Manual for the Veterinary Medicines Regulatory Agencies

Self-Assessment Tool (VMRA-SAT)

Foreword

Many countries lack the capacity to fully assess how effective their National Regulatory Authorities (NRAs) are in regulating veterinary medicines. This gap often leads to weak regulation, poor-quality or counterfeit medicines on the market and the misuse of antimicrobials.

The World Organisation for Animal Health (WOAH) supports countries in addressing these challenges by promoting enabling tools to help strengthen regulatory systems, improve veterinary medicine quality control and protect both animal and public health.

To bridge this gap, the United Kingdom Veterinary Medicine Directorate (UK-VMD) has developed and is piloting the Veterinary Medicines Regulatory Agency Self-Assessment Tool (VMRA-SAT). This pilot phase is intended to assist countries in evaluating the effectiveness of their regulation of veterinary medicinal products (VMPs). It has demonstrated how jurisdictions can systematically review their regulatory frameworks, identify areas for improvement and enhance oversight of veterinary medicinal products.

What the Tool Assesses

The VMRA SAT assesses the overall strength, maturity and effectiveness of a country's veterinary medicines regulatory system. It examines whether the national authority has the legal framework, governance arrangements, organisational structures, regulatory processes, technical capacity, and transparency needed to regulate veterinary medicinal products properly. This includes assessing how well the authority performs across the core functions of regulation, such as registration and marketing authorisation, pharmacovigilance, market surveillance and control, licensing, inspection, laboratory testing, and batch release of biological products. In practice, it looks not only at whether these systems exist, but also at how well they are implemented, coordinated, resourced, and able to support consistent and credible regulatory decision making.

What the VMRA SAT provides is more than a simple assessment of the current situation. It provides a structured and country owned framework that helps authorities identify strengths, pinpoint gaps, and understand priorities for improvement. It generates a clearer picture of regulatory maturity across the system and gives countries a practical basis for planning reforms, developing institutional development plans, and tracking progress over time. Because it is a self assessment tool rather than an external audit, it supports honest reflection and national ownership, while also helping authorities make the case for stronger investment, better coordination, and long term regulatory strengthening. Ultimately, it provides a practical pathway for improving the regulation of veterinary medicines in ways that support animal health, public health, food safety, emergency preparedness, and action against antimicrobial resistance.

Shaped by International Standards

To design the tool, the UK-VMD reviewed several assessment and benchmarking tools, including WOAH's PVS Pathway, WHO's Global Benchmarking Tool, the EU's BEMA system and the World Bank's EBA reports. It identified WHO's Global Benchmarking Tool as the best fit. The VMRA-SAT adopts this tool's structure – covering legal, institutional and operational

areas – while tailoring its indicators to reflect how veterinary medicines are regulated in practice.

Collaboration and Pilot studies

The UK-VMD, in partnership with GALVmed and WOAH under the Better Regulation Project, piloted the VMRA-SAT in several regions including Africa, the Americas and Asia Pacafic regions with more pilots planned. The long-term goal is to fit the VMRA-SAT tool into a global veterinary regulatory strengthening framework that helps countries assess, compare and strengthen their veterinary medicines regulation.

Why It Matters

Effective regulation of veterinary medicines ensures that veterinary products used in animals are safe, effective and of high quality. This contributes directly to improved animal health and food safety while supporting global efforts to contain the development and spread of antimicrobial resistance (AMR).

Acronyms and abbreviations used in the Tool

ADR – Adverse Drug Reaction

AE – Adverse Event

AMR – Antimicrobial Resistance

GDP – Good Distribution Practice

GMP – Good Manufacturing Practice

GRP – Good Regulatory Practice

GXP – GMP/GDP

IDP – Institutional Development Plan

IVMP - immunological veterinary medicinal product

KPI - Key Performance Indicator

MA – Marketing Authorisation

MAH – Marketing Authorisation Holder

ML – Maturity Level

MRL – Maximum Residue Level

NCL – National Control Laboratory

NGO – Non-Governmental Organisation

NRA – National Regulatory Authority

OOS – Out Of Specification

PhV – Pharmacovigilance

QMS – Quality Management System

QRM - Quality Risk Management

SOP – Standard Operating Procedure

SPC – Summary of Product Characteristics

SFVP – Substandard and Falsified Veterinary Products

VMP – Veterinary Medicinal Product

VMRA-SAT – Veterinary Medicines Regulatory Agency - Self-Assessment Tool

WHO – World Health Organisation

WOAH – World Organisation for Animal Health

Words and Terms Used in the Tool

Adverse Drug Reaction (ADR) - an unwanted or harmful reaction which occurs after administration of a medicine (drug).

Adverse Event (AE) - as any observation in animals, whether or not considered to be product-related, that is unfavourable and unintended and that occurs after any use of VMP (off-label and on-label uses). AEs include suspected lack of expected efficacy (SLEEs).

Appeal - a formal request to an appointed person or institution to challenge a ruling or decision made by an NRA.

Assessment – a data-driven evaluation of facilities, processes, systems or resourcing to determine performance, identify risks and measure compliance against established standards.

Batch Release - The release of a veterinary medicinal product onto the market following laboratory testing by the manufacturer that confirms that that batch of medicine has the correct composition and is of appropriate quality to ensure the desired therapeutic effect.

Benchmarking – a collaborative learning exercise where NRAs compare their management systems and processes with one another — not to audit or rank them, but to share knowledge and drive internal improvements.

Biologicals - Also referred to as biologics - are veterinary medicinal product where an active substance is produced by or extracted from a biological source.

Clinical Field Trial - A single scientific experiment conducted in a target species to test at least one hypothesis relevant to the proposed effectiveness claim(s)...

Complaint - an expression of dissatisfaction about a product or service.

Distribution - the controlled movement of a veterinary medicinal product throughout the supply chain.

Drug - a veterinary medicinal product (VMP).

Ectoparasiticides - an antiparasitic drug used to kill parasites that live on an animal's body surface.

Enforcement – the process of ensuring compliance with applicable legislation.

Establishment - a physical premises or location engaged in carrying out an activity regulated by an NRA.

Export - the sale or supply and transportation of a veterinary medicinal product from one country to another country.

Good Distribution Practice (GDP) - requires that medicines are obtained from the licensed supply chain and are consistently stored, transported and handled under suitable conditions,

as required by the MA or product specification. GDP also applies to the sourcing, storage and transportation of active pharmaceutical ingredients and other ingredients used in the production of the medicines.

Good Manufacturing Practice (GMP) - is a system for ensuring that medicines are consistently produced and controlled according to quality standards; and must:

- be of consistent high quality
- be appropriate to their intended use
- meet the requirements of the marketing authorisation (MA) or product specification.

Guidelines - statements or principles that provide direction or advice on how to proceed in a particular situation.

Immunologicals – an immunological veterinary medicinal product (IVMP) intended to be administered to an animal in order to produce immunity or diagnose immunity.

Import - the purchase or supply and transportation of a veterinary medicinal product from a country for use, sale, or distribution in the local market.

Inspection – the systematic process of measuring, examining and testing facilities, processes, systems and products against established safety, quality, and regulatory specifications and standards.

Institutions - an established organisation having an important role in veterinary medicines legislation.

Key Performance Indicator (KPI) - a quantifiable measure of performance over time for a specific objective.

Legislation - the process of making or enacting laws.

Manufacture - the industrial-scale process of synthesising, preparing, and packaging veterinary medicinal products.

Medicated Feed - a mixture of animal feed and a veterinary medicinal product produced under controlled conditions.

National Regulatory Authority (NRA) - the institution in charge of assuring the quality, safety, and efficacy of veterinary medicinal products as well as ensuring the relevance and accuracy of product information.

National Residue Monitoring System - a residue surveillance programme designed, implemented and controlled by an NRA.

Pharmaceutical – a pharmacologically active chemical substance administered to animals for therapeutic purposes.

Pharmacovigilance - the science and activities relating to detection, assessment, understanding and prevention of adverse effects.

Placing on the Market - when a veterinary medicinal product is first made available in the country, whether following manufacture in that country or imported.

Procedures - a series of actions carried out in a certain order or manner.

Promulgated – legislation that has been officially proclaimed, published and put into law by a government authority.

Quality defect - an attribute of a medicine, or component, affecting the quality, safety and/or efficacy of the product; and/or medicine that does not comply with some element of its MA.

Quality Management System (QMS) - a structured framework that defines and documents an organisation's policies, processes, procedures and responsibilities to plan, control and improve quality, ensuring products or services consistently meet regulatory and stakeholder requirements.

Quality Risk Management (QRM) - a systematic process for assessing, controlling, communicating, and reviewing risks to the quality of veterinary medicinal products throughout the product life cycle.

Residue Surveillance - the systematic monitoring and analysis of food-producing animals for residues.

Sale - the transfer of ownership of a veterinary medicinal product between a seller and a buyer.

Self-assessment – an organisations data-driven evaluation of its own facilities, processes, systems or resourcing to determine performance, identify risks and measure compliance against established standards.

Stakeholder – any person or group that can affect or be affected by the achievement of an organisation's objectives.

Standard Operating Procedure (SOP)- a documented, step-by-step instruction designed to help employees perform routine operations correctly and consistently.

Summary of Product Characteristics (SPC) - a document describing the properties and the officially approved conditions of use of a medicine, which form the basis of information for healthcare professionals on how to use the medicine safely and effectively.

Use - administration of a veterinary medicinal product.

Vaccine - a substance used to stimulate immunity to a particular infectious disease or pathogen.

Veterinary Pesticide – a pesticide substance used to treat a range of parasitic conditions in animals.

Introduction

This Handbook is intended to help and support veterinary medicines regulatory agencies to carry out a self-assessment of their regulatory systems.

The VMRA-SAT is intended to give a veterinary medicines NRAs an indication of its maturity level (ML) and identify potential areas for improvement.

It is likely that an NRA that is just starting off as a regulator or has undergone a great deal of change will assess itself as Pre-Bronze or Bronze whilst a well-established regulator will assess itself as Silver or Gold (or even Gold-Plus). But it should be remembered that the self-assessment is not intended to identify non-compliance nor is it a competition between regulators – it's a means of identifying where a regulator is currently, where it could be in the future and the changes necessary to make that transition.

The outcome/output of the VMRA-SAT is, however, only as good as the information entered onto it, so it should be completed objectively and impartially. The results of the self-assessment are not shared with anyone else, unless the NRA chooses to be benchmarked. As such, if an NRA is not sure what it should select in the self-assessment then it is better to err on the side of caution, by assuming the information is not available or not in place.

Structure of the VMRA-SAT

The SAT is structured into three levels:

1. Functions
2. Indicators
3. Sub-Indicators

There are 8 Functions, with a total of 56 Indicators and 236 Sub-Indicators, with 'Function 01 - Veterinary Medicines National Regulatory System (VRS)' having the greatest number of each.

The Functions, Indicators and Sub-Indicators are set out in www.vmra-sat.org/factsheets/

1. Functions

The eight overarching themes called *Functions* are:

- 01 - Veterinary Medicines National Regulatory System (VRS)
- 02 - Veterinary Medicines Registration and Marketing Authorisation (VMA)
- 03 - Veterinary Medicines Pharmacovigilance (VPV
- 04 - Veterinary Medicines Market Surveillance and Control (VMS)
- 05 - Veterinary Medicines Licensing Establishment (VLE)
- 06 - Veterinary Medicines Regulatory Inspection (VRI)
- 07 - Veterinary Medicines Laboratory Testing (VLT)
- 08 - Veterinary Medicines Batch Release (VBR)

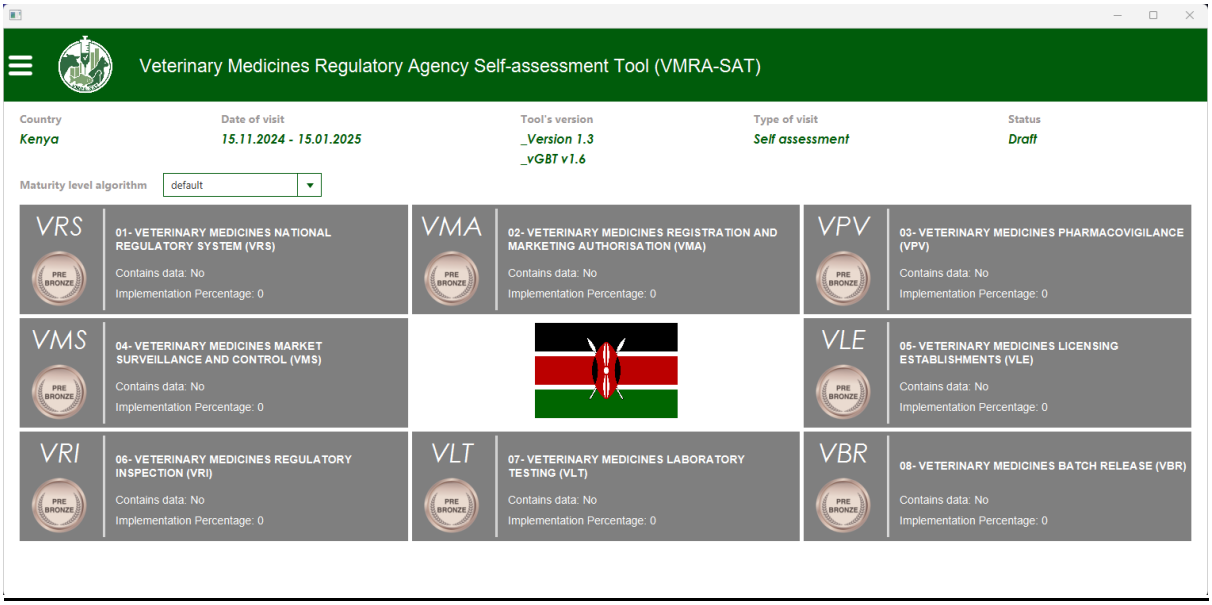

Figure 1. Homepage showing the 8 Functions

2. Indicators

Each Function has several *Indicators*, which set out the high-level requirements of a regulatory system, e.g. in '01 VRS', Indicator number 1 (VRS01) states:

'Legal Provisions and/or regulations and guidelines required to define regulatory framework of veterinary national regulatory system (VRS).'

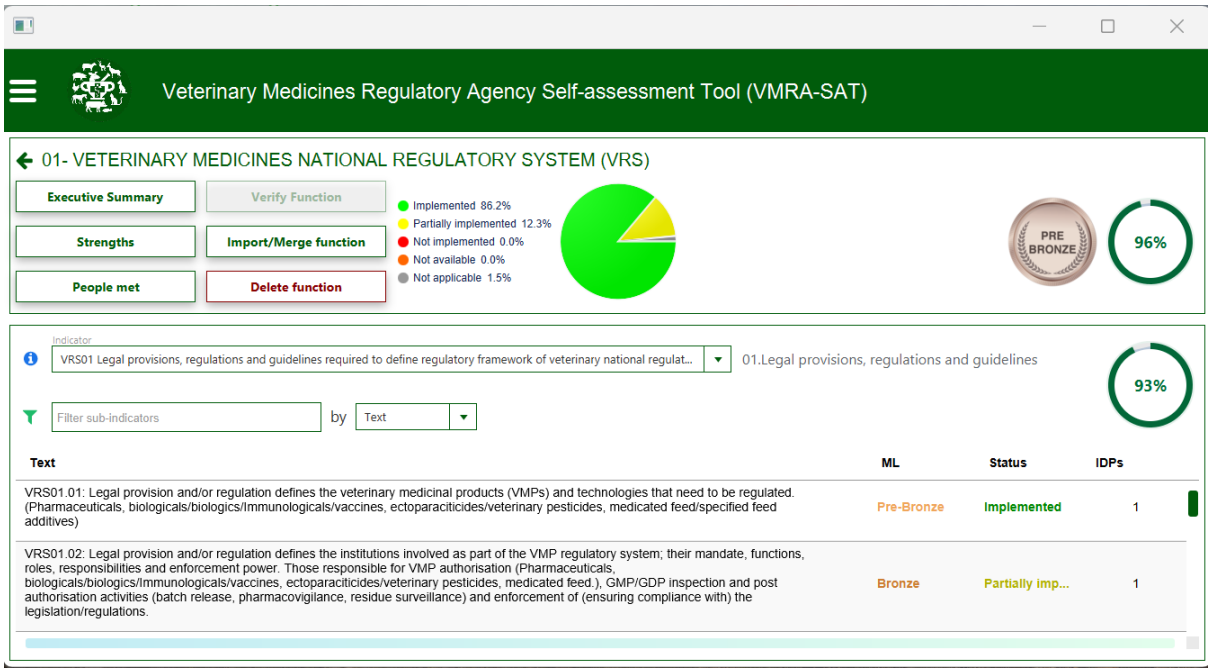

Figure 2: Function 01-VRS showing the first two Indicators (VRS01.01 and VRS01.02)

3. Sub-Indicators

Each Indicator is further sub-divided into several *Sub-Indicators,* which are more specific/detailed requirements of a regulatory system, e.g. Sub-Indicator VRS01.02 states:

'Legal provision and/or regulation defines the institutions involved as part of the VMP regulatory system; their mandate, functions, roles, responsibilities and enforcement power. Those responsible for VMP authorisation (Pharmaceuticals, biologicals/biologics/Immunologicals/vaccines, ectoparaciticides/veterinary pesticides, medicated feed.), GMP/GDP inspection and post authorisation activities (batch release, pharmacovigilance, residue surveillance) and enforcement of (ensuring compliance with) the legislation/regulations.'

Each Sub-Indicator has the following sub-headings:

Scope – the product area(s) to which the sub indicator applies.

Objective – what the sub-indicator is trying to achieve.

Requirement - a concise requirement statement or requirement title that captures what must be in place to meet the sub indicator.

References – lists useful reference material that may assist NRAs to complete its self-assessment.

Framework - A field that is used to classify the type of element the sub-indicator relates to.

Rating Scale – It sets out defined rating categories and their meanings..

Limitations and Remarks – sets out any qualifying statements such as why a rating of 'not applicable' is not an option for a sub-indicator.

Evidence to Review – lists what documents or other material should be reviewed and included as part of the assessment.

Description – this field provides narrative explanatory guidance about what the sub-indicator covers and what the assessor should look for.

NRA input - The NRA is expected to provide comprehensive information, explanations and clarifications in response to the sub-indicator's requirements. This should be based on the objective and description outlined for the sub-indicator. The NRA should deliver a full and clear description of how it fulfils the requirements. Where applicable, the NRA must also highlight any gaps, ambiguities or transitional arrangements that are currently in place. The information provided by the NRA is crucial in informing the appropriate status for the sub-indicator and, where applicable, the Institutional Development Plan (IDP).

External Assessor input - Information, observations and judgements provided by the appointed external assessors during a benchmarking process, based on interviews, document review and verification activities. External assessor input is used to validate NRA input and to determine the final status of sub-indicators.

Reviewed documents - Documents and other forms of evidence that are provided to verify the implementation status of sub-indicators. These are normally listed in the 'Evidence to review' section of the sub-indicator. (If it is a benchmarking exercise, these evidence should be made available to be reviewed by the external assessors).

Status - The outcome of the assessment of the sub-indicator, expressed through the rating scale categories, which reflect the level of implementation of the requirement. Status is determined based on the information in the NRA input and reviewed

documents and following the guidance provided in the ‘Rating scale’. (In the case of benchmarking, assessor judgement will also be crucial).

Institutional Development Plan (IDP) – this requires proactive identification of all gaps and areas for improvement highlighted through the sub-indicator assessment as identified in the NRA input and evidence review. For each gap, the necessary action should be clearly described, with a priority assigned, a realistic timeline established and required resources specified. Each IDP entry must be presented as a single, actionable item, with additional lines provided for further activities where appropriate. The format should enable straightforward tracking of progress and allow for updating of each action’s status as work advances. This approach ensures the IDP remains practical and focused, supporting the ongoing enhancement of regulatory capacity and facilitating effective monitoring of progress towards closing identified gaps.

Strictly speaking the above is a recommendation or an action intended to close the gap identified. However, a when all the recommendations are compiled together, they form a structured plan that become the IDP which is developed following completion of the self-assessment. The IDP supports progressive improvement of regulatory capacity and maturity and provides a practical roadmap for national implementation.

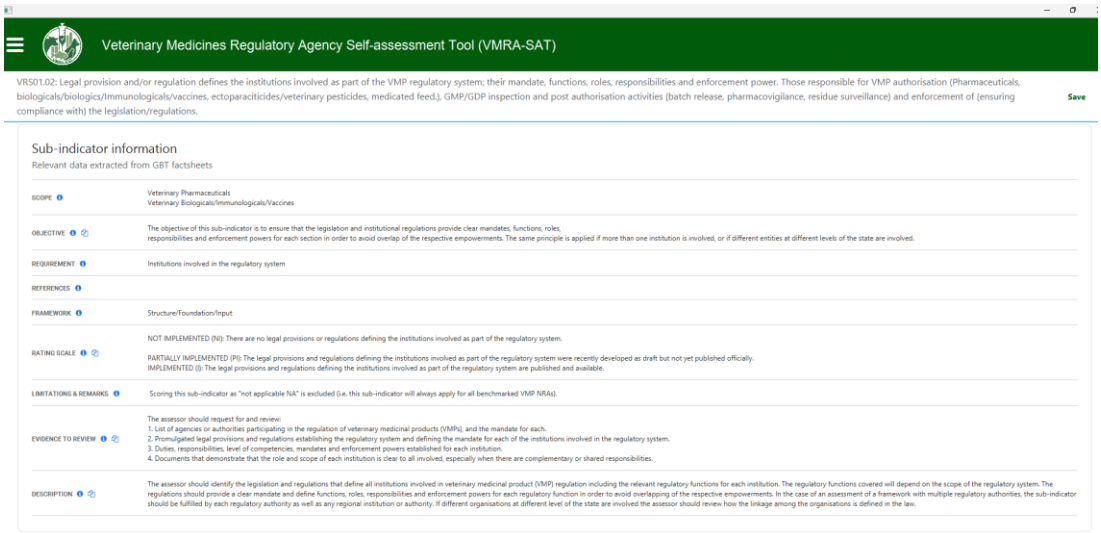

Figure 3 showing part of the top section of Sub-Indicator VRS01.02

4. Maturity Levels, Status and Institutional Development Plan

Each Sub-Indicator has three further fields associated with it – a *Maturity Level (ML),* a *Status* and an *Institutional Development Plan (IDP).*

- Maturity Level (ML). The ML indicates the shows the stage of development that that Sub-Indicator is likely to be seen. It ranges from Pre-Bronze , which is a ‘Must Have’ requirement to Gold-Plus, which is a ‘Nice to Have’ requirement. These are pre-determined in the SAT and so the NRA doesn’t select the ML. However, the NRA can use the outcome of its self-assessment to identify which Sub-Indicators it could focus on to achieve effective regulation.

  The five *MLs* are:
  - **Pre-Bronze** – minimum operating capability; essential to have in place to ensure basic but effective regulation.
  - **Bronze** – elements of regulatory system exist.

- **Silver** – Evolving regulatory system that performs essential regulatory function.
- **Gold** – Stable well-functioning system.
- **Gold-Plus** – Advanced level of performance; beyond legal requirements.

- The Status identifies to what level an NRA has implemented the requirements of a Sub-Indicator.

  There are four possible *Statuses*:
  - Implemented
  - Partially Implemented
  - Not Implemented
  - Not Applicable

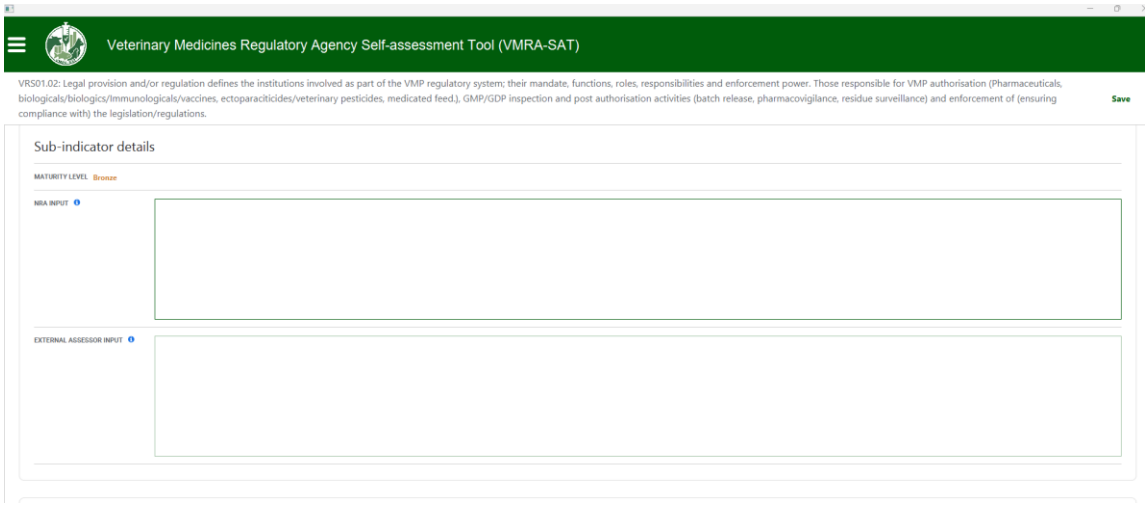

Figure 4 Section 1 of the Sub-Indicator for completion by the NRA Assessor and External Assessor

- The Institutional Development Plan (IDP). The IDP outlines what changes/improvements the NRA considers necessary to address a Sub-Indicator that hasn't been implemented or that has only been partially implemented.

- Reviewed Documents. This is a field for adding references to the evidence (documents) reviewed during the assessment.

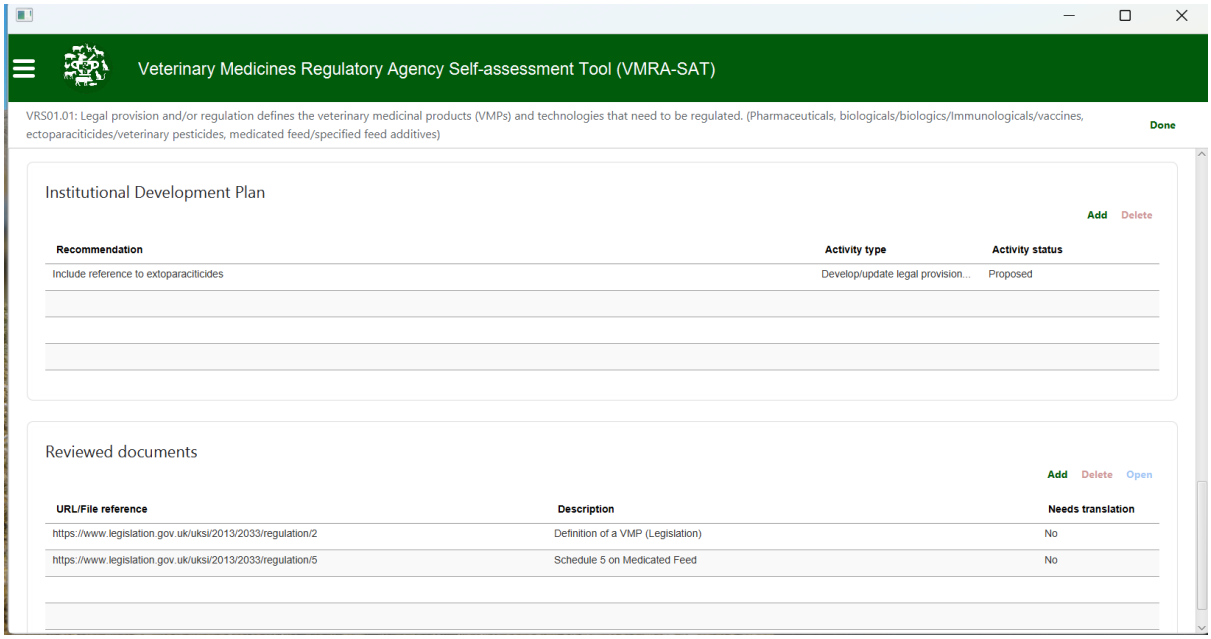

Figure 5 The IDP and Reviewed Documents sections of the Sub-Indicator being assessed