



GOVERNMENT OF ROMANIA

EMERGENCY ORDINANCE

amending Article 37 of Law No 160/1998 on the organisation and practice of the veterinary profession

Considering the particular importance of veterinary medicinal products in the protection of public health, animal health and the environment;

Taking into account the numerous serious accidents in humans and animals caused by poisoning resulting from the application of treatments with emulsifiable concentrated external veterinary antiparasitic medicinal products, purchased illegally without a veterinary prescription and used without complying with the indications in the package leaflet;

Taking into account the public health problems faced by paediatric hospitals in the country with regard to serious poisoning in children with organophosphorus and carbamate insecticides;

Having regard to the illegal use of these products in humans for the treatment of sarcoptic mange and lice infestations, with very serious consequences on human health;

Considering the need to limit the access of animal keepers to these products, in order to avoid any accidents due to overdosing or incorrect handling of these products;

Having regard to the obligation of strict adherence to the manner of use provided for in the package leaflet of veterinary medicinal products;

Whereas serious cases of poisoning followed by the death of children and a large number of animals have been caused by the use of products containing insecticides purchased in veterinary pharmacies, in order to limit the risk to animal health and in particular to public health, it is necessary to prohibit the retail sale of these categories of products;

In order to adopt urgent measures to prevent the occurrence of such accidents in humans and animals with negative health consequences;

Whereas current legislation does not allow the purchase and use of medicinal products containing narcotic and psychotropic substances by veterinarians in establishments using animals for scientific purposes and by veterinarians employed by a public institution in the field of justice or employed in public institutions of defence, public order and national security, which have their own veterinary structures;

In order to avoid the purchase by the owners of food-producing animals intended for human consumption of hormonal veterinary medicinal products intended for pet animals but used illegally in food-producing animals without being prescribed/administered by the veterinarian, thereby endangering public health;

Taking into account the need to take appropriate measures to reduce antimicrobial resistance through the correct, judicious and prudent use of antimicrobial veterinary medicinal products;

Taking into account the problems encountered in the reporting of data on the use of antimicrobials in animals by self-employed veterinarians in establishments providing veterinary care and veterinary pharmacies, as well as the risks involved in not reporting such data annually to the European Medicines Agency within the time limits laid down in European Union legislation;

Having regard to the fact that failure to adopt the proposed provisions swiftly, in the absence of concrete and rapid measures, could expose vulnerable populations and animals to particularly serious accidents with an impact on public and animal health and to economic losses in the livestock sector;

Whereas the elements presented are in the public interest and constitute an urgent and extraordinary situation, whose regulation cannot be postponed;

On the grounds of Article 115(4) of the Romanian Constitution, republished,

The Government of Romania hereby adopts this Emergency Ordinance.

Article I. - Article 37 of Law No 160/1998 on the organisation and practice of the veterinary profession, republished in the Official Gazette of Romania No 209 of 24 March 2014, Part I, as amended, is hereby amended to read as follows:

'Article 37.- 1. Veterinary medicinal products shall only be wholesaled by wholesale distributors of veterinary medicinal products or by manufacturers of veterinary medicinal products in accordance with Article 99 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; veterinary medicinal products shall be retailed only through veterinary pharmacies and veterinary pharmaceutical outlets in accordance with the requirements laid down by the National Sanitary Veterinary and Food Safety Authority.

2. The establishment and operation of wholesale distributors of veterinary medicinal products, veterinary pharmacies, and veterinary pharmaceutical outlets shall be carried out under the conditions laid down by order of the President of the National Sanitary Veterinary and Food Safety Authority; in the case of veterinary pharmacies and veterinary pharmaceutical outlets established on the basis of Companies Law No 31/1990, republished, as amended, a share of the share capital must be held by a veterinarian, in compliance with the decision of the Court of Justice of the European Union (CJEU) of 1 March 2018 in Case C-297/16.

3. The activity within veterinary pharmacies and veterinary pharmaceutical outlets shall be carried out under the supervision of a registered veterinary practitioner, respon-

sible for the placing on the market of veterinary medicinal products, in compliance with the legal provisions in force, who fulfils one of the following conditions:

- a) is a shareholder and/or manager of the company that owns the veterinary pharmaceutical establishment;
- b) is a veterinarian who is the holder of the veterinary pharmaceutical establishment;
- c) is employed under an individual employment contract by the veterinary pharmaceutical establishment.

4. The wholesale distributors of veterinary medicinal products, veterinary pharmacies, and veterinary pharmaceutical outlets operate on the basis of the sanitary-veterinary authorisation/registration issued by the National Sanitary Veterinary and Food Safety Authority, through the sanitary-veterinary and food safety directorates of the counties, respectively of the municipality of Bucharest.

5. Veterinary pharmacies shall dispense veterinary medicinal products for which a veterinary prescription has been issued, limited to the species and weight of the animal, the condition concerned, the duration of treatment and the recommended dose, and shall indicate the series and number of the veterinary prescription on the relevant receipt.

6. In veterinary pharmacies and pharmaceutical outlets, only veterinary medicinal products whose retail sale is not prohibited shall be sold, according to the legislation in force, with or without a veterinary prescription, as the case may be.

7. All veterinary medicinal products used for euthanasia, injectable medicinal products containing narcotic and psychotropic substances, as well as injectable medicinal products containing substances under national control, shall be administered only by registered veterinary practitioners, both at the premises of the establishments where veterinary medical assistance is provided and under field conditions, as well as by veterinarians within establishments using animals for scientific purposes and by veterinarians employed by a public institution in the field of justice or employed in public institutions of defence, public order and national security, which have their own veterinary structures.

8. The administration of medicinal products is the responsibility of the registered veterinary practitioner; by way of exception from paragraph (1), the establishments where veterinary medical assistance activities are carried out may retail veterinary medicinal products that are used in the medical, prophylactic or curative act, if their retail marketing is not prohibited by the legislation in force, as well as other complementary products used for the purpose of prevention, improvement and cure of diseases and to ensure an adequate level of animal health and welfare, but with the obligation to register medicinal products that are issued on the basis of a veterinary prescription in the register of consultations and treatments, as a multidisciplinary activity related to the medical act that does not require additional authorisation.

9. It shall be prohibited to prescribe, dispense and retail injectable antimicrobial veterinary medicinal products in packages of more than 10 millilitres, injectable veterinary medicinal products containing substances having a hormonal, thyrostatic or beta-agonist action, injectable antiparasitic veterinary medicinal products, biological veterinary medicinal products, including immunological ones, veterinary medicinal products used for euthanasia, veterinary medicinal products containing anaesthetic substances and injectable tranquillisers, veterinary medicinal products containing external antiparasitic substances presented as an emulsifiable suspension/concentrate and used by external application in cattle, sheep, goats, swine, equidae, birds or for fumigating strips in

bees, veterinary medicinal products containing narcotic and psychotropic substances, and veterinary medicinal products containing substances under national control.

10. Online retailing is permitted only for veterinary medicinal products that are dispensed without a veterinary prescription and solely by veterinary pharmaceutical establishments, authorised/registered in accordance with sanitary-veterinary regulations, under the conditions established by order of the President of the National Sanitary Veterinary and Food Safety Authority.

11. Pharmacies open to public governed by Pharmacy Law No 266/2008, republished, as subsequently amended and supplemented, shall dispense medicinal products for human use, including narcotics, psychotropic substances, and those under national control, on the basis of veterinary prescriptions issued by registered veterinary practitioners, in situations where there is no similar veterinary medicinal product authorised or available to be marketed on the Romanian market.

12. Holdings that keep animals and are authorised/registered for veterinary health purposes may purchase veterinary medicinal products on the basis of an order form endorsed by a registered veterinary practitioner, organised in accordance with the law, who provides veterinary medical assistance and continuously monitors the health status of the animal(s).

13. By order of the President of the National Sanitary Veterinary and Food Safety Authority, the list of veterinary medicinal products that are administered exclusively by a registered veterinary practitioner, those that are administered under his supervision or responsibility, as well as the maximum limit of the quantities of antimicrobial medicinal products that may be kept in stock by commercial livestock holdings shall be established.

14. Veterinary pharmaceutical outlets may only retail veterinary medicinal products authorised to be dispensed without a veterinary prescription.

15. Registered/authorised veterinary commercial holdings raising and keeping terrestrial and aquatic animals, as defined in Article 4(2) and (3) of Regulation (EU) 2016/429 of the European Parliament and of the Council of 6 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health, including their associative forms, as well as the associative forms of natural persons raising and keeping terrestrial and aquatic animals, may not establish or own establishments carrying out veterinary healthcare activities and veterinary pharmaceutical establishments, nor may they hold a share in their share capital.

16. Wholesale distributors of medicinal products for human use shall supply, exclusively for use in veterinary medical practice, medicinal products for human use, including those in the category of narcotic drugs, psychotropic substances, and those under national control, for which there is a marketing authorisation, in situations where there is no similar veterinary medicinal product authorised or available for marketing on the Romanian market, to establishments where veterinary medical assistance activities are carried out, based on the certificate of registration in the Single Register of Veterinary Practices, with or without legal personality, and the order note signed by the veterinarian right-holder.

17. Official controls on the import, manufacture, marketing authorisation, wholesale distribution, retailing, storage and use of veterinary medicinal products by establishments with this legal right, including establishments providing veterinary medical assistance, commercial and non-professional animal holdings, as well as animal owners/holders, shall be carried out by the National Sanitary Veterinary and Food Safety Authority, as well as by the sanitary-veterinary and food safety directorates of the counties, respectively of the municipality of Bucharest.

18. Veterinary healthcare establishments and veterinary pharmacies shall report to the Institute for Control of Biological Products and Veterinary Medicines the situation regarding antimicrobial veterinary medicinal products and medicated feed containing antimicrobials used in animals by medical act and retail, including for commercial holdings, in accordance with Commission Delegated Regulation (EU) 2021/578 of 29 January 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals and Commission Implementing Regulation (EU) 2022/209 of 16 February 2022 establishing the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council.'

Article II. – 1. From the date of entry into force of this Emergency Ordinance, the purchase by veterinary pharmacies of products prohibited for retail sale in accordance with the legal provisions in force shall be prohibited.

2. Veterinary pharmacies which, on the date of entry into force of this Emergency Ordinance, hold in stock veterinary medicinal products used for euthanasia, veterinary medicinal products containing anaesthetic substances and injectable tranquilisers, veterinary medicinal products containing external antiparasitic substances presented as suspension/emulsifiable concentrate and used by external application in cattle, sheep, goats, pigs, equidae, poultry or for smoke strips in bees, veterinary medicinal products containing narcotic and psychotropic substances, as well as veterinary medicinal products containing substances under national control, shall report them to the county or Bucharest sanitary-veterinary and food safety directorates and may market them until their stocks are exhausted, but for no longer than 90 days.

3. Veterinary pharmacies which, on the date of entry into force of this Emergency Ordinance, hold in stock products other than those referred to in paragraph (2) and which are prohibited from being sold at retail, shall report them to the County or Bucharest Sanitary Veterinary and Food Safety Directorates and may market them until their stocks are exhausted, but for no more than one year.

Article III. – This Emergency Ordinance shall enter into force 10 days after its publication.

PRIME-MINISTER