MCAZ Medicines Control Authority of Zimbabwe

REF: B/279/35/08/2019

8th March 2019

To: APPLICANTS AND PRINCIPALS

CIRCULAR 08/2019

OPENING OF EXPEDITED REVIEW CHANNEL FOR ASSESSMENT OF APPLICATIONS FOR REGISTRATION OF HUMAN ALLOPATHIC MEDICINES IN 2019

Generic medicines
Please be advised that the channel for expedited review of applications for registration of medicines will be opened periodically, beginning **1st April 2019**. Ten (10) applications for registration of **generic** medicines will be accepted in the first call. Of the 10, only one (1) can be an application for a biosimilar. The expedited review channel will then be closed upon receipt of the tenth application.

The next call for expedited review applications will be later in the year. You will be advised of the reopening of the expedited review channel 3 weeks in advance of its opening. Applicants are kindly advised to regularly check the website for updates.

Innovator medicines
Since **2nd January 2018**, there has and continues to be an expedited review pathway for **SRA-approved innovator products** registered in their country of origin. This pathway is open throughout the year. {SRAs (stringent regulatory agencies) are agencies that are members, associates and observers of ICH, e.g., USFDA, EMA, etc}.

Eligibility
Please note that only products manufactured at plants (unit and block level) deemed GMP-compliant by MCAZ or in SRA-regulated countries with SRA-issued GMP certification are eligible for expedited review.

Procedure
Interested applicants should submit to adminEVR@mcaz.co.zw (cc tmakamure@mcaz.co.zw), completed EVR quotation confirmation forms (EVRF32), that clearly indicate the products to be applied for and which have the expedited review option selected.

Successful applicants will be notified by way of an EVR Quotation Confirmation Form signed by MCAZ. This signed form should be used when making payments. This form should also be provided together with the product dossier and proof of payment at the point of dossier

submission. Failure to pay the relevant application fees (as per the current MCAZ fee schedule) **and** to submit a dossier within 5 days of issuing of the EVR signed quotation confirmation form will result in removal of the product from the expedited review pathway and the slot being given to another applicant.

60 days will be given to respond to queries after an evaluation cycle. **Responses to queries should be clearly labelled 'EXPEDITED REVIEW' and should be on both hardcopy and soft copy (CD).**

Instances where applications will be removed from the expedited review to the normal review channel with no reimbursement of fees:

1. Failing screening
2. Any request for an extension to the deadline to respond to queries

Lastly, please be reminded that expedited review does not guarantee registration. Registration will be granted only to applications meeting all technical and administrative requirements.

Yours faithfully,
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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G.N. MAHLANGU (Ms)
DIRECTOR-GENERAL