THE MEDICINES CONTROL AUTHORITY OF ZIMBABWE (MCAZ)

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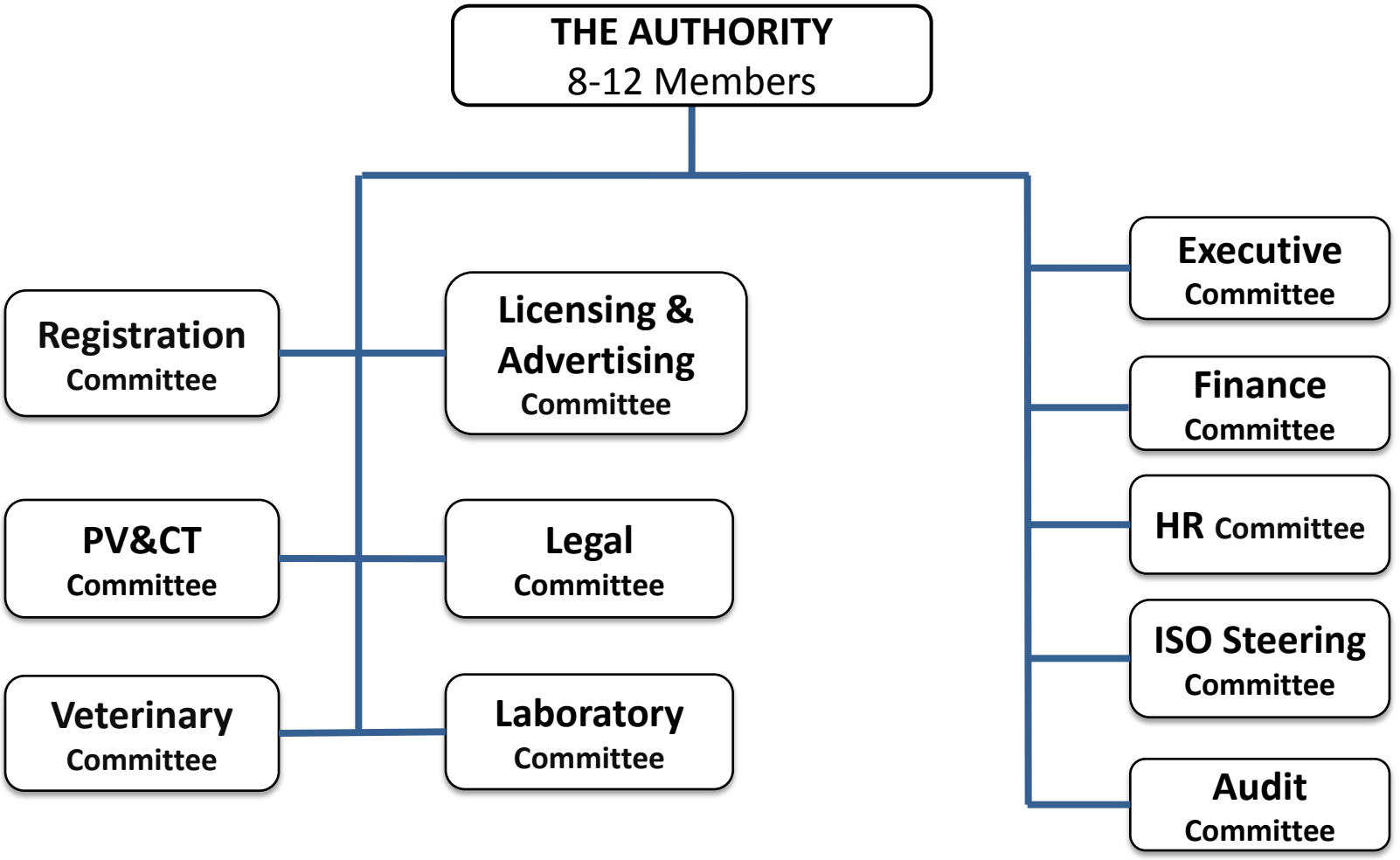
Protecting Your Right to Quality Medicines and Medical Devices

Background

- MCAZ is located in Harare, capital city.
- 100% of funding derived from fees collected for services.
- MCAZ reports to the Minister of Health and Child Welfare.
- MCAZ has approximately 60 technical staff and a total staff complement of 102.

MCAZ Board & Expert Committees



Regulatory Responsibilities

- Administration of the following legal instruments
  - Medicines and Allied Substances Control Act (MASCA) and Regulations.
  - Dangerous Drugs Act and Regulations.
  - Import and Export Regulations.
  - *Condom / Glove Regulations*.
  - International Drug Conventions.
  - -Single convention on Narcotic Drug 1961.
  - -Convention on Psychotropic Substances 1972.
  - -Convention against illicit traffic in Narcotics and Psychotropic Substances 1888.

Functions of MCAZ (1)

- Licensing and inspection of manufacturers, wholesalers, retail outlets, industrial clinics, dispensing doctors and veterinary surgeons, premises and persons.
- Registration of both human and animal medicines.
- Inspection of pharmaceutical premises and distribution channels.
- Authorisation and control of Clinical trials.
- *Quality control of medicines & medical devices.*

Functions of MCAZ (2)

- Control of Narcotic drugs and Psychotropic Substances.
- Monitoring Adverse Drug Reactions.
- *Training of* evaluators, GMP inspectors and *analysts*.

Laboratory Services (1)

- Comprises of Microbiology, Medical Devices and Chemistry labs.
- Main function is quality control testing of pharmaceutical products, medical devices and allied substances
- *Why test/assess medicines or medical devices?*
- Medicines and medical devices are different from other products as patients and even health care professionals are not able to judge their quality or fitness for use visually, by taste or smell. Hence the need to test & regulate.

Laboratory Services (2)

- Samples analyzed are for purposes of
  - Registration
  - Pre-distribution assessment
  - Post-market surveillance
  - Quality checks after adverse drug reaction on the market
- Overall objective is to ensure quality, safety and efficacy of medicines and medical devices circulate in Zimbabwe through testing/conformity assessment.

Medical Devices (1)

- Conformity testing of Medical Devices prior to distribution in ISO 17025 accredited facility.
- Condoms (Public sector and Private Sector condoms)
- Gloves (Examination and Surgical gloves).
- Quality control in two categories:

  *Compliance testing

  *Quality monitoring.
- Training of analysts in quality testing of Medical Devices (RCORE).

Medical Devices (2)

Condom Tests

- Air Burst Test (Volume and Pressure)
- Water Leak Test
- Dimensions Test (Length, Width & Thickness)
- Package Seal and Integrity

Glove Tests

- Water Leak Test
- Dimensions Test (Length, Width & Thickness)

The Future

Medicines and Allied Substances Control (Medical Devices) Regulations, 2016

Medicines and Allied Substances Control (In-Vitro Diagnostics) Regulations, 2016

Draft **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 update that database regularly.

Draft **Medical Devices Regulations(2)**

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.

Draft **Medical Devices Regulations(3)**

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.

Draft **Medical Devices Regulations (4)**

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

In-Vitro Diagnostics Regulations

Pending –at consultation stage. Legislative framework proposed by consultant. Drafting to begin in 2016.

Thank you!!