Council of the European Union

Brussels, 15 March 2016
(OR. en)

6875/16

Interinstitutional File:
2014/0257 (COD)

CODEC 260
AGRILEG 26
VETER 22
PHARM 11
MI 133
IA 8
PE 32

INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products - Outcome of the European Parliament's first reading (Strasbourg, 7 to 10 March 2016)

I. INTRODUCTION

The Committee on the Environment, Public Health and Food Safety submitted 290 amendments to the proposal for a Regulation (amendments 1-290). In addition:

- the ENF political group tabled four amendments (amendments 291-294);
- the Greens/EFA political group tabled 16 amendments (amendments 295-310);
- the EPP political group tabled two amendments (amendments 311-312);
- the EUL/NGL and EFDD political groups tabled nine amendments (amendments 313, 315-316 and 318-323); and
- the EUL/NGL political group on its own tabled two amendments (amendments 314 and 317).

II. DEBATE

The debate, which took place on 9 March 2016, was a joint debate that covered two separate proposals:

- the proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products **[2014/0257 (COD) / Rapporteur: Mrs Françoise GROSSETÊTE (EPP - FR)] -** ***see section III below for the voting results***; and
- the proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency **[2014/0256 (COD) / Rapporteur: Mr Claudiu TĂNĂSESCU (S&D - RO)] -** ***see doc. 6874/16 for the voting results.***

Mrs GROSSETÊTE (EPP - FR) opened the debate and:

- recalled that the Committee on the Environment, Public Health and Food Safety had had to process over 1,000 draft amendments and more than 150 articles;
- stressed the increasing danger posed by resistance to antibiotics and the need to address the problem at its roots. The work needs to begin with stock-breeders;
- drew attention to her Committee's wish to ban purely preventative use of antibiotics, to shift from mass treatment to individualised treatment, to ban the veterinary use of antibiotics that are crucial for human medicine and to end the on-line sale of antibiotics, vaccines and psychotropic substances. These measures should reduce the quantity of antibiotics that end up on consumers' plates;
- stressed the need to avoid reducing the therapeutic armoury of vets, who are professional and trustworthy people and are best placed to choose the most suitable treatment in the given circumstances. The regulation should make their work easier and not excessively regulate a profession that has already demonstrated its commitment to the greatest ethical rigour;

- underlined the real problem of availability of medicines on the veterinary market. To maintain animal health, it is necessary to improve the quality of treatment and to reduce the use of medicines that have not been authorised for placing on the market. In order to do so, it is necessary to encourage research and innovation in this sector. The Committee had therefore proposed to extend certain periods of commercial exclusivity (notably those for medicines intended for minor species) in order to create strong incentives for research;
- argued that the burden of administrative procedures (notably as regards pharmacovigilance) is another brake on the marketing of innovative products. Based on the Commission's proposals, the Committee reviewed certain measures in order to establish a new pharmacovigilance system that is more flexible, more effective and less bureaucratic. Accelerated procedures should also allow laboratories to respond quickly to, for example, epidemics - but without compromising quality and safety standards that are amongst the highest in the world;
- stressed the fact that the proposed regulation should help farmers to care for their livestock, not stigmatise them. The Committee had tried to ensure that the new rules would be applicable on the ground and that they would not add to an already onerous administrative burden; and
- emphasised the need for quick action. The Parliament is ready. The ball is now in the Council's court.

Commissioner ANDRIUKAITIS:

- with regard to Mrs Grossetête's file, expressed the Commission's appreciation of the Committee's efforts to propose constructive amendments and concrete alternatives regarding the provisions related to labelling, environmental risk assessment, harmonisation of all products, pharmacovigilance and antimicrobial resistance. The Commission welcomed the spirit of these amendments, which are in line with the co-objectives of the proposals;
- with regard to Mr Tănăsescu's file, expressed the Commission's appreciation of the efforts made to improve the proposal so that it takes into account the specific characteristics of the veterinary sector;
- underlined the excellent cooperation between the Parliament and the Commission on both files;

- stated that he was convinced that a first-reading agreement is both possible and desirable for both files;
- stated his belief that the Parliament's plenary vote would be an important incentive for the Council to accelerate its work; and
- reaffirmed his commitment to combatting anti-microbial resistance. His main ambition and first priority is to make the EU a best-practice region in this field. He hoped that every Member State would be equipped with a comprehensive action-plan following the one-health approach. He would in the coming months establish a network to bring together Member States' experts from both the veterinary and human health areas as well as actors from the environmental sector.

Mr TĂNĂSESCU:

- stated that the amendments would establish all the principles required to analyse the Agency's budget;
- called for the Parliament to be fully involved in the process of fixing the charges used to fund the Agency;
- argued that the Agency should be permitted to provide analytical materials that would allow Member States to set prices and reimbursement (an area of national competence);
- supported internet sales of veterinary medicines, with the exception of certain categories; and
- argued that antibiotics should not be used prophylactically.

Speaking on behalf of the Committee on Agriculture and Rural Development, Mr Jasenko SELIMOVIC (ALDE - SE):

- stressed the need to limit the use of antibiotics. He opposed group and prophylactic use of antibiotics; and
- welcomed incentives to encourage the pharmaceutical industry to develop new medicines.

Also speaking on behalf of the Committee on Agriculture and Rural Development, Mr Stanislav POLČÁK (EPP - CZ) argued that the Agency's fee structure and the way experts are paid should be decided by codecision rather than as an implementing act.

Speaking on behalf of the EPP political group, Mr Alberto CIRIO (EPP - IT) argued that the proposed provisions would not create an undue administrative burden, but would instead make life easier for the dairy sector, because they would deregulate the sector in an even-handed manner across the EU to create a level playing-field and thus prevent different Member States' farmers under-cutting each other.

Speaking on behalf of the S&D political group, Mrs Karin KADENBACH (S&D - AT) called for health-driven restrictions and for the fostering of innovation.

Speaking on behalf of the ECR political group, Dr Bolesław PIECHA (ECR - PL):

- noted the challenge posed by advertising and distribution, particularly by the internet;
- warned that bad regulation relating to data protection can smother the innovative work that is so much needed in this field; and
- expressed his doubts concerning so-called homeopathic medicines. He had the impression that they were driven by ideology rather than science. There is no scientific evidence that homeopathic medicines have any effect on animals. They may exercise a placebo effect on humans, but this can hardly be the case for animals.

Speaking on behalf of the ALDE political group, Mrs Gesine MEISSNER (ALDE - DE):

- supported the cascade approach, according to which certain antibiotics should only be used to treat humans. Any exceptions should be extremely restricted; and
- argued that homeopathic medicines should be permitted because, regardless of whether or not this has been scientifically proven, they have had good effects.

Speaking on behalf of the EUL/NGL political group, Mrs Merja KYLLÖNEN (EUL/NGL - FI) welcomed the fact that committee-level negotiations had resulted in an agreement to amend the Commission's proposal so that Member States such as Finland would still have the right to apply stricter controls.

Speaking on behalf of the Greens/EFA political group, Mr Martin HÄUSLING (Greens/EFA - DE):

- stated the need to address the current lack of sufficient data; and
- opposed any discrimination against homeopathic medicines. He therefore called for support for amendments 115 and 116.

Speaking on behalf of the EFDD political group, Mr Piernicola PEDICINI (EFDD - IT) stressed the need to develop new antibiotics and warned against granting excessive and over-long patent privileges that would overly limit the use of generic medicines and harm small pharmaceutical concerns.

Speaking on behalf of the ENF political group, Mrs Mireille D'ORNANO (ENF - FR):

- welcomed the work done to date, but stated that she still had some concerns that should be addressed;
- argued that animals that have undergone clinical trials should not be put back into the food chain. The acceptance of a precautionary deadline signifies the acceptance that a risk exists. Such a risk cannot be taken in the area of food safety;
- called for a greater framework for the on-line sale of veterinary medicines. It should not be possible to sell over the internet any medicines which require a prescription by vets or other qualified professionals; and
- opposed the authorisation for export to non-EU countries of meat derived from animals that have been treated by non-veterinary professionals.

Dr Peter LIESE (EPP - DE):

- called on the Council and the Commission to take note of amendments 245 and 246, as well as the consequences of one Member State using significantly more antibiotics than another;
- stressed the need to avoid prophylactic use of antibiotics in farming; and
- stressed the need for innovation (referring to amendment 22) - not only in veterinary medicine but also in human medicine. He called on the Commission to submit a concrete proposal on this.

Mrs Julie GIRLING (ECR - UK):

- supported the Rapporteur’s approach regarding the restriction on prophylactic use;
- thanked the Rapporteur and Shadows for heeding the concerns of the UK, which wishes to continue its long-established and highly regarded practice of using specially qualified individuals. She welcomed this flexibility and the recognition that one-size-fits-all does not always work; and
- opposed the re-tabled GM-banning amendment, because this would remove 19 well-used veterinary products from the market. That would be a dangerous precedent. It is important to distinguish between GM crops and GM science for medicine.

Mrs Susanne MELIOR (S&D - DE) welcomed the fact that the Committee's amendments would ensure traceability at every stage, from manufacture right through to use.

Mrs Christel SCHALDEMOSE (S&D - DK) welcomed the work done at Committee level to counter the spread of antimicrobial resistance, but regretted the fact that vets would not be banned from selling the medicines that they prescribe.

Commissioner ANDRIUKAITIS once more took the floor and:

- stated that the Commission welcomed the further provisions addressing antimicrobial resistance, considering most of them to be positive;
- welcomed the amendment introducing precise conditions on prophylactics and methaphylactic use of antimicrobials, inter alia prophylactic use restricted to clinically ill animals and to single animals that are identified as being at high risk of contamination. He was sure that the trilogue stage would see very interesting discussions on this issue;
- stressed the importance of innovation as a major tool to safeguard public health;
- noted the need to debate many other issues in detail. For example, the proposal to collect data at farm level needs to be further assessed as it might create additional administrative burdens; and
- called on the Council to follow the Parliament's good example and to speed up its work on the two proposals with a view to reaching a first-reading agreement.

Mrs GROSSETÊTE once more took the floor and:

- recalled her lengthy and constructive discussions with her Committee colleagues to ensure that due account was taken of certain Member States' particular circumstances - but without compromising the overall purpose of her proposal;
- once again stressed the importance of innovation;
- noted that the Committee's amendments would authorise the on-line sale of veterinary medicines - except for antibiotics and immunological or psychotropic products;
- stated that the Committee's amendments had taken the environmental impact into account; and
- expressed her fear that the Council is dealing with her proposal a little negligently, taking its time and not feeling any real concern.

III. VOTE

When it voted on 10 March 2016, the plenary adopted 285 amendments:

- 275 amendments of the Committee on the Environment, Public Health and Food Safety (amendments 1-11, 13-36, 38-98, 100-111, 113-130, 132-134, 136, 138-139, 141-201, 203-247, 249, 251-2, 255-277 and 279-289);
- seven amendments of the Greens/EFA political group (amendments 295, 298 and 301-305);
- the two amendments of the EPP political group (amendments 311-312); and
- one amendment of the EUL/NGL political group (amendment 314).

The text of the adopted amendments is annexed to this note.

The vote on the legislative resolution was postponed to a later session, thereby not closing the first reading. The matter was then referred back to the Committee, pursuant to Rule 61(2) of the Parliament's Rules of Procedure.

Veterinary medicinal products ***I

Amendments adopted by the European Parliament on 10 March 2016 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))[1]

(Ordinary legislative procedure: first reading)

[1] The matter was referred back to the committee responsible for reconsideration pursuant to Rule 61(2), second subparagraph (A8-0046/2016).

Amendment 1

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) In the light of the experience acquired and following the assessment by the Commission of the functioning of the market for veterinary medicinal products, the legal framework for veterinary medicinal products should be adapted to scientific progress, the current market conditions and economic reality.	(2) In the light of the experience acquired and following the assessment by the Commission of the functioning of the market for veterinary medicinal products, the legal framework for veterinary medicinal products should be adapted to scientific progress, the current market conditions and economic reality***, with respect to animals, nature and their interaction with man***.

Amendment 2

Proposal for a regulation
Recital 6

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

	diseases, prevent antimicrobial resistance and ensure proper nutrition of livestock.

Amendment 3

Proposal for a regulation
Recital 7

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

Amendment 4

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) This Regulation aims at ensuring a high level of protection of both animal and human health while securing the protection of the environment. Therefore, the precautionary principle should be applied. This Regulation should ensure that industry demonstrates that pharmaceutical substances or veterinary medicinal products produced or placed on the market have no harmful effects on human or animal health nor have any unacceptable effects on the environment.

Amendment 5

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 small and medium-sized enterprises (SMEs).***

Amendment 6

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) Where a Member State or the Commission considers that there are reasons to believe that a veterinary medicinal product may present a potential serious risk to human or animal health or to the environment, a scientific evaluation of the product should be undertaken at Union level, leading to a single decision on the area of disagreement, binding on the Member States concerned, being taken on the basis of an overall benefit-risk assessment.	(14) Where a Member State or the Commission considers that there are reasons to believe that a veterinary medicinal product may present a potential serious risk to human or animal health or to the environment, a scientific evaluation of the product should be undertaken at Union level, leading to a single decision on the area of disagreement, binding on the Member States concerned, being taken on the basis of an overall benefit-risk assessment. ***The authorisation procedure for veterinary medicinal products should be adjusted so as to eliminate other administrative procedures that might hamper the development of research and***

innovation for the purpose of identifying new medicines.

Amendment 7

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) However, there may be situations where no suitable authorised veterinary medicinal product is available. In those situations, by way of exception, veterinarians should be allowed to prescribe other medicinal products to the animals under their responsibility in conformity with strict rules and in the interest of animal health or animal welfare only. In case of food-producing animals, veterinarians should ensure that an appropriate withdrawal period is prescribed, so that harmful residues of those medicinal products do not enter the food chain.	(17) However, there may be situations where no suitable authorised veterinary medicinal product is available. In those situations, by way of exception, veterinarians should be allowed to prescribe other medicinal products to the animals under their responsibility in conformity with strict rules and in the interest of animal health or animal welfare only. ***In such cases, antimicrobial medicinal products for human use could be employed only subject to the issuing of a prescription by a veterinarian and the granting of authorisation by the veterinary authority responsible for monitoring the work of the veterinarian in question***. In case of food-producing animals, veterinarians should ensure that an appropriate withdrawal period is prescribed, so that harmful residues of those medicinal products do not enter the food chain***, and particular care should therefore be taken when administering antibiotics to food-producing animals.***

Amendment 8

Proposal for a regulation
Recital 18

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

situation in a Member State so requires.	Member State so requires.

Amendment 9

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) Directive 2010/63/EU of the European Parliament and of the Council[15] lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Clinical trials for veterinary medicinal products are exempted from that Directive. The design and performance of clinical trials, which provide essential information on the safety and efficacy of a veterinary medicinal product, should be ***such as*** to provide the most satisfactory results whilst using the minimum number of animals, the procedures should be ***the least likely to cause*** pain, suffering or distress to animals and should take into account the principles established by Directive 2010/63/EU.	(20) Directive 2010/63/EU of the European Parliament and of the Council[15] lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Clinical trials for veterinary medicinal products are exempted from that Directive. The design and performance of clinical trials, which provide essential information on the safety and efficacy of a veterinary medicinal product, should be ***optimised in order*** to provide the most satisfactory results whilst using the minimum number of animals, the procedures should be ***designed to avoid causing*** pain, suffering or distress to animals and should take into account the principles established by Directive 2010/63/EU.
[15] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).	[15] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

Amendment 10

Proposal for a regulation
Recital 23

Text proposed by the Commission	*Amendment*
(23) Companies have less interest in developing veterinary medicinal products for markets of a limited size. In order to promote the availability of veterinary medicinal products within the Union for	(23) Companies have less interest in developing veterinary medicinal products for markets of a limited size. In order to promote the availability of veterinary medicinal products within the Union for

those markets, in ***some*** cases it should be possible to grant marketing authorisations without a complete application dossier having been submitted, on the basis of a benefit-risk assessment of the situation and, where necessary, subject to specific obligations. In particular, this should be possible in the case of veterinary medicinal products for use in minor species or for the treatment or prevention of diseases that occur infrequently or in limited geographical areas.	those markets, in ***exceptional*** cases it should be possible to grant marketing authorisations without a complete application dossier having been submitted, on the basis of a benefit-risk assessment of the situation and, where necessary, subject to specific obligations. In particular, this should be possible in the case of veterinary medicinal products for use in minor species or for the treatment or prevention of diseases that occur infrequently or in limited geographical areas. ***Such products should only be used on the basis of a prescription.***

Amendment 11

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(25) Tests, pre-clinical studies and clinical trials represent a major investment for companies which they need to make in order to submit the necessary data with the application for a marketing authorisation or to establish a maximum residue limit for pharmaceutical active substances in the veterinary medicinal product. That investment should be protected in order to stimulate research and innovation, so that it is ensured the necessary veterinary medicinal products are available in the Union. For that reason data submitted to a competent authority or the Agency should be protected against use by other applicants. That protection should, however, be limited in time in order to allow competition.	(25) Tests, pre-clinical studies and clinical trials represent a major investment for companies which they need to make in order to submit the necessary data with the application for a marketing authorisation or to establish a maximum residue limit for pharmaceutical active substances in the veterinary medicinal product. That investment should be protected in order to stimulate research and innovation, ***in particular on veterinary medicinal products for minor species and antimicrobials,*** so that it is ensured the necessary veterinary medicinal products are available in the Union. For that reason data submitted to a competent authority or the Agency should be protected against use by other applicants. That protection should, however, be limited in time in order to allow competition.

Amendment 311

Proposal for a regulation
Recital 25 a (new)

Text proposed by the Commission	*Amendment*
	(25a) Research should be incentivised, not only through the commercial protection of innovative active substances, but also through the protection of significant investments in data generated to improve or maintain on the market an existing veterinary medicinal product. In such cases, only the new data package would benefit from the period of protection and not the active substance or any associated products.

Amendment 13

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. That can lead to divergent decisions being taken on products with similar effects on the environment, especially in the case of products authorised before the environmental impact assessment was carried out. The establishment of a single***

	centralised assessment of the environmental properties of active substances for veterinary use by means of a monograph system could be a potential alternative. The Commission should therefore submit a report to the European Parliament and the Council examining the feasibility of monographs and potential alternative options as soon as possible.

Amendment 14

Proposal for a regulation
Recital 27 a (new)

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

Amendment 15

Proposal for a regulation
Recital 31

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

Amendment 16

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) In certain circumstances where a significant animal or public health concern exists but scientific uncertainty persists, appropriate measures can be adopted taking into account Article 5(7) of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures which has been interpreted for the Union in the Communication from the Commission on the precautionary principle[17]. In such circumstances, Member States or the Commission should seek to obtain additional information necessary for a more objective assessment of the particular concern and should review the measure accordingly within a reasonable period of time.	(32) In certain circumstances where a significant animal***, environmental*** or public health concern exists but scientific uncertainty persists, appropriate measures can be adopted taking into account Article 5(7) of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures which has been interpreted for the Union in the Communication from the Commission on the precautionary principle[17]. In such circumstances, Member States or the Commission should seek to obtain additional information necessary for a more objective assessment of the particular concern and should review the measure accordingly within a reasonable period of time.
[17] Communication from the Commission on the precautionary principle, COM (2000) 1 (final).	[17] Communication from the Commission on the precautionary principle, COM (2000) 1 (final).

Amendment 17

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) Antimicrobial resistance to human and veterinary medicinal products is a growing health problem in the Union and worldwide. Many of the antimicrobials used in animals are also used in humans. Some of those antimicrobials are critical for preventing or treating life-threatening infections in humans. In order to fight antimicrobial resistance a number of measures should be taken. It needs to be ensured that appropriate warnings and	(33) Antimicrobial resistance to human and veterinary medicinal products is a growing health problem in the Union and worldwide***, thus involving a common responsibility of all actors concerned***. Many of the antimicrobials used in animals are also used in humans. Some of those antimicrobials are ***highly*** critical for preventing or treating life-threatening infections in humans ***and their use on animals, whether or not covered by the***

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

Amendment 18

Proposal for a regulation
Recital 34 a (new)

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

Amendment 19

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) The combined use of several antimicrobial active substances may represent a particular risk with respect to the development of antimicrobial resistance. Combinations of antimicrobial substances should therefore only be authorised where evidence is provided that the benefit-risk balance of the combination	(35) The combined use of several antimicrobial active substances may represent a particular risk with respect to the development of antimicrobial resistance. Combinations of antimicrobial substances should therefore only be authorised ***exceptionally*** where evidence is provided that the ***long-term*** benefit-risk

is favourable.	balance of the combination is favourable.

Amendment 20

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) The development of new antimicrobials has not kept pace with the increase of resistance to existing antimicrobials. Given the limited innovation in developing new antimicrobials it is essential that the efficacy of existing antimicrobials is maintained for as long as possible. The use of antimicrobials in ***veterinary*** medicinal products may accelerate the emergence and spread of resistant micro-organisms and may compromise the effective use of the already limited number of existing antimicrobials to treat human infections. Therefore the misuse of antimicrobials should not be allowed.	(36) The development of new antimicrobials has not kept pace with the increase of resistance to existing antimicrobials. Given the limited innovation in developing new antimicrobials it is essential that the efficacy of existing antimicrobials is maintained for as long as possible. The use of antimicrobials in medicinal products may accelerate the emergence and spread of resistant micro-organisms and may compromise the effective use of the already limited number of existing antimicrobials to treat human infections. Therefore, the misuse of antimicrobials should not be allowed. ***Preventive treatments using antimicrobials should be regulated more strictly and recommended only in certain specific, well-defined cases, in compliance with animal health, biosecurity and nutritional requirements.***

Amendment 21

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) In order to preserve as long as possible the efficacy of certain antimicrobials in the treatment of infections in humans, it ***may be*** necessary to reserve those antimicrobials for humans only. ***Therefore*** it should be possible to decide that ***certain*** antimicrobials, following the scientific recommendations of the Agency, should not be available on	(37) In order to preserve as long as possible the efficacy of certain antimicrobials in the treatment of infections in humans, it ***is*** necessary to reserve those antimicrobials for humans only. ***As a baseline, that should apply for the highest priority critically important antimicrobials identified by the World Health Organisation (WHO). Moreover,*** it should be possible to decide that ***other***

the market in the veterinary sector.	***critically important*** antimicrobials, following the scientific recommendations of the Agency, should not be available on the market in the veterinary sector.

Amendment 22

Proposal for a regulation
Recital 37 a (new)

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

Amendment 23

Proposal for a regulation
Recital 38

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

together promote responsible use. Therefore the supply of veterinary antimicrobials by ***veterinarians or other persons authorised under national law*** should be restricted to the amount required for treatment of the animals under their care***, and only once a veterinary diagnosis has been established following a clinical examination of the animal, or, in exceptional cases, in the light of continuous health checks on the animal***.

Amendment 24

Proposal for a regulation
Recital 38 a (new)

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

Amendment 25

Proposal for a regulation
Recital 38 b (new)

Text proposed by the Commission	*Amendment*
	(38b) In order to facilitate responsible use of antimicrobials, there is an imperative need for rapid, reliable and efficacious veterinary diagnostics both to identify the cause of disease and to perform antibiotic sensitivity testing. That would facilitate correct diagnosis, allow for a targeted use of antimicrobials, support using as little as possible critically important antimicrobials and therefore, inhibit the development of antimicrobial resistance. There is clear need for future innovation specifically for pen-site diagnosis, and a need to consider carefully whether there is a case for more harmonisation and

regulation in this sector.

Amendment 26

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) It is important to consider the international dimension of the development of antimicrobial resistance when assessing the benefit-risk balance of certain veterinary antimicrobials in the Union. ***Any measure restricting the use of those products may affect the trade of products of animal origin or the competitiveness of certain animal production sectors in the Union. Moreover,*** antimicrobial resistant organisms can spread to humans and animals in the Union through consumption of products of animal origin imported from third countries, from direct contact with animals or humans in third countries or by other means. Therefore, ***measures restricting the use of veterinary antimicrobials in*** the Union should be ***based on scientific advice and should be considered in the context of cooperation with third countries and international organisations addressing*** antimicrobial resistance ***in order the ensure consistency with their activities and policies***.	(39) It is important to consider the international dimension of the development of antimicrobial resistance when assessing the benefit-risk balance of certain veterinary antimicrobials in the Union. Antimicrobial resistant organisms can spread to humans and animals in the Union through consumption of products of animal origin imported from third countries, from direct contact with animals or humans in third countries or by other means. Therefore, the Union should be ***active in advocating the creation of an international strategy to combat*** antimicrobial resistance***, in line with the recent Global Action Plan adopted by the WHO***.

Amendment 27

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(40) There is still a lack of sufficiently detailed and comparable data at Union level to determine the trends and identify possible risk factors that could lead to the development of measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already	(40) There is still a lack of sufficiently detailed and comparable data at Union level to determine the trends and identify possible risk factors that could lead to the development of measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already

introduced. Therefore it is important to collect data on the sales and use of antimicrobials in animals, data on the use of antimicrobials in humans and data on antimicrobial resistant organisms found in animals, humans and food. To ensure that the information collected can be used effectively, appropriate rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data on the use of antimicrobials under the coordination of the Agency.	introduced. Therefore it is important to collect data on the sales and use of antimicrobials in animals, data on the use of antimicrobials in humans and data on antimicrobial resistant organisms found in animals, humans and food. ***Better data are needed on how, when, where and why antimicrobials are being used. Therefore, the data collected should be broken down by type of antimicrobial, species, disease or infection treated.*** To ensure that the information collected can be used effectively, appropriate rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data on the use of antimicrobials under the coordination of the Agency.

Amendment 28

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission	*Amendment*
	(40a) Commercial sensitivity should not be used as an excuse to deny citizens access to information about chemicals affecting their bodies or those of other non-target species in the wider environment. Maximum transparency should be ensured while protecting the most commercially sensitive information.

Amendment 29

Proposal for a regulation
Recital 49

Text proposed by the Commission	*Amendment*
(49) ***It is necessary,*** in specific cases***, or*** from a public health ***and*** animal health perspective, to complement the safety and efficacy data available at the time of authorisation with additional information following the placing of the product on the	(49) In specific cases ***it is necessary,*** from a public health***,*** animal health ***or environmental*** perspective, to complement the safety and efficacy data available at the time of authorisation with additional information following the placing of the

market. Therefore the obligation to conduct post-authorisation studies should be imposed on the marketing authorisation holder.	product on the market. Therefore the obligation to conduct post-authorisation studies should be imposed on the marketing authorisation holder.

Amendment 30

Proposal for a regulation
Recital 50

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

Amendment 314

Proposal for a regulation
Recital 52 a (new)

Text proposed by the Commission	*Amendment*
	(52a) In order to ensure that the imports from third countries of veterinary medicinal products, active substances, intermediate products and excipients used as starting materials have been manufactured in accordance with the animal welfare standards established in the Union, unlike for instance the current production method utilised in third countries for "pregnant mare serum gonadotropin" (PMSG), the Commission should revise Directive 91/412/EEC and

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

Amendment 31

Proposal for a regulation
Recital 56

Text proposed by the Commission	*Amendment*
(56) The conditions governing the supply of veterinary medicinal products to the public should be harmonised in the Union. Veterinary medicinal products should only be supplied by persons authorised to do so by the Member State where they are established. At the same time, in order to improve access to veterinary medicinal products in the Union, retailers that are authorised to supply veterinary medicinal products by the competent authority in the Member State where they are established should be allowed to sell prescription and non-prescription veterinary medicinal products via the Internet to buyers in other Member States.	(56) The conditions governing the supply of veterinary medicinal products to the public should be harmonised in the Union. Veterinary medicinal products should only be supplied by ***veterinarians or other*** persons authorised to do so by the Member State where they are established***. However, Member States which do not allow prescriptions to be issued by persons other than veterinarians could refuse to recognise prescriptions issued by persons other than veterinarians in other Member States in accordance with their national laws***. At the same time, in order to improve access to veterinary medicinal products in the Union, retailers that are authorised to supply veterinary medicinal products by the competent authority in the Member State where they are established should be allowed to sell prescription and non-prescription veterinary medicinal products***, except for antimicrobials,*** via the Internet to buyers in ***their own or*** other Member States. ***In order to minimise the risk to animal and human health, online sales of antimicrobials should be prohibited***.

Amendment 32

Proposal for a regulation
Recital 56 a (new)

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

Amendment 33

Proposal for a regulation
Recital 56 b (new)

Text proposed by the Commission	*Amendment*
	(56b) Any ban on veterinarians supplying medicines could make it impossible for some Member States to maintain a network of veterinarians covering all of their territory. Such territorial coverage is of key importance in ensuring high-quality epidemiological monitoring of existing and emerging diseases.

Amendment 34

Proposal for a regulation
Recital 57

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

and, therefore, Member States ***may*** impose conditions for supplying medicinal products to the public within the limits of the Treaty.	***potentially dangerous for human use.*** Account should be taken of the fact that specific conditions for supply of medicinal products to the public have not been harmonised at Union level. ***To minimise the risks to animal and human health, the online sale of antimicrobials should be prohibited.*** Member States ***might*** impose conditions for supplying medicinal products to the public within the limits of the Treaty.

Amendment 35

Proposal for a regulation
Recital 58 a (new)

Text proposed by the Commission	*Amendment*
	(58a) Member States should, after informing the Commission, be able to subject the supply of veterinary medicinal products offered for sale to stricter conditions justified by the protection of public health, animal health and the environment, provided that these conditions are proportionate to the risk and do not unduly restrict the functioning of the internal market.

Amendment 36

Proposal for a regulation
Recital 62

Text proposed by the Commission	*Amendment*
(62) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a ***member of a regulated animal health profession*** for an individual animal or group of animals, it should in principle be possible for that veterinary prescription to be recognised and for the medicinal product to be dispensed in another Member State. The removal of regulatory and administrative barriers to such recognition	(62) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a ***veterinarian or other persons authorised to do so under national law*** for an individual animal or group of animals, it should in principle be possible for that veterinary prescription to be recognised and for the medicinal product to be dispensed in another Member State***, provided that the other Member State***

should not affect any professional or ethical duty for dispensing professionals to refuse to dispense the medicine stated in the prescription.	***authorises persons with similar qualifications to issue prescriptions***. The removal of regulatory and administrative barriers to such recognition should not affect any professional or ethical duty for dispensing professionals to refuse to dispense the medicine stated in the prescription.

Amendment 295

Proposal for a regulation
Recital 65

Text proposed by the Commission	*Amendment*
(65) The verification of compliance with the legal requirements through controls is of fundamental importance to ensure that the objectives of the Regulation are effectively achieved across the Union. Therefore the competent authorities of the Member States should have the power to perform inspections at all stages of production, distribution and use of veterinary medicinal products. In order to preserve the effectiveness of the inspections, ***authorities should have the possibility to perform*** unannounced inspections.	(65) The verification of compliance with the legal requirements through controls is of fundamental importance to ensure that the objectives of the Regulation are effectively achieved across the Union. Therefore the competent authorities of the Member States should have the power to perform inspections at all stages of production, distribution and use of veterinary medicinal products ***and should publish annual inspection reports***. In order to preserve the effectiveness of the inspections, ***all inspections should be*** unannounced inspections.

Amendment 38

Proposal for a regulation
Recital 67

Text proposed by the Commission	*Amendment*
(67) In certain cases failures in Member States' control system can substantially hinder the achievement of the objectives of this Regulation and may lead to the emergence of risks to public and animal	(67) In certain cases failures in Member States' control system can substantially hinder the achievement of the objectives of this Regulation and may lead to the emergence of risks to public and animal

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

Amendment 39

Proposal for a regulation
Recital 71

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

Amendment 40

Proposal for a regulation
Recital 71 a (new)

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

Amendment 41

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 information technology services with the aim of reducing bureaucracy,*** should be funded through fees charged to enterprises ***and through an increased financial contribution from the Commission***. Those fees, however, should not affect the right of Member States to charge fees for activities and tasks at national level.

Amendment 42

Proposal for a regulation

Article 1 – paragraph 1

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

Amendment 43

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

Text proposed by the Commission	*Amendment*
	1a. Member States may impose stricter conditions, justified on grounds of public health, animal health and environmental protection, for the use and retail of veterinary medicinal products on their territory, provided that these conditions are proportionate to the risk and do not unduly restrict the functioning of the internal market.

Amendment 44

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

Text proposed by the Commission	*Amendment*
	1b. The Member States shall notify the measures referred to in paragraph 1a to the Commission.

Amendment 45

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

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

Amendment 46

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

Text proposed by the Commission	*Amendment*
	(eb) medicated feed and intermediate products as defined, respectively, in points (a) and (b) of Article 2(2) of Regulation (EÚ) .../... of the European Parliament and of the Council [1a+];
	[1a] Regulation (EÚ) .../... of the European Parliament and the Council of ... on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC (OJ L ...).
	[+] OJ: Please insert the number in the text, and in the footnote, the number, date and publication reference of document COD 2014/0255.

Amendment 47

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

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

Amendment 48

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

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

Amendment 49

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

Text proposed by the Commission	*Amendment*
(b) ***its purpose is to*** be used in or administered to animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;	(b) ***it may*** be used in***,*** or administered to***,*** animals with a view ***either*** to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;

Amendment 50

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

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

Amendment 51

Proposal for a regulation

Article 4 – paragraph 1 – point 2 – introductory part

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

Amendment 52

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

Text proposed by the Commission	*Amendment*
(a) human,	(a) human, ***for example human blood and human blood products;***

Amendment 53

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

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

Amendment 54

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

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

Amendment 55

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

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

Amendment 56

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

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

Amendment 57

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

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

Amendment 58

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

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

Amendment 59

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

Text proposed by the Commission	*Amendment*
	(2a) 'active substance' means a substance

with a pharmacological activity;

Amendment 60

Proposal for a regulation
Article 4 – paragraph 1 – 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;

Amendment 61

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

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

Amendment 62

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

Text proposed by the Commission	*Amendment*
	(7a) ‘herbal medicinal product’ means any medicinal product, exclusively

	containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations;

Amendment 63

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

Text proposed by the Commission	*Amendment*
(8) ‘antimicrobial resistance’ means the ability of microorganisms to survive or to grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to ***inhibit*** or kill microorganisms of the same species;	(8) ‘antimicrobial resistance’ means the ability of microorganisms to survive or to grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to ***halt the growth of*** or kill microorganisms of the same species;

Amendment 64

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

Text proposed by the Commission	*Amendment*
	(8a) ‘antimicrobial’ means any compound with a direct action on micro-organisms used for treatment or prevention of infections; antimicrobials include anti-bacterials, anti-virals, anti-fungals and anti-protozoals; in the context of this Regulation, an antimicrobial substance refers to an antibacterial;

Amendment 65

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

Text proposed by the Commission	*Amendment*
	(8b) 'antiparasitic' means a medicinal product or substance used in the treatment of parasitic diseases attributable

	to various causes;

Amendment 66

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

Text proposed by the Commission	*Amendment*
	(8c) 'antibacterial' means a compound with a direct action on bacteria used for treatment or prevention of infections;

Amendment 67

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

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

Amendment 68

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

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

Amendment 69

Proposal for a regulation

Article 4 – paragraph 1 – point 11 – introductory part

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

Amendment 70

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

Text proposed by the Commission	*Amendment*
(12) ‘common name' means the international non-proprietary name recommended by the World Health Organisation ***for a veterinary medicinal product***, or, if one does not exist, the name ***generally used***;	(12) ′common name' means the international non-proprietary name recommended by the World Health Organisation, or, if one does not exist, the ***usual common*** name;

Amendment 71

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

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

Amendment 72

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

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

Amendment 73

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

Text proposed by the Commission	*Amendment*
(21) ‘pharmacovigilance' means ***the process of monitoring and investigating*** adverse events;	(21) ’pharmacovigilance' means ***scientific, control and administrative activities relating to detection, reporting, assessment, understanding, prevention and communication of*** adverse events ***which include continuous evaluation of the risk-benefit balance of veterinary medicinal products***;

Amendment 74

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

Text proposed by the Commission	*Amendment*
(24) 'veterinary prescription‘ means any prescription for a veterinary medicinal product issued by a professional person qualified to do so in accordance with applicable national law;	(24) 'veterinary prescription‘ means any prescription for a veterinary medicinal product issued by a ***veterinarian or another*** professional person qualified to do so in accordance with applicable national law ***once a veterinary diagnosis has been established following a clinical examination of the animal***;

Amendment 75

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

Text proposed by the Commission	*Amendment*
(25) 'withdrawal period' means the ***minimum*** period between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal ***which under normal conditions of use is necessary to ensure*** that such foodstuffs do not contain residues in quantities ***harmful to public health***;	(25) 'withdrawal period' means the period ***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).

Amendment 76

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

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

Amendment 77

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

Text proposed by the Commission	*Amendment*
	(27a) 'essentially similar product' means a generic product that satisfies the criteria of having the same qualitative and quantitative composition in terms of active substances, of having the same pharmaceutical form, and of being bioequivalent to the original product, unless it is apparent in the light of scientific knowledge that it differs from the original product as regards safety and efficacy;

Amendment 78

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

Text proposed by the Commission	*Amendment*
	(27b) 'marketing authorisation holder' means the holder of a marketing authorisation granted in accordance with this Regulation;

Amendment 79

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

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

Amendment 80

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

Text proposed by the Commission	*Amendment*
	(27d) 'responsible use of veterinary medicinal products' means ensuring good husbandry and management practices such as biosecurity measures aiming to keep groups of animals healthy or to limit the spread of disease within an animal population, as well as asking veterinary advice, following vaccination programmes and prescription instructions, and ensuring good hygiene, appropriate nutrition and regular monitoring of health and welfare;

Amendment 81

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

Text proposed by the Commission	*Amendment*
	(27e) 'adverse events' means any of the undesirable events set out in Article 73(2);

Amendment 82

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

Text proposed by the Commission	*Amendment*
	(27f) 'serious adverse events' means any adverse event which results in death, is life-threatening, results in significant disability or incapacity, is a congenital anomaly or birth defect, or which results in permanent or prolonged signs in the animals treated;

Amendment 83

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

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

Amendment 84

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

Text proposed by the Commission	*Amendment*
	(27h) 'control treatment (metaphylaxis)' means the treatment of a group of animals after the diagnosis of clinical disease in part of the group, with the aim of treating the clinically sick animals and controlling the spread of the disease to animals in close contact and at risk which may already be subclinically infected; the presence of such a disease in the group shall be established before the product is used;

Amendment 85

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

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

occurrence of disease or infection;

Amendment 86

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

Text proposed by the Commission	*Amendment*
	(27j) 'parallel importation' means the importation into a Member State of a veterinary medicinal product authorised in another Member State in accordance with this Regulation and having the same characteristics as the veterinary medicinal product authorised in the Member State of import, in particular with:
	(a) the same qualitative and quantitative composition in terms of active substances and excipients and the same pharmaceutical form;
	(b) the same therapeutic indications and target species.
	The medicinal product authorised in the Member State and the product imported in parallel shall have been either harmonised under Article 69 or 70 or authorised in accordance with Articles 46 and 48;

Amendment 87

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

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

Amendment 88

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

Text proposed by the Commission	*Amendment*
	(27l) 'wholesale distribution' means all activities consisting of procuring, holding, supplying or exporting veterinary medicinal products, whether in return for payment or free of charge, apart from retail supply; such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorised or entitled to supply medicinal products to the public in accordance with applicable national law;

Amendment 89

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

Text proposed by the Commission	*Amendment*
	(27m) 'name of veterinary medicinal product' means the name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trademark or the name of the marketing authorisation holder;

Amendment 90

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

Text proposed by the Commission	*Amendment*
	(27n) 'pre-mix for medicated feedingstuffs' means any veterinary medicinal product prepared in advance with a view to the subsequent

manufacture of medicated feeding stuffs in accordance with Regulation (EU) .../... of the European Parliament and of the Council*[+]*.

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

Amendment 91

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
1. A veterinary medicinal product shall be placed on the market only when a marketing authorisation has been granted in respect of the product by a competent authority ***in accordance with Articles 44, 46 or 48*** or by the Commission in accordance with ***Article 40***.	1. ***Without prejudice to other provisions of this Regulation,*** a veterinary medicinal product shall be placed on the market ***of a Member State*** only when a marketing authorisation has been granted in respect of the product by a competent authority ***of that Member State*** or by the Commission in accordance with ***this Regulation***.

Amendment 92

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. A marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period of time**.**	2. A marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period of time***, unless risks to public health, animal health and the environment are detected or new scientific knowledge gives grounds for re-examination of the benefit risk balance. In such situations Member States or the Commission shall refer the matter to the Agency in accordance with the procedure described in Article 84.*** ***When a previously authorised veterinary medicinal product has not been present on the market in any Member State for a period of five consecutive years, the***

	authorisation granted for that veterinary medicinal product shall cease to be valid.
	The competent authority may, in exceptional circumstances, and on human or animal health grounds, grant an exemption from the termination of validity referred to in the second subparagraph. Such exemptions shall be duly justified.
	The marketing authorisation holder shall be responsible for marketing the medicinal product. The designation of a representative shall not relieve the marketing authorisation holder of its legal responsibility.

Amendment 93

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

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

Amendment 94

Proposal for a regulation
Article 6 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Applications shall be submitted electronically***. For applications submitted in accordance*** with the ***centralised marketing authorisation procedure, the formats made available by*** the Agency shall ***be used***.	3. Applications shall be submitted electronically ***or saved in exceptional circumstances and following agreement with a competent authority or in the case of centralised application,*** with the ***Agency. The Commission, in collaboration with the Member States and with*** the Agency shall ***adopt detailed guidelines on the format of electronic applications***.

Amendment 95

Proposal for a regulation

Article 6 – paragraph 5

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

Amendment 96

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

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

Amendment 97

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

Text proposed by the Commission	*Amendment*
(b) information about risk mitigation measures to limit antimicrobial resistance development related to the use of veterinary medicinal product.	(b) information about risk mitigation measures to limit antimicrobial resistance development related to the use of veterinary medicinal product***, including specifications that the product is not to be used as a routine prophylactic or metaphylactic measure in food-producing animals, and is not to be used in prophylactic group treatments where there has been no diagnosis of disease***.

Amendment 98

Proposal for a regulation
Article 7 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the application concerns a veterinary medicinal product intended for food-producing target species and containing pharmacologically active substances that are not listed in Table 1 of the Annex to Regulation (EU) No 37/2010 for the animal species in question, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council[22] ***shall be submitted in addition to the information listed in paragraph 1.***	3. Where the application concerns a veterinary medicinal product intended for food-producing target species and containing pharmacologically active substances that are not listed in Table 1 of the Annex to Regulation (EU) No 37/2010 for the animal species in question, a document ***shall be submitted in addition to the information listed in paragraph 1 of this Article*** certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council[22] ***and that at least six months has elapsed from submission of such application.***
[22] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, 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).	[22] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

Amendment 100

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
2. ***Approvals of clinical trials shall be***	2. ***Member States shall not permit test***

granted on condition that food-producing animals used in the clinical trials or their produce do not enter the human food chain unless:	***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.***

Amendment 101

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

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

Amendment 102

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

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

Amendment 103

Proposal for a regulation
Article 9

Text proposed by the Commission	*Amendment*
Labelling of the immediate packaging of veterinary medicinal products	Labelling of the immediate packaging of veterinary medicinal products
1. The immediate packaging of a veterinary medicinal product shall contain only the following information:	1. The immediate packaging of a veterinary medicinal product shall contain only the following information***:***
(a) the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;	(a) the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;
(b) a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using their common names;	(b) a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using their common names;
(c) the batch number, preceded by the word "Lot";	(c) the batch number, preceded by the word "Lot";
(d) the name or corporate name or logo name of the marketing authorisation holder;	(d) the name or corporate name or logo name of the marketing authorisation holder;
(e) the target species;	(e) the target species;
(f) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp.";	(f) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp.";
(g) special storage precautions, if any.	(g) special storage precautions, if any.
	1a. In exceptional cases, additional information in accordance with Article 30 may be included, on request of the applicant or the competent authority when it is absolutely necessary to ensure the safe and correct administration of the product.
2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or, where appropriate, abbreviations or pictograms common throughout the Union.	2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or, where appropriate, abbreviations or pictograms common throughout the Union.
	2a. In addition, all the information listed in points (a) to (g) of paragraph 1 shall

	also appear in a format that is electronically readable, such as a barcode. Data shall be made available for other documentation systems through standards interface.

Amendment 104

Proposal for a regulation
Article 10

Text proposed by the Commission	*Amendment*
Labelling of the outer packaging of veterinary medicinal products	Labelling of the outer packaging of veterinary medicinal products
1. The outer packaging of a veterinary medicinal product shall contain only the following information:	1. The outer packaging of a veterinary medicinal product shall contain only the following information***:***
(a) the information listed in Article 9(1);	(a) the information listed in Article 9(1);
(b) the contents by weight, volume or number of immediate packaging units of the veterinary medicinal product;	(b) the contents by weight, volume or number of immediate packaging units of the veterinary medicinal product;
(c) warning that the veterinary medicinal product must be kept out of the sight and reach of children;	(c) warning that the veterinary medicinal product must be kept out of the sight and reach of children;
(d) warning that the veterinary medicinal product is for animal treatment only;	(d) ***a common pictogram*** warning that the veterinary medicinal product is for animal treatment only;
(e) recommendation to read the package leaflet;	(e) recommendation to read the package leaflet;
(f) requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products ***and, if appropriate, additional precautions as regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products;***	(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 ***in accordance with the applicable law;***
(g) in case of homeopathic veterinary medicinal products, the statement "homeopathic veterinary medicinal product".	(g) in case of homeopathic veterinary medicinal products, the statement "homeopathic veterinary medicinal product".
	1a. In exceptional cases, additional

	information in accordance with Article 30 may be included, on request of the applicant or the competent authority when it is absolutely necessary to ensure safe and correct administration of the product.
2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or, where appropriate, abbreviations or pictograms common throughout the Union.	2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, ***as well as in machine-readable format***, or, where appropriate, abbreviations or pictograms common throughout the Union.
3. Where there is no outer packaging, all the particulars listed in paragraph 1 shall appear on the immediate packaging.	3. Where there is no outer packaging, all the particulars listed in paragraph 1 shall appear on the immediate packaging.

Amendment 105

Proposal for a regulation
Article 11

Text proposed by the Commission	*Amendment*
Labelling of small immediate packaging units of veterinary medicinal products	Labelling of small immediate packaging units of veterinary medicinal products
By way of derogation from Article 9, small immediate packaging units shall contain only the following information:	By way of derogation from Article 9, small immediate packaging units shall contain only the following information***:***
(a) the name of veterinary medicinal product;	(a) the name of veterinary medicinal product;
(b) the quantitative particulars of the active substances;	(b) the quantitative particulars of the active substances***, unless the product exists in only one concentration or the concentration is reflected in the name;***
(c) the batch number, preceded by the word "Lot";	(c) the batch number, preceded by the word "Lot";
(d) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp."	(d) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp.".
	In exceptional cases, additional information in accordance with Article 30 may be included, on request of the applicant or the competent authority when it is absolutely necessary to ensure safe and correct administration of the product.

Amendment 106

Proposal for a regulation
Article 12

Text proposed by the Commission	*Amendment*
Package leaflet of veterinary medicinal products	Package leaflet of veterinary medicinal products
1. The package leaflet shall be available ***for*** each veterinary medicinal product and shall contain at least the following information:	1. The package leaflet shall be ***directly*** available ***with*** each veterinary medicinal product and shall contain at least the following information:
(a) the name or corporate name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer and, where applicable, of the representative of the marketing authorisation holder;	(a) the name or corporate name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer and, where applicable, of the representative of the marketing authorisation holder;
(b) the name of the veterinary medicinal product or, where applicable, a list of the names of the veterinary medicinal product, as authorised in different Member States;	(b) the name of the veterinary medicinal product or, where applicable, a list of the names of the veterinary medicinal product, as authorised in different Member States;
(c) the strength and pharmaceutical form of the veterinary medicinal product;	(c) the strength and pharmaceutical form of the veterinary medicinal product;
(d) the target species, the dosage for each species, the method and route of administration and advice on correct administration***, if necessary***;	(d) the target species, the dosage for each species, the method and route of administration and***, if necessary,*** advice on correct administration;
(e) the therapeutic indications;	(e) the therapeutic indications;
(f) the contra-indications and adverse events in so far as this information is necessary for the use of the veterinary medicinal product;	(f) the contra-indications and adverse events in so far as this information is necessary for the use of the veterinary medicinal product;
(g) the withdrawal period, even if this is nil, in the event that the target species are food-producing animals;	(g) the withdrawal period, even if this is nil, in the event that the target species are food-producing animals;
(h) special storage precautions, if any;	(h) special storage precautions, if any;
(i) information essential for safety or health protection, including any special precautions relating to use and any other warnings;	(i) information essential for safety or health protection, including any special precautions relating to use and any other warnings;
(j) requirement to use take-back schemes for veterinary medicinal products for the	(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;***	disposal of unused veterinary medicinal products or waste materials derived from the use of such products ***in accordance with the applicable law;***
(k) the marketing authorisation number;	
(l) in case of generic veterinary medicinal products, the statement ‘generic veterinary medicinal product’;	(l) in case of generic veterinary medicinal products, the statement ‘generic veterinary medicinal product’;
(m) in case of homeopathic veterinary medicinal products, the statement "homeopathic veterinary medicinal product".	(m) in case of homeopathic veterinary medicinal products, the statement "homeopathic veterinary medicinal product"***;***
	(ma) qualitative and quantitative composition.
2. The package leaflet may bear additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation, provided that the information is not promotional. This additional information shall appear in the package leaflet clearly separated from the information referred to in paragraph 1.	2. The package leaflet may bear additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation, provided that the information is not promotional. This additional information shall appear in the package leaflet clearly separated from the information referred to in paragraph 1.
3. The package leaflet shall be written and designed to be clear and understandable, in terms that are comprehensible to the general public.	3. The package leaflet shall be written and designed to be clear***, readable*** and understandable, in terms that are comprehensible to the general public.

Amendment 107

Proposal for a regulation
Article 13

Text proposed by the Commission	*Amendment*
Package leaflet of homeopathic veterinary medicinal products	Package leaflet of homeopathic veterinary medicinal products
By way of derogation from Article 12(1), the package leaflet for homeopathic veterinary medicinal products registered in accordance with Articles 89 to 90 shall	By way of derogation from Article 12(1), the package leaflet for homeopathic veterinary medicinal products registered in accordance with Articles 89 to 90 shall

contain only the following information:	contain only the following information:
(a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the European Pharmacopoeia or, in the absence thereof, of the pharmacopoeias currently used officially in Member States;	(a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the European Pharmacopoeia or, in the absence thereof, of the pharmacopoeias currently used officially in Member States; ***if the homeopathic veterinary medicinal product is composed of more than one stock, the scientific names of the stocks may be supplemented by a brand name in the label;***
(b) name and address of the marketing authorisation holder and, where appropriate, of the manufacturer;	(b) name and address of the marketing authorisation holder and, where appropriate, of the manufacturer;
(c) method of administration and, if necessary, route;	(c) method of administration and, if necessary, route;
(d) the expiry date, in the format "mm/yyyy", preceded by the abbreviation "Exp.";	
(e) pharmaceutical form;	(e) pharmaceutical form;
(f) special storage precautions, if any;	(f) special storage precautions, if any;
(g) target species;	(g) target species, ***as well as dosage levels for the different target species;***
(h) a special warning if necessary for the medicinal product;	(h) a special warning if necessary for the medicinal product;
(i) the batch number, preceded by the word "Lot";	
(j) registration number;	(j) registration number;
(k) withdrawal period, if applicable.	(k) withdrawal period, if applicable;
(l) the statement "homeopathic veterinary medicinal product".	(l) the statement "homeopathic veterinary medicinal product".

Amendment 108

Proposal for a regulation
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purpose of this Section, where the active substance consists of salts, esters, ethers, isomers and mixtures of isomers, complexes or derivatives differing	2. For the purpose of this Section, where the active substance consists of salts, esters, ethers, isomers and mixtures of isomers, complexes or derivatives differing

from the active substance used in the reference veterinary medicinal product, it shall be considered to be the same active substance as that used in the reference veterinary medicinal product, unless it differs significantly in respect of properties with regard to safety ***or*** efficacy. Where it differs significantly in respect of those properties, the applicant shall submit additional information in order to prove the safety and/or efficacy of the various salts, esters or derivatives of the authorised active substance of the reference veterinary medicinal product.	from the active substance used in the reference veterinary medicinal product, it shall be considered to be the same active substance as that used in the reference veterinary medicinal product, unless it differs significantly in respect of properties with regard to safety***,*** efficacy ***and behaviour of residues***. Where it differs significantly in respect of those properties, the applicant shall submit additional information in order to prove the safety and/or efficacy of the various salts, esters or derivatives of the authorised active substance of the reference veterinary medicinal product.

Amendment 109

Proposal for a regulation
Article 16 – paragraph 6

Text proposed by the Commission	*Amendment*
6. ***A*** competent authority or the Agency ***may require the applicant to provide*** safety data concerning the potential risks posed by the generic veterinary medicinal product to the environment ***in case the marketing authorisation for the reference veterinary medicinal product was granted before 20 July 2000 or in case the second phase environmental risk assessment was required for the reference veterinary medicinal*** product.	6. ***The applicant shall submit to the*** competent authority or the Agency***, on their request,*** safety data concerning the potential risks posed by the generic veterinary medicinal product to the environment ***if there are well founded reasons to believe that authorisation can result in an increased risk to the environment from the generic product as compared to the reference*** product.

Amendment 110

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

Text proposed by the Commission	*Amendment*
By way of derogation from Article 7(1)(b) an application for a marketing authorisation for a veterinary medicinal product containing a combination of active substances that have each already been used in authorised veterinary medicinal	By way of derogation from Article 7(1)(b) an application for a marketing authorisation for a veterinary medicinal product containing a combination of active substances that have each already been used in authorised veterinary medicinal

products***, but have not hitherto been authorised in that combination ('combination veterinary medicinal product')*** shall satisfy the following criteria:	products shall satisfy the following criteria:

Amendment 111

Proposal for a regulation
Article 21

Text proposed by the Commission	*Amendment*
Reduced data requirements for applications for limited markets	Reduced data requirements for applications for limited markets
1. By way of derogation from Article 7(1)(b), a marketing authorisation for a veterinary medicinal product intended for a limited market shall be granted ***although*** the quality and/or efficacy documentation required in accordance with Annex II ***has not been provided, if all the*** following conditions ***are met***:	1. By way of derogation from Article 7(1)(b), a marketing authorisation for a veterinary medicinal product intended for a limited market shall be granted ***even when***, ***for objective, verifiable reasons, the applicant is unable to provide*** the quality and/or efficacy documentation required in accordance with Annex II***, subject to the*** following conditions:
(a) the benefit of the immediate availability on the market of the veterinary medicinal product to the animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided;	(a) the benefit of the immediate availability on the market of the veterinary medicinal product to the animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided;
(b) the applicant provides the evidence that the veterinary medicinal product is intended for a limited market.	(b) the applicant provides the evidence that the veterinary medicinal product is intended for a limited market.
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 ***five*** years. ***At the end of that period, the holder may request, in the light of scientific data and on grounds of pharmacovigilance and efficiency, that this authorisation be converted into an open-ended authorisation.***
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	3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only limited ***information on its*** quality

and/or efficacy has been ***conducted due to the lack of comprehensive efficacy and/or quality data***.	***and*** efficacy has been ***submitted***. ***The packaging shall bear a warning with the same information.***
	3a. A veterinary medicinal product that has been granted marketing authorisation in accordance with this Article may only be issued on the basis of a prescription.

Amendment 113

Proposal for a regulation
Article 22

Text proposed by the Commission	*Amendment*
Data requirements for applications in exceptional circumstances	Data requirements for applications in exceptional circumstances
1. By way of derogation from Article 7(1)(b), in exceptional circumstances related to animal or public health, where the applicant has demonstrated that for objective, verifiable reasons he is unable to provide the quality, safety and/or efficacy documentation required in accordance with Part 1, Part 2 and Part 3 of Annex II, a marketing authorisation may be granted subject to any of the following:	1. By way of derogation from Article 7(1)(b), in exceptional circumstances related to animal or public health, ***including unmet needs with respect to animal health,*** where the applicant has demonstrated that for objective, verifiable reasons he is unable to provide the quality, safety and/or efficacy documentation required in accordance with Part 1, Part 2 and Part 3 of Annex II, a marketing authorisation may be granted subject to any of the following:
(a) a requirement to introduce conditions or restrictions, in particular concerning the safety of the veterinary medicinal product;	(a) a requirement to introduce conditions or restrictions, in particular concerning the safety of the veterinary medicinal product;
(b) a requirement to notify the competent authorities of any ***incident*** relating to the use of the veterinary medicinal product;	(b) a requirement to notify the competent authorities of any ***adverse event*** relating to the use of the veterinary medicinal product;
(c) a requirement to ***conduct*** post-authorisation studies***.***	(c) a requirement to ***provide further data based on either*** post-authorisation studies ***or on data collected on the performance of the product in the field, where data from the field is identified as more appropriate based on a risk-benefit assessment.***
2. ***By way of derogation from Article 5(2),*** a marketing authorisation ***in exceptional circumstances*** shall be ***granted for a period of 1 year***.	2. ***The continuation of*** a marketing authorisation ***granted in accordance with paragraph 1*** shall be ***tied to an annual review of the conditions set out in that***

	paragraph, until all those conditions are fulfilled.
3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment of quality, safety and/or efficacy has been conducted due to the lack of comprehensive quality, safety and/or efficacy data.	3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment of quality, safety and/or efficacy has been conducted due to the lack of comprehensive quality, safety and/or efficacy data. ***The packaging shall bear a warning with the same information.***
	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.
	3b. A veterinary medicinal product that has been granted marketing authorisation in accordance with this Article may only be issued on the basis of a prescription.

Amendment 114

Proposal for a regulation
Article 25 – paragraph 1

Text proposed by the Commission	*Amendment*
The competent authority shall ascertain that the manufacturers of veterinary medicinal products from third countries are able to manufacture the veterinary medicinal product concerned and/or carry out control tests in accordance with the methods described in the documentation submitted in support of the application in accordance with Article 7(1).	The competent authority shall ascertain that the manufacturers of veterinary medicinal products from third countries ***comply with applicable Union law,*** are able to manufacture the veterinary medicinal product concerned and/or carry out control tests in accordance with the methods described in the documentation submitted in support of the application in accordance with Article 7(1) ***and that they minimise environmental pollution***.

Amendment 115

Proposal for a regulation
Article 28 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission ***may*** require the marketing authorisation holder to conduct post-authorisation studies in order to ensure that the benefit-risk balance remains positive with a view to the possible development of antimicrobial resistance.	3. Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission ***shall*** require the marketing authorisation holder to conduct post-authorisation studies in order to ensure that the benefit-risk balance remains positive with a view to the possible development of antimicrobial resistance.

Amendments 116 and 298

Proposal for a regulation
Article 29

Text proposed by the Commission	*Amendment*
Requirement for a veterinary prescription	Requirement for a veterinary prescription
1. ***A competent authority or the Commission shall classify the*** following veterinary medicinal products ***as*** subject to veterinary prescription:	1. ***The*** following veterinary medicinal products ***shall be*** subject to ***mandatory*** veterinary prescription:
(a) veterinary medicinal products which contain psychotropic drugs or narcotics, including those covered by the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the United Nations Convention on Psychotropic Substances of 1971;	(a) veterinary medicinal products which contain psychotropic drugs or narcotics, including those covered by the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the United Nations Convention on Psychotropic Substances of 1971;
(b) veterinary medicinal products for food-producing animals;	(b) veterinary medicinal products for food-producing animals;
(c) antimicrobial veterinary medicinal products;	(c) antimicrobial veterinary medicinal products;
(d) products intended for treatments of pathological processes which require a precise prior diagnosis or the use of which may have effects which impede or interfere with subsequent diagnostic or therapeutic	(d) products intended for treatments of pathological processes which require a precise prior diagnosis or the use of which may have effects which impede or interfere with subsequent diagnostic or therapeutic

measures;	measures;
(e) officinal formulae intended for food-producing animals;	(e) officinal formulae intended for food-producing animals;
(f) veterinary medicinal products containing an active substance that has been authorised for less than 5 years in the Union.	(f) veterinary medicinal products containing an active substance that has been authorised for less than 5 years in the Union;
	(fa) veterinary medicinal products for which marketing authorisations have been granted in accordance with Article 21 and/or 22.
	1a. Member States may on their territories provide for additional legal subcategories in accordance with the respective national law.
2. ***A competent authority or the Commission may classify a*** veterinary medicinal product as subject to veterinary prescription where special precautions are contained in the summary of product characteristics referred to in Article 30, and in particular potential risks to:	2. A veterinary medicinal product ***may be classified*** as subject to ***mandatory*** veterinary prescription where special precautions are contained in the summary of product characteristics referred to in Article 30, and in particular potential risks to:
(a) the target species,	(a) the target species,
(b) the person administering the products to the animal,	(b) the person administering the products to the animal,
(c) the environment	(c) the environment.
3. By the way of derogation from paragraph 1, a competent authority or the ***Agency*** may ***not classify*** a veterinary medicinal product ***as subject to*** veterinary prescription if all of the following conditions are fulfilled:	3. By the way of derogation from paragraph 1, a competent authority or the ***Commission*** may ***exempt*** a veterinary medicinal product ***from a mandatory*** veterinary prescription if all of the following conditions are fulfilled:
(a) the administration of the veterinary medicinal product is restricted to pharmaceutical forms requiring no particular knowledge or skill in using the products;	(a) the administration of the veterinary medicinal product is restricted to pharmaceutical forms requiring no particular knowledge or skill in using the products;
(b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal(s) treated, to the person administering the product or to the environment;	(b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal(s) treated, to the person administering the product or to the environment;
(c) the summary of the product characteristics of the veterinary medicinal product does not contain any warnings of	(c) the summary of the product characteristics of the veterinary medicinal product does not contain any warnings of

potential serious ***side effects*** deriving from its correct use;	potential serious ***adverse events*** deriving from its correct use;
(d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent adverse event reporting;	(d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent adverse event reporting;
(e) the summary of the product characteristics does not refer to contraindications related to other veterinary medicinal products commonly used without prescription;	(e) the summary of the product characteristics does not refer to contraindications related to other veterinary medicinal products commonly used without prescription;
(f) the veterinary medicinal product is not subject to special storage conditions;	
(g) there is no risk for public health as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly;	(g) there is no risk for public health as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly;
(h) there is no risk to public or animal health as regards the development of resistance ***to anthelmintic substances*** even where the veterinary medicinal products containing those substances are used incorrectly.	(h) there is no risk to public or animal health as regards the development of ***antiparasitic*** resistance even where the veterinary medicinal products containing those substances are used incorrectly.

Amendment 117

Proposal for a regulation
Article 29 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Notwithstanding paragraph 1, medicinal products for veterinary use may be used without prescription if:
	(a) they are registered as single homeopathic products and released for sale in pharmacies, have a dilution of not less than D4 (1:10 000) and are not produced using alcohol;
	(b) they are registered as complex homeopathic products, contain no individual components below a dilution of D4, are released for sale in pharmacies and are not produced using alcohol.

Amendment 118

Proposal for a regulation
Article 30 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) qualitative and quantitative composition of the active substances ***or other*** constituents stating the common name or the chemical description of the substances or other constituents;	(b) qualitative and quantitative composition of the active substances ***and all the essential*** constituents**,** stating the common name or the chemical description of the substances or other constituents;

Amendment 119

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***,

Amendment 120

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

Text proposed by the Commission	*Amendment*
(xiii) special conditions for use, including restrictions on the use of antimicrobials in order to limit the risk of development of antimicrobial resistance,	(xiii) special conditions for use, including restrictions on the use of antimicrobials in order to limit the risk of development of antimicrobial resistance, ***and specifying that the product is not allowed to be used as a routine preventive measure,***

Amendment 121

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

Text proposed by the Commission	*Amendment*
	(iiia) list of excipients,

Amendment 122

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

Text proposed by the Commission	*Amendment*
	(ea) information from the environmental risk assessment of the product, in particular environmental endpoints and risk characterisation data, including ecotoxicological information on effects on non-target species and persistence of active substances and active metabolites in soil and water;

Amendment 123

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

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

Amendment 124

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

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

effects.

Amendment 125

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

Text proposed by the Commission	*Amendment*
(d) the product is an antimicrobial veterinary medicinal product presented for use as performance enhancer in order to promote the growth of treated animals or to increase yields from treated animals;	(d) the product is an antimicrobial veterinary medicinal product presented for use as performance enhancer in order to promote the growth of treated animals***,*** or to increase yields from treated animals***, or as a routine prophylactic in food producing animals, or to be added to feed or water for mass medication when no disease has been diagnosed in any of the animals;***

Amendment 126

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

Text proposed by the Commission	*Amendment*
(e) the withdrawal period is not ***long enough to ensure food safety***;	(e) the ***proposed*** withdrawal period ***to ensure food safety*** is not ***well justified, or the proposed withdrawal period by the Agency or by the competent authorities is not taken into account***;

Amendment 127

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

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

Amendment 128

Proposal for a regulation

Article 32 – paragraph 1 – point g b (new)

Text proposed by the Commission	*Amendment*
	(gb) active substances within the product which meet the criteria for being persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to EMA guidelines, or are considered as having endocrine-disrupting properties that risk causing adverse effects in the environment;

Amendment 129

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

Text proposed by the Commission	*Amendment*
	(ha) the product poses significantly higher risks to the treated animal, public health or the environment compared to the standard reference treatment;

Amendment 130

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

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

Amendment 132

Proposal for a regulation
Article 32 – paragraph 2

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

Amendment 133

Proposal for a regulation
Article 32 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to establish rules for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of certain active substances in humans.	3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 ***and taking into consideration the scientific advice of the Agency*** in order to establish rules for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of certain active substances in humans. ***The Agency, in its advice, shall consider appropriate designations at the class, substance or even the indication level and shall consider also the route of administration.*** ***Member States which implement or wish to implement stricter rules shall be allowed to do so.***

Amendment 134

Proposal for a regulation
Article 32 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	4. The Commission shall, by means of implementing acts ***and taking into consideration the scientific advice of the Agency as well as the work already carried out by the WHO***, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. Those implementing acts shall be adopted in accordance with the examination procedure referred to in

Article 145(2).

Such designations, where relevant, shall be done at the class, substance or even the indication level and shall consider also the route of administration.

Amendment 301

Proposal for a regulation
Article 33 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Safety information with regard to the environmental effects of veterinary medicinal products shall not be protected.

Amendment 136

Proposal for a regulation
Article 34

Text proposed by the Commission	*Amendment*
Periods of the protection of technical documentation	Periods of the protection of technical documentation
1. The period of the protection of technical documentation shall be:	1. The period of the protection of technical documentation shall be:
(a) 10 years for the veterinary medicinal products for cattle, sheep, pigs, chickens, dogs and cats;	(a) 10 years for the veterinary medicinal products for cattle, sheep ***(reared for meat)***, pigs, chickens, ***salmon,*** dogs and cats;
(b) 14 years for antimicrobial veterinary medicinal products for cattle, sheep, pigs, chickens, dogs and cats containing an antimicrobial active substance which has not been an active substance in a veterinary medicinal product authorised within the Union on the date of the submission of the application;	(b) 14 years for antimicrobial veterinary medicinal products for cattle, sheep, pigs, chickens, ***salmon***, dogs and cats containing an antimicrobial active substance which has not been an active substance in a veterinary medicinal product authorised within the Union on the date of the submission of the application;
(c) ***18*** years for veterinary medicinal	(c) ***20*** years for veterinary medicinal

products for bees;	products for bees;
(d) 14 years for veterinary medicinal products for animal species other than listed in paragraph 1(a) and (c).	(d) 14 years for veterinary medicinal products for animal species other than listed in paragraph 1(a) and (c).
2. The protection shall apply from the day when the marketing authorisation for the veterinary medicinal product was granted in accordance with Article 7.	2. The protection shall apply from the day when the marketing authorisation for the veterinary medicinal product was granted in accordance with Article 7.
	2a. Where the veterinary medicinal product has been authorised for more than one species, the period shall be extended in accordance with the prolongation periods provided for in Article 35.

Amendment 312

Proposal for a regulation
Article 34 a (new)

Text proposed by the Commission	*Amendment*
	Article 34a
	Period of protection of new data packages related to existing veterinary medicinal products
	1. Any new studies and trials, submitted by the applicant for a marketing authorisation to the competent authorities for an existing veterinary medicinal product no longer covered by any protection period shall benefit from a stand-alone period of protection of four years, provided that they are:
	(a) needed to extend a marketing authorisation in respect of dosages, pharmaceutical forms or routes of administration;
	(b) needed for a reevaluation requested by the Agency or the competent authorities post-authorisation, unless they have been requested by competent authorities as a follow-up to post authorisation pharmacovigilance concerns, or requested as a condition of authorisation or as a post-

	authorisation commitment at the time of authorisation. Each period of protection shall operate independent from any other that may operate concurrently and shall therefore not be cumulated.
	2. No other applicant may use the results of these trials or studies for commercial purposes during that four year period without the written consent of the holder of the marketing authorisation in the form of a letter of access to those trials or studies.

Amendment 138

Proposal for a regulation
Article 35

Text proposed by the Commission	*Amendment*
Prolongation of the periods of the protection of technical documentation	Prolongation of the periods of the protection of technical documentation
1. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to another species listed in Article 34(1)(a), the period of the protection provided for in that ***Article*** shall be prolonged by ***1 year*** for each additional target species, provided that the variation has been submitted at least 3 years before the expiration of the protection period laid down in Article 34(1)(a).	1. Where ***the first marketing authorisation is granted for more than one species or*** a variation is approved in accordance with Article 65***,*** extending the marketing authorisation to another species listed in Article 34(1)(a), the period of the protection provided for in that ***Article 34*** shall be prolonged by ***two years*** for each additional target species ***in the original dossiers,*** provided that the variation has been submitted at least 3 years before the expiration of the protection period laid down in Article 34(1)(a). ***The information on the submission for extension of the marketing authorisation shall be made publicly available.***
2. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to a another species not listed in Article 34(1)(a), the period of the protection provided for in Article 34 shall be prolonged by 4 years.	2. Where ***the first marketing authorisation is granted for more than one species or*** a variation is approved in accordance with Article 65***,*** extending the marketing authorisation to a another species not listed in Article 34(1)(a), the period of the protection provided for in Article 34 shall be prolonged by 4 years***, provided that the variation has been submitted at least three years before the expiration of the***

	protection period laid down in Article 34. The information on the submission for extension of the marketing authorisation shall be made publicly available.
3. The period of the protection of the first marketing authorisation prolonged by any additional periods of protection due to any variations or new authorisations belonging to the same marketing authorisation ('overall period of the protection of technical documentation') shall not exceed ***18*** years.	3. The period of the protection of the first marketing authorisation prolonged by any additional periods of protection due to any variations or new authorisations belonging to the same marketing authorisation ('overall period of the protection of technical documentation') shall not exceed ***14*** years ***for products referred to in Article 34(1)(a). For products referred to in Article 34(1)(b) and (d), this period shall not exceed 18 years.***
4. Where an applicant for a marketing authorisation for a veterinary medicinal product or for a variation to the terms of the marketing authorisation submits an application in accordance with Regulation (EC) No 470/2009 for the establishment of a maximum residue limit, together with clinical trials during the application procedure, other applicants shall not use ***those*** trials for a period of 5 years from the granting of the marketing authorisation for which they were carried out, unless the other applicant has obtained written agreement in the form of a letter of access with regard to those trials.	4. Where an applicant for a marketing authorisation for a veterinary medicinal product or for a variation to the terms of the marketing authorisation submits an application in accordance with Regulation (EC) No 470/2009 for the establishment of a maximum residue limit, together with clinical trials during the application procedure, other applicants shall not use ***the results of these*** trials ***for commercial purposes*** for a period of 5 years from the granting of the marketing authorisation for which they were carried out, unless the other applicant has obtained written agreement in the form of a letter of access with regard to those trials.

Amendment 139

Proposal for a regulation
Article 38 – paragraph 1

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

Amendment 141

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 date of the submission of the application;	(c) veterinary medicinal products containing an active substance which has not been authorised as a veterinary medicinal product within the Union at the date of the submission of the application***, with the exception of veterinary medicinal products subject to authorisation under Articles 21 and 22***;

Amendment 142

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

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

Amendment 143

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.

Amendment 144

Proposal for a regulation

Article 38 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission, taking into account the state of animal and public health in the Union, shall be empowered to adopt delegated acts in accordance with Article 146 in order to amend the list set out in paragraph 2.	***deleted***

Amendment 145

Proposal for a regulation
Article 46 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Applications for decentralised marketing authorisation shall be submitted to the Member State chosen by the applicant ***(‘***reference Member State'***)***.	1. Applications ***and the dossier*** for decentralised marketing authorisation shall be submitted to ***all the Member States.*** The Member State chosen by the applicant ***shall be the*** reference Member State.

Amendment 146

Proposal for a regulation
Article 46 – paragraph 2

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

Amendment 147

Proposal for a regulation
Article 48 – paragraph 1

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

Amendment 148

Proposal for a regulation
Article 48 – paragraph 2

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

Amendment 149

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

Text proposed by the Commission	*Amendment*
(c) an information about the Member States in which an application for a marketing authorisation submitted by the applicant for the same veterinary medicinal product is under examination;	***deleted***

Amendment 150

Proposal for a regulation
Article 48 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Within ***90*** days of receipt of a valid	4. Within ***45*** days of receipt of a valid

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

Amendment 151

Proposal for a regulation
Article 49 – paragraph 1

Text proposed by the Commission	*Amendment*
1. If a Member State raises, within the time period referred to in Article 46(4) or Article 48(5) its objections to the assessment report, proposed summary of product characteristics or proposed labelling and package leaflet, a detailed statement of the reasons shall be provided to the reference Member State, the other Member States and the applicant. The points of disagreement shall be referred without delay to the coordination group for mutual recognition and decentralised procedures set up by Article 142('the coordination group') by the reference Member State.	1. If a Member State raises, within the time period referred to in Article 46(4) or Article 48(5) its objections to the assessment report, proposed summary of product characteristics or proposed labelling and package leaflet, ***on grounds of a potential serious risk to human or animal health or to the environment,*** a detailed statement of the reasons shall be provided to the reference Member State, the other Member States and the applicant. The points of disagreement shall be referred without delay to the coordination group for mutual recognition and decentralised procedures set up by Article 142 ('the coordination group'***)*** by the reference Member State.

Amendment 152

Proposal for a regulation
Article 49 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Within the coordination group, a rapporteur shall be appointed in order to	***deleted***

prepare a second assessment report for the veterinary medicinal product.

Amendment 153

Proposal for a regulation
Article 49 – paragraph 4

Text proposed by the Commission	*Amendment*
4. In the event of an opinion in favour of granting a marketing authorisation, the reference Member State shall record the agreement of Member States, close the procedure and inform Member States and the applicant accordingly.	4. In the event of an opinion in favour of granting ***or amending*** a marketing authorisation, the reference Member State shall record the agreement of Member States, close the procedure and inform Member States and the applicant accordingly.

Amendment 154

Proposal for a regulation
Article 50 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Within 15 days after receipt of the assessment report referred to in Article 46(3) or in Article 48(4) the applicant may provide written notice to the ***Agency*** requesting a re-examination of the assessment report. In that case the applicant shall forward to the Agency detailed grounds for the request within 60 days of receipt of the assessment report. The application shall be accompanied by proof of payment of the fee payable to the Agency for the re-examination***.***	1. Within 15 days after receipt of the assessment report referred to in Article 46(3) or in Article 48(4) the applicant may provide written notice to the ***Coordination group*** requesting a re-examination of the assessment report. In that case the applicant shall forward to the Agency detailed grounds for the request within 60 days of receipt of the assessment report. The application shall be accompanied by proof of payment of the fee payable to the Agency for the re-examination.

Amendment 155

Proposal for a regulation
Article 50 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***The re-examination procedure shall***	3. ***The Committee shall define the scope***

deal only with the points of the assessment report identified by the applicant in the written notice.	***of the examination, taking into account the information supplied by the applicant.***

Amendment 156

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.

Amendment 157

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 a marketing authorisation be granted, the draft shall include or refer to the documents listed in Article 28.
	Where the draft decision proposes that a marketing authorisation be refused, the

	grounds for refusal shall be stated in accordance with Article 32.
	Where the draft decision does not concur with the Committee's opinion, the Commission shall attach detailed explanations of the grounds for these differences.
	The Commission may, by means of implementing acts, take a final decision on the granting of a marketing authorisation under the decentralised or mutual recognition procedure. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).
	The Agency shall forward to the applicant the documents provided for by Article 28.
	The Agency shall make the opinion publicly available, after deleting any commercially confidential information.

Amendment 158

Proposal for a regulation
Article 51 – paragraph 1

Text proposed by the Commission	*Amendment*
1. A Union database on veterinary medicinal products ('product database') shall be set up and maintained by the Agency.	1. A Union-***wide*** database on veterinary medicinal products ('product database') shall be set up and maintained by the Agency.

Amendment 159

Proposal for a regulation
Article 51 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) veterinary medicinal products authorised within the Union by the Commission and by the competent authorities, together with their summaries of product characteristics, package leaflets and lists of sites where each product is	(a) veterinary medicinal products authorised within the Union by the Commission and by the competent authorities, together with their summaries of product characteristics, package leaflets**,** and lists of sites where each product is

manufactured;	manufactured ***and reference numbers to the pharmacovigilance system master file***;

Amendment 160

Proposal for a regulation
Article 52 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Marketing authorisation holders shall have full access to the information in the product database concerning their own marketing authorisations.	2. Marketing authorisation holders shall have full access to the information in the product database concerning their own marketing authorisations ***and limited access to other products***.

Amendment 161

Proposal for a regulation
Article 52 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The general public shall have access to information in the product database as regards the list of the authorised veterinary medicinal products, their summaries of product characteristics ***and*** package leaflets.	3. The general public shall have access to information in the product database as regards the list of the authorised veterinary medicinal products, their summaries of product characteristics***,*** package leaflets ***and their environmental data, and all safety information***.

Amendment 162

Proposal for a regulation
Article 54 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall collect relevant ***and*** comparable data on the volume of sales and the use of veterinary antimicrobial medicinal products.	1. Member States shall collect relevant comparable ***and sufficiently detailed*** data, ***at per-farm level***, on the volume of sales ***in terms of weight and cost for each antimicrobial type*** and the use of veterinary antimicrobial medicinal products ***including the species treated, the disease diagnosed and the route of***

administration.

Amendment 163

Proposal for a regulation
Article 54 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall send data on the volume of sales and the use of veterinary antimicrobial medicinal products to the Agency. The Agency shall analyse the data and publish an annual report.	2. Member States shall send data on the volume of sales and the use of veterinary antimicrobial medicinal products to the Agency. The Agency shall ***cooperate with other European agencies to*** analyse the data and publish an annual report ***which shall also include the corresponding data for human use of antimicrobials as well as the current situation on antimicrobial resistance in the Union and, where appropriate, issue guidelines and recommendations***.

Amendment 164

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

Text proposed by the Commission	*Amendment*
	3a. Member States shall collect relevant and comparable data on the volume of sales and the use of anti-parasitic and hormonal veterinary medicinal products, and make these available to the Agency.

Amendment 165

Proposal for a regulation
Article 54 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Data requirements for adopting those implementing acts shall include animal species, the dose, the duration and type of treatment, the number of animals treated

and the administration route or routes. In addition, any off-label use of antimicrobials shall be mandatorily reported to national authorities.

Amendment 166

Proposal for a regulation
Article 54 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. The use of antibiotics in drinking water shall be restricted to cases where most of the animals or the whole herd are sick. Five years after the entry into force of this Regulation, the Commission shall publish a report examining the different routes used to administer antibiotics to food-producing animals, and in particular the oral routes used through feed and water, and their subsequent impact on antimicrobial resistance.

Amendment 167

Proposal for a regulation
Section 2 a (new)

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

Amendment 168

Proposal for a regulation
Article 56 a (new)

Text proposed by the Commission	*Amendment*
	Article 56a
	Import authorisations

1. An import authorisation shall be required for the following actions:

(a) the importation of veterinary medicinal products used in the context of Article 8, point (a)(ii) of Article 115(1), point (b) of Article 116(1), point (b) of Article 116(2) and point (a) of Article 116(3) by a veterinarian or by any person authorised to deliver veterinary medicinal products in the Member States;

(b) the parallel importation of veterinary medicinal products by a manufacturer or distributor authorised in a Member State that is independent of the holder of the marketing authorisation. The imported veterinary medicinal product and the national reference medicinal product shall have:

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

(ii) the same therapeutic effects and the same target species.

The national reference medicinal product and the veterinary medicinal product imported in parallel are required to have been harmonised under Article 69 or 70, or authorised in accordance with Articles 46 and 48;

(c) the parallel distribution of veterinary medicinal products by a distributor independently of the holder of the marketing authorisation.

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

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

under Article 51.

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

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

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

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

Amendment 169

Proposal for a regulation
Article 56 b (new)

Text proposed by the Commission	*Amendment*
	Article 56b
	Import authorisation applications
	1. An import authorisation application as referred to in point (a) of Article 56a(1) shall be submitted to the competent authority of the Member State of the importer.
	These authorisations shall be granted for a single operation.
	Any change in the information submitted in order to obtain authorisation shall be notified to the competent authority, which shall accordingly alter the initial authorisation if necessary.
	An import authorisation application shall contain at least the following information:
	(a) the name of the veterinary medicinal product, its strength, its pharmaceutical

form and its therapeutic indications;

(b) the Member State of origin and details of the marketing authorisation;

(c) details of the distributor responsible for the sale of the product;

(d) the quantities imported.

2. An import authorisation application as referred to in point (b) of Article 56a(1) shall be submitted to the competent authority of the Member State of the importer.

These authorisations shall be granted for a period of five years.

Any change in the information submitted in order to obtain authorisation shall be notified to the competent authority, which shall accordingly alter the initial authorisation if necessary.

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

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

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

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

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

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

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

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

	3. An import authorisation application as referred to in point (c) of Article 56a(1) shall be submitted to the Agency.
	These authorisations shall be granted for a period of five years.
	Any change in the information submitted in order to obtain authorisation shall be notified to the Agency, which shall accordingly alter the initial authorisation if necessary.
	The application shall contain information concerning:
	(a) the name or company name of the applicant, of the manufacturer involved in relabelling, and the parallel distributor;
	(b) the name of the qualified person responsible for pharmacovigilance;
	(c) the Member State of origin and destination.
	4. The competent authority or the Agency may suspend or withdraw parallel import or parallel distribution authorisations if Article 56a and paragraphs 1, 2 and 3 of this Article are no longer complied with or if the product presents a risk to human or animal health or to the environment.

Amendment 170

Proposal for a regulation
Article 57 a (new)

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

	marketing authorisations for the veterinary medicinal product into a centralised marketing authorisation granted by the Commission which shall be valid throughout the Union.
	2. The application for the conversion into a centralised marketing authorisation shall be submitted to the Agency and shall include the following:
	(a) a list of all decisions granting marketing authorisations concerning this veterinary medicinal product;
	(b) a list of variations introduced since the first marketing authorisation in the Union was granted;
	(c) a summary report on pharmacovigilance data.
	3. Within 30 days of receipt of the documents listed in paragraph 2, the Commission shall prepare a draft of the decision granting the Union marketing authorisation in conformity with the assessment report referred to in Articles 46(3), 48(4) and 69(3) or, where appropriate, an updated assessment report, a summary of the product characteristics, and a labelling and package leaflet.
	4. The Commission shall, by means of implementing acts, take a final decision on the granting of the centralised marketing authorisation.
	This Article shall only apply to veterinary medicinal products that have been authorised through a mutual recognition procedure, a decentralised procedure or a marketing authorisation harmonisation procedure after the date of the application of this Regulation.

Amendment 171

Proposal for a regulation
Article 64 – paragraph 1

Text proposed by the Commission	*Amendment*
1. If a variation application fulfils the requirements laid down in Article 61, the competent authority or the Agency, or a competent authority assigned in accordance with Article 63(3) shall acknowledge receipt of a complete application.	1. If a variation application fulfils the requirements laid down in Article 61, the competent authority or the Agency, or a competent authority assigned in accordance with Article 63(3) shall acknowledge receipt of a complete application ***in 15 days***.

Amendment 172

Proposal for a regulation
Article 68

Text proposed by the Commission	*Amendment*
Preparatory phase of the harmonisation exercise	Preparatory phase of the harmonisation exercise
	-1a. A single marketing authorisation holder or a group of marketing authorisation holders may, in accordance with Article 69, request a harmonisation of different national marketing authorisations that have been granted for a particular veterinary medicinal product.
	-1b. A harmonised summary of product characteristics shall be prepared for the particular veterinary medicinal product, for which national marketing authorisations have been granted in different Member States. The coordination group shall draw up detailed rules of procedure for harmonisation.
	-1c. National marketing authorisations may be harmonised with decentralised and/or mutual recognition marketing authorisations if they are for the same product or for essentially similar products
1. ***A*** harmonised ***summary of product characteristics*** shall be prepared in accordance with the procedure laid down in Article 69 for veterinary medicinal products, other than homeopathic veterinary medicinal products, which have	1. Harmonised ***conditions of use as set out in Article 69(4)*** shall be prepared in accordance with the procedure laid down in Article 69 for ***groups of essentially similar*** veterinary medicinal products, other than homeopathic veterinary

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').***	medicinal products, which have the same qualitative and quantitative composition of their active substances and the same pharmaceutical form ***and have been shown to be bio-equivalent ('essentially similar' products)*** and for which national marketing authorisations have been granted in different Member States ***before the entry into force of this Regulation.***
2. For the purposes of determining qualitative and quantitative composition of the active substances, different salts, esters, ethers, isomers, mixtures of isomers, complexes and derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy.	2. For the purposes of determining qualitative and quantitative composition of the active substances, different salts, esters, ethers, isomers, mixtures of isomers, complexes and derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy.

Amendment 173

Proposal for a regulation
Article 69

Text proposed by the Commission	*Amendment*
Procedure for harmonisation of summaries of products characteristics	Procedure for harmonisation of summaries of products characteristics
1. By *[12 months after the date of application of this Regulation for OP to insert the actual date]* competent authorities shall provide the coordination group with lists of all products for which national marketing authorisations have been granted ***before 1 January 2004***.	1. By *[12 months after the date of application of this Regulation for OP to insert the actual date]* competent authorities shall provide the coordination group with lists of all products for which national marketing authorisations have been granted.
2. The coordination group shall establish groups of similar products. For each of ***the*** groups of similar products, the coordination group shall appoint one member to act as a rapporteur.	2. The coordination group shall establish groups of ***essentially*** similar products ***as identified in point (b) of Article 68(4).*** For each of ***these*** groups of ***essentially*** similar products, the coordination group shall appoint one member to act as a rapporteur.
3. Within 120 days of his appointment, the rapporteur shall present the coordination group a report ***regarding possible*** harmonisation of ***summaries of product characteristics for the*** similar veterinary medicinal products ***in the group and***	3. Within 120 days of his appointment, the rapporteur shall present to the coordination group a report ***proposing*** harmonisation of ***the conditions of use for the group of essentially*** similar veterinary medicinal products ***or of the marketing authorisation***

propose a harmonised summary of products characteristics.	***of a particular veterinary medicinal product.***
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:
(a) all species mentioned in the marketing authorisations granted by Member States in respect of the similar products in the group;	(a) all species mentioned in the marketing authorisations granted by Member States in respect of the ***essentially*** similar products in the group;
(b) all therapeutic indications mentioned in the marketing authorisations granted by Member States in respect of the similar products in the group;	(b) all therapeutic indications ***and posology*** mentioned in the marketing authorisations granted by Member States in respect of the ***essentially*** similar products in the group;
(c) ***the shortest*** withdrawal period ***of those stated in the summaries of the product characteristics.***	(c) ***a*** withdrawal period ***which ensures that consumers are adequately protected;***
	(ca) special precautions regarding impact on the environment.
	4a. Further than the conditions of use, other elements of the summary of product characteristics and data quality set, may be harmonised.
5. Upon presentation of a report, the coordination group shall act by a majority of the votes cast by the members of the coordination group represented at the meeting. The rapporteur shall record the agreement, close the procedure and inform Member States and the marketing authorisation holders accordingly.	5. Upon presentation of a report, the coordination group shall act by a majority of the votes cast by the members of the coordination group represented at the meeting. The rapporteur shall record the agreement, close the procedure and inform Member States and the marketing authorisation holders accordingly.
6. In the event of an opinion in favour of adopting ***a*** harmonised ***summary of the product characteristics***, each Member State shall vary ***a*** marketing authorisation in conformity with the agreement within 30 days of receipt of the information regarding the agreement from the rapporteur.	6. In the event of an opinion in favour of adopting harmonised ***conditions of use***, each Member State shall vary ***the*** marketing authorisation ***or authorisations of the products in their territory so that the elements listed in paragraph 4, where they are already included in the summaries of characteristics for a product belonging to that group, are*** in conformity with the agreement within 30 days of receipt of the information regarding the agreement from the rapporteur. ***Once an opinion in favour of adopting harmonised conditions of use has been issued, marketing authorisations for a particular product shall be eligible to be considered***

	to be mutual recognition marketing authorisations granted under this Regulation.
7. In the event of an unfavourable opinion, the procedure referred to in Article 49 shall apply.	7. In the event of an unfavourable opinion, the procedure referred to in Article 49 shall apply.

Amendment 174

Proposal for a regulation
Article 70

Text proposed by the Commission	*Amendment*
Harmonisation of summary of products characteristics following reassessment	Harmonisation of summary of products characteristics following reassessment
1. By way of derogation from Article 69, the Committee may recommend to the Commission groups of similar veterinary medicinal products for which a scientific reassessment is necessary before a harmonised ***summary of the product characteristics is*** prepared.	1. By way of derogation from Article 69, ***and where harmonisation of the conditions of use of a group of products is in the interests of public or animal health at Union level,*** the Committee may recommend to the Commission groups of similar veterinary medicinal products for which a scientific reassessment is necessary before harmonised ***conditions of use are*** prepared.
	1a. For the purpose of harmonisation under this Article similar veterinary medicinal products shall refer to products, not all of which are bioequivalent, and other than homeopathic veterinary medicinal products, that have the same active substance or active substances and the same pharmaceutical form or a range of veterinary medicinal products belonging to the same therapeutic class.
2. The Commission shall, by means of implementing acts, adopt decisions on groups of product for which a reassessment is necessary. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	2. The Commission shall, by means of implementing acts, adopt decisions on groups of ***similar*** products for which a reassessment is necessary. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).
3. By way of derogation from Article 69, veterinary medicinal products ***authorised before 20 July 2000 as well as veterinary medicinal products authorised after that***	3. By way of derogation from Article 69, veterinary medicinal products ***which have not been subject to an environmental risk assessment in the Union*** shall be ***assessed***

date but which were identified as potentially harmful to the environment in the course of the environmental risk assessment shall be ***reassessed*** before ***a*** harmonised ***summary of the product characteristics is*** prepared.	***in accordance with Annex II*** before harmonised ***conditions of use are*** prepared. ***For that purpose, marketing authorisation holders shall update accordingly the documentation mentioned in point (b) of Article 7(1).***
	3a. By way of derogation from Article 69, antimicrobial veterinary medicinal products shall be reassessed within five years of the entry into force of this Regulation.
4. For the purposes of paragraphs 1 and 3, the procedure for a Union interest referral in accordance with Articles 84 to 87 shall apply accordingly.	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.

Amendment 175

Proposal for a regulation
Article 71

Text proposed by the Commission	*Amendment*
Position of marketing authorisation holder	Position of marketing authorisation holder
Upon request from the coordination group or the Agency, holders of the marketing authorisations for products included in a group of similar products identified for a harmonisation of the summaries of the product characteristics shall submit information concerning their products.	Upon request from the coordination group or the Agency, holders of the marketing authorisations for products included in a group of products identified for a harmonisation of the summaries of the product characteristics ***or the holders of a particular product identified for harmonisation of marketing authorisations*** shall submit information concerning their products

Amendment 176

Proposal for a regulation
Article 72 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Marketing authorisation holders shall elaborate and maintain a system for collecting information on the ***risks*** of veterinary medicinal products as regards	1. Marketing authorisation holders shall ***ensure that risk-benefit balance of authorised veterinary medicinal products is evaluated on a continuous basis and***

animal health, public health and the environment ***enabling them*** to fulfil ***their*** pharmacovigilance responsibilities listed in Articles 73, 76 and 77 (‘pharmacovigilance system').	***that appropriate measure are taken by the marketing authorisation holders in order to ensure that this balance remains positive for the authorised veterinary medicinal products. To this end, the marketing authorisation holders shall*** elaborate and maintain a system for collecting***, investigating, assessment and communicating of*** information on the ***adverse events*** of veterinary medicinal products as regards animal health, public health and the environment***. The system shall serve to coordinate the necessary measures*** to fulfil ***the*** pharmacovigilance responsibilities listed in Articles 73, 76 and 77 (‘pharmacovigilance system').

Amendment 177

Proposal for a regulation
Article 72 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Competent authorities and the Agency shall supervise the pharmacovigilance systems of marketing authorisation holders.	2. Competent authorities and the Agency shall supervise the pharmacovigilance systems of marketing authorisation holders ***and shall not have any conflict of interest with regard to the marketing authorisation holder.***

Amendment 178

Proposal for a regulation
Article 73 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States, the Commission***,*** the Agency ***and marketing authorisation holders*** shall collaborate in setting up ***and maintaining a system*** to monitor the safety of authorised veterinary medicinal products***, enabling them*** to fulfil their responsibilities as listed in ***Articles 77 and*** 79 ***(‘Union pharmacovigilance system’)***.	1. Member States, the Commission ***and*** the Agency shall collaborate in setting up***, interconnecting and further developing their systems*** to monitor the safety***, effectiveness and quality*** of authorised veterinary medicinal products ***in order*** to fulfil their responsibilities as listed in ***Article*** 79. ***Marketing authorisation holders shall set up and maintain a system to monitor the safety, effectiveness and***

	quality of their products, enabling them to fulfil their responsibilities as listed in Articles 77 and 78.

Amendment 179

Proposal for a regulation
Article 73 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Competent authorities, the Agency and marketing authorisation holders shall make available to healthcare professionals ***and*** animal holders different means of reporting to them the following events whether or not the event is considered to be product-related ***('adverse events')***:	2. Competent authorities, the Agency and marketing authorisation holders shall make available to healthcare professionals***,*** animal holders***, environmental authorities of the Member States and other interested parties*** different means of reporting to them the following events ***('adverse events')*** whether or not the event is considered to be product-related:
(a) any response in an animal to a veterinary or human medicinal product, that is noxious and unintended***;***	(a) any response in an animal to a veterinary or human medicinal product, that is noxious and unintended***, regardless of whether or not the event is considered to be product-related and whether or not the product was administered in accordance with the summary of product characteristics;***
(b) any observation of a lack of efficacy of a veterinary medicinal product following ***administration to*** an animal ***in accordance with the summary of product characteristics***;	(b) any observation of a lack of efficacy of a veterinary medicinal product***, including potential signs of antimicrobial resistance,*** following ***its use on*** an animal;
(c) any ***environmental incidents observed*** following administration of a veterinary medicinal product to an animal;	(c) any ***adverse, unforeseen, or unintended impact in the environment (including ground and surface water)*** following administration of a veterinary medicinal product to an animal;
(d) any infringements of withdrawal period following administration to an animal of a veterinary ***or human*** medicinal product***;***	(d) any infringements of withdrawal period following administration to an animal of a veterinary medicinal product;
(e) any noxious ***response*** in humans to a veterinary medicinal product;	(e) any noxious ***reaction*** in humans to a veterinary medicinal product;
(f) any finding of an active substance in a produce of a food-producing animal exceeding the levels of residues established	(f) any finding of an active substance in a produce of a food-producing animal exceeding the levels of residues established

in accordance with Regulation (EC) No 470/2009.	in accordance with Regulation (EC) No 470/2009***;***
	(fa) any suspected unintended transmission via a veterinary medicinal product of any infectious agent.

Amendment 180

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

Text proposed by the Commission	*Amendment*
	2a. Competent authorities and the Agency shall, in addition to the events provided under paragraph 2, make available to healthcare professionals and animal holders different means of reporting to them any response in an animal to a human medicinal product.

Amendment 181

Proposal for a regulation
Article 73 a (new)

Text proposed by the Commission	*Amendment*
	Article 73a
	No later than six months before the date of application of this Regulation, the Commission shall present a report to the European Parliament and the Council on a feasibility study of a substance-based review system ('monographs') and other potential alternatives for the environmental risk assessment of veterinary medicinal products, to be accompanied, if appropriate, by a legislative proposal.

Amendment 182

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. Maintaining the database shall include electronic archiving of the original reports, related subsequent reports and continuous quality control of the data.***

Amendment 183

Proposal for a regulation
Article 74 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency shall, in ***collaboration*** with the Member States ***and*** the Commission, draw up the functional specifications for the pharmacovigilance database.	2. The Agency shall, in ***consultation*** with the Member States***,*** the Commission ***and interested parties***, draw up the functional specifications for the pharmacovigilance database. ***These shall include environmental monitoring data which would report undesirable effects on non-target species in the ecosystem, and extend sources of inputs to the pharmacovigilance system to include observation and monitoring by specialists who are not necessarily veterinarians.***

Amendment 184

Proposal for a regulation
Article 74 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall ensure that	3. The Agency shall ensure that

information reported to the pharmacovigilance database is uploaded and made accessible in accordance with Article 75.	information reported to the pharmacovigilance database is uploaded and made ***publicly*** accessible in accordance with Article 75.

Amendment 185

Proposal for a regulation
Article 74 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Agency shall ensure that the transfer of information between its pharmacovigilance database and the national pharmacovigilance databases of the individual Member States is safeguarded.

Amendment 186

Proposal for a regulation
Article 75 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) the number of adverse events reported each year, broken down by product, animal species and type of adverse event;	(a) the number of adverse events reported each year, broken down by ***type of*** product ***and active substance***, animal species and type of adverse event;

Amendment 187

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

Text proposed by the Commission	*Amendment*
	(ba) information about incidence of adverse events.

Amendment 188

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.

Amendment 189

Proposal for a regulation
Article 76 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Competent authorities shall record in the pharmacovigilance database ***all*** adverse ***events which were reported to them by healthcare professionals and animal holders and that occurred in the territory of their Member State,*** within ***30*** days following the receipt of ***the*** adverse event report.	1. Competent authorities shall record ***and assess all adverse events of which they learn under Article 73 and which occur*** in the ***territory of their Member State and shall enter them immediately, but no later than 15 days following the receipt of the information, in the*** pharmacovigilance database***. Competent authorities shall record any serious*** adverse ***event in animals, noxious response in humans to a veterinary medicinal product or environmental incident observed following administration of a veterinary medicinal product to an animal*** within ***15*** days following the receipt of ***such an*** adverse event report.

Amendment 190

Proposal for a regulation
Article 76 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Marketing authorisation holders shall record in the pharmacovigilance database all adverse events which were reported to them by healthcare professionals and animal holders and that occurred within the Union or in a third country with regard to their authorised veterinary medicinal products**,** within ***30*** days following the receipt of ***the*** adverse event report.	2. Marketing authorisation holders shall record in the pharmacovigilance database ***and evaluate*** all adverse events which were reported to them by healthcare professionals and animal holders and that occurred within the Union or in a third country with regard to their authorised veterinary medicinal products***. Serious adverse event in animals, noxious response in humans to a veterinary medicinal product and environmental incidents observed following administration of a veterinary medicinal product to an animal shall be reported*** within ***15*** days following the receipt of ***such*** adverse event report. ***Less serious adverse events relating to the use of veterinary medicinal products shall be reported no later than 42 days following receipt of the information. Different requirements shall apply for adverse events observed in clinical trials, as specified in the Good Clinical Practice guidelines for clinical trials***.

Amendment 191

Proposal for a regulation
Article 76 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Competent authorities may, on their own initiative or on request from the Agency, request the marketing authorisation holder to ***collect*** specific pharmacovigilance data, ***in particular*** regarding the use of a veterinary medicinal product in specified animal species, in the context of public and animal health, safety of the persons administering the product, ***and*** the protection of the environment. The	3. Competent authorities may, on their own initiative or on ***a*** request from the Agency, request the marketing authorisation holder to ***provide*** specific pharmacovigilance data, ***such as, information relating to ongoing risk-benefit balance evaluations*** regarding the use of a veterinary medicinal product in specified animal species, in the context of public and animal health, safety of the persons administering the product, ***or*** the

authority shall state in detail the reasons for the request and inform other competent authorities and the Agency thereof.	protection of the environment. The authority shall state in detail the reasons for the request and inform other competent authorities and the Agency thereof. ***Marketing authorisation holders shall be required to comply with such a request within an appropriate deadline set by the competent authority***.

Amendment 192

Proposal for a regulation
Article 77 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder shall be responsible for the pharmacovigilance of the products for which he holds a marketing authorisation.	1. The marketing authorisation holder shall be responsible for the pharmacovigilance of the products for which he holds a marketing authorisation ***and shall take all appropriate steps to encourage members of the health professions and animal holders to report adverse events***.

Amendment 193

Proposal for a regulation
Article 77 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the pharmacovigilance tasks have been contracted out by the marketing authorisation holder to a third party, ***those arrangements*** shall be set out ***in details*** in the pharmacovigilance system master file.	2. Where the pharmacovigilance tasks have been contracted out by the marketing authorisation holder to a third party ***(contractor)***, ***the responsibilities of both parties*** shall be set out ***explicitly in a contract and*** in the pharmacovigilance system master file.

Amendment 194

Proposal for a regulation
Article 77 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The marketing authorisation holder shall be required to check regularly that the contractor is carrying out the work in accordance with the requirements of the contract.

Amendment 195

Proposal for a regulation
Article 77 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The marketing authorisation holder shall permanently have at his disposal ***one or more*** appropriately qualified ***persons*** responsible for pharmacovigilance. ***Those persons*** shall reside and operate in the Union***. Only one qualified person shall be designated by the marketing authorisation holder per pharmacovigilance system master file***.	3. The marketing authorisation holder shall permanently have at his disposal ***an*** appropriately qualified ***person*** responsible for pharmacovigilance. ***That person*** shall reside and operate in the Union***. The qualified person responsible for pharmacovigilance may delegate specific areas of work to appropriately trained staff but shall remain responsible for the marketing authorisation holder's pharmacovigilance system and for the safety profile of his veterinary medicinal products.***

Amendment 196

Proposal for a regulation
Article 77 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where the tasks of the qualified person responsible for pharmacovigilance listed in Article 78 have been contracted out to a third party, ***those*** arrangements shall be ***detailed in the*** contract.	4. Where the tasks of the qualified person responsible for pharmacovigilance listed in Article 78 have been contracted out to a third party, ***the relevant*** arrangements shall be ***set out explicitly in a*** contract.

Amendment 197

Proposal for a regulation

Article 77 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The marketing authorisation holder shall not communicate information regarding adverse events to the general public in relation to the veterinary medicinal product without ***giving prior notification of his intention*** to the competent authority or authorities having granted the marketing authorisation or to the Agency where the marketing authorisation was granted in accordance with the centralised authorisation procedure.	6. The marketing authorisation holder shall not communicate information regarding adverse events ***and potential pharmacovigilance concerns*** to the general public in relation to the veterinary medicinal product without ***sending in advance a copy of that communication*** to the competent authority or authorities having granted the marketing authorisation or to the Agency where the marketing authorisation was granted in accordance with the centralised authorisation procedure.

Amendment 198

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.

Amendment 199

Proposal for a regulation
Article 78

Text proposed by the Commission	*Amendment*
Qualified person responsible for pharmacovigilance	Qualified person responsible for pharmacovigilance
Qualified persons responsible for pharmacovigilance as referred to in Article 77(3) shall ***carry out*** the following tasks:	Qualified persons responsible for pharmacovigilance as referred to in Article 77(3) shall ***ensure that*** the following tasks ***are carried out :***
(a) elaborating and maintaining a detailed description of the pharmacovigilance system used by the marketing authorisation holder ***with respect to the veterinary medicinal product for which the authorisation has been granted*** (‘pharmacovigilance system master file’) for all products under their responsibility;	(a) elaborating and maintaining a detailed description of the pharmacovigilance system used by the marketing authorisation holder (‘pharmacovigilance system master file’) for all products under their responsibility;
(b) allocating reference numbers to the pharmacovigilance system master file and communicating the reference number of the pharmacovigilance master file ***of each product*** to the product database;	(b) allocating reference numbers to the pharmacovigilance system master file and communicating the ***relevant*** reference number of the pharmacovigilance master file to the product database ***for each product***;
(c) notifying the competent authorities and the Agency of the place where the qualified person operates and where the pharmacovigilance system master file is accessible in the Union;	(c) notifying the competent authorities and the Agency of the place where the qualified person operates and where the pharmacovigilance system master file is accessible in the Union;
(d) establishing and maintaining a system which ensures that all adverse events which are brought to the attention of the	(d) establishing and maintaining a system which ensures that all adverse events, ***including on non-target species and the***

marketing authorisation holder are collected and recorded in order to be accessible at least at one site in the Union;	***environment***, which are brought to the attention of the marketing authorisation holder are collected and recorded in order to be accessible at least at one site in the Union;
(e) preparing the adverse event reports referred to in Article 76;	(e) preparing the adverse event reports referred to in Article 76;
(f) ensuring that collected adverse event reports are recorded in the pharmacovigilance database;	(f) ensuring that collected adverse event reports are recorded in the pharmacovigilance database;
(g) ensuring that any request from the competent authorities or the Agency for the provision of additional information necessary for the evaluation of the benefit-risk balance of a veterinary medicinal product is answered fully and promptly, including providing information about the volume of sales or prescriptions of the veterinary medicinal product concerned;	(g) ensuring that any request from the competent authorities or the Agency for the provision of additional information necessary for the evaluation of the benefit-risk balance of a veterinary medicinal product is answered fully and promptly, including providing information about the volume of sales or prescriptions of the veterinary medicinal product concerned;
(h) providing competent authorities or the Agency with any other information relevant to detecting a change to the benefit-risk balance of a veterinary medicinal product, including appropriate information on post-marketing surveillance studies;	(h) providing competent authorities or the Agency with any other information relevant to detecting a change to the benefit-risk balance of a veterinary medicinal product, including appropriate information on post-marketing surveillance studies;
(i) evaluating by means of the pharmacovigilance system all information, considering options for risk minimisation and prevention and taking appropriate measures if necessary;	(i) evaluating by means of the pharmacovigilance system all information, considering options for risk minimisation and prevention and taking appropriate measures if necessary;
(j) monitoring the pharmacovigilance system and ensuring that if needed, an appropriate corrective action plan is prepared and implemented;	(j) monitoring the pharmacovigilance system and ensuring that if needed, an appropriate corrective action plan is prepared and implemented;
(k) ensuring that all personnel involved in the performance of pharmacovigilance activities receives continued training;	(k) ensuring that all personnel involved in the performance of pharmacovigilance activities receives continued training ***tailored to their duties, on an ongoing basis; training courses are documented and their effectiveness reviewed;***
(l) communicating any regulatory measure that is taken in a third country and is based on pharmacovigilance data to the competent authorities and the Agency within 15 days of receipt of such	(l) communicating any regulatory measure that is taken in ***another Member State or*** a third country and is based on pharmacovigilance data to the competent authorities and the Agency within 15 days

information.	of receipt of such information;
	(la) conducting for each product an annual risk-benefit review taking into account all pharmacovigilance surveillance data available on the product concerned, including pharmacovigilance signal monitoring. This review shall be documented by the marketing authorisation holder and the outcome recorded in the pharmacovigilance database. The marketing authorisation holder shall provide the documentation supporting the outcome of the review on request from the national competent authority or during the conduct of an inspection carried out in accordance with Article 128;
	(lb) the authorisation holder shall be required to ensure that the qualified person responsible for pharmacovigilance is authorised to maintain and further develop the pharmacovigilance system and to ensure compliance with requirements.

Amendment 200

Proposal for a regulation
Article 79 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Competent authorities shall evaluate all adverse events reported to them by healthcare professionals and animal holders, manage risks and take the measures referred to in Articles 130 to 135 concerning marketing authorisations where necessary.	1. Competent authorities shall evaluate all adverse events reported to them by ***marketing authorisation holders,*** healthcare professionals and animal holders, manage risks and take the measures referred to in Articles 130 to 135 concerning marketing authorisations where necessary.

Amendment 201

Proposal for a regulation
Article 79 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Competent authorities and the Agency shall ***provide the general*** public***, veterinarians and other healthcare professionals with*** all important information on adverse events relating to the use of a veterinary medicinal product in a timely manner electronically or through other publicly available means of communication.	4. Competent authorities and the Agency shall ***make*** public all important information on adverse events relating to the use of a veterinary medicinal product in a timely manner electronically or through other publicly available means of communication. ***Competent authorities and the Agency shall ensure that veterinarians receive feedback on adverse events reported and regular feedback on all adverse reactions reported***.

Amendment 203

Proposal for a regulation
Article 80 – paragraph 1

Text proposed by the Commission	*Amendment*
1. A competent authority may delegate any of the tasks entrusted to it as referred to in Article 79 to a competent authority in another Member State subject to the written agreement of the latter.	1. A competent authority may delegate any of the tasks entrusted to it as referred to in Article 79 to a competent ***public*** authority in another Member State subject to the written agreement of the latter.

Amendment 204

Proposal for a regulation
Article 81

Text proposed by the Commission	*Amendment*
Signal management process	Signal management process
1. Competent authorities and the Agency shall cooperate in monitoring the data in the pharmacovigilance database to determine whether there is any change to the benefit-risk balance of veterinary medicinal products with a view to detecting risks to animal health, public health and protection of the environment (‘signal management process’).	1. ***Marketing authorisation holders***, competent authorities, ***other concerned authorities*** and the Agency shall cooperate in monitoring the data in the pharmacovigilance database to determine whether there is any change to the benefit-risk balance of veterinary medicinal products with a view to detecting risks to animal health, public health and protection of the environment (‘signal management

process’).

2. Competent authorities and the Agency shall establish groups of veterinary medicinal products for which signal management process can be combined with a view of detecting risks to animal health, public health and protection of the environment.	Competent authorities and the Agency shall establish groups of veterinary medicinal products for which signal management process can be combined with a view of detecting risks to animal health, public health and protection of the environment.
3. The Agency and the ***coordination*** group shall agree on sharing of the monitoring of data on groups of veterinary medicinal products recorded in the pharmacovigilance database. For each group of veterinary medicinal products a competent authority or the Agency shall be appointed as responsible for the monitoring thereof (‘lead authority’).	3. The Agency and the ***veterinary pharmacovigilance*** group shall agree on sharing of the monitoring of data on groups of veterinary medicinal products recorded in the pharmacovigilance database. For each group of veterinary medicinal products a competent authority or the Agency shall be appointed as responsible for the monitoring thereof (‘lead authority’).
4. The results of the signal management process shall be agreed upon by the competent authorities and, where appropriate, the Agency. The lead authority shall record the results in the pharmacovigilance database.	4. ***Given that marketing authorisation holders are the primary source of expertise and information concerning the products under their responsibility, the lead authority may where necessary consult them during the signal management process.*** The results of the signal management process shall be agreed upon by the competent authorities and, where appropriate, the Agency. The lead authority shall record the results in the pharmacovigilance database.
5. Where necessary, based on the results of the signal management process referred to in paragraph 4 the competent authorities or the Commission shall take appropriate measures as referred to in Articles 130 to 135.	5. Where necessary, based on the results of the signal management process referred to in paragraph 4 the competent authorities or the Commission shall take appropriate measures as referred to in Articles 130 to 135.

Amendment 205

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	Before the expiry of the period of validity of ***five*** years, marketing authorisations for a limited market granted in accordance with

Article 21 shall be re-examined on application from the marketing authorisation holder. After the initial re-examination, it shall be re-examined every ***5*** years.	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 ***five*** years.

Amendment 206

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).	

Amendment 207

Proposal for a regulation
Article 88 – paragraph 1

Text proposed by the Commission	*Amendment*
1. By way of derogation from Article 5, homeopathic veterinary medicinal products that satisfy the requirements set out in Article 89 and are not immunological homeopathic veterinary medicinal products shall be registered in accordance with Article 90.	1. By way of derogation from Article 5, homeopathic veterinary medicinal products that satisfy the requirements set out in Article 89 and are not immunological homeopathic veterinary medicinal products shall be registered in accordance with Article 90. ***Veterinary medicinal products registered or approved in accordance with national rules before 31 December 1993 shall not be affected by this Article.***

Amendment 208

Proposal for a regulation
Article 88 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The veterinary homeopathic medicinal products not subject to Article 89(1) shall be authorised in accordance with the general regulations. Where the safety tests, preclinical and clinical trials of veterinary homeopathic medicinal products are not subject to Article 89(1), a Member State may introduce or retain on its territory specific rules in accordance with the principles and characteristics as practised in that Member State.

Amendment 209

Proposal for a regulation
Article 89 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product shall not contain more than one part per 10 000 of the mother tincture***;***	(b) there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product shall not contain more than one part per 10 000 of the mother tincture***, unless the ingredients of the medicinal***

product are included in Table 1 of Regulation (EU) No 37/2010 with the comment "No maximum residue level (MRL) required";

Amendment 210

Proposal for a regulation
Article 90 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered;	(a) scientific name or other name given in a pharmacopoeia ***or documented in a monograph*** of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered;

Amendment 211

Proposal for a regulation
Article 91 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) in addition to a manufacturing authorisation, the manufacturers in question shall be required to have proof and confirmation of compliance with good manufacturing practices ('GMP');

Amendment 212

Proposal for a regulation
Article 91 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	A manufacturing authorisation shall also not be required for preparation, filling or changes in packaging or presentation where these processes are carried out solely for dispensing by pharmacists in a pharmacy or by veterinarians in a

veterinary practice.

Amendment 302

Proposal for a regulation
Article 92 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) details about the manufacturing site where the veterinary medicinal products are to be manufactured or tested;	(c) details about the manufacturing site where the veterinary medicinal products are to be manufactured or tested***, including data about emissions, discharges and losses of the active substance and its precursors to the environment***;

Amendment 213

Proposal for a regulation
Article 93 – paragraph 5

Text proposed by the Commission	*Amendment*
5. A manufacturing authorisation may be granted conditionally, subject to a requirement for the applicant to ***undertake actions or introduce specific procedures*** within a given time period. The manufacturing authorisation may be suspended if these requirements are not complied with.	5. A manufacturing authorisation may be granted conditionally ***where minor shortcomings are identified***, subject to a requirement for the applicant to ***rectify the shortcomings*** within a given time period. The manufacturing authorisation may be suspended if these requirements are not complied with. ***The manufacturing authorisation shall be refused if manufacturing causes unacceptable risks to the environment.***

Amendment 214

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

Text proposed by the Commission	*Amendment*
	(ca) comply with the rules on good manufacturing practice for medicinal products established in the Union and use as starting materials only active substances which have been manufactured in accordance with the rules on good manufacturing practice for starting materials established in the Union;

Amendment 215

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. Such an authorisation shall not apply to the supply, by a manufacturer, of veterinary medicinal products which it has itself manufactured, nor to the retail sale of veterinary medicinal products by persons entitled to conduct such sales in accordance with Article 107.***

Amendment 216

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

Text proposed by the Commission	*Amendment*
	4a. On the basis of the best practices model that already exists for medicinal products for human use, the Commission

	shall adopt, within 24 months of the entry into force of this Regulation, principles and guidelines, to which wholesalers shall be obliged to adhere, for best practices in the wholesale distribution of veterinary medicinal products.

Amendment 217

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

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

Amendment 218

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 points (ca) and (cc) of Article 105(3) with regard to supply of medicinal products.

Amendment 219

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 veterinary medicinal products;	(a) has at his disposal technically competent staff and suitable and sufficient premises complying with the requirements laid down by the Member State concerned as regards the storage and handling of veterinary medicinal products***, and which***

***premises representatives of the competent authority may enter at any time*;**

Amendment 220

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), is able to guarantee permanently an adequate range of medicinal products to meet the requirements of the territory being supplied and to deliver the supplies requested within a very short time over the whole of the territory in question;

Amendment 221

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

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

Amendment 222

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

Text proposed by the Commission	*Amendment*
	(cc) is able to notify the competent authority of any shortage of stock likely to

be detrimental to animal health needs in the Member State in question.

Amendment 223

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 assume the responsibility referred to in paragraph 1, if that person personally fulfils those conditions as specified above.
	3. The competent authority shall ensure that the obligations of qualified persons referred to in this Article are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct. The competent authority may temporarily suspend such persons upon the commencement of administrative or disciplinary proceedings against them for failure to fulfil their obligations.

Amendment 224

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 ***immediate*** care, ***subject to an appropriate veterinary diagnosis and examination of the animal(s) concerned,*** and only in the amount required for the treatment concerned***. In the case of food-producing animals, the continuation of the treatment with antimicrobial products shall be decided based on a renewed clinical examination by a veterinarian.***

Amendment 225

Proposal for a regulation
Article 107 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Member States may impose stricter conditions, justified on grounds of public health, animal health and environment protection, for the retail of veterinary medicinal products on their territory, provided that these conditions are proportionate to the risk and do not unduly restrict the functioning of the internal market.

Amendment 226

Proposal for a regulation
Article 107 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. Any commercial participation in companies which trade in, manufacture or import veterinary medicinal products shall be prohibited.

Amendment 227

Proposal for a regulation
Article 107 – paragraph 2 c (new)

Text proposed by the Commission	*Amendment*
	2c. Given the risks associated with antimicrobial resistance, no economic incentives may be provided in any form, directly or indirectly, by pharmaceutical companies to persons who prescribe veterinary medicinal products.

Amendment 228

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***:

Amendment 229

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.

Amendment 230

Proposal for a regulation
Article 108

Text proposed by the Commission	*Amendment*
Retail of veterinary medicinal products at a distance	Retail of veterinary medicinal products at a distance
1. Persons permitted to supply veterinary medicinal products in accordance with Article 107(1) may offer veterinary medicinal products ***by means of information society services in the meaning of Directive 98/34/EC of the European Parliament and of the Council***[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, ***with the exception of antimicrobials, psychotropic and biological or immunological veterinary medicinal products, on the internet*** to natural or legal persons established in the Union under the condition that***:***
	(a) the veterinary medicinal products and the prescriptions comply with the law of the destination Member State;
	(b) the natural or legal person offering veterinary medicinal products is permitted or qualified to supply prescription and non-prescription veterinary medicinal products to the public, including at a distance, in accordance with the national law of the Member State in which that person is established;
	(c) the person referred to in point (a) has notified at least the following information to the Member State of establishment:
	(i) the name or corporate name and the permanent address of the place of business from where the veterinary medicinal products are supplied;
	(ii) the date on which veterinary medicinal products were first offered for sale at a distance to the public on the internet;
	(iii) the address of the website used for that purpose and all information necessary to identify that website.
	1a. On grounds of public or animal health, animal welfare or environmental

	protection, Members States shall be able to limit or condition, or both, the sale at a distance on the internet to the public on their territory of veterinary medicinal products or of other prescription veterinary medicinal products for food producing animals.
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 the 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:
(a) the contact details of the competent authority of the Member State in which the retailer offering the veterinary medicinal products is established;	(a) the contact details of the competent authority of the Member State in which the retailer offering the veterinary medicinal products is established;
(b) a hyperlink to the website of the Member State of establishment set up in accordance with paragraph 5;	(b) a hyperlink to the website of the Member State of establishment set up in accordance with paragraph 5;
(c) the common logo established in accordance with paragraph 3 clearly displayed on every page of the website that relates to the offer for sale at a distance to the public of veterinary medicinal products and containing a hyperlink to the entry of the retailer in the list of authorised retailers referred to in point (c) of paragraph 5.	(c) the common logo established in accordance with paragraph 3 clearly displayed on every page of the website that relates to the offer for sale at a distance to the public of veterinary medicinal products and containing a hyperlink to the entry of the retailer in the list of authorised retailers referred to in point (c) of paragraph 5.
3. A common logo shall be established that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering veterinary medicinal products for sale at a distance to the public is established. The logo shall be clearly displayed on websites offering veterinary medicinal products for sale at a distance.	3. A common logo shall be established that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering veterinary medicinal products for sale at a distance to the public is established. The logo shall be clearly displayed on websites offering veterinary medicinal products for sale at a distance.
4. The Commission shall adopt the design of the common logo by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	4. The Commission shall adopt the design of the common logo by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).
5. Each Member State shall set up a website regarding sale of veterinary	5. Each Member State shall set up a website regarding sale of veterinary

medicinal products at a distance, providing at least the following information:	medicinal products at a distance, providing at least the following information:
(a) information on its national legislation applicable to the offering of veterinary medicinal products for sale at a distance ***to the public by means of information society services,*** including information on the fact that there may be differences between Member States regarding the classification of the supply of the veterinary medicinal products;	(a) information on its national legislation applicable to the offering of veterinary medicinal products for sale at a distance ***on the internet***, including information on the fact that there may be differences between Member States regarding the classification of the supply of the veterinary medicinal products;
(b) information on the common logo;	(b) information on the common logo;
(c) a list of retailers established in the Member State authorised to offer veterinary medicinal products for sale at a distance to the public ***by means of information society services*** in accordance with paragraph 1 as well as the website addresses of those retailers.	(c) a list of retailers established in the Member State authorised to offer veterinary medicinal products for sale at a distance to the public ***on the internet*** in accordance with paragraph 1 as well as the website addresses of those retailers***; and also a hyperlink to the website of the Agency set up in accordance with paragraph 6;***
	(ca) information on applicable procedures for the safe disposal of medicinal products, specifying the public or private body responsible at national or local level for the disposal of veterinary medicine residues and the collection points for disposal free of charge;
	(cb) hyperlinks to the web pages of the bodies responsible in Member States for listing authorised national retailers.
The websites set up by Member States shall contain a hyperlink to the website of the Agency set up in accordance with paragraph 6.	
6. The Agency shall set up a website providing information on the common logo. The Agency's website shall explicitly mention that the websites of Member States contain information on persons authorised to offer veterinary medicinal products for sale at a distance to the public ***by means of information society services*** in the Member State concerned.	6. The Agency shall set up a website providing information on the common logo. The Agency's website shall explicitly mention that the websites of Member States contain information on persons authorised to offer veterinary medicinal products for sale at a distance to the public ***on the internet*** in the Member State concerned. ***The Agency's website shall be linked to the web pages of the appropriate Member State bodies which list authorised retailers in Member States.***

7. Members States may impose conditions, justified on grounds of public health protection, for the retail on their territory of medicinal products offered for sale at a distance to the public by means of information society services.

7a. Member States shall take the measures necessary to ensure that persons other than those referred to in paragraph 1 offering veterinary medicinal products for sale at a distance to the public on the internet and operating on their territory are subject to effective, proportionate, and dissuasive penalties in case of abuse or illegal practice, or the failure to act according to their professional code of conduct.

7b. No later than (six) months after the date of application of this Regulation, the Commission shall adopt guidelines supporting the Member States in the development of a harmonized system of digital prescription across the Union, including measures for controlling cross-border veterinary prescriptions.

7c. On the basis of the guidelines referred to in paragraph 7b, Member States shall be encouraged to develop a system of digital prescription at national level, to include measures for the delivery and control of prescriptions. Member States shall also be encouraged to set up a system to facilitate the e-submission of prescriptions by means of a national database, directly linked to all pharmacies (both shop and internet ones), national competent authorities and veterinarians.

---

[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).

[29] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of

[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).

[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).	information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 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).***

Amendment 231

Proposal for a regulation
Article 109 – title

Text proposed by the Commission	*Amendment*
Retail of anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic ***veterinary medicinal products***	Retail ***only*** of ***medicinal products which are subject to prescription, or active substances, with*** anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal, ***immunological*** or psychotropic ***properties***

Amendment 232

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 ***prescription only*** veterinary medicinal products which have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal***, immunological*** or psychotropic properties or substances which may be used as veterinary medicinal products having those properties. ***In the***

	case of non-food producing animals (i.e. companion and small animals) all retailers, ranging from supermarkets, pet stores, to traditional and online (veterinary) pharmacies,shall be allowed to sell anti-parasitic and anti-inflammatory products, without the need to be specifically authorised to do so.

Amendment 233

Proposal for a regulation
Article 109 – paragraph 3 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
3. Those manufacturers and suppliers shall keep detailed records of the following information in respect of each purchase and sale transaction:	3. Those manufacturers and suppliers shall keep detailed records of the following information in respect of each purchase and sale transaction ***of prescription for veterinary medicinal products***:

Amendment 234

Proposal for a regulation
Article 109 – paragraph 3 – subparagraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) name and address of the supplier in the event of purchase***, or of the recipient in the event of sale***.	(d) name and address of the supplier in the event of purchase.

Amendment 235

Proposal for a regulation
Article 110

Text proposed by the Commission	*Amendment*
Veterinary prescriptions	Veterinary prescriptions
1. A veterinary prescription shall contain at least the following elements (‘minimum requirements’):	1. A veterinary prescription shall contain at least the following elements (‘minimum requirements’):
(a) identification of the animal under	(a) identification of the animal ***or class of***

treatment;	***animal*** under treatment ***and the condition which is being treated;***
(b) full name and contact details of the animal owner or keeper;	(b) full name and contact details of the animal owner or keeper;
(c) issue date;	(c) issue date;
(d) full name and contact details, qualifications and professional membership number of the person writing the prescription;	(d) full name and contact details, qualifications and professional membership number of the person writing the prescription;
(e) signature or an equivalent electronic form of identification of the person ***writing*** the prescription;	(e) signature or an equivalent electronic form of identification of the person ***issuing*** the prescription;
(f) name of the prescribed product;	(f) name of the prescribed product ***and the active substance(s);***
(g) pharmaceutical form (tablet, solution, etc.);	(g) pharmaceutical form (tablet, solution, etc.);
(h) quantity;	(h) quantity ***and in cases where the treatment has to be repeated, it shall also contain the number of times it can be repeated;***
(i) strength;	(i) strength;
(j) dosage regimen;	(j) dosage regimen;
(k) withdrawal period if relevant;	(k) withdrawal period if relevant;
(l) any necessary warnings;	(l) any necessary warnings ***and restrictions, including, where relevant, the risks entailed by imprudent use of antimicrobials;***
(m) if a product is prescribed for a condition not mentioned in the marketing authorisation for that product, a statement to that effect.	(m) if a product is prescribed for a condition not mentioned in the marketing authorisation for that product, a statement to that effect***;***
	(ma) period of validity of prescription.
2. A veterinary prescription shall only be issued by a person qualified to do so in accordance with applicable national law.	2. A veterinary prescription shall only be issued by a ***veterinarian or other*** person qualified to do so in accordance with applicable national law***, following a proper assessment of the health status of the animal concerned***.
	2a. A veterinary prescription of a veterinary medicinal product which has anabolic, anti-inflammatory, anti-infectious (other than anthelmintic), anti-cancer, hormonal or psychotropic properties or substances shall only be

	issued by a veterinarian after a clinical examination and diagnosis.
3. Where a veterinary medicinal product is supplied on prescription, the quantity prescribed and supplied shall be restricted to the amount required for the treatment or therapy concerned.	3. Where a veterinary medicinal product is supplied on prescription, the quantity prescribed and supplied shall be restricted to the amount required for the treatment or therapy concerned. ***The maximum quantity of veterinary medicinal products supplied at one time shall not, however, exceed one month's treatment. For chronic diseases and for periodic treatments the maximum quantity shall not exceed three month's treatment.***
4. Veterinary prescriptions shall be recognised throughout the Union. A veterinary medicinal product prescribed shall be supplied in accordance with applicable national law.	4. Veterinary prescriptions ***issued by a veterinarian*** shall be recognised throughout the Union. A veterinary medicinal product prescribed shall be supplied in accordance with applicable national law. ***Those provisions shall not apply to prescriptions issued under the exceptional circumstances set out in Articles 115 and 116. Those Member States that recognise prescriptions in their national systems issued by any person other than a veterinarian shall immediately notify the Commission, which shall forward such information to all Member States.***

Amendment 236

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

Text proposed by the Commission	*Amendment*
	4a. The removal of regulatory and administrative barriers to such recognition shall not affect any professional or ethical duty for dispensing professionals to refuse to dispense the medicine stated in the prescription.

Amendment 237

Proposal for a regulation
Article 111 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Veterinary medicinal products shall be used in accordance with the terms of the marketing authorisation.	1. Veterinary medicinal products shall be used ***responsibly*** in accordance ***with the principle of good animal husbandry and*** with the terms of the marketing authorisation ***or registration when no marketing authorisation is required.***

Amendment 238

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

Text proposed by the Commission	*Amendment*
	2a. Antimicrobial veterinary medicines shall not under any circumstances serve to improve performance or compensate for poor animal husbandry. Routine prophylactic use of antimicrobials is therefore prohibited. Prophylactic use of antimicrobial veterinary medicines shall only be permitted on single animals and when fully justified by a veterinarian in exceptional indications, of which a list shall be drafted by the Agency.
	Metaphylactic use of antimicrobial veterinary medicines shall be restricted to use in clinicall-ill animals and to those single animals that are identified as being at a high risk of contamination, to prevent further spread of the disease in the group. Where such products are to be used for non-routine metaphylaxis, owners and keepers of food-producing animals shall ensure that they have a health plan specifying appropriate non-medical measures to reduce the need to resort to metaphylactic use in the future. Moreover, they shall be required to comply with the following measures:
	(i) using good healthy breeding stock with suitable genetic diversity;
	(ii) conditions that respect the behavioural

needs of the species, including social interactions/hierarchies;

(iii) stocking densities that do not increase risk of disease transmission;

(iv) isolation of sick animals away from the rest of the group;

(v)for chickens and smaller animals, subdivision of flocks into smaller, physically separated groups;

(vi) implementation of existing animal welfare rules already in cross compliance under the Common Agricultural Policy's horizontal Regulation 1306/2013, Annex II, SMRs 11, 12, 13.

(Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes (OJ L 221, 8.8.1998, p. 23) Council Directive 91/630/EEC of 19 November 1991 laying down minimum standards for the protection of pigs (OJ L 340, 11.12.1991, p. 33), Council Directive 91/629/EEC of 19 November 1991 laying down minimum standards for the protection of calves (OJ L 340, 11.12.1991, p. 28))

Amendment 239

Proposal for a regulation
Article 111 a (new)

Text proposed by the Commission	*Amendment*
	Article 111a
	Supply and use of antimicrobials
	1. Member States may restrict or prohibit the supply or use, or both, of certain antimicrobials in animals on their territory if either of the following conditions is fulfilled:
	(a) the antimicrobials are critically important for use in humans; or
	(b) the administration of antimicrobials to animals is contradictory to the implementation of a national policy on

	prudent use of antimicrobials and that the policy is in line with the precautionary principle.
	2. Before adopting measures referred to in paragraph 1, the Member State shall ensure that relevant stakeholders have been consulted.
	3. Measures adopted by Member States on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of protection of animal and public health.
	4. A Member State adopting a measure on the basis of paragraph 1 shall inform the Commission thereof.

Amendment 240

Proposal for a regulation
Article 112 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Owners or, where the animals are not kept by the owners, keepers of food-producing animals shall keep records of the veterinary medicinal products they use and, if applicable, a copy of the veterinary prescription.	1. Owners or, where the animals are not kept by the owners, keepers of food-producing animals shall keep records of the ***veterinarian-prescribed*** veterinary medicinal products ***and veterinary medicinal products with a withdrawal period higher than nil*** they use and, if applicable, a copy of the veterinary prescription.

Amendment 241

Proposal for a regulation
Article 112 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) date of administering the veterinary medicinal product to the animal;	(a) date of administering the veterinary medicinal product to the animal ***and the disease treated***;

Amendment 242

Proposal for a regulation
Article 112 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) name and address of the supplier;	(d) name and address of the supplier ***and, if applicable, a copy of the delivery note***;

Amendment 243

Proposal for a regulation
Article 112 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) identification of the animals treated;	(e) identification of the animals treated ***and the diagnosis of the disease treated***;

Amendment 244

Proposal for a regulation
Article 112 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Particulars already contained in the prescription or in a delivery note shall not need to be recorded again if a clear reference can be made to the corresponding prescription and delivery note.

Amendment 245

Proposal for a regulation
Article 112 a (new)

Text proposed by the Commission	*Amendment*
	Article 112a
	Examination of therapy frequency
	1. The national competent authority shall

identify on the basis of the numbers determined under Article 112, for each half year, the average number of treatments with antibacterial effective substances and the treatment frequency following a standard European key, based on the particular business and the particular type of animals kept, taking into account the type of use.

2. The competent national authority shall inform the farmer in accordance with paragraph 1 about the biannual therapy frequency for the particular species of animals held by him in consideration of their type of use.

3. The information collected under paragraph 1 by the national competent authority are evaluated by the Commission and compared throughout the Union.

4. Member States may request data beyond.

Amendment 246

Proposal for a regulation
Article 112 b (new)

Text proposed by the Commission	*Amendment*
	Article 112b
	Reduction of therapy approaches based on antibacterial substances
	1. In order to facilitate the effective reduction regarding the use of pharmaceuticals which contain antibacterial substances, anyone who engages in animal husbandry shall:
	(a) determine, respectively, two months after the disclosure of the key figures in accordance with paragraph 112b established therapy prevalence, if the biannual therapy prevalence concerning his reared animal species, and considering the type-of-use during the elapsed time frame, lies above the average

	therapy prevalence;
	(b) take immediate record of the results of the assessment under point 1.
	2. In a case where the operational, biannual therapy prevalence of the animal husbandman with respect to his business lies above the biannual average, the animal husbandman under consultation of a veterinarian has to assess the reasons that may have led to exceeding the average, and how the treatment of his cattle with pharmaceuticals containing antibacterial substances may be decreased.
	If the assessment of the animal husbandman comes to the result that a therapy by means of the concerned pharmaceuticals may be reduced, the husbandman shall take all necessary steps in order to accomplish the reduction. The husbandman shall consider the wellbeing of his cattle and guarantee the required medical care.
	3. Member States may determine measures extending beyond the above mentioned requirements.

Amendment 247

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 ***the interest of animal health and welfare***, exceptionally treat the animal concerned with the following, ***in descending order of preference***:
(a) ***a*** medicinal product:	(a) ***any veterinary*** medicinal product ***authorised under this Regulation with the exception of antimicrobial products used***

	as routine prophylactic measure, unless specifically authorised by the Committee for Medicinal Products for Veterinary Use;
(i) a veterinary medicinal product authorised under this Regulation in the Member State concerned for use with another animal species, or for another condition in the same species;	
(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 or another Member State in accordance with Directive 2001/83/EC of the European Parliament and of the Council[30] or Regulation (EC) No 726/2004. Antimicrobial medicinal products for human use may only be employed subject to the issuing of a prescription by a veterinarian and the approval by the veterinary authority responsible for monitoring the work of the veterinarian in question;
	(ii) a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription by a person authorised to do so under national law.
[30] Directive 2001/83/EC of the European Parliament and of the Council of 6	[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).	November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Amendment 303

Proposal for a regulation
Article 115 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. By way of derogation from paragraph 1, homeopathic medicinal products may be administered to non-food producing animals.

Amendment 249

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 ***the interest of animal health and welfare***, exceptionally treat the animal concerned with the following***, in descending order of preference***:
(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***;	(a) ***any*** veterinary medicinal product authorised under this Regulation ***with the exception of antimicrobial products used prophylactically in an individual or a group where there is no diagnosis of disease in any of the animals;***
(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;	
	(ba) if there is no product as referred to in point (a):
(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.	
	(i) a medicinal product for human use authorised in the Member State concerned in accordance with Directive 2001/83/EC or under Regulation (EC) No 726/2004. Antimicrobial medicinal products for human use may be employed subject to the issuing of a prescription by a veterinarian and the approval by the veterinary authority responsible for monitoring the work of the veterinarian in question and treatment with a veterinary medicinal product as referred to in point (a) or point (ba) is not possible; or
	(ii) a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription issued by a person authorised to do so under national law.

Amendment 251

Proposal for a regulation
Article 116 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) veterinary medicinal products authorised under this Regulation in

	another Member State for use in the same aquatic species or in another food-producing aquatic species for the condition in question or for another condition.

Amendment 252

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.

Amendment 304

Proposal for a regulation
Article 116 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. By way of derogation from paragraphs 1 to 3, homeopathic medicinal products

	may be administered to treat food-producing animals under the responsibility of the veterinarian provided that they contain only active ingredients listed in Table 1 of the Annex to Regulation (EU) No 37/2010 as substances for which no maximum limit needs to be set.

Amendment 255

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) No 37/2010. The veterinarian shall specify an appropriate withdrawal period in accordance with Article 117.	6. Pharmacologically active substances included in the medicinal product used in accordance with paragraph 1 ***and paragraph 3(b)*** shall be listed in Table 1 of the Annex to Regulation (EU) No 37/2010. The veterinarian shall specify an appropriate withdrawal period in accordance with Article 117.

Amendment 256

Proposal for a regulation
Article 117 – paragraph 4

Text proposed by the Commission	*Amendment*
4. ***With regard to*** homeopathic veterinary medicinal products ***the withdrawal period shall be established at zero days***.	4. ***The withdrawal period shall be established at zero days for*** homeopathic veterinary medicinal products ***containing solely active substances listed in Table 1 of Regulation (EU) No 37/2010 with the classification "No maximum residue level (MRL) required".***

Amendment 257

Proposal for a regulation
Article 117 – paragraph 5 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	Data on the use of antibiotics outside the terms of authorisation shall be collected and mandatorily reported to national authorities in accordance with Article 54.

Amendment 258

Proposal for a regulation
Article 118 – title

Text proposed by the Commission	*Amendment*
Use of antimicrobial ***veterinary medicinal products*** for species or indications outside the terms of the marketing authorisation	Use of antimicrobial ***substances*** for species or indications outside the terms of the marketing authorisation

Amendment 259

Proposal for a regulation
Article 118 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Antimicrobial medicinal products shall only be used in accordance with Articles 115 and 116 to treat conditions for which there is no other treatment available, and the use of which would not present a risk to public or animal health.	1. Antimicrobial medicinal products shall only be used in accordance with Articles 115 and 116 to treat conditions for which there is no other treatment available, and the use of which would not present a risk to public or animal health. ***Articles 115 and 116 do not apply to critically important antimicrobials as referred to in Article 32(2).***

Amendment 260

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	2. The Commission ***shall***, by means of implementing acts in accordance with the

examination procedure referred to in Article 145(2), and taking into consideration scientific advice of the Agency, establish a list of antimicrobial ***medicinal products*** 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.	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.

Amendment 261

Proposal for a regulation
Article 118 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The principles to be used to establish the list of antimicrobials to be restricted in veterinary medicine shall not interfere with or deter Member States from prohibiting the use of certain antimicrobials in some species if they deem it appropriate.

Amendment 262

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

Text proposed by the Commission	*Amendment*
(a) risks to public health if the antimicrobial product is used in accordance with paragraph 1;	(a) risks to public health if the antimicrobial product is used in accordance with paragraph 1***, including the risks involved in using antimicrobials critical to human health in food producing animals***;

Amendment 263

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

Text proposed by the Commission	*Amendment*
	(ca) availability of other farming methods

that could prevent the outbreak of the disease;

Amendment 264

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

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

Amendment 265

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.

Amendment 266

Proposal for a regulation

Article 119 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By way of derogation from Article 111, in the event of an outbreak of a listed disease as referred to in Article 5 of Regulation (EC) No…/…. of the European Parliament and the Council[31] [Office of Publications, please insert number and, in a footnote, date, title and the OJ reference for the Regulation on animal health] a competent authority may allow, for a limited period of time and under specific restrictions, the use of an immunological veterinary medicinal product authorised in another Member State.	2. By way of derogation from Article 111, in the event of an outbreak of a listed disease as referred to in Article 5 of Regulation (EC) No…/…. of the European Parliament and the Council[31] [Office of Publications, please insert number and, in a footnote, date, title and the OJ reference for the Regulation on animal health] ***or any critical health situation acknowledged by the Chief Veterinary Officer of the Member State*** a competent authority may allow, for a limited period of time and under specific restrictions, the use of an immunological veterinary medicinal product ***without a marketing authorisation in the Member State in question but which is*** authorised ***either*** in another Member State ***or in accordance with the laws of a third country, in the absence of a suitable medicinal product and after informing the Commission of the detailed conditions of use***.
[31] Regulation of the European Parliament and the Council of….. on animal health (OJ L……).	[31] Regulation of the European Parliament and the Council of….. on animal health (OJ L……).

Amendment 267

Proposal for a regulation
Article 122 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Within two years of entry into force of this Regulation, the Commission shall develop, through delegated acts, a harmonised system for collecting these types of products and waste materials at Union level.

Amendment 268

Proposal for a regulation
Article 123 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Member States may provide for additional conditions in terms of advertising of veterinary medicinal products to protect public and animal health, animal welfare and the environment including conditions in terms of comparative and misleading advertising or unfair commercial practices.

Amendment 269

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 to advertising to persons permitted to prescribe or supply veterinary medicinal products.

Amendment 270

Proposal for a regulation
Article 125 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Competent authorities shall perform controls of manufacturers, importers, marketing authorisation holders, wholesale distributors and suppliers of the veterinary medicinal products regularly, on a risk-basis, in order to verify that the requirements as set out in this Regulation are complied with.	1. Competent authorities shall perform controls of manufacturers, importers, marketing authorisation holders, wholesale distributors and suppliers of the veterinary medicinal products ***as well as animals and foodstuff*** regularly, on a risk-basis, in order to verify that the requirements as set out in this Regulation are complied with.

Amendment 271

Proposal for a regulation
Article 125 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Commission shall ensure a harmonised approach to inspections and controls of veterinary medicines throughout the Union.

Amendment 272

Proposal for a regulation
Article 125 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. To combat fraud, the competent authorities shall establish a plan for spot checks on veterinary practices and herds to verify that medicinal products held comply with quality standards.

Amendment 273

Proposal for a regulation
Article 125 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
If necessary, the inspections ***may*** be carried out unannounced.	***All*** inspections ***shall*** be carried out unannounced.

Amendment 274

Proposal for a regulation
Article 125 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Inspections may also be carried out on the premises of manufacturers of active substances used as starting materials for

	veterinary medicinal products where there are grounds for suspecting non-compliance with good manufacturing practices.

Amendment 275

Proposal for a regulation
Article 125 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Inspection reports shall be uploaded to the appropriate database, with continuous access for all competent authorities.	6. Inspection reports shall be uploaded to the appropriate database, with continuous access for all competent authorities. ***A summary of the inspection results shall be made publicly available.***

Amendment 276

Proposal for a regulation
Article 128 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Agency and the Commission shall ensure a harmonised approach to veterinary medicine inspections.

Amendment 277

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.

Amendment 279

Proposal for a regulation
Article 136 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall designate the competent authorities to carry out tasks under this Regulation.	1. Member States shall designate the competent authorities to carry out tasks under this Regulation. ***The competent authorities shall, inter alia, be responsible for providing the scientific expertise for assessment of all applications under this Regulation.***

Amendment 280

Proposal for a regulation
Article 136 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The management of funds intended for activities connected with requirements provided under this Regulation, the operation of communication networks and market surveillance shall be under the permanent control of the competent authorities in order to guarantee the independence of these authorities.

Amendment 281

Proposal for a regulation
Article 136 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The competent authorities shall cooperate with each other in the performance of their tasks under this Regulation and shall give the competent authorities of other Member States necessary and useful support to this end. Competent authorities shall communicate the appropriate information to each other, particularly regarding compliance with the requirements for the manufacturing and wholesale distribution authorisations, for the certificates of good manufacturing practice or for marketing authorisations.	2. The competent authorities shall cooperate with each other ***and other concerned authorities*** in the performance of their tasks under this Regulation and shall give the competent authorities of other Member States necessary and useful support to this end. Competent authorities shall communicate the appropriate information to each other ***and other concerned authorities***, particularly regarding compliance with the requirements for the manufacturing and wholesale distribution authorisations, for the certificates of good manufacturing practice or for marketing authorisations.

Amendment 305

Proposal for a regulation
Article 140 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. All members, alternate members and accompanying experts shall provide a publicly accessible declaration of interest.

Amendment 282

Proposal for a regulation
Article 140 – paragraph 7

Text proposed by the Commission	*Amendment*
7. The Committee may co-opt a maximum of five additional members chosen on the basis of their specific scientific competence. These members shall be appointed for a term of three years, which	7. The Committee may co-opt a maximum of five additional members chosen on the basis of their specific scientific competence. These members shall be appointed for a term of three years, which

may be renewed, and shall not have alternates.	may be renewed, and shall not have alternates. ***The co-opted members may act as rapporteurs.***

Amendment 283

Proposal for a regulation
Article 141 – paragraph 1 – point h a (new)

Text proposed by the Commission	*Amendment*
	(ha) tackle the contribution of farming practices to the development of antimicrobial resistance, by building on the existing action plans of the Commission and Member States, specifically by developing and implementing strategies to:
	– reduce overall use,
	– reduce the use of antimicrobials that are critically important for human use, and
	– end routine prophylactic use.
	That work shall be laid out in a plan submitted by the Committee to the Commission no later than two years after the adoption of this Regulation. That plan shall contain targets for the reductions in use and a timetable for achieving these reductions.

Amendment 284

Proposal for a regulation
Article 144 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) examine questions concerning pharmacovigilance of veterinary medicinal products authorised in Member States;	***deleted***

Amendment 285

Proposal for a regulation
Annex 2 – part 1 – point 1.1 – paragraph 7

Text proposed by the Commission	*Amendment*
Experiments on animals ***other than clinical trials*** shall be conducted in accordance with Directive 2010/63/EU.	***Member States shall ensure that all*** experiments on animals shall be conducted in accordance with Directive 2010/63/EU. ***As specified in Directive 2010/63/EU, it shall be necessary to replace, reduce or refine testing on vertebrate animals. These methods shall be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved.***

Amendment 286

Proposal for a regulation
Annex 2 – part 1 – point 1.3 – subpoint 1.3.1 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) the potential risks relating to the development of antimicrobial resistance.	(e) the potential risks relating to the development of antimicrobial resistance ***during production and use***.

Amendment 287

Proposal for a regulation
Annex 2 – part 1 – point 1.3 – subpoint 1.3.1 – paragraph 7 – introductory part

Text proposed by the Commission	*Amendment*
This assessment shall normally be conducted in two phases. The first phase of the assessment shall always be performed and the second phase shall be performed if necessary. The details of the assessment shall be provided in accordance with accepted guidance. The assessment shall indicate the potential exposure of the environment to the product and the level of risk associated with any such exposure taking into account in particular the following items:	This assessment shall normally be conducted in two phases. ***All available data of sufficient reliability and relevance shall be considered, including information gained during the drug discovery process.*** The first phase of the assessment shall always be performed and the second phase shall be performed if necessary. The details of the assessment shall be provided in accordance with accepted guidance. The assessment shall indicate the potential exposure of the environment to the product and the level of risk associated with any such exposure

taking into account in particular the following items:

Amendment 288

Proposal for a regulation
Annex 2 – part 1 – point 1.3 – subpoint 1.3.1 – paragraph 8

Text proposed by the Commission	*Amendment*
In the second phase, further specific investigation of the fate and effects of the product on particular ecosystems shall be conducted, in accordance with established guidance. The extent of exposure of the product to the environment, and the available information about the physical/chemical, pharmacological and/or toxicological properties of the substance(s) concerned, including metabolites, shall be taken into consideration.	In the second phase, further specific investigation of the fate and effects of the product on particular ecosystems shall be conducted, in accordance with established guidance***, and taking into account the pharmacological effect of the product as well as any relevant side effects***. The extent of exposure of the product to the environment, and the available information about the physical/chemical, pharmacological and/or toxicological properties of the substance(s) concerned, including metabolites, shall be taken into consideration.

Amendment 289

Proposal for a regulation
Annex 2 – part 1 – point 1.3 – subpoint 1.3.1 – paragraph 8 a (new)

Text proposed by the Commission	*Amendment*
	The environmental risk assessment shall be updated when new information becomes available that would change the estimation of the risk.