



REF: B/279/35/1/2022

6th January 2022

**TO: ALL CURRENT AND PROSPECTIVE, LOCAL AND EXTERNAL,
APPLICANTS FOR REGISTRATION OF MEDICINES**

CIRCULAR 1 of 2022

**RE: PUBLICATION OF PRODUCT INFORMATION FOR REGISTERED
MEDICINAL PRODUCTS (SUMMARY OR PRODUCT CHARACTERISTICS)**

This circular serves to inform all applicants that the Medicines Control Authority of Zimbabwe has commenced publication of product information for registered medicines. This product information will be in the form of a Summary of Product Characteristics. The information will include:

- Qualitative and quantitative composition of the medicine, with respect to the active pharmaceutical ingredient(s) and any excipients with known effect.
- Clinical particulars- this will include, where applicable, a summary of pharmacokinetic data obtained from bioequivalence studies conducted with the product.
- Pharmacological properties
- Pharmaceutical particulars of the medicine
- Applicant and drug product manufacturer details
- Zimbabwean registration number and category for distribution

The publication of product information of approved medicines on the Authority's website serves to increase access to information by health care professionals, pharmaceutical industry, medicines regulatory affairs personnel, those in academia, and any other interested members of the public.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE


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Richard Rukwata (Mr)
ACTING DIRECTOR GENERAL