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

[F1TITLE 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.

[F1 3a 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.

[F1 5 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

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

F1 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.