ARMENIA

Veterinary Medicines Regulatory System:

Country Snapshot

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Role and Organisation: Focal Point of Veterinary Product of WOAH

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Mandate and legal basis

• **Law of the Republic of Armenia "On Veterinary Medicine" (2014):** The principal legislation governing the veterinary sector, including the regulation of veterinary medicinal products.

•**Article 28 – Veterinary Medicinal Products:** Provides for the state registration of veterinary medicinal products in accordance with applicable legal requirements.

•**Law of the Republic of Armenia "On Medicines" (2016):** Establishes the general legal framework for the circulation of medicinal products, including relevant provisions concerning products intended for veterinary use.

•**Law of the Republic of Armenia HO-75-N (2026):** Introduces amendments to the licensing legislation, including provisions relevant to veterinary pharmacy activities. The amendments are scheduled to enter into force on 1 January 2027.

•**Secondary legislation and EAEU requirements:** Applicable regulations govern the registration, import, distribution, sale and regulatory control of veterinary medicinal products, subject to the scope of the relevant legal provisions.

Which authority or body is responsible for each of these?

Activity	Responsible authority	Notes (shared, outsourced, not performed)
Authorisation of veterinary pharmaceuticals	Ministry of Economy (MoE)/Ministry of Health (MoH)/Food Safety Inspection Body (FSIB)	The registration/authorisation process includes the assessment of the submitted dossier and, where required, laboratory testing of veterinary medicinal products.
Authorisation of veterinary biologicals and immunologicals	MoE / FSIB	Separate registration pathway for vaccines, sera and diagnostic products
Authorisation of ectoparasiticides (veterinary pesticides)	MoE/ FSIB	Veterinary medicinal products are currently addressed under the pesticide registration system, while a dedicated regulatory framework is under development.
Authorisation of veterinary medicines for fish	MoE /MoH/ FSIB	No separate dedicated system identified
Pharmacovigilance	MoE/ MoH / FSIB	Formal veterinary pharmacovigilance system: limited/not fully established under the development
Authorisation and inspection (GDP) of the distribution chain	MoH/FSIB	The implementing regulations governing the state control and inspection of the storage, transport, and sale of veterinary medicinal products are currently under development.
Authorisation and inspection 9GMP) of the		Regulatory arrangements are fragmented,

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

•**Manufacture:** Veterinary medicinal products are manufactured by licensed or registered operators, subject to the applicable regulatory requirements. The Ministry of Health (MoH) and the Food Safety Inspection Body (FSIB) have relevant oversight responsibilities, including veterinary control.

•**Import**: Importation is subject to applicable registration and import requirements. The State Revenue Committee, MoE, MoH and FSIB are involved in customs procedures and veterinary import control, respectively.

•**Distribution:** Distribution is carried out by registered or licensed operators, as required by law, with the relevant authorities responsible for inspection and regulatory oversight.

•**Sale:** Registered veterinary medicinal products are supplied through authorised operators in accordance with applicable legal requirements. The FSIB is responsible for relevant market surveillance and food-chain safety controls.

How are veterinary medicines classified for supply?

•**Prescription-only veterinary medicines:** Intended to be supplied by veterinary pharmacies against a veterinary prescription. The relevant legal provisions are currently under development in the draft legislation.

•**Non-prescription veterinary medicines:** May be supplied by veterinary pharmacies without a veterinary prescription, in accordance with applicable requirements.

•**Antimicrobials:** Stricter requirements are envisaged for specified systemic antimicrobials, including mandatory veterinary prescriptions under the draft legislation.

•**Practical implementation:** Enforcement of veterinary prescription requirements is not yet fully consistent, and direct purchase of veterinary medicinal products by farmers or animal owners without a veterinary prescription may occur in practice.

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

• **FSIB inspections and market surveillance:** Sampling of veterinary medicinal products and laboratory testing, where necessary, following the entry into force of the relevant law.

•**Complaints and adverse-event reports:** Information received from veterinarians, farmers, and animal owners regarding suspected adverse effects or product-quality issues.

•**Alerts from the MoH, MoE, and other competent authorities:** Information concerning suspicious products and potential safety or quality risks.

•**Annual statistics and findings:** Data and findings are not routinely consolidated at the national level; therefore, alerts from external sources remain an important source of information for identifying potential risks.

When did you last remove a product from the market?

- **No recent veterinary medicine recall identified.**
- **Detection:** no documented national case available.
- **Action:** withdrawal/recall would follow the legal procedure.
- **Verification:** follow-up inspection and market checks.

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

- **Recommendation:** Establish a formal, digitized national veterinary pharmacovigilance system to facilitate the centralized reporting, recording, and assessment of adverse events and veterinary medicinal product quality complaints.

- **Expected benefit:** Strengthen the early detection of potential safety and quality issues associated with veterinary medicinal products and enable timely risk assessment and appropriate response.

- **Main challenges:** Limited availability of qualified personnel/pharmacist and insufficient technical capacity to establish and maintain the system effectively.

Thank you

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