UGANDA

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

PHARMACOVIGILANCE BULLETIN

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MESSAGE FROM THE DIRECTOR PRODUCT SAFETY

It is with great pride that I share this latest edition of the Pharmacovigilance Bulletin, which reflects our collective effort in ensuring the safety and efficacy of medicines and health products used across Uganda.

This issue brings to the fore important updates including local case safety reports, international drug safety alerts, and recent changes to product safety labels. These developments remind us of the dynamic nature of pharmacovigilance and the necessity for timely, data-driven action.

We have also continued our regular support supervision visits to health facilities, where we work directly with healthcare professionals to improve pharmacovigilance reporting practices. The positive feedback and increased reporting rates are a testament to the growing awareness and commitment within our healthcare system.

Our Quarter Three data analysis further provides a snapshot of the current safety trends and emerging concerns. Such data is vital in guiding our regulatory decisions and public health advisories.

Let us remain vigilant and committed to fostering a culture of safety. I encourage everyone to continue reporting suspected adverse drug reactions and to stay informed about product safety updates. Together, we can protect the health of all Ugandans.

Dr. Helen Byomire Ndagije (PhD), FISoP
Director, Product Safety
National Drug Authority

LOCAL SAFETY INFORMATION

DRUG INDUCED HEPATIC DAMAGE OF ANTI-TBS AUGMENTED WITH ALCOHOL

After starting him on anti-TB medications, MR, a 38-year-old man with an alcohol problem but no known chronic illness, was taken to the emergency room unconscious and exhibiting signs of drug-induced hepatic damage (RHZE). He weighs 50 kg and began taking medication on November 19, 2023, but the reaction began on January 2, 2024. After the medication was stopped, MR began to get better.

Tuberculosis (TB) is usually caused by a bacterium, Mycobacterium tuberculosis (M.tb) complex (such as Mycobacterium tuberculosis, Mycobacterium bovis, Mycobacterium africanum and Mycobacterium microti)[1]. The main cause of tuberculosis in Uganda is M. tuberculosis.

Tuberculosis is usually spread when a patient suffering from pulmonary TB who is not on effective treatment expels into the environment air containing droplets with the bacilli (coughing, singing or sneezing) and these droplets are inhaled in by a susceptible person for example immunocompromised patients[1]. These patients are those with conditions like HIV infection, diabetes mellitus, alcoholism, cancer, and use of immunosuppressive drugs, malnutrition, advancing age and many others.

Treatment of drug susceptible tuberculosis is generally either a 4 month regimen (rifapentine and moxifloxacin) or a 6 or 9 month regimen (RHZE)[2].

The 6-month regimen is composed of intensive phase of 2 months treatment with RHZE and the continuation phase of 4 months treatment with RH.

Adverse medication responses that are linked to TB treatment are mild and infrequent. For these negative events to be detected early, close observation is required. Hepatic and peripheral nerve damage are the two main types of drug-specific adverse events that might happen with TB treatment. While minor hepatic damage manifests as an asymptomatic increase in serum liver enzyme values, more severe hepatotoxicity may manifest.

A patient on TB treatment should be suspected of having hepatotoxicity if they exhibit any of the following symptoms: anorexia, nausea, vomiting, abdominal pain, persistent weakness or lethargy, dark urine, pale faeces, or jaundice[3]. These adverse events are more prevalent in individuals with history of liver disease; **regular use of alcohol**; chronic liver disease; HIV infection; age more than 35 years; and pregnancy[4].

Since MR was a known alcoholic, close monitoring was paramount before and after initiating him on RHZE so as to prevent the alcohol augmented adverse events that include hepatic injury.

One of the complications of hepatic damage is reversible hepatic encephalopathy where the liver is unable to remove toxins like ammonia from the body and they end up affecting the brain cells. However, the use of rifaximin and lactulose has been effective in such patients[5].

BULGING FONTANELLE, FEVER, AND CONVULSIONS ASSOCIATED WITH BENZYLPENICILLIN

On 13/1/2025, an 11-month-old girl of Munyankole ethnicity who was taking benzylpenicillin and gentamicin to treat otitis media developed a bulging fontanelle, fever, and convulsions.

The second most frequent paediatric diagnosis in the emergency room, after upper respiratory infections, is acute otitis media (AOM), which is an infection of the middle ear. Acute otitis media is most frequently observed between the ages of 6 and 24 months, while it can happen at any age[6].

Middle ear infections can be caused by bacteria, viruses, or coinfections. Streptococcus pneumoniae is the most frequent bacterium that causes otitis media, followed by Moraxella catarrhalis and non-typeable Haemophilus influenzae (NTHi)[7].

Antibiotic treatment of otitis media is debatable and directly connected to the specific subtype of otitis media.

In the absence of appropriate care, middle ear suppurative fluid can spread to nearby anatomical sites and cause problems like hearing loss, lateral and cavernous sinus thrombosis, brain abscess, mastoiditis, labyrinthitis, petrositis, meningitis, tympanic membrane (TM) perforation, and others[8].

The main treatment for otitis media according to the Uganda Clinical Guidelines is amoxicillin/erythromycin for acute infection and hydrogen peroxide/ciprofloxacin for chronic infection. The use of systemic antibiotics is not recommended because they are considered not useful and can create resistance[9].

However, this infant was initiated on benzylpenicillin and gentamicin (systemic antibiotics) for management of otitis media. According to the manufacturer, benzylpenicillin is known to cause fever, or augment seizures/convulsions in patients at risk r example those with a history of epilepsy, cerebral edema or meningitis. Therefore, proper history taking and management is highly advisable before and after initiating the patient on benzylpenicillin.

Additionally, the infant was initiated on gentamicin which according to the manufacturer causes convulsions as one of its nervous system adverse drug reactions hence a need for strict monitoring. Therefore, these adverse drug reactions especially convulsions could have been as a result of gentamicin being augmented with benzylpenicillin or treatment failure of otitis media due to bacterial resistance leading to meningitis.

The Bulging fontanelle on the other hand could have been as a result of bacterial meningitis that developed due to treatment failure.

HYPERGLYCEMIA BEING ASSOCIATED WITH ANTI-TBS

ME, who is 70 kg and 60 years old, has a family history of diabetes mellitus. After two months of RHZE treatment for tuberculosis, he began RH. His RBS of 30 mmol/L indicated hyperglycaemia.

Evidence that tuberculosis (TB) can induce diabetes in people who have never been diagnosed with the disease is weak. Although the World Health Organization (WHO) advises DM screening at the start of TB treatment, it is still unclear which patients with TB-associated hyperglycaemia are more likely to develop DM and might benefit from more frequent monitoring[10]. According to the manufacturer, isoniazid which is part of the combination of anti-TBs used in both initiation and continuing phases, has the potential to cause hyperglycemia. Therefore, blood glucose levels at baseline should be noted and continued monitoring of patients on isoniazid is highly encouraged.

An intricate interaction between disrupted cytokine and hormone production can lead to stress hyperglycaemia associated with tuberculosis (TB), which can cause insulin resistance and increased hepatic glucose production. This interference can persist for one month or more[10].

On the hand, the life style modifications of patients on anti-TBs which include smoking, sedentary life style, drinking alcohol and diseases like HIV can predispose such patients to hyperglycemia hence acquiring diabetes mellitus.

ERECTILE DYSFUNCTION AND DIFFICULTY IN MAINTAINING AN ERECTION BOTH ASSOCIATED TO DTG BASED ART REGIMEN

BJ, a 30Y/M who weighs 75 kg, began experiencing decreased libido and difficulty maintaining an erection on July 10, 2023, following the start of a DTG-based ART regimen (TDF/3TDF/DTG).

The manufacturer does not associate the above adverse drug reactions with TLD in whatsoever. However, a qualitative exploratory research study was conducted involving sixteen in-depth interviews and six focus groups with 48 participants between August and September 2021 with patients at seven medical facilities in mid-Western Uganda who reported "new" sexual dysfunction following the switch to DTG-based regimens[11]. Decreased libido was reported in both sexes of patients within weeks of transition to DTG-based regimens.

Gordijn and colleagues have urged health care providers to regard sexual ADR monitoring as part of routine clinical practice to optimize drug treatment in this case ART[12] while Scanavino has gone further to recommend hormonal therapy such as testosterone replacement for males experiencing sexual ADRs [13].

TDF CAUSING GENERAL BODY PARALYSIS

GJ, a 49-year-old person of unknown sex, is taking TDF, Lopinavir, and Ritonavir for HIV.He complained of general body paralysis and has PUD as an underlying health condition. After switching to ABC due to his complaints of overall body paralysis, he saw a rapid and continuous recovery.

HIV treatment should be optimized with a regimen suitable for each individual so as to suppress the virus and have an undetectable viral load. However, GJ being initiated on a tenofovir based combination, he started developing issues related to general body paralysis. This adverse drug reaction is not associated to tenofovir according to the manufacturer's information.

However, according to literature and the manufacturer, tenofovir is known to cause Fanconi syndrome associated Sjögren syndrome[14]. Hypokalemic paralysis (HP) is a medical emergency that may be curable. It is easily separated into two groups.

*G*Acute transfer of K into cells causes hypokalemic periodic paralysis (HPP), while a significant K shortage causes non-HPP. In terms of treatment, a significantly higher dose of KCl is needed to replenish the severe K deficit in non-HPP, but a smaller amount is needed in HPP to prevent rebound hyperkalemia[14].

Both glandular and extra glandular organs are affected by the autoimmune exocrinopathy known as Sjögren syndrome (SS). Xerophthalmia and xerostomia are common glandular symptoms. Nonetheless, extra glandular symptoms occur in about 40% of individuals, either concurrently with or before classic sicca disease. One of the most frequent extra glandular involvements is the kidney. Even so, the most prevalent renal symptom is a malfunction in the distal tubular system prompting the failure of the kidneys to fully reabsorb the potassium ions. This in the long run can manifest as body paralysis.

Therefore, potassium supplementation, monitoring and switching to a more favorable drug is advisable.

SAFETY REPORTS FROM OTHER COUNTRIES

NEUROPSYCHIATRIC REACTIONS WITH MONTELUKAST

Australia. The Therapeutic Goods Administration (TGA) has updated the Product Information for all montelukast-containing medicines to highlight the risk of serious behaviour and mood-related changes. Although previously known, these warnings have been strengthened due to ongoing reports of neuropsychiatric reactions such as agitation, depression, and suicidal thoughts. These effects may occur during or after treatment. The update follows expert review and aims to improve awareness among patients and healthcare professionals, with warnings now placed more prominently in the product and consumer information.

Health-care professionals are advised to:

· Monitor patients for signs of neuropsychiatric reactions, such as agitation, irritability, restlessness, anxiety, depression, hallucinations, sleep disturbances (including sleep-walking), tremor, disorientation, and suicidal thoughts or behaviour.

· Discontinue montelukast treatment if such symptoms occur or worsen.

· Inform patients and their carers about these potential risks and provide the updated Consumer Medicine Information as needed.

Patients and carers are advised to:

· Be vigilant for any changes in mood or behaviour while taking montelukast.

· Immediately seek medical attention if symptoms such as aggressive behaviour, hallucinations, depression, or suicidal thoughts are noticed in themselves, their children, or those they care for.

Reference: Safety updates, TGA, (link to the source within www.tga.gov.au)

OMEPRAZOLE AND HYPERTENSION

Eritrea. A recent analysis of global pharmacovigilance data by the National Medicines and Food Administration, Ministry of Health, Eritrea, raised concerns about a potential causal link between omeprazole and hypertension, even though hypertension is not listed as an adverse event in the drug's approved SmPC.

Key Findings:

· 1,043 hypertension cases associated with omeprazole were reported across 36 countries in VigiBase.

· A statistical signal was found (IC_{025}: 0.12) indicating a possible association.

· 65% of cases were serious, and 10.6% were fatal.

· In 85 cases, hypertension resolved after omeprazole withdrawal, and 14 cases showed recurrence after reintroduction.

Conclusion: The evidence suggests a potential link between omeprazole and hypertension. Healthcare professionals should monitor blood pressure in patients using omeprazole, especially if no other cause is found.

Recommendations:

· Healthcare professionals are advised to monitor blood pressure in patients taking omeprazole, particularly where no other cause of hypertension is evident.

· Any suspected cases of omeprazole-related hypertension should be reported to national pharmacovigilance authorities.

· Further epidemiological studies are recommended to confirm the strength of this suggested association.

Key words; omeprazole, hypertension, pharmacovigilance, and causality assessment https://doi: 10.1007/s40801-024-00441-2.

RISK OF PULMONARY ASPIRATION WITH GLP-1 AND DUAL GIP/GLP-1 RECEPTOR AGONISTS DURING

United Kingdom. The Medicines and Healthcare Products Regulatory Agency (MHRA) issued new safety advice regarding the use of GLP-1 and dual GIP/GLP-1 receptor agonists in patients undergoing surgery or procedures involving general anesthesia. These medicines, including dulaglutide, exenatide, liraglutide, lixisenatide, semaglutide, and tirzepatide, are used in the management of type 2 diabetes.

GLP-1 and dual GIP/GLP-1 receptor agonists are known to delay gastric emptying, which may increase the risk of residual gastric contents despite standard preoperative fasting. This raises the potential for pulmonary aspiration during anesthesia, a serious complication that may lead to aspiration pneumonia.

A recent European review concluded there is sufficient evidence to support an association between these medicines and aspiration risk during procedures requiring general anesthesia. The Pharmacovigilance Expert Advisory Committee of the Commission on Human Medicines (CHM) has endorsed these findings, and product information for all GLP-1 and dual GIP/GLP-1 receptor agonists has been updated to include warnings on aspiration risk. Healthcare professionals are advised to assess patients for aspiration risk during preoperative evaluation, particularly in individuals with diabetic gastroparesis, obesity, gastroesophageal reflux disease, or symptoms of delayed gastric emptying. Patients may not disclose use of these medicines if obtained for off-label weight loss, so direct questioning is recommended.

VISIBLE PARTICLES IN SELECT BATCHES IN DISODIUM FOLINATE (SODIOFOLIN®)INJECTION

United Kingdom. The MHRA in agreement with medac GmbH, issued a safety communication regarding Sodiofolin® (folinic acid) 50 mg/ml solution for injection/infusion, following the detection of visible particles in select batches.

Sodiofolin® (folinic acid) 50 mg/ml solution is indicated for use in combination with 5-fluorouracil in cytotoxic treatment and as an antidote to methotrexate toxicity. It may be administered as either an infusion or a bolus injection.

The affected batches **—C240164A, C240218B, and C240218C—present a potential risk of thrombo-embolic events if administered without a suitable filter.**

Until further notice, healthcare professionals are advised to:

·Use pump systems with particle filters made of polyethersulfone (PES) or polyvinylidene fluoride (PVDF), with a pore size ≤ 5 µm, for infusions.

·Use syringe filters made of PES or PVDF with a pore size ≤ 5 µm for bolus injections.

The cause of the particle formation is still under investigation.

However, the active ingredient concentration remains unaffected, and no dose adjustment is required. These precautionary measures are intended to mitigate the risk of intravenous particle-related complications until a formulation free from particle formation becomes available, which is expected later this year.

Healthcare professionals should follow the updated recommendations to ensure patient safety.

Reference: Drug Safety Update, MHRA, 28 January 2025 (link to the source within www.gov.uk/mhra)

VEOZA (FEZOLINETANT)

Europe. The European Medicines Agency and the Health Products Regulatory Authority, in agreement with Astellas Pharma Ltd., issued new recommendations on liver function monitoring for patients treated with Veoza (fezolinetant) following reports of drug-induced liver injury (DILI).

Fezolinetant is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.

Key safety recommendations:

- Liver function tests (LFTs) must be performed before starting treatment.

Treatment must not be initiated if ALT or AST levels are ≥2x the upper limit of normal (ULN) or if bilirubin levels are ≥2x ULN.

- Monthly LFTs are required during the first 3 months of treatment. After 3 months, LFTs should be guided by clinical judgment or repeated if liver-related symptoms appear.

- Treatment must be discontinued if:

ALT/AST ≥3x ULN with bilirubin >2x ULN or symptoms of liver injury;

ALT/AST >5x ULN.

Patients should be advised to seek immediate medical attention if they experience signs or symptoms of liver injury, such as fatigue, pruritus, jaundice, dark urine, pale stools, nausea, vomiting, decreased appetite, or abdominal pain.

The Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) for Veoza are being updated. "Drug-induced liver injury" is now listed as an adverse reaction with frequency 'not known'.

Reference: Drug Safety Update, HPRA, January 2025 (link to the source within www.hpra.ie)

SAFETY LABEL VARIATIONS

A safety labelling update is an update to any safety section in the label which is clinically meaningful. The safety and efficacy changes refer to changes that have an impact on the clinical use of the bio therapeutic product in relation to safety, efficacy, dosage and administration, and that require data from clinical or post-marketing studies, and in some instances clinically-relevant nonclinical studies, to support the change. The benefit risk profile of innovative products changes over time as more data about the product in "real-life" clinical settings becomes available. This leads to the need to update the product information to advise health care professionals about the best way to care for their patients. The following are the safety label variations approved by National Drug Authority between **1st January and 31st March 2025.**

Product Name	License holder	Summary of approved changes	Date of NDA approval
Fexinidazole (FEXINIDAZOLE WINTHROP®)	Sanofi – Aventis South Africa (Pty) Ltd.	Change of therapeutic indication involving extension of indication to include treatment of both first stage (Haemo-Lymphatic) and second stage meningoencephalitis) of human African trypanosomiasis (HAT) due to trypanosome brucei rhodensiense.	6th February 2025
Finerenone (FIRIALTAA®)	Bayer East Africa Ltd.	Update in the sections 4.1,4.8,5.1 and 5.8 of the SmPc based on the data from FIGARO-DKD phase 3 study, pooled analysis from the FIGARO-DKD and FIDELIO –DKD studies, as well as the phase 1 drug interaction study of finerenone with rosuvastatin. Some notable changes include: 1. Inclusion of study results for renal and cardiovascular events. 2. Addition of hyperuricaemia as a common undesirable effect. 3. Additional primary and secondary time- to – event endpoints.	10th February 2025
Bevacizumab (AVASTIN®)	F. Hoffmann La-Roche SWITZERLAND	Clarification of the warning and precautions: Hypersensitivity reactions/infusion reactions to include anaphylactic shock.	21st February 2025
Dolutegravir + Abacavir + Lamivudine (TRIUMEQ®)	VIIV Healthcare UK Limited.	Update of the SmPc involving TSC 3- Sections: Clinical studies, pregnancy and lactation – NTD wording updated in view of Tsepamo March 2022 and Eswantini September 2022 data and APR wording updated in view of January 2023 data.	27th February 2025

Product Name	License holder	Summary of approved changes	Date of NDA approval
Dapagliflozin (FORXIGA®)	Astrazeneca UK Ltd.	1. Addition of treatment of heart failure in adult's indication as a result of the DELIVER study. 2. Update of the SmPc to reflect changes made in EU FORXIGA SmPc as a result of Deliver approval and addition of Lithium drug-drug interaction in section 4.5 of the core data sheet.	10th March 2025
Vildagliptin/Metformin (GALVUS MET)	Norvatis Pharma AG KENYA	Update to the SmPc in section 7 (Adverse drug reaction) to include a post marketing ADR "Cholectstitis" with frequency "Not Known"	14th March 2025
Etravirine (INTELENCE)	Janssen-Cilag International NV BELGIUM	Change in the SmPc labelling, or package leaflet due to the following safety concerns that are approved by the EU; 1. In section 4.4 Special warnings and precautions for use – Removal of the disease information relating to sexual transmission of HIV 2. In section 4.6 Fertility , pregnancy and lactation – Amendment of the section related to breast feeding.	18th March 2025
Vidagliptin (VIDAGLIPTIN ®	Norvartis AG KENYA	Update to the SmPc in section 7 to include a post marketing ADR "Cholecystitis" with frequency "Not Known".	18th March 2025
Dolutegravir Sodium (TIVICAY)	VIIV Healthcare UK Limited.	Update in the prescribing information regarding Neural Tube defects in sections of "Antiretroviral Pregnancy Registry (APR), Clinical studies, Pregnancy and Lactation" to replace the old data with new data obtained from the Tsepamo and Eswatini (Botswana) birth outcome surveillance studies, i.e., • There were no increased risk of neural tube defects with dolutegravir exposure at conception. • The prevalence of neural tube defects in infants born to women taking dolutegravir at conception in the two studies did not differ significantly from the background rate in women without HIV or other exposure groups. • The APR data was amended based on the January 23 data.	19th March 2025

Product Name	License holder	Summary of approved changes	Date of NDA approval
Dolutegravir Sodium + Rilpivirine Hydrochloride (JULUCA)	VIIV Healthcare UK Limited.	Update in the prescribing information regarding Neural Tube defects in sections of "Antiretroviral Pregnancy Registry (APR), Clinical studies, Pregnamcy and Lactation" to replace the old data with new data obtained from the Tsepamo and Eswatini (Botswana) birth outcome surveillance studies, i.e., • There was no increased risk of neural tube defects with dolutegravir exposure at conception. • The prevalence of neural tube defects in infants born to women taking dolutegravir at conception in the two studies did not differ significantly from the background rate in women without HIV or other exposure groups. • The APR data was amended based on the January 23 data.	19th March 2025
Triploridine HCL/ Pseudoephedrine/ Guaiphenisin (ACTIFED WET COUGH AND COLD)	Glaxosmithkline Limited. KENYA	Update to the SmPc to add a warning related to Acute Systemic Vasocontrictive events i.e, the existing warning related to ischaemic colitis, posterior reversible encephalopathy/ reversible celebral vasoconstriction syndrome (RCVS) has been widened to include the term "Acute systemic vasoconstrictive events" and impart more clarity on signs and symptoms.	19th March 2025

PHARMACOVIGILANCE SUPPORT SUPERVISION IN HEALTH FACILITIES

In February 2025, the National Drug Authority (NDA) conducted pharmacovigilance support supervision and sensitization of healthcare workers across various regions of Uganda. The initiative was driven by the growing need for enhanced safety surveillance amidst the continued introduction of new drugs and vaccines.

Objectives of the Activity:

- Sensitize and train healthcare workers on identifying and reporting Adverse Drug Reactions (ADRs) and Adverse Events Following Immunization (AEFIs), regardless of severity.
- Identify barriers to ADR/AEFI reporting.
- Collect physical ADR/AEFI reports from health facilities.
- Distribute IEC materials to raise awareness on available reporting platforms.

Scope and Reach:

- Visited 125 public and 9 private health facilities.
- Engaged 837 healthcare workers through focus groups and in-person sessions.

Key Observations:

- Most healthcare workers had basic pharmacovigilance knowledge, and reporting tools were available in many facilities but underutilized.
- Knowledge gaps existed in properly filling ADR/AEFI forms.
- Reports were often limited to serious cases, with non-serious or expected reactions overlooked.
- Workers were well informed on good storage practices for medicines and vaccines.

Outcome:

- Collected 2 physical ADR/AEFI reports.
- Received 3 market complaints (Diclofenac injection, ABOA M.D Jelly, Phenytoin tablets), referred to the Post-Market Surveillance Unit.
- Highlighted delayed or uncollected recalled drugs at facilities (e.g., Ketoconazole, Glibenclamide).

Challenges Identified:

- Inadequate training on outbreak response.
- Underreporting of ADRs/AEFIs due to workload and staff shortages, especially with reduced vaccination roles for Nursing Assistants.

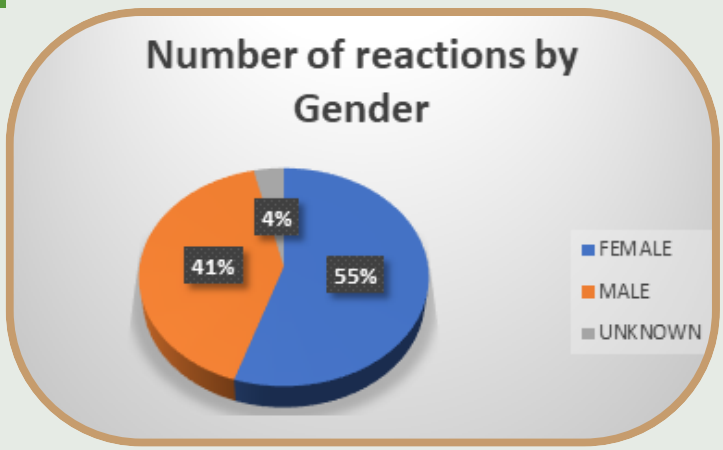
Recommendations:

- Conduct additional pharmacovigilance supervisions to reach more health workers.
- Partner with UNEPI for joint field activities to streamline vaccine and AEFI information dissemination.
- Provide tools for reporting product quality complaints beyond ADRs/AEFIs.

Q3 PHARMACOVIGILANCE DATA ANALYSIS

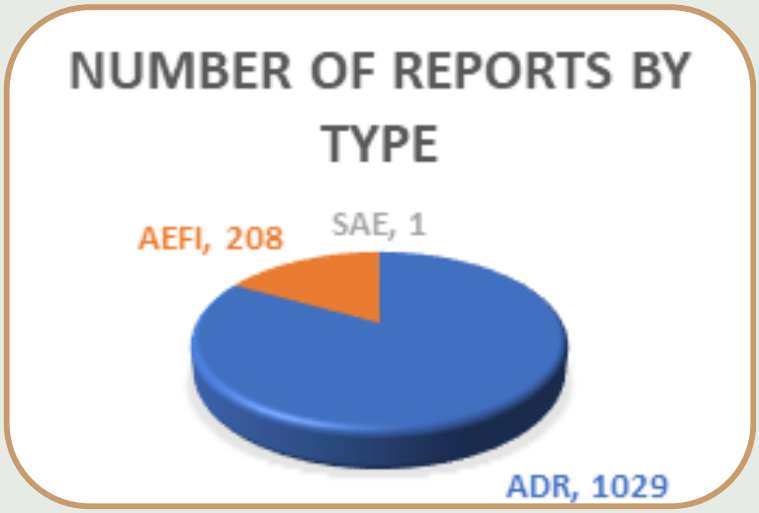
REPORTING BY GENDER

Gender	No of reports
FEMALE	538
MALE	403
UNKNOWN	36
Grand Total	**1238**



TYPE OF REPORT

Report type	Number of reports
ADR	1029
AEFI	208
SAE	1
Grand Total	**1238**

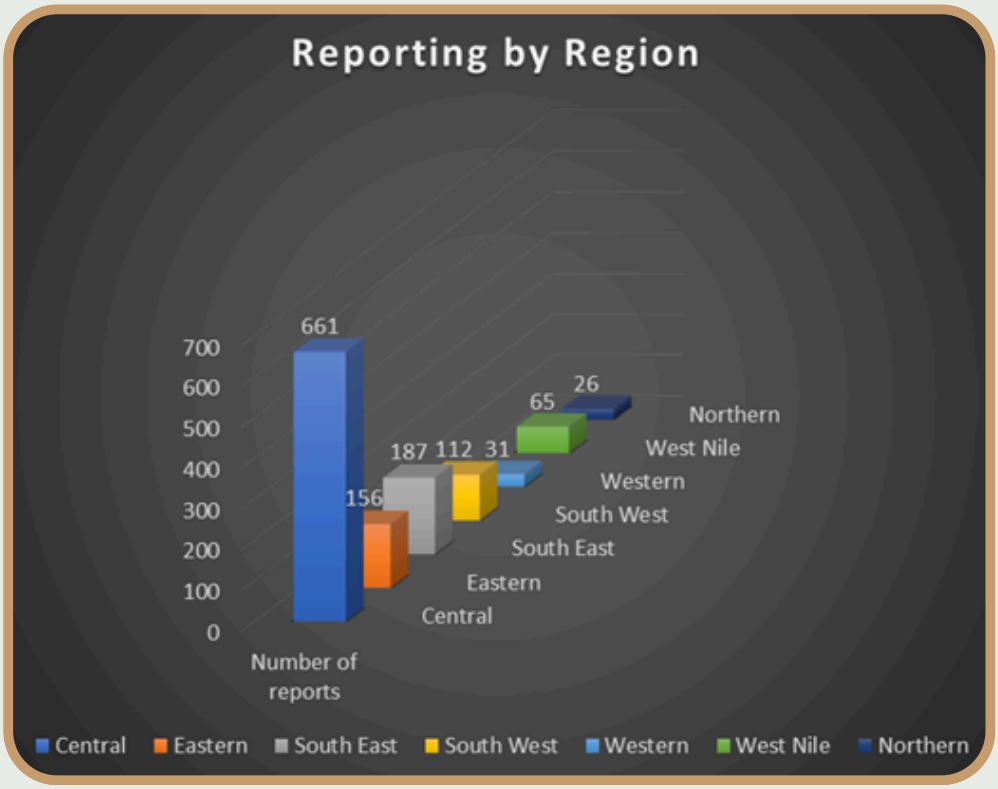


NATURE OF REACTIONS

Nature of reaction	Number of reports
Not serious	749
Serious	489
Grand Total	**1238**

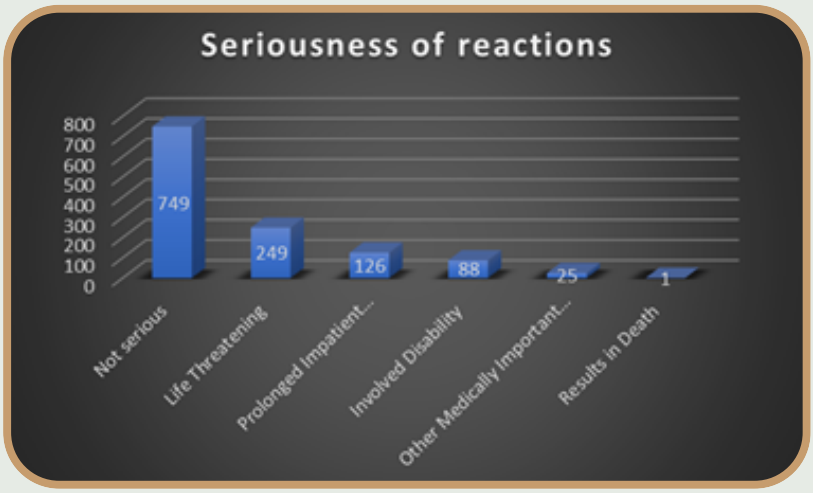
REPORTING BY REGION

Region	Number of reports
Central	661
Eastern	156
South East	187
South West	112
Western	31
West Nile	65
Northern	26
Grand Total	**1238**



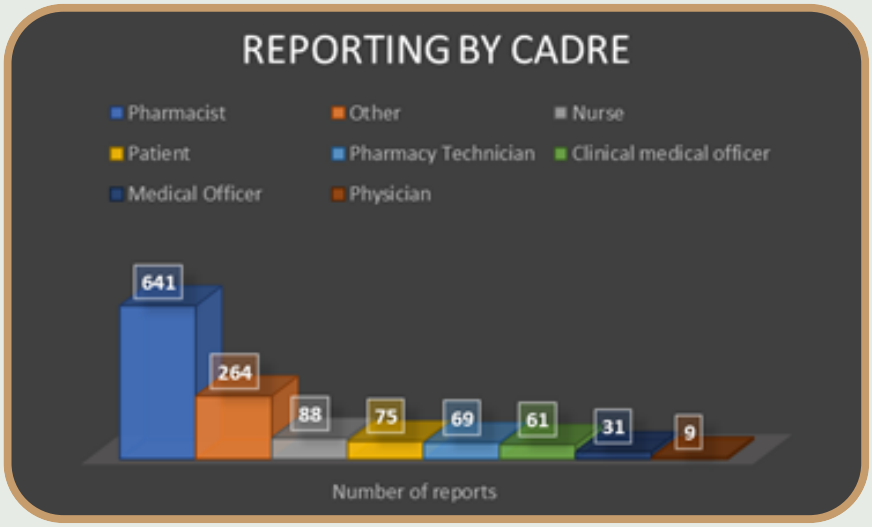
SERIOUSNESS OF REACTION

Seriousness of reaction	Number of reports
Not serious	749
Life Threatening	249
Prolonged Impatient Hospitalization	126
Involved Disability	88
Other Medically Important condition	25
Results in Death	1
Grand Total	1238



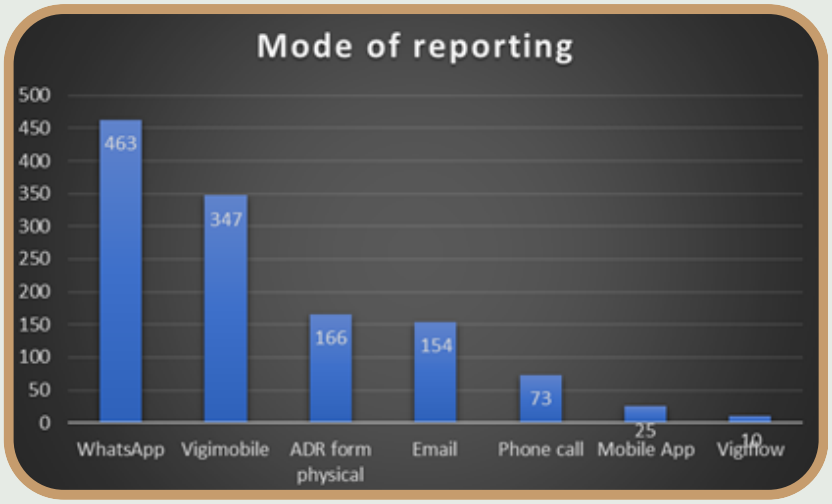
REPORTING BY CADRE

Cadre	Number of reports
Pharmacist	641
Other	264
Nurse	88
Patient	75
Pharmacy Technician	69
Clinical medical officer	61
Medical Officer	31
Physician	9
Grand Total	1238



MODE OF REPORTING

Mode of reporting	Number of reports
WhatsApp	463
Vigimobile	347
ADR form physical	166
Email	154
Phone call	73
Mobile App	25
Vigiflow	10
Grand Total	**1238**



TOP REPORTING FACILITIES

HEALTH FACILITY	NUMBER OF REPORTS
ENTEBBE RRH	251
JINJA RRH	170
MBARARA RRH	80
DIRECT PATIENT REPORT	75
LUWEERO GENERAL HOSPITAL	158
BUSOLWE GENERAL HOSPITAL	41
KARITA HC IV	39
INFECTIOUS DISEASE INSTITUTE-MAKERERE UNIVERSITY	82
MUGABI MEDICAL CENTER	26
KATAKWI GENERAL HOSPITAL	23
IDI MULAGO	15
KAYUNGA RRH	14
MJAP MULAGO	12
PRODUCT OF FAITH INTERNATIONAL MEDICAL CENTRE	12
ANYEKE HC IV	12
MBALE RRH	12
YUMBE RRH	10
KIRUDDU NRH	10
ARUA RRH	47
HOIMA RRH	8
SOROTI RRH	7
MYANZI HC III	7
ITOJO GENERAL HOSPITAL	5
MWIZI HC III	5
AMUDAT GENERAL HOSPITAL	5
BUDUDA GENERAL HOSPITAL	5
UGANDA HEART INSTITUTE	5
MULAGO NRH	5

TOP REPORTING DISTRICTS

District		Number of reports
Wakiso		284
Jinja		172
Luweero		162
Kampala		147
Mbarara		86
Amudat		48
Butaleja		42
Katakwi		23
Kayunga		14
Hoima		14
Oyam		13
Mukono		13
Arua		50
Yumbe		11
Soroti		9
Kassanda		8
Rwampara		6
Bududa		6
Nakaseke		5
Mayuge		5
Masaka		5

TOP REPORTED DRUGS

Row Labels	Count of DOR
TDF/3TC/DTG	181
F75	103
COVID-19 VACCINE	75
TENOFOVIR	73
RUTF	57
EBOLA VACCINE	54
NIFEDIPINE	48
RHZE	46
BEDAQUILINE	37
ETONOGESTREL	32
PCV/PENTA VALENT	30
BUPIVACAINE	30
DOLUTEGRAVIR	24
LEVONORGESTREL	20

Row Labels	Count of DOR
CEFTRIAXONE	18
F100	17
BENDROFLUMETHIAZIDE	16
METRONIDAZOLE	13
PENTA VALENT	11
TRAMADOL	11
BUPIVACAINE/MISOPROSTOL	11
SULFAMETHOXAZOLE/TRIMETHOPRIM	10
METFORMIN	10
BCG VACCINE	9
AMLODIPINE	8
LEVOFLOXACIN	8
LINEZOLID	8
HEPATITIS B VACCINE	8

REPORT ADVERSE DRUG REACTIONS TO NDA USING THE FOLLOWING PLATFORMS

UGANDA

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

HEAD OFFICE

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