



Medicines Control Authority of Zimbabwe

*REF:* B/279/35/10/2019

8<sup>th</sup> April 2019

To: APPLICANTS AND STAKEHOLDERS

CIRCULAR 10/2019

**NOTIFICATION OF CHANGE IN THE DIVISION RESPONSIBLE FOR PROCESSING OF QUALITY RELATED AMENDMENTS / VARIATIONS TO REGISTERED MEDICINES**

The Medicines Control Authority of Zimbabwe (MCAZ) would like to notify all applicants and stakeholders that with effect from **01 June 2019** the Evaluations and Registration (EVR) Division will be taking over the processing and evaluation of applications for quality related amendments/variations to registered medicines as well as applications for reinstatement of previously registered products which were formerly processed in the Pharmacovigilance and Clinical Trials (PVCT) Division.

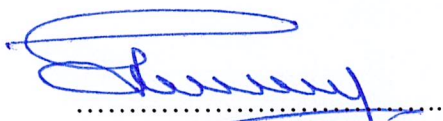
Please note that safety related amendments/variations, for example, category of distribution, indications, promotional material, package insert updates and periodic safety updates traditionally considered by the Pharmacovigilance and Clinical Trials Committee will continue to be processed by the PVCT division.

The change is made to ensure stakeholder/client satisfaction through a streamlined approach to processing applications at pre and post registration stages of the product life cycle. Information on the process for submission of variations, guidelines and forms will be uploaded on the Evaluations and Registration homepage on the MCAZ website <https://www.mcaz.co.zw/index.php/how-we-regulate/evaluation-registration> prior to the date the change comes into effect. Any comments on the proposed change can be submitted to [mcaz@mcaz.co.zw](mailto:mcaz@mcaz.co.zw) Cc: [adminivr@mcaz.co.zw](mailto:adminivr@mcaz.co.zw) .

Your cooperation and patience during the transition period is greatly appreciated.

Yours faithfully

**MEDICINES CONTROL AUTHORITY OF ZIMBABWE**

  
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G.N. MAHLANGU (Ms)  
**DIRECTOR-GENERAL**