

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 6

1 A veterinary medicinal product may not be the subject of a marketing authorisation for the purpose of administering it to one or more food-producing species unless the pharmacologically active substances which it contains appear in Annexes I, II or III to Regulation (EEC) No 2377/90.

2 If an amendment to the Annexes to Regulation (EEC) No 2377/90 so warrants, the marketing authorisation holder or, where appropriate, the competent authorities shall take all necessary measures to amend or revoke the marketing authorisation within 60 days of the date on which the amendment to the Annexes to that Regulation was published in the *Official Journal of the European Union*.

3 By way of derogation from paragraph 1, a veterinary medicinal product containing pharmacologically active substances not included in Annexes I, II or III to Regulation (EEC) No 2377/90 may be authorised for particular animals of the equidae family that have been declared, in accordance with Commission Decision 93/623/EEC of 20 October 1993 establishing the identification document (passport) accompanying registered equidae<sup>(1)</sup> and Commission Decision 2000/68/EC of 22 December 1999 amending Decision 93/623/EEC and establishing the identification of equidae for breeding and production<sup>(2)</sup>, as not being intended for slaughter for human consumption. Such veterinary medicinal products shall neither include active substances that appear in Annex IV to Regulation (EEC) No 2377/90 nor be intended for use in the treatment of conditions, as detailed in the authorised Summary of Product Characteristics, for which a veterinary medicinal product is authorised for animals of the equidae family.]

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**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.](#)

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- (1) [<sup>F1</sup>OJ L 298, 3.12.1993, p. 45. Decision as amended by Commission Decision 2000/68/EC (OJ L 23, 28.1.2000, p. 72).]
- (2) [<sup>F1</sup>OJ L 23, 28.1.2000, p. 72.]

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- 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.