MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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

Training Seminar for National Veterinary Products Focal Points, Malawi
05-07 September 2023

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WOAH National Focal Point Veterinary Medicine

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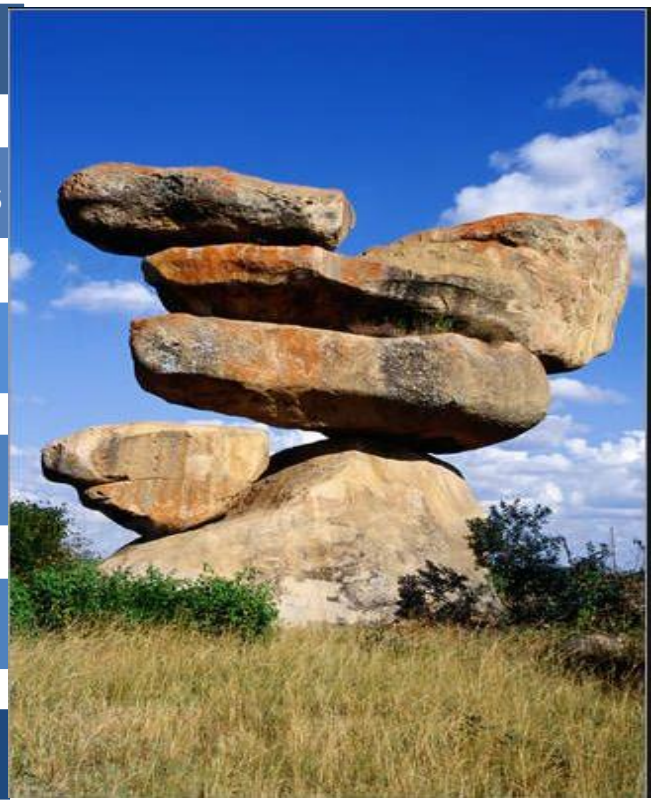
- Introduction
- Enabling Legislation & Governing Bodies for VMPs
- Regulatory Functions
- Harmonisation of VMPs –Vet Zazibona
- Reliance
- Global Benchmarking exercise



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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

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Governing Bodies VMPs

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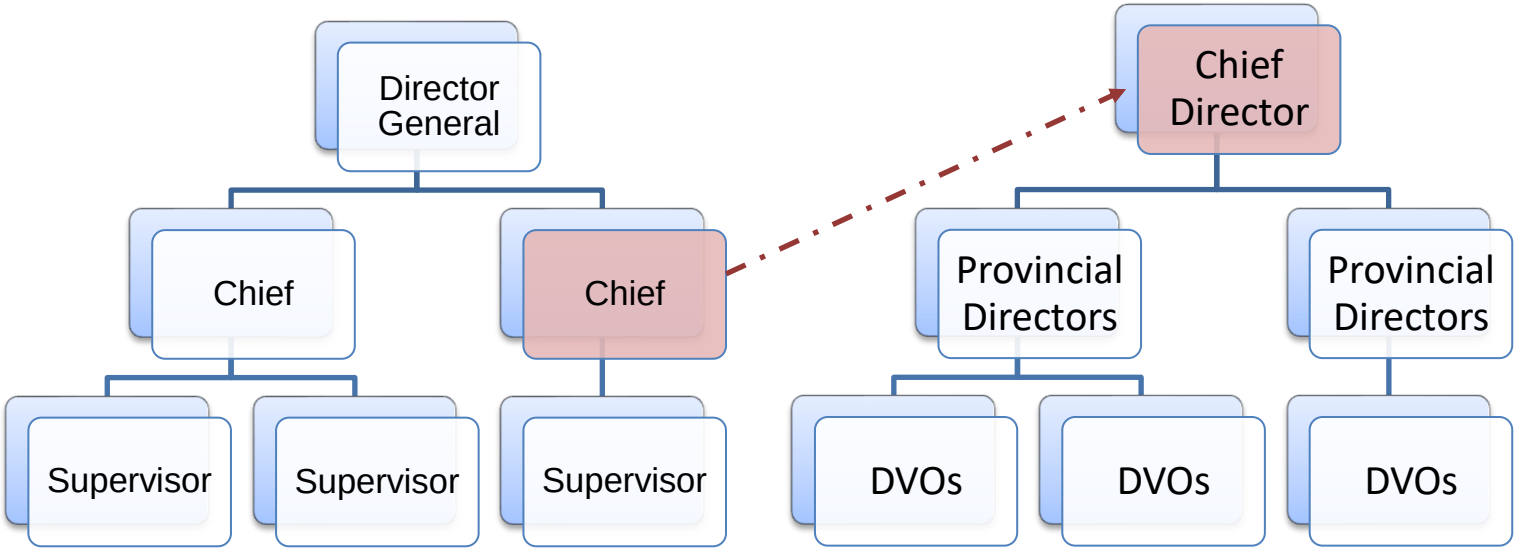
DIVISION OF VETERINARY SERVICES



Pharmaceuticals, Biologicals, Pesticides

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.

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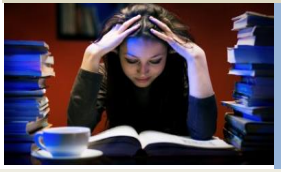
1 **Dossier Evaluation Veterinary Medicines**

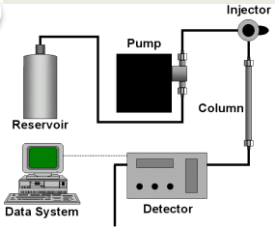


MCAZ Assessors
Guidelines
VICH GLs/WOAH

2 **GMP Inspection**

GMP Inspectors
GMP Guidelines
WHO TRS/PICs

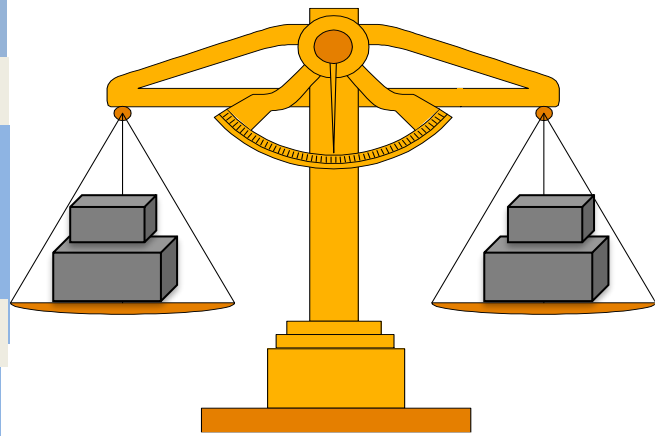
3 **Sample analysis**



MCAZ Laboratory:
ISO 17025
Accredited
WHO prequalified

Registration Committee

Veterinary Committee



Refusal

Approval Certificate

√**Quality**
√**Safety**
√ **Efficacy**

PMS

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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.

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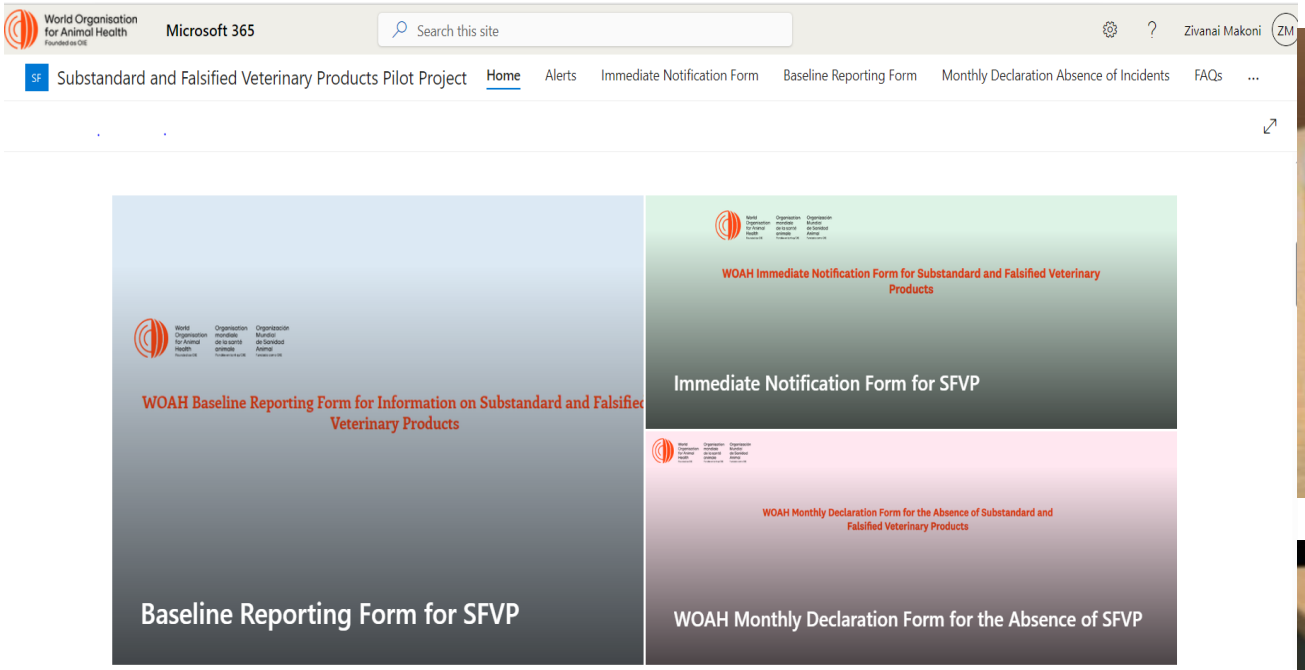
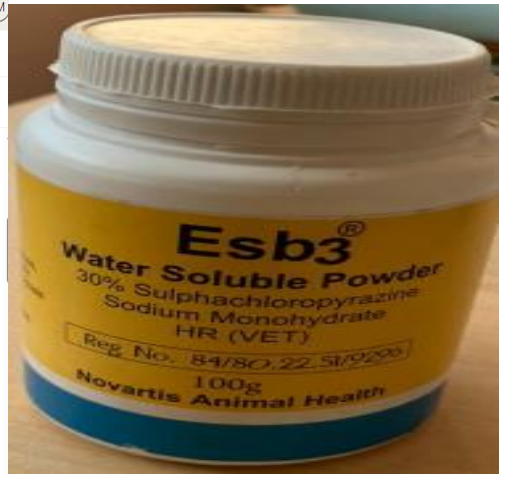
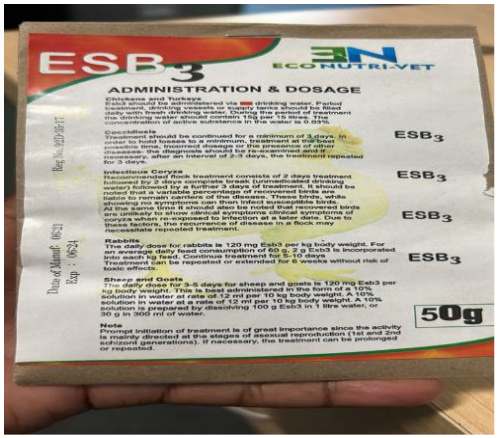
Post marketing Surveillance







MCAZ participates in the WOAH pilot for SFVP pilot project

- ❑ Immediate Notifications
- ❑ Declaration for absence of SFVP

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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 Techinical 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

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

The Pilot VMP Zazibona Initiative

1

1st April 2022

Publishing of the EoI for Veterinary Pharmaceuticals

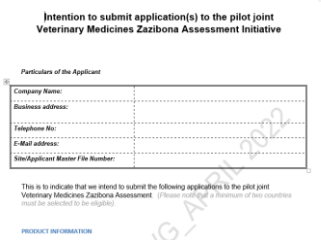
Pre-submission process (30days)

2

21st April 2022

Sensitization Workshop to Veterinary Pharmaceutical Industry

3



By 30th April 2022

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

4

By 30th April 2022

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

5

Joint Assessment

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

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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**

Mar 2011	Nov 2012	Sep 2014	May 2019	Aug 2021	May 2023
WHO vaccine assessment of MCAZ	IDP follow up visit of MCAZ by WHO	WHO prequalification of MCAZ laboratory	Regional self-benchmarking workshop	WHO formal benchmarking of medicine regulatory system in Zimbabwe as represented by MCAZ	WHO formal [re-] benchmarking of medicine regulatory system in Zimbabwe as represented by MCAZ

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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

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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

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Thank you for your attention!

MC AZ