

REF: B/279/35/21/2024

CIRCULAR 21 of 2024

Date: 24/10/2024

To: ALL PRINCIPALS, APPLICANTS, MANUFACTURERS AND LOCAL TECHNICAL REPRESENTATIVES

RE: NOTIFICATION FOR ALIGNMENT WITH LEGAL PROVISIONS PRESCRIBED IN THE MEDICINES AND ALLIED SUBSTANCES CONTROL REGULATIONS WHEN CONDUCTING BUSINESS WITH THE AUTHORITY

In accordance with the Medicines and Allied Substance Control (General) Regulations, S.I. 150 of 1991, and the subsequent statutory application form (MC8 Form), there are **only three parties** to an application. The **principal**, as the owner of the product, has the privilege of appointing the **applicant** as well as the **manufacturer**. Once the applicant is appointed, they are the only party with the legal mandate to communicate with the Authority.

Stakeholders have complained over the years about the failure to receive timely communication regarding applications due to the involvement of local technical representatives (LTRs) acting on behalf of applicants. Further complaints have been about delayed communication on the progress of screening, assessment, final regulatory decisions, retention fee invoices, import and export controls on applications.

After conducting an exercise in the third quarter of 2024 to address these challenges, the Authority will implement the following changes **effective from 1st January 2025**:

1. The Authority will only communicate officially with applicants and their designated employees.
2. The Authority will no longer recognize LTRs in communication for services offered to applicants.
3. The Authority will levy appropriate fees for changes in the applicant's name and address in line with the MCAZ Variations Guidelines and Fees Schedule.

Realising the inconveniences this decision might cause to applicants who have been dependent on LTRs for some time, the Authority would like to offer the following guidance:

Option 1:

Where the applicant decides to conduct business in their name, but in the absence of an LTR, no change will be necessary. However, the applicant is advised to inform the Authority of the names, contact details, and designations of its staff who will be communicating directly with the Authority.

Option 2:

Where the applicant intends to utilise local persons as its representatives, the applicant is advised to ensure that natural persons handling communication with the Authority are appointed as their employees and are resident in Zimbabwe.

Option 3:

Principals can appoint juristic persons (e.g., local companies) as applicants who will be duly authorised to communicate with the Authority officially.

Principals and applicants are required to communicate their legal position on the matter to the Authority by **31st December 2024**.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE



R. T. Rukwata (Mr.)

DIRECTOR-GENERAL