MCAZ Medicines Control Authority of Zimbabwe

Client Service Charter

Protecting Your Right To Quality Medicines and Medical Devices

This Charter aims to set service quality standards to the services provided by MCAZ. This charter also sets service time delivery standards for selected key services provided by the Authority's Divisions and Units.

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Acting Director General: _____ 27/6/2022

R. T. Rukwata (Mr) **Date**

Introduction

Medicines Control Authority of Zimbabwe (MCAZ) is a statutory body established by an Act of Parliament, The Medicines and Allied Substances Control Act (MASCA) [Chapter 15.03]. This Client Service Charter has been developed and is managed according to the standards set out by ISO 9001:2015: Quality Management System, in order to uphold the Authority's commitment to continuous improvement of service provision to its valued customers.

Our Client Service Charter provides information on what you can expect, including our service standards, and outlines how you can help us continue to meet your expectations in our delivery of service standards.

About MCAZ

Medicines Control Authority of Zimbabwe (MCAZ) is a statutory body established by an Act of Parliament, The Medicines and Allied Substances Control Act (MASCA) [Chapter 15.03]. MCAZ is a successor of the Drugs Control Council (DCC) and the Zimbabwe Regional Drug Control Laboratory (ZRDCL).

Mission

"To ensure access to safe, effective and good quality medical products and allied substances for the protection of public and animal health."

Vision

"To be an effective and efficient regulator for medical products and allied substances in Zimbabwe, and a comparative regulator globally."

Credo

Protecting your right to quality medicines and medical devices.

Core Values

Customer Focus
Being reliable, responsive to needs, communicating and creating a conducive environment.

Integrity
Being ethical, professional, objective, honest and adhering to moral values.

Continuous Improvement
The ability to be responsive and adapt policies, systems and processes.

Accountability
Taking full responsibility for our actions.

Innovation
Being innovative in our problem solving

Teamwork
Being collaborative, working together as one pursuit of defined outcomes.

MCAZ DEPARTMENTS AND THEIR FUNCTIONS

Chemistry Laboratory

Carries out chemical analysis of medicines/pharmaceutical products for quality, efficacy and safety so as to ensure that medicines/pharmaceutical products in the country meet the required specifications.

Evaluations and Registration Division

Registration of human and veterinary medicines and review of complementary medicines.

Finance Unit

Controls cash flows and expenditure and also manage investments.

Human Resources Unit

Provide leadership and guidance in, and have control over, all the human resources affairs of the Authority through policies and procedures designed to ensure that the Authority achieves its objectives.

Information Communication and Technology Unit

Defines the ICT policies and strategies of the Authority, as well as ensure their implementation and provide daily technical support to users of ICT infrastructure and technology within the Authority, so that the MCAZ achieves its vision and mission.

Internal Audit Unit

Reviews internal control systems, risk management procedures, information system, financial systems and governance processes. This also involves periodic testing of transactions, best practice reviews, special investigations, appraisals of regulatory requirements, and measures to help prevent and detect fraud

Licensing and Enforcement Division

This Division comprises of three functional units:

Licensing

1. Licensing of Persons and Premises
2. Inspection of premises for new applications to verify compliance with the minimum requirements for licensing
3. Approval of applications for the importation of unregistered medicines/donations under the provision of section 75 for individuals and institutions
4. Processing and approval of narcotic and psychotropic licenses, and precursor permits are submitted on a quarterly basis to the International Narcotics Control Board (INCB)

5. Reviewing of advertising material submitted for approval
6. Administration of the forensic examinations

Enforcement

1. Inspections
2. Product Defects and Recalls
3. Market Surveillance and Control
4. Complaints

Import and Export

1. Processing of applications for import and export of medicines
2. Verification of consignments at the ports of entry
3. Training and liaison with port officials

Legal and Corporate Affairs Unit

Reviews and drafts legislation to ensure that it suites the changing needs of the industry and give legal advice to the Authority.

Medical Devices Laboratory

Conformance testing of latex male condoms and medical gloves.

Microbiology Laboratory

Conducts microbiological quality control analysis of medicines/pharmaceutical products for quality, efficacy and safety so as to ensure that medicines/pharmaceutical products in the country meet the required specifications.

Pharmacovigilance and Clinical Trials Division

Pharmacovigilance (PV) (safety monitoring of medicines, vaccines & medical devices) including active PV programs & projects and regulation of clinical trials of medicines, vaccines and medical devices.

Procurement and Administration Unit

Facilitates procurement, maintains the registry and protects all asset.

Projects and Public Relations

Unit within the Director General's office, that is responsible for driving the Authority's Public Relations Strategy, with a focus on public awareness and public engagement.

Quality Unit

Ensures implementation of organizational Quality Management Systems and provides quality oversight to all MCAZ units and divisions

Key timelines

The timelines for the relevant departments processes that interface with the external customers that are outlined below:

Key timelines – Chemistry

The set timeline for chemical analysis is 30 working days
(NB: Where excursions may occur, the customer will be notified.)

Key timelines – Evaluation and Registration

1. WHO Collaborative Registration Procedure – 3 months (MCAZ time)
2. Expedited registration pathway – 6 months (MCAZ time)
3. Zazibona pathway – 9 months (joint review recommendation) & 3 months (country assessment)
4. Complementary medicines – 12 months
5. Veterinary medicines – 15 months
6. Other products – 18 to 24 months overall (including MCAZ & applicant time)

NB: These timelines depend on the completeness and quality of the submission

Key timelines – Licensing and Enforcement

1. Import permit (Registered medicines, Unregistered Medicine, Precursor Substances; Narcotics and Donations) 5 working days
2. Export permit - 2 working days
3. Investigation of product defects and recalls - within 24hours of receipt
4. Complaints - Immediately or within 10 working days for service complaints and 90 working days for regulatory complaints.
5. Verification of consignments at Harare International Airport - 10.30hrs to 12.30hrs Monday to Friday excluding public holidays
6. New Premises License issuance - 2 days from a satisfactory inspection [Note that all matters pertaining to fulfilment of the requirements of the application should be resolved within sixty (60) days of submitting an application.]
7. License/Permit Renewal - 10 working days
8. New premises Inspections - 2 working days within Harare and 5 working days outside Harare (NB: Where excursions may occur, the applicant will be notified.)

Key timelines – Medical Devices

The set timeline for Medical Devises analysis is 13 working days for registered devices and 4-6 weeks for unregistered devices

Key timelines – Microbiology

The set timeline for microbiological analysis is 30 working days.
(NB: Where excursions may occur, the customer will be notified.)

Key timelines – Pharmacovigilance and Clinical Trials

1. Applications for authorisation of Clinical Trials – 60 working days
2. Applications for amendments to clinical trials – 20 working days
3. Clinical trials post-authorisation reports:
    a. Annual reports – 60 working days
    b. Final Reports – 60 working days
    c. Data Safety Monitoring Board (DSMB) /Study Monitoring Committee (SMC) /Data Monitoring Committee(DMC) reports – 60 working days
4. Clinical Trials notifications:
    a. Protocol deviations and violations – 60 working days
    b. Serious Adverse Event (SAE) reports – 60 working days
    c. Safety reports/Updates – 60 working days
5. Applications for authorisation to import investigational products – 5 working days
6. Applications for variations to registered medicines:
    a. Safety updates/Package insert updates – 60 working days
    b. Change of category for distribution – 90 working days
    c. Promotional material – 60 working days
7. Safety signals – 60 working days
8. Spontaneous Adverse Drug Reaction (ADR) reports and Targeted Spontaneous Reports – 60 working days
9. SAE reports from Pharmaceutical Industry – 30 working days
10. Adverse Event Following Immunisation (AEFI) reports:
    a. Serious Events – 30 working days
    b. Non-Serious Events – 60 working days
11. Periodic Safety Update Reports (PSUR) – 60 working days
12. Risk Management Plans (RMP) – 60 working days

NB: These timelines depend on the completeness and quality of the submission/reports, and do not include the time taken by the applicant to respond to queries

ORGANIZATION'S OBLIGATIONS TO THE CLIENTS IN TERMS OF SERVICE PROVISION

Clients' Rights in accessing goods and services

As an administrative body, MCAZ commits to fulfilling the provisions of Section 68 of the Constitution of Zimbabwe, that is, to assure the client's right to administrative conduct that is lawful, prompt, efficient, reasonable, proportionate, impartial and both substantively and procedurally fair.

Clients' Obligations in terms of service provision.

To enable us to assure the client's right to just administrative action, we ask that our clients provide us with all requested information and details in the prescribed format within the prescribed timelines. We also ask that our clients treat our staff with courtesy and respect and refrain from offering gifts, money or other favours.

Review

The MCAZ will endeavour to review the Client Charter every two (2) years to take advantage of the changing environment as well as the needs of its clients, both internal and external.

Feedback

Please feel free to communicate with us when you feel that elements of this charter are not being fulfilled, or if you feel that certain services are not satisfactorily delivered. See contact details below, which you can use to make enquiries or find out about our comprehensive listing of all the services we provide. We are committed to ensuring that all our clients receive fair and reasonable attention, and an efficient standard of service. We value your suggestions and we will attend to complaints in a timely and professional manner. When you provide feedback, your privacy and confidentiality will be respected and protected. You can provide feedback without giving your name. Your compliments are welcome; let us know where we are performing well. Feedback helps us to improve the quality of our information, products and services

How to get in touch with us

You can provide feedback about any aspects of the services provided by the Authority, by:

- Completing a complaint form at 106 Baines Avenue, Harare.
- Completing an online feedback form at www.mcaz.co.zw/contact_us
- Sending an email to the Director General on the email address indicated below.
- Telling any staff member. All staff members are mandated to ensure that all complaints are channeled through the approved process.
- Calling our reception on the telephone numbers indicated below.
- Using the Authority's social media (Facebook, Twitter and LinkedIn) handles - @mcazofficial
- Writing to the Director General using the details given below.

Physical Address: 106 Baines Avenue, Harare
Postal Address: P O Box 10559, Harare, Zimbabwe
Telephone: +263-242-736981/5; 708255; 792165; 0772 145191/2/3
WhatsApp: +263 772 256 303
E-mail: mcaz@mcaz.co.zw
Website: www.mcaz.co.zw

Protecting Your Right To Quality Medicines and Medical Devices

MCAZ Clients

Internal Clients
Staff

External Clients
Applicants
Manufacturers
Distributors
Retailers
Industrial clinics
Persons (dispensers)
Hospitals and clinics
Researchers
Public
Other stakeholders such as Ministry of Health and Child Care, Natpharm, ZNFPC, NAC, UNDP, UNICEF and other Development Partners

SERVICE COMMITMENTS AND STANDARDS

Courtesy

We at the Medicines Control Authority of Zimbabwe commit to being courteous and approachable in our relations with the public. When answering correspondence, telephone calls and e-mails, we shall try as much as possible to be helpful and to reply to the questions that are asked.

Legitimate expectations and consistency

We commit to respect the legitimate and reasonable expectations of members of the public.

Fairness

We commit to act fairly and reasonably.

Acknowledgement of receipt

Every letter or complaint to the Authority shall receive an acknowledgement of receipt within 24 hours

Reasonable time-limit for taking decisions

We shall ensure that a decision on every request or complaint to the Authority is taken within a reasonable time limit but if requiring the decision of the Committee, not later than two months from the date of receipt. The same rule shall apply to answering letters from members of the public. If a request or a complaint to the Authority cannot be decided upon within the above-mentioned time-limit, because of the complexity of the matters which it raises, we shall inform the author thereof as soon as possible. In that case, a definite decision should be notified to the author in the shortest possible time.

Service complaints shall be addressed within **10 working days** from the date of receipt of the complaint in the Unit/Division.

Regulatory complaints are to be addressed within 90 working days, depending on the nature of the complaint.