

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. de

Justification

The 'restricted market' for veterinary medicinal products should also apply to sheep.

Amendment 248
Michel Dantin, Angélique Delahaye, Cristian-Silviu Buşoi

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

Amendment 249
Pavel Poc, Susanne Melior

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 ***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

Definition of pharmacovigilance as prosed in the Commission draft is too narrow and it only focuses on the process of monitoring and investigating of adverse events. Pharmacovigilance has to 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 for a veterinary medicinal product throughout its lifecycle. This is of particular importance for products, benefit:risk balance of which is prone to change over time, like antimicrobial or antiparasitic

medicines. As a result, definition of pharmacovigilance has to be adapted accordingly.

Amendment 250
Susanne Melior

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 issued by a ***veterinarian following the provision of a veterinary diagnosis in the context of clinical examination of the animal or of a check on the state of health of the animal***;

Or. de

Justification

Veterinary medicinal products which are subject to prescription should be prescribed only by persons with the highest relevant qualifications. Treatment using veterinary medicinal products subject to prescription must be based on an examination and diagnosis which only a veterinarian can provide.

Amendment 251
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 animals only if he/she has examined the knowledge of the condition of the animals and made a diagnosis before the prescription or has personal knowledge of the condition of the animals to make a diagnosis and***

prescribe. A written or electronic prescription is always required when the medicine is not dispensed by the prescriber but instead by another dispenser (pharmacy), in accordance with applicable national law;

Or. en

Amendment 252
Norbert Lins

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 issued by a ***veterinarian or another*** professional person qualified to do so in accordance with applicable national law; ***("if adopted, modification needed throughout the whole text")***

Or. en

Amendment 253
Iratxe García Pérez, Soledad Cabezón Ruiz

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 ***or human*** medicinal product issued by a ***veterinarian once a veterinary diagnosis has been established following a clinical examination of the animal or in the light of continuous health checks on the animal***;

Or. en

Justification

Veterinarian is the only professional capable of prescribe medicinal products for animals. On the other hand, a prescription made by a veterinarian should cover not only veterinary medicinal products but also human products (under cascade prescription).

Amendment 254
Biljana Borzan

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 issued by a ***veterinarian to the owner or the*** person ***taking care of the animal(s), only after diagnosis or in the light of a regular animal health visit.***

Or. en

Amendment 255
Pavel Poc, Susanne Melior

Proposal for a regulation
Article 4 – paragraph 1 – point 25

Text proposed by the Commission	*Amendment*
(25) 'withdrawal period' means the ***minimum*** period between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal which under normal conditions of use is necessary to ensure that such foodstuffs ***do not contain residues in quantities harmful to public health***;	(25) 'withdrawal period' means the period between the last administration of a veterinary medicinal product to an animal ***under normal conditions of use and in accordance with the provisions of this Regulation*** and the production of foodstuffs from that animal which under normal conditions of use is necessary to ensure that such foodstuffs ***comply with requirements laid down pursuant to Regulation (EC) 470/2009***;

Or. en

Justification

It is necessary to relate the withdrawal period to the provision of Regulation 470/2009. There may be different assessments and outcomes for the same substance used in the veterinary medicinal products and, for example feed additives, e.g. anticoccidials. This may result in possibly different interpretation of the legal provisions and the definition has to be adapted.

Amendment 256
Pavel Poc

Proposal for a regulation
Article 4 – paragraph 1 – point 26

Text proposed by the Commission	*Amendment*
(26) 'making available on the market' means any supply of a veterinary medicinal product for distribution, consumption or use on the ***Union market*** in the course of a commercial activity, whether in return for payment or free of charge;	(26) 'making available on the market' means any supply of a veterinary medicinal product for distribution, consumption or use on the ***market of a Member State*** in the course of a commercial activity, whether in return for payment or free of charge;

Or. en

Justification

In the area of veterinary medicinal products, the requirement for marketing authorization of any product which shall be placed on the market shall be required as it is stipulated in the draft Regulation. In addition, the draft Regulation correctly preserves different types of marketing authorization procedures to accommodate specific needs of industry as well as specific needs of the Member States. In principle, without marketing authorization, the veterinary medicinal product cannot be placed freely in the Member State or in those Member States which did not grant the marketing authorization for such product.

Amendment 257
Pavel Poc

Proposal for a regulation
Article 4 – paragraph 1 – point 27

Text proposed by the Commission	*Amendment*
(27) 'placing on the market' means the first making available of a veterinary medicinal	(27) 'placing on the market' means the first making available of a veterinary medicinal

product on the ***Union*** market.	product on the ***Member State*** market.

Or. en

Justification

In the area of veterinary medicinal products, the requirement for marketing authorization of any product which shall be placed on the market shall be required as it is stipulated in the draft Regulation. In addition, the draft Regulation correctly preserves different types of marketing authorization procedures to accommodate specific needs of industry as well as specific needs of the Member States. In principle, without marketing authorization, the veterinary medicinal product cannot be placed freely in the Member State or in those Member States which did not grant the marketing authorization for such product.

Amendment 258
Iratxe García Pérez, Clara Eugenia Aguilera García

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

Text proposed by the Commission	*Amendment*
	(27a) "industrial process" referring to veterinary medicinal products containing autologous or allogeneic cells or tissues include list all process that should be considered as industrial for these specific product.

Or. en

Justification

In recent years all Agencies have received an increasing number of requests for advice related to therapies that are entirely new to the veterinary domain. Where there is no experience within the veterinary regulatory community with respect to the therapy concerned, there is a need to provide guidance in the future legislation.

Amendment 259
Pilar Ayuso, Esther Herranz García

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

Text proposed by the Commission	*Amendment*
	(27a) "Marketing authorisation holder": the holder of an authorisation granted in accordance with the legislation.

Or. en

Justification

It is necessary to define what the Marketing authorisation holder is.

Amendment 260
Marit Paulsen, Fredrick Federley, Jan Huitema, Anneli Jäätteenmäki, Frédérique Ries

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

Text proposed by the Commission	*Amendment*
	(27a) "good animal husbandry" means the management and care of animals by humans for profit whilst assuring the health and welfare of these animals by respecting and ensuring the specific needs of each species and by minimising as much as possible the need to use veterinary pharmaceutical products;

Or. en

Amendment 261
Jytte Guteland

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

Text proposed by the Commission	*Amendment*
	(27a) Good manufacturing practice shall mean the part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended

use, including the requirements that follow from article 98 and 103 a new.

Or. en

Amendment 262
Iratxe García Pérez, Clara Eugenia Aguilera García

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

Text proposed by the Commission	*Amendment*
	(27b) "Summary product characteristics" is the resume of the product technical characteristics on quality, safety and efficacy for the healthcare professionals.

Or. en

Justification

It is necessary to define what is the Summary of the product characteristics that is describe in art. 28(1)(a) and art. 30.

Amendment 263
Pilar Ayuso, Esther Herranz García

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

Text proposed by the Commission	*Amendment*
	(27b) "Periodic safety update report" is the report that collect all adverse events known by the marketing authorisation holder of a product that shall be submitted to the competent authorities.

Or. en

Justification

It is necessary to define what is the Periodic Safety Update Report because it is proposed to maintain it as it is absolutely necessary for a good post marketing surveillance.

Amendment 264
Iratxe García Pérez, Clara Eugenia Aguilera García, Soledad Cabezón Ruiz

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

Text proposed by the Commission	*Amendment*
	(27c) "Adverse events" is any of the undesirable events described in art. 73 (2).

Or. en

Justification

It is necessary to define what is Adverse events because it is used several times in the document.

Amendment 265
Iratxe García Pérez, Clara Eugenia Aguilera García, Soledad Cabezón Ruiz

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

Text proposed by the Commission	*Amendment*
	(27d) "Serious adverse events" is an adverse events which results in death, is life-threatening, results in significant disability or incapacity, is a congenital anomaly/birth defect, or which results in permanent or prolonged signs in the animals treated.

Or. en

Justification

It is necessary to define what is Serious adverse events because depending on the seriousness

the adverse events should be notified in a different times.

Amendment 266
Pavel Poc

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

Text proposed by the Commission	*Amendment*
	'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

It is hereby proposed to add a definition of the wholesale distribution to the Article 4 of the draft Regulation. For the sake of clarity and predictability and It is essential that the new Regulation clearly defines, what wholesale distribution means. Without 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 267
Pavel Poc

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

Text proposed by the Commission	*Amendment*
	'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

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

Amendment 268
Pavel Poc, Susanne Melior

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

Text proposed by the Commission	*Amendment*
	'pre-mix for medicated feedingstuffs' means any veterinary medicinal product prepared in advance with a view to the subsequent manufacture of medicated feeding stuffs according to the Regulation 2014/0255(COD) on the Manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EC

Or. en

Justification

It is very important, that the provisions on veterinary medicinal products and on medicated feeding stuffs are properly interconnected in order to be able to serve for the purpose. Antimicrobials are the most important class of drugs which is used by means of medicated feeding stuffs and the quality, safety and efficacy of veterinary medicinal products to be incorporated to the medicated feeding stuffs has to be properly assessed. Only for pre-mixes for medicated feeding stuffs specific requirements have been established in terms of

homogeneity, stability and other important properties which predetermine quality, safety and efficacy of this specific pharmaceutical form in the final medicated feed. This is also reflected in the requirements of the European Pharmacopoeia, where specific requirements are established for medicated pre-mixes. As a result, the legislation on veterinary medicinal products should clearly require, that only medicated pre-mixes can be authorised for use for subsequent manufacture of medicated feeding stuffs.

Amendment 269
Pavel Poc

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. ***Without prejudice to other provisions of this Regulation,*** a veterinary medicinal product shall be placed on the market ***of a Member State*** only when a marketing authorisation has been granted in respect of the product by a ***the*** competent authority ***of that Member State*** or by the ***Commission in*** accordance ***this Regulation***.

Or. en

Justification

It is necessary to amend the definition from several reasons. First, the definition proposed by the COM does not reflect the fact, that outside the authorized product, other products are used in the veterinary medicines such as magistral or officinal formulae or autogeneous vaccines, which are legally prepared and use products. The proposed definition is restrictive and would not make it possible to make use of these important groups of products in the Member States.

Amendment 270
Norbert Lins

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	***deleted***

valid for an unlimited period of time.

Or. de

Amendment 271
Pilar Ayuso, Esther Herranz García

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 272
Martin Häusling

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

Justification

Time-limited marketing authorisations are crucial to ensure that authorisations are updated. Unforeseen problems may occur in particular in the first years, so it is inappropriate to immediately grant an unlimited authorisation. The current system of a first approval for five years should be maintained. Renewal is a means to adapt approvals to fill data gaps, to update data, and address previously unforeseen or hidden effects.

Amendment 273
Karin Kadenbach

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***.

Or. de

Amendment 274
Susanne Melior

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. de

Justification

Unconditional, unlimited authorisation of a veterinary medicinal product is not consistent with animal welfare. Even after authorisation has been granted, veterinary medicinal

products must constantly be tested to check that they are safe.

Amendment 275
Pavel Poc

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. ***Without prejudice to Article (...references to be completed...),*** marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period of time.

Or. en

Justification

The legislation should be clear that in certain cases, the marketing authorization shall cease to exist, for example based on the request of the marketing authorization holder or in other cases provided under the Regulation.

Amendment 276
Martin Häusling

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

Text proposed by the Commission	*Amendment*
	2a. The authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance based on the latest state of scientific knowledge, taking into account adverse effects reported under Article 76. The renewal of an authorisation shall be limited to periods not exceeding 15 years.

Or. en

Justification

Renewals of authorisations should be limited to 15 years (renewable) to ensure that the safety, efficacy and quality of veterinary drugs is adequately reassessed. Renewal is an important means to adapt approvals to fill data gaps, to update data, and address previously unforeseen or hidden effects.

Amendment 277
Pilar Ayuso, Esther Herranz García

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 278
Pavel Poc

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

Text proposed by the Commission	*Amendment*
	2a. The marketing authorisation holder shall be responsible for marketing the medicinal product. The designation of a representative shall not relieve the marketing authorisation holder of his legal responsibility.

Or. en

Justification

The new paragraph stating for the responsibility of the marketing authorization holder shall be included in this part of the Regulation, similarly to the requirement that the MAH is established in the EU as provided under Art. 5, par. 4 in the draft Regulation.

Amendment 279
Pavel Poc

Proposal for a regulation
Article 6 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the decentralised procedure laid down in Articles 45 ***and 46***;	(b) the decentralised procedure laid down in Articles 45***, 46 and 57***;

Or. en

Justification

For the sake of clarity, an in order to be correct and complete, the provisions shall also include reference to the procedures on subsequent use of mutual recognition procedure.

Amendment 280
Pavel Poc

Proposal for a regulation
Article 6 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the mutual recognition procedure laid down in Articles 47 ***and 48***.	(c) the mutual recognition procedure laid down in Articles 47***, 48 and 57***.

Or. en

Justification

For the sake of clarity, an in order to be correct and complete, the provisions shall also include reference to the procedures on subsequent use of mutual recognition procedure.

Amendment 281
Pavel Poc

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 ***or saved in exceptional circumstances and following agreement with a competent authority, or, in case of central application,*** with the ***Agency. The Commission, in collaboration with the Member States and with*** the Agency shall ***adopt detailed guidelines for the format of electronic applications***.

Or. en

Justification

The draft regulation shall keep the flexibility in terms of the requirements for electronic submission as in certain cases this requirements may be restrictive any have negative effect on availability or innovation, like in case of certain SMEs, limited market products, in urgent situations etc.

Amendment 282
Merja Kyllönen

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 ***using a single digital portal. For all applications submitted under this regulation***, the formats made available by the Agency shall be used. *(Identical to rapporteur's AM21.)*

Or. en

Amendment 283
Pavel Poc

Proposal for a regulation
Article 6 – paragraph 5

Text proposed by the Commission	*Amendment*
5. ***Within 15 days of receipt of the application***, the competent authority or the Agency shall notify the applicant of ***whether all data required in accordance with Article 7*** have been ***presented***.	5. ***Without prejudice to specific provisions related to Mutual Recognition Procedure and Decentralised Procedure***, the competent authority or the Agency shall***, within 15 days of receipt of the application,*** notify the applicant of ***the formal requirements laid down in this Regulation for the application concerned*** have been ***met and whether the application can be subject to scientific assessment***.

Or. en

Justification

The provision needs to be amended to make it clear, that the notification only concerns compliance with the formal requirements and does not concern scientific assessment of the application in question. In addition, mutual recognition procedure and decentralised procedure show specificities which have to be respected.

Amendment 284
Pavel Poc

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. An application for a marketing authorisation shall contain the following information:	***deleted***
(a) the administrative information set out in Annex I;	
(b) technical documentation satisfying the requirements set out in Annex II;	
(c) the information to be provided in the immediate packaging, outer packaging and the package leaflet in accordance with Articles 9 to 14.	

Or. en

Amendment 285
Pavel Poc

Proposal for a regulation
Article 7 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The application for a marketing authorisation shall contain all administrative information and scientific documentation necessary for demonstrating the quality, safety and efficacy of the veterinary medicinal product in question. The dossier shall be submitted in accordance with Annex I and shall contain, in particular, the following information:
	(a) name or business name and permanent address or registered place of business of the person responsible for placing the product on the market and, if different, of the manufacturer or

manufacturers involved and of the sites of manufacture;

(b) name of veterinary medicinal product;

(c) qualitative and quantitative particulars of all the constituents of the veterinary medicinal product, including its international non- proprietary name (INN) recommended by the WHO, where an INN exists, or its chemical name;

(d) description of the method of manufacture;

(e) therapeutic indications, contra-indications and adverse reactions;

(f) dosage for the various species of animal for which the veterinary medicinal product is intended, its pharmaceutical form, method and route of administration and proposed shelf life;

(g) reasons for any precautionary and safety measures to be taken when storing the veterinary medicinal product, administering it to animals and disposing of waste, together with an indication of potential risks that the veterinary medicinal product might pose to the environment, to human and animal health and to plants;

(h) indication of the withdrawal period in the case of medicinal products intended for food-producing species;

(i) description of the testing methods employed by the manufacturer;

(j) results of:

– pharmaceutical (physico-chemical, biological or microbiological) tests,

– safety tests and residue tests,

– pre-clinical and clinical trials;

– tests assessing the potential risks posed by the medicinal product for the environment. This impact shall be studied and consideration shall be given on a case-by-case basis to specific provisions seeking to limit it.

(k) proof of validity of the pharmacovigilance system master file;

(l) a summary of product characteristics in accordance with Article 30 as well as the information to be provided in the immediate packaging, outer packaging and the package leaflet in accordance with Articles 9 to 14

(m) proof of a manufacturing authorisation for all

Or. en

Justification

The requirements shall be a part of the Regulation and they shall be provided on a high level basis. They should be further specified in the detailed technical Annex adopted by the Council and Parliament.

Amendment 286
Martin Häusling

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***,*** animal health ***and the environment*** of use of the antimicrobial veterinary medicinal product in animals,

Or. en

Justification

Antimicrobials can also affect the environment. Antimicrobials can kill soil bacteria, which in turn endangers soil ecosystems, depressing natural fertility, nutrient cycling, weed and pest suppression by beneficial micro-organisms. Antimicrobial-resistant bacteria can also spread to humans via environmental routes. Therefore the documentation should also include the risks to the environment.

Amendment 287
Marit Paulsen, Fredrick Federley, Gerben-Jan Gerbrandy, Frédérique Ries

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

Amendment 288
Nessa Childers

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***, also stating that the product is not to be used as routine preventative measure in food producing animals***.

Or. en

Amendment 289
Martin Häusling

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***, in particular***

when used for control treatment (metaphylaxis).

Or. en

Justification

If the prophylactic use of antimcrobials is prohibited, there is a risk that metaphylactic use becomes the new prophylactic use. In high-density livestock farming, there will always be a sick animal, which could be abused as pretext for treating not only the group of animals in close contact, but the whole herd. It is therefore very important that the application contains information about the risk mitigation measures in case of metaphylactic use.

Amendment 290
Pavel Poc

Proposal for a regulation
Article 7 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the application concerns a veterinary medicinal product intended for food-producing target species and containing pharmacologically active substances that are not listed in Table 1 of the Annex to Regulation (EU) No 37/2010 for the animal species in question, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council[22] ***shall be submitted in addition to the information listed in paragraph 1.***	3. Where the application concerns a veterinary medicinal product intended for food-producing target species and containing pharmacologically active substances that are not listed in Table 1 of the Annex to Regulation (EU) No 37/2010 for the animal species in question, a document ***shall be submitted in addition to the information listed in paragraph 1*** certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council ***and that at least six months has elapsed from submission of such application***
[22] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin,	[22] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin,

repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).	repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

Or. en

Justification

It is important to have the time span of the 6 months between submission of the application for a maximum residue limit and the submission of the application for a marketing authorisation. It happens often, that the maximum residue limit as proposed by the applicant is changed following the assessment and before a final MRL is known it is not possible to establish valid withdrawal period. This may lead to substantial problems in terms of the marketing authorisation procedures and timelines to be followed.

Amendment 291
Martin Häusling

Proposal for a regulation
Article 7 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Where the application concerns a veterinary medicinal product containing or consisting of genetically modified organisms within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council[24] the application shall in addition to the documents listed in paragraph 1 be accompanied by:	***deleted***
(a) a copy of the written consent of the competent authorities to the deliberate release into the environment of the genetically modified organisms for research and development purposes, as provided for in Part B of Directive 2001/18/EC;	
(b) the complete technical file supplying the information required under Annexes	

III and IV to Directive 2001/18/EC;

(c) the environmental risk assessment in accordance with the principles set out in Annex II to Directive 2001/18/EC; and

(d) the results of any investigations performed for the purposes of research or development.

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

Or. en

(Linked to the new point (ia) to Article 32(1).)

Justification

Veterinary medicinal product should not contain or consist of genetically modified organisms.

Amendment 292
Martin Häusling

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

Text proposed by the Commission	*Amendment*
	5a. When applying for renewal, publically 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 293
Pavel Poc, Susanne Melior

Proposal for a regulation
Article 7 – paragraph 7

Text proposed by the Commission	*Amendment*
7. ***The Commission*** shall be ***empowered to adopt delegated acts in accordance with Article 146 in order to amend Annexes I and II to adapt the information and documentation requirements to technical and scientific progress***.	7. ***Annex I*** shall be ***adopted by the Council and European Parliament acting under the conditions provided for by the Treaty on a proposal from the Commission***.

Or. en

Justification

Annex I to the Regulation is an essential part of the Regulation providing for the requirements of the dossier which is a basis for the decision on the marketing authorization for a veterinary medicinal product. As a result, the Annex should be adopted under the control of the European Parliament of the Council. As development of the veterinary medicinal products takes a long time, typically between 2 to 10+ years, with the longer times for the innovative products, it is essential, that the legal framework provides a high level of stability and legal predictability for the veterinary pharmaceutical industry.

Amendment 294
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Article 8 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. Approvals of clinical trials shall be granted on condition that food-producing animals used in the clinical trials or their produce do not enter the human food chain ***unless:***	2. Approvals of clinical trials shall be granted on condition that food-producing animals used in the clinical trials or their produce do not enter the human food chain**.**

Or. fr

Amendment 295
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Article 8 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) the tested product is a veterinary medicinal product authorised for the food-producing species used in the clinical trial, and the withdrawal period set out in the summary of the product characteristics is respected, or	***deleted***

Or. fr

Amendment 296
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Article 8 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) the tested product is an authorised veterinary medicinal product for target species other than the food-producing species used in the clinical trial and the withdrawal period set out in accordance with Article 117 is respected.	***deleted***

Or. fr

Amendment 297
Sirpa Pietikäinen

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

Text proposed by the Commission	*Amendment*
	(ba) data are provided to support an experimental withdrawal period

Or. en

Justification

For new products in clinical development with an active substance for which no MRL has been set yet, the authorities should continue to have the possibility to set a (conservative and sufficiently long) experimental withdrawal period that ensures consumer safety. Otherwise, this means that all food-producing animals participating in clinical trials in the European Union will need to be (unnecessarily) euthanized.

Amendment 298
Sirpa Pietikäinen

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

Text proposed by the Commission	*Amendment*
	4a. The principles of replacement, reduction and refinement concerning the care and use of live animals for scientific purposes should be taken into account during the design and performance of clinical trials.

Or. en

Justification

The Commission proposal already refers to the 3Rs (replace, reduce and refine) in the Recitals (20 and 21) and Annex II (1.4.1), therefore it is important to have follow through of the principles in the Articles. The EU Directive 2010/63/EU on the protection of animals used for scientific purposes makes the principles of the 3Rs a firm legal requirement however clinical trials are exempt from this legislation therefore it is necessary to make reference to the 3Rs as there is overall support to pay full respect to them when designing and carrying out experiments and they should be considered systematically at all times when animals are used.

Amendment 299
Pilar Ayuso, Esther Herranz García

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 300
Françoise Grossetête

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 only the information ***listed below. The applicant may include additional information in accordance with Article 30, if the packaging so permits***:

Or. fr

Justification

There are no grounds for imposing restrictions on the list of items of information that must appear on the immediate packaging of a veterinary medicinal product. It is necessary to lay down the common information which must appear there, while allowing manufacturers to provide additional information if they so wish.

Amendment 301
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. it

Amendment 302
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 minimum mandatory information that must be included on the immediate label of a veterinary medicinal product needs to be defined by legislation. However, 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 label shave much more space than others, and can accommodate more information. For some categories of product that can be sold direct to the public without prescription it may be important to include additional information on the immediate packaging. There also needs to be flexibility to allow new and future technologies (such as QR codes). All label text must be consistent with the authorised information about the product in Article 30 (the "summary of product characteristics"), which is approved by the regulatory authority during the authorisation procedure.

Amendment 303
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

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

Text proposed by the Commission	*Amendment*
(e) the target species;	(e) the target species ***and the time required for elimination from the food chain for food-producing animals, for each species;***

Or. fr

Amendment 304
Piernicola Pedicini, Eleonora Evi, Marco Affronte

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

Text proposed by the Commission	*Amendment*
	(ga) details of 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 precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products;

Or. it

Amendment 305
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

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

Text proposed by the Commission	*Amendment*
	(ga) whether it can be used in organic farming, and the necessary precautions, where applicable;

Or. fr

Amendment 306
Claudiu Ciprian Tănăsescu

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or, where appropriate, abbreviations or pictograms common throughout the Union.	2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or, where appropriate, abbreviations or pictograms common throughout the Union. ***In exceptional cases, the applicant(s), or the competent authority may request additional text to be included where this is justified to ensure safe and correct administration of the product.***

Or. en

Amendment 307
Françoise Grossetête

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 only the information ***listed below. The applicant may include additional information in accordance with Article 30, if the packaging so permits***:

Or. fr

Justification

There are no grounds for imposing restrictions on the list of items of information that must appear on the outer packaging of a veterinary medicinal product. The manufacturer must be

free to add information, provided it complies with Article 30.

Amendment 308
Claudiu Ciprian Tănăsescu

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 only the ***information below. In exceptional cases the applicant, or the competent authority, may request additional text to be included where this is justified to ensure the safe and correct administration of the product.***

Or. en

Amendment 309
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. In addition, the Regulation needs to be able to accommodate future developments in packaging technologies (such as QR codes). All outer packaging text must be consistent with the authorised

information about the product in Article 30 (the "summary of product characteristics"), which is approved by the regulatory authority during the licencing procedure.

Amendment 310
Claudiu Ciprian Tănăsescu

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;	(d) ***a common pictogram*** warning that the veterinary medicinal product is for animal treatment only;

Or. en

Amendment 311
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 systems already in place***;

Or. it

Amendment 312
Piernicola Pedicini, Eleonora Evi, Marco Affronte

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) 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 precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products;

Or. it

Amendment 313
Claudiu Ciprian Tănăsescu

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) 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 ***according to national law***; ***to this end, the European Commission shall develop a harmonised system for collecting these types of products/waste materials at EU level.***

Or. en

Amendment 314
Susanne Melior

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

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

Or. de

Justification

The waiting period between the last instance of the administration of the veterinary medicinal product to an animal and the production of foodstuffs from that animal must not be specified only on the package leaflet.

Amendment 315
Claudiu Ciprian Tănăsescu

Proposal for a regulation
Article 10 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or, where appropriate, abbreviations or pictograms common throughout the Union.	2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or, where appropriate, abbreviations or pictograms common throughout the Union. ***In exceptional cases, the applicant or the competent authority may request additional text to be included where this is justified to ensure the safe and correct administration of the product.***

Or. en

Amendment 316
Françoise Grossetête

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

Text proposed by the Commission	*Amendment*
By way of derogation from Article 9,	By way of derogation from Article 9, small

small immediate packaging units shall contain only the ***following*** information:	immediate packaging units shall contain only the information ***listed below. The applicant may include additional information in accordance with Article 30, if the packaging so permits***:

Or. fr

Justification

There is no reason to place limits on the list of information that should appear on small immediate packaging units of veterinary medicinal products.

Amendment 317
Claudiu Ciprian Tănăsescu

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

Text proposed by the Commission	*Amendment*
By way of derogation from Article 9, small immediate packaging units shall contain only the following ***information:***	By way of derogation from Article 9, small immediate packaging units shall contain only the following ***information. In exceptional cases, the applicant or the competent authority may request additional text to be included where this is justified to ensure the safe and correct administration of the product.***

Or. en

Amendment 318
Eleonora Evi

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

Text proposed by the Commission	*Amendment*
(b) the quantitative particulars of the active substances;	***deleted***

Or. en

Amendment 319
Martin Häusling

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

Text proposed by the Commission	*Amendment*
(b) the quantitative particulars of the active substances;	(b) the quantitative particulars of the active substances***, unless the product exists in only one concentration or the concentration is reflected in the brand name***;

Or. en

Justification

For small containers such as ampoules, the listing of all active substances and concentration can be difficult. Art. 59(2) of the current directive provided the possibility of an exemption. As the quantitative particulars are on the outer packaging and on the package leaflet, it is only necessary to provide them on small containers if the product exists in several concentrations, or if the concentration is not reflected in the brand name.

Amendment 320
Eleonora Evi

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.'***.	(d) the expiry date, in the format: ‘mm/yyyy', preceded by the abbreviation ***"for use by";***

.

Or. en

Amendment 321
Eleonora Evi

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

Text proposed by the Commission	*Amendment*
	(da) (e) route of administration

Or. en

Justification

For small containers such as ampoules, in particular in the case of the frequently used homeopathic combination medicinal products, listing of all active substances and amount contained on the ampoule is normally not feasible due to space limitations. Art. 59 (2) of DIR 2001/82/EC therefore offered a possible exception to this provision. The Human Medicine Directive DIR 2001/83/EC also abstains from requiring the listing of active substance amounts on small containers (ampoules) in Art. 55 (3). Deletion of the quantitative particulars for the active substances is also justified because they are already listed on the outer packaging and in the package leaflet, providing for sufficient labelling. This way of handling the matter in no way affects safe use of the medicinal product, whether human or veterinary. On the other hand, indication of the method of administration on the ampoule, as stipulated to date in Art. 59 (1) of DIR 2001/82/EC and proposed above, is desirable to ensure safe use. Instead of the word "Lot", Batch No." should be used and, instead of the abbreviation "Exp." the words "for use by:".

Amendment 322
Pavel Poc, Susanne Melior

Proposal for a regulation
Article 12 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The package leaflet shall be ***available for*** each veterinary medicinal product and shall contain at least the following information:	1. The package leaflet shall be ***attached to*** each veterinary medicinal product and shall contain at least the following information:

Or. en

Justification

The Regulation shall clearly stipulate, that that the package leaflet shall be supplied together with the veterinary medicinal product in order to make sure that the product user has all relevant information for the safe and efficacious use available.

Amendment 323
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

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

Text proposed by the Commission	*Amendment*
(d) the target species, the dosage for each species, the method and route of administration and advice on correct administration, if necessary;	(d) the target species, the dosage for each species, the method and route of administration and advice on correct administration, if necessary; ***whether it can be used for organically-farmed animals;***

Or. fr

Amendment 324
Piernicola Pedicini, Eleonora Evi, Marco Affronte

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

Text proposed by the Commission	*Amendment*
(j) requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and***, if appropriate, additional*** precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products;	(j) requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products;

Or. it

Amendment 325
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

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

Text proposed by the Commission	*Amendment*
(m) in case of homeopathic veterinary medicinal products, the statement " homeopathic veterinary medicinal product" .	***deleted***

Or. fr

Amendment 326
Iratxe García Pérez, Clara Eugenia Aguilera García

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 composition of veterinary medicinal products are not included like many other health products, food products, etc.

Amendment 327
Susanne Melior

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 regardless of the circumstances and the print should be sufficiently large.

Amendment 328
Martin Häusling

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

Text proposed by the Commission	*Amendment*
(a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the European Pharmacopoeia or, in the absence thereof, of the pharmacopoeias currently used officially in Member States;	(a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the European Pharmacopoeia or, in the absence thereof, of the pharmacopoeias currently used officially in Member States; ***if the homeopathic veterinary medicinal product is composed of more than one stock, the scientific names of the stocks may be supplemented by a brand name in the label;***

Or. en

Justification

The possibility of using a brand name for homeopathic combinations is allowed to date in the current Directive (see Article 64 (2)). Brand names are important to ease communication of a certain homeopathic veterinary medicinal product.

Amendment 329
Eleonora Evi

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

Text proposed by the Commission	*Amendment*
(a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the European Pharmacopoeia or, in the absence thereof,	(a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the European Pharmacopoeia or, in the absence thereof,

of the pharmacopoeias currently used officially in Member States;	of the pharmacopoeias currently used officially in Member States;
	If the homeopathic veterinary medicinal product is composed of more than one stock, the scientific names of the stocks can be supplemented by a brand name in the labelling;

Or. en

Justification

The possibility of using a brand name for homeopathic combinations has been allowed to date in Art. 64 (2), 1st dash of DIR 2001/82/EC. This possibility also continues to be available for human medicines (see Art. 69 (1), 1st dash DIR 2001/83/EC).

Amendment 330
Martin Häusling

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.';	***deleted***

Or. en

Justification

The package leaflet is used for several batches of the same product and is thus independent of a given expiry date. For this reason, the listing of the expiry date on the package insert is pointless and should be abandoned.

Amendment 331
Eleonora Evi

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.';	***deleted***

Or. en

Amendment 332
Claudiu Ciprian Tănăsescu

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

Text proposed by the Commission	*Amendment*
(g) target species;	(g) target species; ***dosage levels for the different target species;***

Or. en

Amendment 333
Martin Häusling

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

Text proposed by the Commission	*Amendment*
(g) target species;	(g) target species***, and the dosage for each species, where applicable***;

Or. en

Justification

Until now, Member States have registered homeopathic veterinary drugs with a fixed dosage. However, dosage may vary between target species, and this should be indicated, as it also the case for conventional veterinary drugs (see Article 12(1d) as well as authorised homeopathic veterinary drugs.

Amendment 334
Eleonora Evi

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

Text proposed by the Commission	*Amendment*
(g) target species;	(g) ***target species and dosage levels for the different*** target species;

Or. en

Amendment 335
Martin Häusling

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

Text proposed by the Commission	*Amendment*
(i) the batch number, preceded by the word 'Lot';	***deleted***

Or. en

Justification

The package leaflet is used for several batches. Listing of the batch number on the package insert is therefore pointless and should be abandoned.

Amendment 336
Eleonora Evi

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

Text proposed by the Commission	*Amendment*
(i) the batch number, preceded by the word 'Lot';	***deleted***

Or. en

Justification

The package leaflet is used for several batches and is thus independent of a given expiry date. For this reason, listing of the expiry date and batch number on the package insert is pointless and should be abandoned.

Amendment 337
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The language or languages of the information on the labelling shall be determined by Member State where the veterinary medicinal product is made available on the market.	1. The language or languages of the information on the labelling shall be determined by ***the*** Member State where the veterinary medicinal product is made available on the market***, with due regard for the rights of linguistic minorities***.

Or. it

Amendment 338
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Proposal for a regulation
Article 14 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Veterinary medicinal products ***may*** be labelled in ***several*** languages.	3. Veterinary medicinal products ***for export shall*** be labelled in ***the*** languages ***of the Member States in which they will be placed on the market***.

Or. it

Amendment 339
Susanne Melior

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 behaviour of residues***. Where it differs significantly in respect of those properties, the applicant shall submit additional information in order to prove the safety and/or efficacy of the various salts, esters or derivatives of the authorised active substance of the reference veterinary medicinal product.

Or. de

Justification

The behaviour of the residues of a veterinary medicinal product has a significant bearing on food safety.

Amendment 340
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 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***	5. ***The clinical information in*** the summary of the product characteristics ***(as 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, that requirement shall not apply to***:***

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.

Or. it

Amendment 341
Giulia Moi

Proposal for a regulation
Article 16 – paragraph 5 – point a (new)

Text proposed by the Commission	*Amendment*
	(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 arrangements for the protection of technical documentation (Articles 33 to 36) at the time when authorisation is granted for the generic veterinary medicinal product or

Or. it

Amendment 342
Giulia Moi

Proposal for a regulation
Article 16 – paragraph 5 – point b (new)

Text proposed by the Commission	*Amendment*
	(b) any subsequent changes to the reference medicinal product.

Or. it

Amendment 343
Iratxe García Pérez, Clara Eugenia Aguilera García, Soledad Cabezón Ruiz

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

For generic applications all efficacy and safety parts of the dossier of the reference product should be assumed once the generic product have demonstrated the bioequivalence. If the competent authority considers that there is a risk for the environment, then he must initiate a referral procedure to clarify the risk of the reference and generic product.

Amendment 344
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***	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 to all the marketing authorisation holders concerned***.

required for the reference veterinary medicinal product.

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 345
Karin Kadenbach

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. ***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, the applicant must*** provide safety data concerning the potential risks posed by the generic veterinary medicinal product to the environment.

Or. de

Amendment 346
Martin Häusling
Martin Häusling

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 application shall contain*** 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 ***30 October 2005*** or in case the second phase environmental risk assessment was required for the reference veterinary medicinal product.

Or. en

Justification

Generics are often used widely, and as such, potentially present a risk to the environment. Environmental risk assessments for veterinary drugs were introduced via Directive 2004/28, which had to be transposed into national law until 30 October 2005. As a result, only products authorized after that date were required to have an environmental risk assessment. Therefore, all generics which relate to a reference product authorized before 30 October 2005, or where a second phase environmental risk assessment was required, should contain a proper environmental risk assessment.

Amendment 347
Claudiu Ciprian Tănăsescu, Matthias Groote

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 that have each already been used in authorised veterinary medicinal products shall satisfy the following criteria:

Or. en

Amendment 348
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 ***one or more of which*** 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. it

Amendment 349
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 ***product*** as referred to in Article 16(1)(b);

Or. it

Amendment 350
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 necessary, appropriate*** documentation on the safety of that combination is provided.

Or. it

Amendment 351
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 referred to in Article 7(1)(b) which is available*** for the reference veterinary medicinal product.	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 documentation ***in respect of*** which he has a ***relevant*** letter of access ***to*** the documentation for the reference veterinary medicinal product.

Or. it

Amendment 352
Karin Kadenbach

Proposal for a regulation
Article 21

Text proposed by the Commission	*Amendment*
Article 21	***deleted***
Reduced data requirements for applications for limited markets	
1. By way of derogation from Article	

7(1)(b), a marketing authorisation for a veterinary medicinal product intended for a limited market shall be granted although the quality and/or efficacy documentation required in accordance with Annex II has not been provided, if all the following conditions are met:

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

(b) the applicant provides the evidence that the veterinary medicinal product is intended for a limited market.

2. By way of derogation from Article 5(2), a marketing authorisation for a limited market shall be granted for a period of 3 years.

3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment of quality and/or efficacy has been conducted due to the lack of comprehensive efficacy and/or quality data.

Or. de

Amendment 353
Claudiu Ciprian Tănăsescu

Proposal for a regulation
Article 21 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. By way of derogation from Article 7(1)(b), ***a marketing authorisation for a veterinary medicinal product intended for a limited market shall be granted although*** the quality and/or efficacy	1. By way of derogation from Article 7(1)(b), ***in exceptional circumstances related to animal or public health, including unmet needs with respect to animal health, where the applicant has***

documentation required in accordance with Annex II ***has not been provided, if all the following conditions are met***:	***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***:

Or. en

Amendment 354
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

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 the animal or public health outweighs the risk inherent in the fact that certain ***information*** has not been provided;

Or. fr

Amendment 355
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

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

Text proposed by the Commission	*Amendment*
(b) the applicant provides the evidence that the veterinary medicinal product is intended for a limited market.	(b) the applicant provides the evidence that the veterinary medicinal product is intended for a limited market***, detailing his sales prospects, in units, over the first five years of sale and the development costs***.

Or. fr

Justification

The exceptional procedure should not be used as a simplified procedure for medicinal products which should be subject to the standard procedure. The procedure must be strictly regulated. Development costs which are exorbitant or which are not amortised over the first five years should alert the examiner as to the actual size of the target market and therefore the appropriateness of the exceptional procedure.

Amendment 356
Ulrike Müller

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 ***5*** years.

Or. de

Justification

Rare animal species or rare diseases create a restricted market which is anyway not properly supplied with veterinary medicinal products. Overly tight time restrictions on authorisation in such cases further reduce the incentives to develop veterinary medicinal products for this area.

Amendment 357
Julie Girling, James Nicholson

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 ***5*** years. ***Following this period it should be renewed and remain valid for an indefinite period unless risks to animal or public health or the environment are***

detected.

Or. en

Justification

3 years is too short to allow for a full assessment of a product's performance; rather, after 5 years a formal re-examination should be conducted to confirm appropriateness of the SmPCs based on the experience of the use of the product in the market. If the competent authority is satisfied , the marketing authorisation should be made indefinite. This should encourage the development, registration and marketing of VMPs for limited markets. This is important as such markets currently lack VMPs.

Amendment 358
Michel Dantin, Angélique Delahaye, Cristian-Silviu Buşoi

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 359
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Article 21 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Member States may ban the use of veterinary medicinal products for limited markets.

Or. fr

Amendment 360
Claudiu Ciprian Tănăsescu

Proposal for a regulation
Article 21 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only ***a limited assessment of*** quality and***/or*** efficacy has been ***conducted due to the lack of comprehensive efficacy and/or quality data***.	3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only ***limited information on its*** quality and efficacy has been ***submitted***.

Or. en

Amendment 361
Martin Häusling

Proposal for a regulation
Article 21 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment of quality and/or efficacy has been conducted due to the lack of comprehensive efficacy and/or quality data.	3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment of quality and/or efficacy has been conducted due to the lack of comprehensive efficacy and/or quality data. ***The packaging shall bear a warning with the same information.***

Or. en

Justification

It should be immediately visible if a product was authorised on the basis of a limited

assessment of quality and/or efficacy.

Amendment 362
Iratxe García Pérez, Clara Eugenia Aguilera García

Proposal for a regulation
Article 21 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. A requirement to notify the competent authorities of any adverse event relating to the use of the veterinary medicinal product.

Or. en

Justification

It is propose to add this paragraph which is similar to the paragraph 1 (b) of art. 22. It is logical to establish a similar system to capture information about any adverse events than in art. 22 because there is a lack of documentation in the application for marketing authorisation.

Amendment 363
Bolesław G. Piecha

Proposal for a regulation
Article 21 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. A veterinary medicinal product that has been granted marketing authorisation in accordance with this article may only be issued on the basis of a prescription.

Or. pl

Amendment 364
Karin Kadenbach

Proposal for a regulation
Article 22

Text proposed by the Commission	*Amendment*
Article 22	***deleted***
Data requirements for applications in exceptional circumstances	
1. By way of derogation from Article 7(1)(b), in exceptional circumstances related to animal or public health, where the applicant has demonstrated that for objective, verifiable reasons he is unable to provide the quality, safety and/or efficacy documentation required in accordance with Part 1, Part 2 and Part 3 of Annex II, a marketing authorisation may be granted subject to any of the following:	
(a) a requirement to introduce conditions or restrictions, in particular concerning the safety of the veterinary medicinal product;	
(b) a requirement to notify the competent authorities of any incident relating to the use of the veterinary medicinal product;	
(c) a requirement to conduct post-authorisation studies.	
2. By way of derogation from Article 5(2), a marketing authorisation in exceptional circumstances shall be granted for a period of 1 year.	
3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment of quality, safety and/or efficacy has been conducted due to the lack of comprehensive quality, safety and/or efficacy data.	

Or. de

Amendment 365
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Proposal for a regulation
Article 22 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) a requirement to introduce conditions or restrictions***, in particular concerning*** the safety of the veterinary medicinal product;	(a) a requirement to introduce conditions or restrictions ***to ensure*** the safety of the veterinary medicinal product ***and that it is only prescribed and supplied by veterinarians***;

Or. fr

Amendment 366
Iratxe García Pérez, Clara Eugenia Aguilera García

Proposal for a regulation
Article 22 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) a requirement to notify the competent authorities of any ***incident*** relating to the use of the veterinary medicinal product***;***	(b) a requirement to notify the competent authorities of any ***adverse event*** relating to the use of the veterinary medicinal product***.***

Or. en

Justification

It is propose to substitute "incident" by "adverse event" to be consistent with the terminology.

Amendment 367
Jan Huitema

Proposal for a regulation
Article 22 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) a requirement to ***conduct*** post-authorisation studies.	(c) a requirement to ***provide further data based on either*** post-authorisation studies ***or on data collected on the performance***

of the product in the field, where data from the field is identified as more appropriate based on benefit-risk assessment.

Or. en

Amendment 368
Julie Girling, James Nicholson

Proposal for a regulation
Article 22 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) a requirement to ***conduct*** post-authorisation studies.	(c) a requirement to ***supply post-authorisation data based on*** post-authorisation studies ***deemed necessary on the basis of risk-benefit assessment, and on data collected from use in the field***.

Or. en

Justification

In exceptional circumstances it is often recognised that some data may not exist. An assessment of the product's performance under field conditions should be taken into account in the risk-benefit assessment and it should be possible to consider these data as part of the data requirements necessary to grant an indefinite renewal.

Amendment 369
Angélique Delahaye, Michel Dantin, Cristian-Silviu Buşoi

Proposal for a regulation
Article 22 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) a requirement to ***conduct*** post-authorisation studies.	(c) a requirement to ***supply post-authorisation data based on*** post-authorisation studies ***identified as necessary on the basis of changes in the benefit-risk balance and on data gathered from the product's use in the field***.

Or. fr

Justification

The use of assessments of product performance in field conditions should be taken into account in the ongoing assessment of the benefit-risk balance in order to reduce the administrative burden and the proliferation of tests, particularly on animals. Furthermore, the use of products in 'real-life' situations can provide important information which laboratory studies cannot always reflect.

Amendment 370
Martin Häusling

Proposal for a regulation
Article 22 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment of quality, safety and/or efficacy has been conducted due to the lack of comprehensive quality, safety and/or efficacy data.	3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment of quality, safety and/or efficacy has been conducted due to the lack of comprehensive quality, safety and/or efficacy data. ***The packaging shall bear a warning with the same information.***

Or. en

Justification

It should be immediately visible if a product was authorised on the basis of a limited assessment of quality and/or efficacy.

Amendment 371
Bolesław G. Piecha

Proposal for a regulation
Article 22 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. A veterinary medicinal product that

has been granted marketing authorisation in accordance with this article may only be issued on the basis of a prescription.

Or. pl

Amendment 372
Pavel Poc

Proposal for a regulation
Article 23 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The competent authority or the ***Agency*** to which the application has been submitted in accordance with Article 6 shall:	1. The competent authority or the ***Committee for Medicinal Products for Veterinary Use set up by Article 139 ("Committee")*** to which the application has been submitted in accordance with Article 6 shall:

Or. en

Justification

The examination of applications is conducted by the Committee for Veterinary Medicinal products and the legislation should be clear on this point. Agency provides a co-ordination and administrative support.

Amendment 373
Martin Häusling

Proposal for a regulation
Article 23 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) assess the veterinary medicinal product regarding the quality, safety and efficacy documentation provided.	(b) assess the veterinary medicinal product ***as such as well as in comparison to the standard reference treatment*** regarding the quality, safety and efficacy documentation provided.

Or. en

Justification

It is important that comparative assessments are conducted so as to ensure maximum quality, safety and efficacy.

Amendment 374
Martin Häusling

Proposal for a regulation
Article 23 – paragraph 2

Text proposed by the Commission	*Amendment*
2. During the process of assessing applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms as referred to in Article 7(5), the necessary consultations shall be held by the Agency with the bodies set up by the Union or Member States in accordance with Directive 2001/18/EC.	***deleted***

Or. en

Justification

There should be no veterinary medicinal products that contain or consist of GMOs.

Amendment 375
Pavel Poc

Proposal for a regulation
Article 23 – paragraph 2

Text proposed by the Commission	*Amendment*
2. During the process of assessing applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms as referred to in Article 7(5), the necessary consultations shall be held by the ***Agency*** with the bodies	2. During the process of assessing applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms as referred to in Article 7(5), the necessary consultations shall be held by the ***Committee*** with the

set up by the Union or Member States in accordance with Directive 2001/18/EC.	bodies set up by the Union or Member States in accordance with Directive 2001/18/EC.

Or. en

Justification

The examination of applications is conducted by the Committee for Veterinary Medicinal products and the legislation should be clear on this point. Agency provides a co-ordination and administrative support.

Amendment 376
Pavel Poc

Proposal for a regulation
Article 24 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The competent authority or the ***Agency*** examining the application may require an applicant to provide samples of the veterinary medicinal product to the Union reference laboratory, an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose to:	1. The competent authority or the ***Committee*** examining the application may require an applicant to provide samples of the veterinary medicinal product to the Union reference laboratory, an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose to:

Or. en

Justification

The examination of applications is conducted by the Committee for Veterinary Medicinal products and the legislation should be clear on this point. Agency provides a co-ordination and administrative support.

Amendment 377
Iratxe García Pérez, Clara Eugenia Aguilera García

Proposal for a regulation
Article 25 – paragraph 1

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,*** 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 manufacturer comply with EU legislation and not only that is able to manufacture and control the product in accordance with the application for marketing authorisation.

Amendment 378
Martin Häusling

Proposal for a regulation
Article 25 – paragraph 1

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 are able to manufacture the veterinary medicinal product concerned and/or carry out control tests in accordance with the methods described in the documentation submitted in support of the application in accordance with Article 7(1) ***and that they minimize environmental pollution***.

Or. en

Justification

A significant part of pharmaceuticals consumed in the EU is produced in third countries.

Production of pharmaceuticals in these countries is often linked to major pollution of the local environment. It is important that competent authorities ascertain that producers in third countries minimize environmental pollution.

Amendment 379
Pavel Poc

Proposal for a regulation
Article 26 – paragraph 1

Text proposed by the Commission	*Amendment*
The competent authority or the ***Agency*** to which the application has been submitted in accordance with Article 6 shall inform the applicant if the documentation submitted in support of the application is insufficient. The competent authority or the ***Agency*** shall request the applicant to provide the documentation within a given deadline. In such case the time limits laid down in Articles 40, 44, 46 and 48 shall be suspended until the deadline has elapsed.	The competent authority or the ***Committee*** to which the application has been submitted in accordance with Article 6 shall inform the applicant if the documentation submitted in support of the application is insufficient. The competent authority or the ***Committee*** shall request the applicant to provide the documentation within a given deadline. In such case the time limits laid down in Articles 40, 44, 46 and 48 shall be suspended until the deadline has elapsed.

Or. en

Justification

The examination of applications is conducted by the Committee for Veterinary Medicinal products and the legislation should be clear on this point. Agency provides a co-ordination and administrative support.

Amendment 380
Pavel Poc

Proposal for a regulation
Article 28 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. ***In case of favourable assessment*** to grant a marketing authorisation, the competent authority or the ***Agency*** examining the application shall prepare an	1. ***If conditions*** to grant a marketing authorisation ***according to this Regulation have been met for the application concerned***, the competent authority or the

opinion including the following documents:	***Committee*** examining the application shall prepare an opinion including the following documents:

Or. en

Justification

„Favourable assessment“ is not a defined term. The legal text has to be clear as to the terms where the authorisation can be granted. The purpose of this amendment is to provide high level of certainty and predictability to both the applicants and the regulators.

Amendment 381
Martin Häusling

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.	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.

Or. en

Justification

For antimicrobial veterinary medicines, there should always be post-authorisation studies to ensure that the benefit-risk balance remains positive .

Amendment 382
Nessa Childers

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.	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.

Or. en

Amendment 383
Karin Kadenbach

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. The following veterinary medicinal products ***shall be*** subject to veterinary prescription:

Or. de

Amendment 384
Biljana Borzan

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 or the Commission shall classify the following veterinary medicinal products as subject to ***mandatory*** veterinary prescription:

Or. en

Amendment 385
Pavel Poc, Susanne Melior

Proposal for a regulation
Article 29 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Member States may on their territories provide for additional legal subcategories in accordance with the respective national legislation.

Or. en

Justification

Legal subcategories exist in several Member States and they are of high importance in terms of ensuring safety of veterinary medicinal products as they serve as important risk mitigation measures (through regulation of distribution / retail supply, conditions for use and certain other means).

Amendment 386
Pavel Poc, Susanne Melior

Proposal for a regulation
Article 29 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. Where the veterinary medicinal product authorised under Article 38 is classified as not subject to veterinary prescription, the Member State may, in order to safeguard animal health or welfare, public health or the environment, classify such product as subject to veterinary prescription in accordance with the respective national legislation.

Or. en

Justification

The current system which does not make it possible to have different legal categories for centrally authorised products leads to a situation where the decision on the legal classification follows the Member States which apply the most stringent rules justified by the specific conditions in those Member States. This may impose unnecessary restrictions on those Member States whose conditions allow less stringent risk mitigation measures (legal classification). The proposed provision shall introduce required level of flexibility for the veterinary medicinal product and help to fit better the adopted risk mitigation measures to the real risks, considering specific conditions in the relevant Member States.

Amendment 387
Karin Kadenbach

Proposal for a regulation
Article 29 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. ***A competent authority or the Commission may classify*** a veterinary medicinal product as subject to veterinary prescription where special precautions are contained in the summary of product characteristics referred to in Article 30, and in particular potential risks to:	2. A veterinary medicinal product ***shall be classified*** as subject to veterinary prescription where special precautions are contained in the summary of product characteristics referred to in Article 30, and in particular potential risks to:

Or. de

Amendment 388
Biljana Borzan

Proposal for a regulation
Article 29 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. A competent authority or the Commission may classify a veterinary medicinal product as subject to veterinary prescription where special precautions are contained in the summary of product characteristics referred to in Article 30, and in particular potential risks to:	2. A competent authority or the Commission may classify a veterinary medicinal product as subject to ***mandatory*** veterinary prescription where special precautions are contained in the summary of product characteristics referred to in Article 30, and in particular potential risks

to:

Or. en

Amendment 389
Karin Kadenbach

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. A competent authority or the Agency may classify a veterinary medicinal product as ***not*** subject to veterinary prescription if ***paragraphs 1 and 2 do not apply and*** all of the following conditions are fulfilled:

Or. de

Amendment 390
Eleonora Evi

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. By the way of derogation from paragraph 1, a competent authority or the Agency ***shall*** classify a veterinary medicinal product as ***not*** subject to veterinary prescription if all of the following conditions are fulfilled:

Or. en

Amendment 391
Pavel Poc

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. By the way of derogation from paragraph 1, a competent authority or the ***Commission*** may not classify a veterinary medicinal product as subject to veterinary prescription if all of the following conditions are fulfilled:

Or. en

Justification

In Article 29, Paragraph 1 and Paragraph 2 correctly provide that the classification in terms of requirement for a veterinary prescription is responsibility of the competent authority or the Commission, while in Paragraph 3, the Agency is mentioned. For the sake of consistency and clarity, Commission shall be mentioned in all provision under 29, where centrally authorized products are concerned.

Amendment 392
Biljana Borzan

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. By the way of derogation from paragraph 1, a competent authority or the Agency may not classify a veterinary medicinal product as subject to ***mandatory*** veterinary prescription if all of the following conditions are fulfilled:

Or. en

Amendment 393
Eleonora Evi

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

Text proposed by the Commission	*Amendment*
(a) the administration of the veterinary medicinal product is restricted to pharmaceutical forms requiring no particular knowledge or skill in using the products;	(a) the administration of the veterinary medicinal product is restricted to pharmaceutical forms requiring no particular knowledge or skill in using the products ***(e.g. s.c. injection)***;

Or. en