



Safe Drugs Save Lives

NATIONAL PHARMACOVIGILANCE CENTRE PHARMACOVIGILANCE

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Bulletin

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NOTE FROM THE

Secretary to the Authority

The mission of the National Drug Authority (NDA) is to protect and promote human and animal health through the effective regulation of drugs and healthcare products. The National Pharmacovigilance Centre through its pharmacovigilance function is mandated to ensure that the final consumer of the medicine is safe and that the medicines are efficacious as indicated in their labels with less or no undesirable effects to the patient.

With every passing year, NDA continues to invest in more efficient ways to improve visibility and create awareness of the Pharmacovigilance Centre and its activities like signing of memoranda of understanding with several regional pharmacovigilance centers and power centers,

annual stakeholder's feedback meetings to interact with and take propositions from them on how we can improve on the monitoring of the safety of drugs. With these investments in place, we have seen a 23.4% increment in the number of reports received at the National Pharmacovigilance Centre at the NDA this concluding financial year.

We are also making strides to automate the pharmacovigilance pathway and have the reporting even more efficient. I continue to appreciate all our stakeholders and their unwavering efforts in making sure that we have safe drugs in Uganda. I therefore welcome you all to this edition of the bulletin.

Dr. David Nahamya
Secretary to the Authority

One Health



National Drug Authority is mandated to protect and promote human and animal health through the effective regulation of drugs and healthcare products.



Humans are linked to the environment



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Foreword

The reporting trends on pharmacovigilance in preceding quarters continued to increase, predominantly from public health programs of TB and HIV care. Analysis of the safety data this quarter revealed some patterns that were suggestive of potential relationship between some drugs and particular events which are discussed in this issue. With the extension of Dolutegravir therapy to children below 1 year, we noted some patterns of constipation. There was also an emergence of cases of memory loss suspected to be caused by cycloserine among MDR-TB patients.

Emerging from the Covid-19 pandemic and lifting of the social distancing mandates allowed us, after 2 years to physically engage with various

parties in pharmacovigilance at the 5th annual pharmacovigilance stakeholders meeting that was held on the 4th of May. This was a key highlight of the fourth quarter.

In Q4, we received a total of 361 Individual Case Safety Reports with Tenofovir/Lamivudine/Dolutegravir (TDF/3TC/DTG) topping the list of reported drugs at 148, followed by Dolutegravir at 88 and isoniazid at 28 reports. Hyperglycemia, arthralgia and headache at 15.2%, 6.6% and 6.4% respectively. Half of the reports were serious at 51.1 and 49.9% unserious ones respectively.

Dr. Helen Byomire Ndagije

Head of the National Pharmacovigilance Centre





Local safety trends;

Constipation with Dolutegravir among infants with HIV

Case: A caretaker reported constipation, reduced appetite, mood changes associated with sudden waking when asleep during day and night of a female 21 months old child.

The consolidated guidelines of 2020 for prevention and treatment of HIV in Uganda recommend that all HIV-infected children weighing less than 20kg can be initiated on Abacavir + Lamivudine + Dolutegravir (ABC + 3TC + DTG) when appropriate DTG formulations and strengths (5mg, 10mg and 25mg) are available. (1) In the database, there are 27 cases of constipation documented in Uganda and only 10 suspected to have been caused by Dolutegravir. Among these, 1 case was between 28 days to 23 months, 3 cases of age between 18 – 44 years and 45 – 64 years. Globally there are 43 cases of Dolutegravir suspected to cause constipation.

Constipation is not a labelled reaction of Dolutegravir, neither among the adults nor in the paediatric population. The summary product characteristic of dolutegravir states that the efficacy and safety of dolutegravir in children aged less than 4 weeks is unknown. The mechanism by which dolutegravir causes constipation is unclear. The SmPc of both abacavir and lamivudine don't list constipation as one of the expected effects.

Generally, the causes of constipation vary and may be multifactorial. It can be grouped into primary and secondary causes where primary causes are intrinsic problems of colonic or anorectal function, while secondary causes are related to diseases or medication.(2,3)

Most common drug that cause constipation include; antiepileptic, antipsychotics, antidepressants especially tricyclic antidepressants, oral iron supplementation and antihypertensive, a detailed drug history should be taken during the history taking.

Management of constipation is laid down in the Uganda Clinical Guidelines of 2016 page 403 as follows;

Management

TREATMENT	LOC
No alarm features or chronic constipation <ul style="list-style-type: none">High dietary fibreAdequate fluid intakeBisacodyl: Adults 10mg at night. Take until stool is passed Child 5-12 years: 5mg (suppository only) Contraindicated in acute abdomen as it aggravates the condition	HC2
<ul style="list-style-type: none">Oral or rectal lactulose (osmotic agent). Provides faster relief than bisacodyl	Hc3
If alarm features or severe chronic constipation are present <ul style="list-style-type: none">Refer to hospital for specialist management	Hospital

These are initial reports that could be suggestive of an emerging signal. We request that health care providers handling children on HIV treatment look out for it and report this reaction to the National Pharmacovigilance center.

1. Ministry of Health-Uganda. Consolidated Guidelines for the Prevention and Treatment of HIV and AIDS in Uganda. Minist Heal Uganda [Internet]. 2020 [cited 2022 Jun 28];(February):142–70. Available from: [https://uac.go.ug/sites/default/files/Consolidated HIV Guidelines 2020.pdf](https://uac.go.ug/sites/default/files/Consolidated%20HIV%20Guidelines%202020.pdf)
2. Andrews CN, Storr M. The pathophysiology of chronic constipation [Internet]. Vol. 25, Canadian Journal of Gastroenterology. 2011 [cited 2022 Jul 4]. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3206564/>
3. Andrews CN, Storr M. The pathophysiology of chronic constipation [Internet]. Vol. 25, Canadian Journal of Gastroenterology. Hindawi Limited; 2011 [cited 2022 Jul 4]. p. 16B. Available from: [/pmc/articles/PMC3206564/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3206564/)

CYCLOSERINE AND NEUROLOGICAL ADRs

Authored by Ian Mugisa

Cycloserine, derived from *Streptomyces orchidaceus* or *Streptomyces garyphalus*, is a synthetic analog of the amino acid d-alanine that interferes with bacterial cell wall synthesis through competitive inhibition of d-alanine components to be incorporated into the cell wall. It is bacteriostatic, and the mechanism of resistance is unknown.

Cycloserine is used to treat mycobacterium tuberculosis and mycobacterium bovis. In Uganda, it is commonly used to treat Multidrug Resistant Tuberculosis (MDR TB) and Extensively Drug Resistant Tuberculosis (XDR TB).

The major adverse effect is neurotoxicity with significant psychologic disturbance, including seizures, acute psychosis, headache, confusion, depression, and personality changes and memory loss. A review of the reported data showed arthralgia, neuropathy peripheral and psychotic disorder as the highest reported reactions to cycloserine in the global database.



It is noted that the 2020 Uganda Clinical Guidelines list Cycloserine as a specialist medication in a formulation of 250mg capsule. It is recommended for treatment of males and non-pregnant females with drug resistant TB.

Although this event is labelled, we continue to receive an increasing number of cases which could be indicative of increased occurrence beyond what was observed during pre-authorization studies. We encourage health workers to take note of this as they manage patients. Patients with underlying risk of psychotic disease should be given therapy with precautionary measures

Updates to the Mirena Summary of Product Characteristics: Information for Health Care Providers

The manufacturer of the Mirena IUD has made the following updates to the Summary of Product Characteristics following post market safety results.

Revisions to section 4.2:

Posology and method of administration:

Previously, the leaflet read that Mirena is inserted into the uterine cavity and is effective for five years. This has now been revised to read as follows: Mirena is inserted into the uterine cavity, and it is effective for 6 years in the indication of contraception and 5 years in the indications of idiopathic menorrhagia, hypermenorrhea, dysmenorrhea, and local progestogen treatment during oestrogen replacement therapy.

Mirena as a contraceptive:

The previous instruction was to remove the device after five years. This has now been revised to indicate that the system should be removed after 6 years in the indication of contraception and after 5 years in the other indications.

Revisions to Section 4.6: Fertility, pregnancy and lactation:

Additional emphasis on removal of the system as soon as possible in case of pregnancy due to the increased risk of abortion and preterm labour.

Previously, there was limited data on effects on pregnancy. The leaflet has now been revised to indicate that an increased risk of virilizing effects

in a female fetus because of the intrauterine exposure to levonorgestrel cannot be excluded. There have been isolated cases of masculinization of the external genitalia of the female fetus following local exposure to levonorgestrel during pregnancy with a hormonal IUS in place

Revisions to Section 4.8: Undesirable effects:

Dizziness has been included as an additional common undesirable effect of the system.

The previous leaflet indicated that periods become shorter after insertion, and after three months of use only 3% of users experience prolonged bleeding. It also stated that in clinical trials during the first year of use, 17% of women experienced amenorrhea for a period of at least three months.

This has been updated with post market use data showing that by the end of Year 6 of Mirena use, prolonged bleeding and irregular bleeding are experienced by 2% and 15% of Mirena users, respectively; amenorrhea occurs in 24%, and infrequent bleeding in 31% of Mirena users.

Summary of additional label changes of different products

Product Name	Licence Holder	Summary of Approved Changes	NDA Date of Approval
Galvus Met	Norvatis	Section 7 updated with the post marketing adverse drug reaction of cutaneous vasculitis with a frequency of “unknown”.	8 th June 2022
5-Fluorouracil	Sandoz GMBH Kenya	Contraindications	25 th May 2022
		Special warnings and precautions for use	
		Fertility, pregnancy and lactation	
		Undesirable side effects.	
Dapiring	International Partnership for Microbicides	Change of Patient Information Leaflet according to EMA recommendations to include Clinical Study Report Version 2.0.	1 st June 2022
Glucophage	Merck Pty Ltd	Expansion of indication to prevent Type 2 Diabetes Mellitus in patients with prediabetes and at least one additional risk factor – second line to lifestyle changes.	26 th April 2022
		Lifting of contraindication in heart failure.	
		Lifting of contraindication in moderate renal failure.	
		Lifting of contraindication on contraindication for concomitant use with iodinated contrast materials.	
		Initiation of treatment in patients with CKD stage 3b (previously not recommended).	
		Reinforcement of warnings and widening of contraindication from “diabetic ketoacidosis” to “ any type of metabolic acidosis ” (such as fatty acidosis, diabetic ketoacidosis).	
		New details on interaction between Metformin and Organic Cation ½ Transporter substrates/inhibitors.	
Implanon NXT	MSD (Pty) Ltd	Label update to reflect PRAC mandated change regarding “suicidality”.	27 th May 2022
		New images and instructions for insertion and removal of the implant.	
		Alignment of PIL and SmPC regarding patient age.	
Levoplant	Pharm Access Africa Ltd	PIL and SmPC updated to replace an incorrectly listed common undesirable effect from “a viral infection called chikungunya” to “viral infection” and include contact information for ADR reporting.	15 th June 2022

Product Name	Licence Holder	Summary of Approved Changes	NDA Date of Approval
Mirena	Bayer East Africa Ltd	Dosage and method of administration	10 th June 2022
		Warnings/precautions	
		Fertility, pregnancy and lactation	
		Undesirable effects	
		Pharmacodynamic properties	
		Pharmacokinetic properties	
Triclofem	Mission Pharma A/S	Alignment of SmPC with WHO PAR	28 th April 2022
Xarelto	Bayer East Africa Ltd	Dosage and method of administration	14 th June 2022
		Special warnings and precautions for use	
		Undesirable effects	
		Overdose	
		Pharmacokinetic properties	
		Shelf life	
		Special precautions for disposal	

INCREASING VISIBILITY AND CREATING AWARENESS OF PHARMACOVIGILANCE

It is one of the strategic areas of pharmacovigilance to establish systems to increase visibility and enhance awareness of pharmacovigilance. This we achieve through regular support supervision visits to health facilities all over the country. This quarter we have visited the following facilities that include public health facilities, private drug outlets and private medical centers;

SERERE

NO.	HEALTH FACILITY
1.	Serere HC IV
2.	Apapai HC IV
3.	Obuliren HC III

PALLISA

NO.	HEALTH FACILITY
1.	Kibale HC III
2.	Kamuge HC III
3.	Gogonyo HC III
4.	Apopeng HC III
5.	Buseta HC III
6.	Agule Community Health Center
7.	Agule HC III

BUTEBO

NO.	HEALTH FACILITY
1.	Kabwangasi HC III
2.	Kolony HC IV

BUDAKA

NO.	HEALTH FACILITY
1.	Mugiti HC III
2.	Naboa HC III
3.	Budaka HC IV
4.	Kadama HC III

BUTALEJA

NO.	HEALTH FACILITY
1.	Busolwe Hospital
2.	Butaleja HC III

ISINGIRO

NO.	HEALTH FACILITY
1.	Ngarama HC III
2.	Kasana HC III
3.	Nyarubungo HC III
4.	Kikokwa HC III
5.	Kikagata HC III
6.	Nshungyezi HC III

NO.	HEALTH FACILITY
7.	Mabona HC III
8.	Kabuyanda HC IV
9.	Kanywamaizi HC III
10.	Ruhira HC III
11.	Nyakitunda HC III
12.	Kakona HC III
13.	Kyabinkwa HC III
14.	Kashumba HC III
15.	Juru HC II
16.	Rubondo HC II MTI facility
17.	Nbaare HC II
18.	Endiizi HC III
19.	Rushasha HC III
20.	Rugaaga HC IV
21.	Nyamuyanja HC IV
22.	Kyerumba HC III
23.	Nakivale HC III MTI facility
24.	Kibongo HC III MTI facility
25.	Rwekubo HC IV
26.	Ruborogota HC III

KIBAALE

NO.	HEALTH FACILITY
1.	Kibaale District Health Offices
2.	Nyamaarwa Health Centre III
3.	EMS Health Clinic
4.	St. Denis Nsonga Health Centre
5.	Buseesa Medical Centre
6.	Mataale Health Centre III
7.	Mugarama Health Centre III
8.	Allustin Health Centre III (NGO)
9.	Kabasekende Health Centre III
10.	Kyebando Health Centre IV
11.	Maisuka Health Centre III
12.	Bubango Health Centre II
13.	Dope Pharmacy
14.	St. Luke Bujuni Health Centre
15.	EMESCO Health Centre III
16.	God's Way Pharmacy
17.	Kibaale Health Centre IV
18.	Star Lite Hotel – Kibaale District

KAGADI

NO.	HEALTH FACILITY
1.	Mabaale Health Centre III
2.	Tumuramy Pharmacy
3.	SA&EM Pharmacy
4.	Marfrey's First Pharmacy – Kagadi Branch
5.	Azeem Pharmacy
6.	Marfrey's First Pharmacy – Mabaale Branch
7.	Tuskam Pharmacy Muhooro
8.	Rugashali Health Centre III
9.	St. Padre Pio Kinyarugonjo Health Centre III
10.	Isunga Health Centre III
11.	Mpeefu Health Centre III
12.	Kyaterokera Health Centre III
13.	Bwikara Health Centre III
14.	Marfrey's First Pharmacy – Muhooro Branch
15.	Nyunyuzi Pharmacy
16.	Muhorro NGO Health Centre III
17.	Kagadi General Hospital
18.	Discount Pharmacy
19.	Pramukh Pharmacy
20.	Kiryanga Health Centre III
21.	St. Ambrose Charity Health Centre
22.	Kagadi District Town Hall

BUGIRI

NO.	HEALTH FACILITY
1.	Bugiri Hospital
2.	Nankoma HC 4
3.	Kayango HC 3
4.	Mayuge HC 3
5.	Bulesa HC 3
6.	Buluguyi HC 3
7.	Muterere HC 3
8.	Iwemba HC 3
9.	Nabukalu HC 3
10.	BMC HC 3
11.	Humnet Pharmacy
12.	Rhode Pharmacy
13.	Fastline Pharmacy
14.	Amir Pharmacy
15.	Muvas Pharmacy

NAMUTUMBA

NO.	HEALTH FACILITY
1.	Nsinze HC 4
2.	Bukonte HC 3
3.	Namutumba HC 3
4.	Bulange HC 3
5.	Magada HC 3
6.	Kasambiika HC 3
7.	Ivukula HC 3
8.	Nabisoigi HC 3
9.	Neha Pharmacy
10.	Qaswa Pharmacy
11.	Mbwali Pharmacy
12.	Abacus Pharma Ltd

BUGWERI

NO.	HEALTH FACILITY
1.	Busesa HC 4
2.	Lubira HC 3
3.	Ibulanku HC 3
4.	Busembatya HC 3
5.	Busowobi HC 3
6.	Makuutu HC 3
7.	Igombe HC 3
8.	Khalid Pharmacy
9.	Kisoboka Pharmacy
10.	Alim Pharmacy

IGANGA

NO.	HEALTH FACILITY
1.	Nawandala HC 3
2.	Nambale HC 3
3.	Namungalwe HC 3

Private pharmacies, drug shops and Medical centres and clinics

SERERE

NO.	Pharmacy and other drug outlets
1.	Alaso Pharmacy
2.	Dawa Pharmacy
3.	Life Again pharmacy
4.	Abilaep Clinic
5.	Bethel Clinic and drug shop
6.	Destiny drug shop
7.	God's Grace drug shop
8.	Salvation drug shop
9.	Devine Grace drug shop
10.	Life care drug shop

PALLISA

NO.	Pharmacy and other drug outlets
1.	Vital Drug shop
2.	Joan's pharmacy
3.	Healers drug shop
4.	Life line drug shop
5.	Asiya drug shop
6.	Bliss pharmacy
7.	R and T pharmacy

BUDAKA

NO.	Pharmacy and other drug outlets
1.	Budaka elite pharmacy
2.	Two sons drug shop
3.	Spartan pharmacy
4.	Welcome pharmacy
5.	Hudson pharmacy
6.	Baraka pharmacy
7.	Sarrob drug shop

BUTALEJA

NO.	Pharmacy and other drug outlets
1.	Namude drug shop
2.	Erica hope for life drug shop
3.	Bugosa drug shop
4.	Agape drug shop
5.	Kwagala pharmacy
6.	Healthcare drug shop

The pharmacovigilance annual stakeholder's feedback meeting

The National Pharmacovigilance Center annually organizes a feedback meeting for all pharmacovigilance stakeholders and its main purpose is to give a report of safety trends of the year, seek for feedback and propositions on how we can improve on the activities of safety surveillance and monitoring of drugs and maintain safety and to award top ADR reporters and top reporting facilities

This year's feedback meeting was held on the 4th May 2022, at Imperial Royale Hotel Kampala where 111 participants including doctors, regional referral hospital directors, pharmacists, clinical officers, Market Authorization Holder (MAH) representatives, nurses, representatives from national programs, IPs and representatives from patient groups CHAIN, Uganda Alliance of Patients

Organizations (UAPO) and Coalition for Health Promotion and Social Development (HEPS).

Some of the activities on the day were, presentations from a pharmacovigilance senior regulatory officer and then from the Director Product safety, presentations from Dr. Manzi who highlighted the progress and achievements from the recommendation of the previous meeting, presentation from Dr. Eva Laker on a quasi-experimental study on use of toll free system for adverse event exporting by patients and clinicians, finally a speech from the guest of honor Dr. Ayume Charles the Chairperson of the parliamentary committee of health, who highlighted several issues emphasizing the importance of visibility of NDA at the ports of entry all over the country with mini-labs at the ports. A plenary session concluded the meeting





The Secretary to the Authority delivering his opening remarks in the presence of the Director Product Safety



Some of the stakeholders in a group photo with some of the team members of the PV team.

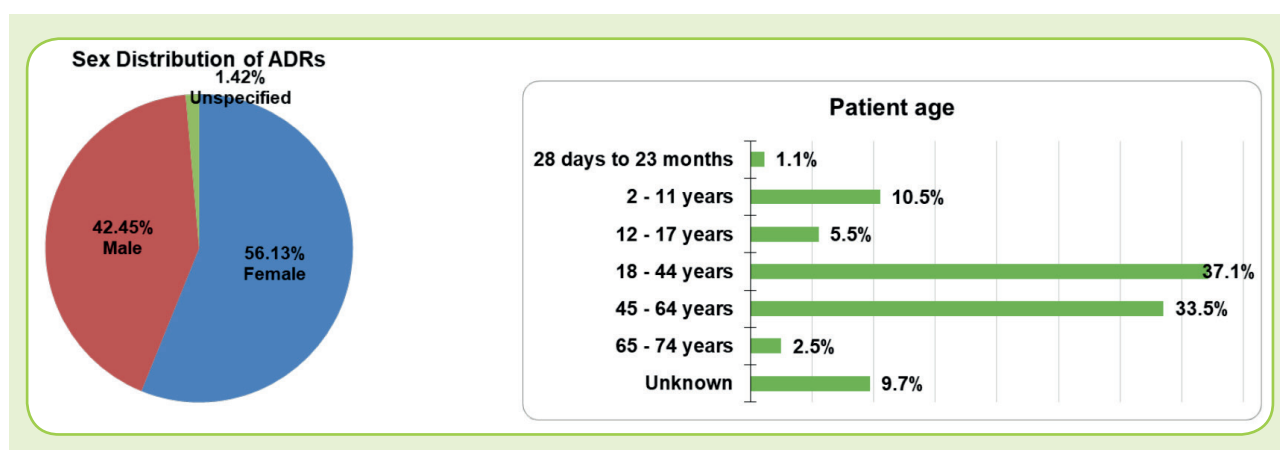
APRIL TO JUNE 2022

ICSR SUMMARY STATISTICS

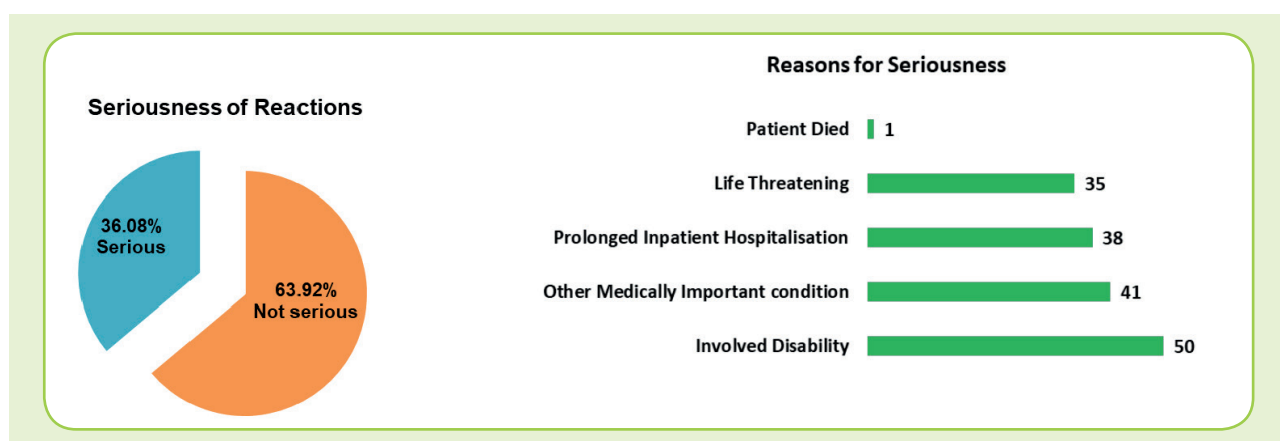
A total of **1496** Individual Case Safety Reports were submitted to the National Pharmacovigilance Centre in the period April to June 2022. Of these, **424** were ADRs, 1069 were AEFIs and 3 were CIOMS reports.

Below is a characterization of the ADR reports received:

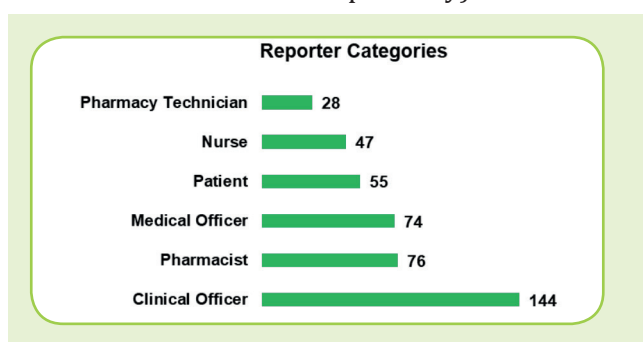
Over half of the reports were from female patients. Report quality has improved greatly and only 1% of the reports had unspecified gender



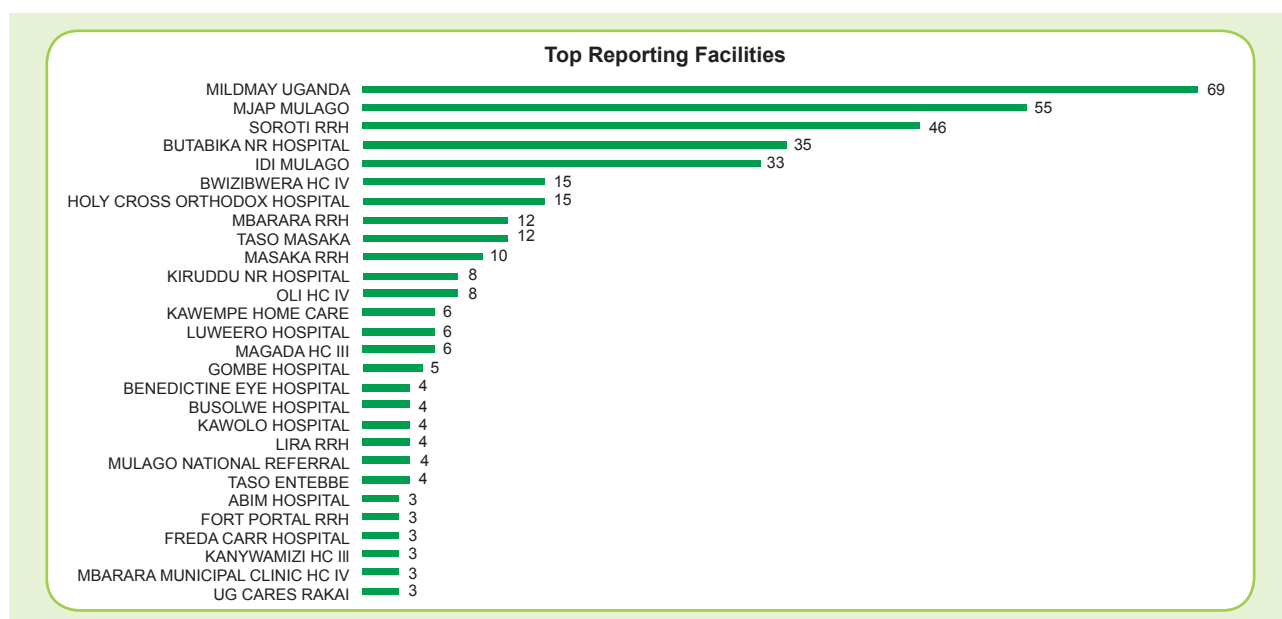
Majority of the patients were aged between 18 and 64 years, with the least reports received from neonates and the elderly.



Majority of the reports were not serious. Of those which were serious, the most common reason was that the reactions were involved disability for the affected patients (visual and bone impairments with Linezolid and Tenofovir respectively).



Clinical Officers submitted the highest number of reports (33.96%), followed by pharmacists (17.92%) and medical officers (17.46%).



Facilities running IP supported programmes are top reporting (Mildmay Uganda and MJAP Mulago), with Soroti Regional Referral Hospital being the top reporting government facility, followed by Butabika National Referral Hospital.

DRUG REACTION PAIRS:

DTG and DTG containing fixed dose combinations continue to be the most commonly suspected drug in all adverse drug reaction reports received at the NPC, with a total of 78 reactions out of the 424 being hyperglycaemia related complaints and symptoms.

Suspected Drug	Count of Reports	Suspected Reaction	Count of Reports
Tenofovir	35	Nephrotoxicity	19
		Ostealgia	10
Linezolid	26	Visual disturbances	11
		Arthralgia	7
		Insomnia	4
Isoniazid	23	Skin hypersensitivity reaction	12
		Peripheral neuropathy	5
Carbamazepine	13	Stevens-Johnson syndrome	13
ABC/3TC/DTG	12	Abdominal pain	4
		Arthralgia	3
		Skin hypersensitivity reaction	2
Levofloxacin	8	Arthralgia	5
		Visual impairment	2
RHZE	7	Arthralgia	3
		Skin hypersensitivity reaction	2
		Drug Induced Liver Injury	1
Lidocaine	6	Facial oedema	5
		Rapid pulse, fainting	1
Fluphenazine	5	Skin hypersensitivity reaction	4
		Joint pains, paralysis	1

Suspected Drug	Count of Reports	Suspected Reaction	Count of Reports
Trifluoperazine	4	Skin hypersensitivity reaction	3
		Joint pains, paralysis	1
Ceftriaxone	3	Skin hypersensitivity reaction	3
Chlorpromazine	3	Hyperpigmentation	3
Cotrimoxazole	3	Skin hypersensitivity	3
Isoniazid/ Rifapentine	3	Dizziness, Headache, Malaise, Pyrexia	1
		Palpitations, Tachycardia	1
		Pruritus, Urticaria	1
Olanzapine	3	Skin hyperpigmentation and scaling	3
Sodium Valproate	3	Oedema, generalized skin reaction	3
Atazanavir/Ritonavir	2	Diarrhoea	1
		Weight loss, dry skin	1
AZT/3TC/DTG	2	Covid-19 bronchopneumonia	1
		Palpitations	1
Bedaquiline	2	Insomnia	1
		QTC prolongation	1
Clofazimine	2	Itchy skin rash	1
		Visual impairment	1
Cycloserine	2	Memory loss, palpitations	2
Efavirenz	2	Generalized macular papular rash, especially face and trunk	1
		Jaundice, abdominal discomfort	1
Lopinavir/Ritonavir	2	Severe vomiting	1
		Severe diarrhoea	1
Methotrexate	2	Burn like wounds in the throat, difficulty breathing	1
		Sore throat, wounds on the tongue and lips, generalised skin rash	1
Phenytoin	2	Inflammation of the lower lip	1
		Itchy skin rash, orchitis, swelling of ears and eyelids	1
Quetiapine	2	Black spots around the neck	1
		Skin eruptions on upper limb, lower lip inflammation	1
Ritonavir	2	Headaches	1
		Skin rash, increased urgency to pass stool	1
TDF/3TC/EFV	2	Generalised piercing sensation	1
		Severe dizziness, confusion, parathesias.	1



TALK TO US

**TOLL
FREE**

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**As a health professional,
I always ask my patients to report back any side
effects with the medicines
I give them.**



Report to the NDA via;



Toll free: 0800101999



Dial *284*99#



0740002070



Med Safety Mobile App



druginfo@nda.or.ug

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ONLINE REPORTING**



Safe Drugs Save Lives

NATIONAL DRUG AUTHORITY