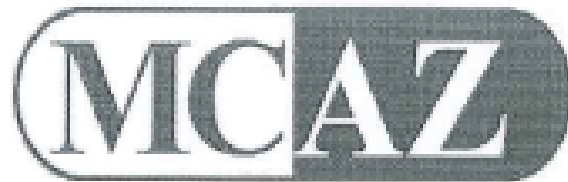




PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

**PHARMACOVIGILANCE ELECTRONIC REPORTING SYSTEM
-EXTERNAL USER MANUAL**



PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

PHARMACOVIGILANCE ELECTRONIC REPORTING SYSTEM- EXTERNAL USER MANUAL

APPROVAL

This Manual has been approved for use by the Director- General.

Signature: _____

G.N. Mahlangu (Ms)

Date: _____

9/6/2020

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1.0 APPLICATION

- 1.1 This manual applies to all users of the MCAZ electronic pharmacovigilance reporting system accessible via the following platforms:
 - 1.1.1 Browser based Web Application (<https://e-pv.mcaz.co.zw>)
 - 1.1.2 Android mobile application (MCAZ Pharmacovigilance)
 - 1.1.3 iOS mobile application (MCAZ Pharmacovigilance)
 - 1.1.4 Windows Desktop application
 - 1.1.5 Mac OS Desktop application (MacBook)
 - 1.1.6 Linux Desktop application

- 1.2 The Mobile Apps and Desktop apps have offline functionality, reports completed offline can be submitted later when internet is available. The following reporting tools are available for each online reporting platform:
 - 1.2.1 Adverse Drug Reaction (ADR) reporting form
 - 1.2.2 MCAZ/MRCZ Serious Adverse Event (SAE) reporting form for approved clinical trials
 - 1.2.3 Adverse Events Following Immunization (AEFI) reporting form
 - 1.2.4 AEFI Investigation Form
 - 1.2.5 E2B/XML file submission

- 1.3 Minimum criteria for reporting are as follows:
 - 1.3.1 An identifiable patient
 - 1.3.2 A suspected medicinal product / Product exposure
 - 1.3.3 An identifiable reporter
 - 1.3.4 An event or outcome with a reasonable suspected relationship

- 1.4 The identities of the reporter and patient will remain confidential. Patient details such as initials/other relevant identifier (E.G. Hospital number) gender and age/date of birth are crucial to allow linkage to other reports while maintaining confidentiality.

2.0 PURPOSE

Before a medicine is authorised for use, evidence of its safety and efficacy is limited to the results from clinical trials, where patients are selected carefully and followed up very closely under controlled conditions. After authorisation the medicine may be used in a large number of patients, for a long period of time and with other medicines. Certain side effects may emerge in such circumstances. It is therefore essential that the safety of all medicines is monitored throughout their use in healthcare practice. The Medicines Control Authority of Zimbabwe (MCAZ) is the National Centre for Pharmacovigilance (PV) and an official member of the World Health Organisation (WHO) Programme for International Drug Monitoring (PIDM). One of the key functions of the Zimbabwe National Pharmacovigilance Centre is to promote pharmacovigilance in the country, collect and manage ADR reports as well as reports of medication errors and suspected counterfeit/substandard drugs.

The scope of pharmacovigilance is wide and includes vaccines and biological products. Safety of vaccines is an essential part of the success of immunization programmes and this activity requires the involvement of various stakeholders, including the Zimbabwe Expanded Programme on Immunization and implementation of the Adverse Events Following Immunisation (AEFI) Surveillance Guidelines by healthcare workers from both the public and private health sector. To report a suspected AEFI, the AEFI reporting form should be completed and for serious AEFIs, a case investigation form is required to be completed and submitted. Further guidance on reporting AEFIs is available in the AEFI Surveillance Guidelines accessible on the MCAZ website.

Pharmacovigilance is now considered to include other patient safety issues in addition to ADRs, such as medication errors, lack of efficacy reports and product quality assessments. Marketing authorisation holders are expected to have effective pharmacovigilance system in place in order to monitor and take responsibility for the safety of their medicines, meet legislative requirements for reporting serious adverse reactions and significant safety issues, identify any changes to the benefit–risk balance of your medicine, take appropriate action in a timely manner when necessary, update product labels and product information with new safety information in a timely way.

The electronic pharmacovigilance system is one of the available reporting tools for adverse drug reactions/events. Each user creates an account/registers before they can use the system. An automated email response will be received when the reports/applications are submitted and when feedback is given by the Authority following consideration of

the report by the Pharmacovigilance and Clinical Trials Committee. This document serves as a manual for users of the electronic pharmacovigilance reporting system.

2.1 Reporters of suspected ADRs

The purpose of pharmacovigilance is to detect, assess, understand and prevent the adverse effects or any other possible drug-related problems, which is not only confined to chemical drugs, but extended to complementary medicines, biologicals, vaccines, blood products and medical devices.

2.1.1 Healthcare Professionals

All health care workers, including doctors, dentists, pharmacists, nurses, other health professionals and the patients are requested to report all suspected adverse reactions to medicines (including vaccines, X-ray contrast media, complementary medicines) especially when the reaction is unusual, potentially serious or clinically significant. Spontaneous reporting is the core data generating system of most pharmacovigilance programmes and spontaneous reports play a major role in the identification of adverse reactions which may not be detected in earlier clinical trials or other pre-marketing studies.

2.1.2 Pharmaceutical Industry

As highlighted in the ICHE2E guidance on Pharmacovigilance planning, the decision to approve a medicine is based on it having a satisfactory balance of benefits and risks within the conditions specified in the product labelling based on the information available at the time of registration. The knowledge related to the safety profile of the product can change over time through expanded use in terms of patient's characteristics and the number of patients exposed. As such, in line with the mandatory policy enacted on March 21st, 2000 which was communicated as a circular notice, all Applicants and Marketing Authorisation Holders (MAH) are required to report suspected ADRs, SAEs and/or AEFIs that occur in Zimbabwe. The MCAZ e-pv platform is E2B compatible. For post-approval safety data, expedited reporting of serious and unexpected ADRs is required as soon as possible, but in no case later than 15 calendar days of initial receipt of the information by the MAH. Cases of non-serious ADRs, whether expected or not, are also to be reported to the MCAZ.

2.1.3 Clinical Trial Reporting

Regulatory requirements, including the Medicines and Allied Substances Control Act Chapter 15:03 (MASCA), International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP), and Guidelines for Good Clinical Trial

Practice in Zimbabwe, set forth safety monitoring and reporting responsibilities of sponsors and investigators to ensure the safety and protection of human subjects participating in clinical trials. Any clinical trial of any medicine authorized in terms of Section eighteen of MASCA shall be subject to such specific and general conditions as the Authority may, with the approval of the Secretary, impose including reporting of all serious adverse events to the MCAZ. In terms of Sections 23 of MASCA, the applicant i.e. investigator/ researcher of a clinical trial is responsible for proper reporting of Serious Adverse Events (SAEs) to the MCAZ. The purpose of reporting SAEs is to ensure participant safety monitoring and to better understand the toxicity and safety of investigational products. Reporting and monitoring of SAEs is required to alert the MCAZ, sponsor, and clinical investigators of real and potential volunteer safety issues including safety information for the investigation product brochure. For fatal or life-threatening, unexpected events during clinical development, the Principal investigator is required to alert the MCAZ as soon as possible but no later than 7 calendar days after first knowledge by the investigator that a case qualifies, followed by as complete a report as possible within 8 additional calendar days. Serious, unexpected reactions that are not fatal or life-threatening must be reported as soon as possible but no later than 15 calendar days after first knowledge

2.1.4 Consumer reporting

Consumers, patients or patient representatives may also report using the e-ADR form or the standard ADR reporting form. Consumer reporting of adverse reactions could be useful for over the counter (OTC) medicines, herbal medicines, and for reporting problems with excipients and potential interactions. Consumers can provide detailed first-hand information about their experiences with medicines and how these medicines have affected their life.

2.1.5 Public Health Programmes and the Private Health Sector

Reporters may be in the public or private health sector. Integration of pharmacovigilance system with public and private health programmes, can result in better health outcomes as a consequence of good information on safety, which allows the early identification and prevention of adverse reactions, resulting in the more rational use of medicines, and better adherence within the target population.

2.1.6 Pharmacovigilance provincial and district sentinel sites of public and private health programmes (PHPs).

Sentinel surveillance is the collection and analysis of data by designated institutions selected for their geographic location, medical specialty, and ability to report high

quality data. Regional or sentinel sites of pharmacovigilance are being identified and set up countrywide in collaboration with all MoHCC public health programs and Directorate Pharmacy Services (DPS-MoHCC) in line with pharmacovigilance indicators including current legislation and guidelines. Private health sector clinics, hospitals including specialists and healthcare professionals are welcome to express interest to MCAZ, and participate as pharmacovigilance sentinel sites.

2.2 The Zimbabwe National Pharmacovigilance Centre

The Medicines Control Authority of Zimbabwe (MCAZ) is the National Centre for Pharmacovigilance (PV) and is an official member of the World Health Organisation (WHO) Programme for International Drug Monitoring (PIDM). In 1968, during the World Assembly, a resolution was called for which was for systemic collection of information on adverse drug reaction (ADR) reports during the development and particularly after medicines have been made available for public use. This led to the formation of the WHO PIDM. Members submit adverse reaction reports associated with medicines and vaccines to WHO Global database known as VigiBase.

One of the key functions of the Zimbabwe National Pharmacovigilance Centre is to promote pharmacovigilance in the country, collect and manage ADR reports as well as reports of medication errors and suspected counterfeit/substandard drugs. The electronic pharmacovigilance system is one of the available reporting tools for adverse drug reactions. Each user creates an account/registers before they can use the system. An automated email response will be received when the reports/applications are submitted, the Pharmacovigilance and Clinical Trials Committee considers the report/application and then feedback is given by the Authority. This document serves as a manual for users of the electronic pharmacovigilance reporting system.

3.0 INTRODUCTION

- 3.1 The mandate of MCAZ is to protect public health ensuring that medicines and medical devices on the market are safe, effective and of good quality National Pharmacovigilance Centre housed under the Pharmacovigilance and Clinical Trials Division at MCAZ, participates in the WHO Programme for International Drug Monitoring. The E-PV system is one of the vigilance tools in place for the collection and assessment of ADRs and AEs as defined by the WHO Global Benchmarking Tool Vigilance indicators. The MCAZ PV system will enable the submission, tracking and reporting of ADR reports, Serious Adverse Event (SAE) reports from approved clinical trials and Adverse Events Following Immunisation (AEFI) reports through interactive web based forms and downloadable mobile/PC applications. Data will be sourced from users via the web, mobile and desktop application using the standard forms for MCAZ for SAE, AEFI and ADR reports and pushed to the MCAZ database. The landing page shows the different forms that a reporter can complete. Once a user is logged in, they can either create a new form or open an existing one on their account.
- 3.2 This document provides guidance on the following:
- 3.2.1 User Registration
 - 3.2.2 The Login Process
 - 3.2.3 Electronic reporting procedures
 - 3.2.4 Submission of follow up information/reports

4.0 DEFINITIONS

- 4.1 Adverse Event:** Any untoward medical occurrence in a patient or clinical investigation subject that may present during treatment or after administration of a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product
- 4.2 Adverse Event Following Immunisation (AEFI):** Any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding symptom or disease.
- 4.3 Adverse Drug Reaction (ADR):** For marketed medicinal products, this is a response to a medicine which is noxious and unintended, which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions
- 4.4 Consumer:** A person who is not a healthcare professional such as a patient, lawyer, friend, or relative of a patient
- 4.5 Home page:** For the purposes of this manual, Home page refers to the landing page for the Desktop and Mobile app as well as the following website; <https://e-pv.mcaz.co.zw/> . The landing page shows the different forms that a user/reporter can fill in.
- 4.6 Individual Case Safety Report (ICSR):** A report that contains information describing a suspected adverse drug reaction related to the administration of one or more medicinal products to an individual patient. These include ADR reports, SAE reports, as well as AEFI reports.
- 4.7 Medicine:** Any substance or mixture of substances which is used, or is manufactured, sold or represented as suitable for use, in the diagnosis, treatment, mitigation or prevention of disease or any abnormal physical or mental state or the symptoms thereof in man or in animals; or restoring, correcting or modifying any physical, mental or organic function in man or in animals.
- 4.8 National Pharmacovigilance Centre (NPVC):** Organisations, usually drug regulatory agencies, recognised to represent their country in the WHO Programme for International Drug Monitoring. A single, governmentally recognized centre within a country with the clinical and scientific expertise to collect, collate, analyse and give advice on all information related to drug safety It is a centre of expertise for the art and science of monitoring and analysis of ADRs, and in use of the information analyzed for the benefit of patients. The

Medicines Control Authority of Zimbabwe (MCAZ) is the Zimbabwe National Pharmacovigilance Centre

- 4.9 Reporter:** Any person, patient or healthcare professional or institute who describes a suspected adverse effect on an ADR or ICSR form for submission to the National Pharmacovigilance Centre or any other relevant organization for further consideration
- 4.10 Serious Adverse Event:** A serious adverse event or reaction is any untoward medical occurrence that at any dose results in death, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity or is life threatening. *Note:* The term "severe" is not synonymous with "serious". "Severe" is used to describe the intensity (severity) of a specific event (as in mild, moderate or severe); the event itself, however, may be of relatively minor medical significance (such as severe headache). Seriousness (not severity) which is based on patient/event outcome or action criteria serves as guide for defining regulatory reporting obligations.
- 4.11 Side Effect:** Any unintended effect of a medicine occurring at normal dosage which is related to the pharmacological properties of the medicine.
- 4.12 Spontaneous report:** An unsolicited communication to a company, regulatory authority, or other organization that describes an adverse drug reaction in a patient given one or more medicinal products and which does not derive from a study or any organized data collection scheme
- 4.13 Unexpected Adverse Drug Reaction:** An adverse reaction, the nature and severity of which is not consistent with the applicable product information e.g. Investigator's Brochure for an unapproved investigational medicinal product. Reports which add significant information on specificity or severity of a known, already documented serious ADR constitute unexpected events. For example, an event more specific or more severe than described in the Investigator's Brochure would be considered "unexpected". A specific example is acute renal failure as a labeled ADR with a subsequent new report of interstitial nephritis.

5.0 PROCEDURES

5.1 Getting Started

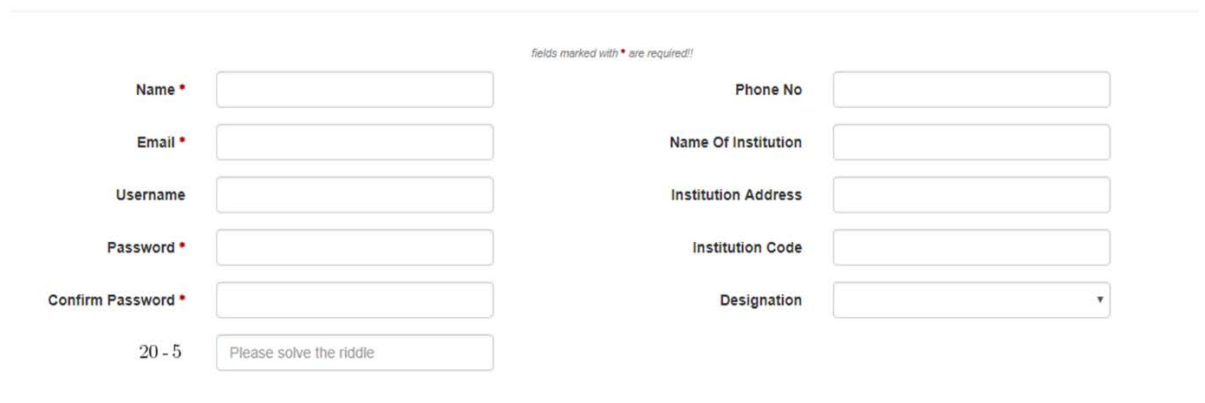
5.1.1 Registration

5.1.1.1 To start using the Pharmacovigilance system a user has to register their details on the electronic reporting platform using any of the following system platforms:

- i. Browser based Web Application (<https://e-pv.mcaz.co.zw>)
- ii. Android mobile application (MCAZ Pharmacovigilance)
- iii. iOs mobile application (MCAZ Pharmacovigilance)
- iv. Windows Desktop application
- v. Mac Os Desktop application (MacBook)
- vi. Linux Desktop application

5.1.1.2 Click on the **Register** ( Register) icon and fill in the details on the User Registration screen as shown below. Fields with an asterix (*) are mandatory and should be completed to facilitate registration.

Register



The screenshot shows a registration form titled "Register". At the top right, it says "fields marked with * are required!!". The form has two columns of input fields. The left column contains: "Name *" (text box), "Email *" (text box), "Username" (text box), "Password *" (text box), "Confirm Password *" (text box), and a CAPTCHA box with "20 - 5" and "Please solve the riddle". The right column contains: "Phone No" (text box), "Name Of Institution" (text box), "Institution Address" (text box), "Institution Code" (text box), and "Designation" (dropdown menu). Below the form is a blue "Register" button with a checkmark icon.

5.1.1.3 Click the **Register** icon at the bottom of the page and once the form has been submitted, the user will be redirected to the login page.

5.1.1.4 A verification and activation email will be sent to facilitate completion of registration. Click on the activation link to complete the registration process.

5.1.1.5 Once the registration process is completed, the user can log on to the system using their credentials

5.12 Login Process

5.1.2.1 The user will be required to enter the username/email and the password utilized during registration.

5.1.2.2 Click on login to access the system. The system will

- i. allow the user to login to the system if the credentials are correct.
- ii. throw an error if the credentials are not correct.

5.1.3 User Dashboard

5.1.3.1 The dashboard allows the users to

- i. Edit their profile
- ii. Change password

- iii. View/download submitted reports/applications
- iv. Track the progress of submissions
 - v. Submit feedback to MCAZ
- vi. View Committee meeting dates
- vii. View public statistics/reports

5.2 Electronic Reporting

5.2.1 Reporting Platform

5.2.1.1 After logging on to the reporting platform using the right credentials, the landing page will display the different forms that a user has access to as listed below:

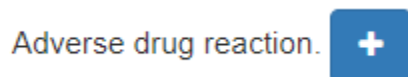
- i. Adverse Drug Reaction (ADR)
- ii. SAE
- iii. AEFI
- iv. AEFI Investigation
- v. E2B Files

5.2.2 New Report Confirmation

Once logged in, a new ICSR reporting form can be created by clicking on the (+) icon on the appropriate reporting category. A new report confirmation window will open and the user is required to confirm by clicking “**SUBMIT**” in order to avoid unnecessary forms being created

5.2.3 Adverse Drug Reaction (ADR) Report

5.2.3.1 Once logged in, create a new ADR form by clicking on the (+) icon illustrated below



5.2.3.2 A new report confirmation window, illustrated below, will open and the user is required to confirm by clicking “**SUBMIT**” in order to avoid unnecessary forms being created.

5.2.3.3 Enter and save the appropriate details regarding the ADR into the corresponding fields. The Spontaneous Adverse Drug Reaction Form

can only be submitted when all mandatory fields, (marked with an asterisk *) are completed.

5.2.3.4 The current medication table is dynamic therefore a user can add multiple items to the table and remove them where necessary.

5.2.3.5 Attach any supporting files that could accompany the submission.

5.2.3.6 Ensure most if not all fields are filled in to avoid the report being rejected.

5.2.3.7 Click on save changes if you wish to resume filling in the form at a later time. Click on cancel to stop editing the form without saving and return to the home menu. A popup will appear confirm if you want to cancel. All changes, unless saved, will be lost if you cancel.

5.2.3.8 When you are satisfied with the information filled in, click on “**Submit to MCAZ**”. Once a form is submitted, it cannot be edited. The submitted document can also be downloaded in PDF format

5.2.4 Follow Up Information for ADR Reports


5.2.4.1 A follow up report cannot be created for un-submitted forms. A user can only add follow up information after submitting a form.

- i. Click “**ADR**” on the landing page after logging in to access all submitted and saved Spontaneous ADR reports. Select the report for
- ii. Click “**Create Follow Up Report**”
- iii. Enter and save the additional information regarding the ADR.
- iv. When you are satisfied with the information filled in, click on “**Submit to MCAZ**”

5.2.5 Serious Adverse Event (SAE) Reports from approved clinical trials

5.2.5.1 The SAE reporting tab is intended for Adverse Event reports from approved clinical trials. The form is a joint MCAZ/MRCZ Serious Adverse Event (SAE) reporting form.

- i. Once logged in, create a new SAE form by clicking on the (+) icon illustrated below

Serious Adverse Event Reporting Form. 

- ii. A new report confirmation window, illustrated below, will open and the user is required to confirm by clicking “**SUBMIT**” in order to avoid unnecessary forms being created

Adverse Event After Immunization (AEFI) Report Form

Zimbabwe Report For Adverse Event Following Immunization

Enter your email address to start:

Reporter email

Submit

- iii. Enter and save the appropriate details regarding the SAE into the corresponding fields. The list of drugs, concomitant medication and lab test tables are dynamic therefore a user can add multiple items to the table and remove them where necessary.
- iv. Attach any supporting files that could accompany the submission.
- v. Ensure most if not all fields are filled in to avoid the report being rejected.
- vi. Click on save changes if you wish to resume filling in the form at a later time. To go back to the home menu without saving any changes, click **“Cancel”**. A popup will appear confirm if you want to cancel. All unsaved changes will be lost if you cancel.
- vii. When you are satisfied with the information entered, click **“Submit to MCAZ”**. The form can only be submitted when all mandatory fields, (marked with an asterisk *) are completed. Once a form is submitted a form cannot be edited. The submitted document can also be downloaded in PDF format.


5.2.6 Follow Up Information for SAE Reports

5.2.6.1 A follow up report cannot be created for un-submitted forms. A user can only add follow up information after submitting a form.

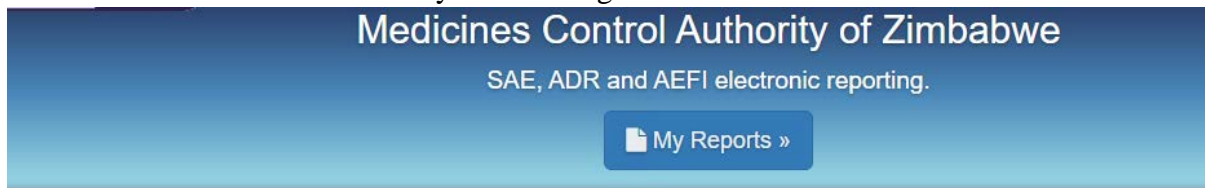
- i. Click **“SAE”** on the landing page after logging in to access all submitted and saved Serious Adverse Event reports. Select the report for which follow up information is to be added.
- ii. Click **“Create Follow Up Report”**
- iii. Enter and save the additional information regarding the ADR.
- iv. When you are satisfied with the information filled in, click **“Submit to MCAZ”**

5.2.7 Adverse Event Following Immunization (AEFI) Reports

5.2.7.1 Once logged in, create a new AEFI form by clicking on the (+) icon illustrated below

Adverse Event Following Immunization. 

5.2.7.2 A new report confirmation window, illustrated below, will open and the user is required to confirm by clicking “SUBMIT” in order to avoid unnecessary forms being created.



Adverse Event After Immunization (AEFI) Report Form

Zimbabwe Report For Adverse Event Following Immunization

Enter your email address to start:

Reporter email

Submit

5.2.7.3 Enter and save the appropriate details regarding the AEFI into the corresponding fields. The vaccine table is dynamic therefore a user can add multiple items to the table and remove them where necessary.

5.2.7.4 Attach any supporting files that could accompany the submission.

5.2.7.5 Ensure most if not all fields are filled in to avoid the report being rejected.

5.2.7.6 Click on save changes if you wish to resume filling in the form at a later time.

5.2.7.7 To go back to the home menu without saving any changes, click cancel. A popup will appear confirming if you want to cancel. All changes unless saved will be lost if you cancel.

5.2.7.8 When you are satisfied with the information entered, click on **Submit to MCAZ**. The form can only be submitted when all mandatory fields, (marked with an asterisk *) are completed.

5.2.7.9 Once a form is submitted a form cannot be edited. The submitted document can also be downloaded in PDF format

5.2.8 Follow up Information for AEFIs

5.2.8.1 A user can add follow up information after submitting a form and there is no limit on the number off follow ups a user can add. However, only the following information can be added:

- i. Vaccine information
- ii. Adverse events
- iii. Date and Time AEFI started
- iv. Was patient hospitalized
- v. Date patient notified event to health system
- vi. Description of AEFI (Signs & Symptoms)
- vii. Treatment provided
- viii. Additional files

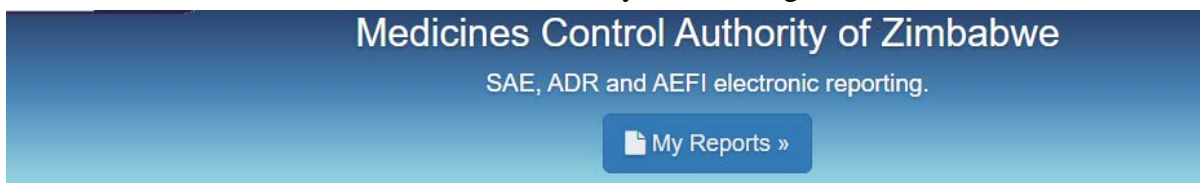
5.2.9 Adverse Events Following Immunization Investigation Form

5.2.9.1 This tab is used for Investigation forms for Serious Adverse Events Following Immunization i.e. those involving death, disability, hospitalization or clusters

- i. Once logged in, create a new investigation form by clicking on the (+) icon illustrated below

Serious Adverse Event Following Immunization. 

- ii. A new report confirmation window, illustrated below, will open and the user is required to confirm by clicking “SUBMIT” in order to avoid unnecessary forms being created.



Adverse Event After Immunization (AEFI) Report Form

Zimbabwe Report For Adverse Event Following Immunization


Enter your email address to start:

Reporter email

- iii. Enter and save the appropriate details regarding serious adverse event into the corresponding fields. The form can only be submitted when all mandatory fields, (marked with an asterisk *) are completed.
- iv. The current medication table is dynamic therefore a user can add multiple items to the table and remove them where necessary.
- v. Attach any supporting files that could accompany the submission.
- vi. Ensure most if not all fields are filled to avoid the report being rejected.
- vii. Click on save changes if you wish to resume filling in the form at a later time. Click on cancel to stop editing the form without saving and return to the home menu. A popup will appear confirm if you want to cancel. All changes, unless saved, will be lost if you cancel.
- viii. When you are satisfied with the information filled in, click on “**Submit to MCAZ**”. Once a form is submitted, it cannot be edited. The submitted document can also be downloaded in PDF format

5.2.10 E2B Files

5.2.10.1 Once logged in, E2B Files can be uploaded by clicking on the (+) icon illustrated below

Send E2B files to MCAZ. 

5.2.10.2 Fill in the information for all the fields marked as mandatory.

5.2.10.3 Attach the file and type in a short description of the file contents

5.2.10.4 Click “**Submit to MCAZ**”.

5.2.11 Editing an Un-submitted report

5.2.11.1 Login to the reporting platform

5.2.11.2 On the landing page select the appropriate icon. Clicking **ADR/AEFI/SAE** on the homepage will redirect the reporter to a page that lists all the available reports.

5.2.11.3 Select the required report reference number and the report will load. Enter the additional information and review the form for correctness. If no further editing is required, click “**Submit to MCAZ**”. If further editing is still required, click “**Save Changes**”.

6.0 KEY RELEVANT DOCUMENTS

Useful resources regarding pharmacovigilance in Zimbabwe are listed below:

- 6.1 Zimbabwe National Pharmacovigilance Handbook 2nd Edition February 2017
- 6.2 Zimbabwe Adverse Events Following Immunization 3rd Edition January 2017
- 6.3 Medicines and Allied Substance Control Act (MASCA) Chapter 15:03 and its Regulations
- 6.4 WHO Handbook for Pharmacovigilance indicators and regional sentinel sites WHO 2015
- 6.5 MCAZ website [http: www.mcaz.co.zw](http://www.mcaz.co.zw)
- 6.6 <https://www.who-umc.org/global-pharmacovigilance/global-pharmacovigilance/glossary/>
- 6.7 Comfort KS, Geraldine H, Sabblah G, Mimi D, Muthuri G, Abwao E, Pandit J, Osakwe A.I, Elagbaye C, Nyambayo P, Khoza S, Dodoo AN, Pal SN. Drug Safety 2015 No; 38 (11) 1115-26.
- 6.8 S Khoza, I Madungwe, P Nyambayo, J Mthethwa, O Chikuni. Adverse drug reactions reporting at a referral hospital in Zimbabwe. Central African Journal of Medicine 2004; 50 (11/12).
- 6.9 P Nyambayo, Gavi S Mahlangu G et al. Impact and feasibility of Pilot Phase of Targeted Spontaneous Reporting (TSR) of ARVs and ant-TBs in Zimbabwe. First African Congress of Pharmacovigilance. Actes du Congress Rabat 2013.
- 6.10 P Nyambayo. Targeted Spontaneous Reporting (TSR) of ARVs and ant-TBs. MOHCC & TARC National Research Forum
- 6.11 ICH E2E :Pharmacovigilance Planning (P), CPMP/ICH/5716/03

7.0 REVIEW OF THE MANUAL

The manual will be the guiding document for all users of the MCAZ electronic pharmacovigilance reporting system and will be reviewed as and when required due to the changes in regulations, standards and best practices as appropriate.