Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance)

CHAPTER VII

SUPPLY AND USE

Section 1

Wholesale distribution

Article 99

Wholesale distribution authorisations

1 The wholesale distribution of veterinary medicinal products shall be subject to the holding of a wholesale distribution authorisation.

2 The holders of a wholesale distribution authorisation shall be established in the Union.

3 Wholesale distribution authorisations shall be valid throughout the Union.

4 Member States may decide that supplies of small quantities of veterinary medicinal products from one retailer to another in the same Member State shall not be subject to the requirement of holding a wholesale distribution authorisation.

5 By derogation from paragraph 1, a holder of a manufacturing authorisation shall not be required to hold a wholesale distribution authorisation for the veterinary medicinal products covered by the manufacturing authorisation.

6 The Commission shall, by means of implementing acts, adopt measures on good distribution practice for veterinary medicinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 100

Application and procedures for wholesale distribution authorisations

1 An application for a wholesale distribution authorisation shall be submitted to the competent authority in the Member State in which the site or sites of the wholesale distributor are located.

2 An applicant shall demonstrate in the application that the following requirements are met:

a the applicant has at its disposal technically competent staff and in particular at least one person designated as responsible person, meeting the conditions provided for in national law;

b the applicant has suitable and sufficient premises complying with the requirements laid down by the relevant Member State as regards the storage and handling of veterinary medicinal products;

c the applicant has a plan guaranteeing effective implementation of any withdrawal or recall from the market ordered by the competent authorities or the Commission or undertaken in cooperation with the manufacturer or marketing authorisation holder of the veterinary medicinal product concerned;

d the applicant has an appropriate record-keeping system ensuring compliance with the requirements referred to in Article 101;

e the applicant has a statement to the effect that it fulfils the requirements referred to in Article 101.

3 Member States shall lay down procedures to grant, refuse, suspend, revoke or change a wholesale distribution authorisation.

4 The procedures referred to in paragraph 3 shall not exceed 90 days, starting, if applicable, from the date on which the competent authority receives an application in accordance with national law.

5 The competent authority shall:

a inform the applicant of the outcome of the evaluation;

b grant, refuse or change the wholesale distribution authorisation; and

c upload the relevant information of the authorisation in the manufacturing and wholesale distribution database referred to in Article 91.

Article 101

Obligations of wholesale distributors

1 Wholesale distributors shall obtain veterinary medicinal products only from holders of a manufacturing authorisation or from other holders of a wholesale distribution authorisation.

2 A wholesale distributor shall supply veterinary medicinal products only to persons permitted to carry out retail activities in a Member State in accordance with Article 103(1), other wholesale distributors of veterinary medicinal products and to other persons or entities in accordance with national law.

3 The holder of a wholesale distribution authorisation shall have permanently at its disposal the services of at least one responsible person for wholesale distribution.

4 Wholesale distributors shall, within the limits of their responsibility, ensure appropriate and continued supply of veterinary medicinal product to persons authorised to supply it in accordance with Article 103(1), so that the needs for animal health in the relevant Member State are covered.

5 A wholesale distributor shall comply with the good distribution practice for veterinary medicinal products as referred to in Article 99(6).

6 Wholesale distributors shall immediately inform the competent authority and, where applicable, the marketing authorisation holder, of veterinary medicinal products they receive or are offered which they identify as falsified or suspected to be falsified.

7 A wholesale distributor shall keep detailed records of at least the following information in respect of each transaction:

a date of the transaction;

b name of the veterinary medicinal product including, as appropriate, pharmaceutical form and strength;

c batch number;

d expiry date of the veterinary medicinal product;

e quantity received or supplied, stating pack size and number of packs;

f name or company name and permanent address or registered place of business of the supplier in the event of purchase or of the recipient in the event of sale.

8 At least once a year, the holder of a wholesale distribution authorisation shall carry out a detailed audit of the stock and compare the incoming and outgoing veterinary medicinal products recorded with veterinary medicinal products currently held in stock. Any discrepancies found shall be recorded. The records shall be available for inspection by the competent authorities for a period of five years.

Article 102

Parallel trade in veterinary medicinal products

1 For the purpose of parallel trade in veterinary medicinal products, the wholesale distributor shall ensure that the veterinary medicinal product it intends to obtain from a Member State (‘source Member State’) and distribute in another Member State (‘destination Member State’) share a common origin with the veterinary medicinal product already authorised in the destination Member State. The veterinary medicinal products are considered as sharing a common origin if they fulfil all the following conditions:

a they have the same qualitative and quantitative composition in terms of active substances and excipients;

b they have the same pharmaceutical form;

c they have the same clinical information and, if applicable, withdrawal period; and

d they have been manufactured by the same manufacturer or by a manufacturer working under licence according to the same formulation.

2 The veterinary medicinal product obtained from a source Member State shall comply with the labelling and language requirements of the destination Member State.

3 Competent authorities shall lay down administrative procedures for the parallel trade in veterinary medicinal products and administrative procedure for the approval of the application for parallel trade in such products.

4 Competent authorities of the destination Member State shall, in the product database as referred to in Article 55, make available to public the list of veterinary medicinal products that are parallel traded in that Member State.

5 A wholesale distributor that is not the marketing authorisation holder shall notify the marketing authorisation holder and the competent authority of the source Member State of its intention to parallel trade the veterinary medicinal product to a destination Member State.

6 Each wholesale distributor intending to parallel trade a veterinary medicinal product to a destination Member State shall comply with at least the following obligations:

a submit a declaration to the competent authority in the destination Member State and take appropriate measures to ensure that the wholesale distributor in the source Member State will keep it informed of any pharmacovigilance issues;

b notify the marketing authorisation holder in the destination Member State about the veterinary medicinal product to be obtained from the source Member State and intended to be placed on the market in the destination Member State at least one month prior to submitting to the competent authority the application for parallel trade in that veterinary medicinal product;

c submit a written declaration to the competent authority of the destination Member State that the marketing authorisation holder in the destination Member State was notified in accordance with point (b) together with a copy of that notification;

d not trade a veterinary medicinal product which has been recalled from the market of the source Member State or destination Member State for quality, safety or efficacy reasons;

e collect suspected adverse events and report them to the marketing authorisation holder of the parallel-traded veterinary medicinal product.

7 The following information shall be attached to the list referred to in paragraph 4 in respect of all veterinary medicinal products:

a name of the veterinary medicinal products;

b active substances;

c pharmaceutical forms;

d classification of the veterinary medicinal products in the destination Member State;

e marketing authorisation number of the veterinary medicinal products in the source Member State;

f marketing authorisation number of the veterinary medicinal products in the destination Member State;

g name or company name and permanent address or registered place of business of the wholesale distributor in the source Member State and of the wholesale distributor in the destination Member State.

8 This Article shall not apply to centrally authorised veterinary medicinal products.