



PHARMACOVIGILANCE BULLETIN

TABLE OF CONTENT

A note from the Secretary to the Authority -----3

Message from the Director Product Safety -----4

Local safety information -----5

Safety reports from other countries -----6

Safety label variations-----8

Pharmacovigilance support supervision in health facilities -----9

Good Vigilance Practices Routine Inspections-----11

ICSR Data analysis for Q4 -----13

EDITORIAL TEAM

Dr Helen Byomire Ndagije Director Product Safety	Ismail Ntale Inspector of Drugs	Twaha Ibrahim Ssebyala Inspector of Drugs
Julius Mayengo Manager Pharmacovigilance	Emmaculate Kwikiriza Inspector of Drugs	Francis Odipiyo Inspector of Drugs
Jonathan Owiny Technical Admin	Mwesigwa Douglas Regulatory Officer	Sophia Nyende Inspector of Drugs
Christabel Yoti Technical Admin		

GUEST AUTHORS

Baluku Godwin MPS	Oniepa Christopher Cox MPS	Nasasira Abert MPS
Nayiga Winnie MPS		

A NOTE FROM THE SECRETARY TO THE AUTHORITY

The National Drug Authority remains steadfast in its mission to protect public health by ensuring that all medicines and health products available in Uganda continue to meet the highest standards of safety, quality, and effectiveness. Central to this commitment is a resilient and responsive pharmacovigilance system capable of detecting, assessing, and mitigating risks associated with the use of medicines, vaccines, and other health products.

Through continuous collection and analysis of adverse drug reaction and adverse event following immunization reports, post-marketing surveillance, and signal detection activities, the Authority identifies emerging safety concerns and implements regulatory actions. These may include issuing safety alerts, initiating product recalls where necessary, and collaborating with stakeholders to minimize risks and enhance patient safety.

This Pharmacovigilance Bulletin continues to serve as an important platform for sharing key insights, updates, and best practices, while fostering a culture of shared responsibility for medicine safety across Uganda. In this quarter's issue, we highlight important safety signals, recent regulatory updates, trends from reports received at the National Pharmacovigilance Centre, and outcomes from our ongoing support supervision and sensitization activities in health facilities.

As regulators, we reaffirm our dedication to building a vigilant, efficient, and collaborative pharmacovigilance system that responds effectively to the needs of our population. I strongly encourage all stakeholders; healthcare workers, patients, and industry partners to actively report any suspected adverse drug reactions, adverse events following immunization, or product quality issues to the NDA. Your reports are essential in helping us maintain the safety and efficacy of medicines and vaccines for all Ugandans.

Dr. David Nahamya
Secretary to the Authority

“

This Pharmacovigilance Bulletin continues to serve as an important platform for sharing key insights, updates, and best practices, while fostering a culture of shared responsibility for medicine safety across Uganda.

”

MESSAGE FROM THE DIRECTOR PRODUCT SAFETY

Vigilance in medicine safety remains central to protecting public health. It is crucial to stay informed about medicine safety as stakeholders responsible for caring for patients. That is why I am pleased to share this new issue of our quarterly Bulletin, which highlights safety concerns both locally and internationally.

In this edition we present key activities undertaken in this quarter; including support supervision in health facilities, routine Good Vigilance Practice (GVP) inspections of Marketing Authorization Holders, and updates on safety label variations.

Our vigilance system continues to evolve, with healthcare professionals serving as the foundation. From routine adverse event reporting to participating in support supervision activities, they have demonstrated their dedication to medicine safety. I sincerely appreciate every health worker contributing to building a more vigilant and safer society.

Safety alerts from other countries remind us that vigilance extends beyond our borders, and that international information can inform our local clinical practices. We recognize the need for extra vigilance on recently approved drugs like Lenacapavir to identify adverse events not seen in clinical trials. Reports of counterfeit weight loss products claiming to contain GLP-1 receptor agonists continue to surface worldwide, and I urge us to remain alert to protect our population from these products.

The routine Good Vigilance Practice (GVP) inspections conducted this quarter reflect our commitment to enhance Pharmacovigilance efforts by every Marketing Authorization Holder (MAH). This underscores the responsibility of each MAH to ensure the safety of all their products on the market, thereby protecting public health.

I commend you all for your efforts in ensuring the safety of drugs that save lives is maintained, and encourage continued reporting of all drug-related events to the National Pharmacovigilance Centre.

Safe Drugs, Save Lives

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

Our vigilance system continues to evolve, with healthcare professionals serving as the foundation. From routine adverse event reporting to participating in support supervision activities, they have demonstrated their dedication to medicine safety.



LOCAL SAFETY INFORMATION

ERECTILE DYSFUNCTION ATTRIBUTED TO RHZE.

Erectile dysfunction is not listed as a known adverse drug reaction in the product information for the RHZE. Notably, this appeared to be the first case reported in Vigiflow associating erectile dysfunction with RHZE, suggesting that the event may represent either a previously undocumented signal or may be related to other patient-specific factors.

Existing literature indicates that tuberculosis itself may negatively affect male sexual and reproductive function. For example, a clinical study evaluating newly diagnosed male tuberculosis patients reported a high prevalence of erectile dysfunction and significantly reduced testosterone levels compared with healthy controls, suggesting that the disease process may impair sexual function through hormonal and systemic effects [1].

Psychological factors may also contribute. Tuberculosis is frequently associated with chronic illness stress, reduced physical capacity, and social stigma, all of which may adversely affect sexual health. Consequently, the erectile dysfunction observed in this case may be related to the underlying pulmonary tuberculosis rather than the anti-tuberculosis treatment itself.

Given that this appeared to be the first case reported in Vigiflow, continued pharmacovigilance monitoring and further case reports would be required to determine whether a causal relationship exists between RHZE therapy and erectile dysfunction.

FAINTING ASSOCIATED WITH TLD (MYLAN)

NJ was a 50-year-old woman with a history of feeling generally unwell, experiencing nausea, and malaise while using the Mylan brand of TLD in the past. In addition to these symptoms, she then reported overall body weakness and had fainting episodes after taking that brand, which was a new reaction she began experiencing in February 2026.

Although fainting is not specifically listed as the expected reaction by the manufacturer of TLD (Mylan), NJ experienced it as a recent adverse reaction. Furthermore, the WHO pharmacovigilance database shows that there have been 12 similar cases reported, with Uganda accounting for 7, Nigeria for 4, and Ethiopia for 1.

There is limited literature that associates this reaction to TLD. According to [Alicja Jakimiuk, et al](#), dolutegravir which is part of the fixed dose combination of TLD is capable of crossing the blood brain barrier after its long term use. However, the CNS reactions that arise from that excluded fainting[2]. This therefore requires healthcare professionals to be more vigilant with patients taking TLD not only the Mylan brand but also other brands because this may be a new safety signal that needs to be validated.

BONE PAIN ASSOCIATED WITH RHZE.

Bone pain is not listed in the manufacturer's information for RHZE. 2 cases have been reported in Uganda and 19 globally. This event was occurring in a 40-year-old male receiving concomitant TLD therapy. According to the manufacturer's information for TLD, musculoskeletal adverse effects, including bone pain, are recognized. Therefore, concomitant TLD therapy should be considered a possible alternative explanation for the event.

Bone pain may also be attributable to tuberculosis itself, as the infection can spread to the skeletal system and cause musculoskeletal tuberculosis. Musculoskeletal tuberculosis affects the bones, joints, and surrounding soft tissues and accounts for approximately 10% of all extra pulmonary TB cases [3]. Tuberculosis is known to cause abnormal osteoclastogenesis triggered by an imbalance of the receptor activator of NF- κ B ligand /osteoprotegerin axis which causes a disturbance of bone homeostasis leading to bone pain [4].

TINNITUS, HEADACHE, NASAL IRRITATION, AND LIGHT HEADEDNESS ASSOCIATED WITH OXYGEN THERAPY

Oxygen is categorized as a medicinal product and ought to be prescribed for particular clinical indications, along with a target oxygen saturation range that has been established with frequent patient response monitoring.

Depending on dosage, duration, and mode of administration, oxygen therapy may cause adverse events even though it is widely used and generally regarded as safe when used properly.

The National Pharmacovigilance Centre received a case about NE, a 40-year-old woman who was admitted and started on oxygen therapy in addition to ceftriaxone and aminophylline. The patient experienced headache, nasal irritation, and dizziness after starting treatment. After her most recent oxygen therapy session, she subsequently reported experiencing tinnitus.

Nasal irritation is a common side effect of normobaric oxygen therapy, according to the manufacturer's product information.

Particularly during hyperbaric oxygen therapy, tinnitus is also known to occur, and lightheadedness, also known as dizziness, is also reported as an expected reaction. Although oxygen therapy is occasionally used therapeutically to treat cluster headaches[5], the manufacturer warns that oxygen toxicity may result in middle ear barotrauma, which can cause headaches.

According to a review of data from the WHO global pharmacovigilance database (VigiBase®), Uganda has contributed one of the 11 cases of tinnitus linked to oxygen therapy that have been reported worldwide. There have been 5 reports of dizziness worldwide, including one from Uganda and there has been one documented case of nasal irritation that came from Uganda.

Even though these incidents are still infrequently reported locally, their occurrence highlights the necessity of maintaining vigilance while receiving oxygen therapy. To improve patient safety and national pharmacovigilance systems, healthcare providers are urged to follow proper prescribing procedures, make sure there is enough monitoring, and report suspected adverse events as soon as they occur.



SAFETY REPORTS FROM OTHER COUNTRIES

RISK OF NON-ARTERITIC ANTERIOR ISCHEMIC OPTIC NEUROPATHY WITH SEMAGLUTIDE.

United Kingdom. The Medicines and Healthcare Products Regulatory Agency (MHRA) has updated the Product Information for all semaglutide-containing medicines (Wegovy, Ozempic and Rybelsus) to include the risk of Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION).

Very rare cases of non-arteritic anterior ischemic optic neuropathy (NAION) have been reported in association with semaglutide. NAION is a serious condition that can cause sudden, painless vision loss, typically in one eye.

Immediate Action: Patients presenting with sudden vision loss or rapid worsening of eyesight must be urgently referred to ophthalmology. Semaglutide

should be discontinued if NAION is confirmed.

Advice for Healthcare Professionals

- Specifically enquire about semaglutide use, including privately prescribed or online-obtained products, as these may not appear in the patient's medical record.
- Advise patients to attend eye casualty or A&E immediately if they experience sudden vision changes or rapidly deteriorating eyesight.
- Report all suspected cases of NAION associated with semaglutide via the Yellow Card scheme.

Advice for Patients: If you experience sudden blindness or rapidly worsening eyesight in one or both eyes while taking semaglutide, attend eye casualty or A&E without delay.

Reporting All suspected adverse drug reactions should be reported via the Yellow Card scheme.

Reference: www.gov.uk/drug-safety-update

COUNTERFEIT WEIGHT LOSS PRODUCTS CLAIMING TO CONTAIN GLP-1 RECEPTOR AGONISTS

Australia: The Therapeutic Goods Administration (TGA) is issuing this updated safety advisory following laboratory testing that has confirmed the presence of counterfeit imported weight loss products. These products falsely claim to contain glucagon-like peptide-1 (GLP-1) receptor agonists or GLP-1 analogues and pose serious risks to public health. This advisory follows an earlier TGA warning regarding imported unregistered GLP-1 weight-loss products.

Key Finding: TGA laboratory testing of several imported unregistered products has confirmed that they contain no GLP-1 or any GLP-1 analogues, despite being labelled as such. The tested products are counterfeit under the Therapeutic Goods Act 1989 and are not included in the Australian Register of Therapeutic Goods (ARTG).

Potential Risks to Consumers: GLP-1 receptor agonists (such as semaglutide, tirzepatide and liraglutide) are prescription-only medicines in Australia and must only be used under medical supervision.

Products purchased online or from overseas may:

- be completely fake
- contain undisclosed and potentially harmful ingredients
- fail to meet Australian standards of quality, safety and efficacy
- provide no medical benefit, even if labelled as a GLP-1 medicine.

Using counterfeit GLP-1 products exposes consumers to serious health and financial risks. Counterfeit products cannot be imported under the Personal Importation Scheme. Importing, supplying or giving away counterfeit therapeutic goods is illegal.

Advice for the Public

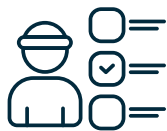
- Only purchase prescription medicines from a local registered pharmacy.
- Do not buy unregistered GLP-1 products through social media or other digital platforms.
- Do not use any GLP-1 product unless it has been prescribed by an Australian-registered healthcare professional.
- If you have used these or similar products and have any concerns, speak to your doctor or pharmacist immediately.
- If you feel unwell or suspect a side effect, report it to the TGA.

Advice for Health Professionals

- Advise patients of the risks associated with unregistered or counterfeit GLP-1 products.
- Report any adverse events involving unapproved or counterfeit medicines to the TGA.

Action by the TGA The TGA continues to actively monitor signals relating to harmful unregistered products and will notify the Australian Border Force to seize and destroy any of these products intercepted at the border.

Reference: www.tga.gov.au



SAFETY LABEL VARIATIONS

Product Name	License holder	Summary of approved changes	Date of NDA approval
Iopromide (ULTRAVIST®)	Bayer Schering Pharma	Addition of a new therapeutic indication of Ultravist 370, solution for injection i.e., the use in adult women in contrast – enhanced mammography to evaluate and detect known or suspected lesions of the breast, as an adjunct to mammography or as an alternative to magnetic resonance imaging (MRI) when MRI is contraindicated or unavailable and update of section 4.4 of the SMPC with the information of hypothyroidism in children.	17th January 2026
Mesterolone (PROVIRON®)	Bayer Pharma Ag	Changes in the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) involving the following; · General update according to current international labeling standards · Section 4.1 and 4.2; Update of indications, adoption of related section 4.2 · Section 4.4: Re-order of warning about use in men only · Restructuring of section 5.3. Inclusion of information on structure-based toxicity. · Implementation of the PSUSA outcome on mesterolone (PSUSA/0010551/202201)	21st January 2026
Denovirus Type 26 Encoding The Zaire Ebolavirus (Ebov) Mayinga Variant Glycoprotein (Gp) (ZABDENO®)	Janssen-Cilag International NV Turnhoutseweg 30 B-2340 Beerse, BELGIUM	Update of the vaccine PIL & PI (pack insert) 1.0X20.0X0.5 ML in Sections 4.2, 4.8, and 5.1 to align with the updated company core data sheet, involving the addition of text on booster dose vaccination in children 1 to 11 years old, text on safety data for children 1 to 17 years, text on immunogenicity data for booster dose in children 1 to 11 years and text for immunogenicity data for children 1 to 17 years of age.	26th February 2026
MVABEA® ONE DOSE (0.5 ML) CONTAINS: MODIFIED VACCINIA ANKARA BAVARIAN NORDIC VIRUS ENCODING THE: ZAIRES EBOVAVIRUS (EBOV) MAYINGA VARIANT GLYCOPROTEIN (GP), SUDAN EBOVAVIRUS GULU VARIANT GP, TAI FOREST EBOVAVIRUS NUCLEOPROTEIN MARRI NUCLEOPROTEIN, MARBURG MARBURGVIRUS MU MARBURGVIRUS MUSOKE VARIANT	Janssen-Cilag International NV Turnhoutseweg 30 B-2340 Beerse, BELGIUM	Safety update for the MVABEA vaccine involving; 1. Update of the product information (SmPC and PIL) to include; - Updated information on the safety, immunogenicity, and recommendation on the use of MVABEA in pregnancy. - A statement that the vaccine may contain trace residues of chicken or egg proteins. 2. Update of the risk management plan (VAC52150 EU-RMP) to include 'Thrombosis with thrombocytopenia syndrome' as an important potential risk. Cumulative reviews in the PBRER/PSUR of thromboembolic events, including potential Thrombosis with Thrombocytopenia Syndrome (TTS) cases, following exposure to Ad26.ZEBOV is added as another form of routine pharmacovigilance activity.	02nd March 2026



PHARMACOVIGILANCE SUPPORT SUPERVISION IN HEALTH FACILITIES

Introduction

In this quarter, the National Drug Authority (NDA) conducted joint pharmacovigilance support supervision and sensitization of healthcare workers across 4 districts in the Western region. The districts visited were; Ntoroko, Kikuube, Bundibugyo, and Hoima, in an initiative driven by the need for enhanced safety surveillance in the region. This activity was coordinated by the district drug inspectors (DDIs) of the respective districts visited to enhance the reach.

Objectives of the activity

- Conduct sensitization sessions for healthcare workers on pharmacovigilance, with a focus on the identification and reporting of adverse drug reactions (ADRs) and drug-related issues such as treatment failures, medication errors and quality defects.
- Distribute ADR reporting booklets, Vigimobile QR code stickers for vaccines and drugs, and education and communication (IEC) materials.
- Document all ADRs, quality concerns and inefficacy issues that were not previously reported, and submit them to NDA.

Achievements

- A total of 55 health facilities were reached.
- Sensitized 252 healthcare workers and support staff.
- Distributed 91 ADR reporting booklets.
- Distributed 144 Vigimobile stickers across the 4 visited districts in the region
- Documented and forwarded 89 ADR reports, previously recorded in various registers but not submitted to NDA/NPC.

Key Findings:

- At one of the Health Centre IV's 2 serious life threatening cases were noted related to bupivacaine which were not reported to the NDA. The health workers only got to realize it could have been bupivacaine related after seeing the recall letter from NDA.
 - Majority of the health centers had the ADR booklets that were not in use. These books were locked either the in-charge's office or stores at the facilities. the health facilities also had the NDA PV posters on their walls though they were old with some information being unreadable.
 - Majority of the patients who reacted to medicinal products were managed and the events were not reported to the National Pharmacovigilance Centre because healthcare workers continue to believe that only serious and rare adverse events need to be reported. This has resulted in many labeled adverse events going undocumented.
 - Reviews of various facility registers revealed that numerous ADRs were recorded but not submitted to the NDA.
 - The ongoing integration of HIV patients into routine outpatient services has significantly increased staff workload, which may adversely affect ADR reporting rates for ART drugs.
 - The current electronic medical record (EMR) systems used in regional and national referral hospitals lack functionality for direct ADR and drug-related issue reporting to NDA, particularly through electronic reporting channels.
- ## Constraints.
- Incomplete and poor-quality records in various facility registers impeded the documentation of many captured ADRs, as essential information

required for valid reporting was often missing.

- Records for certain services, such as vaccination (EPI), did not include provisions for documenting ADRs that occurred. So, details of ADRs/AEFIs that occurred in these departments which were not captured could not be traced for documentation and reporting to NDA.

- Staff workload was excessive, and in some cases, personnel were unable to allocate sufficient time for supervision activities due to long patient queues.

- Some facilities, particularly HC IIIs, either misplaced or lost the ADR/AEFI booklets provided during previous visits.

- The current electronic medical record (EMR) systems used at regional and national referral hospitals lack functionality to report ADRs and other drug-related issues, including quality complaints, medication failures and medication errors.

Recommendations.

- Sustain routine support supervision, alongside continuous sensitization and periodic retraining

of healthcare workers on accurate and complete data capture in patient registers. This is essential to strengthen data quality and reliability of records within the registers.

- Work collaboratively with the Ministry of Health and UNEPI to revise patient and vaccination registers by incorporating dedicated sections for capturing ADRs/AEFIs. This modification will facilitate systematic documentation and enable efficient traceability of ADR/AEFI records during active surveillance campaigns.

- Strategic engagement with Ministry of Health and the developers of the electronic medical records (EMR) system to upgrade and standardize the system to include ADR/AEFI reporting modules.

- Establish mechanisms for accountability and periodic review of ADR reporting performance, incorporating feedback to continuously improve pharmacovigilance practices. Design a database that reflects ADR reporting at various facilities per district and share with respective DHOs.



A health worker extracting data from the Family planning register to fill and ADR booklet (Left) and another HW sticking the Vigimobile sticker on the wall (Right).



GOOD VIGILANCE PRACTICES ROUTINE INSPECTIONS

In accordance with the National Drug Policy and Authority (Pharmacovigilance) Regulations, 2014 (Regulation 3), all marketing authorization holders (MAH) and their local technical representatives (LTRs) holding GMP certification from the National Drug Authority are required to establish and maintain a functional pharmacovigilance system. This requirement ensures that they take full responsibility and accountability for monitoring and safeguarding the safety, efficacy, and quality of their products on the Ugandan market. To achieve this objective, the National Pharmacovigilance Centre conducts routine Good Vigilance Practice (GVP) inspections to support MAH's and their LTR's to strengthen their Pharmacovigilance systems.

This quarter we conducted 5 GVP inspections at the following facilities; Abacus Pharma (A) Ltd the LTR of Troikaa Pharmaceuticals Ltd; Vitacare Ltd the LTR of Panacea Biotec Pharma Ltd; OncoPharm (U) Limited representing Biocad Biotechnology Company; Quality Chemical Industries Ltd; and Acculife Pharma Limited.

Scope and findings from the Inspection

These were one-day, announced routine Good Pharmacovigilance Practice (GVP) inspections conducted to assess pharmacovigilance activities at the Local Technical Representative (LTR) facilities for each Marketing Authorization Holder (MAH). The inspections began with opening meetings involving key personnel, including the facility's Qualified Person for Pharmacovigilance (QPPV).

During the inspections, the QPPVs presented their respective company pharmacovigilance systems to the inspection team. This was followed by a detailed review of documentation required for a functional PV system. Additional insights were obtained through interviews with staff responsible for pharmacovigilance activities at the facilities. The inspectors evaluated key components required for a functional pharmacovigilance (PV) system. These included the quality management system; training of personnel in pharmacovigilance; availability and maintenance of the Pharmacovigilance System Master File (PSMF); processes for handling safety-relevant information; signal detection and management; preparation and submission of Periodic Safety Update Reports (PSURs); implementation of risk management plans; safety communication practices; and the conduct of Post-Authorization Safety Studies (PASS) by Marketing Authorization Holders (MAHs). In general, the facilities inspected had major non-conformances in their PV systems that included;

- Absence of a functional Pharmacovigilance system. Most facilities visited did not integrate components of pharmacovigilance in their Quality manual, it was also noted that local facilities did not have pharmacovigilance site master files (PSMF), and also lacked documented procedures, policies and guidelines for handling and processing safety data.
- Unclear roles and responsibilities in the Pharmacovigilance system.

Majority of MAH's inspected had a QPPV and a deputy QPPV however, these were not formerly appointed and had no clear job descriptions, there was no clear delegation frameworks between QPPV and deputy QPPV and most of the Pharmacovigilance work was delegated to regulatory officers.

- Inadequate training framework for Pharmacovigilance personnel. MAH facilities did not provide evidence of training of personnel involved in vigilance work

- Weak safety data collection and reporting systems. Most facilities inspected lacked clear channels for reporting safety information by clients, their systems relied solely on spontaneous reports and lacked adequate ADR/ICSR processing procedures like casualty assessment.

- Absence of core vigilance activities at MAH premises was observed at majority of the facilities inspected. There was no evidence of signal detection and

management, no evidence of PSUR preparation, and involvement of QPPV's in their submission to the National Pharmacovigilance Center.

Majority of the LTRs systems are largely dependent on the MAH system, with minimal local implementation, rendering them non-compliant with regulatory requirements and incapable of effectively ensuring medicine safety at the local level. At the end of the inspection an exit meeting was then convened to communicate and discuss preliminary findings of the inspection with the Pharmacovigilance team. The inspectors compiled a report and shared it with the MAH and in case of any conformances the MAH was required to file a CAPA report to the regulator.

REFERENCE

- [1] K. E. O. A, and K. V, "Tuberculosis as a Reason for Male and Female Sexual Dysfunction," *J. Antimicrob. Agents*, vol. 04, no. 01, pp. 1–8, 2018, doi: 10.4172/2472-1212.1000160.
- [2] A. Jakimiuk, A. Piechal, A. Wiercińska-Drapała, A. Nowaczyk, and D. Mirowska-Guzel, "Central nervous system disorders after use of dolutegravir: evidence from preclinical and clinical studies," *Pharmacol. Rep.*, vol. 75, no. 5, pp. 1138–1151, Oct. 2023, doi: 10.1007/s43440-023-00515-y.
- [3] M. K. Leonard and H. M. Blumberg, "Musculoskeletal Tuberculosis 23," 2017, doi: 10.1128/microbiolspec.TNMI7-0046-2017.
- [4] W. Ma et al., "Mycobacterium tuberculosis Induced Osteoblast Dysregulation Involved in Bone Destruction in Spinal Tuberculosis," *Front. Cell. Infect. Microbiol.*, vol. 12, no. April, pp. 1–10, 2022, doi: 10.3389/fcimb.2022.780272.
- [5] H. Mo, S. J. Chung, T. D. Rozen, and S.-J. Cho, "Oxygen Therapy in Cluster Headache, Migraine, and Other Headache Disorders," *J. Clin. Neurol.*, vol. 18, no. 3, pp. 271–279, May 2022, doi: 10.3988/jcn.2022.18.3.271.



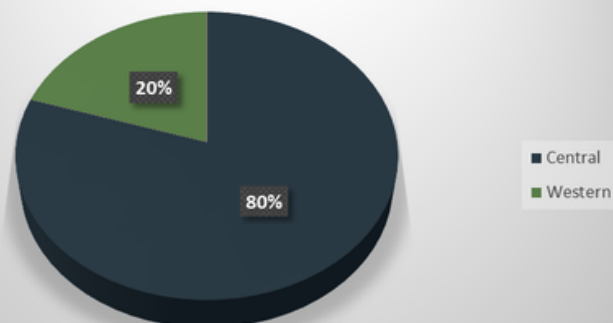
ICSR DATA ANALYSIS FOR Q3

TOTAL REPORTS = 832

TYPE OF REPORT

Type of report	Number of reports
ADR	715
AEFI	117
Grand Total	832

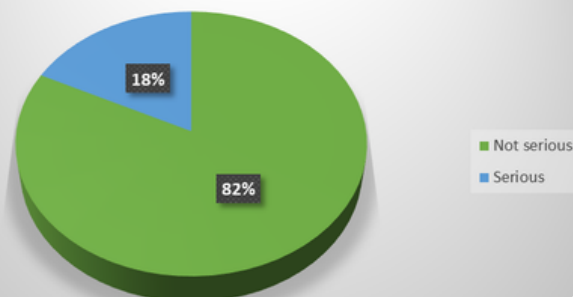
Category of report



NATURE OF REACTIONS

Nature of reactions	Number of reports
Not serious	685
Serious	147
Grand Total	832

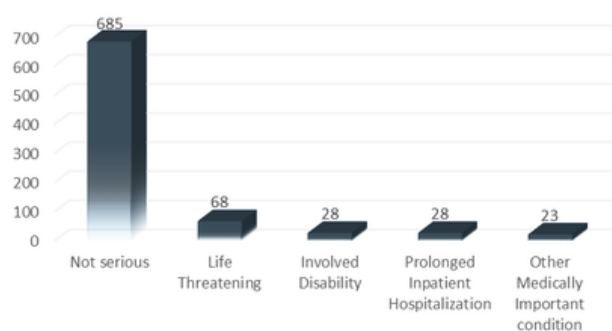
Nature of reaction



SERIOUSNESS OF REACTION

Seriousness of the reaction	Number of reports
Not serious	685
Life Threatening	68
Involved Disability	28
Prolonged Inpatient Hospitalization	28
Other Medically Important condition	23

SERIOUSNESS OF THE REACTION



TOP REPORTED DRUGS

Drug	Number of Reports
TDF/3TC/DTG	109
MALARIA VACCINE	68
MEDROXYPROGESTERONE ACETATE	49
ETONOGESTREL	46
NIFEDIPINE	43
AMLODIPINE	23
DOLUTEGRAVIR	23
MORPHINE	22
METFORMIN	21
RHZE	20
CEFTRIAZONE	19
BENDROFLUMETHIAZIDE	18
LEVONORGESTREL	18
TRAMADOL	13
COVID-19 VACCINE	13
METRONIDAZOLE	13
ABC/3TC/DTG	9
INSULIN	9
DICLOFENAC	8

Drug	Number of Reports
TENOFOVIR	8
AMITRIPTYLINE	8
PARACETAMOL	7
AMLODIPINE/LOSARTAN/H	7
ACETYLSALICYCLIC ACID	6
TDF/3TC/DTG/RHZE	6
LINEZOLID	5
ARTESUNATE	5
RIFAPENTINE/ISONIAZID	5
COPPER IUD	5
TELMISARTAN/H	5
SULFAMETHOXAZOLE/TRI METHOPRIM	4
PENTA VALENT/PCV	4
FUROSEMIDE	4
HYDROXYUREA	4
TDF/3TC/DTG/AMLODIPINE	4

TOP REPORTING HEALTH FACILITIES

Health Facility	Number of reports
LUWEERO GENERAL HOSPITAL	390
KIRUDDU NR HOSPITAL	106
FORT PORTAL RRH	32
DIRECT PATIENT REPORT	25
IHK	25
KARUGUTU HC IV	24
ARUA RRH	15
KATAKWI GENERAL HOSPITAL	15
MUGUSU HC III	13
NTOROKO HC III	12
BWERAMULE HC III	11
ENTEBBE RRH	11
YERYA HC III	11
JINJA RRH	9
NYAHUKA HC IV	8
RWEBISENGO HC IV	6
NAKASEKE GENERAL HOSPITAL	5
KAYUNGA RRH	5
RWIMI HC III	5
VIRIKA HOSPITAL	5
LIRA RRH	4
KAWEMPE HOME CARE	4
MUHWIJU HC III	4
NDEJJE HC IV	4
MBARARA RRH	4
KIBIITO HC IV	4
KYAZANGA HC IV	4

REPORT ADVERSE DRUG REACTIONS TO NDA USING THE FOLLOWING PLATFORMS

DRUG SIDE EFFECT



VACCINE SIDE EFFECT



E-mail

druginfo@nda.or.ug

WhatsApp

0740 002 070

Toll free

0800 101 999



Safe Drugs Save Lives

HEAD OFFICE
P.O BOX 23096, KAMPALA – UGANDA PLOT 93,
BUGANDA ROAD
TEL: RECEPTION : +256 [0]417 788 100

