24 June 2019

Circular 16 of 2019

To:
1) Ministry of Health and Child Care Public Health Programs including, ART & TB, DPS, M&E, and City of Health Hospitals and clinics etc.
2) Private hospitals and clinics
3) Private Hospital Association of Zimbabwe (PHAZ)
4) Healthcare workers (HCWs)
5) Retail and Hospital Pharmacies
6) Zimbabwe Medical Association (ZiMA)
7) Pharmaceutical Society of Zimbabwe (PSZ)
8) Retail Pharmacists Association
9) Medical Aid Societies (CIMAS, PSMAS, etc.)
10) Applicants and Principals
11) Researchers and Academia
12) Consumer Council of Zimbabwe

Dear all,

RE: Launch of the MCAZ National Pharmacovigilance Centre e-ADR Reporting system for Individual Case Safety Reports (ICSRs) (ADRs, SAEs, AEFI & AEFI case investigation)

The Authority would like to advise all its stakeholders that with effect from 25th June 2019, the following online platforms will be available for all our stakeholders and the user manuals will be accessible on the MCAZ website:

- Browser-based Web application
  https://e-pv.mcaz.co.zw
- Android mobile application (MCAZ Pharmacovigilance)
- iOS mobile application (iPhone, iPad) – (MCAZ Pharmacovigilance)
- Windows Desktop application
- Mac OS Desktop application (MacBook)
- Linux Desktop application

Please note that Mobile apps and Desktop apps have offline functionality and reports can be completed offline, then sent later when internet is available.

The following reporting tools would be available for each online reporting platform:

1. Adverse Drug Reaction (ADR) reporting form
2. MCAZ/MRCZ Serious Adverse Event (SAE) reporting form for approved clinical trials
3. Adverse Events Following Immunization (AEFI) reporting form and
4. AEFI Investigation Form.

For researchers of clinical trials of medicines and vaccines, please note that it is mandatory to submit adverse drug reactions (ADRs) and Serious Adverse Events (SAEs), using the joint MCAZ/MRCZ SAE reporting form now also available on the new e-ADR system.

For all applicants and principals of medicines and vaccines, please be advised that you are now required to submit individual case safety reports (ICSRs) online by uploading an E2B file onto the MCAZ e-ADR online reporting platform. For applicants and principals of medicines and vaccines, a period of one year to build the capacity of E2B/XML file ICSRs is granted until 31st July 2020.

Please note that to promote patient safety the MCAZ will still accept hardcopy ICSRs (ADRs, SAEs, AEFI and AEFI case investigation reports) from those who are unable to access the online reporting tools. Completed signed and scanned ADR forms may also be emailed to MCAZ email address: mcaz@mcaz.co.zw.

All ICSRs (ADRs, SAEs, AEFI and AEFI case investigation reports) received by MCAZ will be processed for causality assessment monthly by the Pharmacovigilance and Clinical Trials (PVCT) expert Committee that is also the National AEFI Committee. All ICSRs will also be uploaded in an anonymous format onto the MCAZ-WHO Vigibase database with inbuilt capabilities for further data analysis and signal detection. The MCAZ also provides written feedback to all reporters and publishes anonymous safety articles in drug information bulletins, peer reviewed journals, and gives presentations at stakeholders’ forums and HCW pharmacovigilance trainings.

We would like to take this opportunity to thank all reporters who have submitted ICSRs (ADRs, SAEs and/or AEFI reports) to the MCAZ. Please keep up the good work in reporting all known and unknown ICSRs that are of concern to the patient or public. Reporting of known, unknown or seemingly ‘unimportant’ adverse reactions may assist to pinpoint a signal or batch related medicine problem that may be minimized if risk mitigation measures are taken early and promote patient safety.

Yours faithfully
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

G N Mahlangu (Ms.)
DIRECTOR-GENERAL