Overview of Medical Devices Regulations
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SAMED Annual Conference 2018

MEDICINES CONTROL
AUTHORITY OF ZIMBABWE

Protecting Your Right to Quality Medicines and Medical Devices
Background

• The Medicines Control Authority of Zimbabwe was established in terms of Section 3 of the Medicines and Allied Substances Control Act (Chapter 15:03).

• The MCAZ functions as the national medicines and healthcare products regulatory authority in Zimbabwe, which includes regulation of medical devices.
Medical Devices Regulations

• The current situation in Zimbabwe is that the Authority only regulates condoms and gloves yet there is need for wider quality assurance for medical devices.

• The public is exposed to substandard devices because there is no holistic regulation of medical devices hence the proposal to introduce a *simple* regulatory process as a starting point.
Medical Devices Regulations

The Status quo

• Medical devices market not regulated (except medical and surgical gloves and condoms).

• “Willing buyer, willing seller”

• In the very near future, there will be some changes....
Medical Devices Regulations

• The starting point…..
• Basic information about the medical devices in use in Zimbabwe.

• WHAT is being imported?
• WHO is importing these products?
• WHO owns these products? (sponsor/principal/owner)
• WHERE are they coming from?
• HOW often are these products being imported?
Medical Devices Regulations

• A draft can be found on the MCAZ website at www.mcaz.co.zw.

• Search for “Medical Devices Regulations”

• All consultative processes have been concluded and the regulations will be gazetted in the near future.
Medical Devices Regulations

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Medical Devices Regulations-
Preliminary

• Covers the title, interpretation, application and classification of medical devices.

• This is important in order to show which devices would be regulated and the rules that apply to each classification. The devices are classified according to the level of control each class is given for example high risk devices have stricter control.
Medical Devices Regulations – Part I

• Provides for **database** of information.
• Since the country will be regulating all devices, it is important for the Authority to maintain a database of all the devices that will be regulated and to update that database regularly.
Medical Devices Regulations – Part I

• There are way more than 500,000 medical devices out there…

• The regulations will be implemented through an online app, accessible to any applicant over the web.

• Applicant declares certain product information, upon verification the product is listed…so no chance of a backlog
The online app...

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The online app...
The online app...

![Notification of Appointment of Authorized Importer](image)

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Medical Devices Regulations – Part II

• Provides for import and export of medical devices.

• *This is critical for the Authority to be able to regulate what enters or leaves the country at any given time.*

• Any import or export of any device would be according to a permit issued by the Authority and through a specified designated port of entry or exit.
Medical Device Regulations – Part III

• Provides for the general conditions of sale of medical devices.
• This section is important because it has provisions that criminalises certain conduct like purchasing devices from unauthorised sources etc.
• It also provides for the withdrawal of devices from the market and destruction of the devices where the Authority deems it fit.
• It also provides for **offences and penalties**.
Medical Device Regulations - Schedules

First Schedule
• Provides for fees

Second Schedule
• Provides for Forms

Third Schedule
• Provides for exempt medical devices

Fourth Schedule
• Provides for the classification of medical devices
Thank you!!

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