

REF: B/279/35/24/2023

CIRCULAR 24 of 2023

Date: 21st of November, 2023

**To: APPROVED WHOLESALER DEALERS, PHARMACEUTICAL
WHOLESALERS ASSOCIATION (PWA), COMMUNITY PHARMACISTS
ASSOCIATION (CPA) AND PRIVATE HOSPITALS ASSOCIATION OF
ZIMBABWE (PHAZ)**

BULK IMPORTATION OF UNREGISTERED MEDICINES

In 2014, the Authority initiated a process for the bulk importation of specific unregistered medicines by wholesale dealers in a bid to enable continuous availability of medicines on the market. It was anticipated that this process would encourage the submission of applications for registration of medicines, as this process would demonstrate to wholesalers and manufacturers that a market existed for those medicines on the Bulk Importation of Unregistered Medicines List (hereinafter referred to as the List for brevity).

The above process has been in operation for the past nine (9) years. However, very few wholesalers have taken up the initiative of submitting applications for registration of products on the above List. The Authority notes with concern that some wholesale dealers have, instead, created business models geared towards capitalising on this List. There is therefore ample evidence that this approach has failed to yield the expected outcome.

The Authority has noted with concern the following issues;

- a. The increase in the number of products that are being continuously added to the List.
- b. The deregistration of some products which are subsequently requested to be added to the List.
- c. The persistent presence of products on the List dating back to 2014.

The Authority's mission is to ensure access to safe, effective, and good quality medical products and allied substances for the protection of public and animal health. The primary process through which this mandate is achieved is through the registration of medicines. The above issues of concern are proof that the above process has become counterproductive to the Authority's execution of its mandate.

Due to the issues stated above, the Authority has therefore revised its position in terms of the requirements for Bulk Section 75 for Wholesalers, Pharmaceutical Wholesalers Association,


Community Pharmacists Association and Private Hospitals Association of Zimbabwe as follows **with immediate effect**:

1. The Authority will approve bulk importation of unregistered medicines by wholesale dealers under Section 75 of the Act only in instances where the applicant has submitted applications for registration and said applications are under review by the Authority. Proof of submission in the form of an **application number** issued by the Evaluations and Registrations Division will be required upon submission of an application under Section 75 of the Act.
2. With respect to product variations, the Authority will approve Section 75 applications for registered medicines where applications for variations, where applicable, would have been submitted to the Authority. This will however be subject to presentation of proof of submission of said applications for variations.
3. The approved Lists from the Pharmaceutical Wholesalers Association, Community Pharmacists Association and Private Hospitals Association of Zimbabwe are no longer considered a basis of approval of any Section 75 application by the Authority.
4. To mitigate any short-term shortages that might ensue from the implementation of this circular, all private hospitals and pharmacies are authorised and encouraged to submit their own applications for importation of unregistered medicines directly to the Authority.
5. Wholesale dealers and importers will still be allowed to act as agents to facilitate #4 above, but the applications shall be in the name of the health institution on whose behalf the importation will be done.

The Authority hopes that these measures will encourage the registration of medicines and improve accessibility of the general public to safe, quality and efficacious medicines.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE



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Richard T. Rukwata (Mr.)

DIRECTOR-GENERAL