UKRAINE UA

Veterinary Medicines Regulatory System:

Country Snapshot

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Role and Organisation: Deputy Director State Scientific-Research Control Institute of VMP and FA

World Organisation for Animal Health
Founded as OIE

Organisation mondiale de la santé animale
Fondée en tant qu'OIE

Organización Mundial de Sanidad Animal
Fundada como OIE

Mandate and legal basis

- What is the primary legislation governing veterinary medicinal products

- *Law of Ukraine «On Veterinary Medicine and Animal Welfare» from 04.02.2021 №1206-IX. In force from 02.03.2026*
    - *Resolution of the Cabinet of Ministers of Ukraine «Regulation on the State Registration of Veterinary Medicinal Products» from 30.09.2026 № 1206. In force from 07.10.2026*

- *Medicated feed (partly): Law of Ukraine «On Feed Safety and Hygiene» from 21.12.2017 № 2264-VIII*
- *Biocidal products: the specialized government draft law "On Making Available on the Market and Use of Biocidal Products".*

Which authority or body is responsible for each of these?

Activity	Responsible authority	Notes (shared, outsourced, not performed)
Authorisation of veterinary pharmaceuticals	State Service of Ukraine on Food Safety and Consumer Protection (**SSUFSCP**)	State Scientific Research Control Institute of Veterinary Medicinal Products and Feed Additives (**SCIVP**) - evaluation registration dossier
Authorisation of veterinary biologicals and immunologicals	SSUFSCP	State Scientific Research Institute of Laboratory Diagnostics and Veterinary-Sanitary Expertise (**SSRI**) - evaluation registration dossier
Authorisation of ectoparasiticides (veterinary pesticides)	SSUFSCP	SCIVP
Authorisation of veterinary medicines for fish	SSUFSCP	SCIVP SSRI
Pharmacovigilance	SSUFSCP	from 2027
Authorisation and inspection (GDP) of the distribution chain	SSUFSCP	from 2027
Authorisation and inspection (GMP) of the manufacturing site	SSUFSCP	from 2027
Laboratory quality testing	SCIVP	

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

- How do you know they are complying?

- *Licenses for manufacturers of VMP are issued by SSUFSCP. Today, more than 100 have been issued. Under the new legislation, a license for production and import is issued based on an inspection. A risk-based approach is used for inspections: once every five years for low-risk enterprises, once every three years for medium-risk enterprises, and once every two years for high-risk enterprises.*
- *Import and distribution licenses will be issued by SSUFSCP till 01.09.2027.*
- *Sales licenses will be issued by SSUFSCP till 01.03.2028.*

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? - No

Prescription is specified on the state registration of such product. Prescription products:

1. *narcotic drugs, psychotropic substances, or their precursors;*
2. *intended for food-producing animals;*
3. *antimicrobial veterinary medicinal products - a stricter category than everything else;*
4. *for the treatment of pathological conditions requiring an accurate prior diagnosis, or the use of which may result in an effect that interferes with or impacts subsequent diagnostic or therapeutic measures;*
5. *used for animal euthanasia;*
6. *containing new active substances, during the first five years following the state registration of such products;*
7. *immunobiological veterinary medicinal products;*
8. *veterinary medicinal products containing active substances with hormonal or thyrostatic action, or beta-agonists;*
9. *medicated feed for food-producing animals.*

The use of this VMP without a veterinary prescription is permitted by a licensed veterinarian personally, provided that the relevant records are maintained.

We do not currently distinguish categories, who may supply each one and from what kind of premises.

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

- *The routes by which information reaches us: internet network, market sampling, laboratory testing, complaints from vets or owners, alerts from other authorities and adverse event reports (from 2027)*
- *Over the past year or two, the Internet has become an effective source for identifying unregistered products.*
- *Information obtained from other countries is useful, as it has already been verified.*

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?

The VMP did not demonstrate the claimed efficacy ---> 26.05.25 laboratory testing (not = tulathromycin)

---> 10.07.25 expert opinion ---> decision-making ---> withdrawal from the market

❑ *Draft Law 15413 from 15.07.2026 on Amendments to the Criminal Code of Ukraine regarding the protection of the legal market for veterinary medicinal products against* ***falsified*** *products.*

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

- What is stopping you?

➢ *A robust state control system—professionally trained personnel, a comprehensive legislative framework regarding responsibilities and sufficient financial support.*

➢ *Requirements for the registration dossier - a clear structure of parts, sections, and subsections is required, specifying the guidelines for conducting studies.*

➢ *Registration procedure - the registration dossier must be submitted directly to the evaluating authority.*

Thank you for attention!



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18 June 2024 – Building 2 of SCIVP was damaged by a russian Shahed-136 (Geran-2)