Serbian Veterinary Medicines Regulatory System: Country Snapshot

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Mandate

- Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Management



- Medicines and Medical Devices Agency of Serbia (ALIMS)

Legal basis

- Law on Medicines and Medical Devices („Official Gazette of the Republic of Serbia“ Nos. 30/2010, 107/2012, 105/17 – other law, and 113/2017 – other law) and the related implementing regulations
- Law on Veterinary Medicine („Official Gazette of the Republic of Serbia“, Nos. 91/2005, 30/2010, 93/2012, 17/2019 - other law, and 109/2025 – other law)

Which authority or body is responsible for each of these?

Activity	Responsible authority	Notes (shared, outsourced, not performed)
Authorisation of veterinary pharmaceuticals	Medicines and Medical Devices Agency of Serbia (ALIMS)	
Authorisation of veterinary biologicals and immunologicals	Medicines and Medical Devices Agency of Serbia (ALIMS)	
Authorisation of ectoparasiticides (veterinary pesticides)	Medicines and Medical Devices Agency of Serbia (ALIMS)	
Authorisation of veterinary medicines for fish	Medicines and Medical Devices Agency of Serbia (ALIMS)	
Pharmacovigilance	Medicines and Medical Devices Agency of Serbia (ALIMS)	
Authorisation and inspection (GDP) of the distribution chain	Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Management	
Authorisation and inspection (GMP) of the manufacturing site	Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Management	
Laboratory quality testing	Medicines and Medical Devices Agency of Serbia (ALIMS)	Some tests can be outsourced

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

- Manufacture – manufacturers authorised by the Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Management: GMP Certificate and Manufacturing Authorisation

- Import and distribution – wholesale distributors authorised by the Ministry of Agriculture, Forestry and Water Management and listed in Registry of Wholesale Distribution Authorisations for Veterinary Medicines; GDP compliance

- Sales: veterinary pharmacies – operating licences issued by the Ministry

- Inspections of marketing authorisation holders, wholesale distributors and veterinary pharmacies are performed both pre-authorisation and post-authorisation

How are veterinary medicines classified for supply?

- The dispensing regime of a medicinal product is established in the marketing authorisation

  All medicines for food-producing animals are prescription-only

- All veterinary medicines are sold only by veterinary pharmacies

- Can a farmer or a cat owner buy an antimicrobial without a veterinary prescription?

  No, all antimicrobials are prescription-only medicines

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

- Substandard medicines – ALIMS laboratory control
- Falsified medicines – Inspectorate of Veterinary Directorate
- Unsafe medicines – rapid alerts, adverse event and PSUR reports, EMA referrals..

When did you last remove a product from the market?

- Removal upon receiving report from ALIMS or rapid alert
- Marketing Authorisation Holders (MAHs) are obliged to have system for withdrawal and destruction
- A marketing ban is imposed until all checks have been carried out
- MAH is obliged to destroy all medicine quantities and to provide appropriate certificate

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

- Building institutional capacity through the employment and training of additional inspectors for veterinary medicines

- Enhancing the capacity of partner institutions involved in these activities and ensuring the provision of appropriately qualified personnel

Thank you

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