Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1950/2006

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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[(1)], and in particular Article 10(3) thereof,

Whereas:

(1) No veterinary medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with Directive 2001/82/EC or in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[(2)].

(2) Veterinary medicinal products for food-producing animals including equidae may be authorised only on conditions that guarantee that the foodstuffs produced will be harmless to consumers as regards any residues of such medicinal products, in accordance with Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin[(3)].

(3) For the reasons set out in the Communication from the Commission to the Council and the European Parliament on 'Availability of veterinary medicinal products'[(4)], the available range of authorised veterinary medicinal products, particularly for food-producing animals, is gradually decreasing.

(4) Consequently, measures aimed at a sustainable broadening of therapies are required in order to meet the health-care and welfare needs of food-producing animals, such as animals of the equidae family, without compromising the high level of consumer protection.

(5) By means of the derogation provided for in Directive 2001/82/EC, equidae intended for slaughter for human consumption may be administered substances essential for their treatment, hereinafter 'essential substances', subject to a withdrawal period of at least six months.

(6) For the purpose of that derogation, the list of essential substances should therefore be established. A substance should only be included in that list in exceptional circumstances where no satisfactory alternative treatment for a therapeutic indication is authorised and where the condition would, if untreated, create unnecessary suffering for the animal.

(7) Specific disease conditions or zootechnical purposes might require a choice of substances to be available in order to cater for different requirements related to the age and utilisation of equidae.

(8) Since, pursuant to Directive 2001/82/EC, substances listed in Annexes I, II or III to Regulation (EEC) No 2377/90 which are not authorised in products intended for equidae may, in certain circumstances, be used for the treatment of equidae, those substances should not appear on the list of essential substances. Furthermore, no substances listed in Annex IV to Regulation (EEC) No 2377/90 should be included in the list. Consequently, the inclusion of a substance in Annexes I to IV to Regulation (EEC) No 2377/90 should preclude its use as an essential substance for the purposes of this Regulation.

(9) It is necessary to ensure an appropriate surveillance of equidae which have been treated with essential substances. Therefore, the control mechanisms laid down in Commission Decision 93/623/EEC of 20 October 1993 establishing the identification document (passport) accompanying registered equidae[(5)] and Decision 2000/68/EC of 22 December 1999 amending Commission Decision 93/623/EEC and establishing the identification of equidae for breeding and production[(6)] to safeguard consumer health should apply.

(10) It is necessary to ensure that any amendment of the list of essential substances is subject to a harmonised scientific evaluation carried out by the European Medicines Agency established by Regulation (EC) No 726/2004. In addition, the Member States and veterinary professional associations which have requested an amendment of that list should duly substantiate their request and provide relevant scientific data.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

(**1**) OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

(**2**) OJ L 136, 30.4.2004, p. 1.

(**3**) OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1451/2006 (OJ L 271, 30.9.2006, p. 37).

(**4**) COM(2000) 806 final, 5.12.2000.

(**5**) OJ L 298, 3.12.1993, p. 45.

(**6**) OJ L 23, 28.1.2000, p. 72.