MCAZ Medicines Control Authority of Zimbabwe

Alignment with Legal Provisions Prescribed in the Medicines and Allied Substances Control Regulations (Circular 21 of 2024)

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Outline

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Definitions

Applicant – Person or entity by, or on whose behalf, an application for registration is made

Principal – Owner of the product.

Manufacturer - A company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of pharmaceuticals.

Local Technical Representative – A local entity, company, that communicates with the Authority on behalf of the applicant.

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Problem

- Applicants and Principals have complained about failure to receive communication from the Authority timeously.
- Delays on communication on:
  - Progress of applications
  - Final regulatory decisions
  - Retention fee invoices
  - Import and export controls on applications
- Unclear representatives for the applications
  - Especially applicants with different LTRs for different product lines

- The lag time between response from:

  Authority → Local Technical Representative → Applicant → Principal

  Principal → Applicant → Local Technical Representative → Authority

- Misplacing of communication by the Local Technical Representative.
- Correspondence being sent to the wrong Local Technical Representative
- Delays in product application finalization of registration process

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Solution

1. The Authority will communicate officially with the 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

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What does this mean?

Only the principal has the authority to appoint the applicant and the manufacturer.

The applicant is the **only party** with the legal mandate to communicate with the Authority

Remedies

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.

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Anticipated results

- Quicker response time from applicants.
- Clear lines of communication from the Authority to the Principal.
- Correspondence reaching the correct and intended recipients.
- Timeous communication
- Quicker timelines

By when should this be done??

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

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THANK YOU

Protecting your right to quality medicines and medical devices