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Committee on the Environment, Public Health and Food Safety

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DRAFT REPORT

on the proposal for a regulation of the European Parliament and of the Council on veterinary medicinal products
(COM(2014)0558 – C8-0164/2014 – 2014/0257(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Françoise Grossetête

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Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council on veterinary medicinal products
(COM(2014)0558 – C8-0164/2014 – 2014/0257(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2014)0558),

– having regard to Article 294(2) and Articles 114 and 168(4)(b) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0164/2014)

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 21 January 2015[1],

– having regard to the opinion of the Committee of the Regions of ...[2],

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A8-0000/2015),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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[1] OJ C 0, 0.0.0000, p. 0. / Not yet published in the Official Journal.
[2] OJ C 0, 0.0.0000, p. 0. / Not yet published in the Official Journal.

Amendment 1

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. At the same time, in order to ensure the widest possible availability of veterinary medicinal products in the Union, the centralised authorisation procedure should be extended to allow for applications for authorisations under that procedure to be submitted for any veterinary medicinal product, including for generics of nationally authorised veterinary medicinal products. ***The use of the centralised procedure should be encouraged in every way, in particular by facilitating access for SMEs.***

Or. fr

Justification

With a view to one day achieving a single centralised procedure, barriers (economic, regulatory, etc.) impeding access to the procedure need to be identified and removed.

Amendment 2

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(27) It is recognised that the potential effect of a product on the environment may depend on the volume used and the resulting amount of the pharmaceutical substance that may reach the environment. Therefore, where there is evidence that a constituent of a medicinal product for which a generic application for a marketing authorisation is submitted is a hazard for the environment, it is appropriate to require data on the potential effect on the environment in order to safeguard the environment. In such cases applicants should endeavour to join efforts in generating such data in order to reduce costs and to reduce testing on vertebrate animals.	(27) It is recognised that the potential effect of a product on the environment may depend on the volume used and the resulting amount of the pharmaceutical substance that may reach the environment. Therefore, where there is evidence that a constituent of a medicinal product for which a generic application for a marketing authorisation is submitted is a hazard for the environment, it is appropriate to require data on the potential effect on the environment in order to safeguard the environment. In such cases applicants should endeavour to join efforts in generating such data in order to reduce costs and to reduce testing on vertebrate animals. ***The 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 decentralised assessment of the environmental properties of active substances for veterinary use by means of a monograph system could be an interesting alternative. The Commission should therefore submit a report to Parliament and the Council as soon as possible.***

Or. fr

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 3

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 animal, or, in exceptional cases, in the light of continuous health checks on the animal***.

Or. fr

Justification

The notion of animals 'under their care' is unclear and needs clarifying to ensure that antibiotics are only sold by professionals authorised to prescribe them.

Amendment 4

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 ***only*** non-prescription veterinary medicinal products via the Internet to buyers in other Member States.

Or. fr

Justification

Online sales of veterinary medicines that are only available on prescription are extremely difficult to monitor and could therefore pose a danger to public health. They should therefore be prohibited.

Amendment 5

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 ***the online sale of prescription veterinary medicinal products should be prohibited.*** Member States may impose conditions for supplying medicinal products to the public within the limits of the Treaty.

Or. fr

Justification

Online sales of veterinary medicines that are only available on prescription are extremely difficult to monitor and could therefore pose a danger to public health. They should therefore be prohibited.

Amendment 6

Proposal for a regulation
Recital 73

Text proposed by the Commission	*Amendment*
(73) In order to protect public health, animal health and the environment, the activities and tasks attributed to the Agency in this Regulation should be adequately funded. Those activities, services and tasks should be funded through fees charged to enterprises. Those fees, however, should not affect the right of Member States to charge fees for activities and tasks at national level.	(73) In order to protect public health, animal health and the environment, the activities and tasks attributed to the Agency in this Regulation should be adequately funded. Those activities, services and tasks***, including the establishment of new IT services with the aim of reducing bureaucracy,*** should be funded through fees charged to enterprises ***and through an increased financial contribution from the Commission***. Those fees, however, should not affect the right of Member States to charge fees for activities and tasks at national level.

Or. fr

Justification

The agency will be given new tasks under this regulation, including the setting-up of

centralised databases. The agency needs to have the means necessary to carry out its tasks effectively.

Amendment 7

Proposal for a regulation
Article 3 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. In cases of doubt where, taking into account all its characteristics, a product may fall within the definition of a 'veterinary medicinal product' within the meaning of Article 4(1), and within the definition of a product covered by other Union legislation, the provisions of this Regulation shall prevail.

Or. fr

Justification

The aim of this amendment is to ensure that the Veterinary Medicinal Products Regulation prevails where there is doubt over the status of a product, as provided for in Directive 2001/82/EC for all categories of regulated products.

Amendment 8

Proposal for a regulation
Article 4 – point 3

Text proposed by the Commission	*Amendment*
(3) 'immunological veterinary medicinal product' means a veterinary medicinal product ***consisting of*** vaccines, toxins, sera or allergen products ***and*** intended to be administered to an animal in order to produce active or passive immunity or to diagnose its state of immunity;	(3) 'immunological veterinary medicinal product' means a veterinary medicinal product ***such as*** vaccines, toxins, sera or allergen products intended to be administered to an animal in order to produce active or passive immunity or to diagnose its state of immunity;

Or. fr

Justification

The European Medicines Agency takes the view that it is neither useful nor desirable to restrict the definition to vaccines, toxins, sera and allergens alone, given that new kinds of immunological products are being developed all the time.

Amendment 9

Proposal for a regulation
Article 4 – 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***, cats, salmon*** and ***sheep reared for their meat***;

Or. fr

Justification

For the sake of consistency, the European Medicines Agency takes the view that salmon, as well as sheep destined for human consumption (unlike ewes reared for their milk) should be deemed to be major species.

Amendment 10

Proposal for a regulation
Article 4 – 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 professional person qualified to do so in accordance with applicable national law***, once a veterinary diagnosis has been established following a clinical examination of the animal or in***

the light of continuous health checks on the animal;

Or. fr

Justification

The notion of animals 'under their care' is unclear and needs clarifying to ensure that antibiotics are only sold by professionals authorised to prescribe them.

Amendment 11

Proposal for a regulation
Article 4 – 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 ***necessary*** between the last administration of a veterinary medicinal product to an animal ***under normal conditions of use,*** and the production of foodstuffs from that animal***, for the purpose of ensuring*** that such foodstuffs do not contain residues in quantities ***greater than the maximum limits established under Regulation (EC) No 470/2009 of the European Parliament and of the Council***[1a];

[1a] 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).

Or. fr

Justification

The existing definition, which explicitly refers to the maximum residue limits laid down in Regulation (EC) No 470/2009, is more suitable. The relationship between the withdrawal period and the maximum residue limits needs to be made clear.

Amendment 12

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

Text proposed by the Commission	*Amendment*
	(27a) 'antimicrobial' means any compound with a direct action on micro-organisms that is used for treatment or prevention of infections. Antimicrobials include anti-bacterials/antibiotics, anti-virals, anti-fungals and antiprotozoals;

Or. fr

Justification

A number of key terms have not been defined by the Commission and need to be clarified in order to avoid confusion and ensure that they are used properly in connection with this proposal.

Amendment 13

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

Text proposed by the Commission	*Amendment*
	(27b) 'antibiotic' is synonymous with 'antibacterial';

Or. fr

Justification

A number of key terms have not been defined by the Commission and need to be clarified in order to avoid confusion and ensure that they are used properly in connection with this proposal.

Amendment 14

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

Text proposed by the Commission	*Amendment*
	(27c) 'curative (therapeutic) treatment' means treatment of an ill animal or group of animals, when the diagnosis of disease or infection has been made;

Or. fr

Justification

A number of key terms have not been defined by the Commission and need to be clarified in order to avoid confusion and ensure that they are used properly in connection with this proposal.

Amendment 15

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

Text proposed by the Commission	*Amendment*
	(27d) 'control treatment (metaphylaxis)' means treatment of a group of animals, after a diagnosis of a clinical disease in part of the group has been made, with the aim of treating the clinically sick animals and controlling the spread of disease to animals in close contact and at risk or which may already be (sub-clinically) infected;;

Or. fr

Justification

A number of key terms have not been defined by the Commission and need to be clarified in order to avoid confusion and ensure that they are used properly in connection with this proposal.

Amendment 16

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

Text proposed by the Commission	*Amendment*
	(27e) 'preventive treatment (prophylaxis)' means treatment of an animal or a group of animals before clinical signs of disease emerge, in order to prevent the occurrence of disease or infection;

Or. fr

Justification

A number of key terms have not been defined by the Commission and need to be clarified in order to avoid confusion and ensure that they are used properly in connection with this proposal.

Amendment 17

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

Text proposed by the Commission	*Amendment*
	(27f) 'parallel importation' means the importation into a Member State of a veterinary medicinal product authorised in another Member State in accordance with this Regulation and having the same characteristics as the veterinary medicinal

product authorised in the Member State of import, in particular with:

(a) the same qualitative and quantitative composition in terms of active substances and excipients and the same pharmaceutical form;

(b) the same therapeutic indications and target species.

The medicinal product authorised in the Member State and the product imported in parallel must have been either harmonised under Article 69 or 70 or authorised in accordance with Articles 46 and 48.

Or. fr

Justification

A number of key terms have not been defined by the Commission and need to be clarified in order to avoid confusion and ensure that they are used properly in connection with this proposal.

Amendment 18

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

Text proposed by the Commission	*Amendment*
	(27g) 'parallel distribution' means distribution from one Member State to another of a veterinary medicinal product authorised under a centralised procedure by an establishment authorised as referred to in Article 105 which is independent of the holder of the marketing authorisation.

Or. fr

Justification

A number of key terms have not been defined by the Commission and need to be clarified in order to avoid confusion and ensure that they are used properly in connection with this proposal.

Amendment 19

Proposal for a regulation
Article 5 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. If, after receiving marketing authorisation, a veterinary medicinal product is not marketed in the Member States concerned within five years, the authorisation shall lapse.

Or. fr

Justification

This amendment makes it possible to uphold the principle that a marketing authorisation should lapse, with the aim of preventing a product from being marketed several years after its authorisation without any updating of the file in the light of new scientific findings and technical developments. However, a derogation from this time lapse principle is permitted for the purpose of protecting human or animal health.

Amendment 20

Proposal for a regulation
Article 5 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. The competent authority may, in exceptional circumstances, and on grounds of the protection of human or animal health, grant exemptions from paragraph 4a.

Or. fr

Justification

This amendment makes it possible to uphold the principle that a marketing authorisation should lapse, with the aim of preventing a product from being marketed several years after its authorisation without any updating of the file in the light of new scientific findings and technical developments. However, a derogation from this time lapse principle is permitted for the purpose of protecting human or animal health.

Amendment 21

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.

Or. fr

Justification

In order to reduce administrative burden, the use of different formats should be avoided and it should be possible to standardise all applications and submit them through a single electronic portal.

Amendment 22

Proposal for a regulation
Article 8 – paragraph 2

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. ***Member States shall not permit test animals to be used as a source of foodstuffs for human consumption unless the competent authorities have established an appropriate withdrawal period. Such***

	period shall either :
(a) ***the tested product is a veterinary medicinal product authorised for the food-producing species used in the clinical trial, and the withdrawal period set out in the summary of the product characteristics is respected, or***	(a) ***be at least as long as the withdrawal period laid down in Article 117, including, where appropriate, a safety factor reflecting the nature of the substance being tested; or***
(b) ***the tested product is an authorised veterinary medicinal product for target species other than the food-producing species used in the clinical trial and the withdrawal period set out in accordance with Article 117 is respected.***	(b) ***if maximum residue limits have been established by the Union in accordance with Regulation (EC) No 470/2009, the period shall be such as to ensure that those residue limits will not be exceeded in foodstuffs.***

Or. en

Justification

Prohibiting animals which have been used in clinical trials from entering the food chain could have a very serious impact on the economic balance of clinical research. Animals which have received medicines that contain a substance to which a maximum residue limit already applies and for which a waiting time can be set should be permitted to enter the food chain.

Amendment 23

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, although, if the packaging so permits, additional information in accordance with Article 30 may also be included***:

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 24

Proposal for a regulation
Article 9 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The items of information listed in paragraph 1(c) and (f) shall appear in machine-readable format.

Or. fr

Amendment 25

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, although, if the packaging so permits, additional information in accordance with Article 30 may also be included***:

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 warning that the veterinary medicinal product is for animal treatment only seems pointless, and can be replaced by a common logo. Lastly, the take-back schemes established for disposal of unused veterinary medicinal products or waste materials derived from them differ from one country to another and cannot be described in detail on the outer packaging of a product.

Amendment 26

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

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

Or. 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 warning that the veterinary medicinal product is for animal treatment only seems pointless, and can be replaced by a common logo. Lastly, the take-back schemes established for disposal of unused veterinary medicinal products or waste materials derived from them differ from one country to another and cannot be described in detail on the outer packaging of a product.

Amendment 27

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 regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products;***	(f) ***the precautions to be taken with regard to*** the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, ***a reference to the take-back schemes established for these particular cases;***

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 warning that the veterinary medicinal product is for animal treatment only seems pointless, and can be replaced by a common logo. Lastly, the take-back schemes established for disposal of unused veterinary medicinal products or waste materials derived from them differ from one country to another and cannot be described in detail on the outer packaging of a product.

Amendment 28

Proposal for a regulation
Article 10 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The information listed in Article 9(1)(c) and (f) must appear in a machine-readable format.

Or. fr

Amendment 29

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 information ***listed below while, if the packaging allows, additional information under Article 30 may also be included***:

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 30

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) ***the precautions to take concerning*** the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, ***a reference to the take-back schemes for these specific cases***

Or. fr

Justification

The take-back schemes for veterinary medicinal products concerning the disposal of unused veterinary medicinal products or waste materials differ from one country to another and cannot therefore be described in detail on the package leaflet. A simple reference will suffice.

Amendment 31

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***	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 ***where there are serious and established reasons to believe that the authorisation of the generic product may pose greater risks to the environment than***

environmental risk assessment was required for the reference veterinary medicinal product.	***does the original product***.

Or. fr

Justification

The environmental risks associated with a generic medicinal product are generally the same as those associated with the original product. This means that no re-evaluation is necessary. It should nevertheless remain an option for the authorities where there are serious and established reasons to believe that the generic product may pose greater problems that its originator.

Amendment 32

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. fr

Justification

The fact that a product is intended for a limited market means that it will be seldom used. A period of three years will therefore only enable limited understanding to be accumulated for use in assessing the way it behaves on the market. The time period should thus be increased.

Amendment 33

Proposal for a regulation
Article 21 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where a medicinal product has been	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***.	granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only limited ***information on its efficacy has been submitted***.

Or. fr

Justification

In the interests of transparency vis-a-vis the user, the summary of product characteristics (SPC) must explicitly state that certain information was not included in the product assessment.

Amendment 34

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
2. ***By way of derogation from Article 5(2),*** a marketing authorisation ***in exceptional circumstances shall be granted for a period of 1 year***.	2. ***Renewal of*** a marketing authorisation ***granted pursuant to paragraph 1 shall be tied to an annual review of the conditions set out in that paragraph, until the conditions are fulfilled.***

Or. fr

Justification

The European Medicines Agency considers a period of validity of one year to be too short, and that a thorough review of the marketing authorisation, with the attendant heavy bureaucratic burden, would not encourage use of the 'exceptional circumstances' procedure. The Agency considers that an annual review of the conditions set out in Article 22(1) would be enough to ensure that marketing authorisation holders are meeting their obligations.

Amendment 35

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

Text proposed by the Commission	*Amendment*
	3a. The competent authority or the Commission may at any time grant a valid marketing authorisation for an unlimited period of time, provided that no safety or efficacy problems have been reported with the product in use and the marketing authorisation holder has supplied the missing quality, safety and efficacy information set out in paragraph 1.

Or. fr

Justification

Once the applicant has supplied all the missing studies, the marketing authorisation should become permanent, like any other authorisation.

Amendment 36

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

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

Or. fr

Justification

Consistency of terminology (need to establish a causal link between the product and the adverse event (i.e. the reaction)).

Amendment 37

Proposal for a regulation
Article 32 – paragraph 2

Text proposed by the Commission	*Amendment*
2. A marketing authorisation for an antimicrobial veterinary medicinal product shall be refused if the antimicrobial is reserved for treatment of certain infections in humans.	2. A marketing authorisation for an antimicrobial veterinary medicinal product shall be refused if the antimicrobial is reserved for treatment of certain infections in humans ***within the meaning of paragraph 4***.

Or. fr

Amendment 38

Proposal for a regulation
Article 32 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to establish rules for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of certain active substances in humans.	3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to establish rules for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of certain active substances in humans. ***The Commission shall, when establishing these rules, draw on the scientific opinions of the Agency, not least in respect of species of animals, indications and routes of administration.***

Or. fr

Justification

In order for these restrictions to be effective, they must be purely science-based and must take due account of the recommendations made by the European Medicines Agency.

Amendment 39

Proposal for a regulation
Article 32 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	4. Commission shall, by means of implementing acts ***and drawing on the scientific recommendations made by the Agency***, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, ***in accordance with the rules under paragraph 3***. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Or. fr

Justification

In order for these restrictions to be effective, they must be purely science-based and must take due account of the recommendations made by the European Medicines Agency.

Amendment 40

Proposal for a regulation
Article 33 – paragraph 3

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

Or. fr

Justification

The amendment excludes antimicrobial medicinal products from the scope of the general marketing authorisation. This will promote research and innovation in the field of antibiotics, and laboratories will be encouraged to develop more effective treatments or ones that enable a reduction in the amount of the medicinal product used.

Amendment 41

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

Text proposed by the Commission	*Amendment*
(b) ***14*** years for antimicrobial veterinary medicinal products for cattle, sheep, pigs, chickens, dogs and cats containing an antimicrobial active substance which has not been an active substance in a veterinary medicinal product authorised within the Union on the date of the submission of the application;	(b) ***18*** years for antimicrobial veterinary medicinal products for cattle, sheep ***reared for meat***, pigs, chickens, ***salmon,*** dogs and cats containing an antimicrobial active substance which has not been an active substance in a veterinary medicinal product authorised within the Union on the date of the submission of the application;

Or. fr

Justification

The period of the protection of technical documentation on antimicrobial veterinary medicinal products should be increased in order to encourage research and innovation in the field of antibiotics.

Amendment 42

Proposal for a regulation
Article 34 a (new)

Text proposed by the Commission	*Amendment*
	Article 34a
	Period of the protection of new technical documentation for existing products
	Any new studies and trials submitted by

the holder of a marketing authorisation to the competent authorities shall have a period of protection of five years, provided that they are:

(a) needed to extend a marketing authorisation in respect of species, dosages, pharmaceutical forms, routes of administration or presentation, or

(b) needed for a re-evaluation requested by the Agency or the competent authorities post-authorisation.

No other applicant may use those trials or studies for that five-year period without the written consent of the holder of the marketing authorisation in the form of a letter of access to those trials or studies.

Or. fr

Justification

The impact assessment by the Commission and the agency heads recognises the need to better protect technical documentation in order to stimulate innovation. The non-cumulative protection of new studies and trials conducted post-authorisation should trigger the development and improvement of existing products, be they originators or already generics.

Amendment 43

Proposal for a regulation
Article 35 – paragraph 1

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

Or. fr

Justification

The extension of only one year for major species is insufficient. It should be increased to two years, in order to encourage research and innovation and thus promote the availability of veterinary medicinal products.

Amendment 44

Proposal for a regulation
Article 38 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Centralised marketing authorisations shall be granted by the Commission in accordance with this Section. They shall be valid throughout the Union.	1. Centralised marketing authorisations shall be granted by the Commission in accordance with this Section. They shall be valid throughout the Union. ***The Commission and the Agency shall develop and encourage use of the centralised procedure, particularly by facilitating access for SMEs.***

Or. fr

Justification

In order ultimately to move towards a single centralised procedure, barriers (economic, regulatory, etc.) to access to this procedure must be identified and tackled.

Amendment 45

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

Text proposed by the Commission	*Amendment*
(c) veterinary medicinal products containing an active substance which has not been authorised as a veterinary medicinal product within the Union at the	(c) veterinary medicinal products containing an active substance which has not been authorised as a veterinary medicinal product within the Union at the

date of the submission of the application;	date of the submission of the application***, with the exception of veterinary medicinal products subject to authorisation under Articles 21 and 22***;

Or. fr

Justification

It is not desirable to make it compulsory to use the centralised procedure in the case of products intended for limited markets or authorised in exceptional circumstances, as these products are by definition not intended for marketing throughout the EU.

Amendment 46

Proposal for a regulation
Article 38 – paragraph 3

Text proposed by the Commission	*Amendment*
3. For veterinary medicinal products other than those listed in paragraph 2 a centralised marketing authorisation may be granted ***if no other marketing authorisation has been granted for the veterinary medicinal product within the Union***.	3. For veterinary medicinal products other than those listed in paragraph 2 a centralised marketing authorisation may ***also*** be granted.

Or. fr

Justification

This qualification is needless and will not encourage greater use of the centralised procedure, which ought however to be more widely accessible in order ultimately to promote the establishment of a genuine single market in veterinary medicinal products.

Amendment 47

Proposal for a regulation
Article 49 – paragraph 6

Text proposed by the Commission	*Amendment*
6. In the event of an unfavourable opinion, ***the marketing authorisation shall be refused by each Member State concerned within 30 days of acknowledgement of the agreement. The scientific conclusions and grounds for revocation of the marketing authorisation shall be annexed to the unfavourable opinion.***	6. In the event of an unfavourable opinion, ***the rapporteur shall inform the Agency of his concern for purposes of the application of the procedure laid down in Article 85 when the interests of the Union are at stake. In other cases, the opinion shall be forwarded to the Commission without delay.*** ***The Commission may request any information from the rapporteur concerning the substance of his opinion. The rapporteur shall forward his outline reply to the Commission within 90 days of receiving its request.*** ***Within 15 days of receipt of the opinion, the Commission shall prepare a draft of the decision associated with the procedure.*** ***If the draft decision proposes that marketing authorisation be granted, the draft shall include or refer to the documents listed in Article 28.*** ***Where the draft decision proposes that marketing authorisation be refused, the grounds for refusal shall be stated in accordance with Article 32.*** ***Where the draft decision does not accord with the rapporteur's opinion, the Commission shall attach detailed explanations of the grounds for these differences.*** ***The draft decision shall be forwarded to Member States and the applicant.*** ***The Commission may, by means of implementing acts, take a final decision on the granting of a marketing authorisation under the decentralised or mutual recognition procedure. Those implementing acts shall be adopted in accordance with the examination***

	procedure referred to in Article 145(2).
	The Agency shall forward to the applicant the documents provided for by Article 28.
	The Agency shall make the opinion publicly available, after deleting any commercially confidential information.

Or. fr

Justification

The coordination group does not have the legitimacy to act as a decision-maker. Its proposals must be considered under the commitology procedure involving the standing committee referred to in Article 145. The decision must be taken at EU level and must be binding on Member States.

Amendment 48

Proposal for a regulation
Article 50 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***The re-examination procedure shall deal only with the points of the assessment report identified by the applicant in the written notice.***	3. ***The committee shall define the scope of the examination, taking into account the information supplied by the applicant.***

Or. fr

Justification

The scope of the review must be defined by the Committee for Medicinal Products for Veterinary Use (CMPVU), as no other body can legitimately take a scientific decision on the matter.

Amendment 49

Proposal for a regulation
Article 50 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Within 15 days of its adoption, the Agency shall forward the opinion of the Committee to the ***coordination group***, together with a report describing the assessment of the veterinary medicinal product by the Committee and stating the reasons for its conclusions. Those documents shall be forwarded ***to the Commission,*** to Member States and to the applicant for information purposes.	4. Within 15 days of its adoption, the Agency shall forward the opinion of the Committee to the ***Commission***, together with a report describing the assessment of the veterinary medicinal product by the Committee and stating the reasons for its conclusions. Those documents shall be forwarded to Member States and to the applicant for information purposes.

Or. fr

Justification

The scope of the examination must be defined by the Committee for Medicinal Products for Veterinary Use (CMPVU), as no other body can legitimately take a scientific decision on the matter.

Amendment 50

Proposal for a regulation
Article 50 – paragraph 5

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

documents listed in Article 28.

Where the draft decision proposes that marketing authorisation be refused, the grounds for refusal shall be stated in accordance with Article 32.

Where the draft decision does not accord with the committee's opinion, the Commission shall attach detailed explanations of the grounds for these differences.

The Commission may, by means of implementing acts, take a final decision on the granting of a marketing authorisation under the decentralised or mutual recognition procedure. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

The Agency shall forward to the applicant the documents provided for by Article 28.

The Agency shall make the opinion publicly available, after deleting any commercially confidential information.

Or. fr

Justification

The scope of the review must be defined by the Committee for Medicinal Products for Veterinary Use (CMPVU), as no other body can legitimately take a scientific decision on the matter.

Amendment 51

Proposal for a regulation
Article 51 – paragraph 8 a (new)

Text proposed by the Commission	*Amendment*
	8a. Within 24 months of the date of entry into force of this regulation, the Commission shall submit a report to the

European Parliament and the Council on the desirability and possible details of the creation of an environmental monograph system for the active substance to assess the environmental impact of veterinary medicinal products, accompanied, if necessary, by a legislative proposal.

Or. fr

Justification

In order to avoid repetitive and potentially divergent assessments of the environmental properties of substances, the establishment of a single decentralised assessment of them by means of a monograph system seems to be a possible solution. In view of the practical difficulties involved in implementing such a system, the Commission is asked to draw up specific proposals on the subject.

Amendment 52

Proposal for a regulation
Section 2 a (new)

Text proposed by the Commission	*Amendment*
	Section 2a
	Imports, parallel imports and parallel distribution

Or. fr

Justification

Articles 115 and 116 provide for the possibility of using veterinary medicinal products authorised in other Member States without applying for import permits, as is required in order to introduce a veterinary medicinal product into a Member State where it is not authorised. It is therefore desirable to provide for, and to harmonise, parallel importation and parallel distribution in the EU Member States.

Amendment 53

Proposal for a regulation
Article 56 a (new)

Text proposed by the Commission	*Amendment*
	Article 56a
	Import authorisations
	1. An authorisation shall be required for the following actions:
	(a) the importation of veterinary medicinal products used in the context of Articles 8, 115(1)(a)(ii), 116(1)(b), 116(2)(b) and 116(3)(a) by a veterinarian or by any person authorised to deliver veterinary medicinal products in the Member States;
	(b) the parallel importation of veterinary medicinal products by a manufacturer or distributor authorised in a Member State, independently of the holder of the marketing authorisation. The imported veterinary medicinal product and the national reference medicinal product shall have:
	(i) the same qualitative and quantitative composition in terms of active substances and excipients, and the same pharmaceutical form;
	(ii) the same therapeutic effects and the same target species.
	The national reference medicinal product and the veterinary medicinal product imported in parallel must have been harmonised under Article 69 or 70, or authorised in accordance with Articles 46 and 48;
	(c) the parallel distribution of veterinary medicinal products by a distributor independently of the holder of the marketing authorisation.

2. Applications for authorisation for these activities shall be submitted to the national authorities responsible for authorisation as referred to in paragraph 1(a) and (b), and to the Authorisations Agency referred to in paragraph 1(c).

The competent authorities and the Agency shall register the authorisation of parallel importation or parallel distribution that they have granted in the database on veterinary medicinal products established under Article 51.

3. The veterinary medicinal product imported in parallel or distributed in parallel shall be marketed in the packaging and with labelling in the language stipulated by each Member State of importation or distribution.

4. By way of derogation from paragraph 1 of this article, the authorisation shall not be required for:

(a) the importation of veterinary medicinal products by a veterinarian service-provider in accordance with Article 114;

(b) the transportation by a holder of a pet animal of veterinary medicinal products required for its treatment other than immunological medicines and within the limit of three months of treatment.

Or. fr

Justification

Articles 115 and 116 provide for the possibility of using veterinary medicinal products authorised in other Member States without applying for import permits, as is required in order to introduce a veterinary medicinal product into a Member State where it is not authorised. It is therefore desirable to provide for, and to harmonise, parallel importation and parallel distribution in the EU Member States.

Amendment 54

Proposal for a regulation
Article 56 b (new)

Text proposed by the Commission	*Amendment*
	Article 56b
	Import authorisation applications
	1. Import authorisation applications as referred to in Article 56a(1)(a) shall be submitted to the competent authority of the Member State of the importer. These authorisations shall be granted for a single operation.
	Any change in the information submitted in order to obtain authorisation shall be notified to the competent authority, which shall accordingly alter the initial authorisation if necessary.
	An import authorisation application shall, at the minimum, contain:
	(a) the name of the veterinary medicinal product, its strength, its pharmaceutical form and its therapeutic indications;
	(b) the Member State of origin and details of the marketing authorisation;
	(c) details of the distributor responsible for the sale of the product;
	(d) the quantities imported.
	2. Import authorisation applications as referred to in Article 56a(1)(b) shall be submitted to the competent authority of the Member State of the importer.
	These authorisations shall be granted for a period of five years.
	Any change in the information submitted in order to obtain authorisation shall be notified to the competent authority, which shall accordingly alter the initial authorisation if necessary.

A parallel import authorisation application shall, at the minimum, contain the following information:

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

(b) details of the imported veterinary medicinal product and of the medicinal product authorised in the Member State of importation, and details of the nature of the relabelling;

(c) the name or company name of the applicant;

(d) the name or company name or logo of the holder of the marketing authorisation or the number of the marketing authorisation of the reference product and of the imported product;

(e) details of the manufacturing site where the veterinary medicinal products are to be relabelled;

(f) the name of the qualified person responsible for pharmacovigilance;

(g) a declaration that the applicant is independent of the holder of the marketing authorisation.

3. Import authorisation applications as referred to in Article 56a(1)(c) shall be submitted to the Agency.

These authorisations shall be granted for a period of five years.
Any change in the information submitted in order to obtain authorisation shall be notified to the Agency, which shall accordingly alter the initial authorisation if necessary.

The application shall contain information concerning:

(a) the name or company name of the applicant, of the manufacturer involved in relabelling, and the parallel distributor;

(b) the name of the qualified person responsible for pharmacovigilance;

(c) the Member State of origin and destination.

4. The competent authority or the Agency may suspend or withdraw parallel import or parallel distribution authorisations if the provisions of Article 56a and of paragraphs 1, 2 and 3 of this article are no longer complied with or if the product presents a risk to human or animal health or the environment.

Or. fr

Justification

Articles 115 and 116 provide for the possibility of using veterinary medicinal products authorised in other Member States without applying for import permits, as is required in order to introduce a veterinary medicinal product into a Member State where it is not authorised. It is therefore desirable to provide for, and to harmonise, parallel importation and parallel distribution in the EU Member States.

Amendment 55

Proposal for a regulation
Article 68 – paragraph 1

Text proposed by the Commission	*Amendment*
1. A harmonised summary of product characteristics shall be prepared in accordance with the procedure laid down in Article 69 for veterinary medicinal products, other than homeopathic veterinary medicinal products, which have the same qualitative and quantitative composition of their active substances and the same pharmaceutical form and for which national marketing authorisations have been granted in different Member States before 1 January 2004 ('similar products').	1. A harmonised summary of product characteristics shall be prepared in accordance with the procedure laid down in Article 69 for ***groups of similar*** veterinary medicinal products, other than homeopathic veterinary medicinal products, which have the same qualitative and quantitative composition of their active substances and the same pharmaceutical form and for which national marketing authorisations have been granted in different Member States before 1 January 2004 ('similar products').

Or. fr

Justification

Consistency of terminology used.

Amendment 56

Proposal for a regulation
Article 69 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Within 120 days of his appointment, the rapporteur shall present the coordination group a report ***regarding possible*** harmonisation of ***summaries of product characteristics for the*** similar veterinary medicinal products ***in the group and propose a harmonised summary of products characteristics***.	3. Within 120 days of his appointment, the rapporteur shall present the coordination group a report ***proposing*** harmonisation of ***the conditions governing the use of the group of*** similar veterinary medicinal products.

Or. fr

Justification

Harmonisation of the summaries of product characteristics(SPCs) is considered to be necessary. However, harmonisation by class would pose a serious problem in terms of competition, to the detriment of SMEs in particular, which do not have the resources to stand up to competition based solely on product prices.

Amendment 57

Proposal for a regulation
Article 69 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. Harmonised ***summaries of product characteristics for veterinary medicinal products*** shall contain ***all of*** the following information:	4. Harmonised ***conditions of use*** shall contain ***at least*** the following information:

Or. fr

Justification

All therapeutic indications for preventive use in the conditions governing the use of antimicrobial medicinal products must be prohibited when the medicinal products are harmonised (b). Moreover, (c), withdrawal periods which enable consumers to be as well protected as possible should be established, without merely referring to the shortest withdrawal period.

Amendment 58

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

Text proposed by the Commission	*Amendment*
(b) all therapeutic indications mentioned in the marketing authorisations granted by Member States in respect of the similar products in the group;	(b) all therapeutic indications ***and dosages*** mentioned in the marketing authorisations granted by Member States in respect of the similar products in the group***, except for indications regarding the prophylactic use of antimicrobials***;

Or. fr

Justification

All therapeutic indications for preventive use in the conditions governing the use of antimicrobial medicinal products must be prohibited when the medicinal products are harmonised (b). Moreover, (c), withdrawal periods which enable consumers to be as well protected as possible should be established, without merely referring to the shortest withdrawal period.

Amendment 59

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

Text proposed by the Commission	*Amendment*
(c) ***the shortest*** withdrawal period ***of those***	(c) ***a*** withdrawal period ***which ensures that***

stated in the summaries of the product characteristics.	***consumers are adequately protected***.

Or. fr

Justification

All therapeutic indications for preventive use in the conditions governing the use of antimicrobial medicinal products must be prohibited when the medicinal products are harmonised (b). Moreover, (c), withdrawal periods which enable consumers to be as well protected as possible should be established, without merely referring to the shortest withdrawal period.

Amendment 60

Proposal for a regulation
Article 69 – paragraph 6

Text proposed by the Commission	*Amendment*
6. In the event of an opinion in favour of adopting a ***harmonised summary of the product characteristics***, each Member State shall vary ***a*** marketing ***authorisation*** in conformity with the agreement within 30 days of receipt of the information regarding the agreement from the rapporteur.	6. In the event of an opinion in favour of adopting a ***harmonisation of conditions of use***, each Member State shall vary ***the*** marketing ***authorisations of the products in their territory so that the elements listed in paragraph 4, where they are already included in the summaries of characteristics for a product belonging to that group, are*** in conformity with the agreement within 30 days of receipt of the information regarding the agreement from the rapporteur.

Or. fr

Justification

Harmonisation of conditions of use would initially appear to be more feasible and realistic than harmonisation of SPCs by class and would make for healthy competition between companies.

Amendment 61

Proposal for a regulation
Article 70 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. By way of derogation from Article 69, antimicrobial veterinary medicinal products shall be reassessed within five years of the entry into force of this Regulation.

Or. fr

Justification

Older products have an increased risk of developing antibiotic resistance when used. The harmonisation of SPCs for antimicrobial medicinal products must therefore be a priority.

Amendment 62

Proposal for a regulation
Article 70 – paragraph 4

Text proposed by the Commission	*Amendment*
4. For the purposes of paragraphs 1 ***and*** 3, the procedure for a Union interest referral in accordance with Articles 84 to 87 shall apply accordingly.	4. For the purposes of paragraphs 1**,** 3 ***and 3a***, the procedure for a Union interest referral in accordance with Articles 84 to 87 shall apply accordingly.

Or. fr

Justification

Older products have an increased risk of developing antibiotic resistance when used. The harmonisation of SPCs for antimicrobial medicinal products must therefore be a priority.

Amendment 63

Proposal for a regulation
Article 71

Text proposed by the Commission	*Amendment*
Upon request from the coordination group or the Agency, holders of ***the*** marketing authorisations ***for products included in a group of similar products identified for a harmonisation of the summaries of the product characteristics*** shall submit information concerning their products.	Upon request from the coordination group or the Agency, holders of marketing authorisations shall submit information concerning their products***, including a proposal for harmonisation of the summaries of the product characteristics for their medicines which belong to the group***.

Or. fr

Justification

Experience has shown that a proposal by each holder of a marketing authorisation concerning harmonisation of SPCs for their products belonging to the same group of similar products is an effective starting point for a harmonisation exercise.

Amendment 64

Proposal for a regulation
Article 74 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Agency shall establish and maintain a Union database on pharmacovigilance of veterinary medicinal products (the " pharmacovigilance database ").	1. The Agency shall establish and maintain a Union database on pharmacovigilance of veterinary medicinal products (the "pharmacovigilance database")***, linked to the database on veterinary medicinal products***. ***The Union database on veterinary medicinal products shall be the only data entry point for adverse events reported by the holders of marketing authorisations.***

Or. fr

Justification

To avoid any overlapping and multiplication of procedures at Member State level, it is necessary to ensure that the Union database replaces national databases.

Amendment 65

Proposal for a regulation
Article 75 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Health professionals shall have access to the pharmacovigilance database as regards the following information:
	(a) the number of adverse events reported each year, broken down by product, animal species and type of adverse event;
	(b) previous declarations made concerning the same product and the number of cases per species in the previous six months;
	(c) information on the results of the signal detection system for veterinary medicinal products and groups of products.

Or. fr

Justification

Animal health professionals, in particular veterinary surgeons, should be more closely linked to the functioning of the pharmacovigilance database and should be able to obtain better information on any further action that is taken in response to their alerts, so that the latter can be genuinely useful.

Amendment 66

Proposal for a regulation
Article 77 a (new)

Text proposed by the Commission	*Amendment*
	Article 77a
	Single master file
	The organisation of the pharmacovigilance operations conducted by marketing authorisation holders shall be described in a single master file, which shall be subject to authorisation by the Member States. The single evaluation procedures for these authorisations shall be defined by the Member States and the resulting decisions shall be recognised throughout the Union.
	The competent authority shall issue a decision on this authorisation within 90 days of the receipt of a complete application.
	The single master file shall be addressed to the competent authority of the Member State in which the qualified person designated by the authorisation holder conducts the operations described in this file. The competent authority concerned shall notify its decision to the authorisation holder and shall record it in the Union database on veterinary medicinal products together with a copy of the relevant single master file.
	The authorisation holder shall also submit to the competent authority any substantive changes to his single master file.

Or. fr

Justification

This amendment seeks to regulate the concept of master file by connecting it to a single authorisation. This authorisation will be based on the information described in the file, which will first be evaluated by the Member States, separately from the procedures for authorising medicinal products. As is the case for manufacturers and distributors, any failure on the part of the authorisation holder and his or her qualified person to comply with their obligations

may be punished by a suspension or withdrawal of the authorisation in question.

Amendment 67

Proposal for a regulation
Article 78 – point b

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

Or. fr

Justification

Clarification of the wording.

Amendment 68

Proposal for a regulation
Article 81 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. To support the signal management process referred to in paragraph 1, marketing authorisation holders shall submit periodic safety update reports on a regular basis during the first three years after the product is placed on the market. The periodic nature of these reports shall be defined by the Commission in accordance with the guidelines laid down in EudraLex - Volume 9.

Or. fr

Justification

The draft regulation no longer refers to 'periodic safety update reports'. However, these reports are essential in terms of health and safety. The proposed amendment thus reintroduces these reports by focusing them on the product's first few years of life, which are the riskiest. The aim of reducing the administrative burden is thus taken into account, while maintaining a satisfactory level of health and safety.

Amendment 69

Proposal for a regulation
Article 82 – paragraph 1

Text proposed by the Commission	*Amendment*
Before the expiry of the period of validity of ***3*** years, marketing authorisations for a limited market granted in accordance with Article 21 shall be re-examined on application from the marketing authorisation holder. After the initial re-examination, it shall be re-examined every 5 years.	Before the expiry of the period of validity of ***5*** years, marketing authorisations for a limited market granted in accordance with Article 21 shall be re-examined on application from the marketing authorisation holder. After the initial re-examination, it shall be re-examined***, if necessary,*** every 5 years.

Or. fr

Justification

The product is intended for a limited market which means that usage thereof will be low. Consequently only limited knowledge can be accumulated within 3 years to assess product behaviour on the market correctly, and so the period of validity needs to be made longer.

Amendment 70

Proposal for a regulation
Article 83

Text proposed by the Commission	*Amendment*
Article 83	***deleted***
Procedure for re-examination of a marketing authorisation in exceptional	

	circumstances
1. Before the expiry of the period of validity of 1 year, marketing authorisations granted in accordance with Article 22 shall be re-examined on application from the marketing authorisation holder.	
2. The application for re-examination shall be submitted to the competent authority that granted the authorisation or the Agency at least 3 months before the expiry of the marketing authorisation.	
3. When an application for re-examination has been submitted, the marketing authorisation shall remain valid until a decision on the application has been adopted by the competent authority or the Commission.	
4. The competent authority or the Commission may at any time grant a marketing authorisation valid for an unlimited period of time, provided that the marketing authorisation holder submits the missing comprehensive safety and efficacy data referred to in Article 22(1).	

Or. fr

Justification

Article 83 no longer appears to be necessary in view of the changes and clarifications applied to Article 22.

Amendment 71

Proposal for a regulation
Article 98 –point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) comply with the principles and the guidelines on good manufacturing practice for medicinal products and use as

	starting materials only active substances which have been manufactured in accordance with the detailed guidelines on good manufacturing practice for starting materials;

Or. fr

Justification

Compliance with good manufacturing practice for veterinary medicinal products and the use of starting materials which have been manufactured in accordance with the latter need to be made binding. Proper enforcement of these requirements will ensure veterinary medicinal products are subject to the same quality standards throughout the European Union, thus guaranteeing that they are efficacious and do not cause harm.

Amendment 72

Proposal for a regulation
Article 104 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***Supplies of small quantities of veterinary medicinal products from one retailer to another shall not be regarded as wholesale distribution.***	3. ***The purchase, sale, import or export of veterinary medicinal products or any other kind of commercial transaction concerning these medicinal products, whether for profit or not for profit, shall be subject to the possession of a wholesale distribution authorisation for veterinary medicinal products. Said authorisation shall not apply to the supply, by a manufacturer, of veterinary medicinal products which it has itself manufactured, nor to the retail sale of veterinary medicinal products by persons entitled to conduct such sales in accordance with Article 107.***

Or. fr

Justification

The principle according to which wholesale distribution authorisations are valid throughout the whole of the European Union must be accompanied by genuine harmonisation, as exists already for medicinal products for human use, of the conditions under which said veterinary medicinal products are distributed by wholesalers.

Amendment 73

Proposal for a regulation
Article 104 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Wholesalers shall comply with the principles and guidelines on good practice for wholesale distribution of veterinary medicinal products.

Or. fr

Justification

The principle according to which wholesale distribution authorisations are valid throughout the whole of the European Union must be accompanied by genuine harmonisation, as exists already for medicinal products for human use, of the conditions under which said veterinary medicinal products are distributed by wholesalers.

Amendment 74

Proposal for a regulation
Article 104 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. Wholesalers shall only obtain their supplies of medicinal products from the manufacturer, from a person designated by the holder of the marketing authorisation or from persons who themselves hold a wholesale distribution authorisation.

Or. fr

Justification

The principle according to which wholesale distribution authorisations are valid throughout the whole of the European Union must be accompanied by genuine harmonisation, as exists already for medicinal products for human use, of the conditions under which said veterinary medicinal products are distributed by wholesalers.

Amendment 75

Proposal for a regulation
Article 104 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. Wholesalers shall comply with the obligations laid down in Article 105(3)(d) and (e) in regard to supply of medicinal products.

Or. fr

Justification

The principle according to which wholesale distribution authorisations are valid throughout the whole of the European Union must be accompanied by genuine harmonisation, as exists already for medicinal products for human use, of the conditions under which said veterinary medicinal products are distributed by wholesalers.

Amendment 76

Proposal for a regulation
Article 105 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) has at his disposal technically competent staff and suitable and sufficient premises complying with the requirements laid down by the Member State concerned as regards the storage and handling of	(a) has at his disposal technically competent staff and suitable and sufficient premises complying with the requirements laid down by the Member State concerned as regards the storage and handling of

veterinary medicinal products;	veterinary medicinal products***, and which representatives of the competent authority may enter at any time***;

Or. fr

Justification

Under the proposal for a regulation, wholesale distribution authorisations become valid throughout the European Union. This principle must be accompanied by harmonisation of the public service obligations applying to veterinary wholesalers, as is the case already for medicinal products for human use. The purpose of these obligations is to ensure optimum availability of veterinary medicinal products, justified on grounds of protection of public and animal health.

Amendment 77

Proposal for a regulation
Article 105 – paragraph 3 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) concerning the supply of medicinal products to persons permitted to carry out retail activities in the Member State in accordance with Article 107(1), he shall guarantee permanently an adequate range of medicinal products to meet the requirements of the territory he is supplying and to deliver the supplies requested within a very short time over the whole of the territory in question;

Or. fr

Justification

Under the proposal for a regulation, wholesale distribution authorisations become valid throughout the European Union. This principle must be accompanied by harmonisation of the public service obligations applying to veterinary wholesalers, as is the case already for medicinal products for human use. The purpose of these obligations is to ensure optimum availability of veterinary medicinal products, justified on grounds of protection of public and animal health.

Amendment 78

Proposal for a regulation
Article 105 – paragraph 3 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) he shall, within the limits of his responsibility, ensure appropriate and continued supplies of medicinal products to persons authorised to carry out retail activities in the Member State in accordance with Article 107(1) so that animal health needs in the Member State in question are covered;

Or. fr

Justification

Under the proposal for a regulation, wholesale distribution authorisations become valid throughout the European Union. This principle must be accompanied by harmonisation of the public service obligations applying to veterinary wholesalers, as is the case already for medicinal products for human use. The purpose of these obligations is to ensure optimum availability of veterinary medicinal products, justified on grounds of protection of public and animal health.

Amendment 79

Proposal for a regulation
Article 105 – paragraph 3 – point c c (new)

Text proposed by the Commission	*Amendment*
	(cc) he shall notify the competent authority of any shortage of stock likely to be detrimental to animal health needs in the Member State in question;

Or. fr

Justification

Under the proposal for a regulation, wholesale distribution authorisations become valid throughout the European Union. This principle must be accompanied by harmonisation of the public service obligations applying to veterinary wholesalers, as is the case already for medicinal products for human use. The purpose of these obligations is to ensure optimum availability of veterinary medicinal products, justified on grounds of protection of public and animal health.

Amendment 80

Proposal for a regulation
Article 106 a (new)

Text proposed by the Commission	*Amendment*
	Article 106a
	Qualified persons
	1. The holder of a wholesale distribution authorisation shall make permanent and continuous use of the services of at least one qualified person satisfying the conditions set out in this Article, who shall be responsible, in particular, for performing the task specified in Article 104.
	2. Qualified persons shall hold a diploma, certificate, or any other form of proof serving to demonstrate that they are properly qualified and have acquired sufficient experience of wholesale distribution. The holder of the authorisation may himself assume the responsibility referred to in paragraph 1, if he personally fulfils those conditions as specified above.
	3. The competent authority shall ensure that the obligations of qualified persons referred to in this Article are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct. The competent authority

may temporarily suspend such persons upon the commencement of administrative or disciplinary proceedings against them for failure to fulfil their obligations.

Or. fr

Justification

If the guiding principle is to be that wholesale distribution authorisations will be valid throughout the EU, the related responsibilities must, by the same token, be harmonised. This implies a need to establish a specific status for persons 'qualified' to engage in wholesale distribution and lay down the basic theoretical and practical training requirements which such persons will have to meet.

Amendment 81

Proposal for a regulation
Article 107 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Persons qualified to prescribe veterinary medicinal products in accordance with applicable national law shall retail antimicrobial products only for animals which are under their care, and only in the amount required for the treatment concerned.	2. Persons qualified to prescribe veterinary medicinal products in accordance with applicable national law shall retail antimicrobial products only for animals which are under their care, ***subject to a veterinary diagnosis based on clinical examination of the animal concerned or, exceptionally, permanent monitoring of its health,*** and only in the amount required for the treatment concerned.

Or. fr

Justification

It is not clear what is meant by animals 'under their care', and the term should therefore be clarified so as to make for the best possible regulation of sales of antibiotics by professionals entitled to prescribe them.

Amendment 82

Proposal for a regulation
Article 107 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. Retailers of veterinary medicinal products shall keep detailed records of the following information in respect of each purchase and sale of veterinary medicinal products:	3. Retailers of veterinary medicinal products shall keep detailed records of the following information in respect of each purchase and sale of veterinary medicinal products ***obtainable only on prescription***:

Or. fr

Justification

When veterinary medicinal products can be bought and sold over the counter, the obligation of keeping records might be considered too sweeping unless it were justified on public health grounds. Member States are best placed to decide whether the supply of non-prescription medicines should be documented.

Amendment 83

Proposal for a regulation
Article 107 – paragraph 3 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Where they consider it necessary, Member States may require that the obligation to keep the above records likewise apply to the purchase and sale of non-prescription veterinary medicinal products.

Or. fr

Justification

When veterinary medicinal products can be bought and sold over the counter, the obligation of keeping records might be considered too sweeping unless it were justified on public health grounds. Member States are best placed to decide whether the supply of non-prescription medicines should be documented.

Amendment 84

Proposal for a regulation
Article 108 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Persons permitted to supply veterinary medicinal products in accordance with Article 107(1) may offer veterinary medicinal products by means of information society services ***in*** the meaning of Directive 98/34/EC of the European Parliament and of the Council[28] to natural or legal persons established in the Union under the condition that ***those medicinal products comply with the legislation of the destination Member State***.	1. Persons permitted to supply veterinary medicinal products in accordance with Article 107(1) may offer veterinary medicinal products ***not subject to veterinary prescription as referred to in Article 29*** by means of information society services ***within*** the meaning of Directive 98/34/EC of the European Parliament and of the Council[28] to natural or legal persons established in the Union under the condition that***:***
[28]Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).	[28]Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).

Or. fr

Justification

Online sales of prescription medicines, including antibiotics, pose a major risk to both public and animal health and must therefore be prohibited. Possible circumvention of the rules and the oversight to be brought to bear on online sales entail dangers and difficulties that cannot be ignored.

Amendment 85

Proposal for a regulation
Article 108 – paragraph 1 – point a (new)

Text proposed by the Commission	*Amendment*
	(a) the natural or legal person offering veterinary medicinal products is permitted or qualified to supply non-prescription veterinary medicinal products to the public, including at a distance, in accordance with the national legislation of the Member State in which that person is established;

Or. fr

Justification

The purpose of this amendment is to allow Member States to set up an authorisation system in order to supervise online distributors of veterinary medicinal products, thereby also making it easier to inspect premises used to store such products. The above provision is modelled on the EU code on medicinal products for human use.

Amendment 86

Proposal for a regulation
Article 108 – paragraph 1 – point b (new)

Text proposed by the Commission	*Amendment*
	(b) the person referred to in point (a) has notified at least the following information to the Member State of establishment:
	(i) the name or corporate name and the permanent address of the place of business from where the veterinary medicinal products are supplied;
	(ii) the date on which veterinary medicinal products were first offered for sale at a distance to the public by means of information society services;
	(iii) the address of the website used for that purpose and all information necessary to identify that website;

Or. fr

Justification

The purpose of this amendment is to allow Member States to set up an authorisation system in order to supervise online distributors of veterinary medicinal products, thereby also making it easier to inspect premises used to store such products. The above provision is modelled on the EU code on medicinal products for human use.

Amendment 87

Proposal for a regulation
Article 108 – paragraph 1 – point c (new)

Text proposed by the Commission	*Amendment*
	(c) the veterinary medicinal products comply with the legislation of the destination Member State.

Or. fr

Justification

The purpose of this amendment is to allow Member States to set up an authorisation system in order to supervise online distributors of veterinary medicinal products, thereby also making it easier to inspect premises used to store such products. The above provision is modelled on the EU code on medicinal products for human use.

Amendment 88

Proposal for a regulation
Article 108 – paragraph 2 - introductory part

Text proposed by the Commission	*Amendment*
2. In addition to the information requirements set out in Article 6 of ***the*** Directive 2000/31/EC of the European Parliament and of the Council[29], websites offering veterinary medicinal products shall contain at least:	2. In addition to the information requirements set out in Article 6 of Directive 2000/31/EC of the European Parliament and of the Council[29] ***and Article 6 of Directive 2011/83/EU of the European Parliament and of the***

***Council*[29a], websites offering veterinary medicinal products shall contain at least:**

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

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

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

Or. fr

Justification

Online transactions involving non-prescription medicines have to comply with the rules on distance selling contracts between professionals and consumers.

Amendment 89

Proposal for a regulation
Article 108 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. Member States shall take the measures necessary to ensure that persons other than those referred to in paragraph 1 offering veterinary medicinal products for sale at a distance to the public by means of information society services and operating on their territory are subject to effective, proportionate, and dissuasive

penalties.

Or. fr

Justification

Member States must have the power to punish persons illegally selling veterinary medicinal products online. The proposal as it stands does not allow for the consequences of illegal trade in these products. This amendment too is modelled on the EU code on medicinal products for human use.

Amendment 90

Proposal for a regulation
Article 109 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Only manufacturers, wholesale distributors and retailers authorised ***specifically*** to do so in accordance with applicable national law shall be allowed to supply and purchase veterinary medicinal products which have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties or substances which may be used as veterinary medicinal products having those properties.	1. Only manufacturers, wholesale distributors and retailers authorised to do so in accordance with applicable national law shall be allowed to supply and purchase veterinary medicinal products which have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties or substances which may be used as veterinary medicinal products having those properties.

Or. fr

Justification

Pharmacists are entitled to dispense medicines in the categories listed above, and that right is recognised in all European countries. Given that they are permitted, as a matter of course, to supply such medicines for human use, it would make no sense if they were required to obtain special authorisation for the same types of products when these were intended for animals.

Amendment 91

Proposal for a regulation
Article 110 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) name of the prescribed product;	(f) ***active substance and*** name of the prescribed product;

Or. fr

Amendment 92

Proposal for a regulation
Article 110 – paragraph 1 – point l

Text proposed by the Commission	*Amendment*
(l) any necessary warnings;	(l) any necessary warnings ***and restrictions***;

Or. fr

Amendment 93

Proposal for a regulation
Article 110 – paragraph 1 – point m a (new)

Text proposed by the Commission	*Amendment*
	(ma) period of validity of prescription;

Or. fr

Amendment 94

Proposal for a regulation
Article 110 – paragraph 1 – point m b (new)

Text proposed by the Commission	*Amendment*
	(mb) batch number, if necessary;

Or. fr

Amendment 95

Proposal for a regulation
Article 110 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where a veterinary medicinal product is supplied on prescription, the quantity prescribed and supplied shall be restricted to the amount required for the treatment or therapy concerned.	3. Where a veterinary medicinal product is supplied on prescription, the quantity prescribed and supplied shall be restricted to the amount required for the treatment or therapy concerned. ***The maximum quantity of veterinary medicinal products supplied at one time may not, however, exceed one month's treatment. Veterinary medicinal products supplied in packaging which allows treatment to be administered over a period of more than one month may be supplied for that period, up to a limit of three months.***

Or. fr

Justification

In order to avoid the misuse of veterinary medicinal products and enhance compliance with prescriptions, the quantity which may be supplied at one time should be limited.

Amendment 96

Proposal for a regulation
Article 110 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. In the exceptional circumstances provided for in Articles 115 and 116, the veterinary prescriptions must not be recognised in a cross-border context.

Or. fr

Justification

In cases where there is no medicinal product authorised in a Member State to treat an animal, the Regulation authorises, by way of exception, the use of other types of medicinal product, for example medicinal products for human use. In such cases, cross-border recognition of veterinary prescriptions should be prohibited. In a cross-border context, the exceptional circumstances justifying the prescription cannot be clearly verified and there is a serious risk of abuse.

Amendment 97

Proposal for a regulation
Article 111 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Antibiotic veterinary medicinal products must not be used on food-producing animals for prophylactic purposes, unless there is a high risk of infection. They must not under any circumstances be used to improve performance or compensate for poor animal husbandry.

Or. fr

Justification

The draft regulation on medicated feed prohibits the preventive use of antimicrobials. The two regulations should be made consistent with each other.

Amendment 98

Proposal for a regulation
Article 115 – paragraph 1

Text proposed by the Commission	*Amendment*
1. By way of derogation from Article 111, where there is no authorised veterinary medicinal product in a Member State for a condition affecting a non-food producing animal, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animal concerned with the following:	1. By way of derogation from Article 111, where there is no authorised veterinary medicinal product in a Member State for a condition affecting a non-food producing animal, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animal concerned with the following:
(a) a medicinal product:	(a) a medicinal product:
(i) a veterinary medicinal product authorised under this Regulation in the Member State concerned for use with another animal species, or for another condition in the same species;	(i) a veterinary medicinal product authorised under this Regulation in the Member State concerned for use with another animal species, or for another condition in the same species;
(ii) a veterinary medicinal product authorised under this Regulation in another Member State for use in the same species or in another species, for the same condition or for another condition;	(ii) a veterinary medicinal product authorised under this Regulation in another Member State for use in the same species or in another species, for the same condition or for another condition;
(iii) a medicinal product for human use authorised in the Member State concerned in accordance with Directive 2001/83/EC of the European Parliament and of the Council[30] or Regulation (EC) No 726/2004;	
(b) if there is no product as referred to in point (a), a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription by a person authorised to do so under national legislation.	(b) if there is no product as referred to in point (a):
	(i) a medicinal product for human use authorised in the Member State concerned in accordance with Directive 2001/83/EC of the European Parliament

	and of the Council[30] or Regulation (EC) No 726/2004;
	(ii) a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription by a person authorised to do so under national legislation.
[30]Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).	[30] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Or. fr

Justification

Although veterinarians have the prime responsible for what they prescribe, the off-label veterinary use of human-use medicinal products should only be considered as a last resort, if no other authorised veterinary medicinal product exists.

Amendment 99

Proposal for a regulation
Article 116 – paragraph 1

Text proposed by the Commission	*Amendment*
1. By way of derogation from Article 111, where there is no authorised veterinary medicinal product in a Member State for a condition affecting a food-producing animal of a non-aquatic species, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animal concerned with any of the following:	1. By way of derogation from Article 111, where there is no authorised veterinary medicinal product in a Member State for a condition affecting a food-producing animal of a non-aquatic species, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animal concerned with any of the following:
(a) a veterinary medicinal product authorised under this Regulation in the Member State concerned for use with another food-producing animal species, or	(a) a veterinary medicinal product authorised under this Regulation in the Member State concerned for use with another food-producing animal species, or

for another condition in the same species;	for another condition in the same species;
(b) a veterinary medicinal product authorised under this Regulation in another Member State for use in the same species or in another food-producing species for the same condition or for another condition;	(b) a veterinary medicinal product authorised under this Regulation in another Member State for use in the same species or in another food-producing species for the same condition or for another condition;
(c) a medicinal product for human use authorised in the Member State concerned in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004. or	
(d) if there is no product as referred to in point (a), a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription by a person authorised to do so under national legislation.	***(c)*** if there is no product as referred to in point (a):
	(i) a medicinal product for human use authorised in the Member State concerned in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004; or
	(ii) a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription issued by a person authorised to do so under national legislation.

Or. fr

Justification

Although veterinarians have the prime responsible for what they prescribe, the off-label veterinary use of human-use medicinal products should only be considered as a last resort, if no other authorised veterinary medicinal product exists.

Amendment 100

Proposal for a regulation
Article 116 – paragraph 3

Text proposed by the Commission	*Amendment*
3. By way of derogation from paragraph 2, and until an implementing act referred to in paragraph 4 is established, if there is no product as referred to in subparagraphs (a) and (b) of paragraph 2, a veterinarian may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat food-producing animals of an aquatic species on a particular holding with:	3. By way of derogation from paragraph 2, and until an implementing act referred to in paragraph 4 is established, if there is no product as referred to in subparagraphs (a) and (b) of paragraph 2, a veterinarian may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat food-producing animals of an aquatic species on a particular holding with:
(a) a veterinary medicinal product authorised under this Regulation in the Member State concerned or in another Member State for use with a food-producing non-aquatic species;	(a) a veterinary medicinal product authorised under this Regulation in the Member State concerned or in another Member State for use with a food-producing non-aquatic species; ***or***
(b) a medicinal product for human use authorised in the Member State concerned in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004.	(b) ***if there is no product as referred to in point (a),*** a medicinal product for human use authorised in the Member State concerned in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004.

Or. fr

Justification

Although veterinarians have the prime responsible for what they prescribe, the off-label veterinary use of human-use medicinal products should only be considered as a last resort, if no other authorised veterinary medicinal product exists.

Amendment 101

Proposal for a regulation
Article 116 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Pharmacologically active substances included in the medicinal product used in accordance with paragraph 1 shall be listed in Table 1 of the Annex to Regulation (EU)	6. Pharmacologically active substances included in the medicinal product used in accordance with paragraph 1 ***and paragraph 3(b)*** shall be listed in Table 1 of

No 37/2010. The veterinarian shall specify an appropriate withdrawal period in accordance with Article 117.	the Annex to Regulation (EU) No 37/2010. The veterinarian shall specify an appropriate withdrawal period in accordance with Article 117.

Or. fr

Justification

All of the substances making up the composition of a medicinal product administered to a food-producing animal must have a withdrawal period to guarantee consumer protection. This requirement also applies to the administration of medicinal products for human use to aquatic species as provided for in point 3(b) of this article.

Amendment 102

Proposal for a regulation
Article 118 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
2. The Commission may, by means of implementing acts in accordance with the examination procedure referred to in Article 145(2), and taking into consideration scientific advice of the Agency, establish a list of antimicrobial ***medicinal products*** that cannot be used in accordance with paragraph 1, or which can only be used for treatment in accordance with paragraph 1 subject to certain conditions.	2. The Commission may, by means of implementing acts in accordance with the examination procedure referred to in Article 145(2), and taking into consideration scientific advice of the Agency, establish a list of antimicrobial ***substances or groups of substances*** that cannot be used in accordance with paragraph 1, or which can only be used for treatment in accordance with paragraph 1 subject to certain conditions.

Or. fr

Justification

Establishing and maintaining a list of medicinal products represents a considerable administrative burden and is not necessarily the best way to avoid the off-label use of antibiotics. An approach based on substances or groups of substances is easier for implementing harmonised rules within the European Union restricting the use of certain antibiotics.

Amendment 103

Proposal for a regulation
Article 118 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Third countries whose legislation authorises the use of antimicrobial medicinal products on the list referred to in paragraph 2 under different conditions from those laid down in that paragraph may not appear on any of the lists of third countries provided for under Community legislation from which Member States are authorised to import farm or aquaculture animals or meat or products obtained from such animals.

Or. fr

Justification

Introduces the concept of reciprocity so that prohibitions or restrictions applying to antimicrobials in Europe are also applicable to sectors producing animals or food of animal origin for import into the EU.

Amendment 104

Proposal for a regulation
Article 118 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. Member States shall also prohibit the importation from third countries on any of the lists referred to in paragraph 2a of:
	(a) farm or aquaculture animals to which substances on the list referred to in paragraph 2 have been administered, unless those substances were administered in compliance with the conditions laid down in paragraph 1;

	(b) meat or products obtained from animals the importation of which is prohibited under point (a) of this paragraph.

Or. fr

Justification

Introduces the concept of reciprocity so that prohibitions or restrictions applying to antimicrobials in Europe are also applicable to sectors producing animals or food of animal origin for import into the EU.

Amendment 105

Proposal for a regulation
Article 124 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The prohibition laid down in paragraph 1 shall not apply to advertising to persons permitted to prescribe or supply veterinary medicinal products.	2. The prohibition set out in paragraph 1 shall not apply***:***
	(a) to advertising to persons permitted to prescribe or supply veterinary medicinal products;
	(b) to advertising concerning immunological veterinary products to the owners of animals for consumption.

Or. fr

Justification

The possibility of informing farmers about the availability of certain vaccines should encourage prevention and make it possible to avoid the occurrence of certain diseases and consequently the use of antibiotics.

Amendment 106

Proposal for a regulation
Article 132 a (new)

Text proposed by the Commission	*Amendment*
	Article 132a
	Suspending and withdrawing wholesale distribution authorisations
	In cases of non-compliance with the requirements laid down in Articles 104, 105 and 106, the competent authority may:
	(a) suspend the wholesale distribution of the veterinary medicinal products;
	(b) suspend the authorisation for wholesale distribution of a category of veterinary medicinal products;
	(c) withdraw the authorisation for wholesale distribution of a category, or all categories, of veterinary medicinal products.

Or. fr

Justification

Penalties should be laid down for wholesale distributers who fail to comply with their obligations.

EXPLANATORY STATEMENT

In September 2014 the Commission published its new draft regulation on veterinary medicinal products. The draft regulation is a total overhaul of the existing rules on medicinal products for veterinary use set out in Directive 2001/82/EC and Regulation EC 726/2004. It will govern the authorisation, manufacturing, marketing, distribution, drug safety and use of veterinary medicinal products over their lifetime.

It is clear that a legal framework specifically tailored to the characteristics of the veterinary sector is necessary. Ever since the current legal framework came in to force, problems have arisen in connection with limited supplies of veterinary products (especially on the smallest markets), the administrative burden imposed by the rules, the functioning of the internal market and, of course, resistance to antibiotics.

In view of Article 114 TFEU (on the single market) and Article 168(4)(b) TFEU (on measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health), the Commission has tabled an ambitious proposal with the following main objectives:

- To improve access to medicinal products and make them more widely available, in particular for the so-called 'minor species',
- To reduce the administrative burden, in particular where the drug safety process is concerned,
- To promote innovation and competitiveness within the sector,
- To ensure that the internal market for veterinary medicinal products functions properly,
- To tackle antibiotic resistance.

The rapporteur gladly welcomes the Commission's draft regulation, believes that it is a move in the right direction and fully agrees with the Commission's objectives and its view that the veterinary medicines market should be separated from the human medicines market, which works very differently. The Commission is right to stress the importance of product availability and simpler administrative procedures without sacrificing the principles of public health and the protection of the environment.

Nonetheless, the Commission has not gone far enough on some points and the draft contains a number of loopholes. It should be much more ambitious in its measures relating to antibacterial resistance and should, in particular, provide clear definitions on the different kinds of treatment (curative, control and preventative) and ban the prophylactic use of antibiotics. It is essential that the rules on medicinal products for human use and the rules on medicinal products for veterinary use agree on this point.

The draft report clearly defines the conditions under which veterinary medicine professionals are permitted to prescribe and sell antibiotics. Without suggesting that the two elements should be split apart, which would pose huge practical difficulties, it would seem that there is

a need to define the notion of animals ‘under their care’ in Article 107.

The Commission plans to draw up a list of critical antibiotics reserved exclusively for human consumption. The rapporteur is in favour of this idea provided that the list is based on solid scientific criteria: the European Medicines Agency has made some excellent recommendations which should be used. Contrary to what the Commission is proposing, the sale of antibiotics (and all prescription-only veterinary products) online should be banned as this would pose a serious threat to public health.

It would also be advisable to boost incentives to encourage innovation. The veterinary medicines market is small and highly fragmented and there is little incentive for manufacturers to create and market new products. The draft report recommends extending the data protection periods proposed by the Commission for antibiotics (18 years instead of 14) and extending the initial marketing authorisation to the major species (two extra years instead of just one). The draft text also suggests putting in place a five-year protection period (which cannot be combined with other periods) for certain new studies or tests carried out after authorisation has been issued, in an effort to encourage developments on or improvements to existing products, both originator and generic.

The Commission’s new approach to drug safety, which is based on risk detection, will be a step forward provided that it does not pose a threat to public health. A system which requires regular drug safety reports for the product’s first few years of life and risk analysis and signal detection after this period seems more suitable.

The Commission suggests making the use of off-licence human drugs on animals easier by giving veterinarians the choice. Although there is no doubt that veterinarians would take a responsible approach, it would be preferable to put in place a more rigid framework in which human medicines can only be used for veterinary purposes as a last resort and if there is no better alternative.

Lastly, special attention must be given to protecting the environment. It will be necessary to establish a single decentralised form of assessment using a monograph system in order to avoid repetitive and potentially conflicting assessments of the environmental properties of a substance. In view of the practical difficulties involved in implementing a system of this kind, the Commission is asked to draw up specific proposals on the subject.