Medicines Control Authority of Zimbabwe

MEDICINES CONTROL AUTHORITY OF ZIMBABWE (MCAZ)

2017 Stakeholders' Forum
Rainbow Towers, Harare

Gugu N Mahlangu
Director-General

Corporate Statements

Vision

To be an effective medicines regulator in Zimbabwe and a leading regulatory authority in the world.

Key focus 2014-2018

To be a centre of regulatory excellence in Africa by 2018.

Corporate Statements

Mission

To protect public and animal health by ensuring that accessible medicines, allied substances and medical devices are safe, effective and of good quality.

Corporate Statements

Values

- Customer focus
- Integrity
- Continuous improvement
- Accountability

Terms of Reference

Medicines and Allied Substances Control Act [*Chapter 15:03*]

Dangerous Drugs Act [*Chapter 15:02*] and International Conventions

Public Finance Management Act [*Chapter 22:19*]

Corporate Governance Framework

WHO Norms and Standards

OIE Animal Health standards

SADC Guidelines

Operating Environment

- Cash liquidity crunch and price hikes in 3rd and 4th quarters of 2017 driving expenditure
- Continued need to collaborate in activities with WHO, SADC, AMRH, WHO-OIE, FAO
- Realignment to the new State Procurement Board rules
- Sustained market indiscipline impacting on MCAZ reputation
- Ease of doing business reforms
- Strong support from Line Ministry and development partners

Key Result Areas on 2014-2018 Strategic Plan

No.	Key Result Area
KRA1	Sustainable Resource Base
KRA2	Effective Automated Systems
KRA3	Effective Regulatory Processes
KRA4	Skilled and Competent People
KRA5	Good Corporate Governance
KRA6	Value for Money Services

Highlights of Performance for 2017

KRA1 Sustainable Resource Base

Successes

- Operational revenue target of $4.1 million at 99% ($4.094 million) end of November.
- Agreements signed amount to $1.376m against a resource mobilisation target of $500 000.

Challenges

- Complementary medicines revenue target not achieved as submissions in 2017 were suppressed.
- Regulation for medical devices (import and export) not yet approved.
- Increase in operating cost might affect revenue retention levels.

Highlights of Performance for 2017

KRA2: Effective Automated System

Successes

- Automation of HR Processes (Employee Self Service-ESS)
- ZIMDIS migration from FOXPRO to SQL.
- Development of e-ADR/Clinical Trials registry system in progress.
- Automation levels exceeded target of 60% of processes

Challenges

- Failure to acquire services of competent local service providers saw implementation of ERP system stagnant at 48%.
- Delays in Initiation of e-ADR and Clinical Trials Registry work due to cost variations (80k to 240k).
- Challenges on procurement of ICT equipment as contractors unable to deliver due to Forex Challenges.

Highlights of Performance for 2017

KRA3: Effective Regulatory Processes

Successes

- Reduced timelines for exports permits processing from 5 to 2 days.
- Finalisation of the Medical Devices (Import and Export) Draft Regulations
- More effective and efficient response to regulatory complaints due to dedicated inspectorate.

Challenges

- Increase in volume in applications of Section 75 affected processing timelines.
- Increase in non-compliance.
- Local industry unable to keep pace with GMP requirements.

Highlights of Performance for 2017

KRA4: Skilled and Competent People

Successes

- Successful use of competence matrices to upgrade staff.
- Refinement of structure for ICT, EVR and Chemistry has led to improved efficiencies.
- MCAZ staff continued to receive invitations to participate at WHO Expert committees.
- Skills retention is above 95%.

Challenges

- Need to improve training strategy and post-training impact assessment
- Need to align staff remuneration with local and regional benchmarks-no room in 2017.

Highlights of Performance for 2017

KRA5: Good Corporate Governance

Successes

- Retention of Accreditation of ISO 17025 and WHO PQ accreditations
- Recognition by OPC for responsiveness in implementing Ease of doing business initiatives to support export of locally manufactured medicines
- MCAZ Corporate Governance Framework finalised
- Unqualified audit report for 2016 Financials.

Challenges

- Failure to meet set timelines for submission of Annual report.

Highlights of Performance for 2017

KRA6: Value for Money Services

Successes

- Establishment of an effective Public Relations team.
- Improved visibility through increased social media presence.
- Research papers published by MCAZ PVCT on ADRs.
- Conducted customer satisfaction survey and developed strategies to close gaps.

Challenges

- Website navigation and content needs improvement.
- Negative perceptions from customers as reflected in customer survey results.

Statistics in Brief (1)
2017 vs 2016 Performance

Human Medicines

Registrations: 176 (17% increase from 150)

Applications evaluated: 229 (11% decrease from 273)

Applications refused registration: 100

Complementary Medicines since June 2016

Total assessed: 132/168

Approvals: 55

Pending applicant response: 75

Veterinary Medicines

Registrations : 13 (22% decrease from 27)

Applications evaluated: 13 (35% decrease from 20)

Statistics in Brief (2)
2017 vs 2016 Performance

Chemistry

Samples Analysed: 1070 samples analysed in 2017 are *15% higher* than the 930 for the same period in 2016.

Revenue generated: $787 223.50 in 2017 is *8% higher* than the $723 942.55 generated for the same period in 2016.

Global Fund LTA: The Chemistry laboratory managed to retain the coveted Global Fund LTA agreement contract testing of medicines supplied to other LIMCs *(e.g. Afghanistan, Burkina Faso, Djibouti, Ethiopia, Southern Sudan, Uzbekistan, Zambia)*. The world still has confidence in Zimbabwe!

The Future (1)

Expansion Regulatory Scope: Blood and Blood Components, Medical Devices Import/Export, *In-vitro* Diagnostics (IVDs) ongoing

Regulatory guidance in revival of Local Industry: Quality Assurance Programme, the PMA-UNIDO-MCAZ Road Map to GMP Compliance, Risk-based approval processes for established (generic) products,

Adopting International Standards: Still on the way to ISO 17020 for Inspection, ISO 9001:2008 for all SBUs.

The Future (2)

Collaboration

- **Hosting SADC Harmonisation:** will implementing as the hosting agency from 2018 onwards
- **RCORE activities:** implementing activities with UZ School of Pharmacy and ICHE
- **Quality standards for herbal products:** MCAZ and AiBST developing standards for quality testing and pharmacovigilance of herbal medicines and assessment of diagnostics
- **ZAZIBONA for Vet products**: Working towards the replication of a ZAZIBONA-like model harmonization of Veterinary Medicines in SADC

The Future (3)

Collaboration

- **Veterinary Antimicrobial Feed Additives and bulk actives**: Review of legislation control veterinary antimicrobial feed additives and active pharmaceutical ingredients
- **Shared Vision of vibrant local industry:** Continue to provide fit-for purpose risk-based guidance to local manufacturers the QAP, GMP Road maps.
- **Establishment of the African Medicines Agency**: Active participation in this initiative

Acknowledgements

- Ministry of Health and Child Care.
- Partners
- Support of the Authority members and Committee members.
- Dedication and commitment of MCAZ staff members.
- Responsive stakeholders.


Thank You