Structure

• MCAZ is based in Harare the capital city of Zimbabwe.
• 100% of funding derived from fees collected for services.
• MCAZ reports to the Minister of Health and Child Welfare.
• MCAZ has approximately 40 technical staff and 32 administrative staff.
Legal Framework

• First established in 1969 as Drugs Control Council under Ministry of Health and Child Welfare of Zimbabwe.

• Medicines Control Authority of Zimbabwe, formerly Drugs Control Council was established by the Medicines and Allied Substances Control Amendment Act (No. 1 of 1996) [Chapter 1503] and became operational as an autonomous Authority in August 1997.

Protecting Your Right to Quality Medicines and Medical Devices
Composition of the Authority

- Constitution of the Authority
- Not less than 8 and not more than 12 members
- The MASCA stipulates who shall be members in terms of profession and qualification

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Organogram of Medicines Control Authority of Zimbabwe

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Responsibilities

- Administration of the following legal instruments
  - Medicines and Allied Substances Control Act (MASCA) and Regulations
  - Dangerous Drugs Act and 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
Scope of Activities Covered by MASCA

- Licensing 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.
- Control of Clinical trials.
- Quality control of medicines & medical devices.
Functions Currently Being Carried Out

• Registration of medicines.
• Licensing and inspection.
• Control of Narcotic drugs and Psychotropic Substances.
• Authorization and control of clinical trials.
• Monitoring Adverse Drug Reactions.
• Quality control of medicines and medical devices.
• Training of evaluators GMP inspectors and analysts.

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Pharmaceutical Sector Information

- 14 domestic pharmaceutical manufacturers
- 104 Pharmaceutical wholesalers (all permitted to import)
- 281 Private Retail pharmacies
- 17 Hospital Pharmacies
- 207 Industrial Clinics
- 9 Dispensing Veterinary Practices
- 52 Dispensing Medical Practices

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Evaluations & Registration Unit

- Evaluate and register Human & Veterinary medicines.
- Service the Registration & Veterinary Committees.
- Execute decisions of the Committees.
- Approximately 150 applications received and processed per annum.

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Licensing & Enforcement Unit

- Licensing of premises and persons.
- Conducting planned, routine & new premises’ inspections for monthly Licensing & Advertising Committee meetings.
- Conducting Market Surveillance and product defect investigations.
- To attend to all import and export issues.
- To attend to all narcotics issues.
Licensing & Enforcement Unit

• To attend to all enforcement issues.
• To assess and process applications for importation of unregistered medicines.
• To service the Licensing & Advertising Committee.
• To record minutes and execute decisions of the Licensing & Advertising Committee.
Pharmacovigilance & Clinical Trials Unit

- Process and authorise Clinical Trial applications.
- Adverse Drug Reactions Monitoring
- Training mainly for external regulators.
- Provide information to other relevant committees.
- Manage special projects.
- Process amendments to registered medicines.
- Manage retention of registrations.
- Post market surveillance – recalls/Withdrawals and General.
- Medicine Review.
Legal & Corporate Affairs Unit

- To draft and review legislation.
- To provide legal advice.
- To promote the Authority’s image through public relations activities.
- To prepare contracts and annual reports.
- To promote efficiency through development of sound corporate processes.
Laboratory Services Unit

- Comprises of Microbiology and Chemistry Labs
- Main function is quality control testing of pharmaceutical products and related substances
Laboratory Services Unit

• Samples analysed are for purposes of
  – Registration
  – Post-market surveillance
  – Pre-distribution analysis (MOHCW/NGO’s)
  – Local pharmaceutical industry.

• Overall objective is to ensure safety and efficacy of medicines in the nation through testing.

• Training of local and regional analysts
Medical Devices Unit

- Conformity testing of Medical Devices prior to distribution.
- Condoms (Public sector and Private Sector condoms)
- Gloves (Examination and Surgical gloves)
- Quality control in two categories:
  - Compliance testing
  - Quality monitoring.
- Training in quality testing of Medical Devices

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Challenges

- Professional staff levels below requirements.
- Replacement of laboratory equipment - a challenge.
- Financial constraints.
- Post market surveillance needs strengthening.
The Future

- Expansion of Medical Devices scope of control.
- Control of Complementary Medicines.
- Creation of a strong Information Technology Unit.
- Expand laboratory services to include analysis of complementary Medicines.

Protecting Your Right to Quality Medicines and Medical Devices
Thank you!!

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