Regulation of Medical Devices in Zimbabwe

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Presentation Outline

- Introduction to MCAZ
- Current Medical Devices Regulatory Framework
- Improvements on current Regulatory Framework
- Roadmap for Implementation of Medical Devices & IVDs Regulations
- Conclusions
- Questions & Answers

Introduction

Who is MCAZ

The Medicines Control Authority of Zimbabwe (MCAZ) was established by an act of parliament, Medicines and Allied Substances Control Act (MASCA) [15:03] of 1996.

- MCAZ's mandate is to protect public and animal health by ensuring medicines, medical devices and allied substances distributed in the country are safe, effective and of good quality.
- This mandate is made possible by the following activities:
  - Pre-market approvals (Evaluations and registrations of new product and variations)
  - Licensing and enforcement
  - Pharmacovigilance
  - Registration and Monitoring of clinical trials
  - Laboratory testing

Current Regulatory Framework for Medical Devices

Currently there are two medical devices being regulated in Zimbabwe, that is, condoms and gloves

Partial quality assurance activities (mainly performance evaluations) are being carried out by Ministry of Health and Child Care for IVDs of public health interest.

Draft Regulations available that have been developed for regulation of Medical Devices and IVDs

-Medicines and Allied Substances Control (In Vitro Diagnostics (IVD) Medical Devices) Regulations

-Medicines and Allied Substances Control (Import and Export of Medical Devices) Regulations

- Medicines and Allied Substances Control (Production and Distribution of locally produced Medical Devices) Regulations

Work on Improvement of Current Medical devices and IVD regulatory Framework

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- Medicines and Allied Substances Control (Production and Distribution of locally produced Medical Devices) Regulations

These regulations are meant to assure the quality of medical devices and IVDs throughout their whole lifecycle.

Regulatory Framework Implementation Road map

CURRENTLY HERE

2021 - 2023

- Drafting of MASC Bill
- Drafting of Medical Devices & IVD Regulations
- Engagement of key stakeholders

2023

- Internal reviews of MASC Bill, IVD and Medical Devices regulations
- Submission of Drafts to MoHCC

2024 Q1-Q3

- Reengagement with MoHCC
- Sensitisation of stakeholders

2024 Q4

- Consultative sessions with key stakeholders
- Review submission of Drafts for gazetting

2025

- Approval of MASC Bill and IVDs &Medical Devices regulations
- Communication of finalized regulation

2026

- Implementation of Basic Level Controls
- Prioritization of Medical devices & IVDs of public health interest

2027 - 2028

- Monitoring and review of basic Level Controls implementation
- Preparation for Expanded level Controls

Conclusion

MCAZ values the contributions of stakeholders, both locally and internationally, in advancing the development and implementation of Medical Devices and IVDs regulations. As such, all contributions are welcomed and encouraged.

Stakeholders are encouraged to regularly visit the MCAZ website for the latest updates on upcoming regulatory changes on medical devices and IVDs.

Thank you/Questions

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