Georgia

Veterinary Medicines Regulatory System:

Country Snapshot

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Role and Organisation: National Food Agency



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Mandate and legal basis

- What is the primary legislation governing veterinary medicinal products

❖ **Law of Georgia — Food/Feed Safety, Veterinary and Plant Protection Code**

❖ **Decrees of the Government of Georgia:**

- **No. 345 (2018) – Requirements for business operators engaged in veterinary activities.**
- **No. 338 (2018) – Rules for Veterinary State Control of Business Operators and Live Animal Markets.**
- **No. 639 (2015) – Pharmacologically active substances and maximum residue limits in food of animal origin.**
- **No. 327 (2015) – State registration of veterinary medicinal products manufactured in or imported into Georgia**.

Which authority or body is responsible for each of these?

Activity	**Responsible authority**	**Notes (shared, outsourced, not performed)**
Authorisation of veterinary pharmaceuticals	NFA	
Authorisation of veterinary biologicals and immunologicals	NFA	
Authorisation of ectoparasiticides (veterinary pesticides)	NFA	
Authorisation of veterinary medicines for fish	NFA	
Pharmacovigilance	NFA	No fully established system in place
Authorisation and inspection (GDP) of the distribution chain	NFA	Formal GDP system not yet implemented
Authorisation and inspection 9GMP) of the manufacturing site	NFA	Manufacturing authorization and pre-authorization inspections are in place; formal GMP system not yet implemented

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

- How do you know they are complying?

❖Manufacturing

Authorization issued by the NFA following a mandatory pre-authorization inspection.

Business and economic activity registration required.

Classified as high-risk — inspected twice per year.

❖Importation

Natural or legal persons may import veterinary medicinal products registered in Georgia, subject to applicable requirements.

❖Distribution

Registered veterinary medicinal products distributed by manufacturers, importers and eligible business operators.

❖Retail Sale

Veterinary medicinal products sold through veterinary pharmacies and other legally permitted outlets.

Classified as lower-risk — inspected once per year.

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?

❖ Currently, Georgia does not have a prescription-based dispensing system for veterinary medicinal products.

❖ Antimicrobial veterinary medicinal products can be purchased without a veterinary prescription.

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

❖ **Main sources of information:**

- **Official market surveillance**
- **Laboratory testing**
- **Complaints and notifications** .
- **Adverse event reports**
- **External alerts**

❖ **Follow-up actions:**

- Investigation, product identification, sampling and laboratory testing.
- Withdrawal, recall or destruction of non-compliant products, as appropriate.
- Administrative measures and sanctions where required.

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?

Detection and Removal of a Falsified Veterinary Medicinal Product Intended for Bees (2022)

- Notification: A business operator reported suspected falsification of a veterinary medicinal product for bees.
- Investigation: NFA inspectors visited the veterinary pharmacy, collected samples, and compared the packaging with that of the officially registered product.
- Confirmation: Minor packaging discrepancies were identified, and laboratory testing confirmed that the product was falsified.
- Enforcement and removal: The pharmacy was fined. Inspectors seized all remaining packages and destroyed them by incineration.

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

- What is stopping you?

❖ **Introduce a mandatory veterinary prescription system**

❖ **Main implementation barriers:**

- **Workforce limitations**
- **Workforce assessment**
- **Professional regulation**
- **Implementation readiness**

Thank you

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