MCAZ Medicines Control Authority of Zimbabwe

Implementation plan for grouped variations and variation notifications

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Protecting your right to quality medicines and medical devices

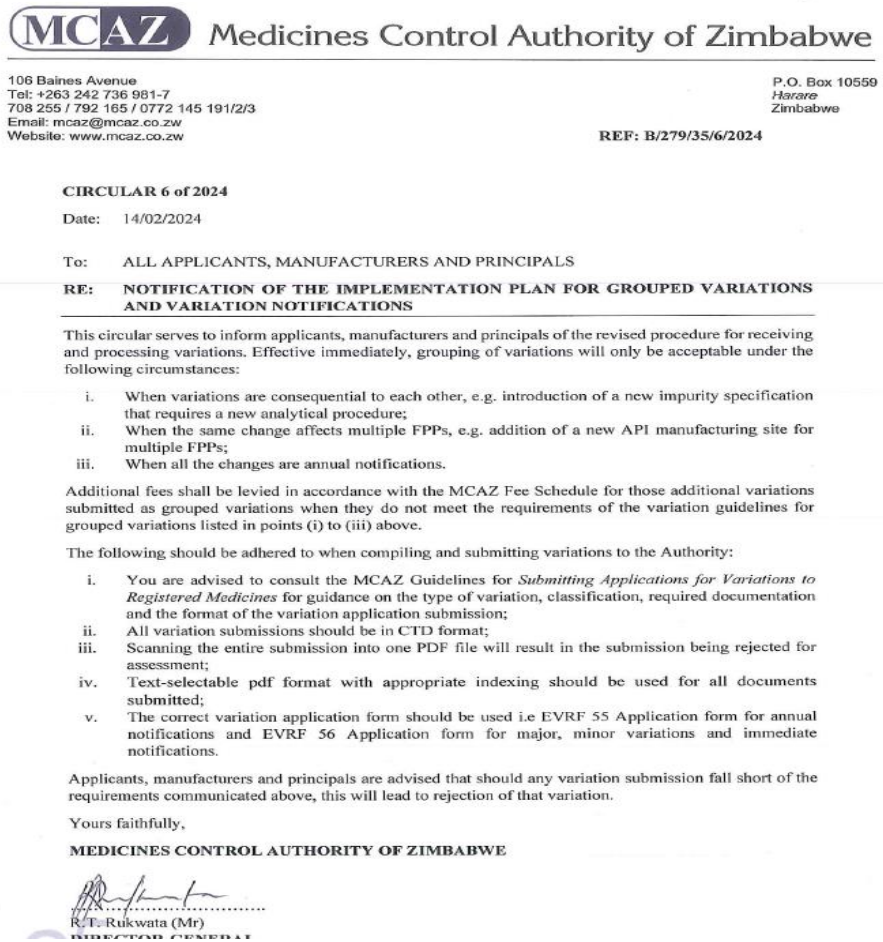
Medicines Control Authority of Zimbabwe

Outline:

1. Updates
2. Grouped variations and variation notifications
3. Fees?
4. Questions

MCAZ Medicines Control Authority of Zimbabwe

Circular 6 of 2024



MCAZ Medicines Control Authority of Zimbabwe

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Date: 14/02/2024

To: ALL APPLICANTS, MANUFACTURERS AND PRINCIPALS

RE: NOTIFICATION OF THE IMPLEMENTATION PLAN FOR GROUPED VARIATIONS AND VARIATION NOTIFICATIONS

This circular serves to inform applicants, manufacturers and principals of the revised procedure for receiving and processing variations. Effective immediately, grouping of variations will only be acceptable under the following circumstances:

i. When variations are consequential to each other, e.g. introduction of a new impurity specification that requires a new analytical procedure;
ii. When the same change affects multiple FPPs, e.g. addition of a new API manufacturing site for multiple FPPs;
iii. When all the changes are annual notifications.

Additional fees shall be levied in accordance with the MCAZ Fee Schedule for those additional variations submitted as grouped variations when they do not meet the requirements of the variation guidelines for grouped variations listed in points (i) to (iii) above.

The following should be adhered to when compiling and submitting variations to the Authority:

i. You are advised to consult the MCAZ Guidelines for *Submitting Applications for Variations to Registered Medicines* for guidance on the type of variation, classification, required documentation and the format of the variation application submission;
ii. All variation submissions should be in CTD format;
iii. Scanning the entire submission into one PDF file will result in the submission being rejected for assessment;
iv. Text-selectable pdf format with appropriate indexing should be used for all documents submitted;
v. The correct variation application form should be used i.e EVRF 55 Application form for annual notifications and EVRF 56 Application form for major, minor variations and immediate notifications.

Applicants, manufacturers and principals are advised that should any variation submission fall short of the requirements communicated above, this will lead to rejection of that variation.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

R.T. Rukwata (Mr)
DIRECTOR GENERAL

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Grouped variations

- Individual changes require the submission of separate variations.
- However, submission of several variations (grouping of variations) is allowed only under the following circumstances:
  - when variations are consequential to each other, e.g. introduction of a new impurity specification that requires a new analytical procedure;
  - when the same change affects multiple FPPs, e.g. addition of a new API manufacturing site for multiple FPPs;
  - when all the changes are annual notification.
- The MCAZ Guideline on Variations clearly specifies the categorization of each variation.

Annual notifications (AN)

- Notifications are changes that could have minimal or no adverse effects on the overall safety, efficacy and quality of the FPP.
- If the variation in question is not specified in the MCAZ Guideline, you are encouraged to contact the MCAZ Variations Team for further assistance.
- At present, all variations require prior approval by MCAZ before implementation.
- For convenience applicants may group several AN changes as a single submission.

Fees

- Fees are as stipulated in the fee schedule on our website.
- Applicants are encouraged to submit the EVR Quotation Confirmation form to allow for the appropriate application fee to be paid.

Common deficiencies

- **Variation application forms**
  - Application forms for variations should be duly completed and ensure that you attach all documents stated and as required by the form.
- **MC8 forms**
  - The MC8 forms being submitted are not signed or dated, and others are not even submitting the MC8 forms, after indicating on the application form that they have attached it.
  - Missing/incorrect pharmacological classification
  - Incorrectly stating of approved name and trade name
  - Incomplete names and addresses of applicants, manufacturers, and principal.
  - Product description that differs from that stated in the PIL.

…continued

- **Labelling**
  - Submission of incomplete labels with missing/incorrect information on generic and trade names, category of distribution, registration number, provision for manufacturing date, batch number and expiry date generic and trade names.
  - Omission of submission for labels
- **Patient information Leaflet**
  - Description, presentation and form of the medicines not included
- **Incomplete documentation**
  - Documentation and conditions to be fulfilled not in line with MCAZ Variations Guidelines

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