MCAZ Medicines Control Authority of Zimbabwe

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CIRCULAR 25 of 2023

21st November, 2023.

To: All Licensed Community Pharmacists
Community Pharmacists Association (CPA) Members
Hospital Pharmacies
Restricted Pharmacies

RE: IMPORTATION OF UNREGISTERED MEDICINES BY PHARMACISTS UNDER STATUTORY INSTRUMENT 57 OF 2008

Preamble

The Authority has noted challenges with access to unregistered medicines mostly by community pharmacists following the withdrawal of Circular 4 of 2019. The following measures are meant to provide for better access by pharmacists to good quality medicines that are safe and efficacious for the good of the Zimbabwean people. This circular will tackle matters that may require further interpretation. It is necessary therefore to point out that the primary responsibility regarding the interpretation of any and all matters addressed in this circular lies with the Director-General of MCAZ.

Reference is made, for the purposes of this circular, to the following statutory instruments, statutory provisions and authorised documents, which are all available on the MCAZ website:

1) Section 75 of the Medicines & Allied Substances Control Act (Chapter 15:03).
2) Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, 2008 (SI 57 of 2008).
3) MCAZ Reliance Guidelines for Regulation of Medicines (MCAZ/EVR/GL-4).
4) Item numbers 10, 35 and 37 of the MCAZ Fee Schedule

Application of SI 57 of 2008 to the importation of unregistered medicines

Specific attention is drawn to sections 2, 3, 4(3), 4(4), 6 and 10 of the Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, 2008 (SI 57 of 2008), hereinafter referred to as "the Regulations" which provide for the importation and exportation of medicines.

Section 2 of the Regulations provides for the definition of "authorized person", 2(b) specifically provides for pharmacies holding licences issued in terms of the Act.

Section 3 of the Regulations provides for the application of the regulations and reads as follows:

3. These regulations shall apply to ***all medicines*** *other than—*
(a) those controlled in terms of the Dangerous Drugs Act [Chapter 15:02]; and
(b) psychotropic substances controlled in terms of the Medicines and Allied Substances Control (General) Regulations, 1991; and
(c) medicines imported in terms of section 75 of the Act for a named person*; and*
(d) medicines imported by an individual for personal use.

It is important to note that in accordance with **Section 3(c)** only medicines imported in terms of s75 of the Act **for a named person** are exempted from the application of the Regulations. All bulk imports of unregistered medicines are therefore duly provided for in the Regulations. **This is the legal basis of the process to be introduced in this Circular.**

Section 4(3) provides for the appointment of persons as authorised importers. For clarity, this provision will **not** apply for the purposes of this Circular, particularly because this Circular addresses the importation of unregistered medicines.

Section 4(4) provides for the control of imports and reads as follows:

(4) Any pharmacist, veterinary surgeon, dental practitioner or medical practitioner may import into Zimbabwe ***any medicine*** *for no other purpose except for resale, from authorized premises, to his or her customers, patients, or clientele, as the case may be.*

It is important to note that this provision, when read with Section 3 above, provides for the importation of unregistered medicines by practitioners, in bulk, strictly for resale to their customers from authorised premises. This Circular applies specifically to community pharmacists, as they are primarily seized with the primary responsibility to acquire and sell medicines to the Zimbabwean public.

Section 6 of the Regulations provides for the issuance of an import or export permit by the Director-General to any authorised person who makes an application in terms of section 5 and further provides for the imposition of such conditions as he or she may consider necessary or desirable.

Section 10 provides that every person who is issued with an import permit in terms of section 6 shall, on the importation of such medicine pay a consignment clearance fee prescribed in the Second Schedule.

Detailed framework for the importation of unregistered medicines by pharmacists under SI 57 of 2008

1. Pharmacists interested in importing unregistered medicines in bulk (i.e. not on a named patient basis) will, with immediate effect, be required to submit applications in terms of Section 5 of SI 57 of 2008.
2. The above applications shall be made in Form I.E.2. For the purposes of this framework the requirement provided under Section 5(2)(h) will be waived, since the medicines will be unregistered.
3. For the purposes of this framework, the provisions of Section 5(3) will apply only in relation to the submission of a copy of a proforma invoice from the supplier, the consent by the Principal will not be required.[1]
4. The applicable fee in terms of Section 5(1)(a) shall be payable upon submission of an application in terms Section 5 of the Regulations.
5. For the time being, in a bid to make this process manageable, each application will be restricted to a total of 10 items, and further, only a single supplier will be authorised per permit. This means an application where the applicant intends to import the products from multiple suppliers will be rejected.
6. The applicable fee under item 10(b)(iii) of the Fee Schedule will be payable per line item for all unregistered medicines.
7. To ensure that the medicines imported under this framework are restricted to the purposes intended under Section 4(4) of the Regulations, the total value per line item will be restricted to a maximum of US$2000.00. This limit can be adjusted upwards or downwards as time progresses as the effectiveness of this framework is evaluated.
8. As this framework may require some significant amendment to the online application process, the Authority may require more time to deal with applications therefore the initial timelines for this process will be a maximum of seven (7) working days for issuance of a permit after submission of a complete and satisfactory application. Timelines should revert to five (5) working days after 90 days of implementation.
9. Upon successful importation under this framework, the applicable verification fees will be payable as prescribed under item 34 of the MCAZ Fee Schedule.
10. The acquisition of "letters of no objection" from local suppliers by applicants prior to authorisation of importation shall no longer be a requirement.
11. 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.[2]

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[1] The Authority is mandated to prevent the importation of counterfeited products therefore it is critical that unregistered medicines imported into Zimbabwe must be traceable back to legally recognisable sources.

[2] The Authority's interest is in promoting the registration of medicines and restricting the importation of medicines only to those that are approved and registered. However, some damning evidence has been submitted proving that some suppliers are engaging in predatory pricing practices. In the interest of encouraging competitive pricing therefore, for the purposes of improving access to medicines, community

12. 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.
13. **It is critical to note that Section 4(4) 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.

Authorised sources for the purposes of this framework

a) Sources whose cGMP status is already approved by the Authority.
b) Sources under Stringent Regulatory Authorities, subject to conditions which the Authority may put in place from time to time.
c) Sources under WHO GBT Maturity Level 3 NMRAs,[3] where cGMP status can be verified and the supplier has an effective pharmacovigilance program.
d) Sources under WHO Listed Authorities, subject to conditions which the Authority may put in place from time to time.
e) Products registered under the ZAZIBONA process in the SADC Regional Economic Community.
f) Products registered by the South African Health Products Regulatory Authority (SAHPRA)[4], such products should be actively marketed in the Republic of South Africa. The link to the SAHPRA register is https://medapps.sahpra.org.za:6006/
g) The Authority may apply the guidance provided in the MCAZ Reliance Guidelines for Regulation of Medicines (MCAZ/EVR/GL-4) with regards to the addition or subtraction of sources for the purposes of this framework.

General rules and disclaimers

1. Applicants should note that the Authority reserves the right to amend this framework without notice, any changes would however only apply prospectively and would not apply to applications already under consideration.
2. To allow for a smooth operational framework, the Authority will be providing training resources for applicants with respect to the implementation of this framework. This

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pharmacists **may** be authorised to import unregistered medicines even where registered alternatives are available, but only consistent with section 4(4) of the regulations, and further upon submission of sufficient justification and also taking into consideration the matter of authorised sources.

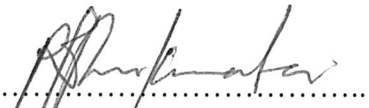
[3] National Medicines Regulatory Authorities

[4] This applies only to products whose status is "registered" on the SAHPRA register, "old medicines" are exempted from the application of this framework unless special authorisation is granted.

should also help in the reduction of rejections of applications which could be costly to applicants. Training will either be free or provided for a fee depending on the method of delivery of the training.

3. The Authority will also provide resources like Frequently Asked Questions (FAQs), clarification on authorised sources and any relevant clarifications emanating from the implementation of this framework. These resources will be shared on the MCAZ website and also shared with the CPA executive for further distribution to CPA members.
4. Application fees, once paid, are not refundable. Applicants are therefore encouraged to seek clarity on any issues prior to submission of applications.
5. The primary purpose of introducing this framework is to improve access to medicines and also to provide for a competitive playing field. It must be noted, however, that the Authority encourages the sale of registered medicines, therefore the primary goal of the Authority will always be to facilitate and encourage the registration of medicines.

Yours faithfully
MEDICINES CONTROL AUTHORITY OF ZIMBABWE



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R.T. RUKWATA (Mr.)
DIRECTOR-GENERAL