MCAZ Medicines Control Authority of Zimbabwe

Medicines Information Bulletin

1st Edition 2025

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Scan the QR code to access VigiMobile for ADRs

Scan the QR code to access VigiMobile for AEFIs

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MCAZ Pharmacovigilance updates

1 January to 30 June 2025 Individual Case Safety Reports

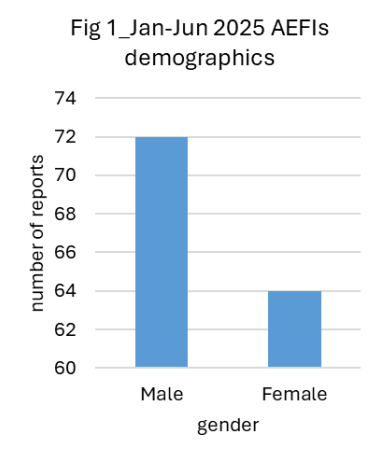
The MCAZ Pharmacovigilance and Clinical trials (PVCT) is the National Centre for Pharmacovigilance and has been a member of the World Health Organisation (WHO) Programme for International Drug Monitoring since 1998. The MCAZ-PVCT conducts spontaneous (voluntary) adverse drug reaction monitoring, and active/ enhanced pharmacovigilance programs of medicines and vaccines on the Zimbabwean market, in collaboration with the Ministry of Health and Child Care (MoHCC) public health programs, private health sectors, healthcare providers, pharmaceutical industry, consumers, patients and partners. Special thanks to all the reporters for their continued support in promoting patient safety.

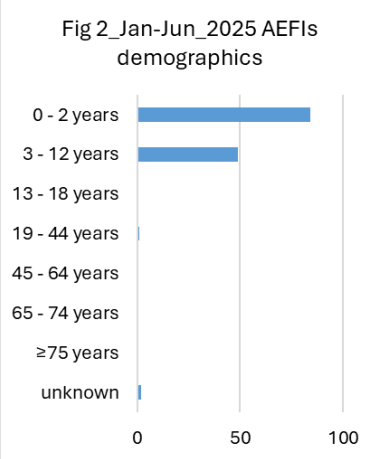
Table 1: Summary of Individual Case Safety Reports (ADRs, AEFIs and SAEs) received at the MCAZ for the period 1 January 2025 to 30 June 2025

Type of ICSR reports	Number and percentage received and processed from 1 January 2025 to 30 June 2025
ADRs from pharmaceutical industry (CIOMs, XML/E2B)	**19 (8%)**
Adverse Events Following Immunization (AEFIs)	**136 (57%)** (*The VigiMobile app and VigiFlow system for AEFI reporting have greatly improved AEFI reporting timelines*)
Adverse Drug Reactions (ADRs) from the TSR of all essential medicines including ARVs and Anti-TBs from public and private sector	**30 (13%)** *ARVs – 7* *Anti-TBs – 12* *Other essential medicines – 11*
Serious Adverse Events (SAEs) from approved clinical trials conducted in Zimbabwe	**52 (22%)**
Total	**237**

Adverse Events Following Immunisation (AEFI) reports

A total of 136 AEFI reports were received in the period January to June 2025. Eighty percent (80%) of the reports were not serious and 20% were serious. At the time of reporting, the majority (78%) of the vaccine recipients had recovered/ were recovering.





Sixty-two percent (62%) of the vaccine recipients were aged between 0 – 2years and 36% were between 3-12years. Causality assessment for all the reports was conducted by the National AEFI Committee using the World Health Organization (WHO) AEFI Aide-Memoire on causality assessment and feedback was provided to the reporters.

Table 1. Common adverse reactions and administered vaccines for AEFI reports received from 1 January 2025 to 30 June 2025

Vaccine(s) administered	Adverse Event	Number of reports
BCG vaccine	Injection site abscess	3
bivalent Oral Polio Vaccine	Crying	3
	Rash	3
Novel oral polio vaccine type 2 (nOPV2)	Rash	22
	Vomiting	15
	Pyrexia	13
	Abdominal pain	8
	Rash pruritic	8
	Decreased appetite	7
	Pruritus	6
	Diarrhoea	5
	Headache	5
	Cough	4
	Crying	4
	Eye swelling	3
	Stomatitis	3
Pneumococcal Conjugate Vaccine	Swelling of vaccinated limb	4
	Crying	3
	Injection site swelling	3
Pentavalent vaccine	Injection site swelling	13
	Injection site abscess	13
	Crying	5
	Injection site pain	5
	Swelling of injected limb	5
	Pyrexia	3
Rotavirus vaccine	Crying	3

Following the national nOPV2 campaign on 7 February 2025, which vaccinated 4,858,596 children under 10, a high number of AEFI reports were received. The adverse reactions included rash, vomiting, pyrexia, abdominal pain etc. Such increases are expected during mass campaigns due to the large number of vaccine recipients. We encourage healthcare professionals to continue reporting adverse events/ reactions to continue promoting public safety.

Post-market surveillance plan (PMS) for 2025 and medicines monitoring

The Medicines Control Authority of Zimbabwe (MCAZ) is a statutory body established by an Act of Parliament to protect public health. The mandate of MCAZ is to ensure that medicines, medical devices, and allied substances available in the market are safe, effective, and of good quality. As part of the many activities to achieve its mandate, the Authority runs a Post-Marketing Surveillance (PMS) plan aimed at monitoring the quality of medicines distributed in Zimbabwe. MCAZ is also the national centre for pharmacovigilance and is responsible for safety monitoring of medicines, and vaccines on the Zimbabwean market, in collaboration with the Ministry of Health and Child Care (MoHCC) public health programs, the private health sector, healthcare providers, pharmaceutical industry, consumers, patients and partners.

The PMS plan

Detailed information on the plan is provided in Circular 27 of 2024 which is available on the MCAZ website. The plan includes targeted sampling and testing of medicines and prioritizes therapeutic categories with a high public health impact. The selection of products for inclusion in the plan is risk-based. The list of products included in the PMS plan is shown in table 1 below.

Table 2: Products included in the 2025 PMS plan

TB	ANTIHYPERTENSIVES	HIV	MALARIA
Bedaquiline 100mg Tablets	Amiloride Hydrochloride 5mg Tablets	Darunavir 600 mg Tablets	Artesunate (w/ 1 Amp NaHCO3 5% + 1 Amp NaCl 0.9%) 60 mg Vial 1 Set
Clofazimine 100mg Capsules	Amiloride hydrochloride/ hydrochlorothiazide 5/50mg Tablets	Ritonavir 100 mg Tablets	Primaquine 15 mg Tablets
Cycloserine 250mg Capsules	Amlodipine Besylate 5mg Tablets	Dolutegravir 50 mg Tablets	Quinine Dihydrochloride 600mg/2mL Ampoules
Delamanid 50mg Tablets	Captopril 25mg tablets	Ritonavir 25 mg Tablets	Artemether/ Lumefantrine 20/120mg Dispersible Tablets
Ethambutol 400mg Tablets	Enalapril maleate 20mg Tablets	Dolutegravir 10 mg Tablets	Artesunate/ Amodiaquine 100/270mg Tablets
Ethionamide 250mg Tablets	Enalapril maleate 10mg Tablets	Nevirapine 10 mg/mL Suspension w/ Syringe 100 mL	Artesunate/Amodiaquine 25/67.5mg Tablets
Isoniazid 100mg Tablets	Enalapril maleate 5mg Tablets	Raltegravir 100mg Tablets	Artesunate/ Amodiaquine 50/135mg Tablets
Levofloxacin 500mg Tablets	Furosemide 40mg Tablets	Atazanavir/Ritonavir 300/100mg Tablets	Sulfadoxine/ Pyrimethamine 500/25mg Tablets

TB	ANTIHYPERTENSIVES	HIV	MALARIA
Linezolid 600mg Tablets	Hydrochlorothiazide 25mg Tablets	Lamivudine/Tenofovir DF 300/300 mg Tablets	
Moxifloxacin 400mg Tablets	Hydrochlorothiazide/ losartan potassium 12.5mg/50mg Tablets	Lopinavir/Ritonavir 200/50mg Tablets	
Pretomanid 200mg Tablets	Losartan 50mg Tablets	Emtricitabine/Tenofovir DF 200/300 mg Tablets	
Pyrazinamide 400mg Tablets	Methyldopa 250mg Tablets	Abacavir/Lamivudine 600/300 mg Tablets	
Pyridoxine 25mg Tablets/ Pyridoxine 50mg Tablets	Prazosin hydrochloride 5mg Tablets	Lamivudine/Zidovudine 30/60mg Tablets	
Rifabutin 150mg Capsules	Prazosin hydrochloride 1mg Tablets	Dolutegravir/ Emtricitabine/Tenofovir AF 50/200/25mg Tablets	
Isoniazid/Rifampicin (150/75) Tablets	Propranolol hydrochloride 40mg Tablets	Dolutegravir/ Lamivudine/Tenofovir DF 50/300/300mg Tablets	
Isoniazid/Rifapentine (300/300) Tablets	Spironolactone 25mg Tablets	Dolutegravir/Abacavir/ Lamivudine 5/60/30 mg Tablets	
Ethambutol/Isoniazid/ Pyrazinamide/Rifampicin 275mg/75mg/400mg/ 150mg Tablets			

Call to action: Report suspected adverse drug reactions (ADRs) or suspected product quality issues

These medicines are also under enhanced surveillance. As the national pharmacovigilance centre, MCAZ urges all healthcare professionals, individuals, patients, and caregivers to actively report any suspected ADRs, or suspected product quality issues associated with these medicines. Suspected product quality issues can be reported to MCAZ using the Report on Medicinal (Pharmaceutical) Product Defect or Problem (LEF 80), available on request and accessible on the MCAZ website. An ADR report should include information on the suspected medicine, the reaction information and patient information (initials, gender, age) and reporter information (to provide feedback). ADR reports may be submitted using any of the following convenient reporting platforms:

1. ADR consumer web - based reporting form on the MCAZ website under "Online Services
2. Adverse Drug Reaction (ADR) reporting form available on the MCAZ website (Physical copies readily available and can be provided on request)
3. Email: mcaz@mcaz.co.zw and pvct@mcaz.co.zw
4. WhatsApp: +263718855934
5. Telephone (Toll free): Telone: 08004507; Econet: 08080641
6. Telephone: +263 772145191/2/3 and +263 242 736981-7

Substandard and Falsified Medicines Alerts

A substandard medical product is an **authorized product** that does not meet quality standards or specifications, produced by a known manufacturer with **no intent to fool or defraud** the patient. A falsified medical product is one that is **deliberately and fraudulently labelled** in a way that misrepresents its identity, source or composition and is often produced in unsanitary and unregulated conditions by an unknown manufacturer.

Alert on falsified Abhayrab rabies vaccine distributed by unauthorised sources

MCAZ identified a falsified ABHAYRAB Rabies vaccine, circulating in the market through unauthorised sources. This falsified product poses a significant threat to public health due to the potential for lack of efficacy, harmful components, and the risk of treatment failure in preventing rabies, a fatal disease. The Authority would like to draw the attention of all licensed wholesalers, pharmacies, public and private clinics and hospitals that they should quarantine any units of the falsified ABHAYRAB Rabies vaccine. Thereafter, these quarantined units must be submitted to the Authority for disposal. The general public who might have purchased the same falsified vaccine is advised to return the product to the pharmacy where they obtained the medicine.

HOW TO DETECT:

	FALSIFIED VACCINE	REGISTERED VACCINE
Product name	RABIES VACCINE, HUMAN I.P.	RABIES VACCINE B.P. 'Rab'
Declared active ingredient	Purified Vero Cell Rabies Vaccine	Purified Vero Cell Rabies Vaccine
Stated manufacturer	Human Biologicals Institute (A division of Indian Immunologicals Limited), Survey No.: 281-284 and 321, Biotech Park, Phase III, Karkapatla Village, Markook Mandal, Siddipet (Dist.) 502 281, Telanagana, India	Human Biologicals Institute (A division of Indian Immunologicals Limited), Kazhipannai, Pudumund P.O., Dr Basavaiah Nagar, Udhagamandalam, Pin: 643007, Tamil Nadu, India
Batch number	KE24002 *(Sample)*	24URAB086 *(Sample)*
Expiry date	05/27 *(Sample)*	OCT27 *(Sample)*

World Health Organization (WHO) Global Surveillance and Monitoring System for Substandard and Falsified Medical Products

Summarized below are alerts communicated by the WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products for the year 2025 (as of 14 May 2025).

Alert No	Alert Summary
Medical Product Alert No. 1/2025 – Falsified (contaminated) OXYCONTIN 80mg identified in the WHO European Region	One batch of falsified OXYCONTIN 80mg (oxycodone hydrochloride) was detected in the unregulated market in Switzerland and reported to WHO in February 2025 by the genuine manufacturer MUNDIPHARMA. In identifying this product as falsified, the following visible discrepancies were noted • The placement of the batch and expiry date on the falsified product was incorrect. • On the falsified product the batch and expiry date are visible on the front side of the blister strip.

Alert No	Alert Summary
	• Genuine OXYCONTIN has the batch and expiry date visible on the back of the blister strip. • On the falsified product the expiry date is on the left and the batch number on the right. • Genuine OXYCONTIN has the batch number on the left and the expiry date on the right. This falsified product has been found to contain undeclared nitazene compounds, which pose a significant risk due to the high likelihood of adverse events, even in small doses. Nitazenes produce effects similar to other opioids. Their high potency carries a high risk of overdose and death.
WHO information notice for users of malaria IVDs 2025/1	In 2024, the World Health Organization (WHO) was informed that various malaria rapid diagnostic tests (RDT) showed faint positive test lines for patients with confirmed malaria infection. Faint test lines may led to misdiagnosis and therefore delayed appropriate treatment. **Actions to be taken by users/healthcare professionals recommended by WHO:** 1. Carefully follow the instructions for use of the product. Read any test line as positive, no matter how faint the test line. Fully fill and dispense completely the blood from the specimen transfer device. 2. Respect storage conditions for the test kit. 3. If the RDT results are negative and no alternative diagnosis is found, advise patients to return for re-evaluation or re-testing if their symptoms worsen or their condition does not improve. 4. Report any unusual testing results to the manufacturer.
Medical Product Alert N°2/2025: **Falsified HEALMOXY (Amoxicillin) Capsules 500mg identified in the WHO African Region**	Four batches of falsified HEALMOXY Capsules 500mg were detected in Cameroon and the Central African Republic and reported to the WHO in March 2025. These products are falsified as they deliberately misrepresent their identity, composition, and source. Analysis of samples of the falsified HEALMOXY found the capsules did not contain the stated active ingredient, specifically amoxicillin. At least two of the falsified products display inconsistent formats for manufacturer and expiry dates. Dates on these falsified products are displayed as day/month/year in eight digits (e.g., 10/01/2027). Health-care professionals advised to report any incident of adverse effects, lack of therapeutic effect or suspected falsification to the MCAZ.
Medical Product Alert N°3/2025: **Falsified IMFINZI (durvalumab) injection**	Three batches of falsified IMFINZI (durvalumab) injection 500mg/10ml were detected in the Islamic Republic of Iran and Türkiye. These falsified products were reported to WHO in March 2025. The falsified lots (lot BAZR and lot BBEG) showed discrepancies in the packaging artwork and text placement, with some text missing. Falsified products were also identified with lot number AVZT which was not recognized by the genuine manufacturer. Any IMFINZI product with this lot number (AVZT) is considered falsified.

Suspected substandard and falsified products can be reported to MCAZ using the Report on Medicinal (Pharmaceutical) Product Defect or Problem (LEF 80), available on request and accessible on the MCAZ website. If you, or someone you know, has or may have used any substandard or falsified medicines and suffered an adverse reaction after use, you are advised to seek immediate medical advice from a healthcare professional and report the adverse event to MCAZ. Adverse events can be reported to MCAZ using the online consumer reporting form available on the MCAZ website or by completing either the Adverse Drug Reaction reporting form or the consumer reporting form both of which are available on request from MCAZ as hard copies and can be downloaded the MCAZ website.

Reference

1. https://www.who.int/teams/regulation-prequalification/incidents-and-SF/full-list-of-who-medical-product-alerts
2. MCAZ Circular 3 of 2025

Approved Change of Category for distribution

The MCAZ Pharmacovigilance and Clinical Trials division is also responsible for reviewing the safety of new and old medicines including category for distribution of medicines. During the last 15-year period, the MCAZ recategorized the following medicines as listed in table 1 below. Letters to applicants and Circulars were already written to their effect and the medicines new categories for distribution will be gazetted as such.

Table 1: MCAZ list of recategorized medicines from 2010 to 30 June 2025

Trade Name	Generic Name	Registration Number	CATEGORY CHANGE	Minute ref/ Year
Grandpa headache	Paracetamol 453,6mg/ aspirin 324/ caffeine 64,8mg	75/2.2/440	From pharmacy medicine (P) to Household Remedy (HR)	2010
All brands	Ibuprofen 200mg	All registered products	Pharmacist Initiated Medicines (PIM) to Household Remedies (HR) for pack sizes of 20 dosage units or less	2010
All brands	Ibuprofen 400mg	All registered products	Prescription Preparations (PP) to Pharmacist Initiated Medicines	2010
All brands	Cimetidine 200mg	All registered products	Prescription Preparations (PP10) to Pharmacist Initiated Medicines (P.I.M)	2010
Coartem Lumartem Lumither	Artemether and Lumefantrine 20mg/120mg	2000/7.5/3664 2009/7.5/4574 2014/7.5/4919	Prescription Preparations (PP) to Pharmacist Initiated Medicines (PIM)	2010
Relcer Gel	Aluminium and Magnesium Hydroxide, Liquorice, Simethicone	2001/16.1/3931	From Pharmacy medicines (P) to Household Remedies (HR)	2014
Patanol	Olopatadine Hydrochloride 0.1%	2002/19.9/4020	Prescription Preparations (PP) to Pharmacist Initiated Medicines (PIM)	2014
Relestat Eye Drops	Epinastine Hydrochloride	2014/19.9/4899	From Prescription Preparation (PP) to Pharmacist Initiated Medicine (PIM)	2015
All brands	Loratadine 10mg tablets in packs of 10 or less dosage units	All registered products	Prescription Preparations (PP) to Pharmacist Initiated Medicines (PIM) in packs of 10 or less dosage units	2016
All brands	Cetirizine 10mg tablets in packs of 10 or less dosage units	All registered products	Prescription Preparations (PP) to Pharmacist Initiated Medicines (PIM) in packs of 10 or less dosage units	2016

Trade Name	Generic Name	Registration Number	CATEGORY CHANGE	Minute ref/ Year
All brands	Omeprazole 20mg in packs of 14 or less dosage units	All registered products	Prescription Preparations (PP) to Pharmacist Initiated Medicines (PIM) in packs of 14 or less dosage units	2016
Andolex C Oral Rinse	Benzydamine hydrochloride; chlorhexidine gluconate	99/20.3.4/3526	Household Remedies (H.R) to Pharmacist Initiated Medicines (P.I.M.)	2016
Andolex C Spray	Benzydamine hydrochloride; chlorhexidine gluconate	2015/20.3.4/4974	Household Remedies (H.R) to Pharmacist Initiated Medicines (P.I.M.)	2016
All brands	Indomethacin Topical Preparations	All registered products	Pharmacist Initiated Medicine (P.I.M.) to Pharmacy Medicine (P)	2017
Cepacol plus original lozenges **Cepacol throat lozenges**	Cetylpyridinium chloride; benzocaine 10mg/ 1.4mg Benzyl alcohol; cetylpyridinium 6.5mg/ 1.47mg	79/20.3.5/866 76/20.3.4/704	Pharmacy medicines (P) to Household Remedies (HR)	2017
Cream E45	Paraffin soft white; liquid paraffin; wool fat	2016/14.4/5231	Pharmacy medicines (P) to Household Remedies (HR)	2018
Novafen Gel	Ibuprofen 5% Gel	2015/3.1/5063	Pharmacy medicines (P) to Household Remedies (HR)	2018
All brands	Pantoprazole 20mg	All registered products	Prescription Preparations (PP) to Pharmacist Initiated Medicines (PIM)	2019
All brands	Lansoprazole 30mg	All registered products	Prescription Preparations (PP) to Pharmacist Initiated Medicines (PIM)	2019
All brands	Rabeprazole 20mg	All registered products	Prescription Preparations (PP) to Pharmacist Initiated Medicines (PIM)	2019
All brands	Esomeprazole 20mg	All registered products	Prescription Preparations (PP) to Pharmacist Initiated Medicines (PIM)	2019
All brands	Mepyramine maleate 2% topical cream	All registered products	Pharmacy medicines (P) to Household Remedies (HR)	2019
All brands	Desogestrel/ Ethinylestradiol 150mcg/30mcg	All registered products	Prescription Preparations (PP) to Pharmacist Initiated Medicines (PIM)	2021
All brands	Loratidine 10mg Loratidine 5mg/5ml	All registered products	Pharmacist Initiated Medicine (P.I.M.) to Pharmacy Medicine (P)	2022
All brands	Cetirizine 10mg Loratidine 5mg/5ml	All registered products	Pharmacist Initiated Medicine (P.I.M.) to Pharmacy Medicine (P)	2022
All brands	N-Acetylcysteine	All registered products	Prescription Preparation (PP) to Pharmacy Medicine (P)	2024

Circular 10 of 2025

Ref: B/279/10/2025

Date: 10th April 2025

To: ALL LICENSED PHARMACEUTICAL WHOLESALERS, PHARMACIES, PUBLIC AND PRIVATE CLINICS AND HOSPITALS

RE: CLASS 11 RECALL UP TO RETAIL LEVEL OF TORRENT CAPROPRIL 25MG TABLETS, REG NO.: 2000/12.3.5/3685, BATCH: B520K001, MANUFACTORED BY TORRENT PHARMACEUTICALS LTD, INDRAD PLANT, NEAR INDRAD VILLAGE, TALUKA KADI, DISTRICT MEHSANA, GUJARAT, INDIA

Torrent Pharmaceuticals Ltd, India. The reported batch of Captopril 25mg tablets is being recalled because an out of specification (OOS) in the limit of Captopril dilsufide (OSS No: OOS/BST/25/004). Non-compliance with specifications of product quality may result in loss of function and harm to the patient.

The Authority would like to draw attention of all licensed wholesalers, pharmacies', public and private clinics and hospitals that they should quarantine any of the affected units of the reported product and cooperate with Torrent Pharmaceuticals Ltd and local distributors of the product in Zimbabwe during the recall process. The general public who might have purchased the same reported batch are advised to return the product to the pharmacy where they obtained the medicine.

Yours Faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

Circular 10 of 2025 is available on the MCAZ website.

Circular 16 of 2025

REF: B/279/35/16/2025

Date: 12th of June 2025

To: ALL INVESTIGATORS AND SPONSORS OF CLINICAL TRIALS

RE: PUBLICATION OF SUMMARISED PUBLIC ASSESSMENT REPORTS FOR CLINICAL TRIAL APPLICATIONS AND PUBLIC INSPECTION REPORTS FOR GOOD CLINICAL TRIAL PRACTICE (GCP) INSPECTIONS

We wish to advise that the Medicines Control Authority of Zimbabwe (MCAZ) will be publishing summarised public assessment reports (PAR) for clinical trial applications and public inspection report (PIR) for GCP inspections on the MCAZ websites and/or e-Clinical Trial Registry Registry Platform. All the clinical trial applications which were authorised or rejected from January 2025 and GCP inspections conducted from January 2025 will be impacted by this procedure.

On closure of the GCP inspection and once the clinical trial application has been authorised or rejected, a copy of the PAR or PIR shall be sent to the Principal Investigator (PI) for comments and if there are any comments, these should be submitted within ten (10) working days of the receipt of the report. If no comments are received within ten (10) working days, the Authority will proceed to publish the report. The public GCP inspection report shall remain valid until the next inspection following which the most recent inspection report will be published.

Publication of summarised PAR for clinical trial applications and PIR for GCP inspections shall be included as conditions of authorisation for all the clinical trials that will be authorised by the MCAZ.

The PAR and PIR shall contain non-confidential information as guided by section 73 of the Medicines and Allied Substance Control Act [Chapter 15:03]. Any confidential and intellectual property will be redacted prior to publication of the reports.

Please note that these new developments are in line with the WHO Global Benchmarking Maturity Level 4 requirements and international good regulatory practices to promote transparency, accountability and communication.

Yours sincerely,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

Circular 16 of 2025 is available on the MCAZ website.

2025 Pharmacovigilance M& E site visits

The MCAZ-PVCT division and the Projects office carried out monitoring and evaluations (M&E) visits in 4 provinces: Matebeleland South, Matebeleland North, Masvingo and Mashonaland Central, sponsored by the Global Fund/ United Nations Development Programme (GF/UNDP). This was done following the VigiMobile/ VigiFlow trainings which were conducted in 2024.

The aims of the visits were to.

1. Verify the extent to which information was cascaded to facility level from the provincial pharmacovigilance trainings that were conducted in August to September 2024
2. Disseminate updates on current pharmacovigilance activities
3. Scale up the use of VigiMobile and VigiFlow for ADR as well as VigiMobile and VigiFlow for AEFI electronic reporting tools,
4. Identify any challenges being faced by health care providers in reporting ADRs and AEFIs
5. Distribute pharmacovigilance materials, and
6. Collect completed paper-based ADR and AEFI reports

A total of 41 sites in 29 districts across the 4 provinces were visited. We thank the health care professionals, Ministry of Health and Child Care (MoHCC), and GF/UNDP for their continued support of the national pharmacovigilance program.