Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

TITLE III

MARKETING

CHAPTER 1

Marketing authorization

[F1 Article 10

1 Member States shall take the necessary measures to ensure that, if there is no authorised veterinary medicinal product in a Member State for a condition affecting a non food-producing species, by way of exception, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animal concerned with:

a a veterinary medicinal product authorised in the Member State concerned under this Directive or under Regulation (EC) No 726/2004 for use with another animal species, or for another condition in the same species; or

b if there is no product as referred to in point (a), either:

(i) a medicinal product authorised for human use in the Member State concerned in accordance with Directive 2001/83/EC of the European Parliament and of the Council or under Regulation (EC) No 726/2004, or

(ii) in accordance with specific national measures, a veterinary medicinal product authorised in another Member State in accordance with this Directive for use in the same species or in another species for the condition in question or for another condition; or

c if there is no product as referred to in subparagraph (b), and within the limits of the law of the Member State concerned, a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national legislation in accordance with the terms of a veterinary prescription.

The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility.

2 By way of derogation from Article 11, the provisions of paragraph 1 of this Article shall also apply to the treatment by a veterinarian of an animal belonging to the equidae family provided that it has been declared, in accordance with Commission Decisions 93/623/EEC and 2000/68/EC, as not being intended for slaughter for human consumption.

[F2 3 By way of derogation from Article 11, the Commission shall establish a list of substances:

— which are essential for the treatment of equidae, or

— which bring added clinical benefit compared to other treatment options available for equidae,

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and for which the withdrawal period shall not be less than six months according to the control mechanisms laid down in Decisions 93/623/EEC and 2000/68/EC.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).**]]**

Textual Amendments

F1 Substituted by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

F2 Substituted by Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (Text with EEA relevance).