Status of Requirements for Registration of Veterinary Medicines in Zimbabwe

GALVmed / OIE Stakeholder Workshop on the Harmonization of the Registration of Veterinary Medicinal Products

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Presented by:

Dr William Wekwete (BVSc, MBA) Head Evaluations and Registration MCAZ 106 Baines Avenue

MCAZ

Protecting Your Right to Quality Medicines and Medical Devices

Country Name: Zimbabwe

- Medicines Control Authority of Zimbabwe (MCAZ)

  – Successor to Drugs Control Council (DCC), since 1st August 1997

  – Line Ministry: Ministry of Health and Child Care (MoHCC)

  – established by the Medicines and Allied Substance Control Act 15:03, *which superseded the Drugs and Allied Substances Control of 1969*

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- MCAZ assesses applications for issue of marketing authorization (MA) and issues import/export permits per consignment SI 57 of 2008
  - MCAZ and DVS authorize importation of veterinary vaccines, biologicals
- MCAZ is responsible for licensing Human medicines as well as Veterinary medicines?
- MA is granted to products that meet safety, quality and efficacy standards in Registration Guidelines
  - OIE standards,
  - ICHE guidelines
  - Statutes.
- Import permits state name of product, the quantity, dosage form and dosage units, manufacturer, registration status, and port of entry.

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If your National Regulatory Authority issues Marketing Authorisations:

- Briefly describe how an application for a Marketing Authorisation (MA) is processed
- Who makes the assessment?
- Is there a committee which takes decisions whether or not to issue MAs?
- How long does it take from receipt of an application before an approval is issued?

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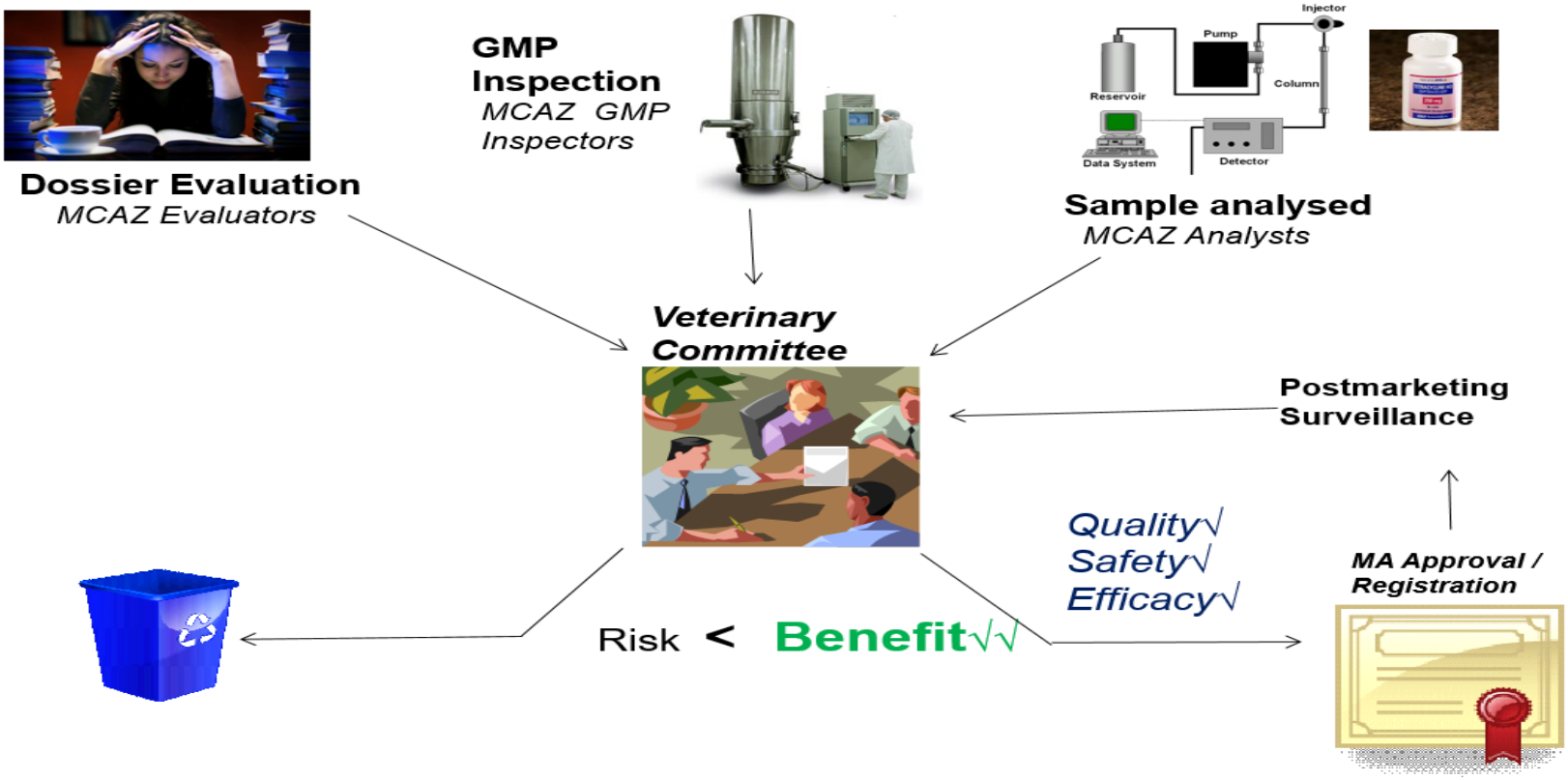

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Country Name: ZIMBABWE

- A total of 322 products (inclusive of vaccines) are currently registered

- About 80% (258) of these are Veterinary Vaccines?

Source:
http://www.mcaz.co.zw/index.php/downloads/file/159-veterinary-medicines-register-march-2017

Country Name: ZIMBABWE

- MCAZ recognises work conducted by Stringent Regulatory Authorities (SRAs)
  - abridged reviews verify the data
  - suitability of the product local conditions

- Zimbabwe looks forward to structured regulatory harmonization, work-sharing and information exchange among African Regulators

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THE END

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CONTACT DETAILS

William Wekwete

Head-Evaluations and Registration

MCAZ 106 Baines Avenue P O Box 10559 Harare

wwekwete@mcaz.co.zw

www.mcaz.co.zw

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