# [Montenegro]

# Veterinary Medicines Regulatory System:

# Country Snapshot

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Role and Organisation: Administration for food safety, veterinary and phytosanitary affairs



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## Mandate and legal basis

- What is the primary legislation governing veterinary medicinal products
- **Law on Medicinal Products** (*Official Gazette of Montenegro*, No. 14/26 and 94/26).
- Establishes the legal framework for veterinary medicinal products, including marketing authorisation, manufacturing, distribution, pharmacovigilance and use.
- Key secondary legislation is in force, including regulations on veterinary marketing authorisation, manufacturing, pharmacovigilance, good distribution practice and veterinary prescriptions.

# Which authority or body is responsible for each of these?

| Activity | Responsible authority | Notes (shared, outsourced, not performed) |
|---|---|---|
| Authorisation of veterinary pharmaceuticals | CInMED | |
| Authorisation of veterinary biologicals and immunologicals | CInMED | |
| Authorisation of ectoparasiticides (veterinary pesticides) | CInMED | |
| Authorisation of veterinary medicines for fish | CInMED | |
| Pharmacovigilance | CInMED | |
| Authorisation and inspection (GDP) of the distribution chain | AFSVPA | |
| Authorisation and inspection 9GMP) of the manufacturing site | CInMED | |
| Laboratory quality testing | CINMED/ Official or authorised | |

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

- How do you know they are complying?

- Manufacture: authorised manufacturers holding a manufacturing authorisation issued by CInMED; pre-authorisation inspection is required.
- Import: import is covered by the manufacturing authorisation issued by CInMED and wholesale distribution authorisation issued by AFSVPA; pre-authorisation inspection is required.
- Wholesale distribution: authorised wholesalers holding a wholesale distribution authorisation issued by AFSVPA; an on-site inspection is required before the conditional authorisation, followed by a second inspection before the final authorisation.
- Sell: authorised veterinary pharmacies and other eligible veterinary clinics holding a retail distribution authorisation issued by AFSVPA; compliance is verified after the authorisation is issued, within three months.

# 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?

- Veterinary prescription medicines: Veterinary medicines classified by CInMED as medicines subject to a veterinary prescription.
- Non-prescription medicines: Veterinary medicines classified by CInMED as medicines not subject to a veterinary prescription, in accordance with the legally prescribed criteria.
- Antimicrobials: All antimicrobial veterinary medicines are classified as veterinary prescription medicines.

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

- Market surveillance and sampling: Veterinary medicines are monitored through official controls and in case of suspected falsified, unsafe or substandard medicine samples would be sampled
- Adverse event reporting: Information on suspected adverse reactions or safety concerns is reported by veterinarians, veterinary medicine users and other relevant persons.
- Complaints and inspections: Complaints from veterinarians, medicine users or other stakeholders, as well as findings
- Alerts and information exchange: Information on suspected substandard, falsified or unsafe veterinary medicines is received through cooperation with competent authorities and international alert systems.

# 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?
- Veterinary medicinal products were identified as having been supplied without the required CInMED import permit, although the accompanying documentation was otherwise complete
- The products were not authorised for use or distribution and were removed from circulation
- The products were destroyed under the supervision of the competent veterinary inspector
- Destruction and final removal were documented in an official inspection report

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

- What is stopping you?
- Strengthen veterinary inspection of veterinary medicinal products through increased involvement of veterinary inspectors in market surveillance and control activities
- Increase the number of veterinary inspectors responsible for controls of veterinary medicinal products to ensure more systematic and regular oversight
- Main constraint: insufficient human resources, as only a limited number of veterinary inspectors are involved in veterinary medicinal product controls

# Thank you

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