UGANDA

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

PHARMACOVIGILANCE

Bulletin

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MESSAGE FROM THE SECRETARY TO THE AUTHORITY

As we conclude the first quarter of 2025, I wish to reaffirm the National Drug Authority's unwavering commitment to safeguarding public health through robust pharmacovigilance systems and effective regulatory oversight.

This quarter's bulletin highlights key adverse drug reaction reports and safety signals identified through national reporting systems, highlighting the critical role of pharmacovigilance in ensuring the continued safety, quality, and efficacy of medicines used in Uganda. The cases presented serve as a reminder that medicine safety monitoring is a shared responsibility that requires vigilance, accountability, and timely reporting by all healthcare providers.

During this period, the Authority intensified efforts to strengthen pharmacovigilance implementation at facility and district levels through targeted supervision, mentorship, and capacity-building initiatives. These engagements emphasized compliance with reporting requirements, the importance of accurate case documentation, and the integration of pharmacovigilance into routine clinical and pharmaceutical practice.

I commend healthcare workers, pharmacovigilance focal persons, partners, and stakeholders for their continued collaboration and dedication to medicine safety. Your contributions directly inform regulatory actions and support evidence-based decision-making to protect the Ugandan population.

As we progress through 2025, I urge all stakeholders to strengthen compliance with pharmacovigilance requirements, actively report adverse events, and uphold the highest standards of professional practice. Together, we can continue to build a responsive, resilient, and effective pharmacovigilance system that supports safe and rational use of medicines nationwide.

Dr. David Nahamya
Secretary, National Drug Authority

MESSAGE FROM THE DIRECTOR PRODUCT SAFETY.

Greetings from me and the team at the National Pharmacovigilance Centre.
I am pleased to share with you our Quarter One Pharmacovigilance Bulletin for the 2025/2026 financial year. This edition highlights key medicine safety concerns drawn from multiple sources, including local safety reports submitted to the National Drug Authority and international safety updates from vigilant regulatory partner agencies.
While medicines save lives, ensuring their safe use remains paramount. The international safety updates featured in this bulletin draw attention to clinically significant safety issues, reaffirm guidance on the use of paracetamol in pregnancy, and warn against unregistered GLP-1 peptide products marketed online. These insights provide important guidance for clinical practice and patient education in our health care setting.
I am encouraged by the continued transformation toward digital reporting, which has significantly improved the timeliness and efficiency of safety surveillance. We appreciate your positive reception and active use of the VigiMobile application rolled out across 18 districts. This initiative has strengthened timely monitoring of adverse events following immunization and fostered a stronger culture of patient safety.
I cannot overemphasize the importance of continued vigilance. Protecting our population from medicine related harm requires sustained commitment to reporting and collaboration. Your contributions to pharmacovigilance have played a vital role in safeguarding public health, and I encourage you to remain actively engaged in this shared mission of saving lives.

Dr. Helen Byomire Ndagije
Director Product Safety

ADR ANALYSIS FOR Q1 FY 2025/26

Total reports 1094

Table 1: Characterization of reactions

Nature of reaction	Number of reports
Not serious	742
Serious	352
Grand Total	**1094**

Fig 1: Characterization of reactions

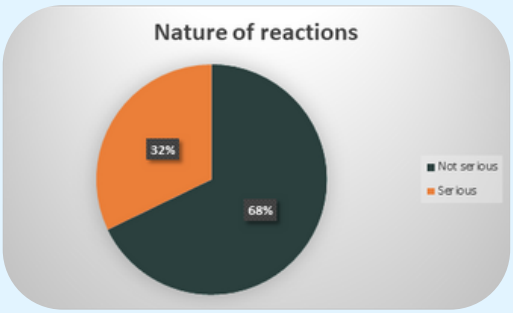


Table 2: Type of Report

Type of report	Number of reports
ADR	691
AEFI	403
Grand Total	**1094**

Fig 2: Type of Report

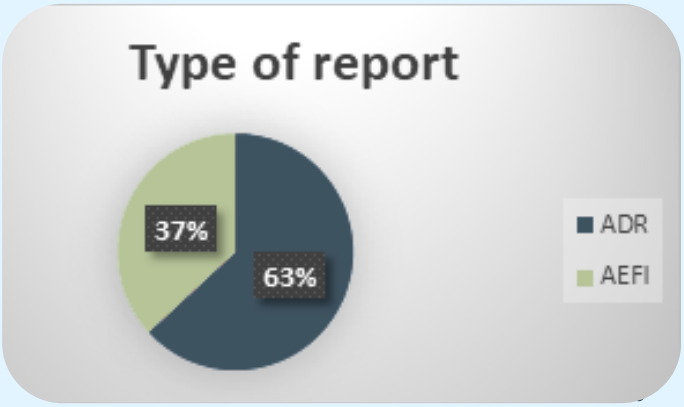


Table 3: Reporting by Gender

Gender	Number of reports
FEMALE	646
MALE	423
UNKNOWN	25
Grand Total	**1094**

Fig3: Reporting by Gender

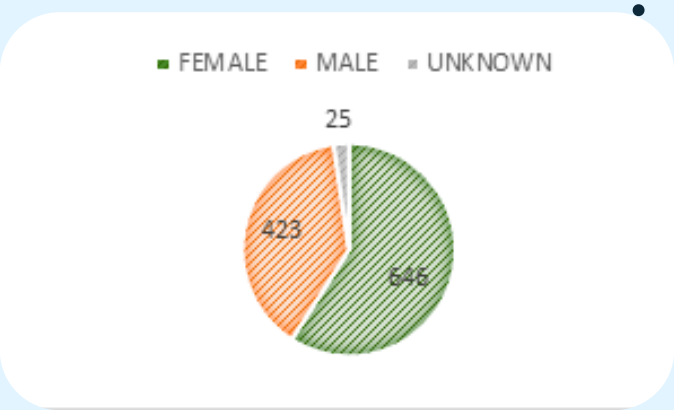


Table 7: Means of reporting

Reporting channel	Number of reports
WhatApp	453
ADR form pysical	229
Mobile App	194
Vigimobile	95
Phone call	56
Vigiflow	47
Email	11
Online	9
Grand Total	**1094**

Fig 7: Means of reporting

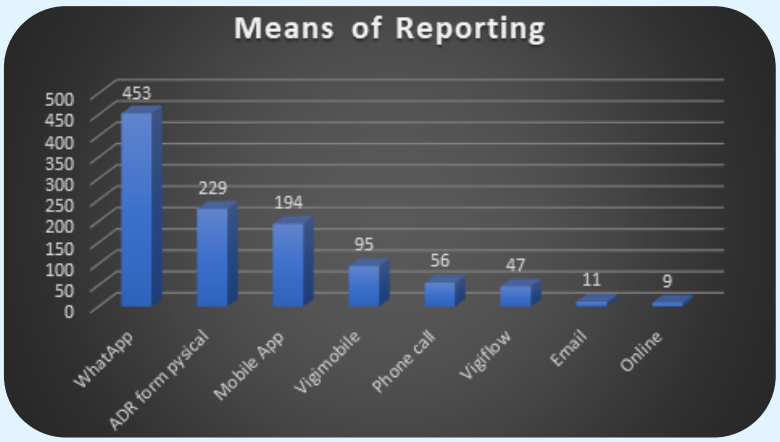


Table 8: Drug reaction pairs

Suspected Drug	Reports	Reported Reactions	Reports
Medroxyprogesterone acetate	25	Bleeding disorder	**24**
		Low libido	**1**
		Backpain	**1**
Bupivacaine	22	Ineffectiveness	**8**
		Unconsciousness	**1**
		Convulsions	**9**
OPV Vaccine	17	Fever	**10**
		Skin rash	**3**
Carbamazepine	17	Reddening and cracking of lips	**7**
		Itching	**7**
		Wounds on lower limbs	

Table 4: Reporting by region

Region	Number of reports
Central	693
South West	138
Eastern	78
West Nile	72
Western	61
Northern	32
South East	20
Grand Total	**1094**

Fig 4: Reporting by region

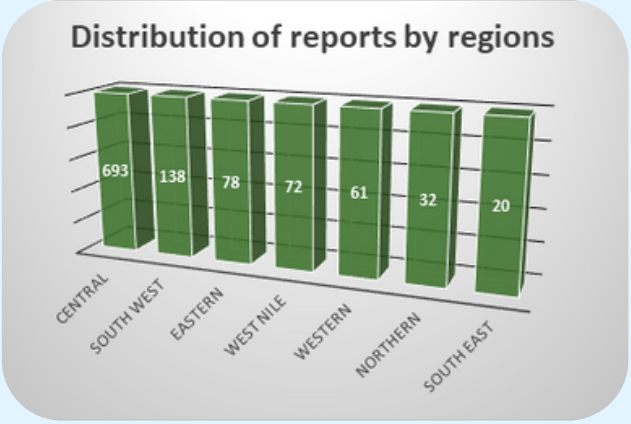


Table 5: Seriousness of reaction

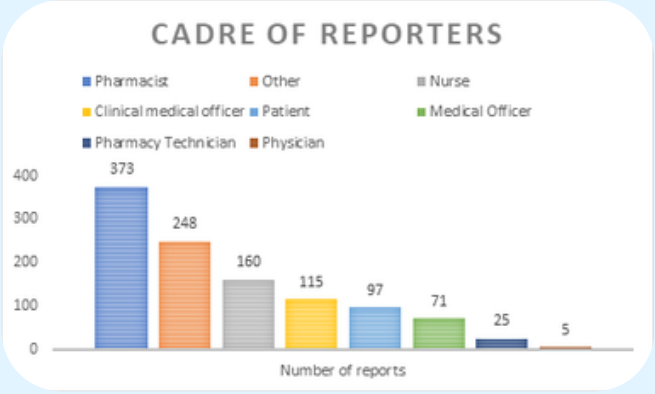
Reaction outcome	Number of reports
Not serious	742
Life Threatening	149
Prolonged	83
Involved	60
Other Medically	42
Patient Died	18
Grand Total	**1094**

Fig 5: Seriousness of reaction

Table 6: Cadre of reporter

Cadre	Number of
Pharmacist	373
Other	248
Nurse	160
Clinical medical officer	115
Patient	97
Medical Officer	71
Pharmacy	25
Physician	5
Grand Total	**1094**

Fig 6: Cadre of reporter



ADR ANALYSIS FOR Q1 FY 2025/26

Table 8: Drug reaction pairs continued ...

Suspected Drug	Reports	Reported Reactions	Reports
COVID 19 VACCINE	80	General Body weakness	30
		Dizziness	2
		Headache	16
		Fever	19
Dolutegravir	75	Hyperglycemia	8
		Erectile Dysfunction	6
		Dizziness	7
		Skin Reaction	10
		Forgetfulness	2
Ebola Vaccine	63	Injection site pain	24
		Fever	10
		Headache	26
		Dizziness	3
TDF/3TC/DTG	49	Neuropathy	7
		Joint pain	4
		Renal injury	5
Malaria Vaccine	47	Fever	37
		Diarrhea	3
		Convulsions	7

ADR ANALYSIS FOR Q1 FY 2025/26

Table 8: Drug reaction pairs continued ...

Suspected Drug	Reports	Reported Reactions	Reports
Measles Rubella vaccine	40	Fever	19
		Skin Rash	18
Tenofovir	39	Bone pain	9
		Nephrotoxicity	10
Nifedipine	37	Headache	25
		Palpitations	3
Etonogestrel	30	Bleeding disorders	27
		Weight gain	2
		LAP	1
RHZE	27	Joint pain	12
		Skin Itching	6
		Skin Itching	5
Levonorgestrel	27	Skin Itching	25
		Skin Itching	2
		Skin Itching	1
		Skin Itching	1

LOCAL SAFETY UPDATES

Cases of Respiratory distress, cardiac arrest, and death after taking paracetamol.

The National Pharmacovigilance Centre received 3 case reports involving patients who ingested paracetamol. Of these, 1 patient developed respiratory distress and 2 patients suffered cardiac arrest that resulted to death.

Case narratives:

Case 1:

O.T. walked into a drug shop and bought paracetamol tablets to manage a headache. On day 2 of taking the medicine, he developed itchy hives all over his body. These got worse as the day went by. He reported to the hospital OPD, the medicine was immediately withdrawn, and he was admitted and he started to develop respiratory distress. The event was managed and he was discharged the following day in the evening.

Case 2:

4-year-old being managed for septicemia and severe anemia. Was transfused with packed red blood cells and the infusion was halted to administer IV ceftriaxone and hydrocortisone. Subsequently IV paracetamol bolus infusion was administered and in about 5 minutes later, he complained of generalized body pains, convulsed, and vomited, then experienced a sudden cardiac arrest. Efforts to resuscitation were unsuccessful. This case continues to be investigated.

Case 3:

A 15-month-old was being treated for septic shock and anemia and developed high fevers of 39°c. Immediately the health care professionals administered IV paracetamol 100mg (10kg) to manage the fever. However, the baby got worsening vitals in a very short time and got cardiac arrest and died 10 minutes after IV paracetamol administration. This case is still under investigation

Discussion

Paracetamol has mild analgesic and antipyretic properties hence recommended for the treatment of most painful and febrile conditions, for example, headache including migraine, toothache, neuralgia, colds and influenza, sore throat, backache, rheumatic pain and dysmenorrhea.

According to the data gathered, OT had no recorded underlying health issues and did not use paracetamol for more than two days. The WHO global database has reported a total of 236 cases of respiratory distress associated with paracetamol and now Uganda has registered 1 case. According to the manufacturer's information respiratory distress is not a labelled adverse effect of paracetamol. Respiratory distress or difficulty in breathing can occur as a compensatory response to severe acidemia linked to high anion gap metabolic acidosis. Instances of high anion gap metabolic acidosis (HAGMA) caused by pyroglutamic acidosis have been documented in individuals experiencing severe illness, such as significant renal failure and sepsis, or in those suffering from malnutrition or other causes of glutathione deficiency (like chronic alcoholism) who received therapeutic doses of paracetamol for an extended period or in conjunction with flucloxacillin. If there is a suspicion of HAGMA due to pyroglutamic acidosis, it is advisable to immediately discontinue paracetamol and monitor the patient closely.

We note that there were 2 reported fatal cases related to cardiac arrest following the use of Paracetamol. However, according to the manufacturer's information cardiac arrest is not listed as an expected reaction of paracetamol. There was no sufficient data in the reports to support the association between the event and the drug like a postmortem report. We have observed 1000 similar cases in the WHO global database and only 2 are from Uganda. The manufacturer states that paracetamol does not cause cardiovascular issues unless patients exhibit certain levels of liver dysfunction that occur during paracetamol over dose. In these cases, the two deceased individuals had normal liver function test results thus eliminating the possibility of hepatotoxicity as the cause.

Recommendation

Conducting a thorough patient evaluation prior to starting paracetamol is essential to prevent adverse drug events. Following this, it is crucial to maintain close observation during the drug's administration in order to address adverse drug events and notify the NDA of any drug events that may arise from paracetamol use.

Seizures resulting from the use of Tenofovir disoproxil fumarate/Lamivudine/Dolutegravir (TDF/3TC/DTG)

TDF/3TC/DTG has been established as a first-line anti-retroviral therapy in Uganda since the introduction of dolutegravir in 2018. This was due to dolutegravir's effectiveness, ease to take and having a high genetic barrier to developing resistance. However, the National Drug Authority has received two cases of individuals experiencing seizures after using TDF/3TC/DTG, with a total of four cases reported worldwide to the WHO global database.

Case narratives

Case 1:

Client was initiated on ART in 2017 and transitioned to TLD in 12/11/2019 and later developed fits and diagnosed with epilepsy on 2/5/2020 and started on sodium valproate. In November was given carbamazepine + Valproate and fluoxetine and in March 2023 presented with lower limb weakness

Case 2:

65-year-old female HIV positive complains of insomnia, seizures, tingling and feeling of pins and needles in feet, yellow urine, skin, hearing loss and dizziness while on the regimen above.

Discussion

According to Johns Hopkins Medicine a seizure is a burst of uncontrolled electrical activity between brain cells that causes temporary abnormalities in muscle tone or movements, behaviours, sensations or states of awareness. Seizures can be caused by trauma, stroke, meningitis, and drugs such as antidepressants, stimulants, and antihistamines.

As per the reports received, the two patients did not have any documented history of trauma, stroke, meningitis, or any drug use that have contributed to the generation of seizures.

According to the manufacturer, TDF/3TC/DTG is not associated with causing seizures unless when co-administered with fampridine. This is because DTG has the potential to inhibit the OCT2 transporter thus increasing the plasma levels of fampridine. However, limited studies have been conducted regarding this hence it is currently contraindicated to co-administer these two drugs.

Recommendation

The continued reporting of such events to the National Pharmacovigilance center provides supporting data which can be used to identify a safety signal in line to the cases. Therefore, all healthcare workers are advised to be vigilant and report any existing cases of seizures being associated to TDF/3Tc/DTG.

Spontaneous abortion associated with cabotegravir

On August 15th, 2025, Cabotegravir was administered to a client who arrived in good condition but indicated that side effects began two days after receiving the treatment. She was not on any other medications, consuming no alcohol, and did not smoke. She experienced nausea, diarrhea, fatigue, fever, headaches, and a reaction at the injection site, which included pain and a severe body rash, along with a dry cough and sore throat, accompanied by intense itching and vomiting. At that time, she was suffering from severe abdominal pain that started on the fifth day and subsequently experienced per vaginal bleeding, ultimately reporting a spontaneous abortion.

Cabotegravir at a dose of 600mg is administered intramuscularly for HIV pre-exposure prophylaxis. Despite its high efficacy, cabotegravir causes adverse events which include nausea, diarrhea, fatigue, fever, headache, injection site reactions like pain, itching, vomiting, abdominal pain, and rash according to the manufacturer's information. The unexpected reactions that this client experienced included; dry cough, sore throat, vaginal bleeding, and spontaneous bleeding.

The manufacturer reiterates that there is limited amount of data from the use of cabotegravir in pregnant women and thus its effect is unknown. Therefore, it is not recommended during pregnancy unless the benefit justifies the potential risk of the fetus.

Recommendation

The manufacturer recommends that healthcare professionals provide guidance and counselling to patients prior to starting cabotegravir and to report any adverse drug reactions that occur while using the medication.

SAFETY REPORTS FROM OTHER COUNTRIES

WARFARIN AND TRAMADOL – HARMFUL DRUG-DRUG INTERACTION

South Africa: The South African Health Products Regulatory Authority warns of a harmful drug-drug interaction between warfarin and tramadol. The concomitant use of these medicines may result in an elevated International Normalized Ratio (INR), leading to severe bleeding, ecchymosis, and, in rare instances, death. The mechanism is not fully understood, but cases typically occur 3–4 days after tramadol initiation in patients Stabilized on warfarin.

Healthcare professionals should:

- Closely monitor INR when initiating or discontinuing tramadol in patients on warfarin.
- Adjust doses or provide additional monitoring if INR elevations occur.
- Educate patients to report signs of bleeding (e.g., bruising, blood in urine or stool, prolonged bleeding, dizziness, or severe headache).
- Advise patients not to start or stop medicines without consultation.

Patients should be informed of the potential interaction and the importance of urgent medical review if bleeding symptoms occur.

Reference: SAHPRA Safety Information Updates/Pharmacovigilance via **www.sahpra.org.za**.

PARACETAMOL AND PREGNANCY – SAFETY REAFFIRMED

United Kingdom: The UK Medicines and Healthcare products Regulatory Agency (MHRA) reaffirms that paracetamol remains the first-line option for pain and fever Management in pregnancy. Recent reports suggesting a link between prenatal paracetamol exposure and autism or ADHD in children are unsupported by substantial evidence. Large-scale registry studies, including one involving 2.4 million births in Sweden found no causal relationship.

Healthcare professionals should:

- Reassure pregnant women that paracetamol remains safe when used at the lowest effective dose for the shortest duration.
- Discourage substitution with NSAIDs (e.g., ibuprofen), which carry fetal risks.
- Emphasize that untreated pain or fever may pose risks to the unborn child.

Patients should continue to follow NHS guidance and seek advice from their healthcare provider regarding any medication during pregnancy.

Reference: MHRA Drug Safety Update Volume 18, Issue 9, April 2025 **www.gov.uk**

UNREGISTERED GLP-1 PEPTIDE WEIGHT-LOSS PRODUCTS

Australia: The Therapeutic Goods Administration (TGA) of Australia has issued a warning about unregistered products marketed online as 'GLP-1 peptides' or 'GLP-1 oral drops' for weight loss. These products are not approved by the TGA or any recognized regulatory authority and may contain undeclared or harmful substances.

Key risks:

- Products may be counterfeit, falsely labeled, or promoted using fake endorsements.
- Potential for serious adverse health effects, including toxicity or allergic reactions.
- Purchasing from unverified online sources poses both safety and financial risks.

Healthcare professionals should educate patients about the dangers of unregistered products and report any adverse events involving these products. Consumers are urged to use GLP-1 receptor agonists (e.g., semaglutide, liraglutide, tirzepatide) only when prescribed by qualified professionals.

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

SAFETY LABEL VARIATIONS: APRIL TO JUNE 2025

Product Name	License holder	Summary of approved changes	Date of NDA approval
Rituximab (MABTHERA®)	F. Hoffmann La-Roche Ltd Grenzacherstrasse 124. CH-4070 Basel, SWITZERLAND	Update of summary of product characteristics (SmPC) and Patient Information Leaflet to include; 1. Addition of serious viral infections in section 2.6 (Warning and precautions) 2. New lactation related text under undesirable effects for autoimmune indications	15th July 2025
Loratadine + Pseudoephedrine (CLARINASE®)	Bayer Pharma Ag 51368 Leverkusen, GERMANY	Update of the Summary of product of characteristics (SmPC) involving the following; 1. Include "renal tubular acidosis" under subsection for patients with renal or hepatic impairement in sections 4.2 and 4.4. 2. To delete the statement "Antiacids increase pseudoephedrine sulphate absorption, kaolin decreases it" from section 4.5	1st August 2025
Acetylsalicylic acid (BAYER ASPIRIN CARDIO®)	Bayer Pharma Ag 51368 Leverkusen, GERMANY	An update of the SmPC to include the following in the section of pregnancy and lactation; 1. "Narrowing of the ductus arteriosis has been reported after treatment in the second trimester, which resolved in most cases after treatment was discontinued". 2. "Consider prenatal monitoring for stenosis of the ducts arteriosis after taking acetylsalicylic acid from 20 weeks of pregnancy. Discontinue acetylsalicylic acid if stenosis of the ductus arteriosis occurs."	01st August 2025

Product Name	License holder	Summary of approved changes	Date of NDA approval
Carbotegravir (APRETUDE®)	GlaxoSmithKline Pharmaceutical Kenya Ltd. Likoni Road, P.O.BOX 78392-00507, Nairobi, KENYA	Update of product SmPC and PIL involving; 1. Addition of suicide attempt and suicidal ideation as new ADRs 2. Update of hypersensitivity ADR	14th August 2025
RIFAMPICIN + ISONIAZID DISPERSIBLE TABLETS	Lupin Limited A-28/1 MIDC Chikalthana Aurangabad INDIA	Update of the SmPC involving addition of the following statement "The tablets should be dispersed in drinking water before administration of the dose. Each tablet should be dispersed in a minimum of 10ml water, the maximum volume of water recommended for dispersion of a dose is 50ml.	01st September 2025
Glutodine (cyproheptadine alpha-ketoglutarare) + Arginine aspartate (DYNAMOGEN®)	Faes Farma S.A Avenida Autonomia, 1048940 Leioa (Bizkaia)	Update of PIL and SMPC to include; 1. Structured adverse reactions table using MEDRA classification. 2. New safety warnings (e.g. blood dyscrasias, masking of ototoxicity, pediatric overdose risks). 3. Updated overdose management guidance. 4. Explicit instructions for adverse reaction reporting.	04th September 2025
Salbutamol (VENTOLIN®)	GlaxoSmithKline Trading Services Ltd. 980 Great West Road Brentford, Middlesex TW8 9GS, UNITED KINGDOM	Update of the SmPC "Warnings and Precautions" section of the product prescribing information involving; 1. Addition of warning on Ventolin overuse. 2. A statement on continuing to use regular asthma anti-inflammatory therapy even when symptoms improve.	22nd September 2025

VIGIMOBILE TRAINING OF TRAINEES FOR HEALTHCARE PROFESSIONALS

The VigiMobile app is a vital tool developed by World Health Organisation (WHO) in partnership with the Uppsala Monitoring Centre (UMC) to facilitate timely and efficient reporting of AEFIs. The National Drug Authority in partnership with WHO conducted a VigiMobile training exercise to equip healthcare professionals (HCPs) with skills to use the VigiMobile application for reporting Adverse Drug Events Following Immunization (AEFIs) to the National Pharmacovigilance Center. This activity was carried out in collaboration between NDA and the districts leadership.

The training was held in South-Western Uganda, covering HCPs from Mbarara, Kazo, Sheema, Kiruhura, Ntungamo, Rwampara, Isingiro, Kabale, Bushenyi, Buhweju, Kisoro, Kanungu, Rubirizi, Rukiga, Rukungiri, Rubanda, Mitooma, and Ibanda districts. The training targeted District Surveillance Focal Person (DSFPs), District Drug Inspectors (DDIs), vaccine focal persons, and other health care workers deemed necessary due to the health service delivery integration policy instituted by Ministry of Health, and were nominated by the district leadership from healthcare facilities within their respective districts.

The training aimed to strengthen routine pharmacovigilance activities and ultimately enhance patient safety in Uganda.

Objectives of the Activity:

- Train Heath Care Professionals on the use of the VigiMobile application for reporting AEFIs and other drug-related problems.
- Promote real-time reporting of AEFIs to enhance pharmacovigilance surveillance.
- Address challenges faced by Health Care Professionals in adopting digital reporting tools.
- Establish district focal persons to champion VigiMobile adoption and reporting.
- To strengthen the collaboration of the district leadership and reporters, managing, and investigating AEFIs.

Achievements:

- Trained 938 Health Care Professionals from eighteen districts on the use of the VigiMobile application.
- Over 1876 QR code stickers for the VigiMobile app were distributed to the participants to pin on their various health facilities and to be used during the training of their colleagues.
- Supported the documentation of 05 previously unreported ADR cases through the VigiMobile app during the training.
- Established VigiMobile focal persons for each of the eighteen districts to champion digital reporting.

Key Findings:

- Limited smartphone access among some Health Care Professionals hindered the adoption of the VigiMobile app.
- Inconsistent internet connectivity in rural areas posed challenges to real-time reporting.
- Some Health Care Professionals lacked basic digital literacy, requiring additional support during training.
- Some Health Care Professionals preferred paper-based reporting due to familiarity and perceived reliability.
- Low awareness of the VigiMobile app's features, such as offline reporting capabilities, was noted.

Conclusion:

The VigiMobile training demonstrated that digital tools can significantly improve adverse event following Immunization (AEFI) reporting and strengthen pharmacovigilance systems. However, challenges such as limited digital literacy among healthcare professionals, unreliable internet connectivity in rural areas, and brief training durations hindered full implementation. Providing incentives helped maintain motivation and engagement among participants, contributing to the training's success. To sustain the use of VigiMobile, continuous capacity building, improved internet infrastructure, and regular feedback to healthcare professionals are essential. Establishing district focal persons would further support local pharmacovigilance activities over the long term. Additionally, the National Drug Authority should create VigiFlow accounts for these district focal persons to facilitate follow-up and monitoring of reporting performance within their respective areas.

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Safe Drugs Save Lives

Report Adverse Drug Reactions to NDA using the following platforms

E-mail

druginfo@nda.or.ug

WhatsApp

0740 002 070

Toll free

0800 101 999

OUR OFFICES

Head office
P.O Box 23096, Kampala – Uganda
Plot 93, Buganda Road , after St. Catherine Hospital
Tel:Reception : +256 [0]417 788 100

Kampala Extra office
Akamwesi Mall
Kyebando, Gayaza Road
Kampala
Tel : 0393 261548

Western Region Office Hoima
Muganwa Center
Plot 30 Old Tooro Road
P.O Box 192 Hoima
Tel/Fax : 0393255257

North Eastern Region Office Soroti
Plot 5C and 5D, Hepper Road
Senior Quarters Soroti
0414662030

South Western Region Office- Mbarara
Plot 26, Johnstone Road, Boma (After Boma Primary School).
P.O Box 1886 Mbarara, Uganda
Tel : 0414 671034

Northern Region Office
Lira Ato Sebbi Road, Junior Quarters
P.O Box 2 Lira
Tel/Fax : 0414 671032

South Eastern Regional Office
Plot No. 64 Gokhale Road
West Jinja
P.O Box 1710 Jinja
0434122176

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Masaka Town
Tel : 0414-672734
P.O Box 23096, Kampala

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West Nile Region Office- Arua
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