Republic of Moldova

Veterinary Medicines Regulatory System:

Country Snapshot

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Role and Organisation: Head of Department,
National Food Safety Agency



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Mandate and legal basis

- What is the primary legislation governing veterinary medicinal products

Existing: Law No119/2018 on veterinary medicinal products,

(harmonizated from Directive 2001/82/CE);

Rules for import, good manufacturing practice, wholesale distribution, retail sale, use of VMPs;

Rules for MRLs, VMP residue control in food products of animal origin, official procedures for investigations on non-compliance cases.

Project: Draft law on veterinary medicinal products

(harmonizes EU Regulation No: 2019/6).

Which authority or body is responsible for each of these?

Activity	Responsible authority	Notes (shared, outsourced, not performed)
Authorisation of veterinary pharmaceuticals	National Food Safety Agency	VMP Commission (interinstitutional commission)
Authorisation of veterinary biologicals and immunologicals	National Food Safety Agency	VMP Commission (interinstitutional commission)
Authorisation of ectoparasiticides (veterinary pesticides)	National Food Safety Agency	VMP Commission (interinstitutional commission)
Authorisation of veterinary medicines for fish	National Food Safety Agency	VMP Commission (interinstitutional commission)
Pharmacovigilance	National Food Safety Agency	--
Authorisation and inspection (GDP) of the distribution chain	National Food Safety Agency	--
Authorisation and inspection (GMP) of the manufacturing site	National Food Safety Agency	--
Laboratory quality testing	IP CNSAPSA or international laboratory	--

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

- How do you know they are complying?

Manufacture, import, wholesale and retail sell only in NFSA authorised facilities.

- VMPs facilities are NFSA controlled (regular risc based controls);
- Control mechanisms, identification of non-compliances and the imposition of sanctions

(Checklists/Special Procedures are used, also VMP controls in animal farms);

Description / Indicator	2024	2025 ↓
1. Importers/wholesale distributors	36	32
2. Manufacturers	2	2 ↓
3. Veterinary farmacies	232	215 ↑
4. Veterinary cabinets/clinics	97	112
Total VMP operators	367	361
Planned controls	269	231
Unlanned controls	4	12
of which, concluded with prescriptions	84	85
of which, finalised with santions	15	9

How are veterinary medicines classified for supply?

- Prescription and non-prescription products;
- Can a farmer or a cat owner buy an antimicrobial without a veterinary prescription?

Authorisation & Control: Farmers have contracted vets for veterinary asistance.
Treatments must be registered in treatments log books.
The *order note* must be coordinated with the contracted vet.

1. Importers/wholesale distributors;
2. Manufacturers.

→ - farms;
- veterinary cabinets/clinics;
- veterinary farmacies.

→ Companion animals & backyard animals.

Companion animals & backyard animals:
- are treated in by veterinary cabinets/clinics or
- based on conclusion of the veterinary pharmacist.

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

A VMP is considered not compliant when:

- is not autorised/registered in the country;
- is lacking traceability or quality documentation (also illegal acquisition);
- nonconform laboratory results; indicating deviations beyond limits, issues regarding active substances, etc. (following random sampling by Competent Authority, or investigations of ineffectiveness or adverse effects);
- have been unpacked, repackaged, or had their packaging changed;
- stored in violation of the conditions specified in the product leaflet & SPS.

When did you last remove a product from the market?

- How did you know it needed to be removed?
- What actions did you take?
- How did you confirm that it had actually gone?

Case 1: One batch of antiparasitic VMP (active subst.- Ivermectin) in 2024 (excess of active substance) – 1,800 packs;

Case 2: several batches of VMPs (repackaging/packaging change) in 2026 – 3,000 packs;

Case 3: several times a year, the Border Police seizes VMPs illegally introduced into the country.

Actions taken:

- control on the spot;
- prohibiting the sale, recall from the market and imposing fines;
- communication.

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

- What is stopping you?

- Existing national legislation must be updated (use and evidence of antibiotics in animals must be more detailed);

- Financial resources NFSA & laboratory to strengthen its the capacity for VMP testing;

- Insufficient number of NFSA territorial inspectors and practicing veterinarians;

- The absence at the national level of capabilities for the destruction of substandard VMPs.

Thank you

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