Medicines Control Authority of Zimbabwe

MCAZ/QU/GL-01

CUSTOMER COMPLAINTS AND APPEALS GUIDELINE

EFFECTIVE DATE: 01/2022

Medicines Control Authority of Zimbabwe

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Authorised by Director General:	 Signature	26/01/2022 Date

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1.0 APPLICATION

This guideline applies to all Medicines Control Authority of Zimbabwe (MCAZ) stakeholders/interested parties/customers.

2.0 PURPOSE

The document serves to guide the public, MCAZ stakeholders/interested parties/customers on how they can forward complaints and/or make an appeal in the case of a regulatory decision regarding MCAZ regulated products or services offered. All complaints and appeals are acknowledged and dealt with fairly, efficiently and effectively. Confidentiality will be maintained at all times. MCAZ values customer feedback as this will continuously assist in improving its services.

3.0 BACKGROUND / INTRODUCTION

The Medicines Control Authority of Zimbabwe is a statutory body established by an Act of Parliament, the Medicines and Allied Substances Control Act, (Chapter 15.03). The mandate of the Authority is to protect public and animal health by ensuring that accessible medicines, allied substances and medical devices are safe, effective and of good quality. The services offered by the Authority include:

3.1 Evaluation and registration of medicines and allied substances
3.2 Licensing of premises and persons
3.3 Pharmacovigilance and clinical trials
3.4 Control of manufacture, distribution and storage of medicines and medical devices
3.5 Inspections and post market surveillance
3.6 Quality control testing of medicines and medical devices
3.7 Administration of the Dangerous Drugs Act on behalf of the Ministry of Health and Child Care

MCAZ is certified and accredited to the following standards:

i. ISO 9001:2015,
ii. ISO 17025:2017,
iii. ISO 17020:2012
iv. and WHO prequalification

thus the Authority is committed to offering services that meet and exceed customer requirements and expectations. Any stakeholder/interested party/customer is as a result free to forward a complaint or appeal to the Authority in the event of dissatisfying services having been offered.

4.0 DEFINITIONS

4.1 **Complaint**: refers to an expression of dissatisfaction with a product or service, filed by a customer and received by the Authority or individual.

4.2 **Regulatory Complaint**: a written, electronic or oral communication by an informant of alleged contraventions against the Medicines and Allied Substances Control Act (Chapter 15:03), the Dangerous Drugs Act (Chapter 15:02) and their regulations committed or being perpetrated by a third party.

4.3 **Service complaint**: a written, electronic or oral communication against the way in which the Authority performance fails to satisfy a need or to fulfil requirements of stakeholders/interested parties/customers. The complainant is affected by the mediocre service from MCAZ be it an inefficient process, an error-ridden document or failure to meet indicated timelines.

4.4 **Appeal**: an objection against a decision that has been made by the Authority on a complaint, hearing, laboratory results or any other forum.

5.0 GUIDELINES

MCAZ stakeholders/interested parties/customers and the public have a right to lodge a complaint or an appeal when dissatisfied with a decision of the Authority in the following regulatory functions:

i. **Marketing Authorization or Registration**
ii. **Inspection and Licensing of manufacturers, importers, exporters and wholesalers and retailers of regulated products**
iii. **Regulatory enforcement actions,** such as-Detention and/or seizure of medical products, Recall and withdrawal of medical products, Disposal of medical products
iv. **Control of clinical trials of medical products**
v. **Control of promotion and advertisement of regulated products**
vi. **Laboratory testing of regulated products**
vii. **Sale of unregistered medicines**
viii. **Sale of expired medicines**
ix. **Complaints on registered medicines-**failure to comply with labelling requirements, no package insert, distribution outside approved category for distribution, illegible writing on package insert/label
x. **Sale or advertising of complementary medicines with medicinal claims**
xi. **Complaints involving persons-**medical practitioner, pharmacist, nurse, pharmacy technician or veterinary in relation to sale or use of medicines and allied substances.
xii. **Complaints involving premises-** dispensing practice, pharmacy, clinic, wholesale dealer, general dealer e.g. VMGD, Supermarket, Tuck shop etc.
xiii. **Any other decision made by the Authority that may affect his or her business**

5.1 Complaints

5.1.1 Customer complaints can be forwarded to Authority as verbal complaints, written complaints, through email, by telephone or any other MCAZ platform such as the website.

5.1.2 Complaints can also be lodged through social media platforms such as WhatsApp, Facebook, Instagram, Twitter etc.

5.1.3 Customer complaints can be recorded on the Customer Complaints form (QF 11a) available at the MCAZ reception (*Appendix I*) or completed electronically from the website: https://www.mcaz.co.zw/documents/quality-assurance-docs/forms/

5.1.4 To aid the Authority in the investigations, the following information shall be submitted with the complaint where possible:

i. Exact location,
ii. Description and possibly directions of the premises to be investigated,
iii. Contact details for the person to be investigated.

5.1.5 An investigation on the cause of the complaint shall be instituted by the Authority to identify the system gaps.

5.1.6 Written feedback highlighting the actions taken by the Authority to address the issues raised shall be sent to the stakeholder/interested party/customer. The feedback shall include findings of the investigation, references to evidence and reasons for the decisions taken. The response shall be sent to the aggrieved person within 20 working days for service complaints and a maximum of 90 working days for regulatory complaints.

5.2 Appeals

5.2.1 Appeals against any decision made by the Authority on regulatory complaints, hearings and decisions from any other forums

In the event that any stakeholder/interested party/customer wishes to contest a decision made by the Authority following a hearing, decisions from any other forum or with regards to regulatory complaints, he/she shall, within 30 days after having been officially informed of such a decision, give notice in writing to the Administrative Court as outlined in Section 62 of the Medicines and Allied Substances Control Act (Chapter 15.03).

5.2.2 Appeals from a service complaint

In the event that any stakeholder/interested party/customer wishes to contest a decision made by the Authority on the service complaint and/or laboratory results, he/she shall, within 14 days after having been officially informed of such a decision, give notice to MCAZ verbally, through email, by telephone or any other MCAZ platform. Appeals can be recorded on the Appeals form (QF 11c) available at the

MCAZ reception (Appendix II) or completed electronically from the website: https://www.mcaz.co.zw/documents/quality-assurance-docs/forms/. The aggrieved person shall ensure that the appeal request includes the following:

i. Reference to the Customer complaint number, Certificate of Analysis Sample Reference number for laboratory results and/or any other documents from which the appeal has risen,
ii. A copy of the initial decision notification letter (or other evidence of notification) stating clearly the regulatory decision for which the appeal is based,
iii. Any information/documentation indicating the reasons why review is requested,
iv. A description of how the interests of the aggrieved person are affected by the regulatory decision.

All the relevant information and documents shall be provided at the time the appeal is presented to the Authority. Any additional information considered necessary shall be requested by the Authority in the course of the investigations.

In the event that the aggrieved person is a third party (i.e. not the main person to whom the regulatory decision was initially issued by the Authority), MCAZ shall also notify in writing, the Responsible person to whom the regulatory decision was initially issued informing them that a request for the review has been received by MCAZ. All appeals received by MCAZ shall be acknowledged and investigated by the responsible Division/Unit as determined by the Director-General. Where required, an Administrative Appeal Committee shall be established to consider new information submitted with the appeal application and come up with the actions plan to be implemented. For laboratory results, the appeal shall be tabled at the Laboratory Committee meeting or any other Committee deemed for consideration and advice.

Written feedback highlighting the actions taken by the Authority to address the issues raised shall be sent to the stakeholder/interested party/customer. The feedback shall include findings of the investigation, references to evidence and reasons for the decisions taken. The response shall be addressed to the aggrieved person within 30 days after submitting an appeal application for service complaints. For laboratory results, the response shall be sent to the aggrieved person within a maximum of 90 working days.

6.0 KEY RELEVANT DOCUMENTS

6.1 Medicines and Allied Substances Control Act
6.2 MCAZ ISO 9001:2015 Quality Policy Manual
6.3 Customer Complaints Procedure, MR 4.8

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Date Reviewed: New Document
N/A	N/A	Reason for Change and Amendment N/A

APPENDICES

APPENDIX I: CUSTOMER COMPLAINT FORM

MCAZ Medicines Control Authority of Zimbabwe

QF 11(a)

QUALITY UNIT

CUSTOMER COMPLAINT FORM

SECTION A: CUSTOMER DETAILS

1.0 Date:_____ Complaint No: _____

1.1 Complaint made by (not mandatory for anonymous complainants):

1.1.1 Name: _____

1.1.2 Address: _____

1.1.3 Telephone:_____ E-mail:_____

1.2 Name of Organisation (if applicable):

_____

1.3 Complaint delivery: Written complaint ☐ E-mail ☐ Telephone ☐ Verbal ☐

Social media platform e,g Whatsapp, facebook, instagram, twitter ☐

1.4 Details of Complaint

_____

To aid the Authority in the investigations, would you please complete the following sections?

1.5 Exact location, description of premises and possibly directions (where applicable) of the premises to be investigated.

_____

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QF 11(a)

1.6 Contact details for the person to be investigated (where applicable)

_____

_____

_____

_____

1.7 Complaint Received at MCAZ By: _____ _____ _____

Name Signature Date

APPENDIX II: APPEALS FORM

MCAZ Medicines Control Authority of Zimbabwe

QF 11(c)

APPEAL FORM

An objection against a decision that has been made by the MCAZ on Complaint Reference number:_____

1.1 Details of Appeal

_____

_____

_____

_____

_____

_____

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_____

_____

_____

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_____

1.2 Appeal Received at MCAZ By:_____ _____ _____
Name Signature Date

FOR MCAZ USE

2.1 Appeal received in Quality Office by:_____ _____
Signature Date

2.2 Appeal forwarded to DG by the Quality Manager:_____ _____
Signature Date

2.3 Appeal received in DG's office by: _____ _____
Signature Date

2.4 DG's Comments:

_____

_____

_____

_____

Signature: _____ Date: _____

QF 11(c)

2.2 Appeal to be investigated by:

_____

(Unit/Division)

2.3 Appeal received in Unit/Division by: _____ _____

Signature Date

3.1 Findings from Investigation

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3.2 Unit/Division Representative

Name	Designation	Signature	Date

4.0 CAPA PLAN and IMPLEMENTATION

Corrective Action	Preventive Action	Responsible Person	Completed Date

QF 11(c)

Corrective Action	Preventive Action	Responsible Person	Completed Date

5.1 Verification of Action by DG/QM

Name Designation Signature Date

6.1 Feedback Sent to Customer: **Reference B/279/ / / Dated** _____

7.1 Recorded By: _____ _____ _____
Name Signature Date