

NATIONAL SANITARY VETERINARY AND FOOD SAFETY AUTHORITY

ORDER

amending the Sanitary-Veterinary Rule on the conditions for the organisation and operation of veterinary pharmaceutical establishments and the procedure for sanitary-veterinary health registration / sanitary-veterinary health authorisation of establishments and activities in the veterinary pharmaceutical sector, approved by Order No 83/2014 of the President of the National Sanitary Veterinary and Food Safety Authority

Having regard to the Approval Reference No 388/26.04.2024, drawn up by the Directorate for Coordination of Laboratories and Veterinary Medicinal Products of the National Sanitary Veterinary and Food Safety Authority;

Having regard to Article 99-101 of 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;

Having regard to the provisions of Commission Implementing Regulation (EU) 2021/1248 of 29 July 2021 as regards measures on good distribution practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council;

Having regard to the provisions of Article 10(b) of Government Order No 42/2004 on the organization of the sanitary-veterinary and food safety activity, approved with amendments and additions by Law No 215/2004, as amended;

Pursuant to Article 3(1) and (3), as well as Article 4(3) of Government Decision No 1415/2009 on the organisation and functioning of the National Sanitary Veterinary and Food Safety Authority and its subordination units, as subsequently amended and supplemented;

the President of the National Sanitary Veterinary and Food Safety Authority hereby issues the following order:

Article I. - The Sanitary-Veterinary Rule on the conditions for the organisation and operation of veterinary pharmaceutical establishments and the procedure for sanitary-veterinary registration / sanitary-veterinary authorisation of establishments and activities in the veterinary pharmaceutical sector, approved by Order No 83/2014 of the President of the National Sanitary Veterinary and Food Safety Authority, published in the Official Gazette of Romania, Part I, No 541 and 541 bis of 22 July 2014, as amended, is hereby amended as follows:

1) Article 3(t) is amended to read as follows:

‘t) authorization for wholesale distribution of veterinary medicinal products, reagents and diagnostic kits for veterinary use - the document issued by the county sanitary-veterinary and food safety directorates, respectively of the municipality of Bucharest, for the wholesale trade of veterinary medicinal products, reagents and diagnostic kits for veterinary use or for activities related to the sale or purchase of veterinary medicinal products, carried out by wholesalers established on the territory of Romania, who meet the sanitary-veterinary conditions laid down by the legislation in force;’

2) In Article 9, paragraph 1 is amended to read as follows:

‘1. The possession and sale in veterinary pharmacies of external anti-parasitic veterinary medicinal products of the emulsifiable concentrate type authorised for food-producing animals, including equidae, veterinary medicinal products containing narcotic and psychotropic substances, substances under national control, anaesthetic and tranquilising substances, substances having a hormonal, thyrostatic or beta-agonist action, and veterinary medicinal products used for euthanasia shall be prohibited.’

3) In Article 27, paragraph 1 shall be repealed.

4) Article 59 is amended to read as follows:

‘Article 59. - In order to obtain authorisation for the wholesale distribution of veterinary medicinal products, reagents and diagnostic kits for veterinary use, the applicant must submit to the competent sanitary-veterinary and food safety authority a dossier containing the following documents:

- a) application for wholesale distribution authorisation, in accordance with the model set out in Annex 9;
- b) the documents relating to the fulfilment of the requirements laid down in Article 100(2) of Regulation (EU) 2019/6;
- (c) proof of payment of the fee provided for in the sanitary-veterinary legislation in force.’

5) In Chapter IV, the title is amended to read as follows:

‘Wholesales of veterinary medicinal products, reagents and diagnostic kits for veterinary use.’

6) Annex 4 is amended to read as follows:

‘Annex No 4 to the Sanitary-Veterinary Rule

ACTIVITIES AND ESTABLISHMENTS

subject to sanitary-veterinary registration / sanitary-veterinary authorisation for operation/authorisation for the wholesale distribution of veterinary medicinal products, veterinary reagents and diagnostic kits by the county sanitary-veterinary authority, respectively that of the municipality of Bucharest

Item No.	Name of the activity	Name of establishment according to specific legislation
1)	Retail sale of veterinary medicinal products	Veterinary pharmacy*) (Is being authorised.)
2)	Retail sale of non-prescription veterinary medicinal products	Veterinary pharmaceutical outlet**)

		(Is being recorded.)
3)	Wholesale distribution of veterinary medicinal products, reagents and diagnostic kits for veterinary use	Wholesaler of veterinary medicinal products, reagents and diagnostic kits for veterinary use ***) (Is being authorised.)

*) In addition to veterinary medicinal products, retail marketing of feed, medicated feed, other veterinary products, medical instrumentation and appliances, medical devices, animal accessories shall be permitted in the veterinary pharmacy, in compliance with the specific legal provisions in force.

***) In addition to veterinary medicinal products that are dispensed without prescription, the retail sale of animal feed, other products for veterinary use, medical instruments and appliances, medical devices and accessories for animals is also permitted through the veterinary pharmaceutical outlet, subject to the specific legal provisions in force.

****) In addition to veterinary medicinal products, the wholesaler may also wholesale other veterinary products, feed, medicated feed, medical instruments and appliances, medical devices, animal accessories, cosmetics furniture, in compliance with the specific legal provisions in force.'

Article II - From the date of entry into force of this Order, the purchase by veterinary pharmacies of external anti-parasitic veterinary medicinal products of the emulsifiable concentrate type authorised for food-producing animals, including equidae, and veterinary medicinal products containing anaesthetic and tranquilising substances, substances with hormonal, thyrostatic or beta-agonist action shall be prohibited.

Article III - External anti-parasitic veterinary medicinal products of the emulsifiable concentrate type authorised for food-producing animals, including equidae, and veterinary medicinal products containing anaesthetic and tranquilising substances, substances with hormonal, thyrostatic or beta-agonist action, in stock in veterinary pharmacies, may be marketed until stocks are exhausted, but not later than 90 days after the entry into force of this Order.

Article IV - This Order was adopted in accordance with the notification procedure laid down in Directive (EU) 2015/1535 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

Article V - This Order shall be published in the Official Gazette of Romania, Part I.

President
of the National Sanitary Veterinary and Food Safety Authority,

Bucharest,.....

No.....