

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 2

**Particular provisions applicable to homeopathic veterinary medicinal products**

*[<sup>F1</sup>Article 16*

1 Member States shall ensure that homeopathic veterinary medicinal products manufactured and placed on the market within the Community are registered or authorised in accordance with Articles 17, 18 and 19, except where such veterinary medicinal products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993. In the case of homeopathic medicinal products registered in accordance with Article 17, Article 32 and Article 33(1) to (3) shall apply.

2 Member States shall establish a simplified registration procedure for the homeopathic veterinary medicinal products referred to in Article 17.

3 By way of derogation from Article 10, homeopathic veterinary medicinal products may be administered to non-food producing animals under the responsibility of a veterinarian.

4 By way of derogation from Article 11(1) and (2), Member States shall permit the administration of homeopathic veterinary medicinal products intended for food-producing species the active constituents of which appear in Annex II to Regulation (EEC) No 2377/90 under the responsibility of a veterinarian. Member States shall take appropriate measures to control the use of veterinary homeopathic medicinal products registered or authorised in another Member State in accordance with this Directive for use in the same species.]

**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.](#)

*Article 17*

[<sup>F11</sup> Without prejudice to the provisions of Regulation (EEC) No 2377/90 on the establishment of maximum residue limits of pharmacologically active substances intended for food-producing animals, only homeopathic veterinary medicinal products which satisfy all of the following conditions may be subject to a special, simplified registration procedure:

- a they are administered by a route described in the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in Member States;
- b no specific therapeutic indication appears on the labelling of the veterinary medicinal product or in any information relating thereto;

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- c there is a sufficient degree of dilution to guarantee the safety of the medicinal product. In particular, the medicinal product shall not contain more than one part per 10 000 of the mother tincture.

If it appears justified in the light of new scientific evidence, points (b) and (c) of the first subparagraph may be adapted in accordance with the procedure referred to in Article 89(2).

At the time of registration, Member States shall determine the classification for the dispensing of the medicinal product.]

2 The criteria and rules of procedure provided for in Chapter 3, with the exception of Article 25, shall apply by analogy to the special, simplified registration procedure for homeopathic veterinary medicinal products referred to in paragraph 1, with the exception of the proof of therapeutic effect.

<sup>F23</sup> .....

#### 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** Deleted 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.](#)

#### Article 18

A special, simplified application for registration may cover a series of medicinal products derived from the same homeopathic stock or stocks. The following documents shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned:

- scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered,
- dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate bibliography; in the case of homeopathic veterinary medicinal products containing biological substances, a description of the measures taken to ensure the absence of pathogens,
- [<sup>F1</sup>manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentiation,]
- manufacturing authorization for the medicinal products concerned,
- copies of any registrations or authorizations obtained for the same medicinal products in other Member States,
- [<sup>F1</sup>one or more mock-ups of the outer packaging and immediate packaging of the medicinal products to be registered,]
- data concerning the stability of the medicinal product<sup>[F1]</sup>,
- [<sup>F3</sup>proposed withdrawal period together with all requisite justification.]

#### 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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**F3** Inserted 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.](#)

### *[<sup>F1</sup> Article 19*

1 Homeopathic veterinary medicinal products other than those referred to in Article 17(1) shall be authorised in accordance with Articles 12, 13a, 13b, 13c, 13d and 14.

2 A Member State may introduce or retain on its territory specific rules for the safety tests and pre-clinical and clinical trials of homeopathic veterinary medicinal products intended for pet species and non-food-producing exotic species other than those referred to in Article 17(1), in accordance with the principles and characteristics of homeopathy as practised in that Member State. In this case, the Member State concerned shall notify the Commission of the specific rules in force.]

#### **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.](#)

### *Article 20*

This Chapter shall not apply to immunological homeopathic veterinary medicinal products.

The provisions of titles VI and VII shall apply to homeopathic veterinary medicinal products.