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FEDERATION OF VETERINARIANS OF EUROPE

FVE/02/122
3 October 2002

FVE AMENDMENTS ENDORSED BY THE EUROPEAN PARLIAMENT COMMITTEE ON ENVIRONMENT, PUBLIC HEALTH AND CONSUMMER POLICY

The European Parliament will vote and is expected to endorse the report of its Committee on the Environment, Public Health and Consumer Policy during its next plenary session to be held in Strasbourg on 18 October

THE CASCADE

The EP Environment Committee accepted the FVE suggestions that:

- *Veterinary surgeons may under their own responsibility use the cascade when no suitable product is available, without further restrictions;*
- *The 'geographical extension' foreseen under article 11 for food-producing animals should be extended to non-food producing animal;*
- *The Commission's proposal to establish a list of products that may be used in horses under the cascade is unpractical and will add little to the protection of consumers;*
- *The use in horses of products containing substances not included in annex I, II or III of Council Regulation 2377/90 can be tolerated from the point of view of consumer protection provided a withdrawal period of 6 months is observed after such use.*

The EP Environment Committee could however not endorse the FVE suggestions that:

- *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be given the authority and the responsibility, on the basis of sound scientific data, such as published articles, unpublished pharmaceutical companies results, FARAD-type data, to set the most suitable withdrawal period when using products under the cascade.*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 EP Environment Committee:

Article 10 (with the FVE amendments)

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:

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a. a veterinary medicinal product authorized 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 (with the FVE amendments)

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 authorized 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.

Unless the medicinal product used indicates a withdrawal period 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 they permit for administration to food-producing animals by virtue of paragraph 1(b), second indent of this Article.

THE VETERINARY PRESCRIPTION

The EP Environment Committee 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 EP Environment Committee:

Article 1.20 (with the FVE amendment)

Any prescription for veterinary medical products issued 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 EP Environment Committee 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 EP Environment Committee:

Article 85b (with the FVE amendment)

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 EP Environment Committee 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 EP Environment Committee:

Article 66 2a (with the FVE amendment)

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 EP Environment Committee accepted the FVE view 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 EP Environment Committee:

Article 58 1j (with the FVE amendment)

"(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."