EUROPEAN PARLIAMENT 2014 - 2019

Committee on Agriculture and Rural Development

2014/0257(COD)

25.3.2015

DRAFT OPINION

of the Committee on Agriculture and Rural Development

for the Committee on the Environment, Public Health and Food Safety

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

Rapporteur: Marit Paulsen

PA_Legam

SHORT JUSTIFICATION

Introduction

There is a pressing need for new legislation which will increase the scope for research into and development and monitoring of veterinary medicinal products and which will increase production and its profitability on the internal market. There is also a growing need for new and better medicines for use in livestock farming, in view of climate change and the worldwide trend towards greater movement. From farmers' point of view, it is of decisive importance that effective and accessible medicines should be available at a reasonable price when they are needed.

Simplification

In many ways, the production of veterinary medicinal products is considerably more complicated than that of medicinal products for human use, as human beings all belong to a single species, whereas animals are of many different species, which makes the market considerably more fragmented. It is therefore extremely important for the development of veterinary medicinal products that laws and regulations should verge on being over-explicit and simple. This means in turn that the European Parliament must make serious efforts to simplify and clarify the proposal submitted by the Commission. The first requirement is to simplify red tape itself, without reducing checks on new products or monitoring of products' side-effects and impact on animal welfare and health or their impact on public health and the environment.

Moreover, one detects a certain hesitancy in the Commission proposal, which leaves rather too many decisions to the authorities of the 28 Member States, while assigning too few to European Union level. It is also an open question how the EU is to adopt clear rules on what a certain competence will have to entail, namely what is meant by a 'competent veterinarian'.

Clarification

Article 4 contains no exact definitions of vital terms such as 'responsible use of veterinary medicinal products'. Here the definitions formulated by EPRUMA ought to be taken as a point of departure, as this cooperative organisation brings together all parties concerned, such as farmers' organisations, veterinary associations and the medical profession.

Antimicrobial resistance

The proposal contains surprisingly little in the way of provisions to tackle the problem of constantly growing antimicrobial resistance, which is an extremely serious threat both to animals and to human beings. It is surely vital to human beings and animals that we should as quickly as possible establish a clear picture of how all antimicrobial medicines are used, so that we can without delay greatly reduce their use and stop all abuses.

Even though Article 54 of the proposal provides for a European database on the use of veterinary medicinal products (which is something that the European Parliament was already calling for in May 2011), there is no clear requirement for the responsible authorities in Member States to collect, compile and report precise information on where, when, how and why an antimicrobial medicine – particularly an antibacteriological medicine – has been used. What is required here is that data should be collected on when, where, to which animal and as a result of what diagnosis a medicine has been administered. The requirement to collect information on diagnosis is particularly essential. It should not be permitted to prescribe any antibacteriological medicine without a clear diagnosis of disease having been made.

Article 108 on online retailing of veterinary medicinal products is a step in the right direction, but does not go far enough. It would be reasonable to permit only non-prescription medicines to be sold over the internet.

In the same way, Article 107 on financial incentives for veterinarians to prescribe medicines is welcome but inadequate. It seems strange that such a distinction should be drawn between the competences of practitioners of human and veterinary medicine: doctors are normally well paid for their work and their competence, whereas in some Member States equally well trained and competent veterinarians have to make ends meet by selling medicines. It would seem logical and reasonable that veterinarians – just like doctors – should keep stocks of medicines to meet immediate needs during the time that it would take to obtain medicines in the usual way, but no profit motive should be associated with this.

At all events, on public health grounds the new regulation should allow Member States to maintain or adopt more far-reaching rules on the use and prescription of antimicrobials.

Environmental impact

The consumption of antimicrobial and other veterinary medicinal products is also creating a growing environmental problem, particularly as regards leakage into the natural environment. Nowadays manure, which is the most important of all fertilisers, spreads large quantities, for example, of antibiotic-resistant bacteria in farmland and water. Data collected concerning side-effects as part of pharmacovigilance measures (Section 6) should also be forwarded to other relevant authorities, for example those responsible for the environment.

AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(40) There is still a lack of sufficiently detailed and comparable data at Union level to determine the trends and identify possible risk factors that could lead to the development of measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already introduced. Therefore it is important to collect data on the sales and use of antimicrobials in animals, data on the use of antimicrobials in humans and data on antimicrobial resistant organisms found in animals, humans and food. To ensure that the information collected can be used effectively, appropriate rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data on the use of antimicrobials under the coordination of the Agency.	(40) There is still a lack of sufficiently detailed and comparable data at Union level to determine the trends and identify possible risk factors that could lead to the development of measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already introduced. Therefore it is important to collect data on the sales and use of antimicrobials in animals, data on the use of antimicrobials in humans and data on antimicrobial resistant organisms found in animals, humans and food. ***In particular, better data is needed on how, when, where and why antimicrobials are being used.*** To ensure that the information collected can be used effectively, appropriate rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data on the use of antimicrobials under the coordination of the Agency.

Or. en

Justification

Builds on the resolution from the Agriculture Committee on antibiotic resistance, adopted by the European Parliament on 12 May 2011.

Amendment 2

Proposal for a regulation
Recital 50

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

Or. en

Justification

We need a holistic approach on the use of veterinary medicines, for instance as regards the environmental problems connected to the leakage of resistant bacteria into soil and water.

Amendment 3

Proposal for a regulation
Recital 58

Text proposed by the Commission	*Amendment*
(58) When examining the compatibility with Union law of the conditions for the supply of medicinal products, the Court of Justice of the European Union has recognised, in the context ***on*** medicinal products for human use, the very particular nature of medicinal products whose therapeutic effects distinguish them substantially from other goods. The Court of Justice has also held that health and life of humans rank foremost among the assets and interests protected by the Treaty and	(58) When examining the compatibility with Union law of the conditions for the supply of medicinal products, the Court of Justice of the European Union has recognised, in the context ***of*** medicinal products for human use, the very particular nature of medicinal products whose therapeutic effects distinguish them substantially from other goods. The Court of Justice has also held that health and life of humans rank foremost among the assets and interests protected by the Treaty and

that it is for Member States to determine the level of protection which they wish to afford to public health and the way in which that level has to be achieved. Since that level may vary from one Member State to another, Member States must be allowed some discretion as regards the conditions for the supply on their territory of medicinal products to the public. Therefore Member States should be able to subject the supply of medicinal products offered for sale ***at a distance by means of information society services*** to conditions justified by the protection of public health. Such conditions should not unduly restrict the functioning of the internal market.	that it is for Member States to determine the level of protection which they wish to afford to public health and the way in which that level has to be achieved. Since that level may vary from one Member State to another, Member States must be allowed some discretion as regards the conditions for the supply on their territory of medicinal products to the public. Therefore Member States should be able to subject the supply of medicinal products offered for sale to ***stricter*** conditions justified by the protection of public health. Such conditions should not unduly restrict the functioning of the internal market.

Or. en

Justification

From a public health point of view, it is very important that Member States may keep or introduce stricter requirements on the use and supply of veterinary medicines on their territory.

Amendment 4

Proposal for a regulation
Recital 62

Text proposed by the Commission	*Amendment*
(62) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a ***member of a regulated animal health profession*** for an individual animal or group of animals, it should in principle be possible for that veterinary prescription to be recognised and for the medicinal product to be dispensed in another Member State. The removal of regulatory and administrative barriers to such recognition should not affect any professional or ethical duty for dispensing professionals to refuse to dispense the medicine stated in the prescription.	(62) Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a ***veterinarian*** for an individual animal or group of animals, it should in principle be possible for that veterinary prescription to be recognised and for the medicinal product to be dispensed in another Member State. The removal of regulatory and administrative barriers to such recognition should not affect any professional or ethical duty for dispensing professionals to refuse to dispense the medicine stated in the prescription.

Or. en

Justification

In view of the global threat of antimicrobial resistance, veterinary medicines must be prescribed by a person with the highest possible competence.

Amendment 5

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

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

Or. en

Justification

Practical definition as suggested by the multi-stakeholder platform Epruma, representing both veterinarians, farmers and manufacturers of animal medicines.

Amendment 6

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

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

Or. en

Justification

Practical definition as suggested by the multi-stakeholder platform Epruma, representing both veterinarians, farmers and manufacturers of animal medicines.

Amendment 7

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

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

Or. en

Justification

Practical definition as suggested by the multi-stakeholder platform Epruma, representing both veterinarians, farmers and manufacturers of animal medicines.

Amendment 8

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

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

Or. en

Justification

Practical definition based on suggestions by the multi-stakeholder platform Epruma, representing both veterinarians, farmers and manufacturers of animal medicines.

Amendment 9

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

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

Or. en

Justification

Practical definition as suggested by the multi-stakeholder platform Epruma, representing both veterinarians, farmers and manufacturers of animal medicines.

Amendment 10

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

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

Or. en

Justification

Practical definition as suggested by the multi-stakeholder platform Epruma, representing both veterinarians, farmers and manufacturers of animal medicines.

Amendment 11

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

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

Or. en

Justification

Practical definition as suggested by the multi-stakeholder platform Epruma, representing both veterinarians, farmers and manufacturers of animal medicines.

Amendment 12

Proposal for a regulation
Article 6 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Applications shall be submitted electronically. For applications submitted in accordance with the centralised marketing authorisation procedure, the formats made available by the Agency shall be used.	3. Applications shall be submitted electronically. For applications submitted in accordance with the centralised marketing authorisation procedure, ***the decentralised procedure or the procedure for mutual recognition,*** the formats made available by the Agency shall be used.

Or. en

Justification

Further simplification of the procedures is needed in order to further encourage research and innovation, and consequently the availability of veterinary medicines.

Amendment 13

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

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

Or. en

Justification

We need a holistic approach on the use of veterinary medicines, for instance as regards the environmental problems connected to the leakage of resistant bacteria into soil and water.

Amendment 14

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

Text proposed by the Commission	*Amendment*
	(a a) the tested product is an unauthorised veterinary medicinal product and the withdrawal period set by the veterinarian in accordance with Article 117 is respected, or

Or. en

Justification

In order to further encourage the development of new veterinary medicines, clinical trials of products which have not yet been authorised must be possible, provided that the relevant withdrawal periods are respected so that there are no health risks involved.

Amendment 15

Proposal for a regulation
Article 35 – paragraph 3

Text proposed by the Commission	*Amendment*
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	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.	to the same marketing authorisation ('overall period of the protection of technical documentation') shall not exceed ***14*** years.

Or. en

Justification

In order to increase the availability of veterinary medicines, while encouraging further research and development, the accumulation of marketing authorisations should not be unreasonably long.

Amendment 16

Proposal for a regulation
Article 54 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall collect relevant ***and*** comparable data on the volume of sales and the use of veterinary antimicrobial medicinal products.	1. Member States shall collect relevant**,** comparable ***and sufficiently detailed*** data on the volume of sales and the use of veterinary antimicrobial medicinal products.

Or. en

Justification

Builds on the resolution on antibiotic resistance by the Agriculture Committee, adopted by the European Parliament on 12 May 2011.

Amendment 17

Proposal for a regulation
Article 54 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall send data on the volume of sales and the use of veterinary antimicrobial medicinal products to the Agency. The Agency shall analyse the data and publish an annual report.	2. Member States shall send data on the volume of sales and the use of veterinary antimicrobial medicinal products to the Agency. The Agency shall analyse the data and publish an annual report ***which shall contain guidelines and recommendations***

as appropriate.

Or. en

Justification

Builds on the resolution from the Agriculture Committee on antibiotic resistance, adopted by the European Parliament on 12 May 2011.

Amendment 18

Proposal for a regulation
Article 73 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) any observation of a lack of efficacy of a veterinary medicinal product following administration to an animal in accordance with the summary of product characteristics;	(b) any observation of a lack of efficacy of a veterinary medicinal product***, including signs of antimicrobial resistance,*** following administration to an animal in accordance with the summary of product characteristics;

Or. en

Justification

Given the high importance of the antimicrobial resistance, that specific problem needs to be high-lighted among the adverse events.

Amendment 19

Proposal for a regulation
Article 79 – paragraph 4

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

Or. en

Justification

Information on adverse events relating to the use of veterinary medicine should not be restricted to medicine agencies alone.

Amendment 20

Proposal for a regulation
Article 81 – paragraph 1

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

Or. en

Justification

We need a holistic approach on the use of veterinary medicines, for instance as regards the environmental problems connected to the leakage of resistant bacteria into soil and water.

Amendment 21

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 ***dispense*** 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

Justification

Similar to a doctor in human medicine, a veterinarian should "sell" expertise, not medicines. However, after a proper diagnosis the veterinarian must be able to provide an emergency dosis for the treatment of the animal under his immediate care.

Amendment 22

Proposal for a regulation
Article 108 – paragraph 1

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

Or. en

Justification

Measure needed to tackle the problem with antimicrobial resistance.

Amendment 23

Proposal for a regulation
Article 108 – paragraph 7

Text proposed by the Commission	*Amendment*
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***.	7. Members States may impose ***stricter*** conditions, justified on grounds of public health protection, for the retail on their territory of medicinal products.

Or. en

Justification

From a public health point of view, it is very important that Member States may keep or introduce stricter requirements on the use and supply of veterinary medicines on their territory.

Amendment 24

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 under treatment ***and the diagnosis of the disease to be treated***;

Or. en

Justification

A proper diagnosis is a precondition for a proper use of antibiotics.

Amendment 25

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

Text proposed by the Commission	*Amendment*
(l) any necessary warnings;	(l) any necessary warnings ***including, when relevant, the risks entailed by not applying a responsible use of antimicrobials***;

Or. en

Justification

Given the importance of the problem with antimicrobial resistance, that specific risk deserves to be specially mentioned.

Amendment 26

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, other than those listed in Article 109(1),*** shall only be issued by a person qualified to do so in accordance with applicable national law.

Or. en

Justification

In view of the global threat of antimicrobial resistance, veterinary medicines must be prescribed by a person with the highest possible competence, i.e. a veterinarian.

Amendment 27

Proposal for a regulation
Article 110 – paragraph 2 – subparagraph 1a (new)

Text proposed by the Commission	*Amendment*
	A veterinary prescription of a veterinary medicinal product which has anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties or substances shall only be

issued by a veterinarian.

Or. en

Justification

In view of the special risks related to these medicines, they must be prescribed by a person with the highest possible competence, i.e. a veterinarian.

Amendment 28

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. ***Prophylactic use of antimicrobials shall not be allowed.***

Or. en

Justification

Measure needed to tackle the problem of antimicrobial resistance.

Amendment 29

Proposal for a regulation
Article 110 – paragraph 3 – subparagraph 1a (new)

Text proposed by the Commission	*Amendment*
	Methaphylactic use of antimicrobials may be allowed only in cases where the diagnosis of clinical disease has been established.

Or. en

Justification

A proper diagnosis is a precondition for a proper use of antimicrobials.

Amendment 30

Proposal for a regulation
Article 110 – paragraph 4

Text proposed by the Commission	*Amendment*
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.

Or. en

Justification

For a prescription to be recognised throughout the Union, it must be issued by a professional who is recognised throughout the Union, i.e. a veterinarian,

Amendment 31

Proposal for a regulation
Article 111 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Veterinary medicinal products shall be used in accordance with the terms of the marketing authorisation.	1. Veterinary medicinal products shall be used ***responsibly*** in accordance ***with the principle of good animal husbandry and*** with the terms of the marketing authorisation.

Or. en

Justification

In accordance with the "One Health" approach, and in order to tackle the problem with antimicrobial resistance, the principles of a good animal husbandry and a responsible use of veterinary medicines must be applied.

Amendment 32

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

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

Or. en

Justification

A proper diagnosis is a precondition for a proper use of antibiotics.

Amendment 33

Proposal for a regulation
Article 136 – paragraph 2

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

Or. en

Justification

We need a holistic approach on the use of veterinary medicines, for instance as regards the environmental problems connected to the leakage of resistant bacteria into soil and water.