

VMRA-SAT

Veterinary Medicines Regulatory Authority Self-Assessment Tool

Strengthening Veterinary Medicines Regulation Worldwide

The Challenges

Veterinary medicines regulation underpins animal health, food safety and the global fight against antimicrobial resistance. Yet across every region, countries face a common set of challenges that weak or fragmented regulatory systems cannot address:

- Antimicrobial resistance is driven in part by the uncontrolled use of veterinary antimicrobials. Without effective registration, pharmacovigilance and market surveillance, antimicrobials reach the market without proper evaluation and are used without monitoring - accelerating the development and spread of resistance.
- Weak oversight empowers criminal networks to flood agricultural markets with substandard and falsified veterinary products (SFVPs) putting animal health, food safety, and public health at risk.
- Fragmented and bureaucratic registration pathways create unpredictable and lengthy regulatory processes, putting off drug manufacturers and creating chronic shortages of essential veterinary therapeutics in the countries.
- The absence of statutory emergency use authorisation routes delays biological defence responses during transboundary epidemiological outbreaks, leaving countries unable to access vaccines and treatments when they are needed most.
- Failure to set and monitor withdrawal periods results in harmful residue levels in food of animal origin, threatening consumer health, AMR and undermining trade access for exporting countries.
- Many countries lack the workforce capacity and institutional structures needed to regulate veterinary medicines effectively, hence the meagre human resources are thinly spread to cover all regulatory functions as they don't have a mechanism to identify trusted regulators who have already approved the product that they can rely on.

These challenges are interconnected. A country with weak registration processes is also likely to struggle with SFVPs, AMR monitoring and residue control. Whilst WOA's Performance of Veterinary Services (PVS) Pathway evaluates the broader performance of Veterinary Services and the Veterinary Legislation Support Programme (VLSP) supports legislative reform, neither provides a detailed, function-level diagnostic specifically focused on the regulation of veterinary medicinal products.

The Solution: VMRA-SAT

The VMRA-SAT is a structured, globally applicable, country-owned and voluntary self-assessment tool designed specifically for national authorities responsible for regulating veterinary medicinal products. It enables authorities to evaluate the maturity and implementation of their veterinary medicines regulatory systems through a self-led, evidence-based process. The tool is modelled on the WHO Global Benchmarking Tool for human medicines and uses a structured hierarchy of eight regulatory functions, 13 indicator areas and 235 sub-indicators.

- National regulatory system governance
- Registration and marketing authorisation

- Pharmacovigilance
- Market surveillance and control
- Licensing of establishments
- Regulatory inspection
- Laboratory testing
- Batch release of biological products

Each function describes a major area of regulatory responsibility. Indicators group related topics within those functions, while sub-indicators describe the specific expected capabilities that are assessed. The desktop version supports detailed evidence capture, maturity scoring, strengths and gap analysis, and preparation of an Institutional Development Plan.

The tool provides a clear, structured pathway from initial capability to advanced regulatory performance, enabling countries to identify their strengths and gaps, agree priorities, develop an institutional development plan, and track progress over time.

Key Features

- Voluntary and country-owned: results remain under the control of the participating authority and are not published or used for ranking.
- Self-assessment, not external audit: the process is led by the country and focused on learning, planning and continuous improvement.
- Evidence-based and structured: the full desktop version covers eight regulatory functions, 13 indicator areas and 235 sub-indicators, supported by guidance, maturity levels and report outputs.
- Two complementary versions available: a comprehensive desktop application for detailed assessment and institutional development planning, and a preliminary web-based version for a lighter starting point.
- Designed for broad accessibility: the desktop tool is available in English, French and Spanish, while the WebApp supports English, French, Spanish and Arabic.
- Complementary to WOAHP mechanisms such as the PVS Pathway and Veterinary Legislation Support Programme, by providing a detailed diagnostic focused specifically on veterinary medicinal products.
- Supported by international engagement with WOAHP, WHO and FAO and developed to align with existing global frameworks and priorities.

How the VMRA-SAT Addresses the Challenges

Challenge	How VMRA-SAT Helps
Antimicrobial resistance	Assesses the functions that support responsible oversight of veterinary antimicrobials, including registration and marketing authorisation, pharmacovigilance, market surveillance, inspection and supply chain controls. This gives authorities evidence to target improvements that support National Action Plans on AMR and wider One Health priorities.
Substandard and falsified veterinary products	Evaluates the regulatory controls needed to prevent, detect and respond to substandard and falsified veterinary products, including market surveillance, laboratory testing, licensing of establishments, regulatory inspection and enforcement-related processes.
VMP availability	Identifies bottlenecks in registration and marketing authorisation pathways and supports authorities to improve predictability, transparency and efficiency without compromising quality, safety or efficacy.
Emergency preparedness	Helps authorities assess whether systems are in place for rapid access to safe, effective and quality-assured veterinary medicines, vaccines or treatments during emergency situations, including arrangements for exceptional or emergency use where applicable.
Food safety and trade	Examines regulatory functions that contribute to consumer protection and trade confidence, including pharmacovigilance, residue-related controls, inspection, market surveillance and evidence-based oversight of products used in food-producing animals.
Workforce capacity	Provides evidence of institutional and human resource gaps across regulatory functions, helping authorities make the case for targeted training, recruitment, prioritisation and institutional development planning.

Evidence from Pilot Countries

The VMRA-SAT has been piloted in 11 countries across four WOAHA regions, selected to reflect diversity in geography, income level and regulatory maturity:

- **Africa:** Rwanda, Botswana, Kenya, Tanzania, Uganda and Zambia
- **Americas:** Mexico and Chile
- **Asia and Pacific:** Australia and Thailand
- **Europe:** United Kingdom

Pilot feedback indicates that VMRA-SAT provides a practical, structured and evidence-based approach for understanding current regulatory capacity, identifying gaps, prioritising improvements and developing concrete plans to strengthen veterinary medicines regulation. Feedback has also highlighted important implementation considerations, including the time and effort required, the need for appropriate human resources, the burden of gathering evidence and the importance of clear interpretation of indicators and scoring.

Why Adoption by WOAHA Matters

- Provides a credible institutional home for a global veterinary medicines regulatory self-assessment tool.
- Anchors VMRA-SAT within the global authority responsible for animal health, veterinary services and international standards.

- Aligns the tool with WOA's existing work on PVS, AMR, One Health and veterinary legislation, while avoiding duplication with broader assessment mechanisms.
- Uses WOA's convening role, technical networks and relationships with Chief Veterinary Officers and national authorities to support consistent, voluntary uptake.
- Supports sustainability, version control, technical updates and long-term accessibility.
- Helps Member Countries and partners use a common framework and language for veterinary medicines regulatory system strengthening.

The Path to Adoption

- May 2026: VMRA-SAT was presented to WOA's Delegates through a side event and kiosk at the 93rd WOA's General Session.
- 2026 to 2027: Continued stakeholder engagement, regional presentations, consultation with WOA's Members, refinement of both tool versions and consolidation of pilot evidence.
- May 2027: A resolution on WOA's adoption of VMRA-SAT is expected to be tabled at the 94th WOA's General Session.

For more information, visit the VMRA-SAT website: www.vmra-sat.org

Contact: info@vmra-sat.org