UGANDA

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

PHARMACOVIGILANCE BULLETIN

Volume 20 Issue 02
October- December 2025

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A NOTE FROM THE SECRETARY TO THE AUTHORITY

The National Drug Authority remains committed to its mission of protecting public health by ensuring that medicines and health products available in Uganda meet the required standards of safety, quality, and effectiveness. A key part of this mission is a strong pharmacovigilance system that allows for the quick detection, assessment, and management of risks related to the use of medicines and vaccines.

Through ongoing collection and analysis of adverse drug reaction reports, post-marketing surveillance activities, and signal detection efforts, the Authority uncovers emerging safety concerns and takes appropriate regulatory actions. These include safety alerts, product recalls when needed, and engaging stakeholders to reduce risks and safeguard patients.

Effective risk communication is central to pharmacovigilance. Providing accurate and timely safety information to healthcare professionals, patients, marketing authorization holders, and the public helps ensure informed decisions and promotes the safe use of medicines. This Pharmacovigilance Bulletin serves as an important platform for sharing such information and encouraging a shared responsibility for medicine safety.

In this issue, we focus on key safety signals, regulatory updates, and trends observed from reports submitted to the National Pharmacovigilance Centre. The insights aim to improve clinical practice, enhance patient outcomes, and support evidence-based regulatory decisions.

As regulators, we reaffirm our dedication to maintaining a vigilant and responsive pharmacovigilance system. I encourage all stakeholders to keep reporting suspected adverse drug reactions and product quality issues to the NDA, as your input is crucial for maintaining the safety of medicines and vaccines for the people of Uganda.

Dr. David Nahamya
Secretary to the Authority

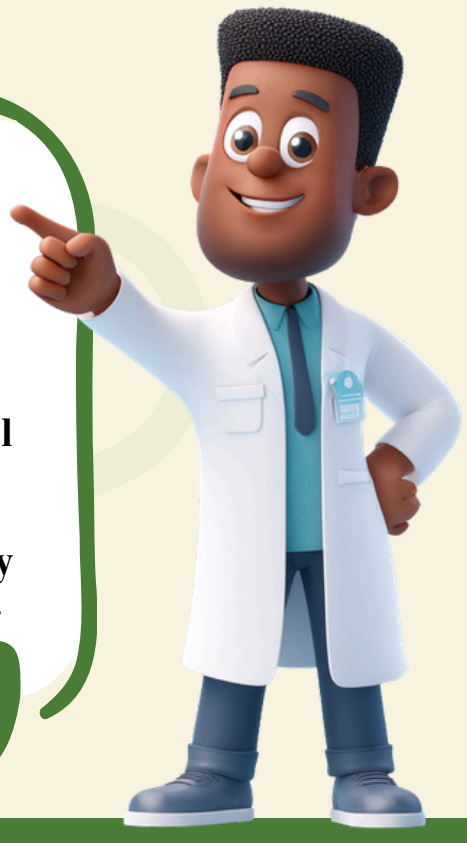
“In this issue, we focus on key safety signals, regulatory updates, and trends observed from reports submitted to the National Pharmacovigilance Centre. The insights aim to improve clinical practice, enhance patient outcomes, and support evidence-based regulatory decisions.”

MESSAGE FROM THE DIRECTOR PRODUCT SAFETY

I am humbled to share this quarter's bulletin with you as our stakeholders. It summarizes the efforts of the National Pharmacovigilance Center (NPC) in protecting public health through medicine safety monitoring. We highlight key local safety concerns, international safety alerts, safety label variations, our support supervision activities in health facilities, and NDA's collaboration with WHO to build the capacity of the Pharmacovigilance team in Risk management plan (RMP) and Periodic Safety Update Report (PSUR) assessment. This bulletin emphasizes that Pharmacovigilance heavily depends on stakeholders and their role; from submitting a single report to the NPC, which is aggregated with others across the country to form a picture of the safety profile of medicines locally. For this reason, I am proud to say that healthcare professionals are our frontline heroes in this collective effort to ensure that we have safe medicines that save lives. The international safety updates reaffirm our commitment to trans-border vigilance. These alerts are eye-opening and draw our attention to medicines of high clinical significance in our setting. From failed dissolution test results of Atorvastatin 20mg and 80mg; providing safety updates on Glucagon - like Peptide -1 (GLP-1) Receptor agonists association with suicidal ideation, the presence of substandard oral liquid medicines, to the recall of Octreotide acetate due to Good Manufacturing Practice deficiencies, these updates offer valuable insights and help us remain extra vigilant about these medicines within our clinical environment. I am grateful for the opportunity offered by WHO, in partnership with Paul - Ehrlich - Institut (PEI), Germany, to strengthen our team's capacity to review RMPs and PSURs effectively and efficiently. I firmly believe this training will enhance our work and enable our staff to make timely decisions to protect the public from medicine-related harm. Finally, I urge everyone to participate in the Vigilance chain to promote a culture of safety. I encourage healthcare workers to continue reporting adverse drug reactions as we strive to improve Public Health. Remember, Safe Drugs, Save Lives.

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

This bulletin emphasizes that Pharmacovigilance heavily depends on stakeholders and their role; from submitting a single report to the National \pharmacovigilance center, which is aggregated with others across the country to form a picture of the safety profile of medicines locally.



LOCAL SAFETY INFORMATION

UNAUTHORISED "PEZO MEGA" CAPSULES ASSOCIATED WITH CARDIOVASCULAR EVENTS AND METABOLISM DISORDERS

The National Pharmacovigilance Centre (NPC) received two peculiar cases on Pezo mega a nutritional supplement used for weight loss purposes. These were related cases in which AC and MJ both females complained of related cardiovascular events and metabolism disorders. The cardiovascular events included rheumatic heart disease, palpitations, hypertension, and heart failure while the metabolism disorder included diabetes mellitus. All events unlike diabetes mellitus were reversed after the withdrawal of the drug, indicating a high likelihood of a causative association with these products.

It should be noted that Pezo mega is not registered by the National Drug Authority highlighting that the safety profile of the product is not well understood. Therefore, the public is cautioned against the use of Pezo mega and advised to be more vigilant and report any unusual occurrences that arise in people exposed to this product. The Authority will continue to investigate and act against these unauthorized agents

BLURRY EYES ASSOCIATED WITH DEPO-PROVERA

WS is a 38-year-old breast feeding female who received a Depo-Provera intramuscular shot. She later experienced blurry eyes, backache, numbness of the lower limbs, spotting, headache, and decreased breast milk. At the time of reporting, she had not recovered from the adverse drug reactions.

Depo-Provera is used for contraception and when administered parenterally at the recommended dose to women, inhibits the secretion of gonadotropins which, in turn prevents follicular maturation and ovulation and causes thickening of cervical mucus which inhibits sperm entry into the uterus.

According to the manufacturer of Depo-Provera, blurry eyes are not expected adverse effects associated with the drug. However, other terms describing various visual disturbances including loss of vision (sudden, partial or full), and diplopia are noted as expected adverse effects linked to Depo-Provera.

There are only 4 reports of blurry vision associated with Depo-Provera in Vigilyze. These events occurred in South Africa, the Netherlands, and the United Kingdom, and Uganda. This indicates that this is a very rare event which may be a potential safety signal that needs validation after more information is gathered. Therefore, the NDA encourages all the health care workers to be vigilant and report any similar cases to the National Drug Authority.

HYPERTENSION ASSOCIATED WITH TENOFOVIR DISOPROXIL FUMARATE-BASED ART REGIMENS

Tenofovir disoproxil fumarate is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults.

According to the manufacturer, approximately a third of people using Tenofovir disoproxil fumarate are expected to experience adverse reactions which are usually mild to moderate. However, the manufacturer does not associate the drug with any cardiovascular events. A prospective cohort study in Malawi showed an increase in blood pressure among people living with HIV on Tenofovir based regimens, however, the association between Anti-retroviral therapy and hypertension remains a unconfirmed[1].

According to the WHO database, a total of 101 similar cases have been reported with Uganda contributing 41 reports. Most of the cases reported in Uganda, lack supportive data especially baseline blood pressure, making it difficult to rule out other causes. In most reported cases, patients were aged >= 40 years of age, and most were females. Since this event is not labelled by the manufacturer, this could be a potential signal that requires further monitoring and evaluation by the regulator. With better documentation, and reporting by healthcare providers, more information can be generated and risk management actions taken.

SAFETY REPORTS FROM OTHER COUNTRIES

ATORVASTATIN 20 MG AND 80 MG FILM-COATED TABLETS – CLASS 3 MEDICINES RECALL

United Kingdom:

The Medicines and Healthcare Products Regulatory Agency (MHRA) has issued a Class 3 Medicines Recall for specific batches of Atorvastatin 20 mg and 80 mg film-coated tablets manufactured by Sun Pharmaceutical Industries Limited. The recall is a precautionary measure following reports of failed dissolution test results identified during ongoing stability studies.

Dissolution testing is a critical quality parameter that ensures the medicine releases the active ingredient appropriately. Failure of this test may potentially affect drug performance, although no reports of harm or reduced efficacy have been received to date.

Affected products:

- Atorvastatin 20 mg Film-coated Tablets (PL: 14894/0714) Batch: PTF6133A (Expiry: 30/11/2027)
- Atorvastatin 80 mg Film-coated Tablets (PL: 14894/0716) Batches: PTF5991D, PTF5991F (Expiry: 30/11/2027)

Healthcare professionals should:

- Immediately stop supplying the affected batches.
- Quarantine all remaining stock and return it to the supplier following approved procedures.
- Remain alert for any reports of reduced efficacy or adverse reactions and report via the MHRA Yellow Card Scheme.

Patients should be advised:

- To continue taking their medicine as prescribed unless advised otherwise by a healthcare professional.
- That the recall is being conducted at the wholesaler level as a precautionary measure.
- To seek medical advice if they experience any adverse reactions or have concerns about their medication.

Reference: Medicines and Healthcare products Regulatory Agency (MHRA), https://bit.ly/4pFHThJ

GLP-1 RECEPTOR AGONISTS – CLASS SAFETY INFORMATION UPDATE ON SUICIDAL IDEATION

Australia:

The Therapeutic Goods Administration has aligned product warnings across the glucagon-like peptide-1 receptor agonist class to ensure consistent information regarding reports of suicidal thoughts and behaviours. GLP-1 RAs are indicated for the management of type 2 diabetes mellitus and obesity.

Following investigations by the TGA and international regulators, and advice from the Advisory Committee on Medicines, there was insufficient evidence to establish a causal association between GLP-1 RAs and suicidal or self-harming behaviours. However, inconsistencies in Product Information and Consumer Medicines Information across the class prompted harmonization to reflect class-level awareness, without implying causality.

GLP-1 RAs currently marketed in Australia include semaglutide (Ozempic®, Wegovy®), liraglutide (Saxenda®), dulaglutide (Trulicity®), and tirzepatide (Mounjaro®).

Healthcare professionals should:

- Monitor patients for new or worsening depression, suicidal thoughts or behaviours, or unusual changes in mood or behavior.
- Carefully consider the benefit–risk balance before initiating or continuing therapy in patients with current or past suicidal ideation or behavior.

- Advise patients to promptly report any mood changes or suicidal thoughts.

Patients should be informed of the importance of seeking urgent medical review if they experience new or worsening mental health symptoms while on GLP-1 RA therapy.

Reference: Therapeutic Goods Administration. Medicines Safety Update www.tga.gov.au/news/safety-alerts

SUBSTANDARD (CONTAMINATED) ORAL LIQUID MEDICINES – SERIOUS SAFETY RISK

Nigeria:

The National Agency for Food and Drugs Administration and Control (NAFDAC) has issued a public alert following a World Health Organization notification on three substandard oral liquid medicines contaminated with diethylene glycol (DEG). The products were identified in India and reported to WHO on 8 October 2025.

The affected products—COLDRIF, Respifresh TR, and ReLife—were manufactured by Sresan Pharmaceutical, Rednex Pharmaceuticals, and Shape Pharma, respectively. Laboratory analysis confirmed the presence of DEG, a toxic industrial solvent. The contamination has been linked to clusters of acute illness and child fatalities in India.

Diethylene glycol ingestion can cause severe toxicity, including acute kidney injury, altered mental state, and death.

Healthcare professionals should:

- Immediately discontinue use of the affected products if identified.
- Be vigilant for symptoms of DEG toxicity, particularly in children.
- Report suspected cases of exposure, adverse events, or product circulation to NAFDAC promptly.

Patients and caregivers should:

- Avoid using the listed products.
- Seek immediate medical attention if symptoms such as vomiting, reduced urine output, …..confusion, or abdominal pain occur.
- Report suspected substandard medicines to NAFDAC.

Reference: NAFDAC Public Alert No. 36/2025 / WHO Medical Product Alert.

OCTREOTIDE ACETATE – PRODUCT RECALL DUE TO QUALITY DEFECTS

Canada:

Health Canada has announced the recall of all strengths of Teva Octreotide for Injectable Suspension due to deficiencies in Good Manufacturing Practices (GMP) identified at a foreign manufacturing site. The deficiencies may result in compromised sterility, foreign particle contamination, or dosing inaccuracies.

Octreotide acetate is a long-acting injectable used in the management of acromegaly and hormone-secreting tumours. Potential health risks include injection-site infections, systemic infections, hypersensitivity reactions, thromboembolic events, lack of therapeutic effect, or overdose-related symptoms.

Healthcare professionals should:

- Immediately stop use of affected lots and switch patients to suitable alternatives.
- Monitor patients for signs of infection, hypersensitivity, or lack of efficacy.
- Report suspected adverse reactions or quality defects to Health Canada.

Patients should:

- Not use the affected product and return it to the pharmacy.
- Seek medical attention if symptoms such as fever, injection-site reactions, or unexpected side effects occur.
- Consult their healthcare provider for replacement therapy.

Reference: Health Canada Recalls and Safety Alerts – Teva Octreotide Recall.

SAFETY LABEL VARIATIONS

Product Name	License holder	Summary of approved changes	Date of NDA approval
Iopromide (ULTRAVIST®)	Bayer Schering Pharma	Addition of a anew 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 in contraindicated or unavailable and update of section 4.4 of the SMPC with the information of hypothyroidism in children.	17th November 2025
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 November 2025
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 November 2025
MVABEA® ONE DOSE (0.5 ML) CONTAINS: MODIFIED VACCINIA ANKARA BAVARIAN NORDIC VIRUS ENCODING THE: ZAIRE EBOLAVIRUS (EBOV) MAYINGA VARIANT GLYCOPROTEIN (GP), SUDAN EBOLAVIRUS GULU VARIANT GP, TAI FOREST EBOLAVIRUS 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 December 2025

Product Name	License holder	Summary of approved changes	Date of NDA approval
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 product information (SmPC and PIL) to include; · Updated information on the safety, immunogenicity, and recommendation on the use of ZABDENO in pregnancy. · Inclusion of a warning on excipients with known effect (ethanol and polysorbate- 80) and Thrombosis with Thrombocytopenia Syndrome (TS). · 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 TTS cases, following exposure to Ad26.ZEBOV is added as another form of routine pharmacovigilance activity.	03rd December 2025

PHARMACOVIGILANCE SUPPORT SUPERVISION IN HEALTH FACILITIES

The National Pharmacovigilance team conducted support supervision in different NDA regions between September and October of 2025. Different districts were selected based on the rececy of previous PV support supervision visits and priority was given to districts that were least visited. This activity was conducted in collaboration with the district drug inspectors (DDIs) of the respective districts visited for proper coordination.

This activity was conducted through multiple engagement activities with healthcare professionals which included;

- Group discussions with facility staff with primary focus on adverse drug reaction (ADR) detection and reporting.
- Conducting document reviews of records such as ART files, counseling notes, family planning registries, and inpatient treatment records in collaboration with facility staff. Any ADRs identified in these records but ..

...not previously reported to NDA/NPC were documented jointly and submitted during the visit, providing staff with practical experience in ADR reporting.

- Delivering continuous medical education (CME) sessions on pharmacovigilance at selected facilities, emphasizing ADR detection and reporting.
- Performing walk-through assessments of drug stores to evaluate the storage and handling of medical products.

The core Purpose / Objectives of this activity were:

- 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 and other information, education and communication (IEC) materials.
- Document all ADRs, quality concerns and inefficacy issues that were not previously reported, and submit them to NDA.

Throughout this activity we visited a total of 106 health facilities with 91 public facilities and 15 Private not for profit (PNFP's) and sensitized 544 healthcare professionals and support staff. We distributed 211 ADR reporting forms and documented 2 product quality related issues. We also documented 715 ADR reports, previously recorded in various registers but not submitted to NDA.

The key findings from this activity were:

1. Most healthcare workers continue to believe that only serious and rare adverse events need to be reported; resulting in many labeled adverse events going undocumented,
2. 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;
3. 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.

The major challenges faced during this activity were;

- 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.

Based on the above challenges the following recommendations were drawn;

1. Expand sensitization and training efforts to include all other healthcare facilities across the country, to improve ADR awareness and reporting.
2. Enhance the functionality of electronic medical record (EMR) systems in regional and national referral hospitals to support direct ADR and drug-related issue reporting to NDA.
3. Implement regular follow-up supervision and refresher training sessions to reinforce ADR reporting and address challenges identified during facility previous support supervision exercises.
4. 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.

Picture taken during sensitization session at St. Matthias Mulumba HC III in Buyende district

RMP AND PSUR ASSESMENT WORKSHOP

In November 2025 the WHO Pharmacovigilance team in conjunction with the Paul-Ehlich-Institut (PEI, Germany), conducted the first ever hands on training of on Risk Management Plan (RMP) and Periodic Safety Update Report assessment in a 3-day long workshop for National Drug Authority Staff in Kampala, Uganda.

The aim of this activity was to strengthen NDA's technical staff capacity in assessing Risk Management Plans and Periodic Safety Update Reports of medicines and vaccines post-approval to enhance safety monitoring using the WHO model RMP and PSUR assessment tools. This is in bid to safeguard the public from the harmful effects of medicines and vaccines in an era of rapid drug discovery.

At this workshop NDA staff from the directorate of product registration and the Pharmacovigilance unit actively participated in practical assessment through group discussions and appreciated the collaborative strength of assessing RMP's and PSUR's together to improve medicine and vaccine safety monitoring in the country.

REFERENCE

[1] H. M. Steffen et al., "Blood pressure changes during tenofovir - based antiretroviral therapy among people living with HIV in Lilongwe , Malawi : results from the prospective LighTen Cohort Study," Clin. Res. Cardiol., vol. 112, no. 11, pp. 1650–1663, 2023, doi: 10.1007/s00392-023-02253-w.

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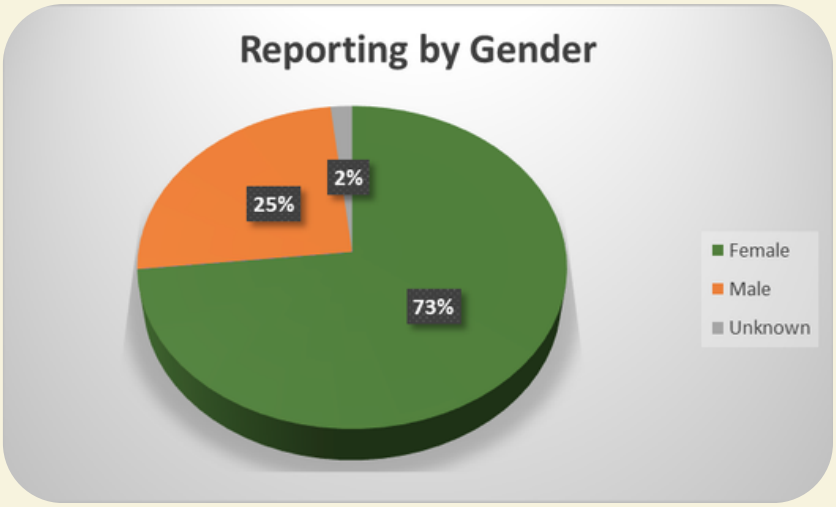
A group photo of NDA staff and a team from WHO and PEI.

ICSR DATA ANALYSIS FOR Q2

TOTAL REPORTS = 1633
ADR= 1491
AEFI= 142

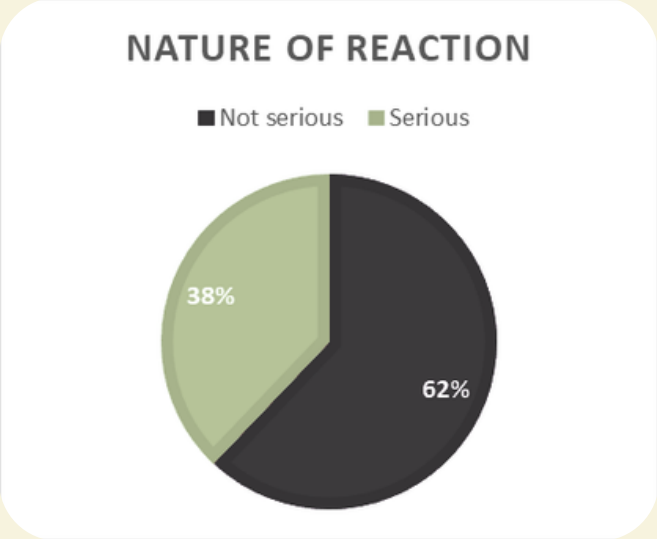
REPORTING BY GENDER

Gender	Number of reports
Female	1197
Male	407
Unknown	29
Grand Total	1633



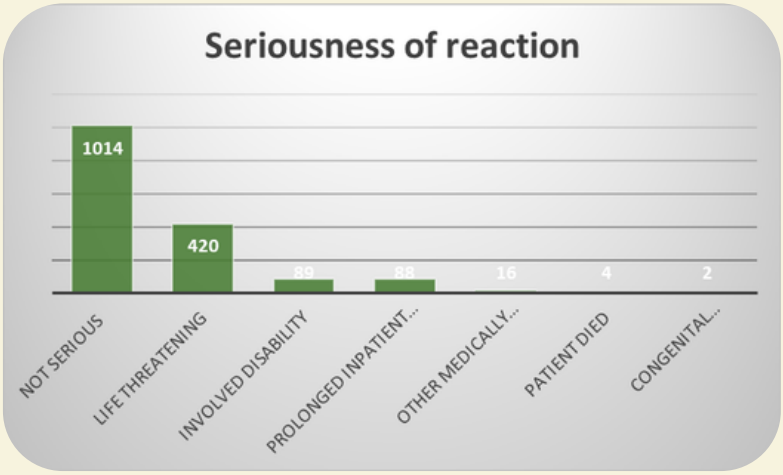
NUMBER OF REACTION

Nature of reaction	Number of reports
Not serious	1014
Serious	619
Grand Total	1633
Nature of reaction	Number of reports



SERIOUSNESS OF REACTION

Seriousness of reaction	Number of reports
Not serious	1014
Life Threatening	420
Involved Disability	89
Prolonged Inpatient Hospitalization	88
Other Medically Important condition	16
Patient Died	4
Congenital abnormality	2
Grand Total	1633



TOP REPORTED DRUGS

Suspect Drug	Number of reports
ETONOGESTREL	267
TDF/3TC/DTG	223
MEDROXYPROGESTERONE ACETATE	166
LEVONORGESTREL	163
RHZE	85
COPPER T IUD	42
PENTA VALENT	41
MALARIA VACCINE	41
MEBENDAZOLE	40
METFORMIN	10

Suspect Drug	Number of reports
TENOFOVIR	36
AMLODIPINE	34
DOLUTEGRAVIR	33
NIFEDIPINE	31
CEFTRIAXONE	20
ISONIAZID	19
YELLOW FEVER VACCINE	15
CARBAMAZEPINE	14
SULFAMETHOXAZOLE/TRIMETHOPRIM	13
POLIO VACCINE	10
FLUOXETINE	10

TOP REPORTED REACTIONS

Reported Reaction	Number of Reports
Heavy bleeding	278
IRREGULAR BLEEDING	64
HYPERTENSION	63
PROLONGED BLEEDING	39
HEADACHE	21
ITCHING	21
FEVER	20
PV BLEEDING	17
GENERALIZED ITCHING	17
SPOTTING	15
SKIN RASH	13
AMENORRHEA	13
SEVERE HEADACHE	11
HYPERGLYCEMIA	11
NEPHROTOXICITY	10
JOINT PAIN	10
DIZZINESS	9
LOWER ABDOMINAL PAIN	8
PROLONGED HEAVY BLEEDING	7
ITCHY RASH	7
BLEEDING FOR 2 WEEKS	7
VACCINATION SITE REACTION	6
MENORRHAGIA	6
PER VAGINAL BLEEDING	5

REPORT ADVERSE DRUG REACTIONS TO NDA USING THE FOLLOWING PLATFORMS

DRUG SIDE EFFECT

SCAN HERE

VACCINE SIDE EFFECT

SCAN HERE

E-mail
druginfo@nda.or.ug

WhatsApp
0740 002 070

Toll free
0800 101 999

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