

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

[^{F1}TITLE VI

**POSSESSION, DISTRIBUTION AND DISPENSING
OF VETERINARY MEDICINAL PRODUCTS]**

Article 65

1 Member States shall take all appropriate measures to ensure that wholesale distribution of veterinary medicinal products is subject to the holding of an authorization and to ensure that the time taken for the procedure for granting this authorization does not exceed 90 days from the date on which the competent authority receives the application.

Member States may exclude supplies of small quantities of veterinary medicinal products from one retailer to another from the scope of the definition of wholesale distribution.

2 In order to obtain the authorization for distribution, the applicant shall have at his disposal technically competent staff and suitable and sufficient premises complying with the requirements laid down in the Member State concerned as regards the storage and handling of veterinary medicinal products.

3 The holder of the authorization for distribution shall be required to keep detailed records. The following minimum information shall be recorded in respect of each incoming or outgoing transaction:

- a date;
- b precise identity of the veterinary medicinal product;
- c manufacturer's batch number, expiry date;
- d quantity received or supplied;
- e name and address of the supplier or recipient.

At least once a year a detailed audit shall be carried out to compare incoming and outgoing medicinal supplies with supplies currently held in stock, any discrepancies being recorded.

These records shall be available for inspection by the competent authorities for a period of at least three years.

[^{F23a} The holder of a distribution authorisation shall have an emergency plan guaranteeing the effective implementation of any recall operation ordered by the competent authorities or undertaken in cooperation with the manufacturer of the medicinal product in question or the holder of the marketing authorisation.]

4 Member States shall take all appropriate measures to ensure that wholesalers supply veterinary medicinal products only to persons permitted to carry out retail activities in accordance with Article 66, or to other persons who are lawfully permitted to receive veterinary medicinal products from wholesalers.

[^{F25} Any distributor, not being the marketing authorisation holder, who imports a product from another Member State shall notify the marketing authorisation holder and the competent authority in the Member State to which the product will be imported of his intention to import

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it. In the case of products which have not been granted an authorisation pursuant to Regulation (EC) No 726/2004, the notification to the competent authority shall be without prejudice to additional procedures provided for in the legislation of that Member State.]

Textual Amendments

F2 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.](#)

Article 66

1 Member States shall take all appropriate measures to ensure that the retail supply of veterinary medicinal products is conducted only by persons who are permitted to carry out such operations by the legislation of the Member State concerned.

2 ^{[F1}Any person permitted under paragraph 1 to supply veterinary medicinal products shall be required to keep detailed records for veterinary medicinal products that may be supplied only on prescription, the following information being recorded in respect of each incoming or outgoing transaction:]

- a date;
- b precise identity of the veterinary medicinal product;
- c manufacturer's batch number;
- d quantity received or supplied;
- e name and address of the supplier or recipient;
- f where relevant, name and address of the prescribing veterinarian and a copy of the prescription.

At least once a year a detailed audit shall be carried out, and incoming and outgoing veterinary medicinal products shall be reconciled with products currently held in stock, any discrepancies being recorded.

^{[F1}These records shall be available for inspection by the competent authorities for a period of five years.]

^{[F13} Member States may permit the supply on their territory of veterinary medicinal products for food-producing animals for which a veterinary prescription is required by or under the supervision of a person registered for this purpose who provides guarantees with respect to qualifications, record-keeping and reporting in accordance with national law. Member States shall notify the Commission of relevant provisions of national law. This provision shall not apply to the supply of veterinary medicinal products for the oral or parenteral treatment of bacterial infections.]

^{F34}

Textual Amendments

F3 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 67

^{[F1}Without prejudice to stricter Community or national rules relating to dispensing veterinary medicinal products and serving to protect human and animal health, a

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veterinary prescription shall be required for dispensing to the public the following veterinary medicinal products:]

- (a) those products subject to official restrictions on supply or use, such as:
- the restrictions resulting from the implementation of the relevant United Nations conventions on narcotic and psychotropic substances,
 - the restrictions on the use of veterinary medicinal products resulting from Community law;

- (aa) [^{F4}veterinary medicinal products for food-producing animals.

However, Member States may grant exemptions from this requirement according to criteria established by the Commission. The establishment of those criteria, being a measure designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).

Member States may continue to apply national provisions until either:

- (i) the date of application of the decision adopted in accordance with the first subparagraph; or
- (ii) 1 January 2007, if no such decision has been adopted by 31 December 2006;]
- (b) those products in respect of which special precautions must be taken by the veterinarian in order to avoid any unnecessary risk to:
- the target species,
 - the person administering the products to the animal,
 - [^{F3}. . . .]
 - the environment;
- (c) those products intended for treatments or pathological processes which require a precise prior diagnosis or the use of which may cause effects which impede or interfere with subsequent diagnostic or therapeutic measures;
- (d) [^{F1}official formula, within the meaning of Article 3(2)(b), intended for food-producing animals.]

[^{F1}Member States shall take all necessary measures to ensure that, in the case of medicinal products supplied only on prescription, the quantity prescribed and supplied shall be restricted to the minimum amount required for the treatment or therapy concerned.

In addition, a prescription shall be required for new veterinary medicinal products containing an active substance that has been authorised for use in a veterinary medicinal product for fewer than five years.]

Textual Amendments

- F3** 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.
- F4** Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

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Article 68

1 Member States shall take all measures necessary to ensure that only persons empowered under their national legislation in force possess or have under their control veterinary medicinal products or substances which may be used as veterinary medicinal products that have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties.

2 Member States shall maintain a register of manufacturers and dealers permitted to be in possession of active substances which may be used in the manufacture of veterinary medicinal products having the properties referred to in paragraph 1. Such persons must maintain detailed records of all dealings in substances which may be used in the manufacture of veterinary medicinal products and keep these records available for inspection by the competent authorities for a period of at least three years.

[^{F43} The Commission shall adopt any amendments to the list of substances referred to in paragraph 1.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).]

Textual Amendments

- F4** Substituted by [Regulation \(EC\) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.](#)

Article 69

[^{F1}Member States shall ensure that the owners or keepers of food-producing animals can provide proof of purchase, possession and administration of veterinary medicinal products to such animals for five years after their administration, including when the animal is slaughtered during the five-year period.]

In particular, Member States may require the maintenance of a record giving at least the following information:

- (a) date;
- (b) name of the veterinary medicinal product;
- (c) quantity;
- (d) name and address of the supplier of the medicinal product;
- (e) identification of the animals treated.

Article 70

[^{F1}By way of derogation from Article 9 and without prejudice to Article 67, Member States shall ensure that veterinarians providing services in another Member State can take with them and administer to animals small quantities of veterinary medicinal products not exceeding daily requirements other than immunological veterinary medicinal products which are not authorised for use in the Member State in which the

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services are provided (hereinafter: ‘host Member State’), provided that the following conditions are satisfied:]

- (a) the authorization to place the product on the market provided for in Articles 5, 7 and 8 has been issued by the competent authorities of the Member State in which the veterinarian is established;
- (b) the veterinary medicinal products are transported by the veterinarian in the original manufacturer's packaging;
- (c) the veterinary medicinal products intended for administration to food-producing animals have the same qualitative and quantitative composition in terms of active substances as the medicinal products authorized in accordance with Articles 5, 7 and 8 in the host Member State;
- (d) the veterinarian providing services in another Member State acquaints himself with the good veterinary practices applied in that Member State and ensures that the withdrawal period specified on the labelling of the veterinary medicinal product concerned is complied with, unless he could reasonably be expected to know that a longer withdrawal period should be specified to comply with these good veterinary practices;
- (e) the veterinarian shall not furnish any veterinary medicinal product to the owner or keeper of the animals treated in the host Member State unless this is permissible on the basis of the rules of the host Member State; in this case he shall, however, supply only in relation to animals under his care and only the minimum quantities of veterinary medicinal product necessary to complete the treatment of animals concerned on that occasion;
- (f) the veterinarian shall be required to keep detailed records of the animals treated, the diagnosis, the veterinary medicinal products administered, the dosage administered, the duration of treatment and the withdrawal period applied. These records shall be available for inspection by the competent authorities of the host Member State for a period of at least three years;
- (g) the overall range and quantity of veterinary medicinal products carried by the veterinarian shall not exceed that generally required for the daily needs of good veterinary practice.

Article 71

1 In the absence of specific Community legislation concerning the use of immunological veterinary medicinal products for the eradication or control of animal disease, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

- a the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal disease, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals;
- b the disease to which the product is intended to confer immunity is largely absent from the territory in question.

[^{F2}The Member State may also invoke the provisions of the first subparagraph in order to withhold marketing authorisation in accordance with a decentralised procedure as provided for in Articles 31 to 43.]

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2 The competent authorities of the Member States shall inform the Commission of all instances in which the provisions of paragraph 1 are applied.

Textual Amendments

- F2** 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.](#)

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.](#)