MCAZ Medicines Control Authority of Zimbabwe

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CIRCULAR 24 OF 2022

28th November 2022

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

IMPORTATION OF MEDICINES

The Authority has noted with concern market control issues that have emanated from Circular 4 of 2019, which allowed parallel importation of medicines during the height of supply chain challenges faced at the time.

The following challenges have been experienced in the implementation of Circular 4 of 2019;

1. It became apparent that there are noted differences between products meant for different jurisdictions in terms of the approved pharmacopeial grade, site of manufacture of the products, and potential batch manufacturing records variations which might be unknown to the Authority.
2. Importers were sourcing the products from parallel distributors who were not under the regulatory oversight of the Authority. Traceability of the products to the manufacturing facilities was becoming a challenge as evidenced by the failure by importers to produce Certificates of Analysis of the imported products and failure to submit quality declarations from the manufacturers or principals of products whenever requested. This exposed the market to substandard and or falsified medical products.
3. Market control also hinges on the presence of Quality Technical Agreements (QTA) between manufacturers and their official distributors. These are legally binding and spell the roles of both parties in Quality Control and Quality Assurance. Parallel importation does not provide for QTA. This puts the public at risk as investigation into out-of- specification results of analysed medicinal products and of product defects may not be possible.

Measures to be adopted going forward are as follows:

1. Circular 4 of 2019 is hereby revoked with immediate effect and replaced by Circular 23 of 2022 which retains issues other than those pertaining to parallel importation as previously authorised.

2. **Parallel importation of medicines has been suspended with immediate effect.** However, normal supply chain importation shall be allowed provided the importer is able to provide official notification of appointment from the principal and manufacturers of products as provided in Section 4 (4) of the Medicines and Allied Substances Control (Import & Exports of Medicines) Regulations 2008, S.I 57 of 2008.
3. The Authority may require the importer to submit Certificates of Analysis and any other Batch Manufacturing Records (BMR) – related documentation to support importation of the products.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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Richard T. Rukwata (Mr.)

Acting - DIRECTOR-GENERAL