

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

Registration, authorisation, and harmonisation of
regulations: National competent authority
perspective

**Training Seminar for National Veterinary Products Focal Points, Malawi
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Zivanai Antony Makoni (Dr)
Chief Regulatory Officer – Evaluations (MCAZ)
WOAH National Focal Point Veterinary Medicine



World Organisation
for Animal Health
Founded as OIE



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Introduction

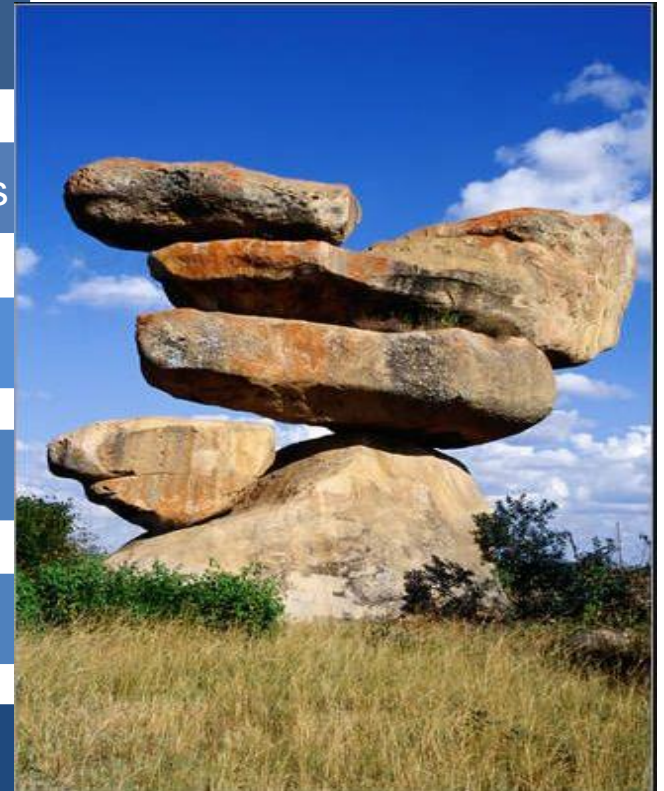
Enabling Legislation & Governing Bodies for VMPs

Regulatory Functions

Harmonisation of VMPs –Vet Zazibona

Reliance

Global Benchmarking exercise



Introduction

Protect and Promote Public & Animal Health

By assuring that medical products marketed in the country are **SAFE, **EFFECTIVE** and of **GOOD QUALITY****



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Enabling Legislation

Acts of Parliament

- Medicines and Allied Substances Control Act [15:03]

Regulations

- Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991
- Medicines and Allied Substances Control (Import/Export) Regulations, SI 57 of 2008
- Medicines and Allied Substances Control (Veterinary Medicines) Regulations*
(pending approval)
- Medicines and Allied Substances Control (Medicated Feeds) Regulations*
(pending approval)

Acts of Parliament

- Dangerous Drugs Act [15:02]

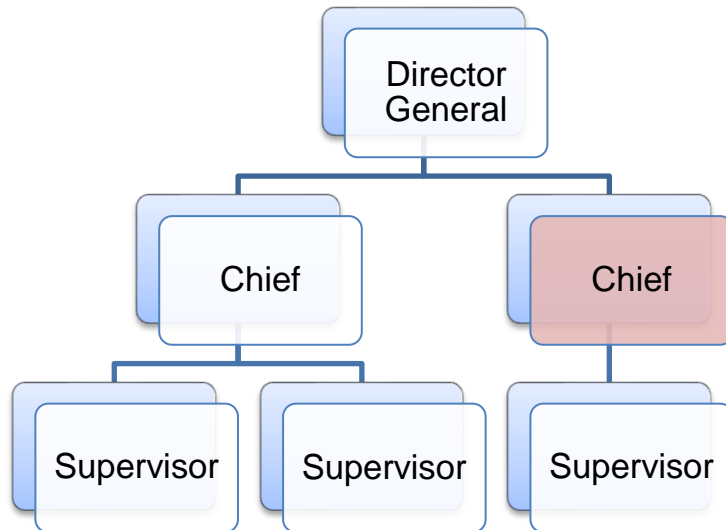
Regulations

- Dangerous Drugs Regulations, 1111 of 1975



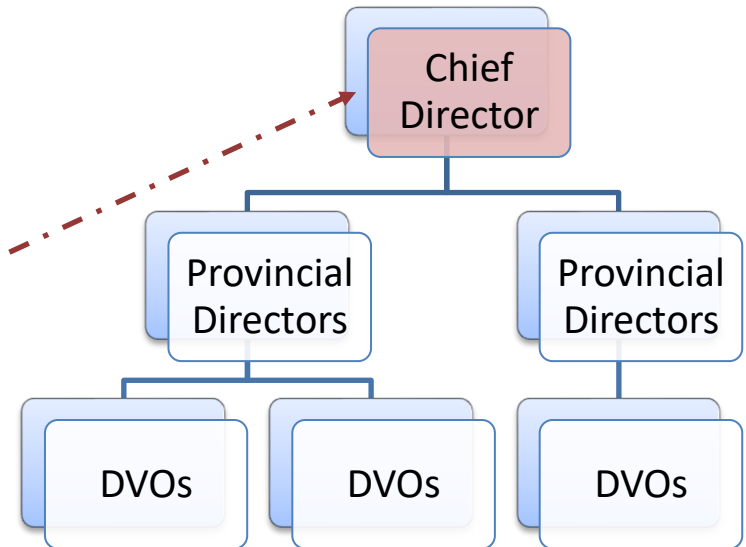
Governing Bodies VMPs

MEDICINES CONTROL AUTHORITY OF ZIMBABWE



Pharmaceuticals, Biologicals, Pesticides

DIVISION OF VETERINARY SERVICES




Biologicals (Field strains)

Chief Regulatory Officer in the Medicines Control Authority of Zimbabwe is the **WOAH Focal Point** for Veterinary Medicines, who reports to **Chief Director in the Division of Veterinary Services**, who is the **WOAH Delegate**.



1

Dossier Evaluation Veterinary Medicines



MCAZ Assessors
Guidelines
VICH GLs/WOAH

2

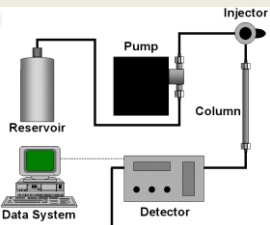
GMP Inspection



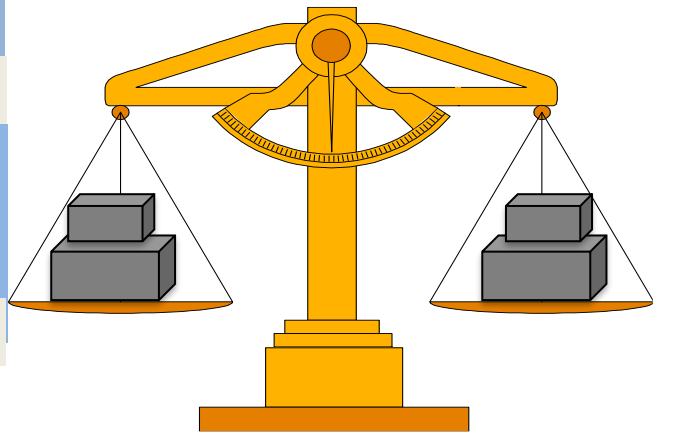
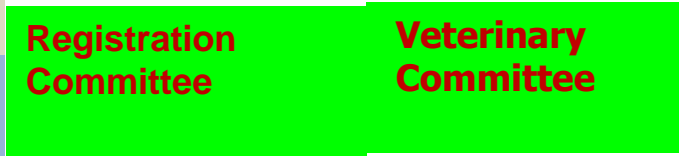
GMP Inspectors
GMP Guidelines
WHO TRS/PICs

3

Sample analysis



MCAZ Laboratory:
ISO 17025 Accredited
WHO prequalified



Refusal



Approval Certificate

- ✓ Quality
- ✓ Safety
- ✓ Efficacy



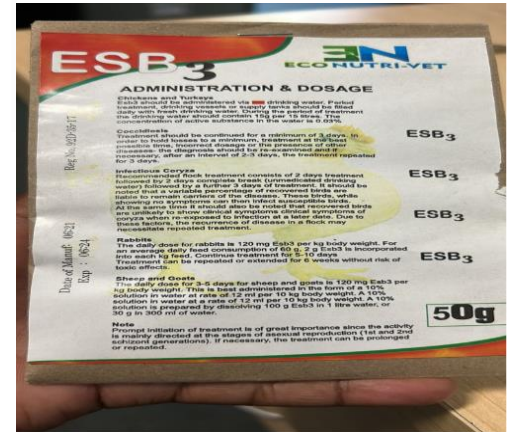
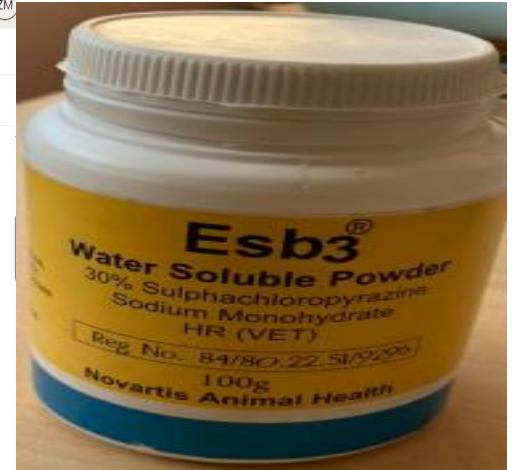
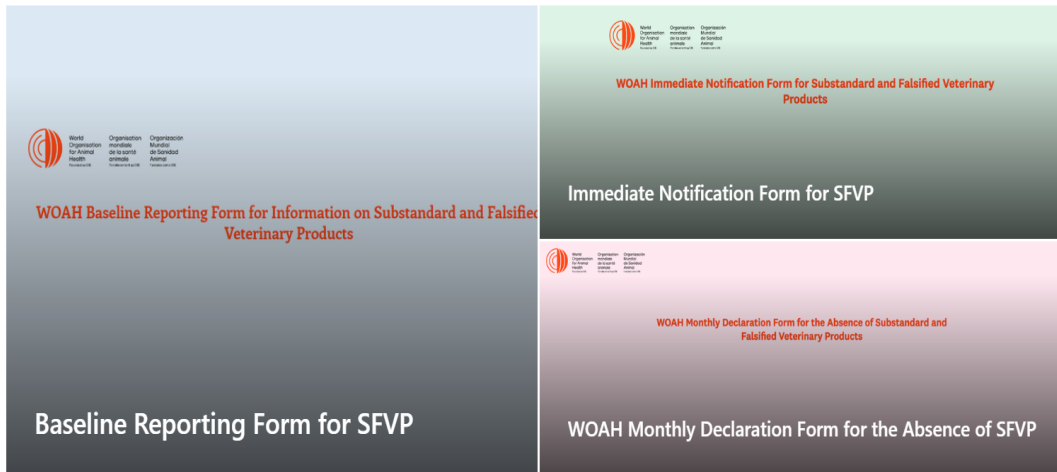
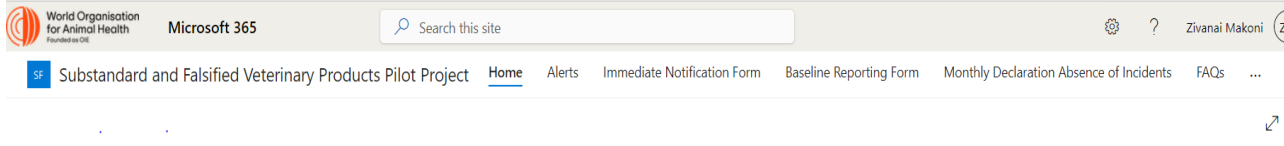
VMP Post-marketing surveillance activities- MPTF



The **surveillance system** will involve the use of handheld devices (e.g., **Raman spectrophotometer** and **Near-Infrared spectrometer**) to detect **SFs** at **ports of entry** and within the medicine **value chain**.

The portable **handheld** devices will be linked to mobile devices on the field that contain **medicine libraries** for all human and animal medicines as references.

Post marketing Surveillance



MCAZ participates in the WOAH pilot for SFVP pilot project

- Immediate Notifications
- Declaration for absence of SFVP





Background SADC VMP Harmonisation initiative

Directive issued by SADC Ministers of Health, 1999

Guidelines for the Regulation of Veterinary Drugs in SADC, 2011

GALVmed/OIE stakeholder workshop on harmonisation of the registration of veterinary, 2017
Recommendation to form SADC TWG on harmonization of VMPs

Development of Concept Note and ToRs for the TWG responsible for harmonization of VMPs:
Assessments, GMP, PV



SADC VMP TWG

April 2023
-LTC endorsed the Veterinary Zazibona initiative

Approval of Concept Note and ToR by SADC Livestock Technical Committee and Head of Agencies in 2018

Formation of the *ad hoc* SADC Technical Working Group (TWG) was, July 2020

Veterinary Medicines Regulatory Conference – May 2022

Monthly meetings 2020-todate:
-Business Plan
-Governance structure
-Draft MoU between MS
-Technical GLs



The Pilot VMP Zazibona Initiative

1st April 2022

Publishing of the EoI for Veterinary Pharmaceuticals
Pre-submission process (30days)

21st April 2022

Sensitization Workshop to Veterinary Pharmaceutical Industry

By 30th April 2022

3 companies have expressed interest to participate and register products through the initiative

By 30th April 2022

Notifications of intent to submit 24 VMP applications had been received.

A meeting for selection of products to Pilot with, was held at SAHPRA Offices on the 6th of May 2022.

The joint assessments of Veterinary Medicines is yet to begin

1



Veterinary Medicines Zazibona

The Veterinary Medicines Zazibona Collaborative Procedure for Veterinary Medicinal Product (VMP) Development Community (SADC) initiative focuses on joint assessment of dossier practices, inspection of manufacturing by the active SADC Member States, early through the initiative in harmonizing and facilitating the Zazibona Collaborative Assessment Harmonization Initiative for joint assessment of human medicine applications and inspection of and the services of other regional collaborative initiatives e.g. the EAC, COMESA/SADC. The initiative, South Africa, Tanzania, Zambia and Zimbabwe, Namibia and Malawi are observed willing to participate in the Veterinary Medicines Zazibona Collaborative Procedure as they may also benefit from this procedure. The Veterinary Medicines Zazibona Collaborative Procedure

- Facilitation of timelines for registration of VMPs
- efficient utilization of available regional resources, and
- improve the availability of essential, safe, effective and good quality veterinary medicines improving animal health and public health.

The procedure is facilitated by the United Kingdom Veterinary Medicines Directorate (UKVMD) and the Malawi Cates Foundation (MCF). The initiative is at its pilot phase and the focus is to test

2



Time	Activity
08:30	Meeting room opened
09:00	1. Welcome Remarks a) Introductions Zuzani Makore MDC b) Welcome Remarks & Workshop Opening Alice Sijiponho GSA/FA
09:10	2. Establishment of the Veterinary Medicines Zazibona TWG Zuzani Makore MDC
09:30	3. VMP Zazibona Pilot assessment Process and Timelines Zuzani Makore MDC

3

Intention to submit application(s) to the pilot joint Veterinary Medicines Zazibona Assessment Initiative

Particulars of the Applicant

Company Name:	
Business address:	
Telephone No:	
E-Mail address:	
Site/Applicant Master File Number:	

This is to indicate that we intend to submit the following application(s) to the pilot joint Veterinary Medicines Zazibona Assessment. (Please note that a maximum of two countries must be selected to be eligible)

PRODUCT INFORMATION

4



5



Presenter Media

Joint Assessment



Roadmap for the formal benchmarking of MCAZ

The Global Benchmarking Tool (GBT) represents the primary means by which the World Health Organization (WHO) objectively evaluates regulatory systems, as mandated by WHA Resolution 67.20 on **Regulatory System Strengthening for medical products**



Status of Regulatory Functions May 2023

MCAZ Function assessed	Nov 2021		May 2023	
	Subindicators implementation %	Maturity level	Subindicators implementation %	Maturity level (Flexible algorithm)
01-NATIONAL REGULATORY SYSTEM (RS)	93.0%	1	94.0%	2
02-REGISTRATION AND MARKETING AUTHORIZATION (MA)	84.0%	1	93.0%	2 → 3
03-VIGILANCE (VL)	85.0%	1	94.0%	3
04-MARKET SURVEILLANCE AND CONTROL (MC)	85.0%	1	93.0%	3
05-LICENSING ESTABLISHMENT (LI)	80.0%	2	92.0%	3
06-REGULATORY INSPECTION (RI)	83.0%	2	82.0%	2
07-LABORATORY TESTING (LT)	93.0%	2	96.0%	2 → 3
08-CLINICAL TRIAL'S OVERSIGHT (CT)	98.0%	3	98.0%	3

Overall Maturity Level

1



2



Future of VMP Benchmarking for MCAZ

- ❑ The exercise is exhausting (Human Resources)
- ❑ Only 3 officers work in VMP Marketing authorisation and Inspectorate
- ❑ Benchmarking planned for 2024

Thank you for your attention!

