MCAZ Medicines Control Authority of Zimbabwe

Medicines Control Authority of Zimbabwe (MCAZ)

Stakeholders' Forum 15 December 2017

Rainbow Towers, Harare

Chairman's Report

Presented by Mrs J. Ncube - MCAZ Chairperson

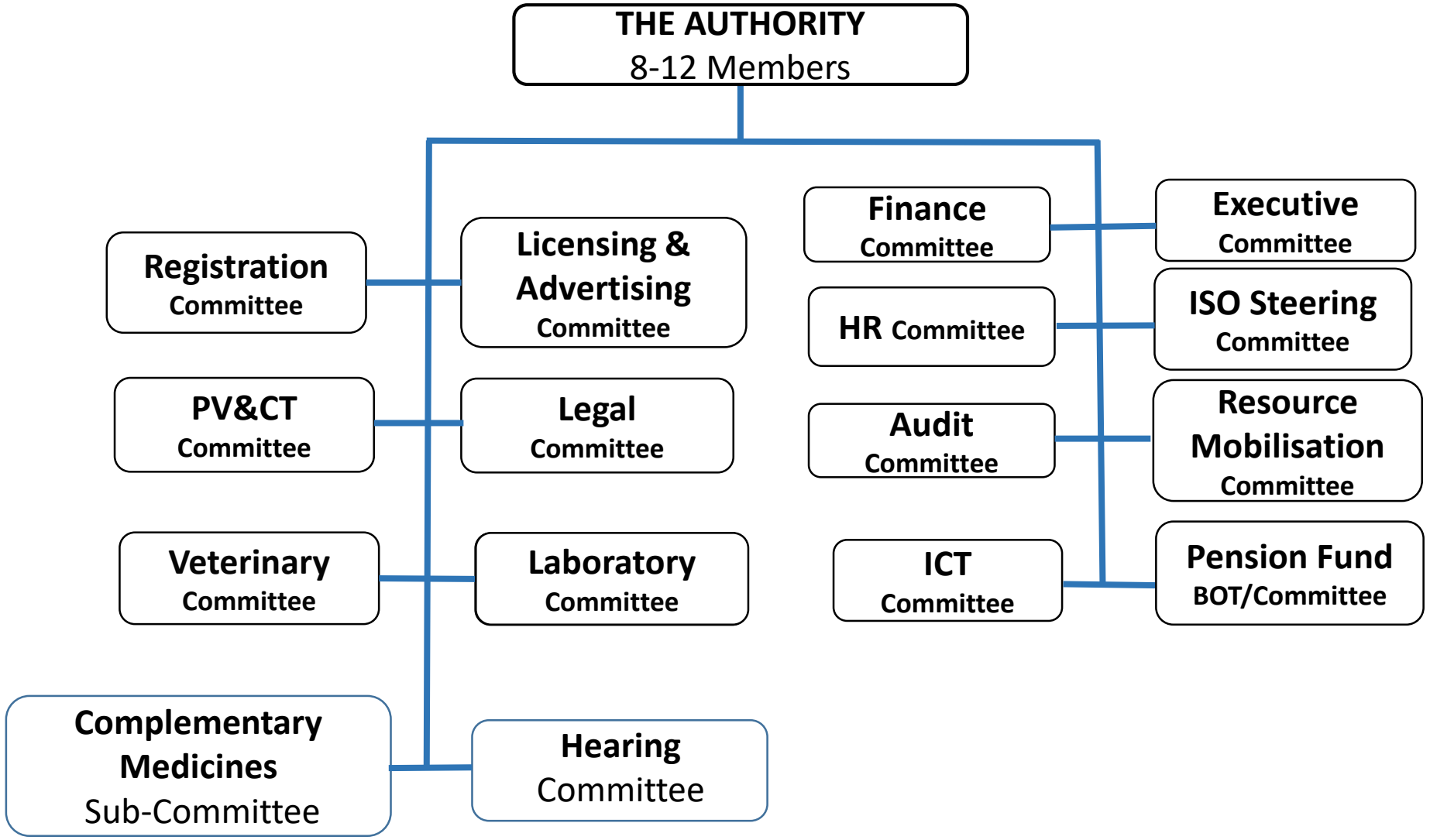
OUTLINE

- MCAZ Mandate
- Board and Expert Committee Structure
- MCAZ Board & Corporate Governance
- Finance Performance
- Highlights of Committee Performance

AUTHORITY'S MANDATE

- Established in terms of the Medicines and Allied Substances Control Act [Chapter 15:03].
- The Authority's mandate is to ensure the availability of safe, effective and good quality medicines and medical devices on the Zimbabwe market.
- This is achieved through the regulation of the manufacturing, distribution, storage and sale of medicines and medical devices.
- The Authority also administers the Dangerous Drugs Act [Chapter 15:20], its Regulations and associated Conventions on behalf of the Ministry of Health & Child Care.

MCAZ BOARD & EXPERT COMMITTEES



MCAZ BOARD & CORPORATE GOVERNANCE

- At the end of each year MCAZ financial statements are **audited by the Auditor-General**.
- The 2016 Annual Report has not been published as the 2016 financial statements are being finalized.
- The MCAZ Corporate Governance Framework adopted by the Authority is being implemented.
- The Authority maintained its subscriptions to Deloittes Tips Off Anonymous in 2017.

EVALUATION OF THE BOARD

- Board and Committee members take their mandate seriously as confirmed by their rate of attendance at scheduled meetings.
- Statistics of attendance by Members are published in the Annual Reports.
- A board induction seminar for new Members of the Board and Committee Members was held in Q3 2017.
- The Board Charter was considered by the Board.

AUDITED FINANCIAL REPORT 2016

- An unqualified audit report was received for 2015.
- The Authority experienced consolidated revenue growth of 9% in 2016 compared to 5% in 2015.
- The Authority reported a deficit of $169k in the year 2016, with consolidated revenue amounting to $4.525m and expenditure totaling $4.695m.
- Revenue collected was made up of income from operations totaling $3.894m, income from grants amounting to $217k, and other income contributing $414k.
- An unqualified audit report for 2016 was received.

FINANCIAL REPORT 2016 CONTINUED …

- The Authority has continued to receive support from various partners and this has helped enhance its operating capacity.

- The Authority maintains a policy of prudent financial management, however, it continues to face challenges in the procurement of assets and remuneration of its critical staff.

Highlights Of Some Committee Activities

Registration Committee

1) Backlog Clearance Activity (to follow)

2) Hosting SADC Medicines Registration Programme

Following a call for expression of interest and review of bids, MCAZ was formally designated Q3, 2017 as the agency to host SADC Medicines Registration programme.

3) Complementary Medicines

Realignment of Complementary Medicines and Allopathic Medicines requirements saw a number of multi-mineral and multi-vitamin preparations below the Recommended Daily Allowances (RDA) being moved to Complementary Medicines General Sale category.

Complementary Medicines Sub-Committee

- A total of 168 applications were received, 55 products have been approved and 75 await applicant responses.
- There is concern that most applicants who received exemption letters before gazetting of SI 97 of 2015 in Sept 2015 did not bring products for approval under the new system.
- The Authority's inspectorate in collaboration with CID Drugs has started ramping up enforcement activities to ensure that only approved complementary medicines are accessible on the market.

Veterinary Committee

1) VICH Outreach Forum

- The Committee authorised MCAZ Secretariat to become members of a forum, the VICH (Veterinary International Conference Harmonisation of technical requirements for registration of veterinary medicines) Outreach forum.
- The Committee updated requirements based on VICH guidelines and OIE standards.

2) Fight against falsified and substandard Veterinary Medicines

- MCAZ continued to fight substandard and falsified veterinary products and has included this in the One Health AMR National plan.

Pharmacovigilance & Clinical Trials Committee

1) Post registration &Post marketing surveillance

- The variation guidelines were revised and circulated in 1St quarter 2017.

2) Clinical trials regulation

- 13 clinical trial applications received and processed.
- Electronic clinical trial application & registry platform is being set up in 4th quarter 2017 with support from UNDP.

3) Pharmacovigilance

- On-line e-ADR are porting tools were revised to include cell-phone and off line reporting forms for vaccines and medicines.
- 923 safety reports received, causality assessment done and one journal publication.
- AEFI causality assessment tools validation project completed by PVCT committee, India New Delhi AEFI committee and WHO.

Licensing and Advertising Committee

1) **Committee Changes**

- Held two (2) Committee meetings per month for part of 2017 - Eighteen 18 meetings were held during the year.

  Will be holding three (3) meetings every two months as from February, 2018.

2) **Regulatory Decisions on Contraventions:** ***The most recurring contraventions were:***

- Poor Supervision of premises.
- Selling of unregistered and / or expired medicines.
- Poor stock management of dangerous drugs.

Regulatory Decision	Year 2016	Year 2017
Warnings	6	9
Strong Warnings	9	8
Final Warnings	113	136
Cases referred for Hearing	40	44

Hearing Committee

- A record 39 Hearings were conducted in the year 2017.
- A total of 7 person's licences were cancelled.
- 1 application to issue a person's licence was refused.
- A total of 9 premises licences were cancelled.

Legal Committee

- The draft Medicines and Allied Substances Control (Import and Export of Medical Devices Regulations were finalized and submitted to the Minister for approval.
- The draft Dangerous Drugs Regulations (Production of Cannabis for Medicinal and Scientific Use) Regulations were drafted and sent to the Minister for approval.
- The MCAZ Corporate Governance framework was finalized in July, 2017.
- The MCAZ Board Charter was finalized in the 7th December, 2017.

Laboratory Committee

- Distribution channels and jurisdictions.
- 1070 samples were analyzed as part of the MCAZ post market surveillance programme and UNDP LTA programme.
- A total of 349 external samples were received compared to 254 samples received in 2016.
- Four HPLCs received from UNDP NFM in 2016 were installed and operational in 2017.
- The Laboratory once again achieved a break-even position.

APPRECIATION

- The Authority would like to express gratitude to the following for support during the year 2015/2016:

1. **The Hon. Minister of Health & Child Care, the Secretary of the Ministry of Health & Child Care and his staff.**
2. **Development Partners who assisted the Authority to execute its mandate in 2016 and 2017.**
3. **Authority and Committee Members.**
4. **Staff and other stakeholders of the MCAZ.**

THANK YOU