MCAZ Medicines Control Authority of Zimbabwe

106 Baines Avenue
Tel: +263-4-736981-7
708255/792165, 0772 145 191/2/3
Email: mcaz@mcaz.co.zw
Website: www.mcaz.co.zw

P.O. Box 10559
Harare
Zimbabwe

REF: B/279/35/13/2022

CIRCULAR 13 of 2022

Date: 22/06/2022

To: All Applicants, Manufacturers, and Market Authorisation Holders (MAHs) for all registered medicines in Zimbabwe.

RE: Pharmacovigilance System Requirements for the Pharmaceutical Industry

This circular serves as a notice to all applicants, manufacturers and Market Authorisation Holders (MAHs) of medicines & vaccines registered and /or granted Emergency Use Authorisation (EUA) that the Authority requires all MAHs to have a functional Pharmacovigilance system in place in line with MCAZ circular 3 of 2022 and the Pharmacovigilance Guideline for Pharmaceutical Industry (MCAZ PVCT GL02 Rev 1_February 2022). A pharmacovigilance system is defined as a system used by an organization to fulfil its legal tasks and responsibilities in relation to pharmacovigilance and designed to monitor the safety of authorized medicinal products and detect any change to their risk-benefit balance.

Please note that you are therefore required to notify the MCAZ in writing of the Pharmacovigilance system that you have in place and who your responsible person for pharmacovigilance or the QPPV is, their curriculum vitae, contact details and their responsibilities no later than **25th July 2022.** The Authority also requests that you complete the checklist attached in annex 1.

We thank you for your usual co-operation.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

……..

R. T. Rukwata (Mr.)
ACTING DIRECTOR-GENERAL

MCAZ Medicines Control Authority of Zimbabwe

PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

Annexe 1

GOOD PHARMACOVIGILANCE PRACTICES CHECKLIST

1. Please tick the appropriate box corresponding to your type of organization

   ☐Applicant ☐Manufacturer ☐Wholesaler

2. Name and address
   ……
   ……
   ……

3. Which of the following Individual Case Safety Reports (ADRs, AEFIs, and SAEs) do you use at your company?

   ☐Company ADR reporting forms ☐CIOMS Forms ☐MCAZ ADR, AEFI and SAE reporting forms ☐MCAZ e-PV System ☐ E2B XML Format

4. Do you have a Pharmacovigilance system in place?

   ☐ Yes ☐ No

5. If you answered yes to the above question, How far are you in setting up the Pharmacovigilance system?

   ☐System set up, not yet functioning ☐System set up and not functioning fully
   ☐ System set up, fully functioning

6. Do you have a Qualified Person Responsible for Pharmacovigilance (QPPV) at your company?

   ☐ Yes ☐No
   If yes please attach the company nomination letter for the QPPV, their curriculum vitae, contact details and their responsibilities.

7. Do you require training on setting up a Pharmacovigilance system?

   ☐ Yes ☐ No

   Additional Comments
   ……
   ……