Ensuring the Quality of Veterinary Medicinal Products (VMPs) in Romania: Current Approach and Practice

Name of speaker Dr. Mihaela DUMITRACHE
Dr. Rodica MORCOV

Position of speaker Director,
Head of Service

Date or location

World Organisation for Animal Health | Organisation mondiale de la santé animale | Organización Mundial de Sanidad Animal

1. Regulatory Framework

1. Does the Member have specific legislation addressing the detection of and enforcement against SFVPs? What does it cover (definitions, offences, penalties)? YES :Criminal Low No.286/2009 on Criminal Code
2. Is this legislation distinct from that covering human medicines, or is it integrated into a single framework? What are the practical implications of this (e.g., shared enforcement bodies, different penalty regimes)? NO: The basic legislation is the same for both veterinary and human medicines. Additionally, specific regulations for human medicines are established at both EU and national levels.
3. Which authorities hold enforcement powers, and do they have sufficient legal mandate to act (seizure, sanctions, prosecution)? ONLY Police

2. Post-Marketing Surveillance

1. How is the quality of VMPs monitored once they are in the field/distribution chain? Does the Member/territory run active surveillance (e.g., planned sampling campaigns), passive surveillance (e.g., complaint- or adverse-event-driven reporting), or both? How is each implemented in practice? The annual control plan regarding the circulation and use of veterinary medicinal products, as well as the annual plan for the sampling and testing of veterinary medicinal products.The Plan for sampling and testing for surveillance and control of veterinary medicinal products is drawn up annually and the veterinary medicinal products included for sampling and testing are selected based on a risk analysis.
2. What triggers an investigation, routine sampling, stakeholder complaints, adverse event reports, or intelligence from other sources? All these aspects can be taken into account for initiating an investigation and collecting samples.

3. Inspections & Testing

1. Where are inspections conducted (e.g., manufacturing sites, points of entry/border, wholesalers, retailers, farms)? Inspections are carried out throughout the entire supply chain for veterinary medicines—from the import of active substances and manufacturing to their use—and even beyond the point of use, through residue control programs covering live animals and animal products.
2. What do inspections cover, documentation and visual/physical checks only, or also laboratory testing (e.g., quality control, identity, potency)? Inspections cover all aspects, including laboratory testing.
3. What laboratory capacity exists for this testing, and is it done in-country/territory or outsourced? Laboratory tests are performed in the country, at a laboratory accredited according to SR EN 17025, a laboratory that performs both microbiological and physico-chemical determinations for pharmaceutical products, but also tests for immunological products.

4. Risk Prioritisation

1. Which types of VMPs are most frequently found to be substandard or falsified in the territory (e.g., by product class, antiparasitics, antimicrobials, vaccines)? To date, two cases of counterfeiting involving external antiparasitic products has been reported and investigated.
2. What criteria are used to prioritise inspection and surveillance efforts (e.g., product risk, species, prior detection history, market value)? All planning and control activities are based on risk analysis. Furthermore, all products authorized for sale and their manufacturers have individual risk analysis records that are updated whenever changes occur.

5. Challenges & Opportunities

1. What are the main challenges in combating SFVPs and ensuring VMP quality (e.g., resources, laboratory capacity, legal gaps, informal markets, cross-border trade)? The main challenges include a lack of personnel and high-performance, state-of-the-art equipment capable of detecting all compounds in counterfeit products; legislative gaps and minor penalties that fail to deter the trade in such goods; sales through unauthorized intermediaries; and the explosion of online commerce.
2. What opportunities or areas for improvement do they foresee (e.g., new technology, regional harmonisation, capacity building)?

- Digitization to ensure product traceability from manufacturer to end-user.

- Introduction of unique QR codes.

- Cooperation among customs officials, police, and veterinary authorities to block the entry of counterfeit products 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

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