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COMPROMISE AMENDMENTS- 3rd part 29 - 39

Draft report
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(PE551.951v01-00)

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

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

Amendment 29
Political groups
EPP-S&D-ECR-ALDE-Verts/ALE-ENF

Compromise amendment replacing Amendments: 31, 343, 344, 345, 346, AGRI 68

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.***

Or. en

Amendment 30
Political groups
EPP-S&D-ECR-ALDE-GUE/NGL-Verts/ALE-EFDD-ENF

Compromise amendment replacing Amendments: 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398

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	(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;	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 measures;	(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;
(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 legislation.
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	3. By the way of derogation from paragraph 1, a competent authority or the ***Commission*** may ***exempt*** a veterinary medicinal product ***from a mandatory***

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;

(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 potential serious ***side effects*** 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;

(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;

(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.

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;

(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 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;

(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;

(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.

Or. en

Amendment 31
Political groups

EPP-S&D-ECR-ALDE-GUE/NGL-Verts/ALE-EFDD-ENF

Compromise amendment replacing Amendments: 41, 42, 437, 438, 439, 440, 441, 442, 443, AGRI 86, AGRI 87

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 products for bees;	(c) ***20*** years for veterinary medicinal 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. The period shall be extended in line with the prolongation periods provided for in Article 35 where the veterinary medicinal product has been authorised for more than one species.

Or. en

Amendment 32
Political groups
EPP-S&D-ECR-ALDE-Verts/ALE-EFDD

Compromise amendment replacing Amendments: 40, 444

Proposal for a regulation
Recital 25 a (new)

Text proposed by the Commission	*Amendment*
	25a. The research on antimicrobials 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 antimicrobial product; in such cases only the new data package would benefit from the period of protection and not the active substance and all associated products.

Proposal for a regulation
Article 34a

Text proposed by the Commission	*Amendment*
	Article 34 a (new)
	Period of protection of new data packages related to existing antimicrobial veterinary medicinal products
	Any new studies and trials, submitted by the applicant for a marketing authorisation to the competent authorities for an existing antimicrobial 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 re-evaluation 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.

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.

Or. en

Amendment 33
Political groups
EPP-S&D-ECR-ALDE-GUE/NGL-Verts/ALE-EFDD-ENF

Compromise amendment replacing Amendments: 43, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, AGRI 88, AGRI 89, AGRI 90, AGRI 91

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 **2** ***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 3 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.

Or. en

Amendment 34
Political groups
EPP-S&D-ECR-ALDE-GUE/NGL-Verts/ALE-EFDD-ENF

Compromise amendment replacing Amendments: 55, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525

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

Text proposed by the Commission	*Amendment*
	(27a) "essentially similar product": 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.

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, or group of, marketing authorisation holder(s) 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 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').***	***4. In addition,*** harmonised ***conditions of use as defined in article 69 paragraph 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 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 new 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.	***5.*** 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.

Or. en

Amendment 35
Political groups
EPP-S&D-ECR-ALDE-Verts/ALE-EFDD-ENF

Compromise amendment replacing Amendments: 56, 57, 58, 59, 60, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548 ,549, 550, 551, 552, AGRI 109

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 ***according to 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 propose a harmonised summary of products characteristics.***	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 group of essentially*** similar veterinary medicinal products ***or of the marketing authorisation of a particular veterinary medicinal products***
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. ***Following harmonisation, 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.

Or. en

Amendment 36
Political groups
EPP-S&D-ECR-ALDE-Verts/ALE-EFDD-ENF

Compromise amendment replacing Amendments: 61, 62, 553, 554, 555, AGRI 110

Proposal for a regulation
Article 70

Text proposed by the Commission	*Amendment*
Harmonisation of summary of products	*Harmonisation of summary of products*

characteristics following reassessment	*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 European 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 mean products, not all of which are bioequivalent, and other than homeopathic veterinary medicinal products, that have the same active substance(s) 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 date but which were identified as potentially harmful to the environment in the course of the environmental risk assessment*** shall be ***reassessed*** before ***a*** harmonised ***summary of the product characteristics is*** prepared.	3. By way of derogation from Article 69, veterinary medicinal products ***which have not been subject to an environmental risk assessment in the European Union*** shall be ***assessed 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 Article 7 (1.b)***
	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	4. For the purposes of paragraphs 1, ***3 and 3a*** the procedure for a Union interest referral in accordance with Articles 84 to

apply accordingly.	87 shall apply accordingly.

Or. en

Amendment 37
Political groups
EPP-S&D-ECR-ALDE-GUE/NGL-Verts/ALE-EFDD-ENF

Compromise amendment replacing Amendments: 63, 556, 557, 558, 559, 560

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

Or. en

Amendment 38
Political groups
EPP-S&D-ECR-ALDE-GUE/NGL-Verts/ALE

Compromise amendment replacing Amendments: 84, 85, 86, 87, 88, 89, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, AGRI 139, AGRI 140

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/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 legislation 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 legislation 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/condition 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 medicinal products at a distance, providing at least the following information:	5. Each Member State shall set up a website regarding sale of veterinary medicinal products at a distance, providing at least the following information:
(a) information on its national legislation applicable to the offering of veterinary	(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;	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. ***The websites set up by Member States shall contain 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) Member States' websites shall also contain 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.	***Deleted***
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 listing 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.	***Deleted***
	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 the professional Code of Conduct..
	7b. No later than (6) 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 EU, including measures for controlling cross-border veterinary prescriptions.
	7c. On the basis of the guidelines mentioned in paragraph 7(b), Member States are encouraged to develop a system of digital prescription at national level, to include measures for the delivery and control of prescriptions. They are also 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).	[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	[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).	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). ***[29a] Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council (OJ L 304, 22.11.2011, p. 64).***

Or. en

Amendment 39
Political groups
EPP-S&D-ECR-ALDE-GUE/NGL-Verts/ALE-EFDD

Compromise amendment replacing Amendments: 91, 92, 93,94, 95, 96, 746, 747, 748/ 749, 750, 751, 752, 754, 753, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 771, 772 1st part, 772 3rd part, 773, 774, AGRI 141, AGRI 142, AGRI 143, AGRI 144, AGRI 145, AGRI 146, AGRI 147

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 treatment;	(a) identification of the animal ***or class of 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; ***in cases where the treatment has to be repeated, it should 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	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.	to the amount required for the treatment or therapy concerned. ***The maximum quantity of veterinary medicinal products supplied at one time may not, however, exceed one month's treatment. For chronic diseases and for periodic treatments the maximum quantity should 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 detailed in Articles 115 and 116. Those Member States who recognise in their national systems prescriptions issued by anyone other than a veterinarian shall immediately notify the Commission, which shall forward this information to all of the Member States.***

Or. en