Medicines Information Bulletin

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Medicines Control Authority of Zimbabwe

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MCAZ Pharmacovigilance Updates

Quarter 1 Individual Case Safety Reports summary

The Medicines Control Authority of Zimbabwe (MCAZ) is the National Centre for Pharmacovigilance (PV), and pharmacovigilance activities are coordinated 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.

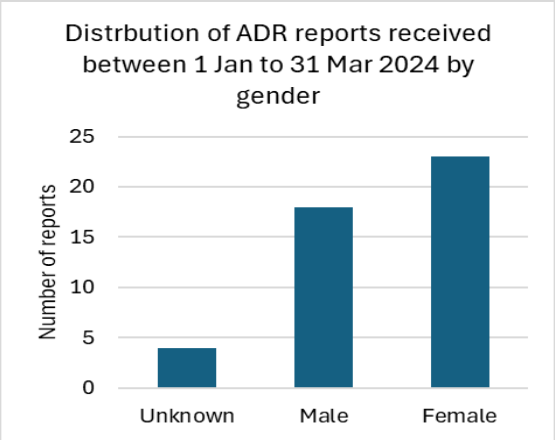
The MCAZ-PVCT conducts spontaneous (voluntary) adverse drug reaction monitoring and active pharmacovigilance programs of all essential medicines, including vaccines, marketed in Zimbabwe for quality, safety, and effectiveness with the aim of promoting patient safety. Special thanks to all the reporters for their continued support in promoting patient safety.

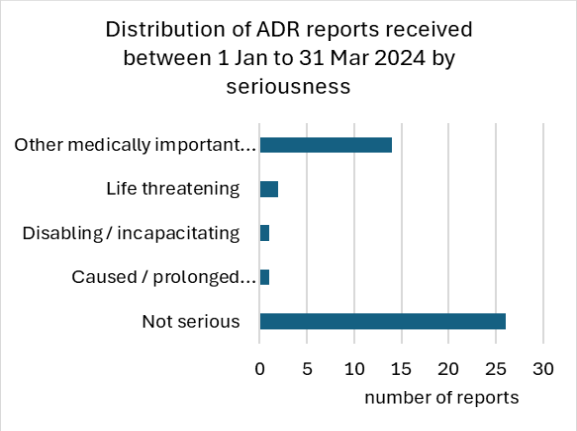
Table 1: Summary of Individual Case Safety Reports (ADRs, AEFIs and SAEs) received at the MCAZ for the period 1 January to 31 March 2024

Type of ICSR reports	ADRs received and processed from January to March 2024
ADRs from pharmaceutical industry (CIOMs, XML/E2B)	**21 (9%)**
Adverse Events Following Immunization (AEFIs)	**157 (65%)** (*The VigiMobile app and VigiFlow system for AEFI reporting have greatly improved AEFI reporting timelines*)
ADRs from the TSR of all essential medicines including ARVs and Anti-TBs from public and private sector	**44 (18%)** *ARVs – 27 (TDF and renal toxicity most reported)* *Anti-TBs – 3* *Other essential medicines – 14*
SAEs from approved clinical trials conducted in Zimbabwe	**20 (8%)**
Total	**242**

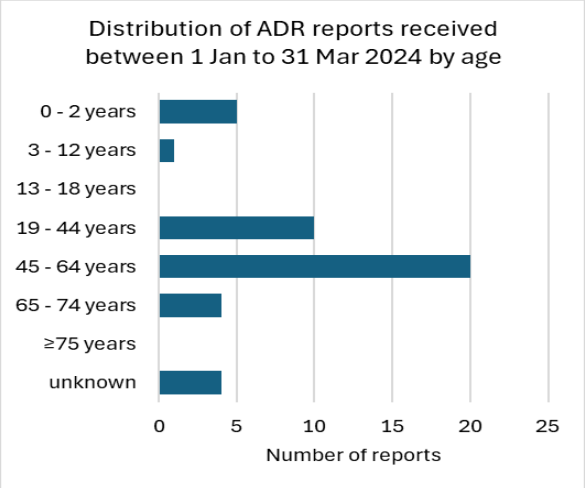
Quarter 1 Adverse Drug Reaction reports summary

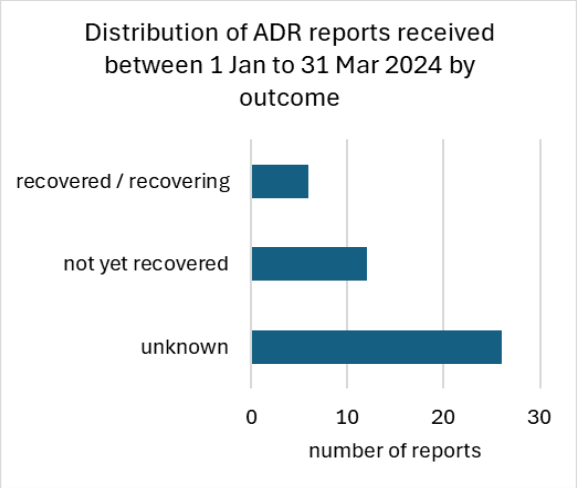
A total of 44 ADR reports from the TSR of all essential medicines including ARVs and Anti-TBs were received in the first quarter of 2024 (Jan to Mar). Females experienced more adverse reactions as compared to males. Most of the reactions were not serious.



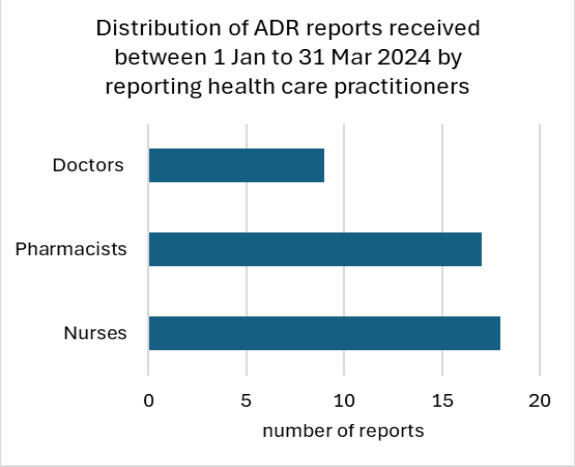


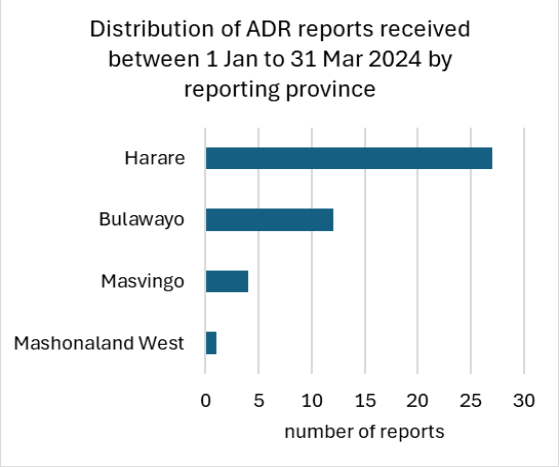
Individuals aged between 45 to 64 years experienced the most adverse reactions. The outcomes of the reactions in the 44 ADR reports were mostly unknown.

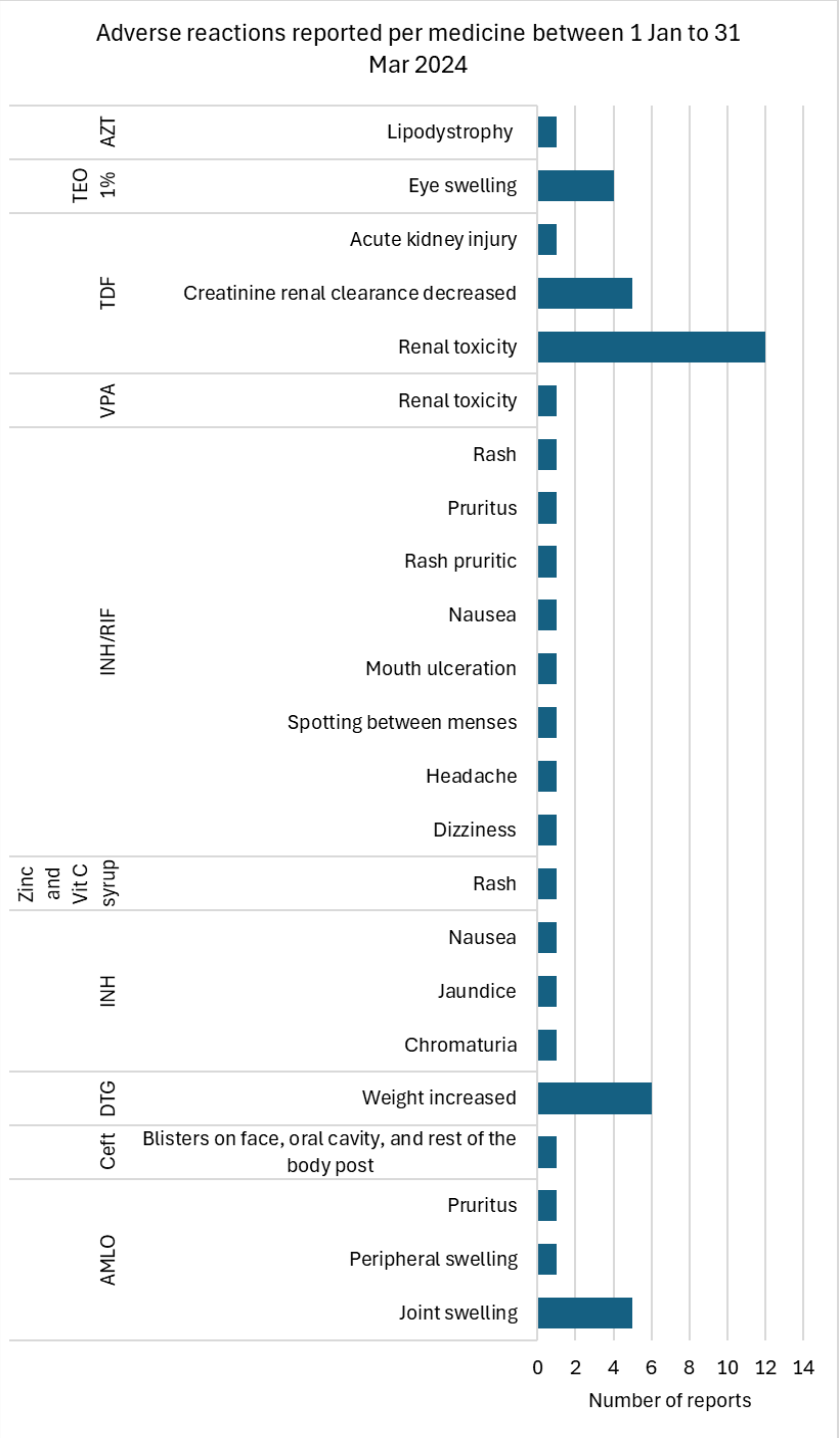




Nurses submitted most of the reports compared to other healthcare practitioners The highest number of reports were received from Harare province.







The most reported adverse reactions were renal and urinary disorders associated with tenofovir disoproxil fumarate. The outcome of the reactions was unknown in 60% of the reports and not yet recovered in 40%. Causality assessment in 80% of these reports was possible.

Key
AMLO- amlodipine
Ceft – ceftriaxone
DTG – dolutegravir
INH/RIF – isoniazid/rifampicin
VPA – sodium valproate
TDF – tenofovir disoproxil fumarate
TEO – tetracycline eye ointment
AZT – zidovudine

Adverse events can be reported to MCAZ using the online consumer reporting form available on the MCAZ website (**www.mcaz.co.zw)** 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 from the MCAZ website.

Submitting AEFI and ADR reports using the VigiMobile and VigiFlow tools

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. In a bid to reinforce AEFI surveillance in Zimbabwe (timely reporting, access to AEFI data at all levels, enables data monitoring and analysis, the VigiMobile app and VigiFlow system were deployed countrywide for AEFI reporting by the Secretary for Health and Child Care on the 17th of April 2023.

Since the deployment, a total of five hundred and sixty-three (563) adverse events following immunization reports have been received using the VigiMobile app and VigiFlow system. Causality assessment has been done by the National AEFI Committee and feedback has been sent to the health care professionals.

We thank all the health care professionals for the continuous support of the national AEFI surveillance program and for promoting patient safety. We look forward to receiving more reports using VigiMobile and VigiFlow for AEFI reporting.

MCAZ is planning to deploy VigiMobile app for medicines (ADR reporting) for use by both health care professionals and consumers. The VigiMobile app for medicines for **test purposes** only can be downloaded on mobile phones, tablets, ipads, and laptops/ computers using the QR codes below or can be accessed the link: https://vigiflow-eformstraining.who-umc.org/zw/zwadr

For test/ training purposes only

We encourage everyone to familiarize themselves with this reporting tool in preparation for its deployment. Any feedback or comments on the Zimbabwe ADR Training eForm and app can be submitted to MCAZ via email to pvct@mcaz.co.zw or on the MCAZ Customer Service WhatsApp number +263718855934

Significant safety issue: Pseudoephedrine containing products

Product information

Pseudoephedrine is a direct- and indirect-acting sympathomimetic agent, which acts as a decongestant of the mucosa of the nose and sinuses to clear nasal congestion and dry nasal secretions.

Pseudoephedrine is taken by mouth and is used alone or in combination with other medicines to treat nasal congestion (a blocked nose) resulting from a cold, flu or allergy. It is also used to temporarily relieve sinus congestion and pressure. Pseudoephedrine will relieve symptoms but will not treat the cause of the symptoms. Pseudoephedrine works by stimulating nerve endings to release the chemical noradrenaline, which causes the blood vessels to constrict (narrow). This reduces the amount of fluid released from the vessels, resulting in less swelling and less mucus production in the nose.

Safety issues of concern

A few cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS), conditions affecting blood vessels in the brain, have been reported in pharmacovigilance databases and medical literature from people using pseudoephedrine-containing products.

What is Posterior reversible encephalopathy syndrome (PRES)?

This is a clinico-radiological syndrome characterized by a headache, seizures, altered mental status and visual loss and is characterized by white matter vasogenic oedema affecting the posterior occipital and parietal lobes of the brain predominantly. Symptoms develop within a few hours up to several days. Medicines linked to PRES are generally used in transplant and cancer patients and include ciclosporin, tacrolimus, sunitinib, immunoglobulin and interferon alpha.

What is Reversible cerebral vasoconstriction syndrome (RCVS)?

This is a rare condition that occurs as the result of a sudden constriction (tightening) of the vessels that supply blood to the brain. The main symptom of RCVS is sudden, severe, and disabling headaches that are sometimes called “thunderclap” headaches. RCVS can be reversed. Medicines associated with RCVS include the antidepressants-selective serotonin reuptake inhibitors (SSRIs) such as Fluoxetine, medicines to treat migraine- triptans and ergotamines, immunosuppressants-cyclophosphamide and tacrolimus, medicines to prevent bleeding after childbirth, anti-parkinson’s medicines-bromocriptine, over-the-counter medicines and supplements-nasal decongestants (pseudoephedrine, ephedrine, phenylpropanolamine), nicotine patches, caffeine-containing energy drinks, ginseng, illegal drugs such as marijuana, cocaine, ecstasy and amphetamines.

PRES

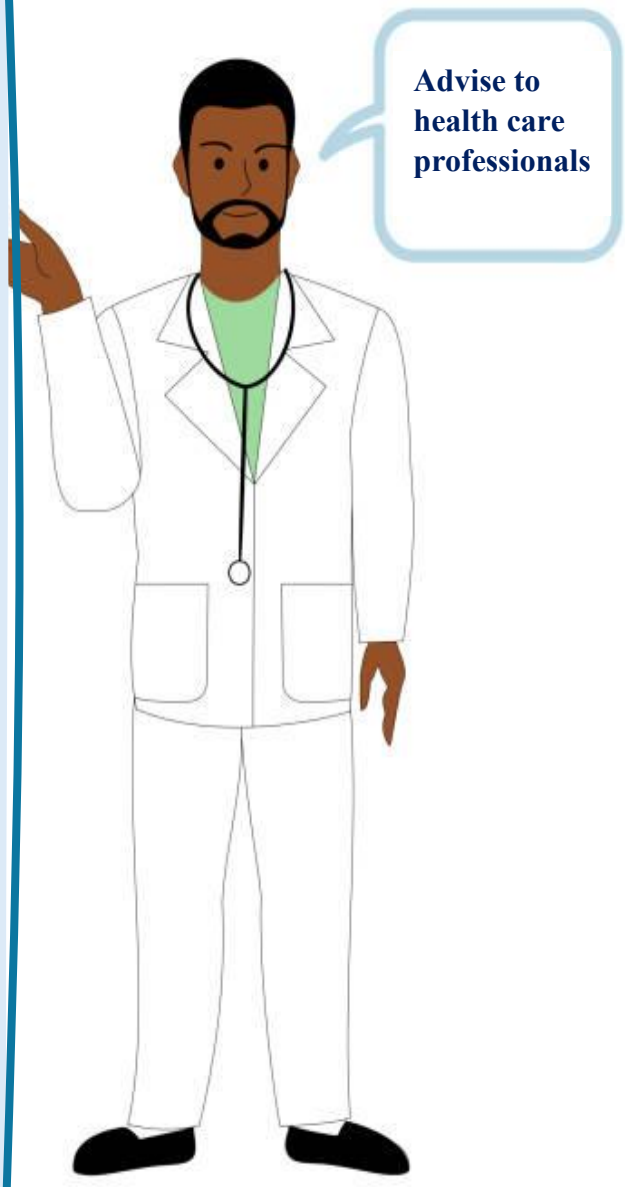
- PRES is usually reversible on prompt diagnosis and treatment of underlying conditions. If recognized and treated early, the clinical syndrome commonly resolves within a week.
- Treatment is targeted to the precipitating cause, with use of antihypertensive agents or withdrawal of offending drugs. The management of seizures includes short-term treatment with antiepileptic drugs, that can be discontinued when the acute phase of PRES has resolved.

RCVS

- Outcomes for RCVS patients range from full recovery in most patients to permanent brain damage in other patients.
- RCVS is most common among females from the ages of 20 to 50.
- Most patients with RCVS recover completely. A minority of patients have neurological problems. RCVS does not usually come back.

Pseudoephedrine-containing products

- Pseudoephedrine containing medicines should not be used in patients with severe or uncontrolled high blood pressure or with severe acute or chronic kidney disease/ failure, unless directed by a physician.
- Healthcare professionals should advise patients to stop using these medicines immediately and seek treatment if they develop symptoms of PRES or RCVs.



Regulatory Actions

The MCAZ agreed that applicants of Pseudoephedrine containing medicines to:

1. update/ amend the package to include PRES and RCVS as a warning and as ADRs.
2. distribute a Dear Healthcare Professional Communication (DHPC) to inform healthcare professional about the risks of PRES and RCVS associated with pseudoephedrine containing products.

References

1. MHRA safety review of medicines containing pseudoephedrine, https://www.gov.uk/government/news/mhra-safety-review-of-medicines-containing-pseudoephedrine
2. Pseudoephedrine-containing medicinal products, https://www.ema.europa.eu/en/medicines/human/referrals/pseudoephedrine-containing-medicinal-products

Pharmacovigilance Regulatory Safety Updates

Package inserts (PI) and Patient Information Leaflets (PIL) are routinely updated by market authorization holders (MAHs) based on information obtained during safety monitoring of marketed products. The following updates have been made to the package inserts of listed products from July 2023 to March 2024.

Product	Package Insert Safety Update
Desogestrel/ Ethinylestradiol tablets	Adverse drug reaction (ADR) for exogenous estrogens of exacerbation of symptoms of hereditary and acquired angioedema with unknown frequency.
Abiraterone acetate tablets	Must be taken as a single dose once daily on an empty stomach. Must be taken at least two hours after eating and food must not be eaten for at least one hour after taking Abiraterone acetate.
Darunavir tablets	Update to add 'crystal nephropathy' to the list of ADRs with *rare* frequency based on recent post-marketing data.
Acetylsalicylic acid tablets	Should be used with caution in patients with abnormal hepatic function. Addition of special warning and precautions for use for patients with impaired renal function, impaired cardiovascular circulation, impaired hepatic function and patients suffering from severe glucose-6- phosphate dehydrogenase deficiency since acetylsalicylic acid may further increase the risk of renal impairment and acute renal failure. Inclusion of new ADR- Intestinal Diaphragm Disease - to undesirable effects. The gastro-resistant tablets should be taken preferably at least 30 minutes before meals.
Ethinylestradiol/ Levonorgestrel tablets	*Contraindications:* Severe hepatic disease; Presence of a risk or high risk of venous or arterial thrombosis, Arterial thromboembolism – current arterial thromboembolism, history of arterial thromboembolism (e.g. myocardial infarction) or prodromal condition (e.g. angina pectoris), Cerebrovascular disease – current stroke, history of stroke or prodromal condition (e.g. transient ischaemic attack, TIA), Known hereditary or acquired predisposition for arterial thromboembolism, such as hyperhomocysteinaemia and antiphospholipid-antibodies (anticardiolipin-antibodies, lupus anticoagulant), History of migraine with focal neurological symptoms, A high risk of arterial thromboembolism due to multiple risk factors or to the presence of one serious risk factor such as diabetes mellitus with vascular involvement, Severe hypertension, Severe dyslipoproteinaemia. *Interactions:* Strong and moderate CYP3A4 inhibitors such as azole antifungals, verapamil, macrolides, diltiazem and grapefruit juice can increase plasma concentrations of the oestrogen or progestin of both.

Product	Package Insert Safety Update
Poliomyelitis virus vaccine	Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be put in place to prevent any injury due to fainting and to manage syncopal reactions.
Vildagliptin/ Metformin tablets	Metformin may decrease serum vitamin B12 levels. The risk of vitamin B12 levels increases with increasing metformin doses and treatment duration. It is recommended to check serum vitamin B12 levels annually. The risk is reversible by discontinuation of metformin and/or by vitamin B12 supplementation. Vildagliptin updated post-marketing ADR Cholecystitis.
Diphenhydramine hydrochloride/ pseudoephedrine hydrochloride/ paracetamol tablets	Contraindications: Concomitant use of monoamine oxidase inhibitors (MAOIs) or use within 14 days of stopping treatment may cause a rise in blood pressure and/or hypertensive crisis.
Bisoprolol tablets	Concomitant use with antihypertensive agents as well as with other drugs with blood pressure lowering potential (e.g. tricyclic antidepressants, barbiturates, phenothiazines) may increase the risk of hypotension. Concomitant use with insulin and oral antidiabetic drugs may increase blood sugar lowering effect since blockade of beta-adrenoreceptors may mask symptoms of hypoglycaemia. Side effect: Erectile dysfunction *rare*.
Tramadol/ Paracetamol tablets	Small amounts of tramadol may pass into breastmilk.
Esomeprazole tablets	Serious cutaneous adverse reactions (SCARs) such as erythema multiforme (EM), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening, have been reported very rarely in association with esomeprazole treatment. Discontinue Esomeprazole immediately upon signs and symptoms of severe skin reactions.
Methylphenidate tablets	Post-marketing ADR: Increased intraocular pressure and erectile dysfunction.
Sildenafil tablets	Use of Sildenafil and Sacubitril/Valsartan at steady state is associated with risk of greater blood pressure reduction.

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 labeled* in a way that misrepresents its identity, source or composition and is often produced in unsanitary and unregulated conditions by an unknown manufacturer.

Summarized below is a medicinal product alert communicated by the World Health Organization (WHO) Global Surveillance and Monitoring System for Substandard and Falsified Medical Products for the year 2024 (as at 15 April 2024).

Alert No	Alert Summary
WHO Medical Product Alert N°1/2024 – **Falsified (contaminated) USP/EP PROPYLENE GLYCOL identified in the WHO Eastern Mediterranean Region**	This WHO Alert refers to falsified DOW USP/EP PROPYLENE GLYCOL detected in Pakistan. Authentic DOW USP/EP Propylene Glycol is a raw material (excipient) utilized in pharmaceutical and other manufacturing processes, adhering to the standards of the United States and European Pharmacopoeias (USP/EP) for medicinal use. Following WHO Medical Product Alert N°8/2023 Product Alert N°8/2023 in December 2023, the Drug Regulatory Authority of Pakistan (DRAP) investigated potential contamination of oral liquid medicines. Suspect drums of Propylene Glycol were identified by DRAP, and samples were tested by Pakistan's Central Drugs Laboratory. The analyses revealed unacceptable levels of ethylene glycol contamination, ranging from 0.76% to 100%. Between January and March 2024, DRAP issued three Rapid Alerts regarding five contaminated batches of DOW USP/EP Propylene Glycol. • DRAP Alert No I/S/01-24-02 (11 Jan 2024) • DRAP Alert No I/S/02-24-11 (7 March 24) • DRAP Alert No I/S/03-24-14 (11 March 2024) DOW has confirmed that the raw materials detailed in the DRAP Alerts, and identified in this WHO Alert are falsified and were not manufactured or supplied by DOW. The quality and safety of these excipients therefore cannot be assured.

Additional information on these alerts can be obtained on the WHO website on the following link: https://www.who.int/teams/regulation-prequalification/incidents-and-SF/full-list-of-who-medical-product-alerts

WHO requests increased surveillance and diligence within the supply chains of countries and regions likely to be affected by these affected raw materials. WHO advises against distributing or promoting any finished products that may have been manufactured using the potentially affected raw materials, without undergoing further testing.

- 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 or unexpected side-effect 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 from the MCAZ website.

References

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

Highlights from the WHO Pharmaceutical Newsletter

The WHO Pharmaceuticals Newsletter provides the latest information on the safety of medicinal products and regulatory actions taken by authorities around the world. This newsletter is available at: https://www.who.int/teams/regulation-prequalification . Summarized below are highlights from the WHO pharmaceutical newsletter edition No 4 (2023) and No. 1 (4):

Tramadol – Risks of sleep-related breathing disorders, adrenal insufficiency, and serotonin syndrome - Ireland.

The Health Products Regulatory Authority (HPRA) has announced that the product information for tramadol has been updated to include the risks of sleep-related breathing disorders and adrenal insufficiency, as well as an update to the information on serotonin syndrome. Tramadol is a centrally acting synthetic opioid analgesic indicated for the treatment of moderate to severe pain. Following a review of available data, the European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) recommended updates to warnings and precautions as follows:

- Tramadol can cause sleep-related breathing disorders including central sleep apnoea (CSA) and sleep-related hypoxemia. The risk of CSA increases in a dose-dependent fashion.
- Tramadol may occasionally cause reversible adrenal insufficiency, requiring monitoring and glucocorticoid replacement therapy.
- Serotonin syndrome has been reported in patients receiving tramadol alone or in combination with other serotonergic agents.

Reference: Drug Safety Newsletter**,** HPRA, 9 June 2023 (link to the source within **www.hpra.ie** **)**

Non-steroidal anti-inflammatory drugs (NSAIDs) Potential risks following prolonged use after 20 weeks of pregnancy – United Kingdom.

The MHRA has announced that the product information for non-steroidal anti-inflammatory drugs (NSAIDs) has been updated to include the risk of oligohydramnios (low levels of amniotic fluid surrounding the baby) and premature closure of the ductus arteriosus (narrowing of a connecting blood vessel in the baby's heart) in the second trimester of pregnancy. It now includes advice to avoid use from week 20 of pregnancy onwards unless considered necessary by a clinician.

Reference: Drug Safety Update, MHRA, 27 June 2023 (link to the source within www.gov.uk/mhra)

Renin-angiotensin system inhibitors Strengthened warning on use in women of childbearing potential -Japan.

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the product information for renin-angiotensin system (RAS) inhibitors will be updated to strengthen warning on the use in women of childbearing potential. The MHLW and the PMDA requested to add the following precautions for the administration of RAS inhibitors to women of child-bearing potential:

- Women of child-bearing potential should be administered RAS inhibitors only if the potential therapeutic benefits are considered to outweigh the potential risks.
- If to be administered, the absence of pregnancy should be confirmed prior to and during the administration periodically. If pregnancy is detected, the administration should be discontinued immediately.
- Patients should consult the physician if pregnancy is planned, and immediately if pregnancy is detected or suspected.

Reference: Safety Information, MHLW/PMDA, 30 May 2023 (link to the source within www.pmda.go.jp/english/)

Topiramate -Risk of neurodevelopmental disorders in children exposed in-utero -New Zealand.

Medsafe has announced that the product information for topiramate (Topamax®) is updated to include the risk of neurodevelopmental disorders and birth defects in children whose mothers were taking topiramate during pregnancy. The risk of neurodevelopmental disorders was noted in an observational study based on data from five Nordic pregnancy registries.

Reference: Safety Communications, Medsafe, 11 April 2023 (link to the source within www.medsafe.govt.nz)

References

1. WHO Pharmaceuticals Newsletter No. 4, 2023. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO.
2. WHO Pharmaceuticals Newsletter No. 1, 2024. Geneva: World Health Organization; 2024. License: CC BY-NC-SA 3.0 IGO.

Public Alert on Benylin Paediatric Formulation

The Medicines Control Authority of Zimbabwe (MCAZ) would like to inform all stakeholders of a critical communication received from National Agency for Food and Drug Administration (NAFDAC) of Nigeria regarding the recall of **Benylin Paediatric** 100ml Syrup, **batch number 329304**, manufactured by Johnson and Johnson, South Africa.

According to NAFDAC, recent laboratory analysis has revealed unacceptably high levels of Diethylene glycol in this formulation. Diethylene glycol is a contaminant which is toxic for humans when consumed. Toxic effects can include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state, and acute kidney injury, potentially leading to death.

Additionally, the South African Health Products Regulatory Authority (SAHPRA) and the manufacturer identified an additional batch that is affected bringing the affected batches to two; **329303 and 329304**.

While the Authority confirms that this product was registered in 2023 for use in Zimbabwe, our import database does not show a record of the importation of this product and more specifically these two batches. However, there is a concern that through illegal means, the aforementioned batches of Benylin Paediatric Syrup may find their way into the local market.

As a precautionary measure, the Authority is issuing a recall notice of this product. In the unlikely event that members of the public are in possession of and/or come across this product, please notify the Authority and/or healthcare provider immediately and desist from administering them to children. The cooperation of all stakeholders is essential in ensuring the right of citizens to safe and good quality medicines is protected. Meanwhile, the Authority will intensify its market surveillance activities through strict premises inspections and public awareness to ensure that these products are not circulated.

The mandate of the MCAZ is to protect public health by ensuring that all medicines and medical devices on the market are safe, effective, and of good quality and will continue to monitor the situation in line with the WHO guidelines. The Authority also urges members of the public to access medicines from licenced persons and premises for easier monitoring. The Authority and law enforcement agencies continue to work together to eradicate any substandard and falsified health products.

Shamu T et al. *Journal of the International AIDS Society* 2024, **27**:e26216
http://onlinelibrary.wiley.com/doi/10.1002/jia2.26216/full | https://doi.org/10.1002/jia2.26216

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

RESEARCH ARTICLE

Body weight and blood pressure changes on dolutegravir-, efavirenz- or atazanavir-based antiretroviral therapy in Zimbabwe: a longitudinal study

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Abstract

Introduction: Dolutegravir (DTG) is widely used for antiretroviral therapy (ART). We compared weight and blood pressure trends and examined the association between high blood pressure and weight gain among people living with HIV (PLHIV) switching to or starting DTG-based, efavirenz (EFV)-based and ritonavir-boosted atazanavir (ATV/r)-based ART in Zimbabwe.

Methods: PLHIV aged 18 years or older who started or switched to DTG, EFV or ATV/r-based ART between January 2004 and June 2022 at Newlands Clinic in Harare, Zimbabwe, were eligible. Weight was measured at all visits (Seca floor scales); blood pressure only at clinician-led visits (Omron M2 sphygmomanometer). We used Bayesian additive models to estimate trends in weight gain and the proportion with high blood pressure (systolic >140 mmHg or diastolic >90 mmHg) in the first 2 years after starting or switching the regimen. Finally, we examined whether trends in the proportion with high blood pressure were related to weight change.

Results: We analysed 99,969 weight and 35,449 blood pressure records from 9487 adults (DTG: 4593; EFV: 3599; ATV/r: 1295). At 24 months after starting or switching to DTG, estimated median weight gains were 4.54 kg (90% credibility interval 3.88–5.28 kg) in women and 3.71 kg (3.07–4.45 kg) in men, around twice that observed for ATV/r and over four-times the gain observed for EFV. Prevalence of high blood pressure among PLHIV receiving DTG-based ART increased from around 5% at baseline to over 20% at 24 months, with no change in PLHIV receiving EFV- or ATV/r-based ART. High blood pressure in PLHIV switching to DTG was associated with weight gain, with stronger increases in the proportion with high blood pressure for larger weight gains.

Conclusions: Among PLHIV starting ART or switching to a new regimen, DTG-based ART was associated with larger weight gains and a substantial increase in the prevalence of high blood pressure. Routine weight and blood pressure measurement and interventions to lower blood pressure could benefit PLHIV on DTG-based ART. Further studies are needed to elucidate the mechanisms and reversibility of these changes after discontinuation of DTG.

Keywords: HIV; dolutegravir; blood pressure; hypertension; body weight; Zimbabwe

Additional information may be found under the Supporting Information tab of this article.

Received 30 August 2023; **Accepted** 23 January 2024

Access to the full article: https://onlinelibrary.wiley.com/doi/full/10.1002/jia2.26216

Safety Monitoring Of Medicines

1. National Pharmacovigilance centre

MCAZ, through the Pharmacovigilance and Clinical Trials (PVCT) Division, is the National Pharmacovigilance Centre. This means that it is responsible for safety monitoring of medicines, particularly adverse drug reactions or side effects monitoring.

2. Side Effects

Side effects, sometimes referred to Adverse Drug Reactions (ADRs), are usually secondary undesirable effects that happen when the body reacts to medicines, even when the medicines have been taken correctly. Side effects can also be exeperienced after taking other medicines such as herbal and traditional medicines.

3. Why report side effects

Reporting helps:

1. to ensure patient safety;
2. to identify new reactions;
3. to record the frequency with which ADRs are reported;
4. to evaluate factors that may increase risk and provide information to prescribers with a view to prevent future ADRs;
5. to reduce risks associated with the use of medicines;
6. regulatory authorities to make vital decisions regarding safe use of medicines

How to report

There are a number of avenues that you can use to submit reports to us:

ADR Form. Can be accessed by visiting your nearest healthcare provider who will assist you to complete one

Online Consumer reporting or Healthcare reporting form

Online reporting via E-PV: e-pv.mcaz.co.zw

Via MCAZ Official Whatsapp

Contact us:

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