Safe Drugs Save Lives

NATIONAL DRUG AUTHORITY

PHARMACOVIGILANCE

VOLUME 14, ISSUE 3, APRIL 2022

Bulletin

IN THIS ISSUE

Note from the **Secretary to the Authority**

I welcome you to the 3rd quarter edition of the PV bulletin. In this episode, we shed more light on two important aspects namely; guidance on safe pharmaceutical waste management and safety monitoring of surgical instruments. These have been included in the safety updates to inform our stakeholders on these aspects.

I would like to thank the pharmacovigilance team at the NPC for preparing and circulating the quarterly bulletins.

Drug safety monitoring is one of the core regulatory functions of National Drug Authority and the National Pharmacovigilance Center (NPC) plays a key role in executing this mandate. The NPC has established regional PV centers across the country that help in monitoring and reporting safety information to NDA in form of adverse drug reactions (ADRs) and adverse events following immunization (AEFIs).

As committed, we analyze these reports and provide feedback to the respective reporters and to the PV stakeholders through the quarterly bulletins and other means. The PV bulletin majorly conveys important medicine safety related information to the stakeholders. I therefore encourage our stakeholders to always be on the lookout for these quarterly safety updates and keep abreast with the safety of medicines on the market.

Lastly, I appeal to the different stakeholders, including patients/general public to report any medicine related problems to NDA so that we are able to address and mitigate these problems. The reports should be relayed to NDA in a timely manner using any of the reporting platforms provided.

I thank you. For God and my Country!

David Nahamya.

Drug Safety Monitoring

Drug safety monitoring is one of the core regulatory functions of National Drug Authority and the National Pharmacovigilance Center (NPC) plays a key role in executing this mandate.

The Editorial Team

1. **Julius Mayengo**
   Senior Regulatory Officer
2. **Nyende Sophia**
   Regulatory Officer
3. **Douglas Mwesigwa**
   Regulatory Officer
4. **Noah Mutebi**
   Regulatory Officer
5. **David Walusimbi**
   Regulatory Officer
6. **Joanitah Atuhaire**
   Regulatory Officer
7. **Francis Odipiyo**
   Regulatory Officer
8. **Ian Mugisa**
   Regulatory Officer
9. **Ismail Ntale**
   Regulatory Officer

Contents

HEAD OFFICE:
Toll Free: 0800 101 999

Rumee Towers, Plot 19 Lumumba Avenue,
P. O. Box 23096, Kampala, Uganda
Tel: (+256) 417 788 100/1, 417 788 124/ 041 788

TOLL FREE **0800 101 999**

REGIONAL OFFICES

Central Regional Office - Kampala
Plot 1-2 Jinja Road
Premier Complex Building Nakawa
P.O. Box 40082 Kampala
Tel: +256 312 261 584

Northern Region Office-Lira
Plot 48 Ogwal, Ajungu Rd
P.O. Box 235 Lira, Tel/Fax: +256 473 420 652

South Western Region Office - Mbarara
Plot 26 Johnstone Road
Boma(after Boma Primary School)
P.O. Box 1886 Mbarara Municipality
Tel: 0485 421 088 Fax: 0485 421 220

Eastern Region Office - Tororo
Plot No: 26 Kwapa Road
P.O. Box 453, Tororo - Uganda
Tel/Fax: (+256) 454 445 195

South Eastern Region Office - Jinja
Plot 64 Gokhale Road
P.O. Box 1710 Jinja Municipality
Tel/Fax: +256 434 122 176

West Nile Regional Office - Arua
P.O Box 1034, Arua Plot.1mt
Wati Road at Anyafio, Tel: +256 372 260 087

Western Regional Office - Hoima
Muganwa Center
Plot 30 Old Tooro Road
P.O. Box 192 Hoima
Tel/Fax: +256 465 440 688

TALK TO US

Word from
THE DIRECTOR PRODUCT SAFETY

We have jotted down in the quarter 3 Pharmacovigilance bulletin are the highlights of the reporting period from January 2022 to March 2022.

Medicines are meant to heal or prevent disease. However, once consumed, they also have a potential to cause harm. The standard operating procedure for you to follow when you have taken any medicine is to report any suspected side effects that may occur after the use of a drug.

What we have jotted down in the quarter 3 Pharmacovigilance bulletin are the highlights of the reporting period from January 2022 to March 2022. Vigilance is not about drugs alone, medical devices and in particular surgical instruments also have a monitoring system that is hereby described with the why, the what and how to report.

When we are done with using drugs, what happens? We hereby also discuss the how's and whys of the NDA guided process of disposal of pharmaceutical waste.

The NDA strategic plan has an objective; to increase the visibility and awareness of pharmacovigilance. During this reporting period, we gave technical pharmacovigilance support to public health facilities and also ventured into private outlets like pharmacies and drug shops with the same goal; a snapshot of the performance of the different cadres of reporters, and how they submitted reports is presented.

Product label changes are a fact of life for regulatory process. A summary of what came to our notice among the approved or authorized drugs on the market enriches our learning.

Knowledge is power. Once again NDA is grateful to you, the reporter for embracing the digital reporting platforms of suspected Adverse Drug Events. Thank you for the feedback you give us on the performance of medicines by reporting these events promptly.

Safe Drugs Save Lives.

Dr. Helen Byomire Ndagije

Surgical knowledge depends on long pratice, not from speculations.

VIGILANCE OF SURGICAL INSTRUMENTS

(Author: Brenda Clare Kitimbo/Dr. Ian Mugisa)

Monitoring of safety profiles of surgical instruments involves the processing and reporting of single adverse incidents through to the removal of the product of the market as part of the safety corrective actions. This is to ensure that the patient's safety is monitored and the action is taken as soon as a safety concern with the surgical instrument arises.

The National Drug Authority (NDA) regulates the import, manufacture, export and supply of surgical instruments in Uganda to safeguard public health.

A surgical instrument, may be a machine, appliance, material intended by the manufacturer to be used, alone or in combination, for human beings and animals for one or more of the specific medical purpose(s) of:

1. diagnosis, prevention, monitoring, treatment or alleviation of disease,
2. diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
3. investigation, replacement, modification, or support of the anatomy, or of a physiological process,
4. supporting or sustaining life,
5. control of conception,
6. disinfection
7. providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Reporting of Adverse Events with surgical instruments is important as a post-market surveillance tool to monitor performance, detect potential instrument related safety issues, and contribute to benefit-risk assessments of these products. Manufacturers and importers are advised to submit reports for adverse events and product problems. In addition, health care professionals, patients, caregivers and consumers submit voluntary reports about serious adverse events that may be associated with a medical device, deficiencies encountered, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide vital information that enables patients' benefit and safety.

Adverse events reporting of surgical instruments

All companies dealing in surgical instruments including importers, manufacturers, suppliers and registrants are required to report adverse events of their products.

What to report

As a general principle, there should be a pre-disposition to report rather than not to report in case of doubt. Any adverse event (AE), which meets the basic reporting criteria listed below, is considered as a reportable adverse event:

1. An adverse event (or potential AE) has occurred.
2. The medical instrument is associated with the AE.
3. The adverse event leads to one of the following outcomes:
   a. It becomes a serious threat to public health.
   b. The death of a patient, user or other person.
   c. Serious deterioration in state of health of patient, user or other person.
   d. There is no death or serious injury in the initial Adverse even but it might lead to death or serious injury of a patient, user or other person if the Adverse Event recurs.
4. A recall or field safety corrective action

Medical device

Report using our website by clicking on the link:

https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=UG

The National Drug Authority (NDA) can also be reached through the following platforms:

1. Toll free line: 0800191999
2. WhatsApp number: 0740002070
3. Email: druginfo@nda.or.ug

PHARMACEUTICAL WASTE MANAGEMENT

WHAT YOU NEED TO KNOW

(Author: Odipiyo Francis & Ochola Benjamin)

Because of the nature of wastes and the potential risks associated, if not properly managed; pharmaceutical wastes pose great danger to both the environment and humans. It is therefore prudent that all pharmaceutical waste generated is appropriately handled to minimize risk to the public health, as well as minimize environmental pollution.

The elimination of pharmaceutical waste from the public and subsequent disposal is embedded in NDAs mandate of ensuring that only safe, efficacious and quality drugs are availed to the entire population of Uganda.

NDA PROCEDURE FOR PHARMACEUTICAL WASTE DISPOSAL

- The client presents a letter to NDA requesting for destruction of pharmaceutical waste, clearly indicating the list and weight of obsolete items to be disposed of.
- NDA issues response to the client providing a list of prequalified waste management service providers, bank slip and the destruction fees payable to NDA.
- The client Liaises with NDA accredited waste management service provider (listed below) to arrange when and where the destruction is to be done.
- Upon confirmation of payment of the destruction fees, NDA provides an Inspector of Drugs to supervise the safe disposal of the obsolete pharmaceuticals.
- NDA charges a fee of Ug X 100,000/= per hour for the supervision of safe disposal of the pharmaceutical waste.
- After destruction of the waste, NDA issues a certificate of destruction to the client indicating the items destroyed, the quantity destroyed and the date and venue of destruction.
- Below is the current list of NDA accredited pharmaceutical waste management companies:

#	Company name	Address	Contact
1	Green Label Services	Plot 14 Tufnell Drive, P.O Box 40303 Kampala,	0414531135/0772423092
2	Array Services Ltd,	Plot 28 Chorley Crescent, Luzira	0701840969/0783516834
3	P.B Holdings Ltd,	P.O Box 72340 Kampala	0703434300/0772434300
4	Soval International Ltd	Garnesh Plaza, Entebbe Rd, Level 4, P.O Box 72340, Kampala	0312517749/0700550174
5	ERB Holdings Ltd	Plot 6 Kamu-Kamu Plaza, Entebbe Road	0701261255
6	Desan Services Ltd	Plot 67, Kira Road, P.O Box 1730, Kampala	0414533442
7	Bin It Services	Plot 134, Bukoto Street, P.O Box 1730 Kampala	0414 530531l
8	PharmaSkill Consult Ltd	Plot 19 Wampewo Avenue Kampala	0782-613901/ 772412923
9	Med Sap Africa Ltd	Buganda Road Flats Block 664K, P.O. Box 12763 Kampala	0772447566 /0772927866
10	De Waste (U) Ltd	Plot 8, Kent Lane, Kamwokya,	0782-704403/0782-012519
11	Swift Waste Masters	Plot 1212 Upper Nsooba, P.O Box 35794 Kampala	0714122334/0772489627
12	Armstrong Limited	Block 660, Buganda Road, 2nd Floor, Flat H	0707400000
13	NLS Waste Services	P.O. 7668, Kampala,	0414-383829/0772400995
14	Waste-man Services Ltd	Plot 78 Semwata Road, Ntinda, Platinum Chambers, Ground Floor Nakawa	0774844470 / 075984771
15	Real An Centre Group of companies International Ltd	International conference centre suit 153, P.O.Box 1432 Kampla – Uganda	0772426505
16	Mukuba Holdings Limited	Masterwood Plaza, Ndeeba, Masaka Road, P.o box 12660, Kampala	0772584805/0700307173
17	Epsilon (U) ltd	Plot 1413 P.O.BOX 12647 Kampala Uganda	0312514790/0414-252076
18	Asante Waste Management	East African Investment Ltd Building, Suite A-2nd Floor Block 243, Plot 2490 Luzira Industrial Park, P. O. Box 10101, Kampala	0788272688

INCREASING AWARENESS **AND** VISIBILITY OF PHARMACOVIGILANCE

(Author: Dr. Douglas Mwesigwa)

One of the strategic areas of Pharmacovigilance, referencing the Pharmacovigilance strategic plan 2019 – 2024 is to establish systems to increase visibility and enhance awareness about the importance of Pharmacovigilance through educational and behavioral change activities. Under this area, we aim at enhancing dissemination of safety information, increase transparency and feedback to relevant stakeholders. We also aim at establishing a mechanism to communicate and manage risks identified through ADR reporting to the public. One of the ways we do this is through constant support supervision visits to the health facilities all over the country.

This year our target is pharmacovigilance sensitization of health professionals in private pharmacies in 50 districts and support supervision of all the health facilities in the catchment of the 50 districts. We are on course to achieve this target, and for Q3, here below is how we have performed;

105 Health facilities were visited, 923 Health Care Practitioners sensitized within the facilities. 06 pharmacies and 14 drug shops visited as seen below;

LIST OF HEALTH FACILITIES VISITED FOR PV SENSITIZATION

KALUNGU

NO.	HEALTH FACILITY
1.	Villa Maria Hospital
2.	Lukaya HC III
3.	Kalungi HC III
4.	Kabaale HC III
5.	Well Spring HC III
6.	Kabungu HC III
7.	Kasambya HC III
8.	Kiragga HC III
9.	St. Monica Birongo HC III
10.	Bukulula HC IV

BUKOMANSIMBI

NO.	HEALTH FACILITY
1.	Mirambi HC III
2.	Butenga HC IV
3.	Luyitayita HC III
4.	Kitanda HC III
5.	St. Mary's maternity and nursing home
6.	Buyoga HC III
7.	Kawoko Muslim HC III
8.	Makukuulu HC III
9.	Bigasa HC III

SEMBABULE

NO.	HEALTH FACILITY
1.	Lwebitakuli HC III
2.	Sembabule HC IV
3.	Mateete HC III
4.	Kyabi HC III
5.	St. Agatha Lwebitakuli HC III
6.	Lwebitakuli NGO HC III
7.	Lwemiyaga HC III
8.	Ntuusi HC IV

LWENGO

NO.	HEALTH FACILITY
1.	Lwengo HC IV
2.	Kiwangala HC IV
3.	St. Francis Mbirizi HC III
4.	Engeye Health Clinic HC III
5.	Nkoni HC III
6.	Kitooro HC III
7.	Kyazanga HC IV

KOTIDO

NO.	HEALTH FACILITY
1.	Kotido General Hospital
2.	405 army brigade HC III
3.	Panyangara HC III
4.	Kacheri HC III
5.	Kanawat HC III
6.	Angeleu pharmacy
7.	Oscar pharmacy
8.	Medhub pharmacy
9.	J and J Kotyang drug shop
10	O & A drug shop
11.	Live on Medical clinic

ABIM

NO.	HEALTH FACILITY
1.	Abim General Hospital
2.	Alerek HC III
3.	Morulen HC III
4.	Oromuge HC III
5.	Tike HC II – OTUKE district

KAPCHORWA

NO.	HEALTH FACILITY
1.	Kapchorwa General Hospital
2.	Tegeres HC III
3.	Chebonet HC III
4.	Chemosong HC III
5.	Sipi HC III
6.	Kaserem HC III
7.	Arapsorowen pharmacy
8.	Sunrise pharmacy and clinic
9.	St Luke pharmacy and clinic
10.	St Roan Medical centre
11.	Rock drug shop
12.	Good luck drug medical supplies
13.	St Victor`s health services
14.	Savio crane drug shop
15.	Friends medical centre
16.	Central drug sop
17.	Sebei road medical devices
18.	Shifa medical centre
19.	Town medical centre
20.	Trust drug shop

KYENJOJO

NO.	HEALTH FACILITY
1.	Kyenjojo Hopital
2.	Kyarusozi Health Centre IV
3.	Kyakatara Health Centre III
4.	Kagorogoro SDA Health Centre II
5.	Nyamabuga Health Centre III
6.	Butiiti Health Centre III
7.	Kyembogo Health Centre III
8.	Kigoyera Health Centre III
9.	Kasaba Medical Centre
10	Mwenge Health Centre III
11.	Bufunjo Health Centre III
12.	Supraze Pharmacy
13.	Bufunjo Pharmacy

KYEGEGWA

NO.	HEALTH FACILITY
1.	Kyegegwa Hospital
2.	Mpara Health Centre III
3.	Ruhangire Health Centre III
4.	Karwenyi Health Centre III
5.	Migamba Health Centre III
6.	Kakabara Health Centre III
7.	Mukondo Health Centre III
8.	Hapuuyo Health Centre III
9.	Kasule Health Centre III
10.	Kazinga Health Centre III
11.	St. Thereza Wekomiire Health Centre III
12.	Bujubuli Health Centre III
13.	Kigambo Health Centre II
14.	Bugogo Health Centre II
15.	Kishagazi Health Centre II
16.	Migongwe Health Centre II
17.	Pramukh Pharmacy
18.	Actual Pharmacy
19.	Tuable Pharmacy
20.	Jowzey Pharmacy
21.	Hica's Pharmacy

SUMMARY OF FACILITIES VISITED

Facility category	Number of facilities visited for sensitization
Hospitals	**06**
Health centre IVs	**08**
Health centre IIIs	**57**
Health centre IIs	**05**
Private health centres/clinics	**10**
Pharmacies	**13**
Drug shops	**06**
Total	**105**

Panyangara HC III Kotido district

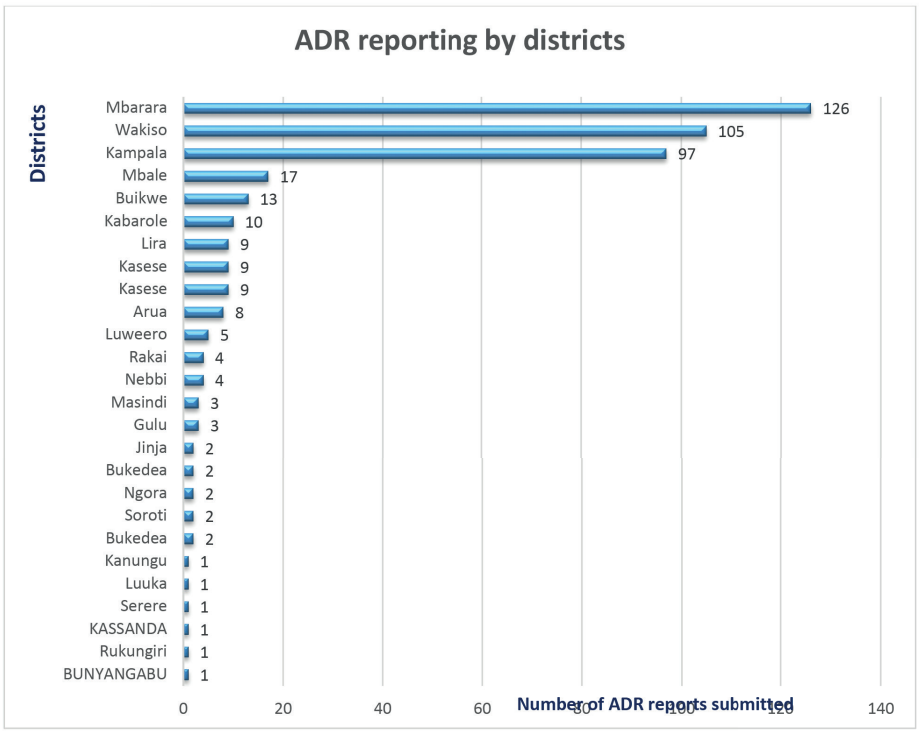
Health workers at Ibulanku community HC III pose for a group photo after PV sensitization

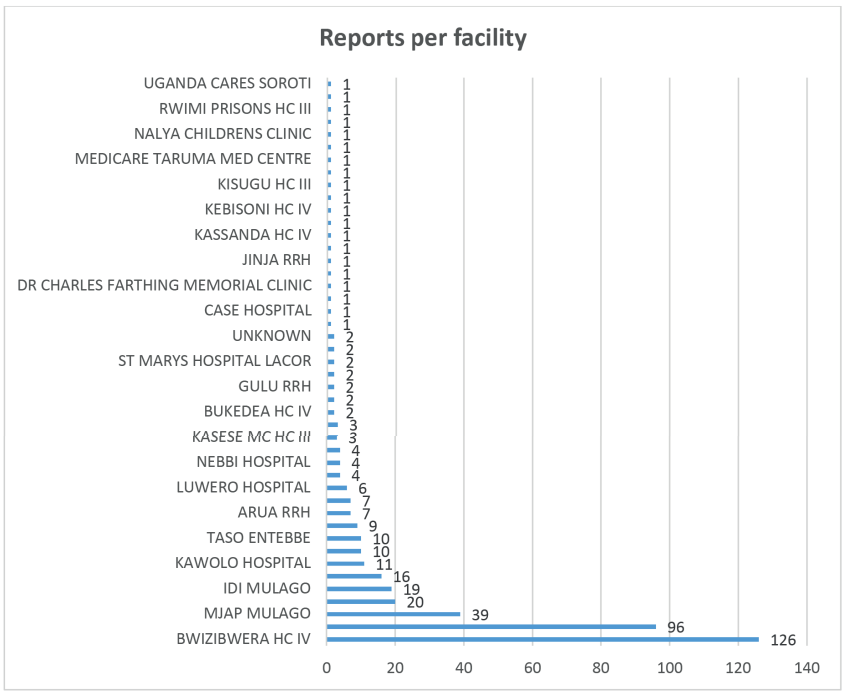
SUMMARY OF ADR REPORTS RECEIVED BETWEEN JAN & MAR 2022

(Author: Odipiyo Francis)

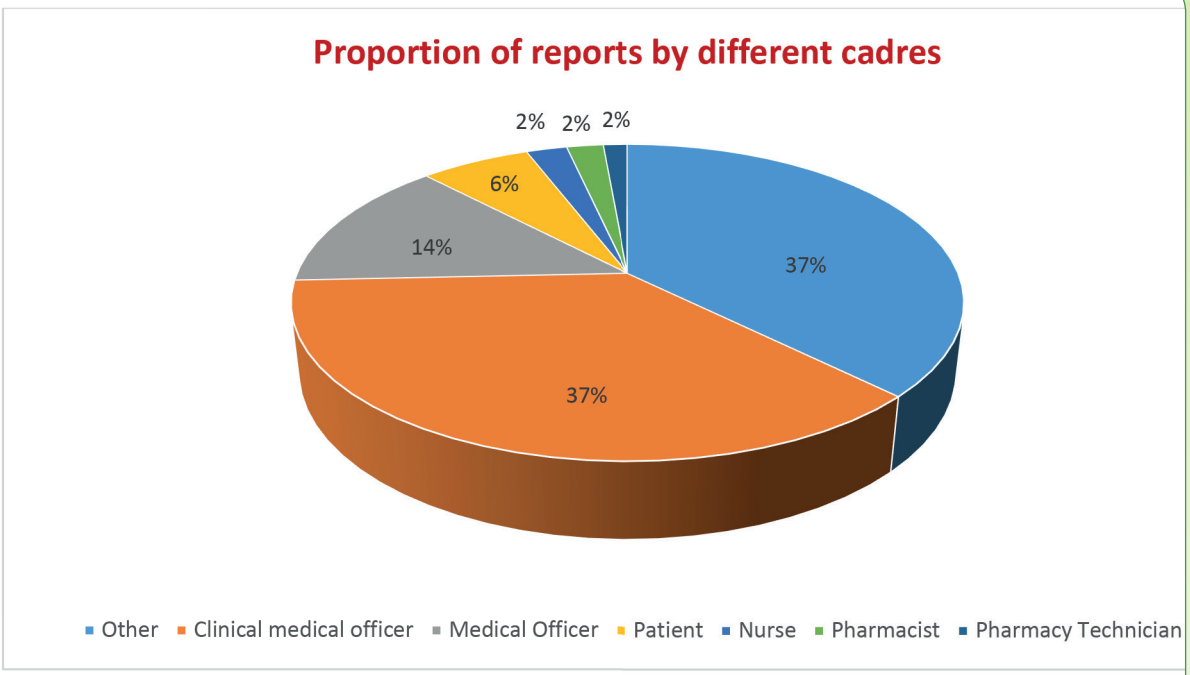
A total of 428 ADR reports were received from various sources across the country. However, most of these reports came from mainly three districts i.e. Kampala, Wakiso and Mbarara as shown below.

Majority of the reports were submitted by Bwizibwera HC IV (n=126; 29.4%) and MJAP Mulago (n=96; 22.4%), accounting for a total of 51.8% of all reports.

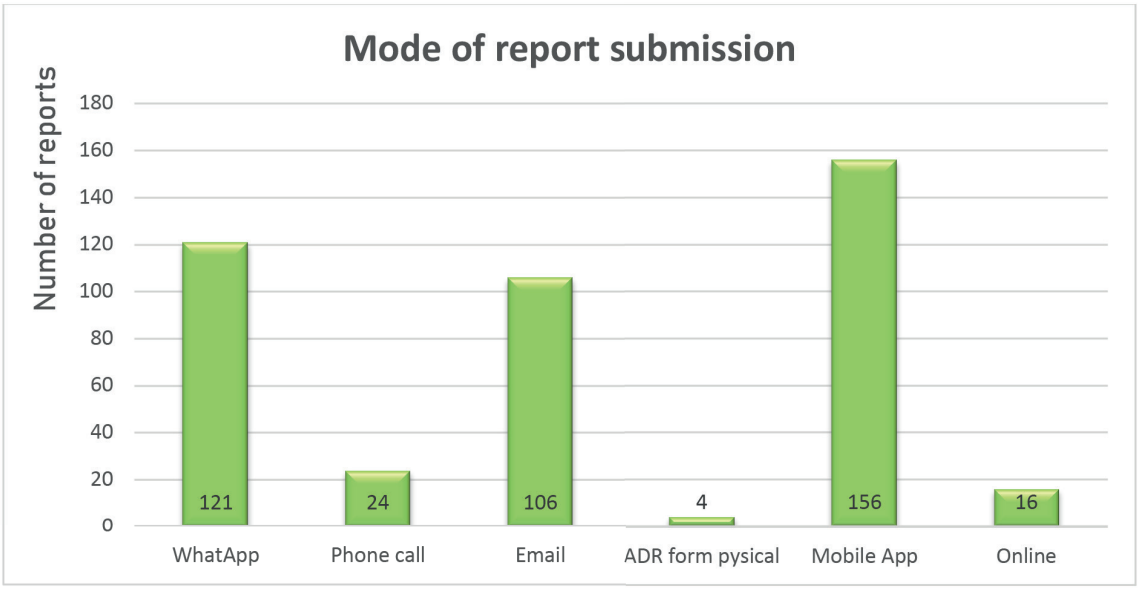




Clinical medical officers submitted the majority of reports (n=158; 37%). Quite many (n=160; 37%) of the reports did not indicate reporter cadre so they were simply captured as Others.

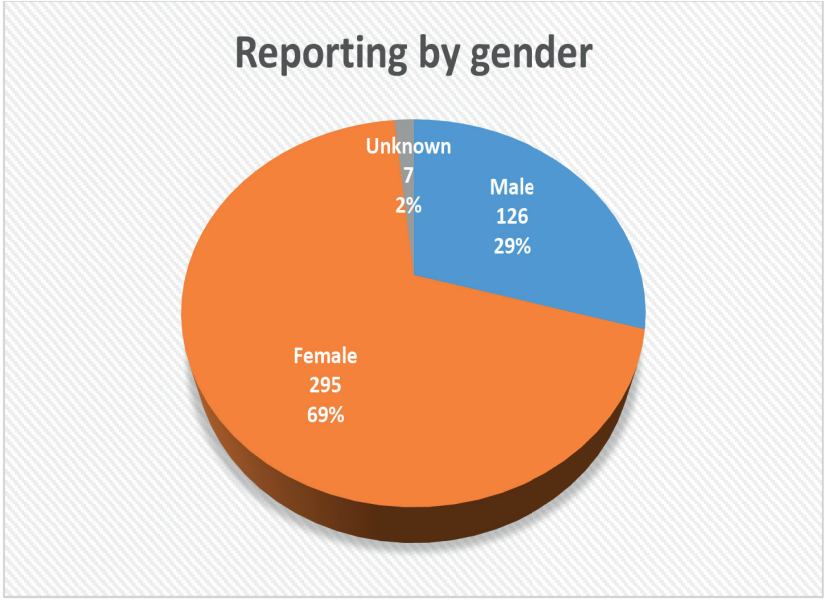


Reporters submitted the majority of reports to NPC using the med safety mobile application (n=156) and via WhatsApp (n=121). Quite few reports (n=04) of filled ADR forms were submitted physically. The shift in trend of report submission from physical to use of mobile phone applications (WhatsApp and Med safety) is due to the convenience and minimal costs associated with the use of mobile phones.

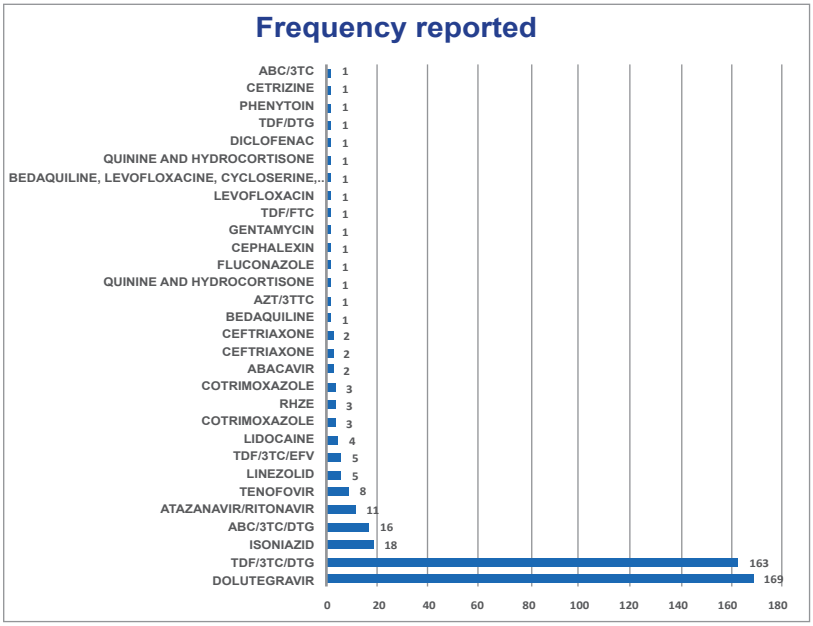


Most of the reports received occurred in female (n=295, 69%) patients/clients than males (n=126; 29%). This could be attributed to the fact that females have better health seeking behaviors than males and since they are main caretakers (home and family), they are more likely to interact with a healthcare provider and report any adverse event compared to the males.

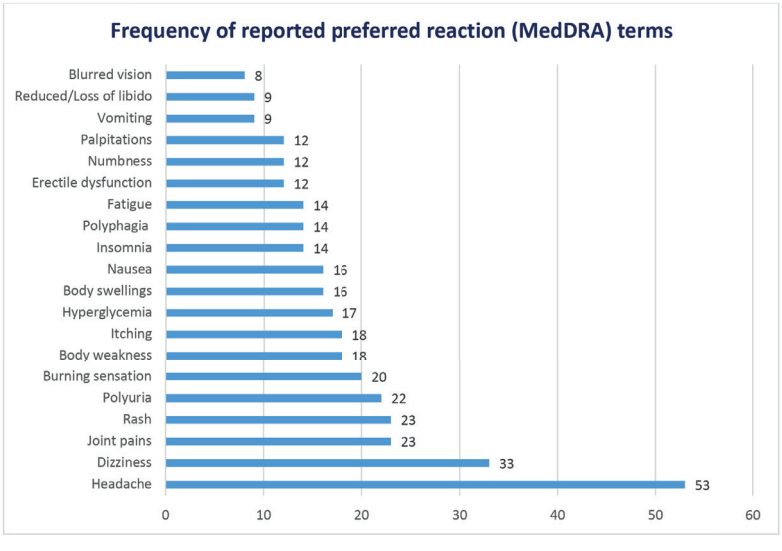
Of the 428 ADR reports, 120 reports were graded as serious, accounting for 28.04% and 308 (71.96%) were not serious.



Almost all ADR cases reported were associated with ART drugs. Commonest drugs associated were Dolutegravir (n=169; 39.49%) and TDF/3TC/DTG (n=163;38.08%); both totaling 77.57%. This could be partly explained by the adequate counseling services offered to the ART clients where they are continuously monitored and encouraged to report any adverse events.



Headache, joint pains, dizziness, rash, polyuria, burning sensations etc. were among the commonly reported preferred (MedDRA) terms. These are common adverse effects labeled on most ART drugs. The frequency of statistical reports of adverse events rhymes with the frequency of drugs associated.



PRODUCT LABEL CHANGES IN QUARTER THREE

(Compiled by: Atuhaire Joanitah)

Product Name	Licence Holder	Summary of Approved Changes	Date of Approval
Anastrozole (Arimidex)	Astrazeneca UK Limited	Included depression and osteoporosis as adverse reactions under the undesirable effects section.	18th March 2022
Candesartan + Hydrochlorothiazide (Atacand Plus)	AstraZeneca UK Limited	Included additional warning related to non-melanoma skin cancer.	15th March 2022
Ticagrelor (Brilinta)	Astrazeneca Sweden	Updates to sections 4.4 and 4.8	31st January 2022
Dapirivine (Dapiring)	IPM South Africa NPC	Data on antiviral activity of Dapirivine on hepatitis E virus	24th February 2022
Dapaglifozin (Forxiga)	AstraZeneca Sweden)	Section on undesirable effects updated to add Fournier's gangrene as a very rare adverse reaction.	31st January 2022
Elvitegravir + Cobistat + Emtricitabine + Tenofovir alafenamide	Gilead Sciences Inc	Drug-drug intreractions between cobistat containing products and cutaneously administered products.	9th February 2022
Hydroxycarbamide (Hydroxyurea)	Sandoz GMBH Kenya	Update of undesirable effects to include haemolytic anaemia.	15th March 2022
Raltegravir (Isentress)	MSD (PTY) Limited	Update of precautions and warnings to include advice to wait at least two hours between taking iron salts and taking Isentress, as these medicines may reduce Isentress efficacy.	24th February 2022
Magnesium hydroxide + Aluminium hydroxide + Simethicone (Maalox Plus)	Sanofi Aventis Kenya Limited	Update to section 4.5 on interactions with other medicinal products and other forms of interaction and section 2.6: fertility, pregnancy and lactation.	10th March 2022
Diclofenac potassium (Voltaren and Cataflam products)	Novartis Pharma Services Inc	Update to section 09: Women of child bearing potential, pregnancy, breastfeeding and fertility to include the risk of fetal renal impairment with subsequent oligohydramnios when NSAIDS are used from week 20 of pregnancy onwards.	19th January 2022
Dihydrostreptomycin sulphate+Penicillin G monohydrate (Pen & Strep)	Norbrook Laboratories Limited	Update of storage conditions to include "Use the product within 2 months when removed from the refrigerator.	19th January 2022
Efavirenz (Stocrin)	MSD (Pty) Ltd	Update of drug interaction between metamizole and efavirenz.	22nd March 2022

If you have any comments, we would be pleased to receive them at druginfo@nda.or.ug_ or you can visit us at: www.nda.or.ug

Safe Drugs Save Lives

NATIONAL DRUG AUTHORITY

0740 002070

ndaug@nda.or.ug
druginfo@nda.or.ug

Uganda National Drug Authority

@UNDAuthority

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NDA Quality Control Laboratory is prequalified by WHO, Geneva; and accredited by ANAB, USA, to ISO/IEC 17025 standard.

To report Adverse Drug Reactions, complete the Adverse Drug Reaction form and return it to any NDA office near you or send a direct online report at https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=UG