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 II

SCOPE

[F1 Article 2

1 This Directive shall apply to veterinary medicinal products, including pre-mixes for medicated feedingstuffs, intended to be placed on the market in Member States and prepared industrially or by a method involving an industrial process.

2 In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'veterinary medicinal product' and within the definition of a product covered by other Community legislation, the provisions of this Directive shall apply.

3 Notwithstanding paragraph 1, this Directive shall also apply to active substances used as starting materials to the extent set out in Articles 50, 50a, 51 and 80 and additionally to certain substances that may be used as veterinary medicinal products that have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties to the extent set out in Article 68.

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 3

1 This Directive shall not apply to:

a medicated feedingstuffs as defined in Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community[(1)];

b inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or the animals of that holding in the same locality;

c veterinary medicinal products based on radio-active isotopes;

d any additives covered by Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[(2)] where they are incorporated in animal feedingstuffs and supplementary animal feedingstuffs in accordance with that Directive; and

e without prejudice to Article 95, medicinal products for veterinary use intended for research and development trials.

However, medicated feedingstuffs referred to in subparagraph (a) may be prepared only from pre-mixes that have been authorised under this Directive.

2 Except for the provisions on the possession, prescription, dispensing and administration of veterinary medicinal products, this Directive shall not apply to:

a any medicinal product prepared in a pharmacy in accordance with a veterinary prescription for an individual animal or a small group of animals, commonly known as the magistral formula; and

b any medicinal product prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and intended to be supplied directly to the end-user, commonly known as the officinal formula.**]**

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 4

1 Member States may provide that this Directive shall not apply to non-inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or the animals of that holding in the same locality.

[F1 2 In the case of veterinary medicinal products intended solely for aquarium fish, cage birds, homing pigeons, terrarium animals, small rodents, and ferrets and rabbits kept exclusively as pets, Member States may permit exemptions, in their territory, from the provisions in Articles 5 to 8, provided that such products do not contain substances the use of which requires veterinary control and that all possible measures are taken to prevent unauthorised use of the products for other animals.**]**

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.

(1) **[**[F1]OJ L 92, 7.4.1990, p. 42.**]**

(2) **[**[F1]OJ L 270, 14.12.1970, p. 1. Directive as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).**]**

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.