

Formation des Points Focaux Produits Vétérinaires - pour l'Afrique francophone.

21 - 23 janvier 2025, Tunis, Tunisie.



Un outil d'auto-évaluation pour les régulateurs des médicaments vétérinaires



Veterinary
Medicines
Directorate

Noel Joseph

Veterinary Medicines Directorate, UK



Contenu

- Pourquoi est-il nécessaire?
- Approche
- Résultat
- Principaux éléments
- Conclusion

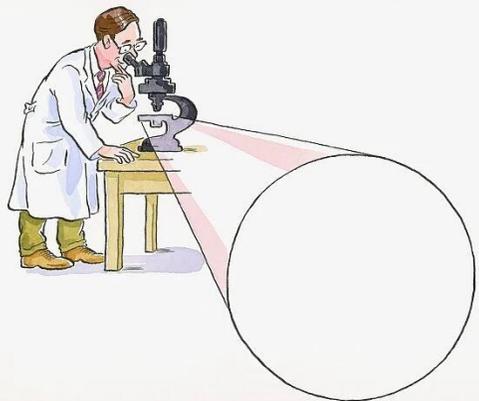


Pourquoi?

- Établir une clarté juridique du rôle et de la fonction
- Mesurer la prestation des services
- Mise en place de l'établissement et de ses fonctions
- Identifier les points forts et les points à améliorer
- Suivre les progrès au fil du temps
- Encourager la « dépendance » et la collaboration régionale
- Contribuer à une utilisation efficace des ressources



Approche



Examen d'autres outils

Outil mondial d'analyse comparative (GBT) de l'OMS pour les ANR des médicaments à usage humain

Outil du Processus PVS de l'OMSA pour la fourniture de services vétérinaires

Benchmarking de l'Agence européenne des médicaments (BEMA) de l'UE

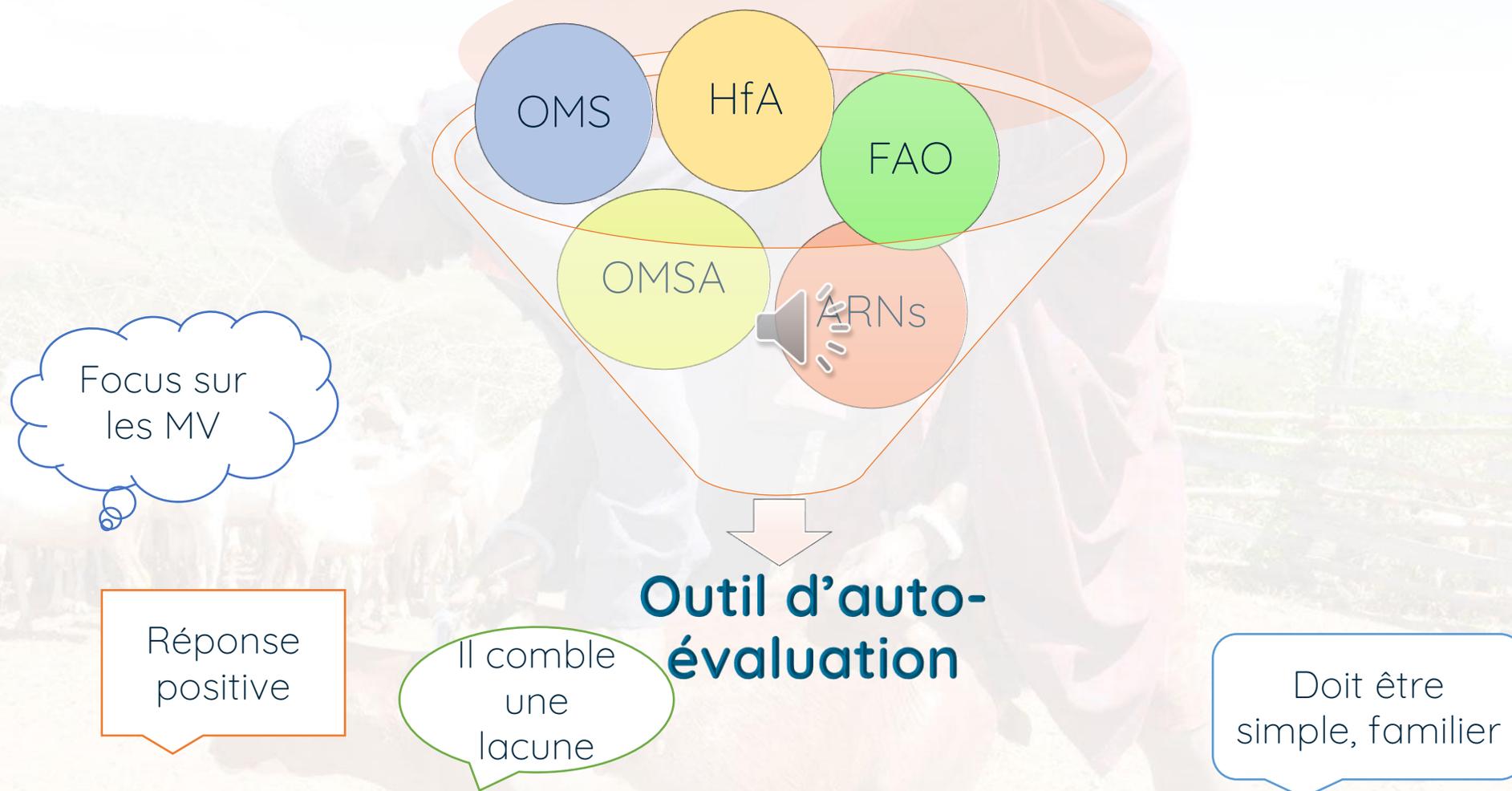
Rapports de la Banque mondiale sur l'initiative Enabling the Business of Agriculture (EBA)

Résultat

- GBT de l'OMS – la meilleure solution
- Couvre les aspects législatifs, institutionnels et opérationnels
- Bonne corrélation entre la réglementation des médicaments humains et vétérinaires 
- Utiliser le GBT de l'OMS comme modèle pour les MV
- Modifier/Ajouter/Supprimer des fonctions, des indicateurs, des sous-indicateurs pour refléter les MV
- Nouvelle catégorisation pour indiquer le niveau de maturité



Engagement des parties prenantes



Composants principaux

Fonctions

MV Système
réglementaire
national
(VRS)

Enregistrement
MV et
autorisation de
mise sur le
marché (VMA)

Locaux de
licence MV
(VLE)

MV Tests par
lots
(VBR)

MV
Pharmacovigila
nce
(VPV)

Surveillance et
contrôle du
marché MV
(VMS)

Inspection
réglementaire
MV
(VRI)

Accès au
laboratoire
MV et tests
(VLT)

Composants principaux

Indicateurs (13)



Composants principaux

Sous-indicateurs (235)

Pre-bronze (6)

Bronze (21)

Argent (28)

Or (154)

Or-plus (26)

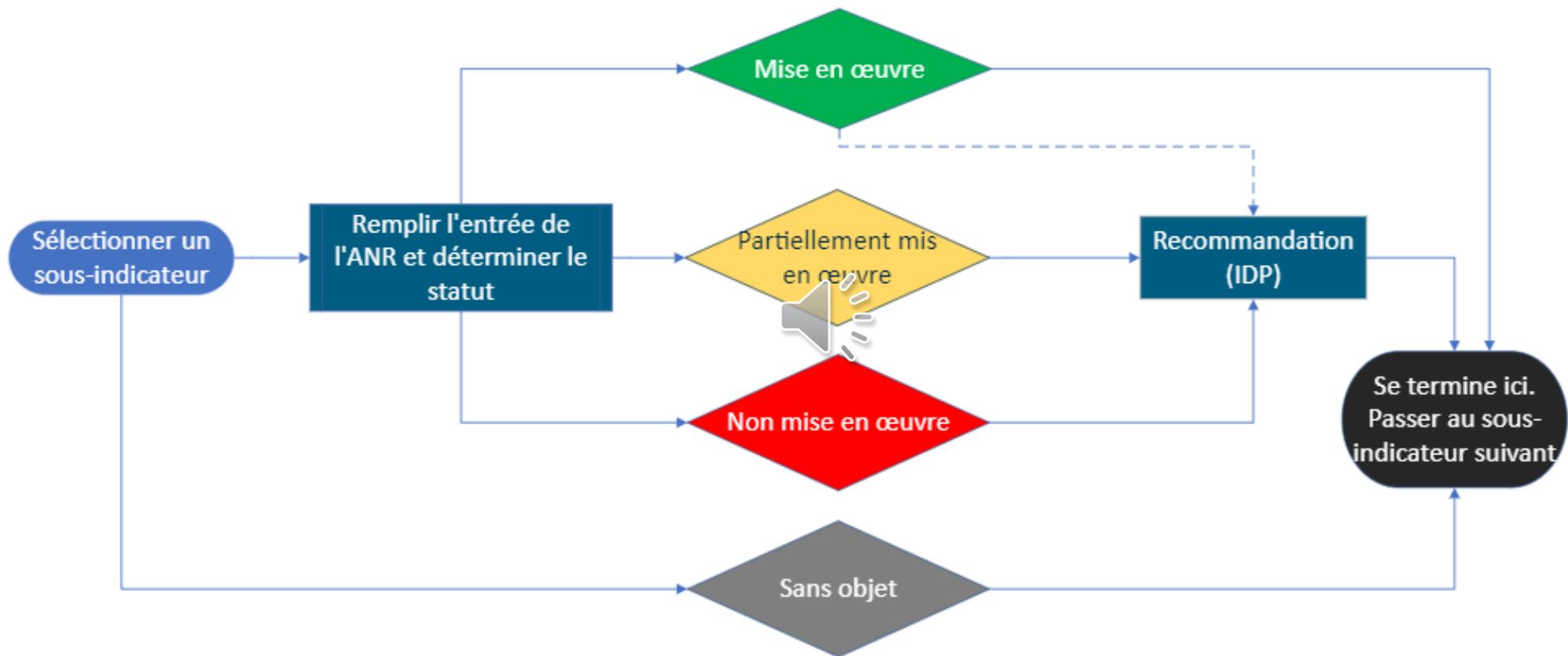
Implémenté

Partiellement mis en œuvre

Non mis en œuvre

Sans objet

Processus



Composants principaux



Pré-Bronze - capacité de fonctionnement minimale



Bronze – Des éléments du système réglementaire existent



Argent – Un système évolutif qui remplit des fonctions régulatrices essentielles



Or - Système de réglementation stable, efficace et intégré



Or+ (Or Plus) – niveau de performance avancé

Capture d'écran



Navigation: LOGO HERE Tool name goes here!

Country	Date of visit	Tool's version	Type of visit	Status
Empty	01.06.2023 - 31.07.2023	_Version 1.3 _vGBT Beta v1.3	Self assessment	Draft

Maturity level algorithm:

VRS 01- VETERINARY MEDICINES NATIONAL REGULATORY SYSTEM (VRS) Contains data: Yes Implementation Percentage: 98	VMA 02- VETERINARY MEDICINES REGISTRATION AND MARKETING AUTHORIZATION (VMA) Contains data: Yes Implementation Percentage: 98	VPV 03- VETERINARY MEDICINES PHARMACOVIGILANCE (VPV) Contains data: Yes Implementation Percentage: 98
VMS 04- VETERINARY MEDICINES MARKET SURVEILLANCE AND CONTROL (VMS) Contains data: Yes Implementation Percentage: 97	Overall ML 	VLE 05- VETERINARY MEDICINES LICENSING ESTABLISHMENTS (VLE) Contains data: Yes Implementation Percentage: 98
VRI 06- VETERINARY MEDICINES REGULATORY INSPECTION (VRI) Contains data: Yes Implementation Percentage: 99	VLT 07- VETERINARY MEDICINES LABORATORY TESTING (VLT) Contains data: Yes Implementation Percentage: 98	VBR 08- VETERINARY MEDICINES BATCH RELEASE (VBR) Contains data: Yes Implementation Percentage: 98

Capture d'écran

01- VETERINARY MEDICINES NATIONAL REGULATORY SYSTEM (VRS)

Fonction

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%

Indicateurs

98%

VRS01 Legal provisions, regulations and guidelines required to define regulatory framework of veterinary national regulatory system (VRS)

Sous-indicateurs

92%

Text	ML	Status	IDPs
VRS01.01: Legal provision and/or regulation defines the veterinary medicinal products (VMPs) and technologies that need to be regulated. (Pharmaceuticals, biologicals/biologics/immunologicals/vaccines, ectoparasiticides/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, responsibilities and enforcement power. Those responsible for VMP authorisation (Pharmaceuticals, biologicals/biologics/immunologicals/vaccines, ectoparasiticides/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 stakeholders.	Silver	Implemented	
VRS01.07: Guidelines for regulatory activities for VMPs are developed and/or recognised, regularly updated and made available to the public.	Gold	Implemented	
VRS01.08: Development of the VMP regulations involves the VMP regulatory authority responsible for their implementation and enforcement.	Bronze	Implemented	

Niveau de maturité désigné

État d'avancement de la mise en

Capture d'écran



Veterinary Medicines Regulatory Agency Self-assessment Tool

VRS01.01: Legal provision and/or regulation defines the veterinary medicinal products (VMPs) and technologies that need to be regulated. (Pharmaceuticals, biologicals/biologics/Immunologicals/vaccines, ectoparasiticides/veterinary pesticides, medicated feed/specified feed additives) Done

Sub-indicator information

Relevant data extracted from GBT factsheets

SCOPE	Veterinary Pharmaceuticals Veterinary Biologicals/Immunologicals/Vaccines
OBJECTIVE	The objective of this sub-indicator is to ensure the existence of legislation and institutional regulations that define the products that should be regulated. It is important to set up the scope and mandate of the regulatory agency in charge of regulating veterinary medicinal products (VMPs) in the country.
REQUIREMENT	Scope of regulated veterinary medicinal products (VMPs)
REFERENCES	
FRAMEWORK	Structure/Foundation/Input
RATING SCALE	<p>NOT IMPLEMENTED (NI): There are no legal provisions or regulations defining the veterinary medicinal products (VMPs) that should be regulated.</p> <p>PARTIALLY IMPLEMENTED (PI): The legal provisions and regulations defining the veterinary medicinal products (VMPs) that should be regulated were recently developed as draft but not yet promulgated and enforced.</p> <p>IMPLEMENTED (I): The legal provisions and regulations defining the veterinary medicinal products (VMPs) are promulgated and enforced.</p>
LIMITATIONS & REMARKS	In a short time, it may not be possible for the assessor to review all aspects that this indicator includes. Preferably the country profile or other documents that provide a good description of the regulatory landscape in the country should be studied beforehand. Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked VMP NRAs).
EVIDENCE TO REVIEW Copy evidence	The assessor should request for and review: 1. Promulgated legal provisions and regulations that define the veterinary medicinal products (VMPs) that should be regulated.
DESCRIPTION Copy description	The assessor should identify within the existing legislation and institutional regulations, the scope of regulatory activities and products that should be regulated. Existing definitions for regulated veterinary medicinal products (VMPs) (e.g., pharmaceuticals, biological products, immunologicals or vaccines and medicated feed) should be used. It is not necessary to have a single (standalone) drug law; however, a promulgated and enforced law should exist. If the base laws and regulations refer to the need for complementary regulation, it is important to access that information.

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  **Veterinary Medicines Regulatory Agency Self-assessment Tool**

VRS01.01: Legal provision and/or regulation defines the veterinary medicinal products (VMPs) and technologies that need to be regulated. (Pharmaceuticals, biologicals/biologics/Immunologicals/vaccines, ectoparasiticides/veterinary pesticides, medicated feed/specified feed additives) Done

Sub-indicator details

MATURITY LEVEL	Pre-Bronze
STATUS	<input type="text" value="Not available"/> ▼
NRA INPUT	<div style="border: 1px solid #ccc; height: 150px;"></div>
ASSESSOR INPUT	<div style="border: 1px solid #ccc; height: 150px;"></div>



Cadre juridique

Normes

Coordination

Communication

Ressources

QMS

Contrôle qualité
Test

Inspection
et audit

Évaluation scientifique et
approbation

Pharmacovigilance et
surveillance du marché

Assurer la
qualité des MV
et mettre en
place des
contrôles
d'utilisation

Réduction des MV non
conformes aux normes/illégaux

Aidez à réduire la résistance
aux antimicrobiens

Merci



n.joseph@vmd.gov.uk ou o.oyati@vmd.gov.uk