MCAZ Medicines Control Authority of Zimbabwe

106 Baines Avenue
Tel: +263 242 736 981-7
708 255 / 792 165 / 0772 145 191/2/3
Email: mcaz@mcaz.co.zw
Website: www.mcaz.co.zw

P.O. Box 10559
Harare
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

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R.T. Rukwata (Mr)
DIRECTOR-GENERAL

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