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Committee on Agriculture and Rural Development

2014/0257(COD)

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AMENDMENTS
357 - 460

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

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

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

AM_Com_LegOpinion

Amendment 357
Marc Tarabella, Michel Dantin, Angélique Delahaye

Proposal for a regulation
Article 107 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The retail of veterinary medicinal products shall be conducted only by persons who are permitted to carry out such operations under national law.	1. The retail of veterinary medicinal products shall be conducted only by persons who are permitted to carry out such operations under national law***, veterinarians where appropriate***.

Or. fr

Amendment 358
Nicola Caputo

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. ***Veterinarians*** qualified to prescribe veterinary medicinal products in accordance with applicable national law shall ***not*** retail antimicrobial products ***and shall only be allowed to provide an emergency dosis after a proper diagnosis for the treatment of animals*** under their ***immediate*** care, and only in the amount required for the treatment.

Or. en

Amendment 359
Pilar Ayuso, Esther Herranz García

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. ***Veterinarians*** qualified to prescribe veterinary medicinal products in accordance with applicable national law shall ***supply*** antimicrobial products only for animals which are under their ***immediate*** care ***after appropriate examination and diagnosis***, and only in the amount required for the treatment concerned.

Or. en

Amendment 360
Norbert Lins, Annie Schreijer-Pierik, Peter Jahr

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. ***Veterinarians*** 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 after examination and diagnosis or recent animal health visit***, and only in the amount required for the treatment concerned.

Or. en

Amendment 361
Marc Tarabella, Michel Dantin, Angélique Delahaye

Proposal for a regulation
Article 107 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Persons qualified to prescribe veterinary	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.	medicinal products in accordance with applicable national law***, veterinarians where appropriate,*** shall retail antimicrobial products only for animals which are under their ***supervision and after diagnosis by a veterinarian***, and only in the amount required for the treatment concerned.

Or. fr

Amendment 362
Miguel Viegas

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. ***Veterinarians, or equivalent professionals as defined in the laws of Member States, prescribing*** 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.

Or. pt

Amendment 363
Momchil Nekov

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	*(Does not affect the English version.)*

amount required for the treatment concerned.

Or. bg

Amendment 364
Edouard Ferrand

Proposal for a regulation
Article 108

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

Or. fr

Amendment 365
Norbert Erdős

Proposal for a regulation
Article 108 – paragraph 1

Text proposed by the Commission	*Amendment*
(1) Persons permitted to supply veterinary medicinal products ***in accordance with Article 107(1) may*** offer veterinary medicinal products by means of information society services ***in the meaning of Directive 98/34/EC of the European Parliament and of the Council***[28] to natural or legal persons established in the Union ***under the condition that those medicinal products comply with the legislation of the destination Member State***.	(1) ***The Member States may authorise*** persons permitted to supply veterinary medicinal products ***requiring a veterinary prescription to*** offer veterinary medicinal products by means of information society services to natural or legal persons established in the Union

[28] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and

of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).

Or. hu

Justification

I do not agree with the proposal regarding internet trade in veterinary medicine. The planned guarantees are not sufficient to ensure control. The internet sale of antibiotics should continue to be prohibited, as it goes against efforts at international and national level to curb anti-microbial resistance. Products requiring a prescription should be subject to tighter conditions.

Amendment 366
Nicola Caputo

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

Text proposed by the Commission	*Amendment*
	7a. Strict control mechanisms, in particular regarding the control of cross-border veterinary prescriptions, shall be in place, leading to dissuasive penalties or prosecutions in case of illegal activity or failure to act according to the professional Code of Conduct. Member States shall develop a system of digital prescription at national level. The Commission shall promote the development of a harmonized system of digital prescription across Europe and assist Member States in its implementation. Delivering and control of prescriptions shall be at national level, at least until a European system enabling the control of cross border prescriptions is in place. A technology system of E-submission of prescriptions on a national database, directly linked to all pharmacies (shops and internet ones), national competent authorities and veterinarians shall be put in place as on-line cross checking by the pharmacy and the prescriber will prevent from frauds and

abuse.

Or. en

Amendment 367
Edouard Ferrand

Proposal for a regulation
Article 108 a (new)

Text proposed by the Commission	*Amendment*
	Article 108a
	Prohibition on marketing veterinary medicinal products online
	Veterinary medicinal products requiring authorisation may not be marketed via the Internet.

Or. fr

Amendment 368
Daniel Buda

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 specifically to do so in accordance with applicable national law shall be allowed to supply and purchase veterinary medicinal products which ***are prescribed by a veterinarian.***

Or. ro

Amendment 369
Annie Schreijer-Pierik

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

Text proposed by the Commission	*Amendment*
Those manufacturers and suppliers shall keep detailed records of the following information in respect of each purchase ***and sale*** transaction:	Those manufacturers and suppliers shall keep detailed records of the following information in respect of each purchase transaction:

Or. en

Amendment 370
Annie Schreijer-Pierik

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.

Or. en

Amendment 371
Clara Eugenia Aguilera García

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

Text proposed by the Commission	*Amendment*
(a) identification of the animal under treatment;	(a) identification of the animal ***or group of animals*** under treatment;

Or. es

Justification

There is not always a system for identifying individuals.

Amendment 372
Miguel Viegas

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

Text proposed by the Commission	*Amendment*
(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 ***veterinarian, or equivalent professional as defined in the laws of Member States,*** writing the prescription;

Or. pt

Amendment 373
Miguel Viegas

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

Text proposed by the Commission	*Amendment*
(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 ***veterinarian, or equivalent professional as defined in the laws of Member States,*** writing the prescription;

Or. pt

Amendment 374
Molly Scott Cato
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	(fa) the condition which is being treated;

Or. en

Amendment 375
Norbert Lins, Peter Jahr

Proposal for a regulation
Article 110 – paragraph 2

Text proposed by the Commission	*Amendment*
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 ***of a veterinary medicinal product*** shall only be issued by a ***veterinarian for animals which are under their care and only after examination and diagnosis or recent animal health visit***.

Or. en

Amendment 376
Miguel Viegas

Proposal for a regulation
Article 110 – paragraph 2

Text proposed by the Commission	*Amendment*
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 an equivalent professional as defined in the laws of Member States, recognised by the appropriate professional association*** in accordance with applicable national law.

Or. pt

Amendment 377
Pilar Ayuso, Esther Herranz García

Proposal for a regulation
Article 110 – paragraph 2

Text proposed by the Commission	*Amendment*
2. A veterinary ***prescription shall*** only be ***issued by a person qualified to do so in accordance with applicable national law***.	2. A veterinary ***medicinal product should*** only be ***prescribed by a veterinarian***.

Or. en

Justification

In our opinion, veterinary medicinal products should be prescribed only by the healthcare professional with the technical qualification to do it, which is the veterinarian.

Amendment 378
Marc Tarabella, Michel Dantin, Angélique Delahaye

Proposal for a regulation
Article 110 – paragraph 2

Text proposed by the Commission	*Amendment*
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 person qualified to do so in accordance with applicable national law***, a veterinarian where appropriate and only after a veterinary diagnosis***. ***These persons shall, by reason of their initial and continuing training, have the skills necessary to prescribe and issue veterinary medicinal products for all the species they treat***.

Or. fr

Amendment 379
Annie Schreijer-Pierik

Proposal for a regulation
Article 110 – paragraph 2

Text proposed by the Commission	*Amendment*
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*** in accordance with applicable national law.

Or. en

Amendment 380
Clara Eugenia Aguilera García

Proposal for a regulation
Article 110 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where a veterinary medicinal product is ***supplied*** on prescription, the quantity prescribed ***and supplied*** shall be restricted to the amount required for the treatment or therapy concerned.	3. Where a veterinary medicinal product is ***prescribed*** on prescription, the quantity prescribed shall be restricted to the amount required for the treatment or therapy concerned ***and take account of the presentations available on the market***. ***Prophylactic use of anti-bacterials shall not be authorised except in cases where said use is expressly authorised by the summary of technical characteristics of the veterinary medicinal product, drawn up in accordance with this Regulation***.

Or. es

Justification

A blanket ban can only be imposed if certain exceptions for which there is a scientific basis are taken into account.

Amendment 381
Albert Deß

Proposal for a regulation
Article 110 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where a veterinary medicinal product is supplied on prescription, the quantity prescribed and supplied shall be restricted to the amount required for the treatment or therapy concerned.	3. Where a veterinary medicinal product is supplied on prescription, the quantity prescribed and supplied shall be restricted to the amount required for the treatment or therapy concerned. ***The prophylactic use of antibiotics shall be permissible only in certain cases specified by the Agency.***

Or. de

Justification

There are situations in which prophylactic use is essential, for example in connection with certain operations or to deal with contagious meningitis. It is for the Agency to define more clearly the situations in question and the antibiotics which may be used. Routine prophylactic use should not be a substitute for good hygiene, proper feeding methods and the provision of an appropriate living environment for animals.

Amendment 382
Nicola Caputo

Proposal for a regulation
Article 110 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where a veterinary medicinal product is supplied on prescription, the quantity prescribed and supplied shall be restricted to the amount required for the treatment or therapy concerned.	3. Where a veterinary medicinal product is supplied on prescription, the quantity prescribed and supplied shall be restricted to the amount required for the treatment or therapy concerned. ***Preventive use of antimicrobials shall be prohibited.***

Or. en

Amendment 383
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 110 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. In the case of antimicrobials critically important for human use, the prescribed medication may only be used for the animals examined by the person who issued the prescription. The prescribed medication may only be used for the diagnosed disease.

Or. en

Justification

CIA, or critically important antimicrobials are in the fluoroquinolone and modern cephalosporin families, and are defined by the WHO. Their widespread use in food-producing animals threatens to provoke a 'post-antibiotic era' in human health. They ought to be reserved for human use, and so severely restricted in animals.

Amendment 384
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

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 in accordance with the terms of the marketing authorisation. ***Nevertheless, the veterinarian should be able, in justified circumstances, to prescribe veterinary medicinal products in different terms to the ones authorised for the product.***

Or. en

Justification

The veterinarian should have the possibility to prescribe products deviating from the terms of the authorisation.

Amendment 385
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 111 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Antimicrobials may only be issued under prescription by a vet or a suitably qualified animal health professional to food producing animals after all the preventive measures listed under Annex 3a have been fulfilled.
	Preventative or prophylactic mass medication in drink or water when no disease has been diagnosed shall be prohibited.
	No antimicrobial group treatments should be permitted, except for where disease has been diagnosed in some of the animals.

Or. en

Amendment 386
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 114 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. A veterinarian ***providing*** services in a Member State other than the one where he is established ***(the 'host Member State') may administer veterinary medicinal products authorised in the host Member State to animals in another Member State which are under his care in the amount required for the treatment of those animals where the following conditions are fulfilled***:	1. A veterinarian ***may neither provide*** services ***nor prescribe*** in a Member State other than the one where he is established.

Or. fr

Amendment 387
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 114 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the authorisation to place the veterinary medicinal product on the market provided for in Article 5 has been issued by the competent authorities of the host Member State or by the Commission;	***deleted***

Or. fr

Amendment 388
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 114 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the veterinary medicinal products are transported by the veterinarian in the original packaging;	***deleted***

Or. fr

Amendment 389
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 114 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) where intended for administration to food-producing animals, the veterinary	***deleted***

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

Or. fr

Amendment 390
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 114 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the veterinarian follows the good veterinary practices applied in that Member State and ensures that the withdrawal period specified on the labelling of the veterinary medicinal product is observed;	***deleted***

Or. fr

Amendment 391
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 114 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) the veterinarian does not retail any veterinary medicinal product to an owner or keeper of animals treated in the host Member State unless this is permissible under the rules of the host Member State, the medicinal product is intended for animals under his care, and only the minimum quantities of veterinary medicinal product necessary to complete the treatment of those animals are retailed;	***deleted***

Or. fr

Amendment 392
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 114 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) the veterinarian keeps detailed records of the animals treated, their diagnosis, the veterinary medicinal products administered, the dose administered, the duration of treatment and the withdrawal period applied, for inspection by the competent authorities of the host Member State for a period of 3 years.	***deleted***

Or. fr

Amendment 393
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 114 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Paragraph 1 shall not apply to immunological veterinary medicinal products which are not authorised for use in the host Member State.	***deleted***

Or. fr

Amendment 394
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

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. ***Member States shall take the necessary measures to ensure that, if*** there is no authorised veterinary medicinal product in a Member State for a condition affecting a non- food producing ***species***, ***by way of exception,*** the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animal concerned with:
(a) a medicinal product:	
(i) a veterinary medicinal product authorised under this Regulation in the Member State concerned for use with another animal species, or for another condition in the same species;	***(a)*** a veterinary medicinal product authorised in the Member State concerned under this Regulation for use with another animal species, or for another condition in the same species; ***or***
	(b) if there is no product as referred to in point (a), either:
	(i) a medicinal product authorised for human use in the Member State concerned in accordance with Directive 2001/83/EC of the European Parliament and of the Council or Regulation (EC) No 726/2004, or
(ii) a veterinary medicinal product authorised under this Regulation in another Member State for use in the same species or in another species, for the ***same*** condition or for another condition;	(ii) ***in accordance with specific national measures,*** a veterinary medicinal product authorised in another Member State in accordance with this Regulation for use in the same species or in another species for the condition ***in question*** or for another condition; ***or***
(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	***(c)*** if there is no product as referred to in ***subparagraph (b), and within the limits of the law of the Member State concerned***, a veterinary medicinal product prepared extemporaneously by a person authorised

national legislation.

to do so under national legislation in accordance with the terms of a veterinary prescription.

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[30] *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).*

[30] *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).*

(Point (iii) of Commission text has become point (i) in Parliament's amendment. The word "or" has been added.)

Or. en

Justification

It is proposed to maintain the cascade prescription established in Directive 2001/82 because it defines a logical order from veterinary products to human products. It is not logical to put on a same level veterinary products and human products.

Amendment 395
Nicola Caputo

Proposal for a regulation
Article 115 – paragraph 1

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

	another animal species, or for another condition in the same species;
(i) a veterinary medicinal product authorised under this Regulation in the Member State concerned for use with another animal species, or for another condition in the same species;	
	(b) a veterinary medicinal product authorised under this Regulation in the Member State concerned for the same or another condition in a different 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;	***(c)*** 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;	***(d)*** 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.	***(e) only*** if there is no product as referred to in ***points (a) - (d),*** a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription by a person authorised to do so under national legislation.
[30] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).	[30] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(Points (i), (ii), (iii) and (b) of Commission text have become points (a), (c), (d), (e) in Parliament's amendment. Besides point (b) (which has become point (e)) is modified.)

Or. en

Justification

A derogation to allow 'use outside the terms of the marketing authorisation' (off-label use)

under certain conditions is in the interest of animal welfare, as veterinary medicines do not exist for many conditions, particularly for minor species. However, the Commission is deleting the obligation for the veterinarian to select first veterinary medicine, if available, before selecting a human medicine ('cascade'). There is, thus, no incentive for manufacturers to invest in product development.

Amendment 396
Miguel Viegas

Proposal for a regulation
Article 115 – paragraph 1 – introductory part

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, the veterinarian responsible***, or the equivalent professional as defined in the laws of Member States,*** may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animal concerned with the following:

Or. pt

Amendment 397
Giulia Moi

Proposal for a regulation
Article 115 – paragraph 1 – introductory part

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

with the exception of anticrobial products used as routine prophylactic measure, unless specifically authorised by the CVMP:

Or. en

Amendment 398
Annie Schreijer-Pierik

Proposal for a regulation
Article 115 – paragraph 1 – introductory part

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:

Or. en

Amendment 399
Peter Jahr, Norbert Lins, Elisabeth Köstinger, Peter Liese

Proposal for a regulation
Article 115 – paragraph 1 – point a – point iii

Text proposed by the Commission	*Amendment*
(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;	(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***. Antimicrobial medicinal products for human use may only be employed, subject to the issuing of a prescription by a veterinarian and***

	approval by the veterinary authority responsible for monitoring the work of the veterinarian in question, if treatment with a medicinal product as referred to in letter (a)(i) or (ii) is not possible;
[30] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).	[30] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Or. de

Justification

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

Amendment 400
Ulrike Müller

Proposal for a regulation
Article 115 – paragraph 1 – point a – point iii

Text proposed by the Commission	*Amendment*
(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***;**	(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 ***if no medicinal product as referred to in letter (a)(i) or (ii) can be used.***
[30] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).	[30] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Or. de

Justification

Veterinary medicinal products authorised for use in treating animals kept for food production purposes must be employed as a matter of priority, as residue behaviour assessments are available for such products. This is important for the safety of the food chain and for the environment. For that reason, medicinal products for human use must be seen as a second choice, but their use should not be ruled out. This should also apply to medicinal products administered to animal species not kept for food production purposes.

Amendment 401
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

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. ***Member States shall take the necessary measures to ensure that, if*** there is no authorised veterinary medicinal product in a Member State for a condition affecting a food-producing species, ***by way of exception,*** the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animals concerned ***on a particular holding*** with:
(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) a veterinary medicinal product authorised in the Member State concerned under this Regulation for use with another animal species, or for another condition in the same species; ***or***
(b) a veterinary medicinal product authorised under this Regulation in another Member State for use in the same species or in another food-producing species for the same condition or for another condition;	***(b) if there is no product as referred to in point (a), either:***
(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	***(i)*** a medicinal product for human use authorised in the Member State concerned in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004, or
	(ii) a veterinary medicinal product authorised in another Member State in

	accordance with this Regulation for use in the same species or in another food-producing species for the condition in question or for another condition; or
(d) if there is no product as referred to in ***point (a),*** a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription by a person authorised to do so under national legislation.	***(c)*** if there is no product as referred to in ***subparagraph (b), and within the limits of the law of the Member State concerned***, a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national legislation in accordance with the terms of a veterinary prescription.

(Point (b) of Commission text has become point (ii) in Parliament's amendment and has been modified.)

Or. en

Justification

It is proposed to maintain the cascade prescription established in Directive 2001/82 because it defines a logical order from veterinary products to human products. It is not logical to put in a same level veterinary products and human products.

Amendment 402
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 116 – paragraph 1 – introductory part

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

Or. en

Amendment 403
Nicola Caputo

Proposal for a regulation
Article 116 – paragraph 1 – introductory part

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

Or. en

Justification

The Commission proposal puts at risk public health and animal health because veterinarians could automatically opt for untested human medicines without authorised correct dose in order to treat a food-producing animal. The 'cascade' should be re-introduced in order to force veterinarians to choose the lowest-risk alternatives first.

Amendment 404
Annie Schreijer-Pierik

Proposal for a regulation
Article 116 – paragraph 1 – introductory part

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 any of the following:

Or. en

Amendment 405
Nicola Caputo

Proposal for a regulation
Article 116 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(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) a veterinary medicinal product authorised under this Regulation in the Member State concerned for another condition in the same species;

Or. en

Amendment 406
Nicola Caputo

Proposal for a regulation
Article 116 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) a veterinary medicinal product authorised under this Regulation in ***another*** Member State ***for use in*** the same	(b) a veterinary medicinal product authorised under this regulation in ***the*** Member State ***concerned for*** the same ***or***

species or in another ***food-producing species for the same*** condition ***or for another condition***;	another condition ***in a different food-producing species***;

Or. en

Amendment 407
Nicola Caputo

Proposal for a regulation
Article 116 – paragraph 1 – point c

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

Or. en

Amendment 408
Peter Jahr, Norbert Lins, Elisabeth Köstinger, Peter Liese

Proposal for a regulation
Article 116 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(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	(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**.** ***Antimicrobial medicinal products for human use may be employed, subject to the issuing of a prescription by a veterinarian and approval by the veterinary authority responsible for monitoring the work of the veterinarian in question, if treatment with a veterinary medicinal product as referred to in letter (a) or (b) is not possible;*** or

Or. de

Justification

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

Amendment 409
Ulrike Müller

Proposal for a regulation
Article 116 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(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***	(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 ***in cases where an authorised veterinary medicinal product as referred to in letters (a) and (b) cannot be used.***

Or. de

Justification

Veterinary medicinal products authorised for use in treating animals kept for food production purposes must be employed as a matter of priority, as residue behaviour assessments are available for such products. This is important for the safety of the food chain and for the environment. For that reason, medicinal products for human use must be seen as a second choice.

Amendment 410
Nicola Caputo

Proposal for a regulation
Article 116 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) ***if there is no*** product ***as referred to in***	(d) ***a medicinal*** product ***for human use***

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.***	***authorised in the Member State concerned*** in accordance with ***Directive 2001/83/EC or under Regulation (EC) No 726/2004, or***

Or. en

Amendment 411
Nicola Caputo

Proposal for a regulation
Article 116 – paragraph 1 – point d a (new)

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

Or. en

Amendment 412
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 116 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By way of derogation from Article 111, where there is no authorised veterinary medicinal product in a Member State for a condition affecting a food-producing aquatic species, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animals concerned with any of the following medicinal products:	***deleted***

(a) veterinary medicinal products authorised under this Regulation in the Member State concerned for use with another food-producing aquatic species, or for another condition in the same aquatic species;

(b) veterinary medicinal products authorised under this Regulation in another Member State for use in the same aquatic species or in another food-producing aquatic species for the condition in question or for another condition.

Or. en

Amendment 413
Nicola Caputo

Proposal for a regulation
Article 116 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. By way of derogation from Article 111, where there is no authorised veterinary medicinal product in a Member State for a condition affecting a food-producing aquatic species, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animals concerned with any of the following medicinal products:	2. By way of derogation from Article 111, where there is no authorised veterinary medicinal product in a Member State for a condition affecting a food-producing aquatic species, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animals concerned with any of the following medicinal products ***(in descending order of preference)***:

Or. en

Justification

The Commission proposal puts at risk public health and animal health because veterinarians could automatically opt for untested human medicines without authorised correct dose in order to treat a food-producing animal. The 'cascade' should be re-introduced in order to force veterinarians to choose the lowest-risk alternatives first.

Amendment 414
Nicola Caputo

Proposal for a regulation
Article 116 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) veterinary medicinal products authorised under this Regulation in ***another*** Member State for use ***in the same aquatic species or in*** another food-producing aquatic species ***for the condition in question or for another condition.***	(b) veterinary medicinal products authorised under this Regulation in ***the*** Member State ***concerned*** for use ***with*** another food-producing aquatic species***;***

Or. en

Amendment 415
Nicola Caputo

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.

Or. en

Amendment 416
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 116 – paragraph 3

Text proposed by the Commission	*Amendment*
3. By way of derogation from paragraph	***deleted***

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;

(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.

Or. en

Amendment 417
Paul Brannen

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

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

Or. en

Justification

In the UK and Ireland, national legislation authorises Suitably Qualified Persons (SQPs) to distribute medicines which do not require prescription. SQPs play an important role in reaching the most remote farms, helping reducing farmers' costs and preserve rural

employment. Therefore, this system should be allowed to continue.

Amendment 418
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 116 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission may, by means of implementing acts, establish a list of veterinary medicinal products authorised in the Union for use in terrestrial animals which can be used for treatment of food-producing animals of an aquatic species in accordance with paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	***deleted***
The Commission shall take account of the following criteria when adopting those implementing acts:	
(a) risks to the environment if aquatic animals are treated with these medicinal products;	
(b) impact on animal health and public health if the aquatic animal affected by the condition cannot receive treatment with the potential listed antimicrobial medicinal product;	
(c) impact on the competitiveness of certain sectors in aquaculture in the Union if the animal affected by the condition cannot receive treatment with the antimicrobial medicinal product concerned;	
(d) availability or lack of availability of other medicines, treatments or measures for prevention or treatment of diseases or certain conditions in aquatic animals.	

Or. en

Amendment 419
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 116 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Commission may, by means of implementing acts, establish a list of veterinary medicinal products authorised in the Union for use in terrestrial animals which can be used for treatment of food-producing animals of an aquatic species in accordance with paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	The Commission may, by means of implementing acts, establish a list of veterinary medicinal products authorised in the Union for use in terrestrial animals which can be used for treatment of food-producing animals of an aquatic species in accordance with paragraph 1. ***This provision is strictly limited to closed aquatic systems with specific waste water treatment facilities.*** Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Or. en

Amendment 420
Giulia Moi

Proposal for a regulation
Article 116 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Commission may, by means of implementing acts, establish a list of veterinary medicinal products authorised in the Union for use in terrestrial animals which can be used for treatment of food-producing animals of an aquatic species in accordance with paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	The Commission may, by means of implementing acts, establish a list of veterinary medicinal products authorised in the Union for use in terrestrial animals which can be used for treatment of food-producing animals of an aquatic species in accordance with paragraph 1. ***This provision is strictly limited to closed aquatic systems with specific waste water treatment facilities.*** Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Or. en

Amendment 421
Molly Scott Cato
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 116 – paragraph 4 – subparagraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) risks to the environment if aquatic animals are treated with these medicinal products;	(a) risks to the environment if aquatic animals are treated with these medicinal products***, in line with Annex II*** ;

Or. en

Justification

This guarantees that the aquatic environment is protected from veterinary medicines which have not undergone a proper environmental risk assessment.

Amendment 422
Momchil Nekov

Proposal for a regulation
Article 116 – paragraph 4 – subparagraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) impact on animal health and public health if the aquatic animal affected by the condition cannot receive treatment with the potential listed antimicrobial medicinal product;	*(Does not affect the English version.)*

Or. bg

Amendment 423
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

Proposal for a regulation
Article 116 – paragraph 5

Text proposed by the Commission	*Amendment*
5. For the purpose of treatment in accordance with ***paragraphs*** 1 ***to 3***, the veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility.	5. For the purpose of treatment in accordance with ***paragraph*** 1, the veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility.

Or. en

Amendment 424**Momchil Nekov**

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	*(Does not affect the English version.)*

Or. bg

Amendment 425
Molly Scott Cato
on behalf of the Verts/ALE Group

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 ***once the applicable conditions outlined in Annex 3a have been fulfilled, and*** the use of which would not present a risk to public or animal health***, and specifically is not for routine prophylactic use or a prophylactic***

group treatment where there is no diagnosis of disease.

Or. en

Justification

Annex 3a outlines preventive measures that should be fulfilled before resorting to antimicrobials.

Amendment 426
Peter Jahr, Elisabeth Köstinger, Peter Liese

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 ***proper*** use of which would not present a risk to public or animal health.

Or. de

Justification

The legislator can only refer to the proper use of antimicrobial medicinal products, and not to their possible misuse.

Amendment 427
Momchil Nekov

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	*(Does not affect the English version.)*

the use of which would not present a risk to public or animal health.

Or. bg

Amendment 428
Momchil Nekov

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

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

Or. bg

Amendment 429
Lynn Boylan, Matt Carthy

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 which will be restricted in veterinary medicine should not interfere with or deter Member States from prohibiting the use of certain antimicrobials in some species if they deem it appropriate.

Or. en

Amendment 430
Molly Scott Cato
on behalf of the Verts/ALE Group

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.***

Or. en

Justification

'Critical antimicrobials' refers to those defined by the WHO, whose use ought to be reserved for humans.

Amendment 431
Momchil Nekov

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;	*(Does not affect the English version.)*

Or. bg

Amendment 432
Momchil Nekov

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

Text proposed by the Commission	*Amendment*
(b) risk for human health in case of development of antimicrobial resistance;	*(Does not affect the English version.)*

Or. bg

Amendment 433
Momchil Nekov

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

Text proposed by the Commission	*Amendment*
(d) availability of other antimicrobial treatments for humans;	*(Does not affect the English version)*

Or. bg

Amendment 434
Momchil Nekov

Proposal for a regulation
Article 119 – paragraph 1

Text proposed by the Commission	*Amendment*
1. By way of derogation from Article 111, a competent authority may allow the use in its territory of veterinary medicinal products not authorised in that Member State, where the situation of animal or public health so requires, and the marketing of those veterinary medicinal products is authorised in another Member State.	*(Does not affect the English version)*

Or. bg

Amendment 435
Paul Brannen

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 laid down in paragraph 1 shall not apply to advertising to persons permitted to ***use,*** prescribe or supply veterinary medicinal products.

Or. en

Justification

Responsible use of medicines requires that also the users of medicines make informed choices.

Amendment 436
Miguel Viegas

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 regularly, ***at predetermined intervals laid down in Member States, and*** on a ***risk basis***, in order to verify that the requirements as set out in this Regulation are complied with.

Or. pt

Amendment 437
Giulia Moi

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 ***ensure common*** 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.

Or. en

Amendment 438
Molly Scott Cato
on behalf of the Verts/ALE Group

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.

Or. en

Justification

This will allow for comparability of data between MS and regions and ease the coordination task of the Agency.

Amendment 439
Michel Dantin, Marc Tarabella, Angélique Delahaye

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

Text proposed by the Commission	*Amendment*
	1a. 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.

Or. fr

Amendment 440
Momchil Nekov

Proposal for a regulation
Article 125 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) the potential impact of non-compliance with the requirements on public health, animal health and the environment.	*(Does not affect the English version)*

Or. bg

Amendment 441
Molly Scott Cato
on behalf of the Verts/ALE Group

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.	***A certain percentage of*** the inspections***, to be determined by delegated acts, shall*** be carried out unannounced.

Or. en

Amendment 442
Giulia Moi

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.	***A defined percentage of*** inspections ***shall*** be carried out unannounced.

Or. en

Amendment 443
Molly Scott Cato
on behalf of the Verts/ALE Group

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. ***Final inspection results shall be made public.***

Or. en

Amendment 444
Giulia Moi

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. ***Final*** inspection reports shall be uploaded to the appropriate database, with continuous access for all competent authorities***, and shall be made public***.

Or. en

Amendment 445
Molly Scott Cato
on behalf of the Verts/ALE Group

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.

Or. en

Amendment 446
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 130 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In the event of a risk to public or animal health or to the environment that requires urgent action, the competent authorities ***or, in the case of centralised marketing authorisations, the Commission*** may impose temporary safety restrictions on the marketing authorisation holder, including suspending the marketing authorisation and/or prohibiting the supply of a veterinary medicinal product. Other Member States ***and, where the temporary safety restriction is imposed by a competent authority, the Commission*** shall be informed of the temporary safety restriction imposed on the following working day at the latest.	1. In the event of a risk to public or animal health or to the environment that requires urgent action, the competent authorities may impose temporary safety restrictions on the marketing authorisation holder, including suspending the marketing authorisation and/or prohibiting the supply of a veterinary medicinal product. Other Member States shall be informed of the temporary safety restriction imposed on the following working day at the latest.

Or. fr

Amendment 447
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 130 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States ***and the Commission*** may refer the issue to the Agency in accordance with Article 84.	2. Member States may refer the issue to the Agency in accordance with Article 84.

Or. fr

Amendment 448
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 131 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The competent authority ***or the Commission*** shall suspend or withdraw the marketing authorisation if the benefit-risk balance of the veterinary medicinal product is unfavourable.	1. The competent authority shall suspend or withdraw the marketing authorisation if the benefit-risk balance of the veterinary medicinal product is unfavourable.

Or. fr

Amendment 449
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 131 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The competent authority ***or the Commission*** shall suspend or withdraw the marketing authorisation or request the marketing authorisation holder to submit an application for a variation to the terms of the marketing authorisation where the withdrawal period is inadequate to ensure that foodstuffs obtained from the treated	2. The competent authority shall suspend or withdraw the marketing authorisation or request the marketing authorisation holder to submit an application for a variation to the terms of the marketing authorisation where the withdrawal period is inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues

animal do not contain residues which might constitute a public health hazard.	which might constitute a public health hazard.

Or. fr

Amendment 450
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 131 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. The competent authority ***or the Commission*** may suspend or withdraw the marketing authorisation or request the marketing authorisation holder to submit an application for a variation to the terms of the marketing authorisation in case of any of the following:	3. The competent authority may suspend or withdraw the marketing authorisation or request the marketing authorisation holder to submit an application for a variation to the terms of the marketing authorisation in case of any of the following:

Or. fr

Amendment 451
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 131 – paragraph 4

Text proposed by the Commission	*Amendment*
4. For the purpose of paragraphs 1 to 3, before taking action, the Commission shall request***, where appropriate,*** the opinion of the Agency within time-limit which it shall determine in the light of the urgency of the matter, in order to examine the reasons. Whenever practicable, the holder of the marketing authorisation for the veterinary medicinal product shall be invited to provide oral or written explanations.	4. For the purpose of paragraphs 1 to 3, before taking action, the Commission shall request the opinion of the Agency within time-limit which it shall determine in the light of the urgency of the matter, in order to examine the reasons. Whenever practicable, the holder of the marketing authorisation for the veterinary medicinal product shall be invited to provide oral or written explanations.

Or. fr

Amendment 452
Edouard Ferrand, Philippe Loiseau

Proposal for a regulation
Article 135

Text proposed by the Commission	*Amendment*
Article 135	***deleted***
Penalties imposed by the Commission	
1. The Commission may impose financial penalties on the holders of marketing authorisations granted under this Regulation if they fail to observe their obligations in accordance with this Regulation.	
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 laying down rules concerning the initiation, duration, time-limits and conduct of the imposition of fines or periodic penalty payments to the holders of marketing authorisations granted under this Regulation, the maximum amounts of these penalties as well as the conditions and methods for their collection.	
3. Where the Commission adopts a decision imposing a financial penalty, it shall publish a concise summary of the case, including the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed, having regard to the legitimate interest of the marketing authorisation holders in the protection of their business secrets.	
4. The Court of Justice shall have unlimited jurisdiction to review decisions whereby the Commission has imposed financial penalties. It may cancel, reduce or increase the fine or periodic penalty payment imposed.	

Or. fr

Amendment 453
Stanislav Polčák

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 be, inter alia, responsible for providing the scientific expertise for assessment of all applications under this Regulation.***

Or. en

Justification

The responsibilities of different parts of the regulatory system are clearly defined in order to ensure the required level of predictability and stability of the system. The Regulation should therefore reflect the fully-fledged EU regulatory system developed over the last 20 years, where the Member States competent authorities play a key role in providing scientific expertise for assessment activities as well as other scientific tasks. Any further development should be built on this time-proven model.

Amendment 454
Molly Scott Cato
on behalf of the Verts/ALE Group
Martin Häusling

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.

This work shall be laid out in a plan submitted to the Commission no later than two years from adoption of this Regulation. The plan shall contain targets for the reductions in use and a timetable for achieving reductions.

Or. en

Amendment 455
Pilar Ayuso, Esther Herranz García, Ramón Luis Valcárcel Siso

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***

Or. en

Justification

The discussions of questions concerning pharmacovigilance should take place at the pharmacovigilance group and not at the Coordination group.

Amendment 456
Momchil Nekov

Proposal for a regulation
Annex 2 – part 1 – section 1.1 – paragraph 4

Text proposed by the Commission	*Amendment*
Where relevant, studies shall be submitted providing information on the direct or indirect risks to human health, food safety or animal health of the use of the antimicrobial product in animals, as well as an assessment of the effects of risk mitigation measures proposed by the applicant to limit antimicrobial resistance development.	*(Does not affect the English version)*

Or. bg

Amendment 457
Momchil Nekov

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

Text proposed by the Commission	*Amendment*
(e) the potential risks relating to the development of antimicrobial resistance.	*(Does not affect the English version)*

Or. bg

Amendment 458
Momchil Nekov

Proposal for a regulation
Annex 2 – part 1 – section 1.3 – subsection 1.3.2 – point A – point A.4 – point A.4.3

Text proposed by the Commission	*Amendment*
A.4.3. Development of resistance	*(Does not affect the English version)*

Or. bg

Amendment 459
Momchil Nekov

Proposal for a regulation
Annex 2 – part 1 – section 1.4 – subsection 1.4.2 – point A – point A.5

Text proposed by the Commission	*Amendment*
A.5. Studies investigating resistance.	*(Does not affect the English version)*

Or. bg

Amendment 460
Molly Scott Cato
on behalf of the Verts/ALE Group
Martin Häusling

Proposal for a regulation
Annex 3 a (new)

Text proposed by the Commission	*Amendment*
	ANNEX IIIa
	Preventative measures to be used before resorting to antimicrobial treatment of entire groups (metaphylaxis) of food producing animals:
	– using good healthy breeding stock that grows naturally, with suitable genetic diversity,
	– conditions that respect the behavioural needs of the species, including social interactions/hierarchies,
	– stocking densities that do not increase risk of disease transmission,
	– isolation of sick animals away from the rest of the group,
	– (for chickens and smaller animals) subdivision of flocks into smaller, physically separated groups,
	– 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

Or. en

(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))