Russian Federation

Veterinary Medicines Regulatory System:

Country Snapshot

Presenter: Anna Babushkina

Role and Organisation: Head of the Department of Internal Veterinary Supervision of the Federal Service for Veterinary and Phytosanitary Supervision (Rosselkhoznadzor)

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

STATE REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VMPs)

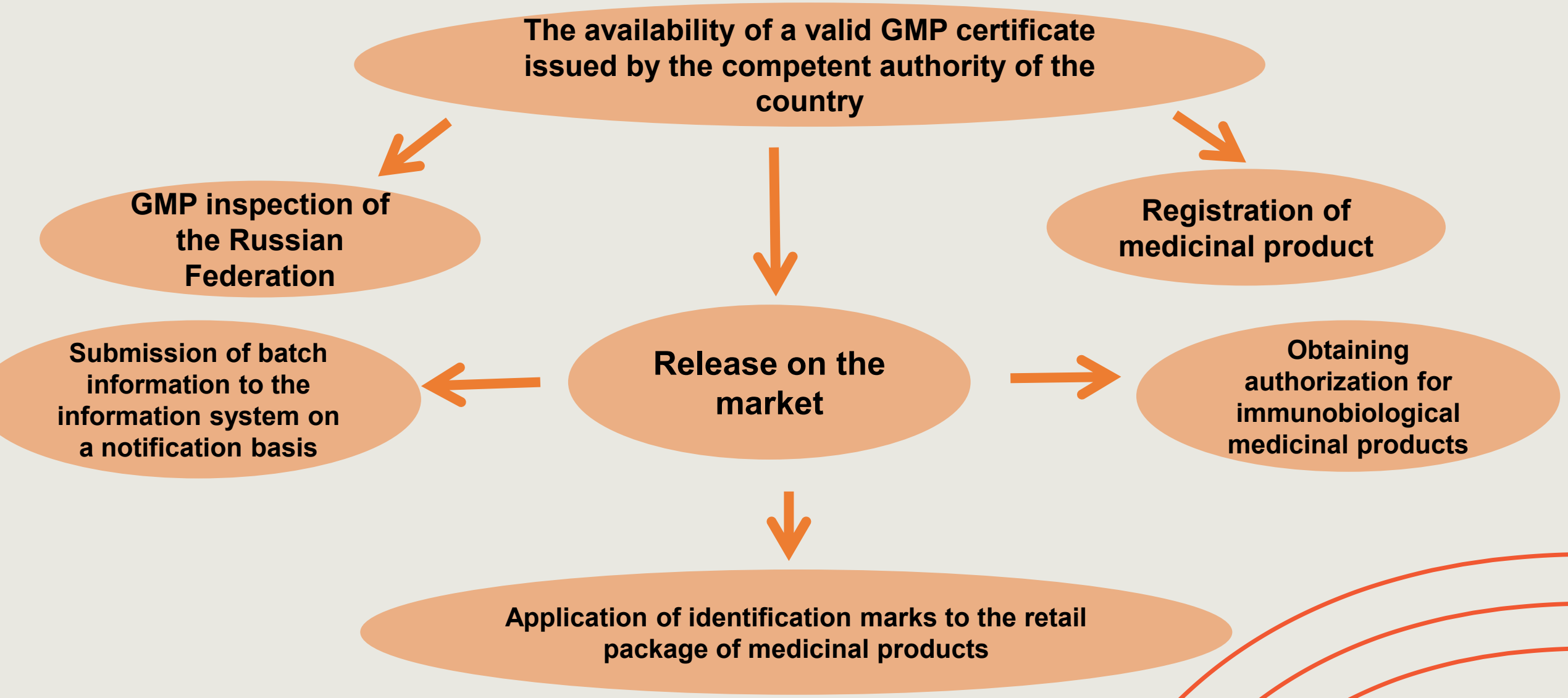
Authority and legal basis

- Decision No. 1 of the Council of the Eurasian Economic Commission dated 21.01.2022 "On the Rules for Regulating the Circulation of Veterinary Medicinal Products within the Customs Territory of the Eurasian Economic Union" (in force, effective from 13.03.2022)
- Decision No. 76 of the Council of the Eurasian Economic Commission dated 03.11.2016 “On the Adoption of the Requirements for the Labelling of Medicinal Products for Human Use and Veterinary Medicinal Products” (in force, effective from 06.05.2017)
- Decision No. 77 of the Council of the Eurasian Economic Commission dated 03.11.2016 “On the Adoption of the Rules of Good Manufacturing Practice of the Eurasian Economic Union” (in force, effective from 06.05.2017)
- Decision No. 100 of the Board of the Eurasian Economic Commission dated 11.08.2020 “On the Pharmacopoeia of the Eurasian Economic Union” (in force, effective from 09.02.2021)
- Decision No. 172 of the Board of the Eurasian Economic Commission dated 22.12.2015 “On Adoption of the Nomenclature of Dosage Forms” (in force, effective from 09.02.2021)
- Federal Law No. 61-FZ dated 12.04.2010 "On Circulation of Medicines" (in force, effective from 01.09.2010)

SYSTEM FOR MONITORING THE CIRCULATION OF VETERINARY MEDICINES

Type of activity	Responsible authority	Notes (jointly, outsourced, not carried out)
Authorisation for the circulation of veterinary pharmaceutical products	The Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor)	Jointly with the Ministry of Agriculture, the EEC, the regional offices of Rosselkhoznadzor and VGNKI
Authorization for the circulation of veterinary biological and immunological products	The Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor)	Jointly with the Ministry of Agriculture, the EEC, the regional offices of Rosselkhoznadzor and VGNKI
Authorization for the circulation of ectoparasiticides (veterinary pesticides)	The Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor)	Jointly with the Ministry of Agriculture, the EEC, the regional offices of Rosselkhoznadzor and VGNKI
Authorisation for the circulation of veterinary medicinal products for fish	The Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor)	Jointly with the Ministry of Agriculture, the EEC, the regional offices of Rosselkhoznadzor and VGNKI
Pharmacovigilance	The Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor)	Jointly with the regional offices of Rosselkhoznadzor
Issuance of permits and inspection of the distribution chain (GDP)	The Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor)	Jointly with the regional offices of Rosselkhoznadzor
Issuance of permits and inspection of manufacturing sites (GMP)	The Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor)	VGNKI carries out GMP inspections
Laboratory quality control	VGNKI	The Institution is subordinate to Rosselkhoznadzor

CONTROL SYSTEM FOR CIRCULATION OF VETERINARY MEDICINAL PRODUCTS



CLASSIFICATION OF MEDICINAL PRODUCTS IN THE RUSSIAN FEDERATION

- Prescription medications: antimicrobials, antiparasitic medications, hormonal preparations, adrenoreceptor blocking agents, sedatives, antipsychotics, analgesics, anaesthetics.

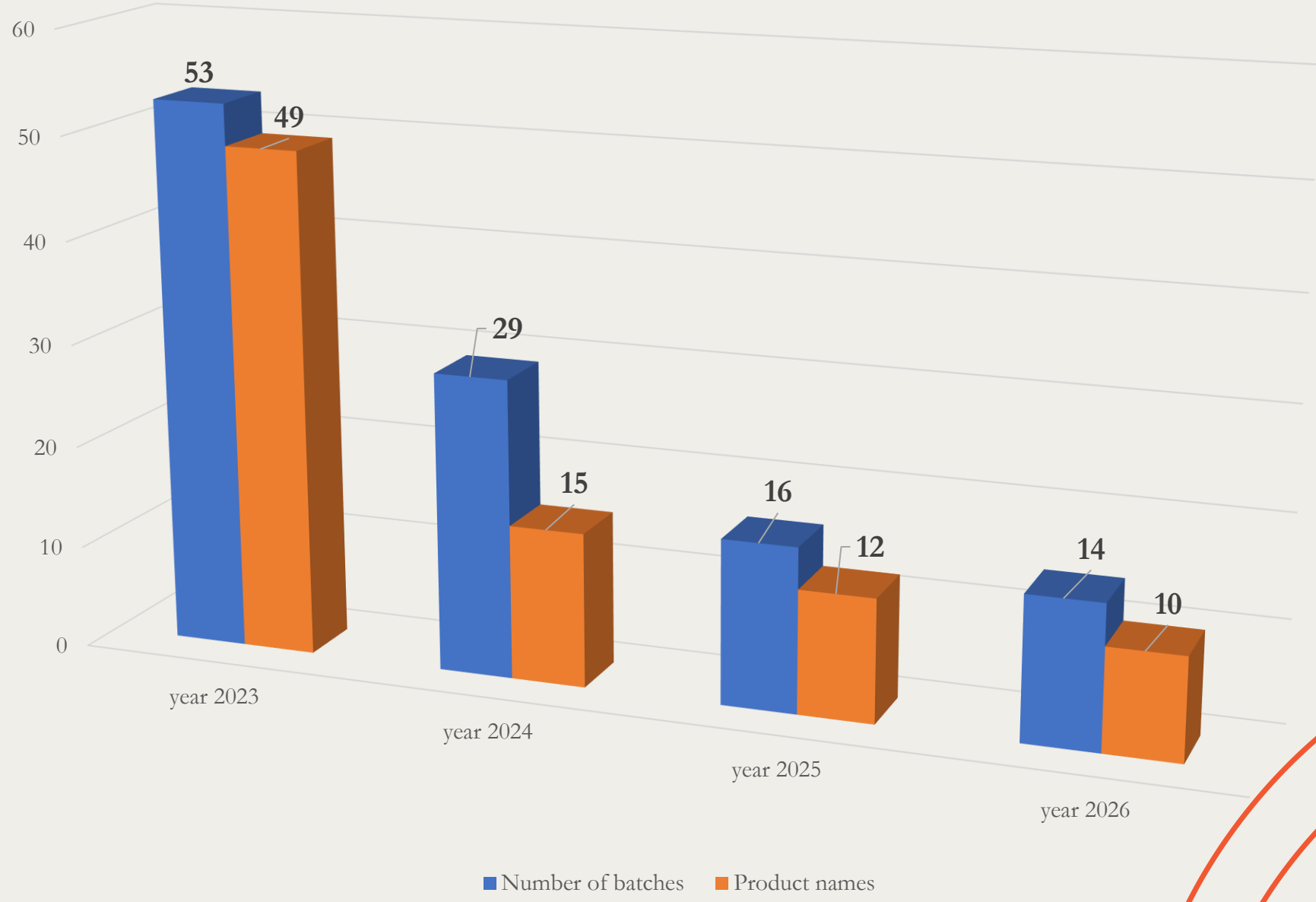
- Pursuant to Order No. 776 dated 02.11.2022 of the Ministry of Agriculture of the Russian Federation, effective from March 1, 2025, the participants involved in the circulation of veterinary medicinal products are obliged to make sure that the prescription, sale, purchase, and use of listed products (antibacterials, antimicrobials, hormonal preparations, and narcotic/psychotropic agents) occur exclusively **on the basis of proper prescription**.

- If no prescription is presents, the veterinary pharmacists must refuse the sale. Non-compliance with these requirements is subject to administrative penalties.

Combating substandard and falsified medicinal products

- Establishment of a regulatory framework for the control of the circulation of medicinal products;
- Carrying out inspections of the places of storage and commercialization of medicinal products for animals by the territorial administrations of the Rosselkhoznadzor. Posting of information on the official website of the Rosselkhoznadzor;
- Establishment of a control system (primary authorization in the form of licensing of manufacturing and pharmaceutical activities, as well as state registration of medicinal products; control over imports and all stages of the circulation of products for veterinary use, including pursuant to complaints received from citizens or organizations; exercise of pharmacovigilance);
- Collection of information on the placing into civil circulation of medicinal products for animals in the information systems of the Federal State Information System VetIS, subsystem “Irena”, “Galen”;
- Assessment of compliance with licensing requirements once every three years for all manufacturers of medicinal products on the territory of the Russian Federation;
- Implementation of the procedure for the withdrawal from circulation of falsified and substandard medicinal products.

Withdrawal of medicinal products from circulation



- Ensuring the transparency of circulation of medicinal products for animals, which could effectively counteract the entry of counterfeit products onto the market. The transparency of the circulation of medicinal products also has a positive effect on protecting legally manufactured medicinal products from damage during transportation and storage.
- Adoption of provisions in the Russian legislation enabling the quality of pharmaceutical substances used for production to be assessed upon importation into the country.

Thank you

12, rue de Prony, 75017 Paris, France
T. +33 (0)1 44 15 19 49
F. +33 (0)1 42 67 09 87

woah@woah.org
www.woah.org

Facebook
Twitter
Instagram
LinkedIn
YouTube
Flickr

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

