# MEDICINES CONTROL AUTHORITY OF ZIMBABWE

# Experience from Member Countries in application of VICH guidelines

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**OiE National Focal Point for Veterinary Medicinal Products**

MCAZ

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# Presentation Outline

- Background of the MCAZ
- Registration process of a VMP (small molecule, vaccine and acaricides)
- What is VICH and VICH GLs
- Evolution of guidelines for registration of veterinary medicines and guidelines
- Experience in the VICH Guidelines use
- Most deficiencies from applicants on using VICH guidelines

MCAZ

# Background

- MCAZ is located in Harare.


- 100% of funding derived from fees collected for services.
- MCAZ reports to the Minister of Health and Child Care.
- MCAZ has approximately 55 technical staff and a total staff complement of 100.

1

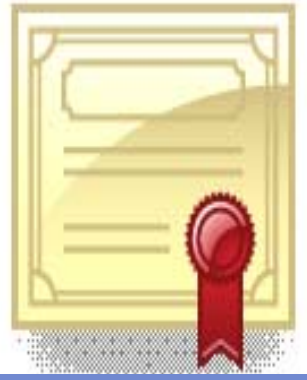
## Dossier Evaluation :(Veterinary) Medicines

MCAZ Assessors Guidelines for Registration derived from **VICH GLs, EU**

**Veterinary Committee**

**Registration**

Risk < Benefit √



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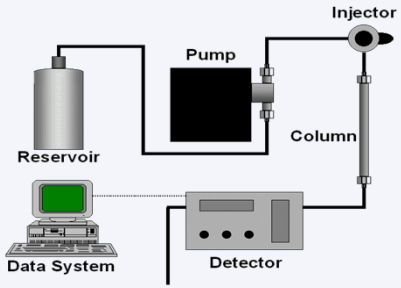
## GMP Inspection

GMP Inspector
WHO training

**Postmarketing Surveillance**
*DVS, Vets, Farmers*

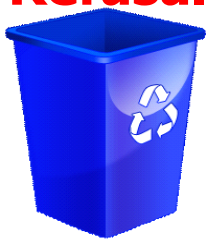

3

## Sample analysis




MCAZ Laboratory:
**ISO 17025**
**Accredited**
**WHO prequalified**

**Refusal**



**M/AUTHORISATION**

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

MCAZ

# What is VICH and VICH GLs

**VICH**

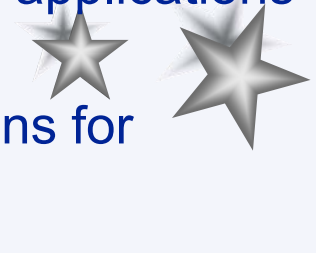
- International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration. *[Launched in 1996].*

**VICH Out-reach Forum**

- The VICH Outreach Forum is a VICH initiative with the main objective of providing a basis for wider international harmonization of technical requirements, improve information exchange and raise awareness of VICH and VICH guidelines with non-VICH countries/regions.

**VICH Guidelines (VICH GLs)**

- **International Guidance** documents that assist **manufacturers** / **applicants** in conducting **scientific** studies and compiling information for submitting applications for registration to **NMRAs or governments.**
- These **guidance documents** also assist **NMRAs** to **review** applications for registration




vichsec.org/guidelines/biologicals/bio-quality/impurities.html
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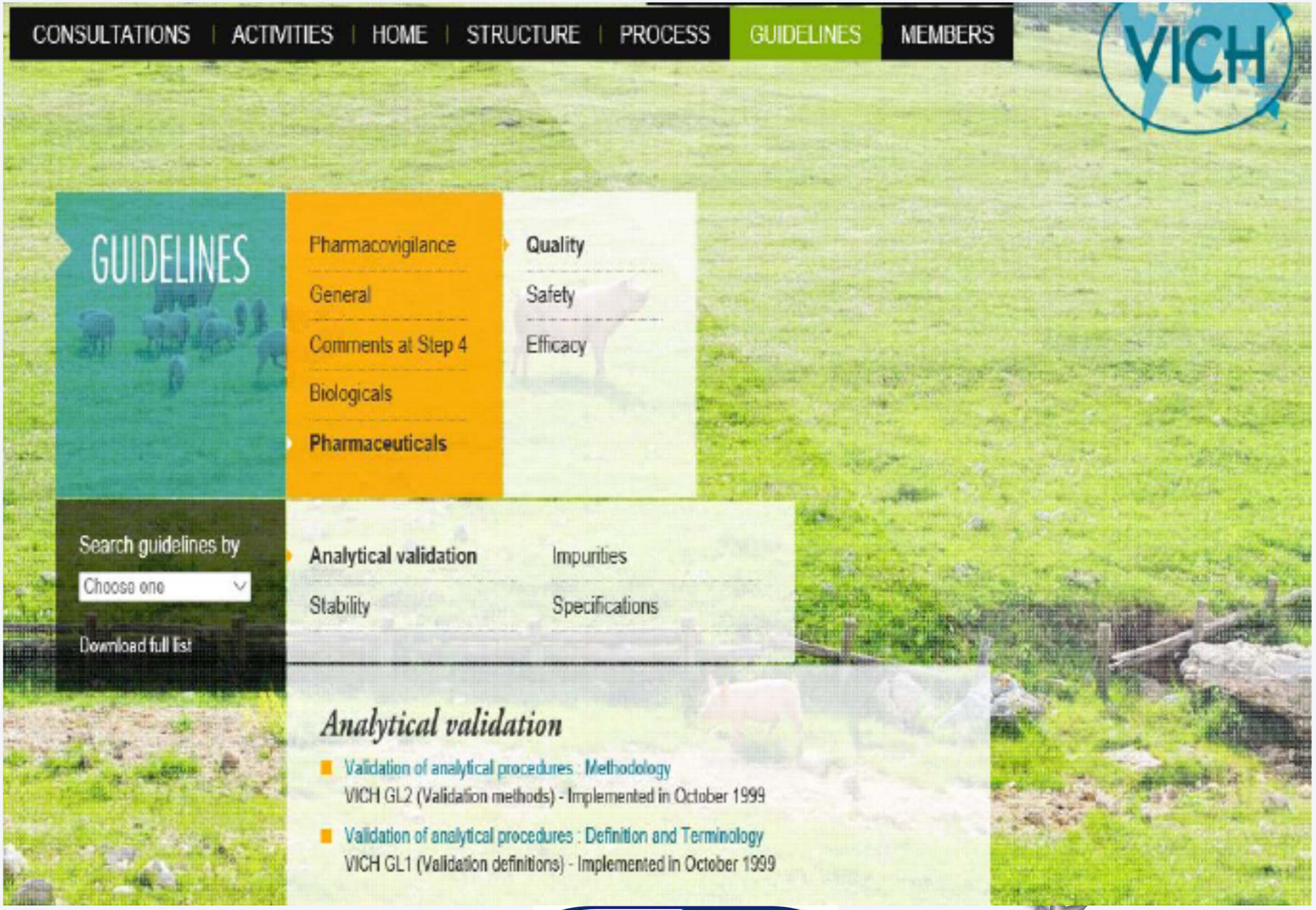
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Analytical validation
Validation of analytical procedures : Methodology
VICH GL2 (Validation methods) - Implemented in October 1999
Validation of analytical procedures : Definition and Terminology
VICH GL1 (Validation definitions) - Implemented in October 1999

# Evolution of veterinary medicine registration guidelines– ZIMBABWE

# Experience in the VICH Guidelines use

# ASANTE SANA!

MEDICINES SHOULD BE **SAFE**, **EFFECTIVE** AND OF GOOD **QUALITY**

Food and Agriculture Organization of the United Nations

World Health Organization

WORLD ORGANISATION FOR ANIMAL HEALTH

MCAZ

Zivanai Makoni 7/12/2017