

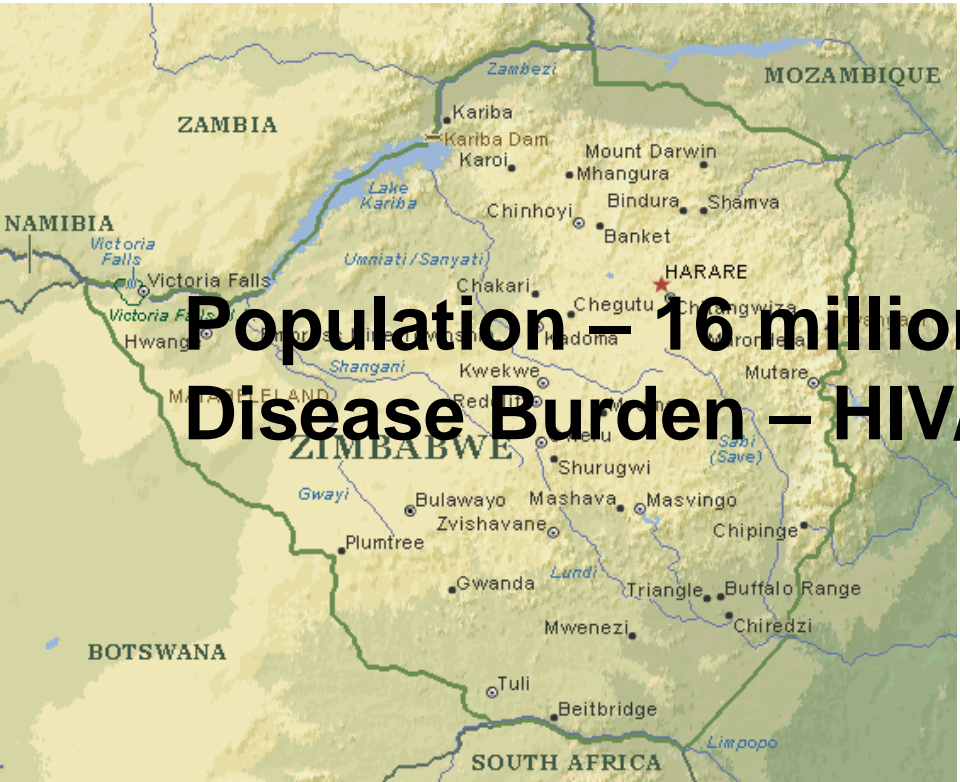
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

Asian Harmonisation Working Party (AHWP) Cebu, 2016

Washington T. Samukange



Medicines Control Authority of Zimbabwe



Population – 16 million (2016 est)
Disease Burden – HIV/AIDS, Malaria, Tuberculosis



Medicines Control Authority of Zimbabwe

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) in 1997

The MCAZ functions as the national medicines and healthcare products regulatory authority in Zimbabwe which includes regulation of medical devices including IVDs.



Medicines Control Authority of Zimbabwe

Structure of Organisation



Medicines Control Authority of Zimbabwe

Structure of Act and Regulations

ACT (Approved by Parliament)

Regulations (Minister)

Guidelines (MCAZ)

SOPs

- Medicines and Allied Substances Control Act (MASCA) and Regulations.
- Condom / Glove Regulations.
- Regulations in the pipeline
 - MASCA (Medical Devices) Regulations
 - IVD Regulations



Medicines Control Authority of Zimbabwe

MCAZ's stepwise approach

2005/2010

- Condom Regulations
- Glove Regulations

2016/2017

- Medical Devices (Import and Export)
- Import and Export, PMS, Database

2017/2018

- In-Vitro Diagnostics
- Registration, PMS



Medicines Control Authority of Zimbabwe

MASCA (Medical Devices) Regulations – 2016/2017

- **Import and Export Controls**
- **Restriction of Advertising**
- **Setting up of Database**
- **Post-marketing surveillance and Vigilance**



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