

# **THE MEDICINES CONTROL AUTHORITY OF ZIMBABWE (MCAZ)**

**Presented by  
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Protecting Your Right to Quality Medicines and Medical Devices

# 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.



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# 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.



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# Composition of the Authority

Constitution of the Authority

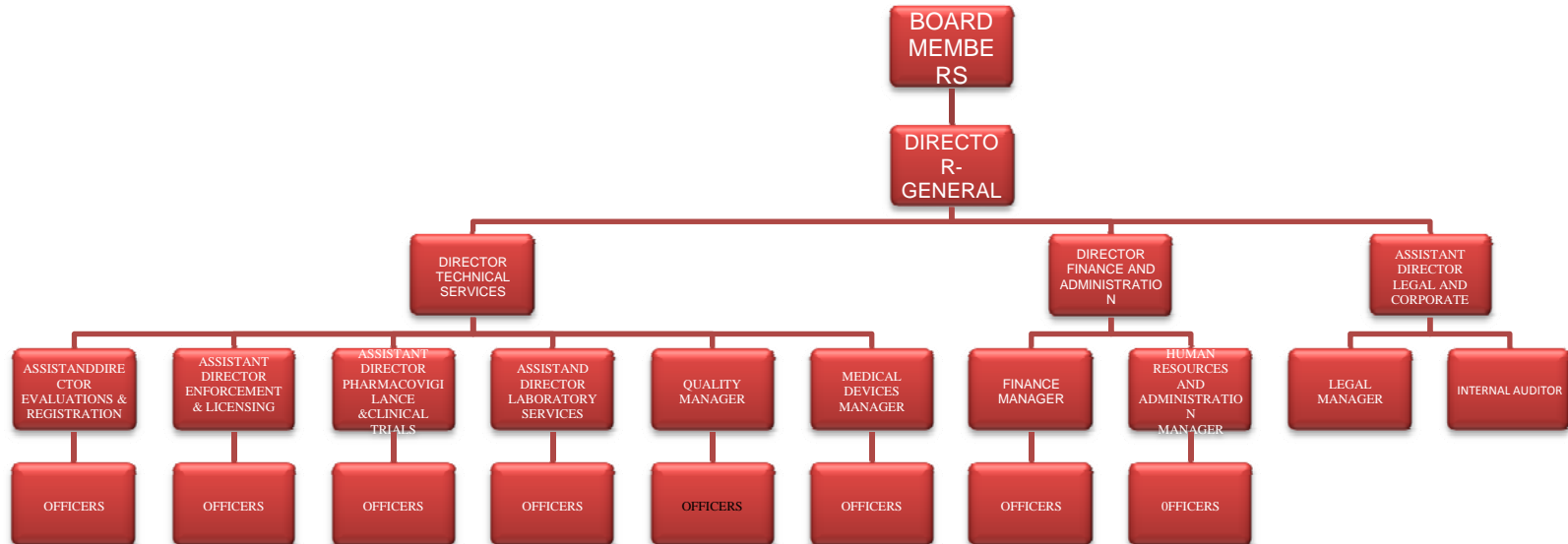
Not less than 8 and not more than 12 members

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



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# 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.



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# 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.



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# 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.



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# 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.



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# 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.



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# Laboratory Services Unit

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



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# 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



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# 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.



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# 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.



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# Thank you!!



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