

VMRA-SAT Briefing Document

Veterinary Medicines Regulatory Authority Self-Assessment Tool, VMRA-SAT

1. Purpose

This briefing outlines what VMRA-SAT is, its main components, how it works in practice and its value proposition for veterinary medicines regulatory authorities and wider animal health systems.

2. What is VMRA-SAT?

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. Its purpose is to help authorities systematically evaluate the maturity and implementation of their veterinary medicines regulatory systems through a self-led, evidence-based process.

It supports authorities to identify strengths, gaps and priorities for improvement and provides a basis for institutional development planning and long-term regulatory system strengthening. The assessment process remains under the control of the participating authority. VMRA-SAT is focused on learning and continuous improvement and is not an external audit, inspection, ranking exercise or, by itself, a determination of legal compliance.

VMRA-SAT was developed to address the specific need for a veterinary medicines regulatory system assessment tool. It complements existing WOH support mechanisms and broader frameworks such as the PVS Pathway and Veterinary Legislation Support Programme by providing a detailed diagnostic focused on veterinary medicinal products.

3. Components of VMRA-SAT

VMRA-SAT uses a structured assessment hierarchy based on Functions, Indicators and Sub indicators. It comprises eight regulatory Functions, 13 Indicator areas and 235 Sub indicators.

Functions describe the major areas of regulatory responsibility involved in regulating veterinary medicines. These functions may be performed by a single institution or shared across multiple institutions. For a robust self-assessment, all institutions involved in implementing the national veterinary medicines regulatory framework should participate in the assessment exercise. Indicators translate each Function into assessable areas such as legislation, governance, leadership, quality management, human resources, procedures, infrastructure, transparency and monitoring of performance. Sub indicators are the most detailed level of assessment and describe specific requirements or practices that can be examined through explanatory information and supporting evidence.

The eight core Functions are Veterinary medicines national regulatory system, Veterinary medicines registration and marketing authorisation, Veterinary medicines pharmacovigilance, Veterinary medicines market surveillance and control, Veterinary medicines licensing of establishments, Veterinary medicines regulatory inspection, Veterinary medicines laboratory testing and Veterinary medicines batch release.

Together, these Functions provide a comprehensive view of the veterinary medicines regulatory system, including governance and legal foundations, authorisation of veterinary medicinal products, post-authorisation safety monitoring, market surveillance and control, licensing and oversight of establishments, regulatory inspection, laboratory testing and batch release of biological products.

Each Sub indicator is assigned a pre-designated maturity level reflecting the level of regulatory development it represents. The maturity scale is Pre-Bronze, Bronze, Silver, Gold and Gold Plus. Users consider whether the requirement has been implemented and record the information and evidence supporting their judgement.

Each Sub indicator is supported by a Fact Sheet containing information such as its purpose, requirements, suggested evidence, references, assessment criteria and any relevant limitations or explanatory notes. This guidance helps users interpret requirements consistently and base their assessment on verifiable information.

4. How VMRA-SAT works

VMRA-SAT may be used as a self-assessment, where the national authority reviews its own system and evidence, or as a facilitated self-assessment, where the national team completes the assessment with methodological support. In both models, the national assessment team determines the status of the assessment using agreed governance arrangements.

The tool is available in two formats. The Desktop Complete Self-Assessment Tool supports a comprehensive assessment across all Functions, Indicators and Sub indicators, with explanatory information and evidence expected to be recorded. The Web Version Preliminary Self-Assessment Tool provides a streamlined entry point for authorities wishing to carry out an initial or preparatory assessment.

The web-based version provides an early indicative view of regulatory maturity across the core Functions and is intended to support progressive engagement. It is accessible on computers, tablets and smartphones with internet access. It does not replace the desktop tool.

For the desktop version, countries request access and receive the software and country data file, together with installation instructions and access to training or guidance materials. Authorities are encouraged to complete the relevant preparation and training before starting to use the tool.

The assessment produces a maturity profile across the eight Functions, identifying strengths and areas for improvement. Countries are encouraged to use the outputs to develop an Institutional Development Plan that prioritises actions, sets timelines, identifies responsibilities and supports resource mobilisation. The tool can be repeated periodically to track progress over time.

5. What VMRA-SAT addresses

VMRA-SAT helps countries assess and strengthen regulatory systems that are important for animal health, public health and trade. It supports authorities in addressing interconnected challenges such as antimicrobial resistance linked to inappropriate or uncontrolled antimicrobial use, substandard and falsified veterinary products, fragmented registration

pathways that may affect product availability, limited access to vaccines and treatments during emergencies, risks linked to residues in food of animal origin, and workforce or institutional capacity constraints.

The tool assesses regulatory functions that support effective oversight across the veterinary medicines lifecycle, including registration and marketing authorisation, pharmacovigilance, market surveillance and control, licensing of establishments, regulatory inspection, laboratory testing and batch release.

6. Value proposition

For veterinary medicines regulatory authorities

VMRA-SAT provides a practical framework to systematically review how regulatory activities are organised, resourced and delivered across the veterinary medicines lifecycle, both before and after authorisation. It supports regulators to examine whether policies, procedures and practices are working as intended, identify what is already in place, recognise where improvement is needed and develop a structured basis for priority setting and institutional development planning.

By using VMRA-SAT, authorities can move beyond ad hoc problem solving towards a more structured approach to planning, prioritisation and continuous improvement. The tool supports internal coherence, transparency, consistency in regulatory decision making, institutional memory and clearer communication of regulatory needs and progress to leadership, government and partners.

For Chief Veterinary Officers and senior leadership

VMRA-SAT supports Chief Veterinary Officers and senior leaders by equipping regulatory authorities with the clarity and evidence needed to make informed decisions, prioritise resources and demonstrate regulatory credibility at national, regional and international levels. It provides a structured and evidence-based foundation for action on national priorities such as antimicrobial resistance, substandard and falsified veterinary products and access to quality-assured medicines.

The outputs can support clearer dialogue with ministers, finance authorities and development partners on identified regulatory needs and priorities.

For authorities with limited resources

The Web Version Preliminary Self-Assessment Tool provides a lighter starting point for authorities that may find a full self-assessment difficult because of staffing, resource, time or documentation constraints. It is intended to be accessible to authorities at different stages of regulatory development and can support readiness for a more comprehensive desktop assessment.

For international cooperation and system strengthening

VMRA-SAT is intended to complement existing WOAHP support mechanisms and broader regulatory system-strengthening frameworks. It supports a common framework and language for veterinary medicines regulatory assessment, benchmarking, cooperation and regulatory learning across authorities.



Because it focuses specifically on veterinary medicinal products, VMRA-SAT provides a detailed function-level diagnostic that complements broader tools such as the PVS Pathway and the Veterinary Legislation Support Programme. It can also support coordinated capacity building and harmonisation discussions across countries and regions.

7. Use and testing

VMRA-SAT has been piloted in countries across WOAHA regions, including countries in Africa, the Americas, Asia and the Pacific and Europe. Pilot countries have included Rwanda, Botswana, Kenya, Tanzania, Uganda, Zambia, Mexico, Chile, Australia, Thailand and the United Kingdom.

Pilot feedback indicates that VMRA-SAT provides a practical, structured and evidence-based approach that helps authorities understand current capacity, identify gaps, prioritise improvements and develop concrete plans to strengthen veterinary medicines regulation. Feedback also highlights common 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.

8. Summary

VMRA-SAT is a voluntary, country-owned and evidence-based self-assessment tool designed specifically for authorities responsible for regulating veterinary medicinal products. It is built around eight regulatory Functions, 13 Indicator areas and 235 Sub indicators, supported by maturity levels and detailed Fact Sheets. It enables countries to assess regulatory maturity and implementation, identify strengths and gaps, develop Institutional Development Plans and track progress over time. By providing a structured and practical diagnostic focused on veterinary medicines regulation, VMRA-SAT supports long-term regulatory system strengthening, national ownership and continuous improvement.