



27 August 2018

To: APPLICANTS AND PRINCIPALS

CIRCULAR 10/2018

SECOND CALL FOR APPLICATIONS FOR REGISTRATION OF HUMAN ALLOPATHIC MEDICINES UNDER THE EXPEDITED REVIEW CHANNEL

Generic medicines

Please be advised that the channel for expedited review of applications for registration of medicines will be opened beginning **3 September 2018**. Twenty (20) applications for registration of generic medicines will be accepted in the second call. Of the 20, only three (3) can be applications for biosimilars. The expedited review channel will then be closed upon receipt of the twentieth application.

Innovator medicines

Please note that the expedited review pathway for **SRA-approved innovator products** registered in their country of origin 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 working days of issuing of the EVR signed quotation



Medicines Control Authority of Zimbabwe

confirmation form will result in removal of the product from the expedited review channel 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

A handwritten signature in black ink, appearing to read 'G N Mahlangu', is written above a dotted line.

pp G N MAHLANGU (Ms.)
DIRECTOR GENERAL