Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription (Text with EEA relevance)

COMMISSION DIRECTIVE 2006/130/EC

of 11 December 2006

implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription

(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 point (aa) of the first paragraph of Article 67 thereof,

Whereas:

(1) Pursuant to Article 67 of Directive 2001/82/EC, in the cases covered by the first and third paragraphs thereof, veterinary medicinal products may be dispensed to the public only against prescription. However, as certain substances, contained in veterinary medicinal products for food-producing animals, do not present a risk to human or animal health or to the environment, exemptions from that general requirement may be granted in accordance with point (aa) of the first paragraph of Article 67. Such exemptions are without prejudice to the application of any other provision of the first and third paragraphs of that Article.

(2) Consequently it is appropriate to establish criteria on the basis of which Member States may grant exemptions from the general rule, provided for in point (aa) of the first paragraph of Article 67 of Directive 2001/82/EC, requiring a prescription for dispensing to the public veterinary medicinal products for food producing animals.

(3) Where the veterinary medicinal products concerned are easy to administer and, even if administered incorrectly, do not present a risk either to the animal being treated or to the person administering the product, it should be possible for those products to be made available without the need for a veterinary prescription. On the other hand, it should not be possible to grant an exemption for products that feature an unfavourable pharmacovigilance profile or harm the environment.

(4) Inappropriate storage conditions may seriously affect the quality, safety and efficacy of veterinary medicinal products. Therefore, products whose quality, safety and efficacy

can be guaranteed only when stored under special conditions should not be granted an exemption.

(5) Exempted veterinary medicinal products should furthermore contain only active substances that do not cause a risk for consumer safety as regards residues in food obtained from treated animals and they should have no potential for causing a risk to human or animal health by developing resistance to antimicrobials or anthelmintics, if used incorrectly.

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive establishes the criteria on the basis of which Member States, in accordance with point (aa) of the first paragraph of Article 67 of Directive 2001/82/EC, may grant exemptions from the requirement to dispense veterinary medicinal products intended for food-producing animals to the public only against prescription.

Article 2

Veterinary medicinal products for food-producing animals may be exempted from the requirement to be dispensed only against veterinary prescription, if all of the following criteria are satisfied:

(a) the administration of veterinary medicinal products is restricted to formulations requiring no particular knowledge or skill in using the products;

(b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment;

(c) the summary of product characteristics of the veterinary medicinal product does not contain any warnings of potential serious side effects deriving from its correct use;

(d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent serious adverse reaction reporting;

(e) the summary of product characteristics does not refer to contraindications related to other veterinary medicinal products commonly used without prescription;

(f) the veterinary medicinal product is not subject to special storage conditions;

(g) there is no risk for consumer safety as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly;

(h) there is no risk to human or animal health as regards the development of resistance to antimicrobials or anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly.

Article 3

1 Where Member States decide to provide for the granting of exemptions pursuant to this Directive, they shall notify the Commission thereof.

2 If a notification in accordance with paragraph 1 has not been made by 31 March 2007 at the latest, the national exemptions referred to in point (aa) of the first paragraph of Article 67 of Directive 2001/82/EC shall cease to apply.

Article 4

1 Within six months of the notification referred to in Article 3, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 5

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 11 December 2006.

For the Commission

Günter VERHEUGEN

Vice-President

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