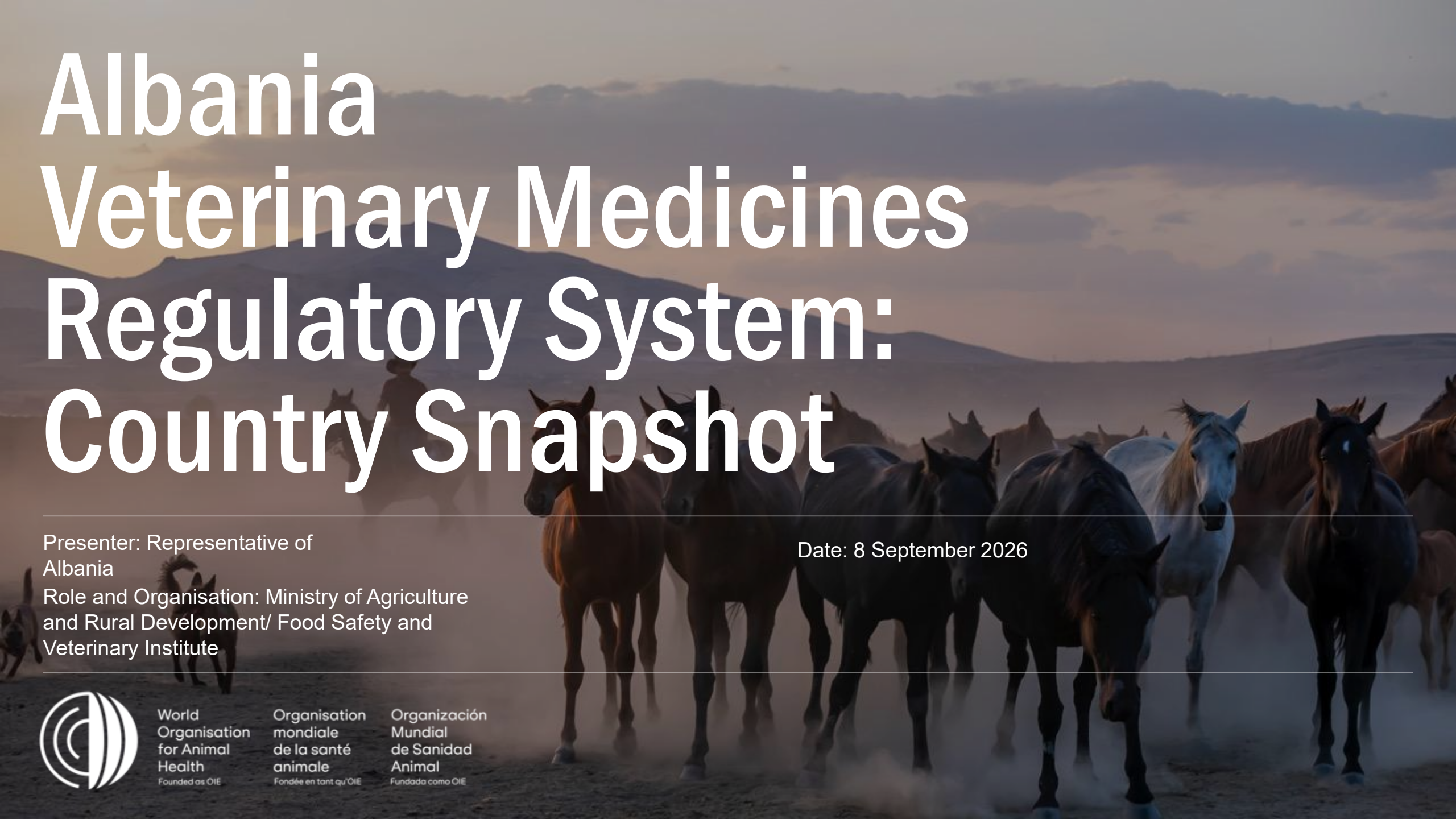
Albania Veterinary Medicines Regulatory System: Country Snapshot



Presenter: Representative of Albania

Role and Organisation: Ministry of Agriculture and Rural Development/ Food Safety and Veterinary Institute

Date: 8 September 2026

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Mandate and legal basis

The legislation governing veterinary medicinal products in Albania consists of the following legal acts:

- **Law No. 10465, dated 29 September 2011, "On Veterinary Service in the Republic of Albania", as amended, serves the primary legal framework governing veterinary medicinal products.**
- **The implementing legislation is Ministerial Order No. 370, dated 29 July 2014, On the approval of Regulation "On Veterinary Medicinal Products", as amended.**
- **Ministerial Order No 780, dated 11.8.2025, on the Principles and Guidelines of Good Manufacturing Practices (GMP) for Veterinary Medicinal Products and the Procedure for Granting Manufacturing Authorisations for VMPs**
- **Together, these legal instruments provide the basis for the regulation of veterinary medicinal products in Albania, covering their manufacture, authorization, import, distribution, prescription, dispensing and use, 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	State Commission of Veterinary Medicinal Products	Performed by State Commission of VMP's
Authorisation of veterinary biologicals and immunologicals	State Commission of Veterinary Medicinal Products	Performed by State Commission of VMP's
Authorisation of ectoparasiticides (veterinary pesticides)	State Commission of Veterinary Medicinal Products	Performed by State Commission of VMP's
Authorisation of veterinary medicines for fish	State Commission of Veterinary Medicinal Products	Performed by State Commission of VMP's
Pharmacovigilance	Directorate of Veterinary Policies National Authority for Veterinary and Plant Protection	Policymaker performed by MARD Pharmacovigilance Activities performed by NAVPP
Authorisation and inspection (GDP) of the distribution chain	Commission for the Verification of Manufacturing Conditions	Performed by the Commission for the Verification of Manufacturing Conditions
Authorisation and inspection (GMP) of the manufacturing site	Commission for the Verification of Manufacturing Conditions	Performed by the Commission for the Verification of Manufacturing

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

1. Manufacturing of VMP is carried out in accordance with the legislation in force
2. Wholesale distribution of VMP is carried out in accordance with the legislation in force.
3. Retail sale of VMPs is carried out only through veterinary pharmacies managers and personnel involved in the sale of VMPs must be veterinarians holding a veterinary-pharmacy course certificate.

Law 10465/2011 “On Veterinary Service in the Rp of Albania”, as amended

Law Nr.10 081/2009 “ On Licenses, Authorizations and Permits in the Rp of Albania”, as amended

Ministry Order no. 370/2014, “On VMPs”, as amended

Ministry Order no. 780/2025 “On GMP”

How are veterinary medicines classified for supply?

1. Prescription-Only VMPs.
2. Conditions for supply without a veterinary prescription, provided that all requirements are met;

- It can be administered without requiring special knowledge or skills;
- It does not pose a direct or indirect risk to animals, users or the environment, even in the event of incorrect use;
- The product information does not indicate any risk of serious adverse effects when used incorrectly;
- The product, or other products containing the same active substance, have not been associated with repeated reports of adverse effects;
- There are no contraindications relating to its use in combination with products commonly supplied without prescription;
- It does not pose a risk to public health due to pharmacologically active residues in food of animal origin;
- It does not pose a risk to animal or public health through the development of antimicrobial resistance, even in cases of misuse.

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

1. VMP regulation 370/2014 covers all aspects regarding suspected adverse reactions, lack of expected efficacy, withdrawal-period issues and other safety information.
2. Official controls: Arts. 30 and 103 of Law 10465/2011 provide for periodic, risk-based supervision, sampling and laboratory testing of VMPs.
3. The VMP lacks therapeutic efficacy in target species as claimed.
4. Qualitative or quantitative composition deviates from specifications;
5. The recommended withdrawal period fails to guarantee residue safety in food derived from treated animals;
6. Owners or keepers of animals may report directly or through veterinarians any suspected case.
7. Upon request by the MAH.
8. Information and alerts received from other Competent Authorities regarding the quality, safety, efficacy, or potential falsification of VMPs.

When did you last remove a product from the market?

No recent VMP market recall case was identified for this year.

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

- We are in the process of aligning our legislation with Regulation (EU) 2019/6.
- It has undergone publish consultation.
- It was submitted to the Commission for Assessment.
- Stakeholder consultation meetings have already been completed.

The process is moving forward effectively.

Thank you

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