Quality Assurance of Veterinary Medicinal Products (VMP) in the Russian Federation: Current Approach and Practice



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1 Regulatory framework

The Federal Law No. 61- FZ of 12.04.2010 “On the Circulation of Medicinal Products” encompasses definitions, norms, requirements and prohibitions during circulation, responsibility for violations, sanctions during circulation related to the use of both human and veterinary medicinal products (VMP). Statutory regulations and liability provisions apply equally to both categories of MP. The executive authority and supervisory functions are separated.

1. Human MP are regulated by the Ministry of Health of the Russian Federation, supervisory authority – the Federal Service for Surveillance in Healthcare (the Roszdravnadzor);
2. Veterinary MP are regulated by the Ministry of Agriculture of the Russian Federation, supervisory authority – the Federal Service for Veterinary and Phytosanitary Surveillance (the Rosselkhoznadzor).

The Federal Service for Veterinary and Phytosanitary Surveillance (the Rosselkhozndazor) is the primary authority responsible for enforcing the rules on falsified veterinary medicinal products.

2 Post-registration surveillance

1.The Russian system of quality monitoring of VMP in circulation constitutes a passive pharmacovigilance mechanism: it relies on gathering reports on Serious Adverse reactions (SAR), Adverse Reactions (AR), and Unexpected Adverse Reactions (UAR) from veterinary professionals and animal owners, with subsequent evaluation by expert institutions. Active pharmacovigilance is implemented through general control measures of the Rosselkhoznadzor, including scheduled on-site inspections of manufacturers of medicinal products and sampling for quality testing.

2. Complaint or information on adverse events serve as a basis for initiating an investigation followed by appropriate measures taken by the regulator (for example, the need to amend a marketing authorization, suspension of medicinal product circulation).

3 Inspections and testing

1. Inspections are carried out at state border checkpoints, at manufacturing sites, at agricultural enterprises and farms, at wholesale and retail sellers' premises.

2. Inspections in Russia comprise document checks, visual examination of products, laboratory testing — the latter is a mandatory element of quality control for VMPs — especially in cases of suspected adulteration, adverse effects, or within the procedures of routine monitoring.

3. In Russia, testing is performed by:

- VGNKI (All-Russian State Centre for Quality and Standardization for Veterinary Drugs and Feed);
- FGBI "ARRIAH" (Federal Centre for Animal Health).

4 Prioritization of risks

1. The types of VMPs frequently found to be non-compliant with standards or adulterated are antiparasitic agents, vaccines, and antimicrobials.

2. Criteria for prioritizing inspections and surveillance efforts are based on:

- Risk-oriented approach;
- Risk of potentially negative consequences in agriculture;
- Results of previous inspections and their findings;
- Ensuring safety and compliance with requirements.

A general approach: the higher the potential harm from a substandard medication and the likelihood of non-compliance, the higher the priority of the inspection.

5 Problems and prospects

1. Main challenges: the legislation lacks the concept of “orphan veterinary medicinal products”. In Russia, there are no registered medicaments for rare animal diseases (for instance, the Cushing’s syndrome). This is the reason why the owners are forced to purchase the medicaments using unofficial sales channels, such as online stores and marketplaces (which often provide adulterated and illegally imported VMPs).

2. Ways for improvement:

- Shift to unified rules for the circulation of VMPs in the EAEU;
- Utilize a global monitoring system (TRUVET).

Thank you!

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