

Medicines Control Authority of Zimbabwe

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REF: B/279/35/17/2022

CIRCULAR 17 of 2022

Date: 18/07/2022

To: ALL LICENSED CANNABIS/HEMP PRODUCERS, MANUFACTURERS,

IMPORTERS/ EXPORTERS, RETAIL PHARMACISTS

RE: APPROVAL OF HEMP-BASED CANNABIDIOL (CBD) PRODUCTS AS COMPLEMENTARY MEDICINES

The Authority advises stakeholders that it will consider applications for approval of Hemp-based cannabidiol (CBD) products as complementary medicines under the following conditions:

- i) Submission of an application for registration (dossier) in line the Guideline for submission of application for Complementary medicines.
- ii) Submission of product samples.
- iii) Submission of certificates of analysis from an accredited laboratory specifying the quantities of the active moieties of cannabidiols and any traces of tetrahydrocannabinols as part of the information in the dossier.
- iv) Clearly specifying the indications, warning and contraindications among other information as part of the product information in line with the Complementary medicines guideline.
- v) Satisfactory inspection of manufacturing site by the MCAZ inspectorate to ensure that the site complies with Good Manufacturing Practices, for the manufacture of Complementary Medicines.
- vi) Payment of complementary medicine product application fees as gazetted.

Any Hemp-based CBD product applications that do not meet the criteria above may not be approved for distribution, and will be confiscated. Further, sellers may be prosecuted for selling unapproved complementary medicines.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

R.T. Rukwata (Mr.)

ACTING DIRECTOR-GENERAL

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