MCAZ Medicines Control Authority of Zimbabwe

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Ref: B/279/35/10/2021

Date: 7 May 2021

Circular 10 of 2021

To:

1) Clinical Trial Applicants and Principal Investigators
2) Clinical Trial Researchers, Academia and Pharmaceutical Industry
3) Clinical Research Organizations
4) Clinical Trials Sponsors

Dear all

Re: Revised Fees for applications to import Clinical Trial Study Medicines in terms of Section 75 of the Medicines and Allied Substances Control Act (Chapter 15:03).

The Authority hereby notifies you on the application fees charged by the Authority for applications to import clinical trial study medicines in terms of Section 75 of the Medicines and Allied Substances Control Act (Chapter 15:03).

The fees were included in the 2021 MCAZ Fee schedule Circular No. 9 of 2021 available on https://mcaz.co.zw/images/led/Circular_9_of_2021_-_Fees_Schedule.pdf. As indicated in section 9c of the fee schedule, the fees are 20 USD per medicine for foreign sponsored clinical trials and 10 USD per medicine for locally sponsored clinical trials. Please note that in addition to the statutory fees, 14.5% Value Added Tax (VAT) is payable on all the applications.

Our bank account details are as follows:

Bank:	Standard Chartered Bank of Zimbabwe
Branch:	Africa Unity Square
City:	Harare
Account Number:	8740423044600 (Nostro Account)
	0100223044600 (ZWL Account)
Swift Code	SCBLZWHXX

Please note that approval to import or export products for clinical trials shall only be granted for use in clinical trials approved by the Authority. In accordance with the Pharmacy Guidelines for Investigational Medical Products, applicants are required to submit an application for authorization to import investigational product which contains the following:

1. A cover letter stating:
   (a) The full name and address of the manufacturer of the study product
   (b) The name/description of the investigational product, placebo and quantities to be imported;
2. Shipment documents and invoices of the product purchased/ to be purchased indicating quantities;
3. Certificate of analysis of investigational products for all batches of each product to be imported;
4. Lot Release certificate(s) (where applicable) for all batches to be imported.

Kindly note that applications should be submitted with proof of payment of the appropriate fee.

The Authority continues to support research and ensuring that researchers comply with Good Clinical Practices to ensure participants' safety.

Yours faithfully
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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R. Rukwata (Mr)
ACTING DIRECTOR-GENERAL