



FEDERATION OF VETERINARIANS OF EUROPE

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PRESS RELEASE

VETERINARY MEDICINAL PRODUCTS

FVE SUGGESTIONS ENDORSED BY EUROPEAN PARLIAMENT

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The European Parliament today adopted the report of Mrs Françoise Grossetête on the Commission proposal for a Directive on the Community Code relating to veterinary medicinal products.

FVE welcomes the report and in particular the amendments relating to the cascade, the veterinary prescription, the advertising of veterinary medicinal products as well as the specific amendments offering solutions to the long-outstanding problem of medicines availability in horses – which were put forward by Mrs Avril Doyle, the Irish MEP.

“These amendments received an overwhelming support and are a clear and strong message from the European Parliament on the way forward, Pierre Choraine, FVE Executive Director, said today, commenting on the adoption.

The veterinary profession, represented in Europe through FVE, would be directly affected by some of the provisions of the Commission proposal. And so would the animals under veterinary care – especially those belonging to the less common “minor species” or suffering from “minor indications”, or simply those in a Member State with a small veterinary product market.

Although the Commission proposal did include a number of incentives – such as an extended market exclusivity for every species added to the datasheet – to encourage the industry to develop new products, FVE was concerned that the positive effects of the proposed measures would not be felt before a decade at least. In the meantime, the problem would continue to exist for veterinary practitioners being caught between their responsibility of treating animals under their care and the dwindling therapeutic arsenal for these same animals.

The European Parliament recognised these concerns and today endorsed several amendments to facilitate the veterinary treatment of animals.

“The adopted amendments underpin the critical role of the veterinarian in the proper use of veterinary medicinal products and pave the way for a coherent legal framework, where veterinarians retain the flexibility necessary to the treatment of the animals under their care”, Mr Choraine added.

The legislative proposal will now move to the Council for another round of discussions. At that stage, it is hoped that Member States’ representatives will fully support the significant improvements as suggested by the European Parliament.

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THE CASCADE

The European Parliament accepted the FVE suggestions that:

- Veterinarians may, under their own responsibility, use the cascade when no suitable product is available;
- Veterinarians may use, both in food-producing and in non food-producing animals, veterinary products licensed in another Member State if they are unavailable in the home country;
- The Commission's proposal to establish a list of products to be used in horses under the cascade system is deemed unpractical;
- It should be possible to treat horses with products containing substances not included in annex I, II or III of Council Regulation 2377/90 - provided a withdrawal period of 6 months is observed;
- Substances without MRLs could be used in exceptional and limited circumstances in food-producing animals (other than horses);
- Veterinary surgeons should be given the authority and the responsibility, on the basis of sound scientific data, such as published articles, unpublished pharmaceutical companies results, FARAD-type data, to set the most suitable withdrawal period when using products under the cascade.

The cascade should therefore read as follows according to the European Parliament:

Article 10

1. *If there is no authorised medicinal product in a Member State for a condition affecting a non food-producing animal, the veterinarian may, by way of exception, particularly in order to avoid causing unacceptable suffering to the animal concerned, under his/her personal responsibility, treat the animal(s) with:*
 - a. *a veterinary medicinal product authorised in the Member State concerned under this Directive or under Regulation (EEC) No 2309/93 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),*
 - 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 the Council or under Regulation (EEC) No 2309/93; or*
 - ii. *a veterinary medicinal product authorised in another Member State in accordance with this Directive for use in the same species for the condition in question or for another condition,*
 - c. *if there is no product as referred to in point (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.*
2. *By way of derogation from Article 11, the provisions of paragraph 1 shall also apply to the treatment by a veterinarian of an animal belonging to the equidae family provided that it has been declared, under Commission Decision 93/623/EEC, as never having been intended for the production of foodstuffs.*

3. *By way of derogation from Article 11, the provisions of paragraph 1 also apply to the treatment by a veterinarian of other animals of the equidae family, not referred to in the previous article, provided such animals do not enter the food chain for human consumption before 6 months after the date of the last treatment with products containing substances not included in Annex I, II or III of Council Regulation No 2377/90 and that the veterinary surgeon fills in the passport of the animal as required in Decision 93/623/EEC.*

Article 11

1. *By way of exception, if there is no suitable authorised medicinal product in a Member State for a condition affecting food-producing animals, the veterinarian responsible may under his/her personal responsibility, treat the animals concerned on a particular holding with:*
 - a. *a veterinary medicinal product authorised in the Member State concerned under this Directive or under Regulation (EEC) No 2309/93 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),*
 - i. *either, a medicinal product authorised for use in the Member State concerned with human beings in accordance with Directive 2001/83/EC or under Regulation (EEC) No 2309/93; or*
 - ii. *a veterinary medicinal product authorised in another Member State in accordance with this Directive for use in the same species for the condition in question or for another condition; or*
 - c. *if the product or products as referred to in point (b) is/are not available and within the limits of the law of the Member State concerned, of 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.*
2. *Paragraph 1 shall apply provided that the pharmacologically active substances included in the medicinal product are listed in Annex I, II or III of Regulation (EEC) No 2377/90 and that the veterinarian responsible specifies an appropriate withdrawal period.*

However, where no such substances exist but good veterinary practice recognises that treatment with substances not included in the Annexes of Council Regulation (EEC) No 2377/90 is indicated, the veterinarian responsible may in exceptional circumstances, such as to avoid animal suffering, treat an animal or a limited number of animals on a particular holding with such substances provided that he/she specifies an appropriate withdrawal period.

In the absence of validated scientific data for the species concerned, the specified withdrawal period shall not be less than:

- a. *7 days eggs,*
- b. *7 days milk,*
- c. *28 days meat from poultry and mammals including fat and offal,*
- d. *500 degree days meat from fish.*

3. *When a veterinarian has recourse to the provisions of paragraphs 1 and 2 of this Article, he/she shall keep adequate records of the date of examination of the animals, details of the owner, the number of animals treated, the diagnosis, the medicinal products prescribed, the doses administered, the duration of treatment and the withdrawal periods recommended, and make these records available for inspection by the competent authorities for a period of at least five years.*
4. *Without prejudice to the other provisions of the Directive, Member States shall take all necessary measures concerning the import, distribution and dispensing of and information on the medicinal products, which may be administered to food-producing animals by virtue of paragraph 1(b), second indent of this Article.*

THE HORSE ISSUE

The European Parliament endorsed two additional amendments, in addition to those relating to the cascade that should bring a definitive and coherent solution to the long out-standing problem of products used in horses.

The first amendment is a definition of food-producing species:

Article 1.28

For the purpose of this Directive, food-producing animals are:

(a) animals bred, raised, kept or slaughtered specifically for the purpose of producing food for human consumption, or

(b) those animals, bred, raised and kept for sport and leisure purposes, from the time when they become destined for the food chain.

The second amendment is a derogation to the current provisions, which require all products licensed for food-producing animals to contain only substances included in annex I, II or III of Regulation 2377/90.

This important derogation will allow the marketing of products to be used in sport and leisure horses and containing substances not included in annex I, II or III of Regulation 2377/90.

The European Parliament decided to add a paragraph to article 6 of the Commission proposal, which reads as follows:

Article 6.3

By way of derogation from paragraph 1 and from Council Regulation (EEC) No 2377/90, for the particular animals belonging to the equidae family which are covered by Article 10(2) of this Directive, products may be placed on the market and contain substances not included in Annexes I, II or III of Council Regulation (EEC) No 2377/90.

THE VETERINARY PRESCRIPTION

The European Parliament supported the FVE view that only veterinary surgeons should be allowed to write prescriptions for veterinary medicinal products.

The definition of the veterinary prescription should therefore read as follows according to the European Parliament:

Article 1.20

Any prescription for veterinary medical products issued in writing by an authorised member of the veterinary profession after a clinical examination of the animal(s) or of a representative sample of the group of animals involved or in accordance with good veterinary practice.

THE ADVERTISING OF POMs VETERINARY MEDICINAL PRODUCTS

The European Parliament shared the FVE concerns about the direct advertising to the general public of POMs veterinary medicinal products and supported the FVE view that such advertising should be prohibited.

A new article on advertising should therefore be inserted and read as follows according to the European Parliament:

Article 85b

Member States shall prohibit the advertising to the general public of veterinary medicinal products which:

- (a) are available on veterinary prescription only,*
- (b) contain psychotropic or narcotic substances within the meaning of international conventions, e.g. the United Nations Conventions of 1961 and 1971."*

THE STOCK OF VETERINARY MEDICINAL PRODUCTS TO BE KEPT ON A FARM

The European Parliament also endorsed the FVE recommendation that stocks of veterinary medicinal products kept on farms should be limited to a minimum and that Member States shall therefore have the power and the duty to control that stocks of medicinal products kept on farms correspond to on-going treatments and have been supplied on a veterinary prescription.

A new article should therefore be inserted and read as follows according to the European Parliament:

Article 66 2a

The Member States shall take all the requisite measures to ensure that, where medicinal products are supplied solely on prescription, the quantity prescribed and supplied shall be restricted to the minimum amount required for the treatment or therapy concerned.'

THE DISPOSAL OF UNUSED PRODUCTS

The European Parliament accepted the FVE view that unused products should not be returned to a pharmacy but to the point where they were purchased.

A new article should therefore be inserted and read as follows according to the European Parliament:

Article 58 1j

"(j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, where appropriate. Unused medicinal products must be returned to the point of purchase. Not to be disposed of with other waste."