Veterinary Medicines Directorate

VMD International

VMRA-SAT

A mirror for veterinary medicines regulators

Regional Workshop on Strengthening Veterinary Product Regulatory Systems

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Today: the story, the method and the tools

- Purpose, development, framework and versions
- Fact Sheets and assessment fields
- Desktop demonstration
- NRA INPUT and IDP examples; status and evidence check
- Desktop review, file control and reporting
- Lite WebApp: preparation, demonstration and results
- Discussion, next steps and lifecycle close

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History and Development

Osi Oyati

The gap: seeing the whole regulatory system

A fragmented picture

Legal powers, procedures and evidence can sit in different organisations. A review of one activity may miss a gap elsewhere.



Ask not only “does it exist?” but “does it work in practice?”

How VMRA-SAT was developed

Review

WHO's **GBT**, WOAH **PVS**, EU **BEMA** and World Bank **EBA**

Adapt

A detailed structure tailored to veterinary medicines regulation

Consult

Regulators and international stakeholders reviewed the prototype

Pilot and refine

Early pilots and user feedback informed revisions



Review



Adapt



Consult



Pilot & refine

A framework that has continued to evolve

Framework

Veterinary-specific functions, indicators and detailed requirements.



Full Desktop

Narrative, evidence, status and improvement planning.



Lite WebApp

A lighter preliminary route for an early indicative view.



Both versions help authorities understand and strengthen their regulatory systems.

A mirror for regulators, not a test



See clearly

Understand strengths, gaps and where evidence is thin.

Act deliberately

Agree priorities and practical institutional development actions.

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Purpose and Function

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Eight connected regulatory functions

VRS
Veterinary Medicines National regulatory system

VMA
Veterinary Medicines Marketing authorisation

VPV
Veterinary Medicines Pharmacovigilance

VMS
Veterinary Medicines Market surveillance

VLE
Veterinary Medicines Licensing of establishments

VRI
Veterinary Medicines Regulatory inspection

VLT
Veterinary Medicines Laboratory testing

VBR
Veterinary Medicines Batch release

A system-wide view, even where responsibilities sit in several institutions.

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A regulatory system that follows the product from entry to ongoing oversight

One product lifecycle. Eight connected functions.



FOUNDATIONS

VRS

National regulatory system

BEFORE MARKET

VMA

Marketing authorisation

MAKE & SUPPLY

VLE + VRI

Licensing | Inspection

QUALITY CHECKS

VLT + VBR

Testing | Batch release

AFTER MARKET

VPV + VMS

Safety | Market surveillance

13 indicators organise 235 sub-indicators

13 indicators

Cover broad areas of regulatory capability.
Each function uses the indicators relevant to it.
Not all 13 appear in every function.

Legal provisions, Governance, QMS, HR ….

235 sub-indicators

Focus on specific expected capabilities.
Each has a pre-designated maturity level.
The assessor judges implementation separately.

Maturity-level allocation

Pre-bronze (6), Bronze (21), Silver (28), Gold (154) and Gold-plus (26).

From foundation to a smart home

Five maturity levels. Each level builds on the previous one.

A stronger, smarter tomorrow

Pre-Bronze

PRE BRONZE

Minimum operating capability



The foundation is in place. Without this, nothing can stand.

Bronze

BRONZE

Elements of regulatory system exist



The walls are built, the roof is on and basic windows are in place. The structure takes shape.

Silver

SILVER

Evolving system that performs essential regulatory functions



The house is functional. Key essentials are in place – beds, fridge, table – and it serves its core purpose.

Gold

GOLD

Stable, well-functioning and integrated system



The house is finished and beautiful. It's painted, has quality flooring and a welcoming design. Everything works together.

Gold+ (Gold Plus)

GOLD +

Advanced level of performance



A smart home. Remotely or voice controlled shutters, lighting, climate and more. Advanced features deliver greater comfort, security and efficiency.

BUILDING A STRONGER TOMORROW, STEP BY STEP

From a function to an evidence-based answer

FUNCTION	A broad regulatory responsibility
INDICATOR	An element of that responsibility
SUB-INDICATOR	A specific expected capability
FACT SHEET	Guidance on scope, requirements, evidence and rating
ASSESSMENT	NRA narrative, reviewed documents, status and action (IDP)
IDP	Single, specific, actionable, focused, measurable and time bound activity

Two versions, two levels of depth

Full Desktop

Approved application and country data file
Detailed NRA narrative and document references
Implementation status and improvement actions
Controlled exports and comprehensive review

Lite WebApp

Browser-based preliminary assessment
Structured Yes or No questions
Shared responses and indicative function results
Evidence kept separately

Start lightly if useful; go deeper when the team is ready.

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Desktop Software

Osi Oyati

Desktop: start with the right files

Approved application

Extract the complete package. Use the release and Windows or macOS build supplied for the assessment

- Download
- Extract
- Run software
- Import data file
- When completed, export datafile.

Correct country file

Import the supplied data file. Verify the country, assessment and software version before entry.

Keep one controlled master file and a recoverable backup.

Fact Sheets: what is inside?

SCOPE	Products, activities and institutions covered
OBJECTIVE & REQUIREMENT	What the sub-indicator is asking the authority to demonstrate
DESCRIPTION & REFERENCES	Explanatory detail, framework context and sources
EVIDENCE TO REVIEW	Documents and records that may support the judgement
RATING SCALE & LIMITATIONS	How to decide status and any exceptions or conditions

Let the Fact Sheet guide the answer

1 DEFINE	Use scope to identify the relevant products, bodies and activities
2 VERIFY	Read requirement, description, limitations and evidence prompts
3 DESCRIBE	Write the current practice and responsible institution
4 SUPPORT	Record precise document references and actual records
5 JUDGE	Apply the rating scale only after reviewing narrative and evidence

Desktop: populate one sub-indicator well

READ	Open the allocated function, indicator and Fact Sheet
WRITE	Describe present practice, responsibility, scope and gaps
EVIDENCE	Add traceable reviewed-document references
STATUS	Choose the implementation status supported by the record
ACTION	Add a specific development action, then save and check

Desktop: complete the assessment record

NRA INPUT | CURRENT PRACTICE

Explain what happens now and who is responsible. Identify what is in place, what is missing, what has not been put into practice, and what remains unknown or undefined.

DOCUMENTS REVIEWED / EVIDENCE

Name each document or record and describe its relevant content, scope, section and exact provision or page. There could be more than one document addressing the evidence and you can add as many as you can individually.

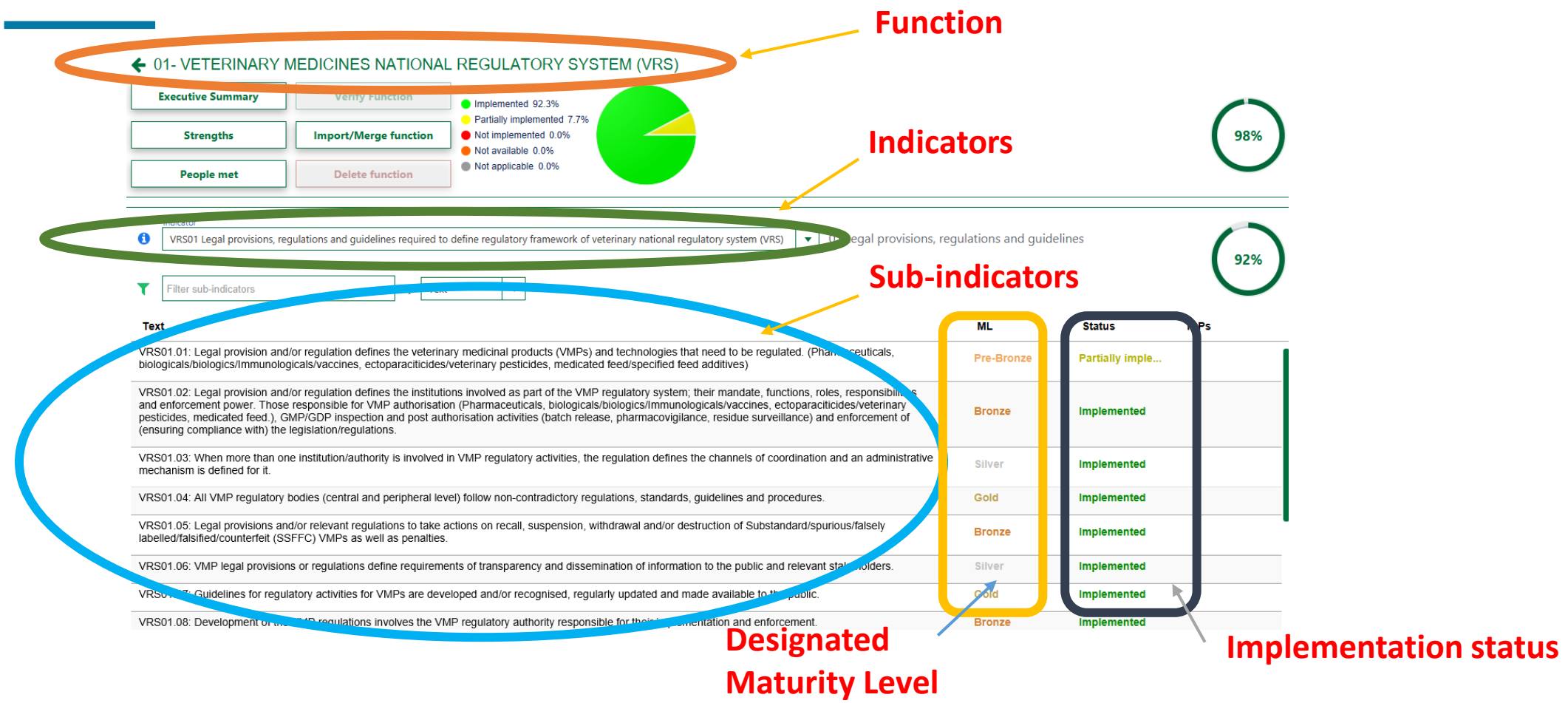
IMPLEMENTATION STATUS

Select the status justified by the narrative and evidence.

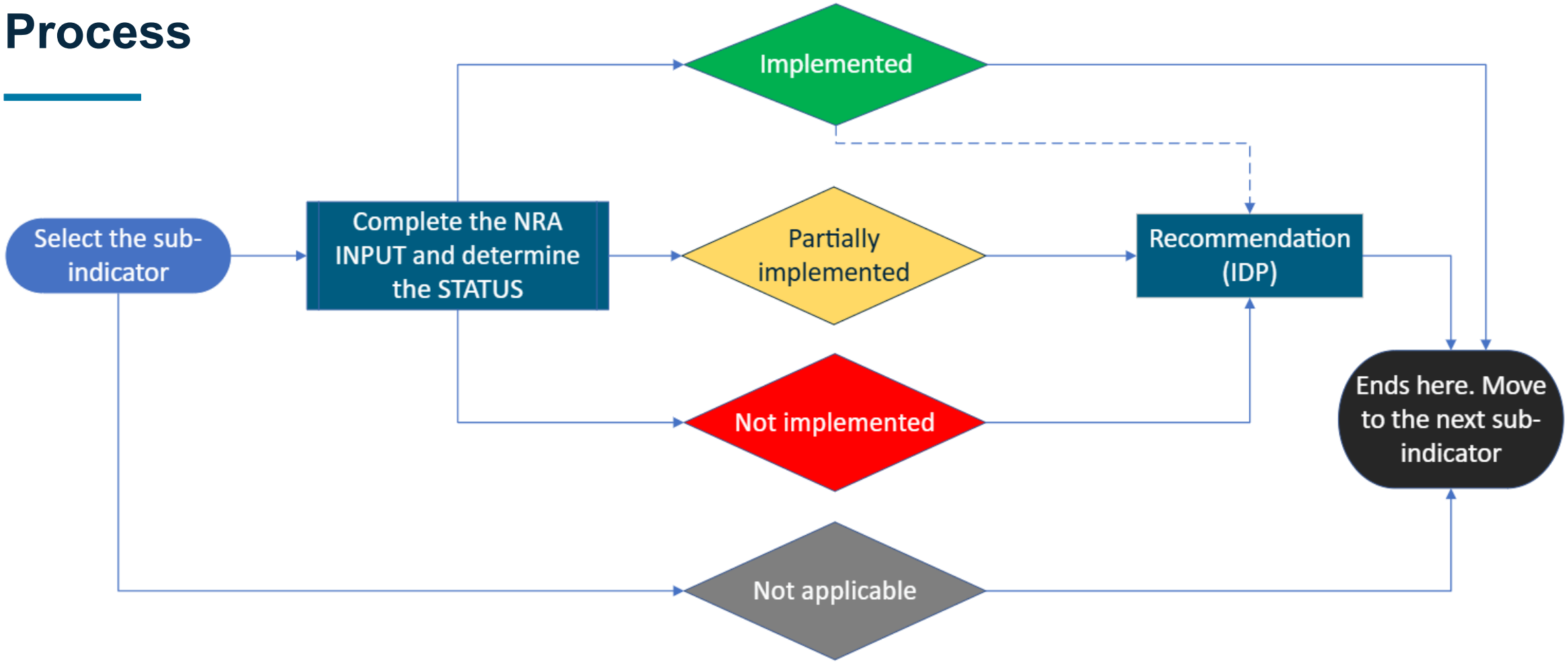
INSTITUTIONAL DEVELOPMENT PLAN (IDP)

Convert each identified gap into an action, owner and milestone.

Screenshot


Function
01- VETERINARY MEDICINES NATIONAL REGULATORY SYSTEM (VRS)
Executive Summary
Verify function
Strengths
Import/Merge function
People met
Delete function
Implemented 92.3%
Partially implemented 7.7%
Not implemented 0.0%
Not available 0.0%
Not applicable 0.0%
98%
Indicators
VRS01 Legal provisions, regulations and guidelines required to define regulatory framework of veterinary national regulatory system (VRS)
egal provisions, regulations and guidelines
92%
Sub-indicators
Filter sub-indicators
Text
ML
Status
Ps
VRS01.01: Legal provision and/or regulation defines the veterinary medicinal products (VMPs) and technologies that need to be regulated. (Pha euticals, biologicals/biologics/Immunologicals/vaccines, ectoparaciticides/veterinary pesticides, medicated feed/specified feed additives)
Pre-Bronze
Partially imple...
VRS01.02: Legal provision and/or regulation defines the institutions involved as part of the VMP regulatory system; their mandate, functions, roles, responsibili s 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.
Bronze
Implemented
VRS01.03: When more than one institution/authority is involved in VMP regulatory activities, the regulation defines the channels of coordination and an administrative mechanism is defined for it.
Silver
Implemented
VRS01.04: All VMP regulatory bodies (central and peripheral level) follow non-contradictory regulations, standards, guidelines and procedures.
Gold
Implemented
VRS01.05: Legal provisions and/or relevant regulations to take actions on recall, suspension, withdrawal and/or destruction of Substandard/spurious/falsely labelled/falsified/counterfeit (SSFFC) VMPs as well as penalties.
Bronze
Implemented
VRS01.06: VMP legal provisions or regulations define requirements of transparency and dissemination of information to the public and relevant sta holders.
Silver
Implemented
VRS0 Guidelines for regulatory activities for VMPs are developed and/or recognised, regularly updated and made available to t public.
Gold
Implemented
VRS01.08: Development of t MP regulations involves the VMP regulatory authority responsible for their i mentation and enforcement.
Bronze
Implemented
Designated Maturity Level
Implementation status

Process


Implemented
Select the sub-indicator
Complete the NRA INPUT and determine the STATUS
Partially implemented
Recommendation (IDP)
Not implemented
Ends here. Move to the next sub-indicator
Not applicable

LIVE DEMO 01 | Full Desktop

From the Fact Sheet to a controlled export

01 Import and verify an approved training country file

02 Open one sub-indicator and read its Fact Sheet

03 Enter a training NRA narrative and precise evidence

04 Choose status, add one IDP action and save

05 Export the partial file and confirm its name and location

NRA input 01 | Legal scope

VRS01.01

WEAK ENTRY

"The NRA has comprehensive legislation for veterinary medicines and complies with all international standards."

WHY IT FALLS SHORT No provision, product scope, evidence or gap.

STRONG ENTRY

"The Veterinary Medicines Act 2018, sections 12–26, assigns authorisation, licensing and enforcement to the NRA for pharmaceuticals, vaccines and medicated feed. Ectoparasiticides are omitted from the statutory definition."

WHY IT WORKS Identifies legal basis, coverage, supporting records and a precise gap.

Illustrative training example. Not a real country assessment.

NRA input 02 | Product recall

VMS04.01

WEAK ENTRY

"All veterinary medicines can be recalled rapidly whenever a problem is identified."

WHY IT FALLS SHORT No trigger, responsible role, effectiveness check or records.

STRONG ENTRY

"An recall procedure approved in March 2024 assigns classification and communication to the Head of Market Surveillance. Class I recalls are notified within 24 hours. Distribution logs and recipient confirmations check effectiveness; three 2025 closure reports are available. No mock recall has been run. Evidence: SOP, notices, logs and closure reports."

WHY IT WORKS Explains process, timing, evidence and the remaining limitation.

Illustrative training example. Not a real country assessment.

IDP 01 | Close the legal scope gap

VRS01.01

WEAK ENTRY

"Improve the law and coordination. Responsible: NRA. Due: soon."

WHY IT FALLS SHORT "Improve" and "soon" are not monitorable; ownership is vague.

STRONG ENTRY

""The Legal and Policy Unit will prepare a draft amendment covering ectoparasiticides to be included by 30 June 2027."

WHY IT WORKS One defined gap, one owner, one action, a date and a tangible output.

Illustrative training example. Not a real country assessment.

IDP 02 | Test recall effectiveness

VMS04.01

WEAK ENTRY

"Purchase recall software and train staff."

WHY IT FALLS SHORT - No link to the diagnosed gap, owner, date or measurable output.

STRONG ENTRY

"The Market Surveillance Unit will run one documented mock recall under the approved procedure by 30 June 2027."

WHY IT WORKS - A focused test with an owner, deadline and evidence of completion.

Illustrative training example. Not a real country assessment.

Status, evidence and actions must agree

Status

Choose Implemented, Partially Implemented, Not Implemented or permitted Not Applicable using the Fact Sheet rating scale.

Evidence

Record title, date or version, issuing body and the specific relevant section or record.

Action

Give each significant gap a practical, owned and monitorable improvement action.

The assigned maturity level is not the status selected by the assessor.

Review, control and report

Review

Check every allocated narrative, document reference, status and action

Agree

Resolve conflicting contributions with the relevant function leads

Control

Keep agreed file naming structure

Report

Export data file(s) or generate report

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Lite Web Version (WebApp)

Noel Joseph

WebApp: prepare before you click

Agree the round

Country, date, assessment name and purpose

Nominate people

Coordinator, function leads and contributors

Gather evidence

Relevant laws, procedures and records

Set ground rules

Who enters answers and how differences are resolved and then share the link for access

WebApp: create, answer, review, report

CREATE	Choose country, date and name; protect code and link
SHARE	Invite authorised contributors using individual names
ASSESS	Open a function, read the fact sheet and answer
REVIEW	Wait for Saved; check completion and disagreements
REPORT	Choose Responses, IDP or Full report

LIVE DEMO 02 | Lite WebApp

Show the journey, not every question

01 Create or join an assessment

02 Open one function, sub-indicator and its linked fact sheet

03 Enter one training answer, implementation status and wait for Saved

04 Review completion and a sample report

Read WebApp results with care

Completion is not strength

100% means applicable questions have answers. It does not mean that every answer is Yes.

Potential is not certification

Indicative maturity is cumulative and shown separately for each completed function.

Keep the evidence and the decisions outside the WebApp.

Where could this help your authority?

Questions for the room

- Which functions involve more than one organisation?
- Who regulates veterinary pharmaceuticals, vaccines, biologicals, ectoparaciticides (also known as veterinary pesticides), aquaculture veterinary products?
- Where would the evidence be hardest to find?
- Which version is the right first step?

Practical next step

Identify a coordinator, agree the assessment purpose and choose an approved training or country assessment route.

A useful assessment starts with a candid account of the present.

Visit www.vmra-sat.org for more information about VMRA-SAT.

Thank you



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