UGANDA

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

ANNUAL PHARMACOVIGILANCE REPORT 2022-23

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NDA'S NEW LABORATORY TOWER

REMARKS FROM THE SECRETARY TO THE AUTHORITY

It is with great pleasure that I present to you this year's Annual Pharmacovigilance Report, a comprehensive documentation of our collective efforts to ensure the safety and well-being of patients nation-wide.

In an era where pharmaceutical advancements continue to revolutionize healthcare, the criticality of medicine safety monitoring cannot be overstated. Pharmacovigilance serves as the sentinel of patient safety, constantly scanning the horizon for potential risks associated with medicinal products. By meticulously collecting, analyzing, and evaluating data on adverse drug reactions, we pave the way for proactive measures that can prevent harm and enhance the therapeutic experience for millions of individuals.

Our commitment to medicine safety monitoring encompasses diverse stakeholders, including fellow regulatory agencies, healthcare professionals, pharmaceutical companies and most importantly, patients themselves. It is through collaborative efforts that we foster a culture of vigilance, where the proactive identification and mitigation of risks become paramount.

Our commitment to medicine safety monitoring encompasses diverse stakeholders, including fellow regulatory agencies, healthcare professionals, pharmaceutical companies and most importantly, patients themselves.

The significance of pharmacovigilance lies in its ability to transform information into action. Every adverse event reported is a crucial piece of a larger puzzle, enabling us to unravel the complex web of drug interactions, identify emerging safety concerns, and refine our understanding of a product's risk-benefit profile. This knowledge, in turn, empowers healthcare professionals to make informed decisions and optimize patient care.

As we reflect on the achievements of the past year, we must also acknowledge the challenges that lie ahead. The global healthcare landscape continues to evolve, with new therapies, personalized medicines, and digital health technologies reshaping the treatment paradigm. With each innovation, the need for robust pharmacovigilance becomes increasingly imperative, ensuring that the benefits of medical interventions far outweigh any potential risks.

It is my sincere hope that this Annual Pharmacovigilance Report serves as a testament to the dedication, expertise, and unwavering commitment of the pharmacovigilance community. Together, we champion patient safety, instilling confidence in the medications we prescribe and administer. Through diligent surveillance, timely interventions, and continuous improvement, we strive to create a future where the pursuit of medical progress is synonymous with the assurance of patient well-being.

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David Nahamya
Secretary to the Authority

NOTE FROM THE DIRECTOR PRODUCT SAFETY

At the National Drug Authority, we are committed to ensuring that patient reporting is accessible, streamlined, and encouraged.

The annual report provides a comprehensive overview of our activities in drug safety monitoring, highlighting key achievements, challenges, and initiatives undertaken during the reporting period. It showcases the collaborative efforts that have facilitated the timely identification and communication of drug safety concerns to healthcare providers and the public, empowering informed decision-making and enhancing patient safety across the nation.

As we celebrate the accomplishments attained this year, we also acknowledge the ever-evolving nature of the pharmaceutical landscape. New challenges, such as the emergence of novel therapeutic modalities and the globalization of drug supply chains, demand our constant vigilance.

As one of the tools and strategies to meet these emerging challenges, we want to foster patient involvement in the drug safety monitoring. Public vigilance is an integral part of the safety ecosystem we seek to create. Patients and their families, armed with awareness and knowledge, are empowered to recognize and report any untoward effects or unexpected outcomes of their medications. By fostering a culture of patient reporting, we open avenues for timely detection and investigation of potential safety concerns.

At the National Drug Authority, we are committed to ensuring that patient reporting is accessible, streamlined, and encouraged. We have provided multiple patient-friendly reporting channels for reporting adverse drug reactions and other medicine related problems, making it convenient for patients to share their experiences. Additionally, we must continue to leverage technologies, collaborations, and fostering of public awareness to ensure to meet these challenges.

Last but not least, we would like to extend our heartfelt appreciation to all the stakeholders, especially the healthcare professionals who diligently collect and submit ADR reports, enabling continuous and timely detection and mitigation of adverse drug experiences with drugs. It is through our collective efforts that we can overcome challenges, embrace opportunities, and build a future where safe and effective medications are accessible to all.

We invite you to delve into the pages of this report, which embodies our commitment to transparency, accountability, and the pursuit of excellence. NDA remains committed to upholding the highest standards of pharmaceutical oversight, assuring the public that the medications they rely on are safe and effective.

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Helen Byomire Ndagije PhD, FISoP

NDA Vision

A world class drug regulatory agency

NDA Mission

To protect and promote human and animal health through the effective regulation of drugs and healthcare products

NDA Mandate

To ensure the availability at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.

Highlights in this year`s report

- we show the country`s ADR reporting trends
- we discuss the potential safety concerns detected in our database this year
- NDA conducted its very first good pharmacovigilance inspections
- We continued to draw on the benefits of our collaboration with the WHO Uppsala monitoring center in Sweden
- We continued to carry the pharmacovigilance message to health professionals and the general public through our sensitisation activities

This year`s report could only be possible with the fervent contribution of the pharmacovigilance team at NDA listed below. Their efforts are greatly appreciated.

Name	Designation	Name	Designation
Mayengo Julius Manager Pharmacovigilance		David Walusimbi	Inspector of Drugs
Francis Odipiyo	Inspector of Drugs	Ismail Ntale	Inspector of Drugs
Joanitah Atuhaire	Inspector of Drugs	Douglas Mwesigwa	Regulatory Officer
Sophia Nyende	Inspector of Drugs	Kwikiriza Emmaculate	Inspector of Drugs
Ian Mugisa	Regulatory Officer	Owiny Jonathan	Unit Administrator (Technical

EDITORIAL

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Inspector of Drugs

ABBREVIATIONS

ADSM	Active Drug Safety Monitoring
ADR	Adverse drug reaction
AEFI	Adverse event following Immunisation
PVIMS	Pharmacovigilance Monitoring System
NDA	National Drug Authority
NPC	National Pharmacovigilance Center
LTR	Local Technical Representative
MAH	Marketing Authorization Holder
NTLP	National TB and Leprosy Program
ACP	Aids Control Program
WHO	World Health Organisation
UNEPI	Uganda National Expanded Program for Immunisation
PSU	Pharmaceutical Society of Uganda
PV	Pharmacovigilance
ART	Antiretroviral therapy
ICSR	Individual Case Series Reports
ICH	International Committee on harmonization
IPT	Intermittent Prophylactic Treatment
PIDM	Programme of International Drug Monitoring
RPVC	Regional Pharmacovigilance Centre
PNFP	Private Not for Profit organizations
NTLP	National Tuberculosis and Leprosy Program
TOT	Training of Trainers
AMR	Antimicrobial Resistance
AIDS	Acquired Immune Deficiency Syndrome
PMS	Post Marketing Surveillance

ADR AND AEFI REPORTING TRENDS OF THE FY 2022/23

Over the years, the number of ADR reports submitted to NDA/NPC has continued to grow as shown in the graph below. The numbers exponentially surged up in FY 2021/22 and 2022/23, with a peak of 7,000 reports during this period. This was mainly due to the mass Covid 19 vaccination exercise and the rigorous sensitization programs the NPC undertook as well as introduction of new and easy reporting channels such as the USSD code.

There was a decline observed in the total number of reports (both ADRs and AEFIs) submitted in this financial year, which was probably due to the reduction in uptake of the Covid 19 vaccines. None the less, the number of ADRs did not drop to the levels of the pre-pandemic period.

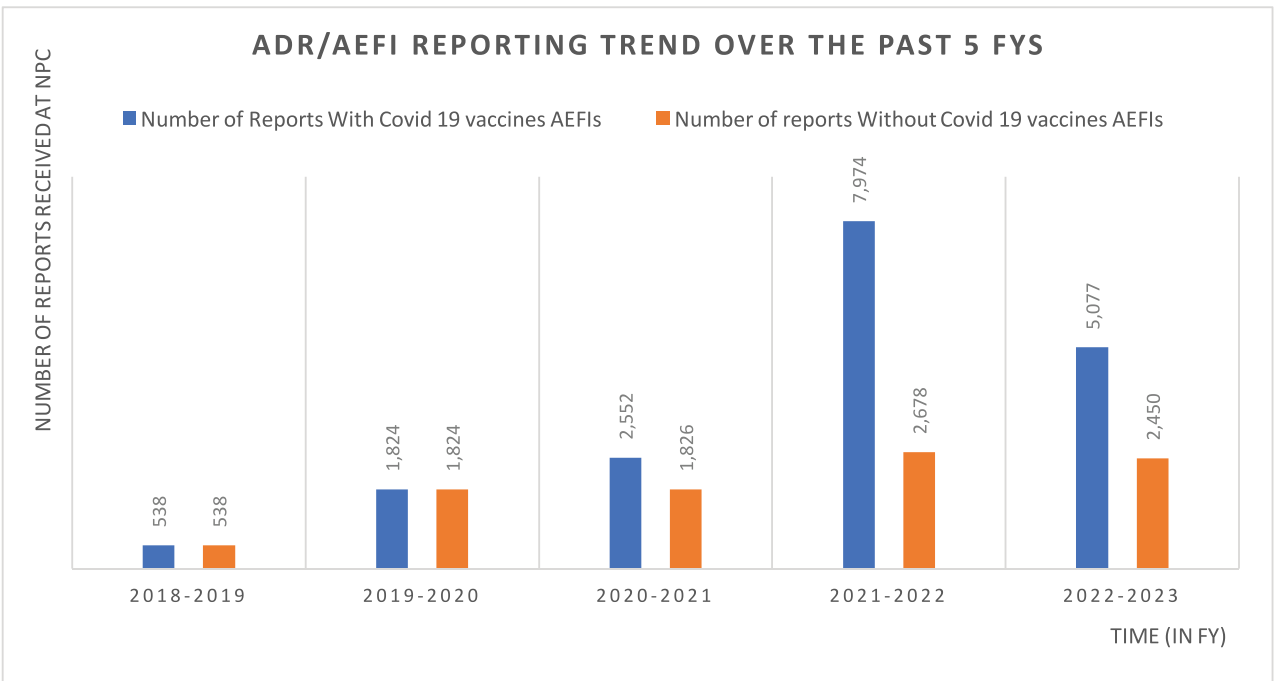


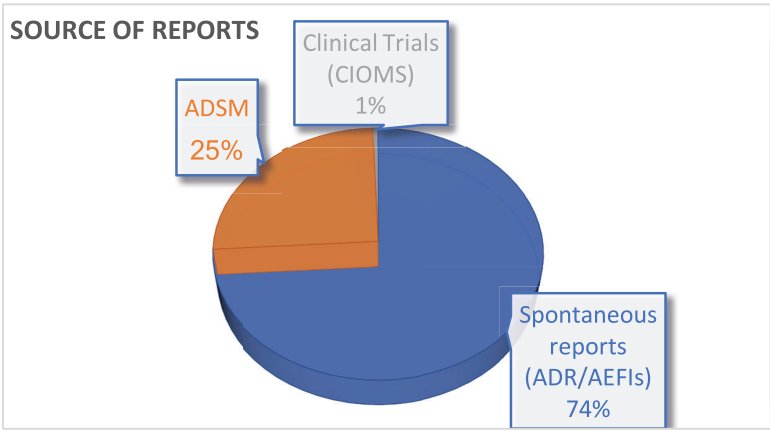
Figure 1 ADR/AEFI reporting trend over the past 5 FYs

In this FY, a total of 2,450 ADR reports were received at the NPC, which is still well below the *expected rate 200 reports /1 million inhabitants. This still depicts low reporting rates.*

Reporting indicator	Rate /proportion
Reports received per million population per year (this is below the WHO recommended rate of 200 reports /1million inhabitants)	104.68
Number of ADRs per 100 000 persons in the population	10.47
Number of ADRs associated with death	13

Table 1: Reporting rates per population

The reports were mainly from spontaneous reporting (ADR/AEFIs) (74%) and a small proportion of ADSM reports (25%), with almost negligible reports from clinical trial studies (CIOMS) (1%). Of the spontaneous reports, slightly more than half (52%) were AEFIs, which were mainly from the Covid 19 vaccines.



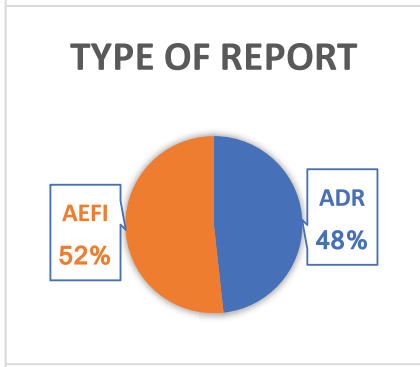


Figure 2: Type of reports

Figure 3: Source of reports

Reporting trends by gender

The distribution of reports received were almost equal in proportion between female and males, although the reports received on males were slightly more than half the total number of reports.

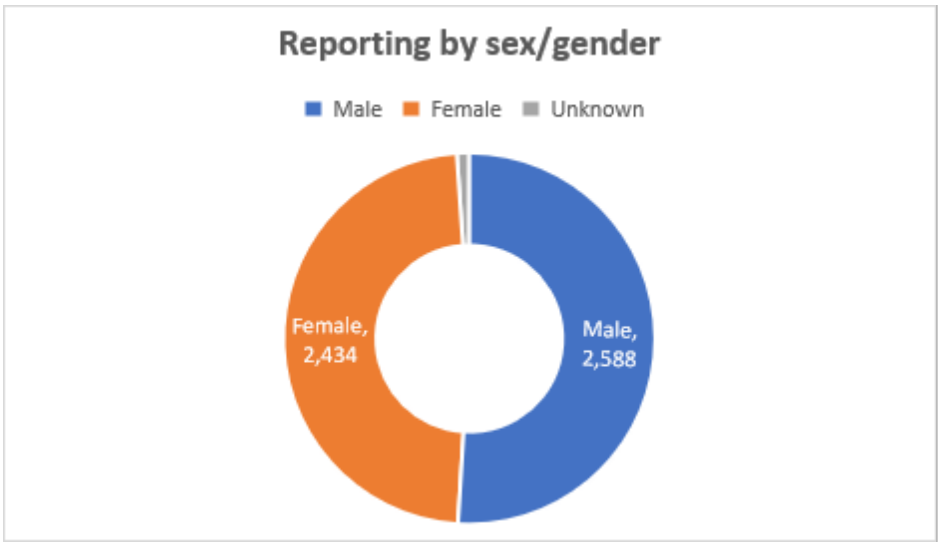


Figure 4: Trends of reported events by gender

Reporting trends by age

Most (71.48%) of the reports were received on age group ranging from 18-44 years, which is a wide range representing majority of the youthful Ugandan population. This age group was probably more exposed to the different drug substances, especially the Covid 19 vaccines hence experiencing more ADRs than any other age group.

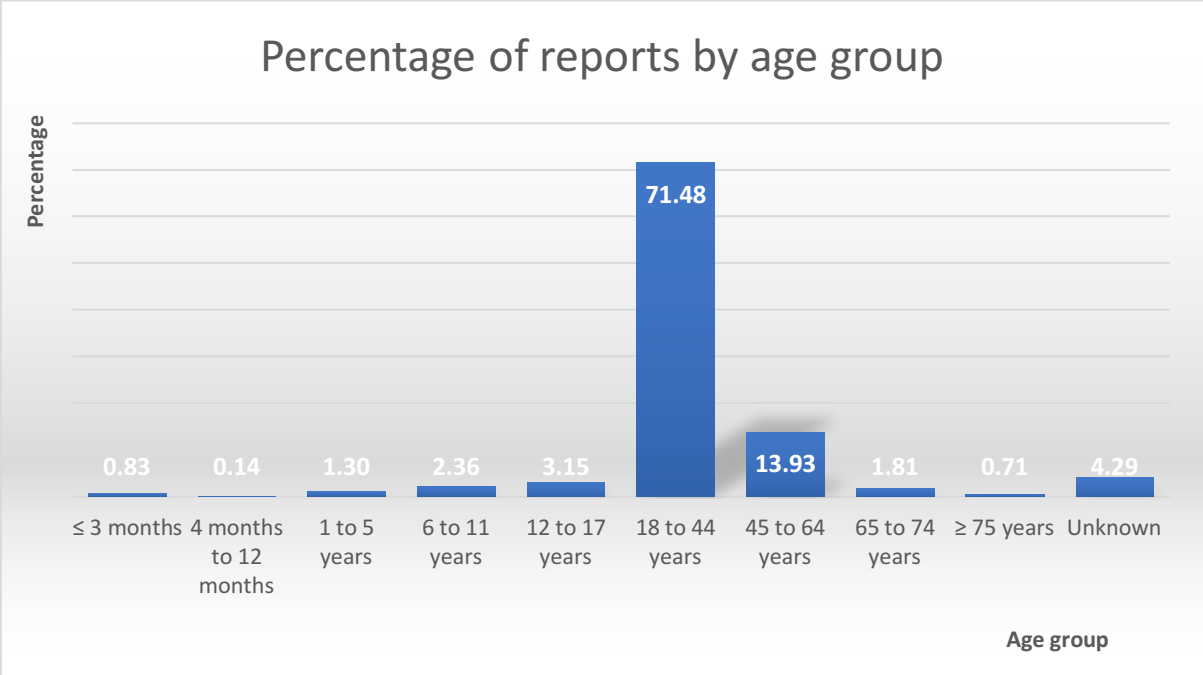


Figure 5: Reporting by age group

Use of reporting channels

The reports came in through various reporting channels, however, the reporters preferred reporting through the direct phone calls (where most of the reports were received; n=2,408) and email (n=1,058) platforms compared to any other. Although all reporting channels have been widely distributed to the PV stakeholders, preference for the two digital reporting platforms (i.e. direct calls using the tollfree line and email) reaffirms the growing influence of the population harnessing technology and internet in conducting PV activities. The large amounts of reports received through direct calls were mainly Covid 19 vaccines AEFIs which were coming from patients directly.

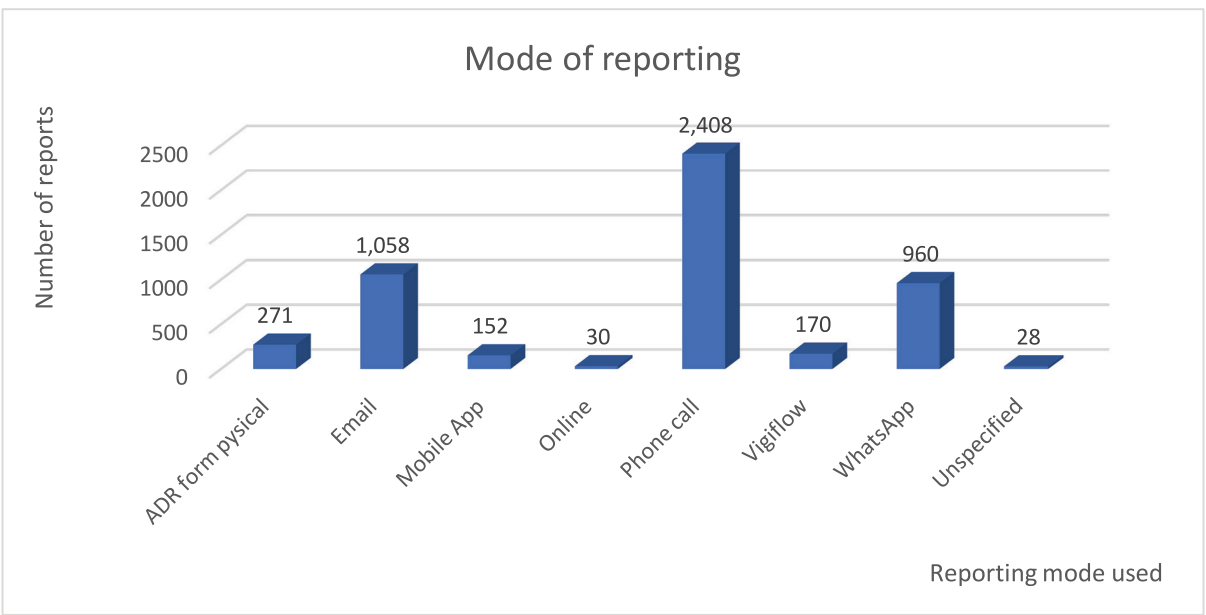


Figure 6: Shows trends in the use of reporting channels

Reporting trends among health professionals

The reports came from various reporters of different qualifications, including patients who reported over 2,000 cases.

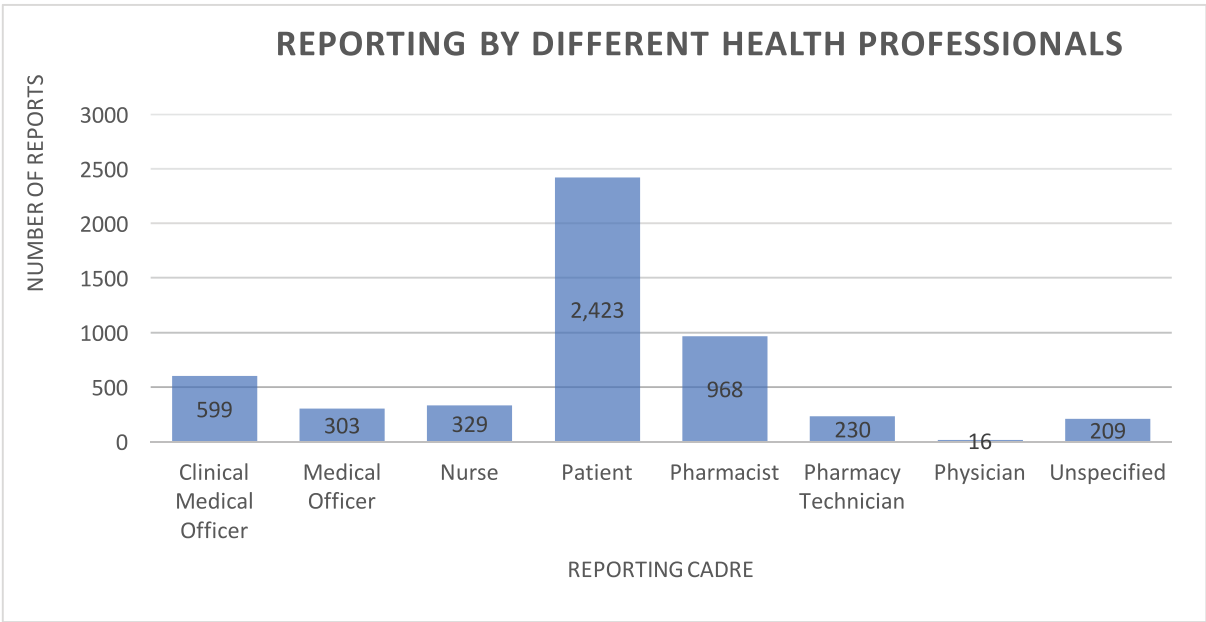
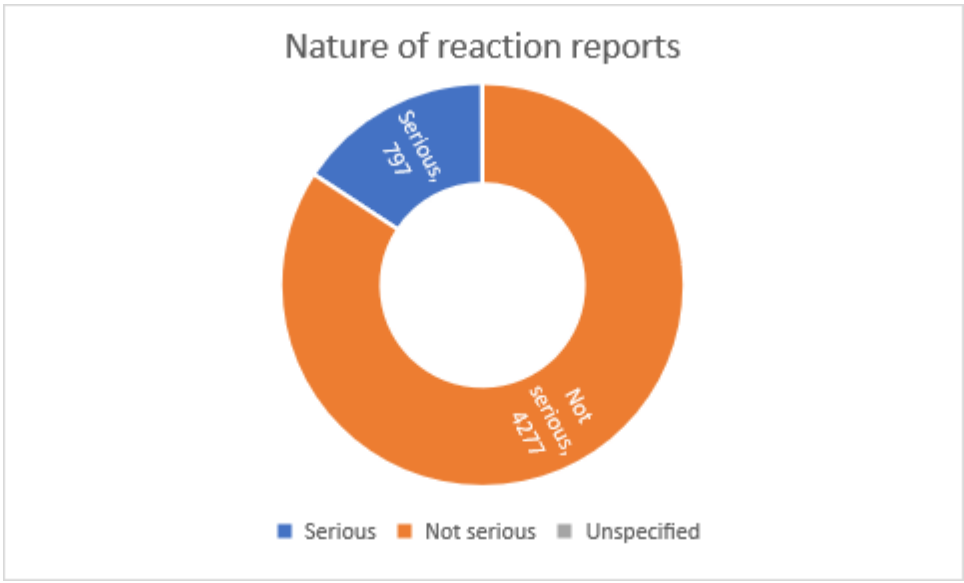


Figure 7: Shows reporting trends among health professionals

Seriousness of the reported events

Majority of the reports were not serious in nature (n=4,277), however, a considerable number (n=797) of the reports were serious in nature, with varied reasons for seriousness. Top most reason for seriousness was that the drug reactions were life threatening in nature (n=316) and they were associated with disability (n=256).



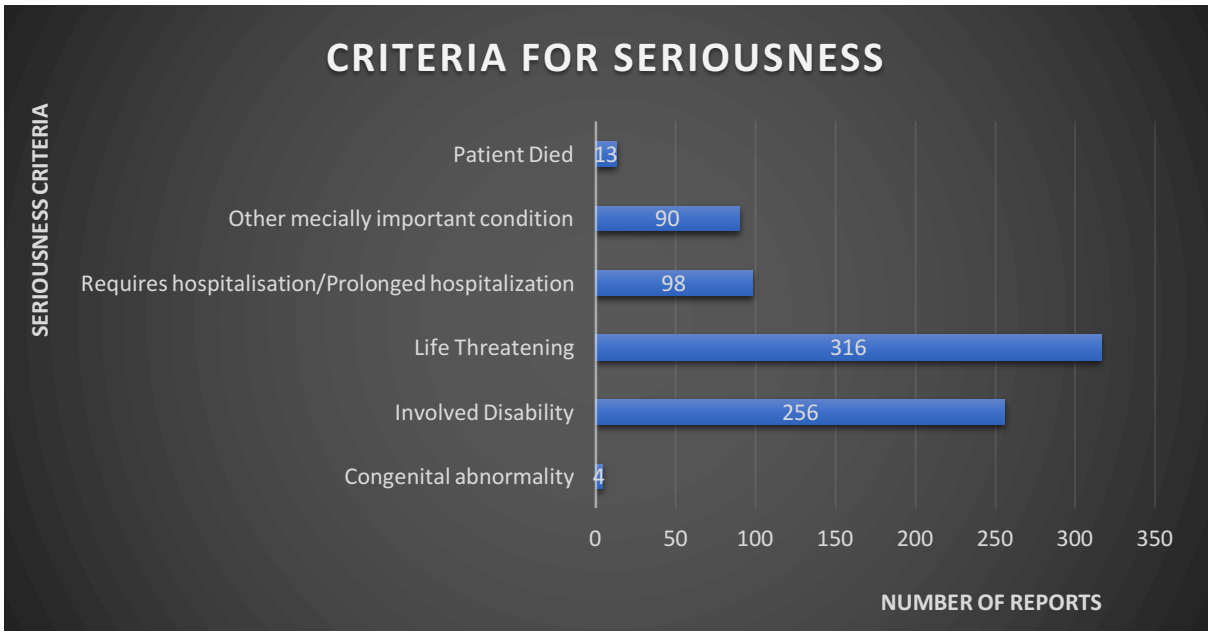


Figure 8: shows reasons for categorising reports as serious events

Most reported drugs and preferred terms

Vaccine AEFIs, especially the Covid 19 vaccines AEFIs were the most reported on (n=2,627), followed by the DTG based ART regimen (in total, n=784) and the anti-TB drug regimen Isoniazid/Rifapentine (n=290). The high number of reports can be attributed to the high number of clients exposed to the Covid 19 vaccines in a short time spell and meanwhile the high ART and anti-TB drug ADRs is attributable to the regular scheduled review programs and the massive counseling sessions the HIV and TB clients are taken through, where they are always encouraged to speak up/report any issues regarding their health and medications.

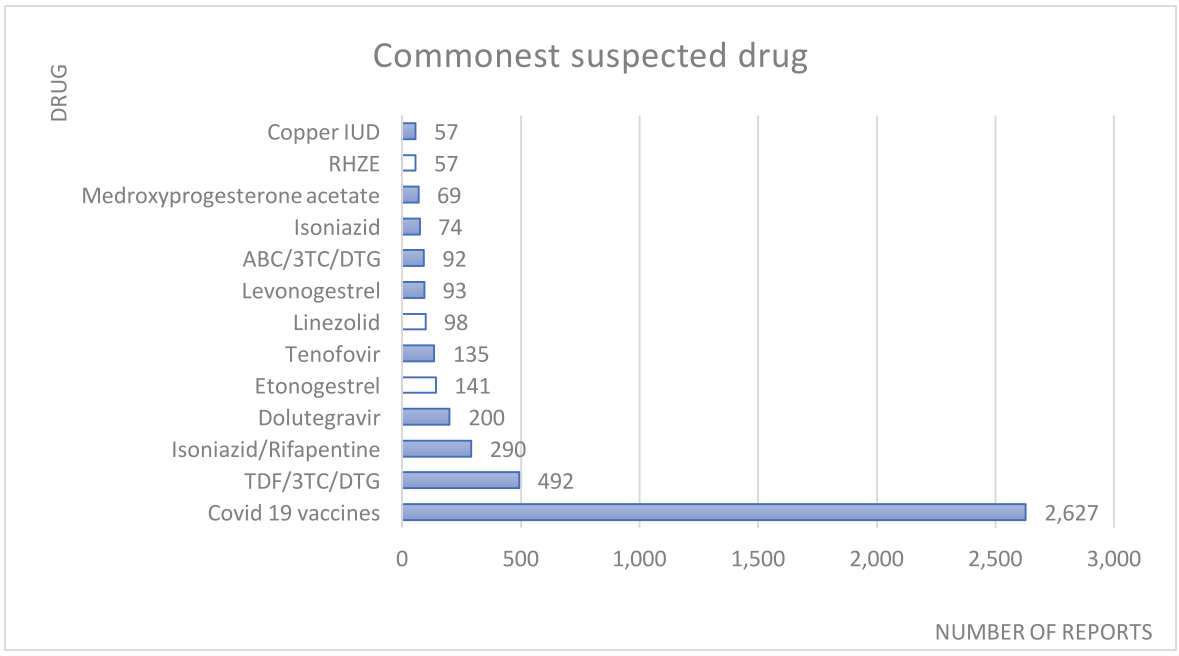


Figure 9: Shows the top 10 most reported drugs

The top most preferred term reported about was generalized body weakness (n=1,417), followed by head ache (n=864), then injection site pain (n=631) and closely followed by fever (n=612). These were symptoms commonly observed in the Covid 19 vaccine recipients.

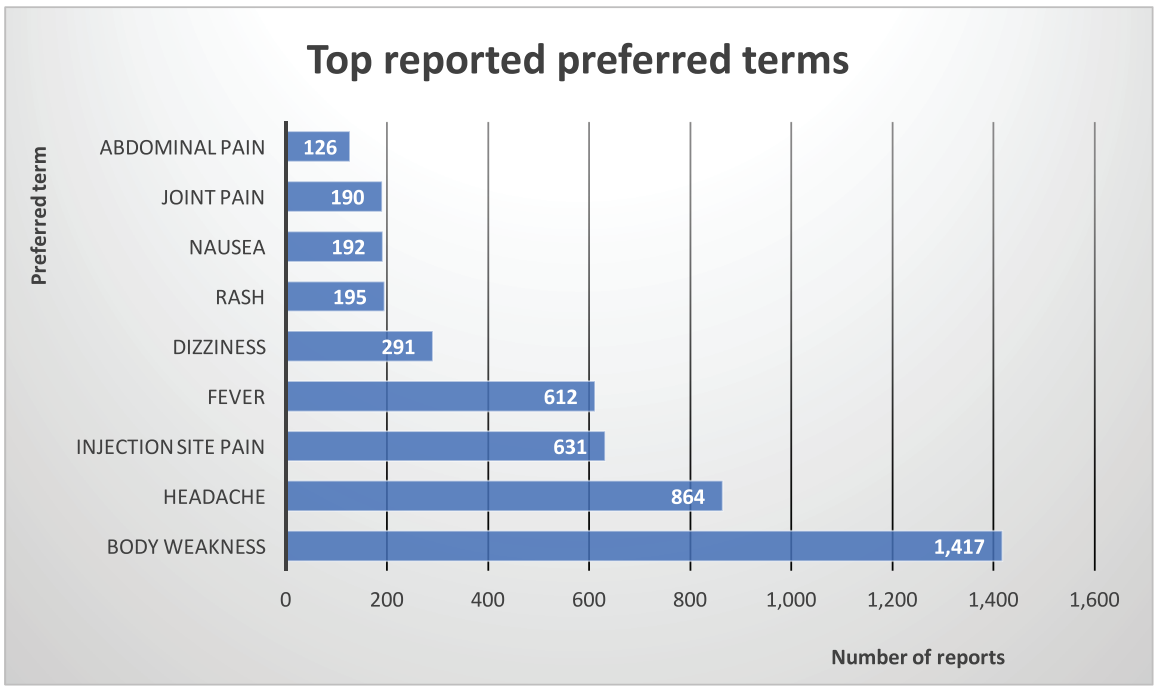


Figure 10: Shows the most reported preferred terms reported

HIGHLIGHTS OF SAFETY SIGNALS DETECTED IN UGANDA

The reports submitted to NDA are drawn from our database and analysed for indicators, patterns, trends or signals of potential risks with particular medicines. Below we describe some signals that were identified from the data received from 1st July, 2021 to 30th June, 2022: The description of a drug as potentially having a given risk doesn't mean that NDA has concluded that the drug has the listed risk. It means that we have identified a potential safety issue, that could be either confirmed or refuted with further investigations and evaluation of the casual relationship between the drug and the risk identified. If confirmed, a number of actions would be taken, including requiring changes to the labeling of the drug, restricting use, requiring development of Risk Management Plans (RMPs), or gathering additional data to better understand the risk.

NDA reiterates that by describing signals, we are not suggesting that healthcare providers should not prescribe the drug or that patients taking the drug should stop the medication. Patients who have questions about the use of the identified drug should contact their health care provider.

There were two important safety signals identified from the ADR reports in this year as described below:

1 Fatal anemia associated with Linezolid:

Case reports were received this term suggestive of fatal anaemia among six (06) MDR-TB patients treated with linezolid. Causality assessment for the drug–reaction pair corresponded to possible association, and some of the cases were supported by positive laboratory tests for anaemia with plausible temporal association.

Further assessment of the cases revealed that the 6 cases demonstrated an average time to onset (time between the initiation of linezolid and the onset of severe anaemia) of 6 months.

Notwithstanding, the reaction could be explained by other concomitant anti-TB medicines which are associated with anaemia and the presence of HIV disease in all but one patient—which is known to affect the bone marrow and thus cause anaemia.

The cases were noted among MDRTB patients taking linezolid for a relatively long period and these reports came from different health facilities, hence demonstrated consistency in occurrence of adverse events.

In conclusion, fatal anemia associated with Linezolid was a possible signal which however needed further follow up and more information for it to be either confirmed or refuted.

2 Chromaturia, severe headaches, and decreased appetite associated with Isoniazid/Rifapentine combination therapy

While headaches and chromaturia are a known side effects of both Rifapentine/Isoniazid, the severity and persistence of the headaches reported in this cluster of cases were unusual. Additionally, the patients were also reported to have decreased appetite which is a new adverse experience among patients on Rifapentine/Isoniazid combination therapy. The fact that these events were not reported among patients taking Isoniazid alone prior to

the introduction of rifapentine could point to an interaction between the two or an adverse outcome of rifapentine alone or just under reporting. Nonetheless, more information is needed to better characterise this signal.

In summary

For all the signals discussed above, NDA continues to investigate them as there is currently inadequate information to fully characterize them to guide risk mitigation measures. We encourage healthcare workers to be on the lookout for any new information about these potential adverse drug related effects and report promptly to NDA.

GOOD PHARMACOVIGILANCE PRACTICES (GVP) INSPECTIONS PILOTED

The GVP inspections are conducted to assess the capacity of the marketing authorization holder`s pharmacovigilance system to monitor, and manage adverse risks associated with their drugs. This is done through an evaluation of the systems compliance to Good Pharmacovigilance Practices (GVP) and the legal provisions.

The goal of these inspections is to ensure that pharmacovigilance processes, (including ADR reporting, data collection, signal detection, and risk management), are effectively implemented and monitored by these companies.

In this financial year, NDA conducted its first GVP inspections. Implementation of GVP inspections by NDA marks a significant milestone in pharmacovigilance in Uganda. This is instrumental in building the capacity of the pharmaceutical companies in the country to establish effective pharmacovigilance systems. Additionally, it grows our team`s competence to conduct GVP inspections.

By strengthening the pharmacovigilance infrastructure, the NDA is poised to enhance drug safety surveillance, promote timely reporting of ADRs, and ultimately protect the health and well-being of the Ugandan population.

NDA piloted GVP inspections in four (04) marketing authorization holders as listed below. More GVP inspections shall be conducted in the coming FYs.

No	MAH	LTR Inspection Site
1	Norbrook	Norbrook Uganda Limited. Plot 703 Banda, Jinja Rd.
2	Abbvie (Pty) Ltd.	Abbvie (Pty) Limited
3	Intas Pharmaceuticals Ltd.	Norvik Limited
4	Eli Lilly (SA) Pty Ltd.	LABOREX Uganda

From these inspections, it was observed that the global PV systems were effectively implemented. Conversely, the local systems still needed further guidance and support to set up the needed structures. The teams inspected had inadequate resources, and facilities to conduct PV activities and there was general understaffing which needs to be addressed.

PHARMACOVIGILANCE SENSITIZATION AND SUPPORT SUPERVISION VISITS CONDUCTED IN 2022/23

Routine pharmacovigilance sensitizations and support supervision visits are aimed at enhancing the knowledge and skills of our pharmacovigilance stakeholders. This is key for timely identification, evaluation, documentation and reporting of adverse drug reactions to NDA. Through interactive sessions, health care workers in different health facilities across the country are engaged to emphasize the need and importance of medicines safety monitoring as well as the ADR reporting channels.

During these sensitization sessions, reporting tools, and pharmacovigilance IEC materials such as posters with safety information and reporting channels/contacts, are issued. All this is done to increase pharmacovigilance awareness amongst healthcare workers in order to enhance promote safety reporting.

We were able to reach out to a total of 762 health facilities including 106 private drug outlets, sensitizing 4,182 healthcare workers

Figure 11: NDA team sensitizing healthcare workers

PHARMACOVIGILANCE TRAINING IN TRAINING INSTITUTIONS

In a bid to "capture them young, and build the culture of drug safety monitoring," we initiated the idea of conducting pharmacovigilance sensitizations/trainings in medical training institutions.

This aims to ensure an early exposure to the concept and relevance of pharmacovigilance for the various categories of personnel engaged in the care of patients. This exposure sensitizes the health professionals early in their career to issues regarding the safety of medicines and is an essential step in enhancing integration of medicine safety reporting within the health-care delivery system.

In the concluded FY, we conducted trainings in 08 medical training institutions, reaching out to 1,031prospective healthcare workers. The schools reached were; (Mbale, Jinja, Mukono diocese, Luweero, Soroti and Double-Cure schools of nursing) and 03 universities (Makerere, Lira and Kampala International universities).

Figure 12: Manager PV poses for a photo moment with staff of KIH after training

Figure 13: Pharmacovigilance training at Mukono Diocese school of Nursing and Midwifery

Additionally, we conducted five (5) training of trainer's sessions, three (03) Continuous Professional Development (CPDs) trainings with Uganda Medical Association (UMA), PSU and Uganda Dental Association (UDA) and four (04) trainings of Village Health Teams, reaching to a total of 52 VHTs.

PHARMACOVIGILANCE WEBINARS

The NDA in conjunction with the Pharmaceutical Society of Uganda (PSU) conducted a series of virtual pharmacovigilance webinars in a bid to widen the pharmacovigilance sensitization/training scope. These webinars were designed to target mainly pharmacists and pharmacy interns.

The purpose of these webinars was to refresh pharmacist's understanding of Pharmacovigilance and its applications in the different fields of pharmacy practice, with the hope that it will influence pharmacists to be at the forefront in drug safety monitoring.

In total, five (05) webinars were conducted, with a total viewership of 829 participants. Different aspects of pharmacovigilance (PV) in research, vaccine pharmacovigilance, PV in industry setting, PV in hospital/clinical setting were discussed during the webinars. The efficiency afforded by the use of this online platform as noted from participant feedback was a big lesson from this initiative that we hope to carry forward.

CAPACITY BUILDING OF PHARMACOVIGILANCE STAFF; - THE UMC EXPERIENCE OF CAUSALITY ASSESSMENT AND SIGNAL DETECTION

The Uppsala Monitoring Centre (UMC) is a WHO collaborating center (CC) for international drug monitoring whose purpose is to carry out the operational activities of the Program for International Drug Monitoring (PIDM) as laid out in an agreement between the WHO and the government of Sweden. The UMC, in its capacity as a WHO CC, maintains the WHO global database of individual case safety reports (ICSRs), VigiBase, develops tools and engages in PV research, trains members of the organizations participating in WHO PIDM and provides them with the relevant tools to collect, manage and analyze PV data.

NDA had the privilege to collaborate with the UMC and have two (2) of its Inspectors of Drugs trained by the pharmacovigilance experts, on causality assessment and signal detection. The UMC imparted valuable knowledge to the NDA inspectors on different methods for signal detection, including data mining techniques, signal evaluation criteria, and the utilization of pharmacovigilance databases.

With this training, the inspectors were empowered to proactively detect emerging safety signals and facilitate prompt remedial actions to protect public health.

WORLD PATIENT SAFETY DAY 2022 COMMEMORATION HIGHLIGHTS

World Patient Safety Day provides an opportunity to emphasize the importance of patient catered healthcare and the issues that affect patients. In monitoring the safety of drugs, patients and their

caregivers are pivotal in reporting any adverse effects they experience during medication use. Their active involvement enables pharmacovigilance systems to gather comprehensive data, leading to better understanding and management of medication-related risks.

Ministry of Health took the lead role in organizing the week-long commemoration activities, which were held at the ministry headquarters in Kampala. The National Drug Authority, World Health Organization-Uganda, Community Health and Information Network (CHAIN), Japan International Cooperation Agency (JICA) and other stakeholders also supported the these awareness events.

Odipiyo Francis, Inspector of Drugs interacting with Hon. Hanifah Kawooya Bangirana; State Minister for Health in charge of General Duties, as MOH officials look on

Dr. Helen B. Ndagije, Director Product Safety delivering speech during World Patient Safety day commemoration at MOH headquarters in Kampala

The global theme for the year's World Patient Safety commemoration set by the World Health Organization was *"Medication without harm,"* which was aimed at reminding healthcare workers to ensure a wholistic healthcare with no harm to the care receiver. Patients and caregivers on the other hand were urged to ensure correct use of medicines in order to minimize or prevent some of the medicine associated harm.

Community Health and Information Network (CHAIN) in collaboration with JICA and NDA organized a community outreach at Namulonge HC III, with various activities such as blood donation, and health exhibitions to mark the day.

ANNUAL PHARMACOVIGILANCE STAKEHOLDERS MEETING

To monitor drug safety, NDA coordinates the national pharmacovigilance system through which adverse drug events and any other medicine related problems can be monitored, documented and reported to NDA for mitigation and preventive actions. The effectiveness of this system depends of several stakeholders including health workers that detect and report drug adverse outcomes, drug manufactures, ministry and public health programs that guide medicines policy.

On an annual basis, NDA organizes a stakeholder feedback meeting that reports on the safety experience observed, emerging safety signals, and discusses key action areas for enhancement of pharmacovigilance in the country.

The 6th annual pharmacovigilance stakeholders meeting was held this year under the theme, *"Holistic approach to medication without harm", a theme chosen to emphasize the need for all health specialties to contribute to drug safety across the health system.*

The meeting drew 134 participants from different disciplines, including officials from the ministry of health, health professionals, MAHs, hospital directors and/or representatives thereof, representatives from national public health programs, implementing partners, local technical representatives/ distributors of pharmaceuticals among others.

As is usually the culture, the event was crowned with appreciations and awarding of pharmacovigilance stakeholders with outstanding performance during the year. These awards are a token of appreciation for their exceptional contribution to pharmacovigilance and are critical in boosting stakeholder morale. The different fields awarded were;

Winner	Award
Falisy Lule	Top reporting health worker for 2020-2021
John Lukoma	1st runner up reporting health worker for 2020-2021
Christine Takan	2nd runner up reporting health worker for 2020-2021
Kiruddu National Referral Hospital	Top national referral Hospital
Mbarara Regional Referral Hospital	Top reporting regional referral hospital

Winner	Award
Kayunga General Hospital	Top reporting general hospital
Kitebi Health Center III	Top reporting Health Center
Habib Hussein	Top legacy reporter

Figure 14: Photograph moment of the awardees with guest of honor and NDA officials

LOCAL SAFETY LABEL UPDATES

Over the FY, a number of safety updates or changes were made on the product labels resulting from the various safety monitoring activities at different levels.

A total of 69 safety updates were made on medicinal products locally available to the Ugandan population. Details of safety label variations/changes throughout the year are presented below;

Product Name	License Holder	Summary of Approved Changes
Dolutegravir sodium (Tivicay®)	Glaxosmithkline Pharmaceutical Kenya Ltd	The frequency of the adverse event of increased weight has been revised from uncommon (one in a thousand) to common (one in a hundred).
Maraviroc (Celsentri®)	Glaxosmithkline Pharmaceutical Kenya Ltd	Under the warning and precautions section, the transmission risk statement has been removed to reflect current information
Dolutegravir sodium (Tivicay®)	Glaxosmithkline Pharmaceutical Kenya Ltd	Update to the pregnancy and lactation sections of the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) of Tivicay to include new information following the DolPHIN-1 study, that DTG (within Tivicay) can be transferred via placenta and breast milk
Dapaglifozin (Forxiga®)	Astrazeneca Pharmaceuticals Lp	Update to the section on special warnings and precautions for use - Chronic kidney disease: There is no experience with dapagliflozin for the treatment of chronic kidney disease in patients without diabetes who do not have albuminuria
Abacavir sulfate + Lamivudine (Kivexa®)	Glaxo Operations UK Ltd	Excipients - KIVEXA tablets contain sunset yellow Aluminium lake (E110) which may cause allergic type reactions
Dolutegravir 50 mg/Rilpivirine 25 mg (Juluca®)	GlaxoSmithKline Pharmaceutical Kenya Ltd	Adverse drug reactions: The frequency of occurrence of the event of weight gain has been revised from uncommon (1 in 1000) to common (1 in 100)
Diclofenac sodium (Voltaren®)	Norvatis Pharma Stein Ag	Update to section 9: Pregnancy, lactation, females and males of reproductive potential: If an NSAID is necessary from the 20th week gestation to the end of the 2nd trimester, limit the use to the lowest effective dose and shortest duration possible. If Voltaren treatment extends beyond 48 hours, consider monitoring with ultrasound for oligohydroamnios. If oligohydroamnios occurs, discontinue Voltaren and follow up according to clinical practice

Product Name	License Holder	Summary of safety changes
Tamoxifen (Novadex®)	Astra Zeneca UK Ltd	A warning on toxic epidermal necrolysis and a risk of exacerbation of hereditary angioedema with tamoxifen. The adverse reaction of 'Depression' and 'toxic epidermal necrolysis' with a frequency of rare and exacerbation of hereditary angioedema with a frequency of not known under section 4.8.
Insulin Lispro (Humalog®)	Eli Lilly Export S.A	Additional text regarding patients not sharing needles, information on reporting of adverse drug reactions; replacing information regarding use of Humalog with a pump infusion set.
Zolendronic acid (Zometa®)	Norvatis Pharma Services Inc	The infertility section was updated to clarify that fertility is decreased in rats dosed subcutaneously with 0.01 mg/kg/day of zolendronic acid. There are no data available in humans.
Dolutegravir Sodium+Rilpirivine Hydrochloride (Juluca®)	GlaxoSmithKline Pharmaceutical Kenya Ltd.	Update 1: TSC 3-Sections: Pregnancy and Lactation - Update to include human data on transfer of DTG via placenta and breast milk based on the population pharmacokinetic analysis of the DolPHIN-1 study. Dolutegravir readily crosses the placenta in humans. In HIV infected pregnant women, the median (range) of foetal umbilical cord concentrations of dolutegravir were 1.28 (1.21 to 1.28) fold greater compared with maternal peripheral plasma concentrations. There is insufficient information on the effects of dolutegravir on neonates.
Zinc chloride + denatured alcohol menthol 95% + thymol (Tartar Control Listerine® Antiseptic)	Johnson & Johnson Pty Ltd	Section 4.6: Fertility, pregnancy and lactation: There are no adequate and well-controlled studies in pregnant women. However, because with recommended use only small volumes of Tartar Control Listerine® Antiseptic would be expected to be swallowed, it is considered unlikely that the recommended use of Tartar Control Listerine® Antiseptic will present a risk to the pregnant woman or foetus. It is not known whether Tartar Control Listerine® Antiseptic is excreted in human breast milk. However because with recommended use only small volumes would be expected to be swallowed, it is considered unlikely that the recommended use will present a risk to the infant.

Product Name	License Holder	Summary of safety changes
Desloratadine (Aerius®)	MSD (Pty) Ltd	Update of section 4.8 of the SmPC to reflect increased incidence of new onset seizure in patients 0 to 19 years.
Tramadol hydrochloride + Paracetamol (Tramapa Fort®)	Ferrer International	4.4. Special warnings and precautions for use: Sleep related breathing disorders - Opioids can cause sleep-related breathing disorders including central sleep apnoea (CSA) and sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose dependent fashion. In patients who present with CSA, consider decreasing the total opioid dosage.
Clopidogrel (Clopidogrel Norvatis Access®)	Sandoz NVS Kenya	SmPC and PIL update for section 4.4; "Special warnings and precautions for use" following update of the same to the innovator product.
Levonogestrel (Mirena®)	Bayer East Africa Ltd	Update of the paragraph on expulsion in section 4.4 (special warning and precaution for use) of Mirena SmPC with respect to factors associated with an increased risk of expulsion.
Capecitabine (Sandoz® Capecitabine)	Sandoz GMBH Kenya	Update of core data sheet to include angioedema among the adverse drug reactions under section 4.8.
Loperamide HCL (Imodium®)	Janssen-Cilag Pharmaceutical (Pty) Ltd	Overdose: Upon cessation, cases of drug withdrawal syndrome have been observed in individuals abusing, misusing or intentionally overdosing with excessively large doses of Loperamide.
Dolutegravir sodium (Tivicay®)	GlaxoSmithKline Pharmaceutical Kenya Ltd.	Update of safety information to include human data on transfer of DTG via placenta and breast milk based on the population pharmacokinetic analysis of the DolPHIN-1 study in sections; before you (take/use), product, pregnancy and lactation and ATC code update.
Darunavir (Prezista®)	Janssen-Cilag Pharmaceutical (Pty) Ltd	SmPC Section 4.5 update: Added text to address co-administration of cutaneously administered corticosteroids sensitive to CYP3A inhibition.

MEDIA ENGAGEMENTS

The NPC annually engages the mainstream media with the aim of enhancing the public`s awareness on the importance of monitoring and reporting adverse drug events.

In the this year, one (01) radio talk show on 91.2 Crooze FM and 01 TV talk show on NBS TV were held. Additionally, we ran SPOT radio informercials in local languages on selected radio stations across five regions in the country for one month (i.e. Arua one FM in Arua, Radio West in Mbarara, Spice FM in Hoima, Busoga one FM in Jinja and Rupiny radio in Gulu.

LIST OF FACILITIES THAT SUBMITTED ADR/AEFI REPORTS TO NPC

DIRECT PATIENT REPORT	2387
MBARARA RRH	566
MILDMAY HOSPITAL	300
MJAP MULAGO	230
LIRA RRH	195
KIRUDDU NR HOSPITAL	170
JINJA RRH	157
BUTABIKA NR HOSPITAL	125
LUWEERO HOSPITAL	122
KAYUNGA RRH	68
TASO MASAKA	58
SOROTI RRH	53
KAWOLO GENERAL HOSPITAL	37
IDI MULAGO	34
KABALE RRH	34
MBARARA MUNICIPAL CLINIC HC IV	30
BAYLOR	28
FORT PORTAL RRH	24
KALANGALA HC IV	23
FREDA CARR HOSPITAL	20
MBALE RRH	20

MULAGO NATIONAL REFERRAL	18
KAWEMPE HOME CARE	12
MASAKA RRH	11
UGANDA CARES MASAKA	11
KITOVU HOSPITAL	11
HOIMA RRH	10
MJAP NAMUTUMBA HC III	10
MRC/UVRI	9
BWIZIBWERA HC IV	7
NEBBI HOSPITAL	7
MUBENDE RRH	7
BUKEDEA HC IV	6
MYLANLABS	6
MOROTO RRH	6
ARUA RRH	6
MRC UVRI	5
ST BALIKUDDEMBE UG CARES	5
ABIM HOSPITAL	5
KATAKWI GENERAL HOSPITAL	5
IDC MBALE	5
KITEBI HC III	5
ECOPHARM KIBUYE	4
KABWOHE HC IV	4
KASANGATI HC IV	4
OMUGO HC IV	4
UGANDA CARES KAMPALA	4
UGANDA CARES RAKAI	4
KAWAALA HC III	4
AMURIA GENERAL HOSPITAL	4
MULANDA HC IV	3
MRC LSHTM	3
RAKAI HOSPITAL	3
PATIENT REPORT	3
ENTEBBE HOSPITAL	3
QUEENYING MEDICAL CENTER	3
YUMBE RRH	3
ST LUKE BUJUNI HC III	3
TASO RUKUNGIRI	3
KAGADI GENERAL HOSPITAL	3
MRC/UVRI AND LSHTM - MASAKA RRH	3
KAMBUNGA HOSPITAL	2
BKI PHARMACY	2
MITYANA GENERAL HOSPITAL	2

ST FRANCIS COMMUNITY HOSPITAL	2
ARUA POLICE HC III	2
KISENYI HC IV	2
REACHOUT MBUYA	2
NABALANGA HC III	2
KASHEKYE HC III	2
MT ST MARY'S HOSPITAL	2
KASEREM HC III	2
ADJUMANI HOSPITAL	2
AIDS INFORMATION CENTER	2
KINONI HC IV	2
YERYA HC III	2
ST MARYS HC III KIGUMBA	2
BUYINDA HC III	2
MUST	2
BUSOWOBI HC III	2
KOBOKO HOSPITAL	2
BUDUDA HOSPITAL	2
GOMBE HOSPITAL	2
YUMBE HC IV	2
MOYO GENERAL HOSPITAL	2
ARUA PRISON HC III	2
RUBAGA HOSPITAL	2
KITAGATA GENERAL HOSPITAL	2
OLI HC IV	2
AHF / UG CARES	2
MAGALE HC IV	2
ECOPHARM	2
IDI Nebbi	2
KYANGENYI HC III	2
DIRECT PATIENT REPORT`	1
LUWERO HOSPITAL	1
BUGEMBE HC IV	1
ABBVIE PHARMA	1
GILEAD	1
KYARUSOZI HC IV	1
MIDAS PHARMACY	1
WABUSANA HC III	1
APAPAI HC IV	1
KOJJA HC III	1
TOROMA HC IV	1
OPV	1
EMESCO HC III	1
KMWEZI HC IV	1

CASE HOSPITAL	1
KIYEYI HC	1
BUKINDA HC III	1
KITWE HC IV	1
ATUTUR HOSPITAL	1
KITUNJO TOWN COUNCIL	1
ALEBTONG HC IV	1
ST. FRANCIS HEALTH CARE SERVICE	1
MRC/UVRI/LSHTM - MASAKA RRH	1
ST. FRANCIS HC IV NJERU	1
GULU RRH	1
KITAGATA HOSPITAL	1
RYEISHE HC III	1
NIAM PHARMACY	1
ZEU HC III	1
NGORA FREDA CARR HOSPITAL	1
DESTINY CLINIC	1
ST MARYS HOSPITAL	1
MILDMAY UGANDA	1
NDA	1
BULISA HEALTH CENTRE IV	1
KIMENYEDDE HC II	1
MCR/UVRI/LSHTM - MASAKA RRH	1
KIGANDALO HC IV	1
TALEMWA PHARMACY	1
KAZO HC IV	1
MASINDI HOSPITAL	1
NAZIGO HC III	1
PAJULU HC III	1
NAMUTUMBA HCIII - MJAP	1
LYANTONDE HOSPITAL	1
NAMUTUMBA HC III	1
LUKAYA HC III	1
NAKASONGOLA PRISON HC III	1
ST CATHERINE HOSPITAL	1
KATIKAMUM HC III	1
HOIMA PRIONS HC III	1
KATIKAMU HC III	1
VILLA MARIA HOSPITAL	1
UGANDA CARES LUKAYA	1
SHUUKU HC IV	1
KASHEKYE HC III,	1
RUSHERE COMMUNITY HOSPITAL	1
ST LUKE HC III BUJUNI	1

RUHUMURO HC III	1
MUWAFU PS	1
DONAU DENTAL CENTER	1
UHUNGA HC II	1
MITYANA HOSPITAL	1
KASANGA PHC	1
COMBONI HOSPITAL	1
KAMWEZI HC IV	1
TASO Masindi COE	1
KAMPALA INTERNATIONA UNIVERSITY TEACHING HOSPITAL	1
UNKNOWN	1
MURCHISON BAY PRISON HOSPITAL	1
BUSHENYI PRISONS HC III	1
ST FRANCIS HOSPITAL NSAMBYA	1
BULIISA HEALTH CENTRE IV	1
KAKINDU HC IV	1
BUKIINDA HC III	1
KAKIIKA PRISONS HC II	1
BUGIRI HOSPITAL	1
KAGOTE HC III	1
TASO ENTEBBE	1
KAGANDO HOSPITAL	1
ST. FRANCIS HEALTH CARE SERVICE, NJERU	1
MULANDA HC III	1
MASINDI MILITARY HOSPITAL	1
ST FRANCIS HOSPITAL NAGGALAMA	1
MASINDI GENERAL HOSPITAL	1
KABUSHAHO HC III	1
ANGEL HOSPITAL	1
TORORO PRISON HC III	1
ALLUSTIN HC III	1
ST ELIZABETH MAGALE HC IV	1
PAJULO HC III	1
JINJA MAIN PRISON HC III	1
ADUKU HC IV	1
JCRC	1
ORIAJIN HC IV	1
ITOJO HOSPITAL	1
MRC/UVRI/LSHTM-MASAKA RRH	1
KYEHORO HC III	1
(blank)	
Grand Total	**5,077**

REPORTING PER DISTRICT

Kampala	956
Mbarara	661
Wakiso	535
Lira	225
Jinja	212
Luweero	168
Masaka	158
Kayunga	100
Soroti	86
Mbale	85
Mukono	79
Buikwe	76
Kabale	60
Kabarole	48
Isingiro	47
Tororo	43
Ntungamo	40
Mayuge	38
Arua	35
Kasese	33
Hoima	33
Mubende	31
Bugiri	28
Bushenyi	27
Kalangala	26
Kyegegwa	26
Iganga	26
Gulu	26
Masindi	25
Kagadi	24
Kamuli	24
Namutumba	24
Kamwenge	23
Kanungu	23
Sembabule	22
Mpigi	21
Mityana	21
Rukungiri	20
Rakai	20

TEREGO	20
Kiruhura	20
Nebbi	19
Namayingo	19
Katakwi	18
KAKUMIRO	18
Yumbe	18
Adjumani	18
Bukedea	18
Ngora	17
Kibaale	17
Kiryandongo	16
Mitooma	16
Bulambuli	16
Nakasongola	16
Ibanda	15
Serere	15
Kumi	15
Kalungu	15
Kyankwanzi	15
Budaka	15
Kassanda	15
Sheema	14
Amuria	14
Buhweju	14
Pallisa	14
KIKUUBE	13
Kyotera	13
Lwengo	13
Kaliro	13
Kisoro	13
Bukomansimbi	12
Buyende	12
Luuka	12
Gomba	11
Zombo	11
Agago	11
Manafwa	11
Kyenjojo	11
Nakaseke	11

Kaberamaido	10
Bugweri	10
Pakwach	10
Buliisa	10
Kiboga	10
BUNYANGABU	10
Namisindwa	10
Rukiga	9
Butaleja	9
Bududa	9
Buvuma	9
Butambala	9
kitagwenda	9
Apac	9
Abim	9
Koboko	9
Moyo	8
Sironko	8
Lyantonde	8
Moroto	8
Kazo	8
Amolatar	8
Oyam	7
Rubirizi	7
Omoro	7
Rubanda	7
Dokolo	7
Kapchorwa	6
Rwampara	6
Busia	6
Ntoroko	6
Bundibugyo	6
Kole	6
Alebtong	5
Butebo	5
Bukwo	5
Kitgum	4
Lamwo	4
Pader	4
Kibuku	4

Nwoya	4
Amuru	3
Kween	3
Kwania	3
Maracha	2
Kasanda	2
Kalaki	2
Kotido	2
Kapelebyong	2
Kaabong	1
Madi-Okollo	1
Nakapiripirit	1
Napak	1
Grand Total	**5,077**

NOTES

NOTES

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