

CIRCULAR 23 OF 2022

28th November 2022

TO: Holders of Premises Licences for Retail, Hospital & Restricted Pharmacies

IMPORTATION OF MEDICINES

The Authority would like to facilitate access to prescription preparations and other essential medicines. Ordinarily medicines are imported by holders of wholesale dealers' permits for distribution to pharmacies. The Authority has noted the increasing number of requests from pharmacies to import medicines for the purposes of meeting the requirements of their customers and the public at large. The importation of registered medicines is already provided for in SI 57 of 2008, and the Authority would like pharmacies to note the following:

- 1. Applications for Import Permits in terms of Section 2(b) of the Medicines and Allied Substances Control (Import & Exports of Medicines) Regulations 2008 (SI 57 of 2008).**
 - 1.1 This procedure applies to registered medicines. Such products are expected to conform to approved labelling requirements and must be manufactured at approved sites.
 - 1.2 A maximum of ten (10) products will be permitted per permit.
 - 1.3 The products imported in terms of this process are intended for use by the importing institution or professional.
 - 1.4 The fees for the import permit will be in accordance with the prevailing fee schedule

- 2. Temporary Authorization for Importation of Bulk Medicines in Terms of Section 75 of the Medicines and Allied Substances Control Act (Chapter 15:03) (MASCA).**


Section 75 of MASCA allows the Authority to set aside the provisions of the Act such as registration requirements as a precondition to importation of a medicine. It is used by the Authority to sanction the importation of products that are not on the Medicines Register but have been prescribed by a registered medical practitioner for a particular patient.

- 2.1 Applications may continue to be submitted by the above listed licence holders in the usual manner for individuals on the basis of prescriptions.
- 2.2 Licence holders will now also be permitted to apply to import in bulk products listed on the PWA list of approved Section 75 bulk imports.
- 2.3 Further, bulk imports will be permitted for products which are not on the list upon submission of supporting evidence, which could be in the form of prescriptions or supporting letters from specialist medical practitioners. Such products should be essential and life-saving prescription preparations.
- 2.4 Products must be sourced from manufacturers located in jurisdictions regulated by ICH member countries or from manufacturers approved by the Authority. These products should be of officially recognised compendia and meant for export market in the country of origin.
- 2.5 Applicants will be required to maintain appropriate dispensing records as these products are not intended for sale to other licence holders.
- 2.6 Application fees for bulk importation of products authorized in terms of section 75 of MASCA are as stipulated in the MCAZ fees circular on the MCAZ website.
- 2.7 A maximum of ten (10) products will be permitted per application.
- 2.8 Whilst the Authority will make every effort to process permits and letters of authorization within the specified timelines, it advises that due to the overwhelming number of applications, it might not be possible to keep within the published timelines. Applicants are therefore requested to allow sufficient time for processing which will not exceed ten (10) working days.

The Authority hopes that these measures will be used responsibly to alleviate the current shortages of essential medicines and is open to feedback from the concerned parties with respect to any further measures that may be taken in the interest of improving accessibility by the general public of safe, quality and efficacious medicines.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE



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R. T RUKWATA (MR)
ACTING DIRECTOR - GENERAL