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Medicines Control Authority of Zimbabwe

MCAZ/LED/GL-05

GUIDELINES FOR SECTION 75 APPLICATIONS TO IMPORT UNREGISTERED MEDICINES

EFFECTIVE DATE: 12/01/2024

Medicines Control Authority of Zimbabwe

106 Baines Avenue

P O Box 10559

Harare

Email: mcaz@mcaz.co.zw

Website: www.mcaz.co.zw

Written by:	Signature	Date 11/01/24
Checked by HoD/HoU:	Signature	Date 11/01/24
Authorised for use by: Quality Manager	Signature	Date 12/01/24
Approved by: Director-General	Signature	Date 12/01/2024

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1.0 APPLICATION

This guideline applies to all licensed and approved persons who intend to import unregistered medicines either for individuals or on behalf of institutions.

2.0 PURPOSE

The purpose of this guideline is to ensure that applications are processed in accordance to Section 75 of the Medicines and Allied Substances Control Act *(Chapter 15:03)*. The guideline also seeks to assist applicants to submit complete applications to avoid unnecessary delays in the processing of their applications.

3.0 BACKGROUND / INTRODUCTION

The Medicines Control Authority of Zimbabwe (MCAZ) may in accordance with Section 75 of the Medicines and Allied Substances Control Act *(Chapter 15:03)* in writing, exempt, subject to such conditions as it may specify, any medicine or substance from the operation of any or all the provisions of this Act. Accordingly, the Authority may authorise the importation of a medicine where there is no registered alternative available in the country. The Authority may also issue authorisation where there is a registered alternative that will not be available on the market at the time.

4.0 DEFINITIONS

4.1 **Authority**: Medicines Control Authority of Zimbabwe (MCAZ)

4.2 **Approved establishment**: one that is registered by the Health Professions Authority of Zimbabwe (HPA)

4.3 **Individual named patient application:** is a type of application submitted on behalf of individual named patient in cases where a medical practitioner would have prescribed an unregistered medicine.

4.4 **Institutions:** is a type of application received from institutions that may apply for Section 75 that include but are not limited to; hospitals, clinics, and non-governmental organisations. Institutions that submit their applications should either be licensed by the Authority or be an approved establishment. In this scenario, certain unregistered medicines need to be available urgently within the institutions and applications for individually named patients may not always be feasible.

5.0 GUIDELINES

5.1 Roles and Responsibilities

5.1.1 Role of the Zimbabwe Registered Medical Practitioner

i. To assess the condition of their patient and their future pharmaceutical needs.
ii. To prescribe products that are registered with the Medicines Control Authority of Zimbabwe (MCAZ).
iii. Where a patient requires a medicine NOT registered in Zimbabwe, an application should be made by the medical practitioner to the MCAZ, seeking approval for the importation of the unregistered specified medicine according to Section 75 of the Medicines and Allied Substances Control Act, *(Chapter 15:03).*

5.1.2 The role of the patient

i. To take their prescription to their pharmacy who can facilitate authorisation from the MCAZ.
ii. The prescription should be submitted to the pharmacy within three (3) months of the prescription being written.
iii. Before or on the last dispensing of the unregistered specified medicine, the patient must return to their practitioner for reassessment and deliver a new prescription accompanied by a progress report.

5.1.3 The role of the Pharmacist

i. To collect all prescriptions and upload them on the online application platform.
ii. To upload the patient clinical information, obtained from the prescribing doctor, on the online application platform.
iii. To pay an application fee as per the fee schedule.
iv. To source on behalf of the patient their unregistered medicine via the best cost-effective means ensuring the highest safety, efficacy and quality profiles of the specified product(s).
v. To procure the medication within six (6) months of the authorisation by the MCAZ.
vi. In order to help the processing facility, the pharmacist must upload proforma invoice with the name and strength of the medicine(s) and the total quantities required.
vii. All letters of authorisation from the MCAZ must be supplied to the Port Authority for scrutiny and ultimate clearance.
viii. Endorsement of script by community pharmacist.

5.1.4 The role of institutions

i. To identify a need for a certain medicine(s) which they know is of clinical significance but is unregistered by the MCAZ. These can be for named patients or for use within the institution.
ii. To upload an application written on the letterhead of the institution stating the unregistered medicine(s), the quantity to be imported, strength of the medicine, dosage form, manufacturer of the medicine and the name of the importer.
iii. To pay an application fee as per the fee schedule.
iv. The hospital pharmacist is to submit monthly returns indicating quantities and to whom supplied by the seventh day of each month.

5.1.5 The role of the Wholesale Dealer

i. To source on behalf of the patient or institution the unregistered medicine via the most cost-effective means ensuring the highest safety, efficacy and quality profiles of the specified product(s).
ii. To procure the medication within six (6) months of the authorisation by the MCAZ.
iii. To notify the Authority in writing in the event that a named patient or institution fails to collect their medicine or exhaust the supply which was imported on their behalf. The notification shall include the details of the new proposed applicant. The Authority will then evaluate and notify the importer of its decision.

5.1.6 The role of the Authority

i. To ascertain whether the specified product is registered in Zimbabwe or not and whether there is a suitable alternative product available in consultation with the relevant doctor and pharmacist.
ii. To assess the quality, safety, and efficacy of the product that the applicant has submitted.
iii. To issue a letter of authorisation within five (5) working days that will allow ease of importation of the unregistered specified medicine via the Port Authority. In the event that the application is rejected, the applicant will be required to address the reasons indicated for the rejection.

5.2 Application process

5.2.1 Applications are submitted through the online platform that can be accessed from the link below;

https://onlineservices.mcaz.co.zw/mcazonlineservices/OnlineUserLogin

5.2.2 **Individual named patients**: A valid prescription should be uploaded for applications for individual named patients.

5.2.3 **Institutions:** A letter on company letterhead, which is dated and signed should be uploaded by institutions. This letter should indicate the name of the medicine (generic and or brand name), strength, dosage form, and quantity to be imported, name of manufacturer and country of origin.

5.2.4 **Timelines:** The application should be processed within five (5) working days. Please be advised that all incomplete applications will be rejected, and the applicant will be required to resubmit the application.

5.2.5 **Bulk importation by wholesalers:**

i. Applications for bulk importation shall apply in cases where the wholesaler has submitted an application for a dossier for registration or has a variation or amendment that was submitted to the Authority and is still being considered. Proof of submission of these documents should be uploaded online at the point of application.
ii. This procedure shall apply to all medicines except for blood products and cancer therapy medicines which are both registered and unavailable, or unregistered medicines. The application should be processed within five (5) working days.

5.2.6 **Bulk importation by Pharmacies:**

i. All bulk imports of unregistered medicines by pharmacies shall be provided for under Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, 2008 (SI 57 of 2008).
ii. The applicant shall complete form I.E.2 and submit online attaching proforma invoice and proof of payment.
iii. Each application will be restricted to a total of 10 items, and only a single supplier will be authorized per permit. This means an application where the applicant intends to import the products from multiple suppliers will be rejected.
iv. The applicant will be required to pay the following fees as prescribed by the fee schedule for the following:
    a. Application for import permit.
    b. Application fee to import unregistered medicines in bulk per product or per line item.
    c. Verification fees upon importation of consignment.
v. The total value per line item will be restricted to $2000 and can be reviewed on a case-by-case basis.

vi. The acquisition of "letters of no objection" from local suppliers by applicants prior to authorisation of importation shall no longer be a requirement.

vii. An applicant, under this framework, may be authorised to import unregistered medicines even when there are registered alternatives, on condition that a separate motivation is submitted to the Authority, explaining why such importation would be desirable. The key motivation must be driven by improvement of access by the people of Zimbabwe to medicines that are safe, of good quality and effective. This process will however be the exception and not the rule. Pharmacists are encouraged to as much as possible procure registered medicines from locally approved wholesale dealers wherever possible.

viii. This framework is not restricted to the importation of essential medicines. Other medicines may be considered on a case-by-case scenario. Applicants are however encouraged to restrict their applications as much as possible to life-saving medicines in the application of this framework.

ix. It is critical to note that Section 4(4) of S. I. 57 of 2008 applies to practitioners and not companies. This means that the responsibility for the sale of these medicines lies with the individual pharmacist who endorses the application submitted under this framework. A further implication is that this process cannot be applied to a company with multiple pharmacies which utilises a centralised buying process. Applications will have to be restricted to a single branch and further, to the pharmacist supervisor who is authorised on the premises licence to supervise that specific branch. These requirements are meant to prevent pharmacists from abusing this framework by engaging in wholesale dealing. Imports under this framework will be restricted to the pharmacists and the approved premises authorised under the permit unless authorisation to transfer stocks is granted by the Authority.

5.3 Points to take note of

5.3.1 **Labelling of medicines:** All medicines must be labelled in the English language; the label on each individual container should contain the international non-proprietary name (INN) or generic name, and the following: batch number, dosage form, strength of the medicine, name of manufacturer, quantity in the container, storage conditions, date of manufacture and expiry date.

5.3.2 **Shelf life:** The medicines should have at least one (1) year shelf life remaining after arrival in Zimbabwe.

5.3.3 **Ports of entry:** The medicines should be imported through the designated ports of entry, and these are as follows;

i. Bulawayo Airport;
ii. Harare Airport;
iii. Beitbridge;
iv. Bulawayo;
v. Harare;
vi. Plumtree; and
vii. Forbes

5.3.4 **Physical examination of consignments:** For consignments of medicines that are cleared at any other port of entry excluding Harare Airport, the importer is required to schedule an appointment with the inspectors for physical examination of the medicines before use or distribution.

5.3.5 **Record keeping:** All records with respect to the sale of unregistered medicines should be maintained and easy to retrieve upon request by the Authority. The records should capture the name of the patient or institution, and the quantity used or distributed.

5.3.6 **Advertising:** Advertising of unregistered medicines is prohibited. According to Section 65 (1b) of the Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991, "No person shall advertise any other medicine without the approval of the Authority in writing."

5.3.7 **Reporting of adverse reactions:** All applicants are advised to report any adverse drug reactions that may be encountered through the use of the Authority's various ADR reporting tools available on the website, www.mcaz.co.zw

6.0 KEY RELEVANT DOCUMENTS

6.1 Medicines and Allied Substances Control Act *(Chapter 15:03)*

6.2 Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	**Reason for change:** System improvement
0	July 2021	**Section 5.1.3** **Changed from** i. To collect all prescriptions and forward them to MCAZ for approval. ii. To pay an application fee as per the fee schedule. iii. To source on behalf of the patient their unregistered medicine via the best cost-effective means ensuring the highest safety, efficacy, and quality profiles of the specified product(s) iv. To procure the medication within six (6) months of the authorisation by the MCAZ v. In order to help the processing facility, the pharmacist must submit an order sheet with the name and strength of the medicine(s) and the total quantities required. vi. All letters of authorisation and stamped prescriptions with authorisation numbers from the MCAZ must be supplied to the Port Authority for scrutiny and ultimate clearance. vii. Endorsement of script by community pharmacist. **Changed to** i. To collect all prescriptions and upload them on the online application platform. ii. To upload the patient clinical information, obtained from the prescribing doctor, on the online application platform. iii. To pay an application fee as per the fee schedule. iv. To source on behalf of the patient their unregistered medicine via the best cost-effective means ensuring the highest safety, efficacy, and quality profiles of the specified product(s). v. To procure the medication within six (6) months of the authorisation by the MCAZ. vi. In order to help the processing facility, the pharmacist must upload proforma invoice with the name and strength of the medicine(s) and the total quantities required.

		vii. All letters of authorisation from the MCAZ must be supplied to the Port Authority for scrutiny and ultimate clearance. viii. Endorsement of script by community pharmacist. **Section 5.1.4** **Changed from:** ii. To submit an application written on the letterhead of the institution stating the unregistered medicine(s), the quantity to be imported, strength of the medicine, dosage form, manufacturer of the medicine and the name of the importer. **Changed to:** ii. To upload an application written on the letterhead of the institution stating the unregistered medicine(s), the quantity to be imported, strength of the medicine, dosage form, manufacturer of the medicine and the name of the importer. **Added Section 5.2.5** **Bulk importation by wholesalers**: (i) Applications for bulk importation shall apply in cases where the wholesaler has submitted an application for a dossier for registration or has a variation or amendment that was submitted to the Authority and is still being considered. Proof of submission of these documents should be uploaded online at the point of application. (ii) This procedure shall apply to all medicines except for blood products and cancer therapy medicines which are both registered and unavailable, or unregistered medicines. The application should be processed within five (5) working days. **Added Section 5.2.6** **Bulk importation by Pharmacies:** (i) All bulk imports of unregistered medicines by pharmacies shall be provided for under Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, 2008 (SI 57 of 2008) (ii) The applicant shall complete form I.E.2 and submit online attaching proforma invoice and proof of payment.

		(iii) Each application will be restricted to a total of 10 items, and only a single supplier will be authorized per permit. This means an application where the applicant intends to import the products from multiple suppliers will be rejected. (iv) The applicant will be required to pay the following fees as prescribed by the fee schedule for the following: a. Application for import permit. b. Application fee to import unregistered medicines in bulk per product or per line item. c. Verification fees upon importation of consignment. (v) The total value per line item will be restricted to $2000 and can be reviewed on a case-by-case basis. (vi) The acquisition of "letters of no objection" from local suppliers by applicants prior to authorisation of importation shall no longer be a requirement. (vii) An applicant, under this framework, may be authorised to import unregistered medicines even when there are registered alternatives, on condition that a separate motivation is submitted to the Authority, explaining why such importation would be desirable. The key motivation must be driven by improvement of access by the people of Zimbabwe to medicines that are safe, of good quality and effective. This process will however be the exception and not the rule. Pharmacists are encouraged to as much as possible procure registered medicines from locally approved wholesale dealers wherever possible. (viii) This framework is not restricted to the importation of essential medicines. Other medicines may be considered on a case-by-case scenario. Applicants are however encouraged to restrict their applications as much as possible to life-saving medicines in the application of this framework. (ix) It is critical to note that Section 4(4) of S. I. 57 of 2008 applies to practitioners and not companies. This means that the responsibility for the sale of these medicines lies with the individual pharmacist who endorses the application submitted under this framework. A further implication is that this process cannot be applied to a company with multiple pharmacies which utilises a centralised buying process. Applications will have to be restricted to a single branch and further, to the pharmacist supervisor who is authorised on the

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