Medicines Control Authority of Zimbabwe

APRIL 2023

MEDICINE INFORMATION BULLETIN

@MCAZofficial

+263-242-736981-7
+263772 145 191/2/3

mcaz@mcaz.co.zw

www.mcaz.co.zw

Contents

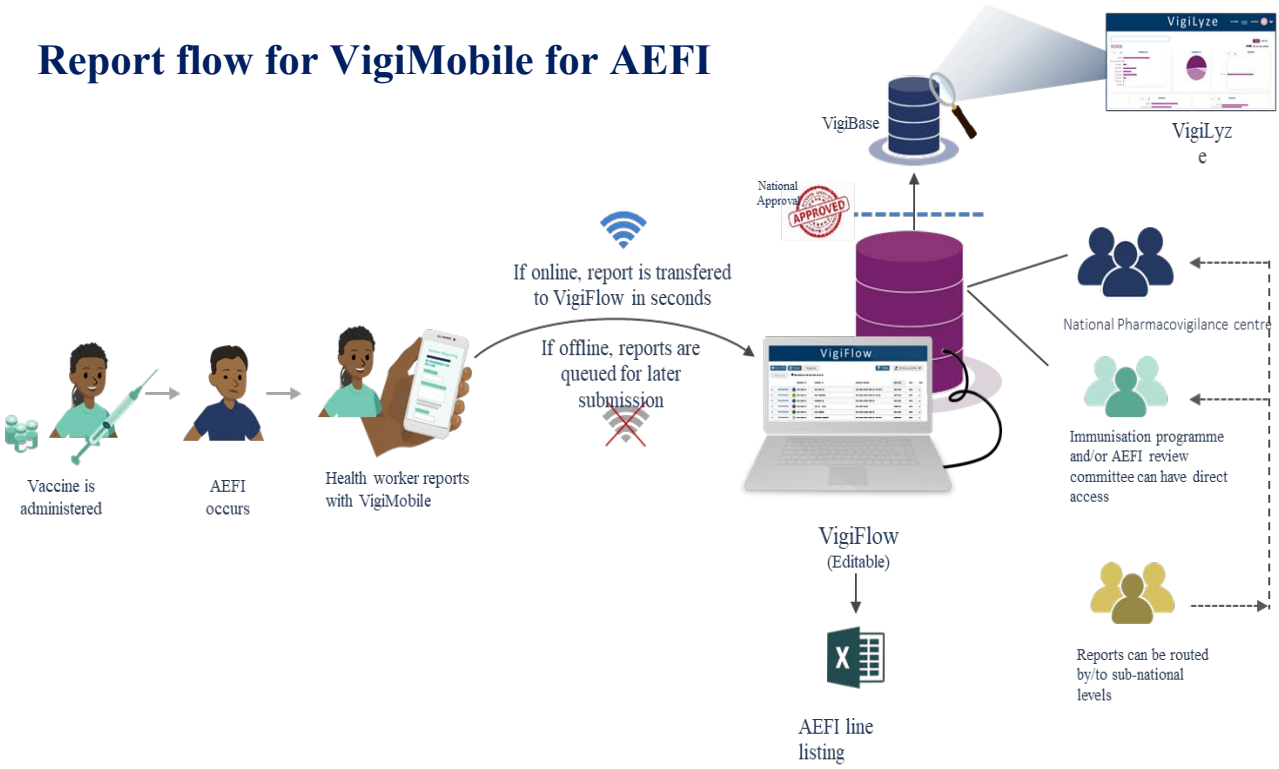
Vaccine safety monitoring: Deployment of the VigiFlow and VigiMobile tools for ADR and AEFI reporting countrywide

AEFI surveillance is an essential strategy for ensuring the safety of vaccines. The MoHCC-ZEPI and the MCAZ are the main drivers of vaccine safety surveillance. There is need to continuously strengthen AEFI surveillance in Zimbabwe (timely reporting, access to AEFI data at all levels, enables data monitoring and analysis), hence the introduction of the VigiFlow and VigiMobile tools.

What is VigiMobile?

VigiMobile is an app specifically developed by the Uppsala Monitoring Centre (UMC) for AEFI field reporting. Immunisation workers can use it to collect data on their smartphone or other mobile device even when they are offline. VigiMobile uses the WHO standard AEFI reporting form based on the 25 core variables recommended by WHO for collecting AEFI data. If the health worker has an internet connection, the report will be transferred to VigiFlow within seconds. If they are offline, the report will be queued for later transmission.

Report flow for VigiMobile for AEFI



The VigiMobile application can be downloaded on mobile phones, tablets, ipads and laptops/ computers using the QR codes below:

OR

The Zimbabwe "live" VigiMobile for AEFI reporting for use by healthcare professionals can also be accessed using the following link: https://vaccine-primaryereporting.who-umc.org/zw_aefi

VigiFlow is a web-based ICSR data management system. It is a national pharmacovigilance database which supports the collection, processing, analyzing and sharing of both ADR and AEFI reports.

VigiFlow allows the reporting of AEFI (and ADR) from the district to the national level allowing supervisors to review, monitor and process the data on the national database (VigiFlow). When integrated with VigiMobile the flexibility is tremendously enhanced permitting AEFI reporting from the field to the national database (VigiFlow) allowing supervisors to review, monitor and process the data on the national database.

The Zimbabwe "live" VigiFlow for AEFI reporting for use by healthcare professionals as can be accessed using the following link: https://vigiflow.who-umc.org

VigiFlow/ VigiMobile tools deployment plan

The National VigiFlow/ VigiMobile tools for AEFI reporting training was conducted from the 27th of February to the 1st of March 2023 and it was facilitated by the WHO with support from the MoHCC-EPI, CDC and the MCAZ. The provincial nursing officers (PNOs), PEPIOs and provincial health information officers (PHIOs) from the eleven provinces in Zimbabwe were in attendance.

The main objective of the meeting was to train health care workers on the VigiMobile and VigiFlow tools for AEFI reporting as well as a refresher on the serious AEFI case investigation process.

Following the National training, the MCAZ and MoHCC-EPI rolled out VigiMobile and VigiFlow in a series of Provincial training were District Nursing Officers (DNOs), District Health Information Officers (DHIOs) and District EPI Officers from all 64 districts were trained from the 14th to the 24th of March 2023.

Plans are underway to further disseminate the VigiMobile/ VigiFlow trainings to all the 1741 health facilities in Zimbabwe. The use and effectiveness of VigiMobile/ VigiFlow will be continuously monitored and evaluated by the MoHCC-EPI and MCAZ.

BioRes Scientia Publishers

Clinical Case Reports and Studies
2023 Volume 2, Issue 1
https://www.doi.org/brs/2023/ccrs/0023

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Descriptive Research Study of the Adverse Events Following Immunization (AEFIs) Surveillance System in Zimbabwe

Priscilla PM Nyambayo[1*], Rumbidzai Manyevere[1], Libert Chirinda[1], Edlyne N Zifamba[1], Steny F Marekera[1], Tatenda Nyamandi[1], Ushma Mehta[2], Michael S Gold[3]

[1]Pharmacovigilance and Clinical Trials Division, Medicines Control Authority of Zimbabwe, Harare, Zimbabwe. [2]Centre for Infectious Disease Epidemiology and Research, School of Public Health, University of Cape Town, South Africa.

[3]University of Adelaide, Discipline of Pediatrics, Women's and Children's Health Network, Adelaide, Australia. ***Corresponding Author:** Priscilla PM Nyambayo, Pharmacovigilance and Clinical Trials Division, Medicines Control Authority of Zimbabwe, Harare, Zimbabwe.

Abstract

Aim: Functional national systems that monitor Adverse Events Following Immunization (AEFIs) are vital for implementing evidence-based vaccination policy while ensuring the safe access to these life-saving technologies. These systems can counteract vaccine hesitancy by increasing public trust and uptake in vaccination minimizing the burden of vaccine-preventable diseases (VPDs). Ensuring that these systems function optimally is a critical public health imperative. This is a novel study evaluating AEFI surveillance system including causality assessment, in Zimbabwe. This study provides a review of Zimbabwe's national AEFI surveillance system since its launch in 1998, highlighting strengths, weaknesses, and opportunities for improvement.

Materials and Methods: We conducted an in-depth analysis of all AEFI reports received until 2021, assessing reporting trends and overall performance of the AEFI system in terms of investigation, causality assessment. The WHO Global Benchmarking Tool (GBT) was used to assess regulatory performance in terms of AEFI surveillance. Duplications were excluded and reports with evidence of AEFI(s) after vaccination were included by examining the WHO 25 AEFI form core variables.

Results: There was a steady increase of AEFI reports per annum particularly from 2006 to 2021 with a more dramatic increase during the COVID-19 epidemic with an AEFI reporting ratio of 43.46/million adults for COVID-19 vaccinations in 2021. The reporting ratio exceeded the WHO recommended minimum AEFI reporting ratio of 10 per 100000 surviving infants during eleven years (47.84%) out of the twenty-three years since inception of the surveillance. The GBT assessment demonstrated that the AEFI surveillance system evolved for all manufacturers or license holders.

Conclusion: Close partnership between the immunization program and regulatory authority has enhanced AEFI surveillance in Zimbabwe. Incomplete AEFI case investigations for and timely AEFI detection are challenges that need to be addressed. System strengthening should include consideration of digital innovations to improve detection, optimizing case investigation of serious AEFI including post-mortems and utilizing VigiPoint disproportionate analysis for signal detection.

Article History

Received: February 20, 2023;
Accepted: March 09, 2023;
Published: March 16, 2023

Keywords

AEFI surveillance system; AEFI causality assessment; mHealth active participant centered (MAPC) AEFI surveillance; VigiGrade completeness score and WHO global bench marking tool Version VI(GBT)

MCAZ Pharmacovigilance updates

The Medicines Control Authority of Zimbabwe (MCAZ) is the National Centre for Pharmacovigilance (PV) implemented by the Pharmacovigilance and Clinical Trials (PVCT) Division. Zimbabwe is a participating member of the World Health Organisation Programme for International Drug Monitoring (WHO PIDM) since 1998 to date, through the MCAZ national PV centre. The MCAZ-PVCT conducts spontaneous (voluntary) adverse drug reaction monitoring and active pharmacovigilance programs of all essential medicines, including vaccines, marketed in Zimbabwe for quality, safety, and effectiveness with the aim of promoting patient safety.

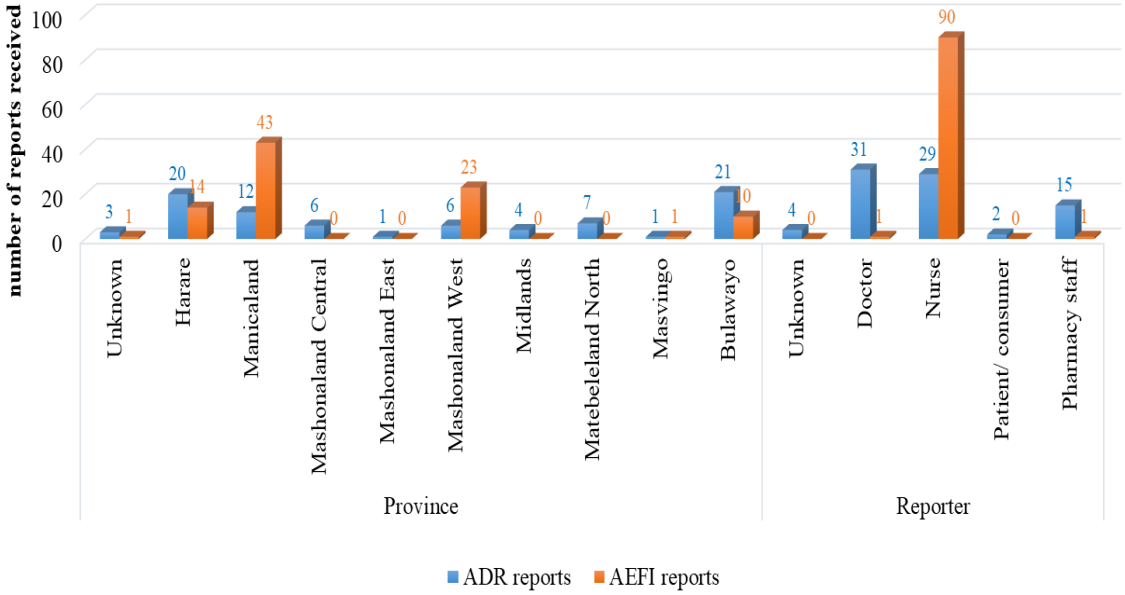
Below is the summary of the ICSRs received at the MCAZ from January to 9 May 2023 from patients and consumers; the pharmaceutical industry, approved clinical trials being conducted in Zimbabwe, public MoHCC sites; and private sector health care facilities including pharmacies, hospitals and clinics. 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 from January to 9 May 2023

Month	ADR and SAEs received from the Pharmaceutical Industry (CIOMs, XML/E2B)	Adverse Events Following Immunization (AEFI) reports from EPI-MoHCC	ADRs from consumers, public MoHCC sites and private sector clinic, hospitals and pharmacies	SAEs from approved clinical trials conducted in Zimbabwe
January	1	0	25	20
February	5	3	0	15
March	1	0	30	22
April	2	62	10	15
May	0	27	16	1
Total	**9**	**92**	**81** ARVs- 36 Anti TBs- 21 Other- 24	**73**

ADRs from the TSR of all essential medicines including ARVs and Anti-TBs from public MoHCC sites and some private sector clinics and doctors (81 reports) and AEFI reports (92) comprised of 68% of the total ICSRs. The most commonly suspected medicines were dolutegravir, isoniazid, isoniazid/ rifapentine and tenofovir disoproxil fumarate. Isoniazid and isoniazid/rifapentine were associated with higher rates of dermatological reactions and tenofovir disoproxil fumarate was associated with higher rates of renal impairment adverse events. Causality assessment for these adverse events and suspected medicines was mostly possible.

Figure 1: Distribution of ADR and AEFI reports received at the MCAZ from 1 January 2023 to 9 May 2023 by province and reporter



Anyone, including (but not limited to) health care professionals, patients, consumers, guardians and caregivers can 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. From January to 9 May 2023, according to figure 1 above; nurses, doctors and pharmacists reported the majority of ADR reports. Nurses reported the majority of the AEFI reports received. Figure 1 above also shows the provinces that have reported ADR and AEFI reports to the MCAZ from January to 9 May 2023. Bulawayo submitted the majority of reports from January to May 2023 whilst Manicaland submitted the majority of AEFI reports. We encourage everyone to continue reporting adverse events hence promoting patient safety. Many thanks to the tenacity and assistance of all our reporters in promoting patient safety.

Safety communication: Pholcodine - containing products

Pholcodine is an opioid medicine that is used for the treatment of non-productive (dry) cough in children and adults. It works directly in the brain, depressing the cough reflex by reducing the nerve signals that are sent to the muscles involved in coughing. Pholcodine-containing products are marketed in Zimbabwe under the brand names **Pholtex Plus** and **Pholtex Forte** with the registration numbers 2018/22.2.5/5734 and 99/22.2.1/3624 respectively.

Safety issue

Available data indicated that the use of pholcodine in the twelve (12) months before genera; anaesthesia with neuromuscular blocking agents (NMBA) such as suxamethonium, and atracurium is a risk factor for developing an anaphylactic reaction upon administration of the NMBA. The hypothesis that pholcodine use could trigger reactions to NMBAs is based on the body producing antibodies against pholcodine, which eventually trigger reactions to the NMBAs (cross-sensitization). Due to the seriousness of the safety risk, all pholcodine-containing products are being withdrawn from the Zimbabwean market.

For health care professionals:

- Advise patients to stop taking pholcodine-containing medicines and consider appropriate alternatives to treat their symptoms.
- Check whether patients scheduled to undergo general anaesthesia with NMBAs have used pholcodine in the previous 12 months and remain aware of the risk of anaphylactic reactions in those patients.

For consumers:

- If you need general anaesthesia and have had a pholcodine-containing medicine in the past 12months, advise your health care professional prior to undergoing the procedure.

For all licenced pharmaceutical wholesalers, pharmacies, public and private clinics and hospitals

- All pholcodine-containing products (Pholtex Plus and Pholetex Forte) must be quarantined.

Reference

1. Instruction to quarantine all pholcodine-containing products, MCAZ Circular 6 of 2023 dated 14 April 2023, https://www.mcaz.co.zw/?smd_process_download=1&download_id=4587

Safety Communication: Azithromycin and the risk of potentially fatal heart rhythms

Azithromycin is a macrolide antibiotic that is widely used to treat various infectious diseases such as respiratory and urinary tract infections. Macrolide antibiotics, primarily erythromycin and clarithromycin, are known to increase cardiac arrhythmogenic risks, including QT interval prolongation, torsades de pointes, and polymorphic ventricular tachycardia[1]. In 2012, a study found an increased risk of cardiac deaths with the use of azithromycin within 5 days after therapy initiation. Several studies have reported the association between azithromycin and QT prolongation[2].

Azithromycin can cause abnormal changes in the electrical activity of the heart that may lead to a potentially fatal irregular heart rhythm. Patients at particular risk for developing this condition include those with known risk factors such as existing QT interval prolongation, low blood levels of potassium or magnesium, a slower than normal heart rate, or use of certain drugs used to treat abnormal heart rhythms, or arrhythmias[2]. The warnings and precautions section for azithromycin package inserts has information related to the risk of QT interval prolongation and torsades de pointes, a specific, rare heart rhythm abnormality. Information has also been added regarding the results of a clinical QT study which showed that azithromycin can prolong the QTc interval[3].

Health care professionals should consider the risk of fatal heart rhythms with azithromycin when considering treatment options for patients who are already at risk for cardiovascular events. The potential risk of QT prolongation with azithromycin should be placed in appropriate context when choosing an antibacterial drug. Alternative drugs in the macrolide class, or non-macrolides such as the fluoroquinolones, also have the potential for QT prolongation or other significant side effects that should be considered when choosing an antibacterial drug.

Groups at higher risk include:

- Patients with known prolongation of the QT interval, a history of torsades de pointes, congenital long QT syndrome, bradyarrhythmias, or uncompensated heart failure
- Patients on drugs known to prolong the QT interval.
- Patients with ongoing proarrhythmic conditions such as uncorrected hypokalemia or hypomagnesemia, clinically significant bradycardia, and in patients receiving Class IA (quinidine, procainamide) or Class III (dofetilide, amiodarone, sotalol) antiarrhythmic agents.
- Elderly patients and patients with cardiac disease may be more susceptible to the effects of arrhythmogenic drugs on the QT interval.

Additional Information for Health Care Professionals

- Health care professionals should consider the risk of torsades de pointes and fatal arrhythmia when considering treatment options with azithromycin or alternative antibacterial drugs.
- Report adverse events involving azithromycin using the ADR reporting forms which MCAZ distributes or can be downloaded from the MCAZ website. The completed forms should be forwarded to the MCAZ physically or can be sent to the email mcaz@mcaz.co.zw. The reporting can also be done online – https://e-pv.mcaz.co.zw

Additional Information for Patients

- **Do not stop** taking azithromycin without talking to your health care professional.
- Discuss any questions or concerns about azithromycin or other antibacterial drugs with your health care professional.
- Seek **immediate** care if you experience an irregular heartbeat, shortness of breath, dizziness, or fainting while taking azithromycin.
- Report any side effects that you experience to your health care professional or directly to MCAZ using the following link https://primaryreporting.who-umc.org/ZW

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MCAZ Medicines Control Authority of Zimbabwe

106 Baines Avenue
Tel: +263 242 736 981-7
708 255 / 792 165 / 0772 145 191/2/3
Email: mcaz@mcaz.co.zw
Website: www.mcaz.co.zw

P.O. Box 10559
Harare
Zimbabwe

REF: B/279/35/05/2023

CIRCULAR 5 of 2023

Date: 23rd of February,2023

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

RE: INSTRUCTION TO QUARANTINE TETRACYCLINE HYDROCHLORIDE OPHTHALMIC OINTMENT USP 1% MANUFACTURED BY GALENTIC PHARMA (INDIA) PVT. LTD, R-673, T.T.C. MIDC RABALE, THANE-BELAPUR ROAD, NAVI MUMBAI-400701, MAHARASHTRA, INDIA

Reference is made to WHO product alert No. 2/2023 for Tetracycline Hydrochloride Ophthalmic Ointment USP 1%, which was received on the 22nd of February 2023. The product alert report indicated that a range of quality issues were detected upon physical examination of random samples of the following product batches: **AF20011, AF21160, AF21161, AF22031, AF22032, AF22093, AF22100, AF22101, AF22107, AF20097, AF22021, AF22105, AF20060A, AF22025, AF22026 & AF22061.** Quality issues detected included particles ranging in colour, size, and shape on the nozzle, in the cap and in the ointment inside each tube, black spots and brown splotches on the inner foil layer of the tube, and phase separation.

The Authority would like to draw the attention of all licensed pharmaceutical wholesalers, pharmacies, public and private clinics, and hospitals that they must quarantine any of the affected batches of the reported product. The above are further instructed to advise the Authority of their stock status if they have any of the affected batches.

The Authority shall communicate a plan of action once investigations are complete.

Yours faithfully
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

.....
C. Samatanga (Mrs.)
for: **DIRECTOR-GENERAL**
/amk

25 YEARS 1997-2022
OF PROTECTING PUBLIC AND ANIMAL HEALTH

Approved Change of Category for distribution of registered medicines from 2010 to date

The MCAZ Pharmacovigilance and Clinical Trials Division is responsible for the safety review of new and old medicines including the category for distribution of medicines. During the last 12-year period, the MCAZ changed the category for distribution of the medicines listed in Table 1 below. Letters to applicants and Circulars were already written to their effect.

Table 1: MCAZ list of recategorized medicines from 2010 to date

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	Cimetidine 200mg	All registered products	Prescription Preparations (PP10) to Pharmacist Initiated Medicines (P.I.M)	2010
Coartem Lumartem Lumither	Artemether and Lumefentrine 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	Olapatadine 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	Loratidine 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
All brands	Omeprazole 20mg in packs of 14 or less dosage units	All registered products	Prescription Preparations (PP) to Pharmacist Initiated Medicines	2016

			(PIM) in packs of 14 or less dosage units	
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 chlroride; 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	Parafin soft white; liquid parafin; 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/ Ethnylestradiol 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 Cetirizine 5mg/5ml	All registered products	Pharmacist Initiated Medicine (P.I.M.) to Pharmacy Medicine (P)	2022

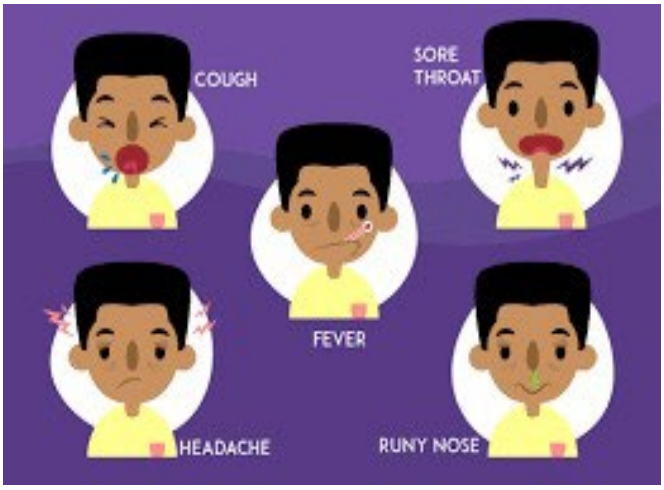
Medicine Safety Alert: Use of Cough and Cold Medicines in Children under the age of two years

The Medicines Control Authority of Zimbabwe reviewed the use of cough and cold medicines in children under the age of two years. The Authority assessed the available safety and efficacy data to support the use of cough and cold medicines in children. Based on the available information the Authority decided to contraindicate the use of cough and cold medicines in children under the age of two years due to an unfavourable risk benefit profile of these medicines in this age group. Oral cough and cold medicines containing the following active ingredients **should not be used** in children **under two years** of age:

guaifenesin	phenylephrine	doxylamine
ipecacuanha	brompheniramine	promethazine
dextromethorphan	chlorphenamine	triprolidine
pholcodine	diphenhydramine	pseudoephedrine

What is the common cold?

The common cold is an upper respiratory tract infection caused by many different viruses. The common cold is a self-limited disease that can generally be managed at home and has no cure. Treatment is directed at relieving signs and symptoms. Cold symptoms such as coughing, runny nose, sore throat and sneezing, usually appear one to three days after the virus enters the body and resolve spontaneously within seven to ten days.



Recommended Alternative treatments for the relief of symptoms of coughs and colds

- Increase the amount of fluid the child drinks.
- Analgesics, such as paracetamol and ibuprofen, can be used to help reduce pain and fever.
- Saline nose drops can be used to help relieve a blocked nose.
- Provide a comfortable environment with adequate humidity (moisture in the air).

- Make sure all members of the household wash their hands to prevent the spread of the virus causing the common cold.

Advice for Healthcare professionals

The Authority urges all healthcare professionals to heed the following warnings and advice before recommending the use of cough and cold medicines in children:

- Cough and cold medicines containing the above-listed ingredients should not be prescribed or used in children under the age of two years.

For children over the age of two years:

- The referred ingredients may only be prescribed by a doctor or initiated by a pharmacist.
- The concurrent use of two or more different cough and cold products in the same patient should be avoided as these can result in serious adverse effects.
- The dosing instructions in the package insert should be read carefully to ensure that the prescribed dosage is within the recommended dosage range and frequency for the patient's age and/ or weight.
- Parents or caregivers should be warned to keep all medicines out of reach of children.
- Parents and caregivers should be reminded that cough and cold medicines may only relieve symptoms and will not treat the cause of the symptoms and will not shorten the length of time a child is ill.
- Report adverse events involving medicines using the ADR reporting forms which MCAZ distributes or can be downloaded from the MCAZ website. The completed forms should be forwarded to the MCAZ physically or can be sent to the email mcaz@mcaz.co.zw. The reporting can also be done online – https://e-pv.mcaz.co.zw .

When will these changes happen?

The MCAZ has been working closely with the pharmaceutical manufacturing companies to update the package labelling of the affected cough and cold medicines to warn against the use of these medicines in children under two years of age.

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Dangers of buying medical products from unauthorized sources

A case of using wrong medicines for the wrong ailment

I once visited my elderly (around 70 years) relative in 2019. She lived at Mbare flats with her son who had brought her from their rural home because she wasn't feeling well. She had already been diagnosed with hypertension and the son wanted to seek additional medical treatment in Harare. The doctor they consulted would routinely prescribe anti-hypertensive medicines for my elderly relative. However, I learned that the son had been buying the tablets and/or capsules using the prescription from the doctor at Mbare musika. I requested to see the medicines their mother had been taking. To my utter disbelief, they assumed that as long as the name of the tablets/ capsules on the box ended with **BP** (which stands for British Pharmacopeia) that meant that the medicines treat high blood pressure also known as **BP**. It turns out that the son had been purchasing and giving their mother these medicines for the past 3 decades. I was shocked. My elderly relative unfortunately passed away in 2021. Do not risk your life by buying and consuming medicines from the street. I encourage members of the public to purchase medicines from reliable, authorized sources such as pharmacies, hospitals and clinics.

Source: An anonymous contributor

E-cigarette or Vaping Product Use-associated Lung Injury (EVALI)

Perspectives from a toxicologist – Prof D. Tagwireyi

There is a general notion amongst teens in Zimbabwe (at least the few that I have interacted with) that vaping is just 'smoking' flavours and thus has no adverse effects on health. They will argue that it is unlike smoking cigarettes which are known to adversely affect almost all the vital body organs. However, a quick look into the literature will show that this is far from true.

For those who may not be aware of what "vaping" is, it is the process of inhaling an aerosol that is created by heating a liquid or wax containing various substances, such as nicotine, cannabinoids (eg, tetrahydrocannabinol, cannabidiol), flavouring, and additives (eg, glycerol, propylene glycol). This process is ordinarily done through the use of electronic-cigarettes which also go by various names including, “e-cigs,” “e-hookahs,” “mods,” “vape pens,” “vapes,” “tank systems.”

Example of a hookah

Example of a vape-mod

Over the past couple of years, there have been reports of what has come to be known as E-cigarette or Vaping Product Use-associated Lung Injury (EVALI). This condition affects the lungs and respiratory system, and may present as trouble in breathing, experiencing excessive coughing, chest pain, nausea, fatigue, vomiting and even fever. There have been documented deaths reported in adolescents and teens from EVALI. The adverse effects towards the respiratory system may be the result of nicotine or tetrahydrocannabinol which are contained in some e-cigarettes. However, vape oils also consist of a number of other chemicals and metals such as nickel, tin, lead, flavourings like diacetyl, and other ultra-fine particles all of which could have potentially adverse effects towards the lungs. Because most vapes contain nicotine in them, there is a danger of brain damage, mouth/gum disease and heart diseases developing in the users.

Example of a vape e-cig

Whilst some may argue that the vapes that they use do not contain nicotine, research from elsewhere has shown that most vapes in fact do.

Now given the potential dangers associated with vaping including EVALI, and also given the increase in vaping amongst teens and adolescents in Zimbabwe, I wonder whether we should be doing more about this. If we do not start doing something about this early, we may wake up when it’s a bit too late. Just my thoughts as a father, teacher, pharmacist and concerned toxicologist!

Risk Minimisation Measures for MabThera® and Hemlibra®

To ensure the safety of medicines post-regulatory approval, a risk management plan (RMP) is established. This provides information on a medicine's safety profile, describing the activities of the marketing authorisation holder to further characterise its safety profile during pharmacovigilance activities and explaining the measures that will be taken to prevent or minimise risks in patients – these are known as risk minimisation measures (RMMs)[1]. Routine risk minimisation is applicable to all medicinal products. These include the use of the summary of product characteristics (SmPC), the patient information leaflet, the labelling, the pack size and design or the legal status of supply of the product[2].

Rituximab 1400mg SC and IV (MabThera®) injections

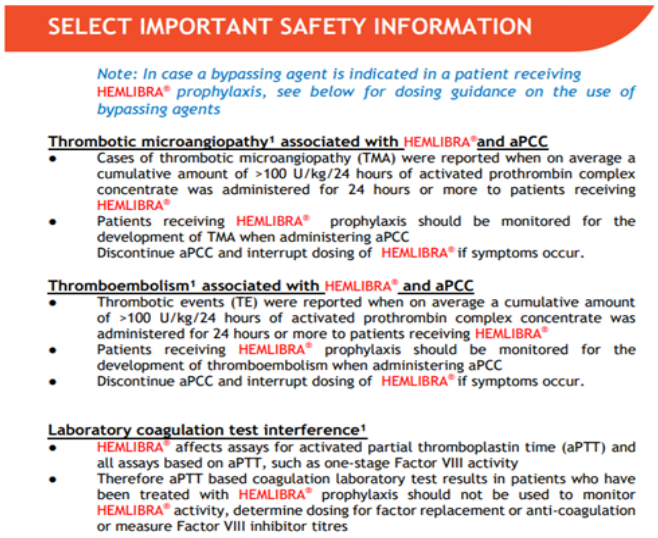
MCAZ approved risk minimisation materials submitted by Roche Products Pty Ltd for Rituximab 1400mg SC and IV (MabThera®) injections. Rituximab is an anti-CD20 chimeric monoclonal antibody which is authorized for use in Chronic Lymphocytic Leukemia, Rheumatoid Arthritis, Granulomatosis with Polyangiitis and Microscopic Polyangiitis, Pemphigus Vulgaris and Non-Hodgkin's Lymphoma. The aim of the distribution is to reduce the risk of administration route error that could result from accidental substitution of the SC and IV formulations (e.g., an error in the hospital pharmacy), or incorrect injection technique when using the SC formulation (e.g., placement of the needle directly into a vein or muscle).

Roche provided guides or educational materials for safe and efficient use of their products by physicians, nurses and pharmacists. The material included comparison card to differentiate between the two formulations of MabThera titled, 'A comparison card to differentiate between the two formulation of MabThera (subcutaneous and intravenous)'and a Healthcare professional guide titled, 'MabThera step by step guide' to assist supply, storage, handling and administration of subcutaneous formulations.

Emicizumab (Hemlibra®)

MCAZ approved risk minimisation materials submitted by Roche Products Pty Ltd for emicizumab (Hemlibra®). The risk minimization materials were disseminated to the healthcare professionals, caregivers and patients. The aim of the distribution was to reduce the risk of life-threatening bleeding due to unreliable standard coagulation tests and inhibitor assays in the setting of emcizumab. Secondly, they aimed to reduce the risk of breakthrough bleeding due to suspected anti-emcizumab antibodies by capacitating physicians. The risk minimisation measures employed include an update to the SmPC on the special warnings and precautions for use and they also recommended that treatment should be initiated under the supervision of an experienced physician in haemophilia and bleeding disorders. Roche provided guides or materials to be disseminated which included a Healthcare professional guide, Patient carer guide and Patient alert card with safety information that a user of Hemlibra® need to know before, during and after treatment.

Below is an extract from Guide for Healthcare Professional to ensure safe use of Hemlibra® for treatment of Haemophilia A by Roche Pty Ltd.

Rituximab 1400mg SC and IV (MabThera®) injections	Emicizumab (Hemlibra®)
Summary of routine risk minimisation measures for MabThera®: Clear package differentiation i. Color differentiation (distinct colored bands) i.e red for SC vial and grey for IV vial ii. Unique cap colors for the vials matching the colored bands iii. Clear statements on both the primary and secondary packaging i.e., words "subcutaneous", "solution for subcutaneous injection" and "Only for subcutaneous use" in red font. iv. Peel-off sticker included on the individual vials of the subcutaneous formulations specifying the strength, the route of administration and the indication. v. SC and IV formulations are covered by separate SmPCs, which include specific warning against incorrect route of administration.	

Before risk minimisation measures can be implemented in Zimbabwe the proposed materials must be assessed at national level by the MCAZ. Only approved risk minimisation measures can be distributed.

Healthcare professionals and patients alike are encouraged to report any adverse drug reactions (ADR) to MCAZ using the following channels: Adverse Drug Reaction (ADR) reporting form which can be obtained from the MCAZ offices at 106 Baines Avenue, Harare or can be downloaded from the MCAZ website: www.mcaz.co.zw or you can report using the ADR electronic reporting platform found on the MCAZ website on the following link: https://primaryreporting.who-umc.org/ZW

References

1. https://www.europeanpharmaceuticalreview.com/article/174008/pharmacovigilance-deep-dive-risk-minimisation-measures/ Hannah Balfour (European Pharmaceutical Review), viewed 14 March 2023
2. https://english.cbg-meb.nl/topics/mah-risk-management-plan, viewed 12 March 2023

Unsafe Use Of Glutathione And Injectable Vitamins As Skin-Lightening Agents

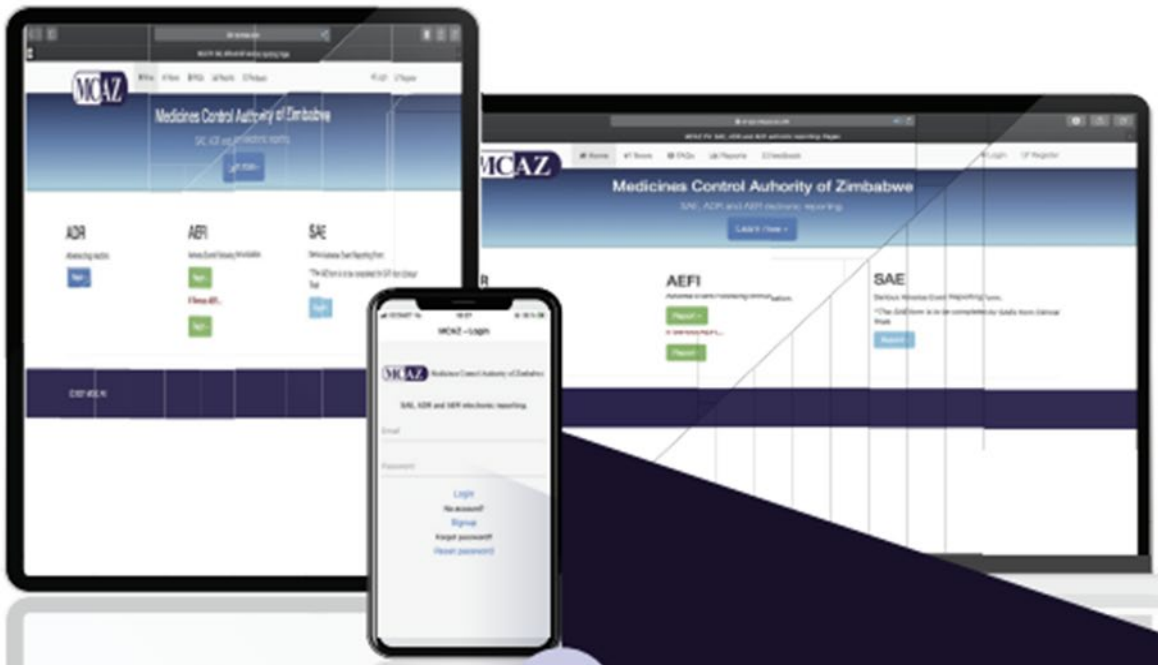
The mandate of the Medicines Control Authority of Zimbabwe (MCAZ) is to protect public health by ensuring that all medicines and medical devices on the market are safe, effective, and of good quality. Thus, in order to uphold this mandate, all medicines should be registered by the MCAZ prior to marketing and use. To know which medicines are approved to be sold in Zimbabwe you should visit the MCAZ online register, https://onlineservices.mcaz.co.zw/onlineregister/frmRegistersHome.aspx where a list of all registered medicines is found.

The MCAZ warns the public about the dangers associated with the use of skin-lightening products such as oral /injectable glutathione and injectable vitamins. To date, there are no published clinical trials that have evaluated the use of oral/injectable glutathione and injectable vitamins for skin lightening. There are also no published guidelines for appropriate dosing regimens. Products containing glutathione and vitamins are registrable products. The MCAZ has not approved/registered any injectable products or such products for skin lightening.

Side effects from the use of injectable glutathione for skin lightening include toxic effects on the liver, kidneys, and nervous system. Furthermore, the side effects may include severe skin reactions such as Stevens-Johnson syndrome, hives or allergic reactions, weight gain, loss of pigmentation of hair, eye infections, and disorders. Glutathione also affects the production of melanin, the pigment that gives the human skin, hair, and eyes their colour. Injectable glutathione is sometimes paired with intravenous vitamin C, and vitamin C injection may form kidney stones if the urine is acidic. Large doses of vitamin C have resulted in hemodialysis in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. Other potential risks include the transmission of infectious agents, such as HIV, hepatitis C, and B. This is of particular concern when a non-medical practitioner administers this treatment, or it is done in a non-sterile facility.

The Authority has noted with concern that several health and beauty salons, wellness, and beauty shops are offering all kinds of beauty enhancements, services, and skin treatments. It is alarming that these also offer services such as intravenous drips or infusions using skin-lightening agents including reduced glutathione tablets or injectables combined with injectable vitamins.

It is an offense to sell unregistered medicines without authorization. As the Authority responsible for protecting public and animal health, MCAZ enforces adherence to the use of registered medicines and will exercise its statutory mandate against perpetrators of these criminal acts.



e-PV Medicines & Vaccines Monitoring

The Medicines Control Authority of Zimbabwe (MCAZ) with support from the Global Fund To Fight AIDS, TB and Malaria, and in partnership with United Nations Development Programme (UNDP) developed an electronic platform for reporting adverse drug reactions (ADR) or side effects, with both online and offline reporting capabilities. This gives healthcare providers and patients a number of reporting options that would allow the Authority to continuously monitor medicines safety.

Contact Us

Email: mcaz@mcaz.co.zw
Website: www.mcaz.co.zw
Contact: +263 772145191-3;
+263 (242) 736981-7

Web based reporting
https://e-pv.mcaz.co.zw

Android/iOS Mobile Apps
Search "MCAZPV" on Apple App Store or "MCAZ Pharmacovigilance" on Google Play Store

Desktop Applications
Windows, MacOs (MacBook) or Linux based operating systems

Patient/Consumer reporting
https://primaryreporting.who-umc.org/ZW

Social Media: mcazofficial

MCAZ Medicines Control Authority of Zimbabwe