ROMANIA

Veterinary Medicines Regulatory System:

Country Snapshot

Presenter: Dr. Mihaela DUMITRACHE
Dr. Rodica MORCOV

Role and Organisation: Director,
Head of Service
Directorate of Laboratory and VMPs Coordination
National Sanitary Veterinary and Food Safety Authority

World Organisation for Animal Health
Founded as OIE

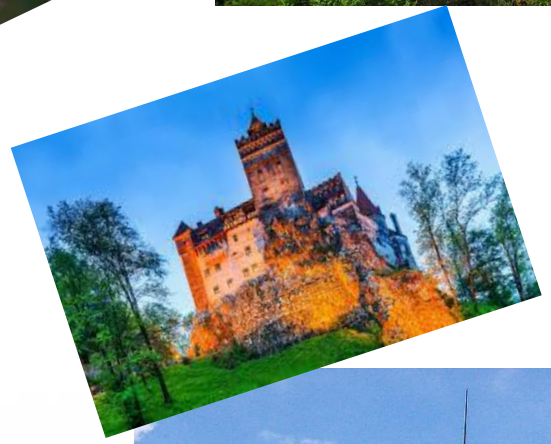
Organisation mondiale de la santé animale
Fondée en tant qu'OIE

Organización Mundial de Sanidad Animal
Fundada como OIE














Mandate and legal basis

- 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;
- Delegated and implementing regulations for Regulation (EU) 2019/6 of the European Parliament and of the Council
- ANSVSA Order No. 83/2014 approving the veterinary sanitary norm regarding the conditions for the organization and operation of veterinary pharmaceutical establishments, as well as the procedure for their registration and authorization.
- ANSVSA Order No. 59/2022 approving the sanitary-veterinary standard for the implementation 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, regarding marketing authorizations, the approval of clinical trials, and the pharmacovigilance of veterinary medicinal products.

Which authority or body is responsible for each of these?

Activity	**Responsible authority**	**Notes (shared, outsourced, not performed)**
Authorisation of veterinary pharmaceuticals	Institute for the Control of Biological Products and Veterinary Medicines (ICBPVM)	-
Authorisation of veterinary biologicals and immunologicals	ICBPVM	-
Authorisation of ectoparasiticides (veterinary pesticides)	ICBPVM	-
Authorisation of veterinary medicines for fish	ICBPVM	-
Pharmacovigilance	ICBPVM	-
Authorisation and inspection (GDP) of the distribution chain	County sanitary-veterinary and food safety directorates	-
Authorisation and inspection (GMP) of the manufacturing site	National Sanitary Veterinary and Food Safety Authoroty	-
Laboratory quality testing	ICBPVM	

Who is allowed to manufacture, import, distribute and sell?

- How do you know they are complying?

Manufacturers and importers must be authorized for manufacturing and certified for Good Manufacturing Practice

(once every 3 years and after each significant change)

Distributors must be authorized for wholesale distribution and comply with Good Distribution Practices

(assessment prior to the start of the activity and subsequently on a periodic basis)

The marketing of veterinary medicinal products is carried out through pharmacies and veterinary pharmaceutical outlets that are authorized or registered for sanitary-veterinary purposes

(assessment prior to the start of the activity and subsequently on a periodic basis)

The import, production, or distribution of active substances used in the manufacture of veterinary medicinal products is carried out only by registered establishments

(assessment prior to the start of the activity and subsequently on a periodic basis)

How are veterinary medicines classified for supply?

- Prescription products (POM)

- Non-prescription products (OTC) !!! EU logo for online sale of veterinary medicines

The EU has introduced a common logo for the sale of veterinary medicinal products by online pharmacies.

- A farmer or a cat owner cannot buy an antimicrobial without a veterinary prescription

- Antimicrobials sit in a stricter category than everything else and have special restrictions regarding use

- Certain special warnings regarding the use of antimicrobial products have been included in the approved specifications.

How do you learn that a product already in use is substandard, falsified or unsafe?

- Analysis of primary and secondary packaging: information on the label and package leaflet not conforming to the approved details; missing batch number, expiry date, etc.; spelling errors; packaging design differing from that of the original product; labels and package leaflets in a different language; differences in the color of the primary packaging, staples, or closure system, etc.
- Lack of effectiveness
- Severe or unexpected adverse reactions
- The information are received following the taking of samples from the market by sanitary-veterinary inspectors, or in the form of reports on adverse events and complaints from veterinarians or owners.

When did you last remove a product from the market?

Practical example

July 2025: withdrawal from the distribution network of the product VITAMIN B1+B6, solution for injection, batch 172321, expiry date 02.2026

Via Notification No. 8546/31.07.2025, the Institute for the Control of Biological Products and Veterinary Medicines informs us that, following laboratory testing, the veterinary medicinal product VITAMIN B1+B6, solution for injection, batch 172321, expiry date 02.2026 failed to meet the specifications for the parameter "pH determination by the potentiometric method.

"In light of the above, and in accordance with the provisions of Art. 127 para. (2) and Art. 134 para. (1) let. b) and para. (2) of Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC, we hereby order the following:

- the withdrawal from the distribution network of the product VITAMIN B1+B6, solution for injection, batch 172321, expiry date 02.2026, for the purpose of its neutralization;
- placing a hold within the distribution network on other batches of VITAMIN B1+B6 (solution for injection) in order to retest them for the specific parameter regarding which the product was found to be non-compliant;
- investigating the cause of the quality defect in VITAMIN B1+B6 (solution for injection), batch 172321, expiry date 02.2026.

The investigation results and the measures taken must be communicated within five days of receipt of this notice to the e-mail address monitorizarepmv@ansvsa.ro.

Following this quality defect, the marcheting holder applied for a variation regarding the change in pH value.

If you could change anything, what would it be and why?

- Stepping up inspections and increasing severity penalties
- Plus, trained and experienced staff.

Thank you

12, rue de Prony, 75017 Paris, France
T. +33 (0)1 44 15 19 49
F. +33 (0)1 42 67 09 87

woah@woah.org
www.woah.org

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