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 2

Retail

Article 103

Retail of veterinary medicinal products and record keeping

1 The rules on retail of veterinary medicinal products shall be determined by national law, unless otherwise provided in this Regulation.

2 Without prejudice to Article 99(4), retailers of veterinary medicinal products shall obtain veterinary medicinal products only from holders of a wholesale distribution authorisation.

3 Retailers of veterinary medicinal products shall keep detailed records of the following information in respect of each transaction of veterinary medicinal products requiring a veterinary prescription under Article 34:

a date of the transaction;

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

c batch number;

d quantity received or supplied;

e 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;

f name and contact details of the prescribing veterinarian and, where appropriate, a copy of the veterinary prescription;

g marketing authorisation number.

4 Where Member States consider it necessary, they may require retailers to keep detailed records of any transaction of veterinary medicinal products not subject to veterinary prescription.

5 At least once a year, a retailer 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 results of the detailed audit and the records referred to in paragraph 3 of this Article shall be available for inspection by the competent authorities in accordance with Article 123 for a period of five years.

6 Member States may impose conditions justified on grounds of protection of public and animal health or of the environment for the retail on their territory of veterinary medicinal

products provided that such conditions comply with Union law, are proportionate and non-discriminatory.

Article 104

Retail of veterinary medicinal products at a distance

1 Persons permitted to supply veterinary medicinal products in accordance with Article 103(1) of this Regulation may offer veterinary medicinal products by means of information society services in the meaning of Directive (EU) 2015/1535 of the European Parliament and of the Council[(1)] to natural or legal persons established in the Union provided that those veterinary medicinal products are not subject to a veterinary prescription pursuant to Article 34 of this Regulation and that they comply with this Regulation and applicable law of the Member State in which the veterinary products are retailed.

2 By way of derogation from paragraph 1 of this Article, a Member State may allow persons permitted to supply veterinary medicinal products in accordance with Article 103(1) to offer veterinary medicinal products subject to a veterinary prescription pursuant to Article 34 by means of information society services, provided that the Member State has provided a secure system for such supplies. Such permission shall only be granted to persons established in their territory and supply shall only occur within the territory of that Member State.

3 The Member State referred to in paragraph 2 shall ensure that adapted measures are in place in order to guarantee that the requirements relating to a veterinary prescription are respected as regards supply by means of information society services and shall notify the Commission and other Member States if it makes use of the derogation referred to in paragraph 2 and shall, when necessary, cooperate with the Commission and other Member States to avoid any unintended consequences of such supply. The Member States shall establish rules on appropriate penalties to ensure that the national rules adopted are respected, including rules on the withdrawal of such permissions.

4 The persons and activities referred to in paragraphs 1 and 2 of this Article shall be subject to the controls referred to in Article 123 by the competent authority of the Member State in which the retailer is established.

5 In addition to the information requirements set out in Article 6 of Directive 2000/31/EC of the European Parliament and of the Council[(2)], retailers offering veterinary medicinal products by means of information society services shall provide at least the following information:

a the contact details of the competent authority of the Member State in which the retailer offering the veterinary medicinal products is established;

b a hyperlink to the website of the Member State of establishment set up in accordance with paragraph 8 of this Article;

c the common logo established in accordance with paragraph 6 of this Article is clearly displayed on every page of the website that relates to the offer for sale at a distance of veterinary medicinal products and contains a hyperlink to the entry of the retailer in the list of permitted retailers referred to in point (c) of paragraph 8 of this Article.

6 The Commission shall establish a common logo pursuant to paragraph 7 that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering veterinary medicinal products for sale at a distance is established. The logo shall be clearly displayed on websites offering veterinary medicinal products for sale at a distance.

7 The Commission shall, by means of implementing acts, adopt the design of the common logo referred to in paragraph 6 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

8 Each Member State shall set up a website regarding sale of veterinary medicinal products at a distance, providing at least the following information:

a information on its national law applicable to the offering of veterinary medicinal products for sale at a distance by means of information society services, in accordance with paragraphs 1 and 2, including information on the fact that there may be differences between Member States regarding the classification of the supply of the veterinary medicinal products;

b information on the common logo;

c a list of retailers established in the Member State permitted to offer veterinary medicinal products for sale at a distance by means of information society services in accordance with paragraphs 1 and 2 as well as the website addresses of those retailers.

9 The Agency shall set up a website providing information on the common logo. The Agency's website shall explicitly mention that the websites of Member States contain information on persons permitted to offer veterinary medicinal products for sale at a distance by means of information society services in the relevant Member State.

10 Members States may impose conditions, justified on grounds of public health protection, for the retail, on their territory, of veterinary medicinal products offered for sale at a distance by means of information society services.

11 The websites set up by Member States shall contain a hyperlink to the website of the Agency set up in accordance with paragraph 9.

Article 105

Veterinary prescriptions

1 A veterinary prescription for an antimicrobial medicinal product for metaphylaxis shall only be issued after a diagnosis of the infectious disease by a veterinarian.

2 The veterinarian shall be able to provide justification for a veterinary prescription of antimicrobial medicinal products, in particular for metaphylaxis and for prophylaxis.

3 A veterinary prescription shall be issued only after a clinical examination or any other proper assessment of the health status of the animal or group of animals by a veterinarian.

4 By way of derogation from point (33) of Article 4 and paragraph 3 of this Article, a Member State may allow a veterinary prescription to be issued by a professional, other than a veterinarian, who is qualified to do so in accordance with applicable national law at the time of entry into force of this Regulation. Such prescriptions shall be valid only in that Member State and shall exclude prescriptions of antimicrobial medicinal products and any other veterinary medicinal products where a diagnosis by a veterinarian is necessary.

Veterinary prescriptions issued by a professional, other than a veterinarian shall be, *mutatis mutandis*, subject to paragraphs 5, 6, 8, 9 and 11 of this Article.

5 A veterinary prescription shall contain at least the following elements:

a identification of the animal or groups of animals to be treated;

b full name and contact details of the animal owner or keeper;

c issue date;

d full name and contact details of the veterinarian including, if available, the professional number;

e signature or an equivalent electronic form of identification of the veterinarian;

f name of the prescribed medicinal product, including its active substances;

g pharmaceutical form and strength;

h quantity prescribed, or the number of packs, including pack size;

i dosage regimen;

j for food-producing animal species, withdrawal period even if such period is zero;

k any warnings necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials;

l if a medicinal product is prescribed in accordance with Articles 112, 113 and 114, a statement to that effect;

m if a medicinal product is prescribed in accordance with Article 107(3) and (4), a statement to that effect.

6 The quantity of the medicinal products prescribed shall be limited to the amount required for the treatment or therapy concerned. As regards antimicrobial medicinal products for metaphylaxis or prophylaxis, they shall be prescribed only for a limited duration to cover the period of risk.

7 Veterinary prescriptions issued in accordance with paragraph 3 shall be recognised throughout the Union.

8 The Commission may, by means of implementing acts, set a model format for the requirements set in paragraph 5 of this Article. That model format shall also be made available in electronic version. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

9 The medicinal product prescribed shall be supplied in accordance with applicable national law.

10 A veterinary prescription for antimicrobial medicinal products shall be valid for five days from the date of its issue.

11 In addition to the requirements set out in this Article, Member States may lay down rules on record-keeping for veterinarians when issuing veterinary prescriptions.

12 Notwithstanding Article 34, a veterinary medicinal product classified as subject to veterinary prescription under that Article may be administered without a veterinary prescription by a veterinarian personally, unless otherwise provided for under applicable national law. The veterinarian shall keep records of such personal administration without prescription in accordance with applicable national law.

(**1**) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

(**2**) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1).