

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

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