Safe Drugs Save Lives

NATIONAL DRUG AUTHORITY

PHARMACOVIGILANCE ANNUAL REPORT

JULY 2019 – JUNE 2020

Message from the Secretary to the Authority

The Mission of the National Drug Authority is to promote and protect public health through the effective regulation of human, and animal medicines and healthcare products.

NDA has taken tremendous steps to strengthen pharmacovigilance to monitor the safety of medicines as enshrined in its mandate of ensuring safe, effective and quality medicines and health care products in Uganda. This year, the Authority has invested itself in automation of drug monitoring through mobile ADR reporting technology, improving the guidance framework on existing drug safety laws and improving stakeholder involvement and awareness.

These efforts have led to an increase in a 60% increase in the adverse event reporting rates, a number of risk management actions including recalls, health care safety communications, and updates to treatment guidelines, and product labels.

The Agency will continue to seek safety information from healthcare providers, patients, and pharmaceutical companies as a means of continued appraisal of the safety of drugs in Uganda, and to take appropriate measures where adverse drug experiences occur.

Much as the COVID-19 pandemic presents unprecedented challenges, the National drug Authority has been able to achieve its milestones in the reporting period.

I extend my sincere appreciation to the Ministry of Health, implementing partners, healthcare providers and the public for the continued support towards the pharmacovigilance cause. I Pledge to regularly report on the Authority's performance as a principle of transparency and accountability.

Dr. David Nahamya

Secretary to the Authority.

For God and my country

Foreword

Dr. Helen Byomire Ndagije

Medicine regulation incorporate several mutually reinforcing activities all aimed at promoting and protecting public health. Pharmacovigilance as one of the regulatory function, is a science that relates to detection, assessment, understanding and preventing of adverse reactions to medicines or any other drug related problems.

Medicines bring widespread benefits for patients and the public but no product is free of risk. Many decisions involve weighing risks of harm against the likelihood of benefits. If a product is available for use, its risks must be acceptable in relation to the potential benefits to patients and users. Some risks are known when a product goes on the market but others will only become known later when it is widely used, especially if adverse events are rare. National drug authority has established systems for monitoring the occurrence of drug reaction by collecting individual case safety reports, collating the data and then providing information and warning to healthcare providers. The aim has been to promote awareness of possible adverse reactions in all therapeutic fields and assist in early recognition of reactions.

This report summarizes the activities that were carried out between July 2019 and June 2020 in order to realize the key pharmacovigilance processes which provide a contribution to the overall strategic objectives of NDA of ensuring safe, efficacious and quality medicines.

In the Financial year 2019 /2020 we registered a 69% increase in the number of adverse drug reaction reports received in comparison to the previous year. In addition, several trainings and awareness campaigns were undertaken as well as collaborative activities with various stakeholders.

There is still room for growth and NDA is committed to promoting pharmacovigilance to enhance patient safety and to increase the number of reported ADRs.

I want to thank all stakeholders for supporting this noble cause.

Thank you.

Director Product safety

Victoria Nambasa,

Manager Pharmacovigilance

Acknowledgement

I wish to acknowledge the team that works tirelessly and unreservedly to perform all the activities that relate to collection, understanding and communicating the risks that emanate from the drugs used in the country.

Julius Mayengo,
Regulatory Officer

Ian Mugisa,
Regulatory Officer

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Regulatory Officer

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Abbreviations

ADR	Adverse Drug Reaction
AEFI	Adverse Events Following Immunization
AIDS	Acquired Immune Deficiency Syndrome
AMR	Antimicrobial Resistance
EAC	East African Community
EPI	Expanded Programme on Immunisation
ICH	International Committee on harmonization
ICSR	Individual Case Study Reports
IGAD	Inter government Authority on Development
IPT	Intermittent Prophylactic Treatment
KCCA	Kampala Capital City Authority
LMIC	Low and Middle Income Countries
MAK	Makerere University
MSH	Management Sciences for Health
NDA	National Drug Authority
NPC	National Pharmacovigilance Centre
NTLP	National Tuberculosis and Leprosy Program
PIDM	Programme of International Drug Monitoring
PMS	Post Marketing Surveillance
PNFP	Private Not for Profit organizations
PV	.Pharmacovigilance
RPC	Regional Pharmacovigilance Centre
TB	Tuberculosis
TOT	Training of Trainers
UHSC	Uganda Health Supply Chain
UMC	Uppsala Monitoring Centre
WHO	World Health Organization

Highlights of the Year

Launch of the Med Safety app 26th February 2020

Incorporation of Pharmacovigilance in ART Care June 2020

Cioms Patient Forum

The Pharmacovigilance program of Uganda

Genesis

In early 2004, two participants from NDA and MOH who had attended a course in South Africa facilitated by staff from Uppsala Drug Monitoring, Sweden came back with a plan of establishing a Pharmacovigilance Centre in Uganda based in National Drug Authority.

In 2005, with assistance from WHO and MOH, a form to monitor adverse drug reactions was developed and printed. At the same time one member of staff from NDA was sent to Uppsala, Sweden to attend a two weeks course to acquire more knowledge and skills to improve on the implementation of Pharmacovigilance activities in the country.

The National Pharmacovigilance Centre was then established at NDA and the objectives of the Centre were:

a) To coordinate, collect, analyze and evaluate adverse drug reaction reports from the field on human drugs.

b) Promote exchange of drug information with Drug Information Centres within and outside the country.

c) To collaborate with WHO Monitoring Centre at Uppsala, Sweden in matters concerning Pharmacovigilance.

Aim

The major aims of the pharmacovigilance program in Uganda are;

a) Early detection of previously unknown adverse reactions and interactions.

b) Detection of increase in known adverse drug reactions.

c) Identification of predisposing risk factors and possible mechanisms underlying adverse reaction.

d) Estimation of quantitative aspects of risk/ benefits analysis and dissemination of needed information to improve drug prescribing, use and regulation.

Scope

The main fuctions of the National Centre are:

a) Distribute ADR report forms and collect ADR reports from Health facilities.

b) Train and sensitize Health professionals and other stakeholders on the importance of Pharmacovigilance.

c) Analyze, evaluate and maintain database of received adverse drug reactions and medicine related problems.

d) Disseminate relevant information to Health Professionals, Policy makers and other stakeholders.

e) To communicate findings to the originators of ADR reports (Feedback)

f) To participate in the WHO intervention programs on Drug Safety Monitoring

Pharmacovigilance working committee

The Pharmacovigilance activities at the NDA are overseen by a Non-Statutory Committee called the Pharmacovigilance and Clinical Trial Non-Statutory Committee. The Committee has a responsibility for:

a) Providing guidance to the drug Authority on issues concerning pharmacovigilance and clinical trials;

b) Providing guidance on matters related to safety and efficacy of drugs, including herbal medicines;

Pharmacovigilance Strategic plan for the year 2019 - 2023

A Pharmacovigilance strategy was developed to harmonize activities of all partners to reduce duplication, maximize utilization of available resources and adequately leverage on existing structures while focusing on identified common goals.

The strategy is a guide on activities to be prioritised in the next five years. The plan includes

a) Pharmacovigilance technical capacity and infrastructure

b) Policy enhancement

c) Collaborations and information exchange

d) Visibility and awareness

Reporting of adverse events in Uganda

Reporting of ADRs, ADEs, and AEFIs is done using the standard NDA form available on the NDA website, public/ private health facilities and Pharmacovigilance centres. This form tries to collect as much information as possible about the suspected ADRs or medicine problems while being mindful of the health professionals or reporters time. Alternative methods of reporting are provided below:

a) Telephone/WhatsApp line; a reporter can call the National Centre or Regional Centre or send a WhatsApp message.

The essential information is captured or transcribed on to the suspected ADR reporting form for follow-up.

i. Tol Free Line: +256 800 101 999

ii. WhatsApp: on +256 791 415 555

iii. Med Safety mobile app downloaded from Google Play Store for android or the App store for iOS

iv. An online reporting platform available at

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

What to report

All suspected adverse drug reactions on all drugs including vaccines are reportable even if one is not certain that the product caused the ADR. A detailed guideline is available on what needs to be reported, however, a summary of what is expected to be reported is provided below.

a) For "new" drug molecules –all suspected reactions, including minor ones are reportable (drug molecules are considered 'new' if the period following their marketing approval is below ten years, for example; Dolutegravir and Bedaquiline).

b) For well-established or well-known drugs all serious and all unexpected (unusual) suspected adverse drug reactions should be reported.

c) Increased frequency of any given reaction even if known (known may mean expected or previously documented)

d) All suspected adverse drug reactions associated with drug-drug, drug-food or drug-food supplements (including herbal and complementary products) interactions

f) Adverse drug reactions in special fields of interest such as drug abuse and drug use in pregnancy and during lactation.

f) Suspected adverse drug reactions associated with drug withdrawals

e) Therapeutic failure for all drugs (new or old): suspected unexpected lack of efficacy should be reported. The sample (if available) should be attached to the report. Lack of efficacy may imply that either; the medicine is of poor quality, there is an interaction, there is resistance or the product is a counterfeit

h) Products of questionable quality

Annual activity Implementation Summary FY2019/2020

PLANNED ACTIVITY	TARGET	ACHIEVEMENTS
Collection of ADR reports	One thousand (1000) ADRS reports from all the regions	Total: 1824 received
Sensitization and awareness meetings	Pharmacovigilance Sensitization meetings at the 7 NDA regions	Fifteen (15) Sensitizations conducted in Fourteen (14) districts; covered seven hundred and fifty-four (754) drug shops Four hundred and nineteen (419) facilities sensitized in all the 7 regions. (Q1= 12, Q2 =118, Q3= 208, Q4 =81)
Feedback and risk communication	4 quarterlybulletins, ADR summary reports	4 ADR quarterly summary reports and bulletins were developed, and disseminated

Investigations of serious ADRS and AEFIs	Two (2) AEFI committee meetings 2 ADRs and AEFIs investigated and action taken	Six (6) AEFI committee meetings held in the year. Seventeen (17) AEFIs investigated and discussed by the AEFI committee	
		ADRs followed	Action taken
		Isoniazid related liver injury and death	Circular written to healthcare providers to monitor and mitigate risk
		Bupivacaine related adverse event	Recall of the batch implicated
		TEN suspected to be related to measles and Rubella vaccine	Communicated to WHO for further investigations
		Isoniazid related cutaneous adverse reactions	Communicated to MoH
Awareness through media	Four (4) talks, Two (2) newspaper articles, 4 IEC INFORMERCIALS	7 talk shows 1 newspaper article Three (3) Posters developed of which Two (2) were translated in Five (5) languages. Additional promotional materials with messages in 5 different languages (T-Shirts, umbrella, banners, Caps and hampers) were developed to promote PV and the reporting Two (2) infomercials were developed to promote pharmacovigilance and the reporting platforms.	
Stakeholder engagement	1 annual PV meeting 4 CPDs with professional bodies	One (1) stakeholder meeting held on 26th February 2020 in which the med safety app was launched and 36 top reporters were awarded with certificates of recognition Four (4) joint CPDs with UMA on Pharmacovigilance	

Annual ADR Reporting

Overall, there were 1824 reports received in the index year which gives a crude reporting of 44 reports per million population per year, based on an estimated population of 45 million in 2020. This annual reporting brings the total cumulative number of ADRs submitted to the global database to 4696. As shown in figure 1, the number of reports have increased over the 13-year period with highest count recorded in 2019 and 2020.

Annual Trend of ADRs

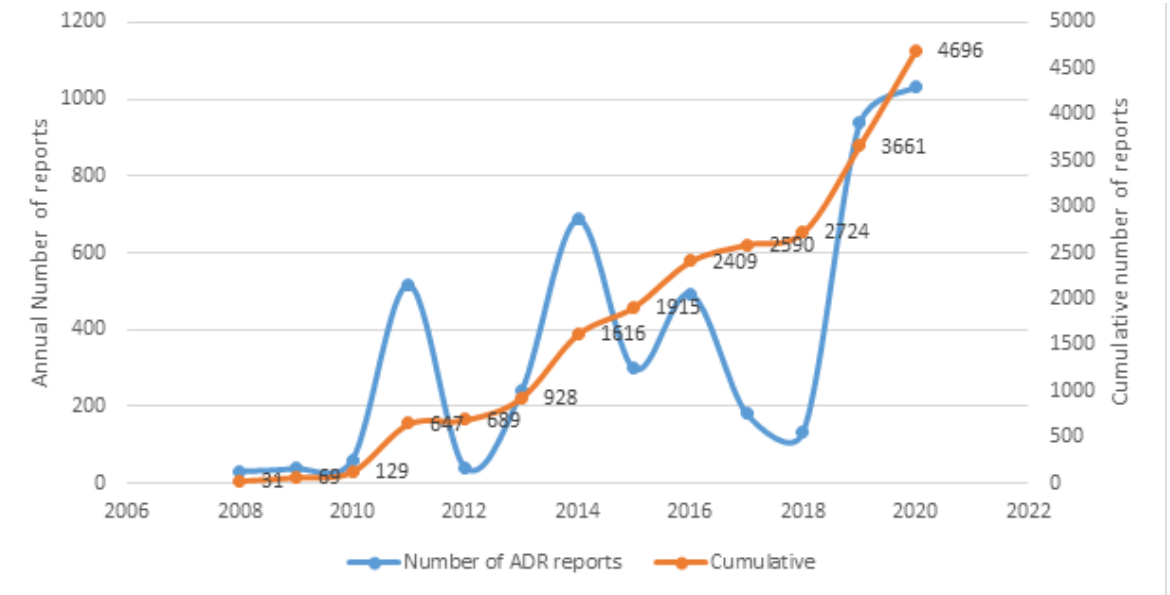


Fig. 1. Annual number of adverse drug reaction (ADR) reports collected over a period of 13 years Uganda National database

Summary of National individual case safety reporting rate

Reporting indicator	Rate /proportion
Reports received per million population per year	43.8
Number of ADRs per 100 000 persons in the population	4.38
Percentage of total reports attributed to therapeutic ineffectiveness received year (9 reports)	0.494%
Number of medicine-related deaths per 100 000 persons in the population (6 deaths recorded)	0.01442877

**expected rate 200 reports /1million inhabitants*

Facility distribution of case reports

The national Pharmacovigilance centre receives reports from health facilities across the country and in various districts. Table 3 provided the percentage contribution of the various health facility based on their levels, while the individual health facility reporting is presented in appendix 2.

Table 1 describes the count of reports by level of facility reporting

Facility level /Establishment	Report count
Regional Referral Hospitals	285
General Hospitals	238
Health Centre IV	92
HCIII	259
HCII	18
Private clinics / health centres	29
Pharmacies	2
UNEPI	88
Specialized ART Clinics (Uganda Cares, MJAP, Baylor, Nsabya Homecare, MUJHU etc.)	380
Pharmaceutical Company	96
Consumer	4
Total	**1,491**

Reporter-type distribution of ICSRs

The centre receives case reports from various stakeholders such as medical doctors, medical clinical officers, nurses, pharmacists, consumers and other health care providers. In general, most of the ADR reports were reported by medical officers (28%), followed by clinical officers (24%), pharmacists (21%), nurses (12%) with least being reported by consumers (figure 2)

The definition of ‘‘other health professionals’’ used in Uganda health system is more comprehensive, and includes: laboratory technicians, records clerks, dental technicians included in national pharmacovigilance system

Reporters by Professional Cadre

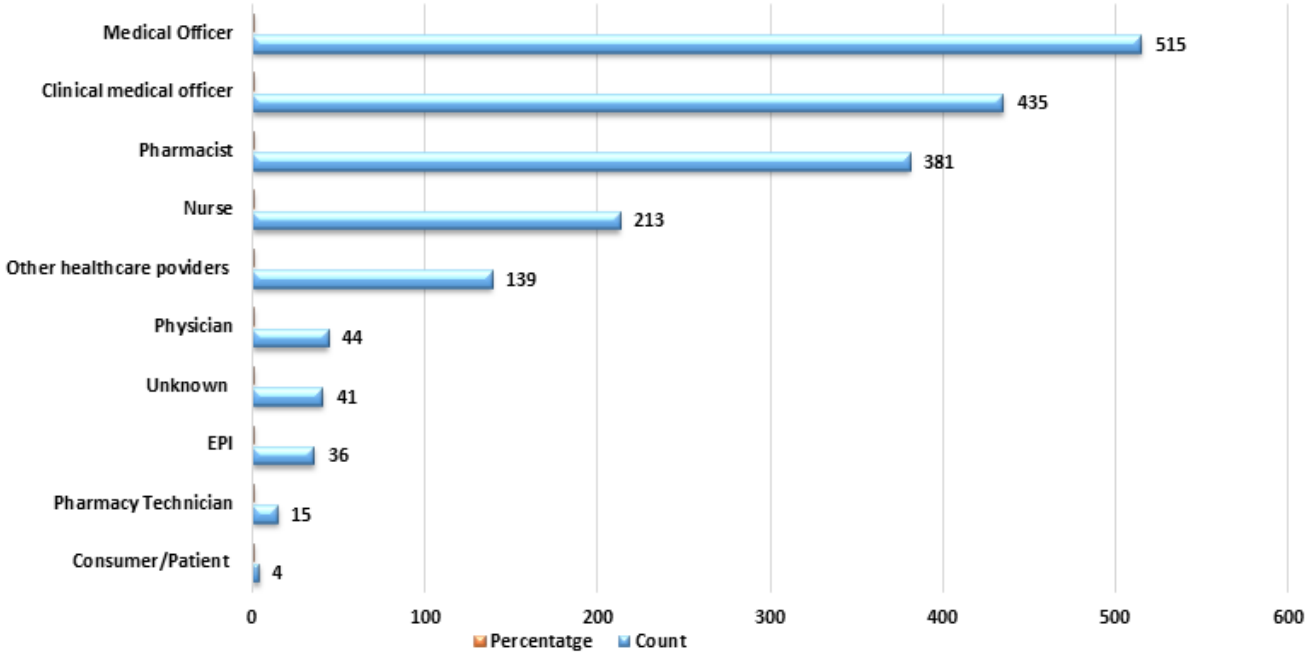


Fig. 2. Reporter distribution by professional cadre

Characteristics of ADR reports

Overall, majority of ADRs (n = 1572; 64%) were reported from females while more than half of the reports were reported as serious (n=1052; 58.0%). Majority of ADRs led to hospitalization (n = 453; 43.2%) and were Life threatening (n=344; 32.8%). Few ADRs reports caused death or a disability (n = 50; 4.8%) and congenital anomalies in the offspring (n = 3; 0.3%). The majority of the ADRs were recovered resolved (n = 920; 39%), were recovering (n = 479; 20.3%) or the outcome was unknown at the time of reporting (n=652; 27.6%).

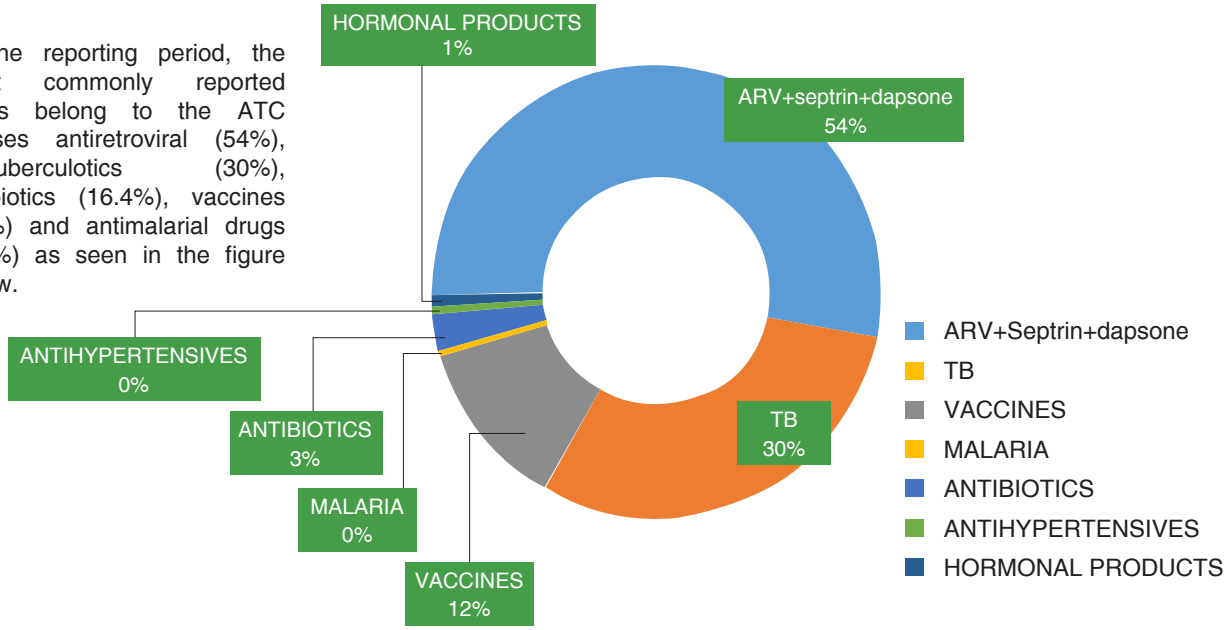
Overall the age distribution shows that most of the adverse drug reaction reports are from patients aged between 35 to 50 years and there are fewer reports from the elderly (above 60 years) and paediatric population Uganda. Stratification by age of patients showed that the highest number of reports were from those aged 25-49 year (n =1323; 56%) followed by 50 years and above (n=346; 14.6) while the reports from children less than 12 years were fewer (11.6%) as shown in table 1.The drug Reaction pairs are presented in the appendix 1

Table 1. Characteristics of ADR reports in the Uganda National Drug Authority pharmacovigilance database, distributed in a year (2019-2020).

Characteristic	Total (N=1823)
	n (%)
Mean age (± SD)	
Patient sex	
Female (n=1172)	1172 (64%)
Male (n=625)	625 (34%)
Unknown (n=26)	26 (1%)
Seriousness	
Yes (n=1,052)	1052 (58.0%)
No (n=711)	711 (39.0%)
Missing (n=60)	60 (3.0%)
Seriousness Criteria	
Prolonged Hospitalization (n=170)	453 (19.8%)
Disabling (n=184)	184 (21.4%)
Life threatening (n=404)	404 (32.8%)
Congenital anomaly/Birth defect (n=29)	29 (3.4%)
Patient died (n=65)	65(7.6%)
Other medically important condition (n=6)	120 (11.5%)
Patient Age groups	
<12 years (n=207)	274 (11.6%)
12-24 years (n=189)	289 (12.2%)
25-49 years (n=847)	1323 (56.0%)
50+ years (n=431)	346 (14.6%)
Unknown (n=150)	130 (5.5%)

The Anatomical Therapeutic Chemical (ATC) classification of medications

In the reporting period, the most commonly reported drugs belong to the ATC classes antiretroviral (54%), antituberculotics (30%), antibiotics (16.4%), vaccines (12%) and antimalarial drugs (6.6%) as seen in the figure below.



ADR reporting in public health programs

The pharmacovigilance centre reviewed majority of individual case reports from the HIV program (60%), followed by EPI, NLTP AND

Table 2: National HIV reporting rates

Category	On ART March 2020	% of ART enrolled patients reported with ADR	% of ART reports with serious events	% of ART reports with DTG	% of ART reports with TDF	% of ART reports with 3TC	number of ADR reports per 1000 individuals exposed to medicines	Number of medicine-related deaths per 1000 individuals exposed to medicines
Overall	1,241,478	0.074%,n=917	65%,n=598	63%,n=574	55%,n=500	55%,n=503	0.73863572	0.00322197
Male	445,296	0.080%,n=358						
Female	796,182	0.069%,n=549	-	-	-	-	-	-
UNKNOWN		12	-	-	-	-	-	--
Age			-	-	-	-	-	-
<15yrs	62,086	0.142%,n=88	-	-	-	-	-	-
15+yrs	1,179,392	0.070%,n=829	-	-	-	-	-	-

Table 3.National tuberculosis and leprosy program reporting rates

Category	Estimated PLTB	On TB 2020	TB Coverage	Number reported with ADR	% of TB enrolled patients reported with ADR	Number of serious events	% of TB reports with serious events	Number of ADRs with INH	% of TB reports with INH
Overall	81,613	66,536	81.53%	514	0.773%	292	57%	477	93%

AEFI surveillance system

The Uganda Ministry of Health in collaboration with the World Health Organization rolled out a mass vaccination campaign for Measles and Rubella vaccine (MR) and bivalent Oral Polio vaccine (bOPV) in October 2019 targeting infants and children aged 9 months to <15 years and <5 years for MR and bOPV respectively. The exercise was conducted in all schools and communities countrywide.

The campaign was not only a response to an outbreak of measles in some parts of the country but also an opportunity to introduce the Measles-Rubella vaccine into the routine immunization schedule of Uganda; replacing the single Measles vaccine with the combined MR vaccine in the schedule. The polio vaccine was a booster dose to ensure the attainment of herd immunity within the population.

During this campaign, over 19,476,110 children representing 105.2% of the MOH target were vaccinated against Measles and Rubella and 7,955,597 children were also vaccinated against Polio. The vaccines used during the vaccination campaign were prequalified by WHO and rendered safe, effective and of good quality by NDA.

Over the FY 2019/20 period, 533 AEFI reports were submitted to the National Pharmacovigilance Centre. Of these, 526 AEFIs were submitted from the mass vaccination campaign with and average age of 7.1 years. 276 AEFIs occurred in female recipients, 219

in male recipients and 38 were not specified. A total of 58 AEFIs were serious in nature with 9 of the AEFIs leading to fatal outcomes.

Commonly reported AEFIs included Pyrexia, skin rash, flue like symptoms, arthralgia, malaise, abdominal pain, headache and abscess. Some rare AEFIs were also reported and are being followed up as a potential signal. These include Steven - Johnson syndrome and Toxic Epidermal Necrolysis.

Vaccine safety activities implemented during the FY2019/20 include hosting National AEFI committee meetings to conduct causality assessment, conducting AEFI investigations for serious AEFIs and conducting AEFI active surveillance in the western region.

Risk management and communication

The centre has risk management strategies, product recall, labelling changes, communicating risk information to health care professionals and the public. In the reporting period the pharmacovigilance activities resulted into one (1) batch specific recall, 4 pharmacovigilance bulletins and one (1) dear health professional letters were disseminated.

Table 3: Signals/safety issues identified and action taken

SIGNAL/CASES THAT REQUIRED REGULATORY ACTION	REGULATORY ACTION TAKEN
Isoniazid – liver toxicity	Dear Dr. letters on awareness and proper screening of patients was issued.
Isoniazid - serious cutaneous reactions	Communication to health workers was made
Bupivaciane serious drug reactions	Batch specific recall undertaken
TEN suspected to be related to measles and Rubella vaccine	communicated to WHO for investigations

Training and sensitization activities

Considering the fact that medical professionals and the public community play a crucial role in the vigilance system, activities for training are necessary. The WHO pharmacovigilance supplementary indicator ST9(a) and the national pharmacovigilance strategy re-emphasise and guides on the importance of enhancing the capacity of health professionals to monitor drug toxicities through regular trainings, educational sessions and educational materials.

This reporting year, a deliberate effort has been put on the training of health workers in public facilities from the lower facilities (, HC III, HCIV) and sentinel sites involved in active monitoring of Dolutegravir based regimen and Isoniazid used for prevention of TB in people living with HIV. As many as 5 CMEs and Four hundred and nineteen (419) facilities were

Graph showing Number of health facilities trained over three year period

sensitised.

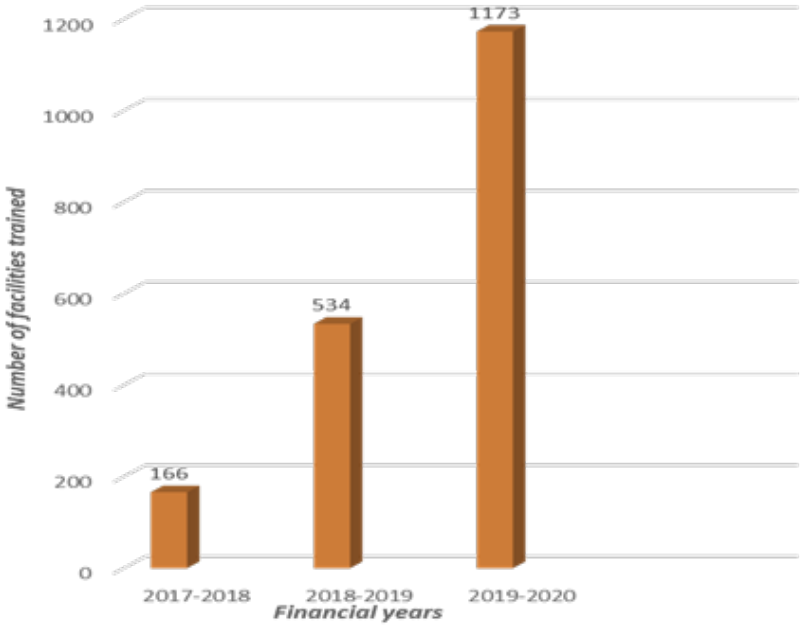


Figure 4. Number of health facilities trained over three year period

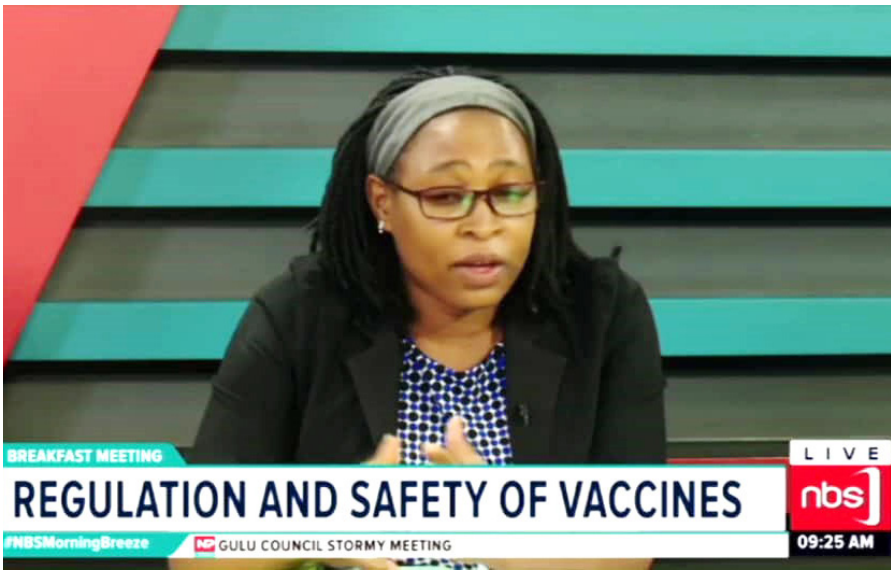
Table 6. Distribution of training activities among the different healthcare facility levels in the country

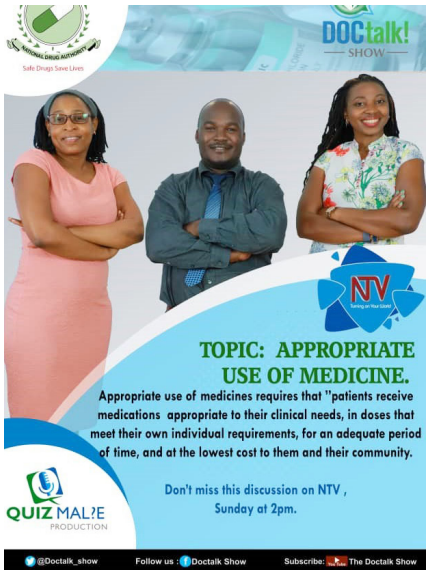
Facility	Q1	Q2	Q3	Q4
Regional Referral Hospitals	3	10	3	1
General Hospitals	4	6	17	6
Health Centre IV	3	16	25	11
HCIII		57	120	50
HCII		2	43	13
Medical Centers	2	2	-	-
Others done in south west		15	-	-
Total	12	108	208	81

Figure 5 Below.Training of healthcare providers at Kakuuto Health Centre IV, Rakai district

Public awareness

The public was engaged through different media platforms platforms including newspaper articles, social media messages, televised messages called “did you know” and television talk shows “Doc talk show at NTV”, Morning breeze on NBS, ‘Omusawo wo’ on radio CBS, ‘Eby’amagara’ on TV West and ‘obulamu bwo’ on Bukedde TV. Through these platforms the public was provided with information with regards to the appropriate use of medicine and how and where they can get medicine related information.





MAH Compliance Program

As enshrined in the National Drug Policy and Authority (pharmacovigilance) Regulations Regulation 37 of 2013).Marketing Authorization Holders (MAH) or licences persons are obliged to submit on-going safety data to enable continual decisions on risk-benefit of registered products. The MAH is expected to leverage on the safety data from both local and international structures to facilitate preparation, quality control, review and submission of PSURs with an impression of the Ugandan safety experience of the MAH`s product(s). During the index year, several pharmaceutical companies have contributed to the pharmacovigilance program through several undertakings summarized in the table 7 below. The detailed information pertaining label changes for the different products is provided in appendix 3.

ACTIVITY	NUMBER OF COMPANIES
PSURs ,PBRER	28
RMP	3
Safety Label Changes	81
ICSR	11
Total	123

Table 7 . Safety information submitted by the pharmaceutical companies

Safety Label and Patient Information Leaflet Changes Received in 2019/2020

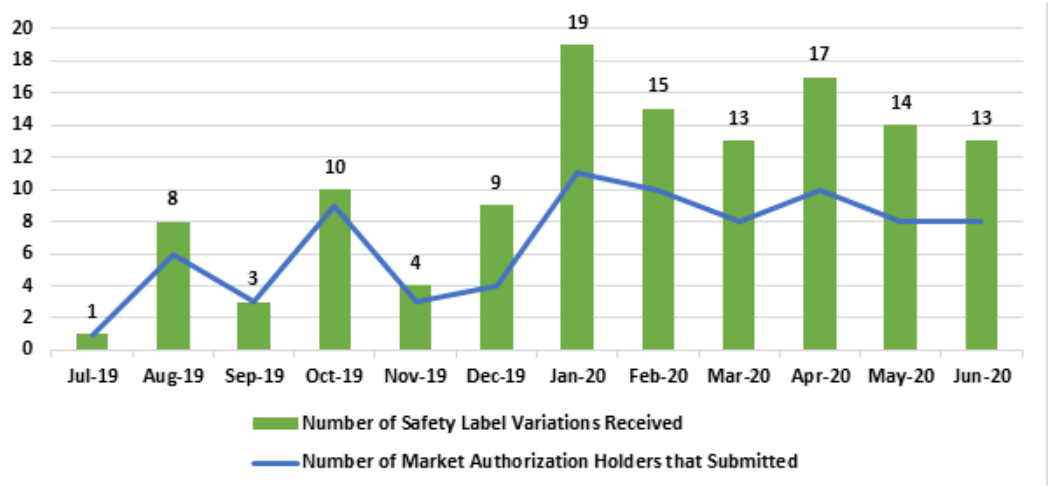


Figure 6 Monthly submission of safety label changes received in the index year

Important Events

Launch of the med safety app

The Med Safety mobile application for reporting suspected adverse drug events on both iOS and Android devices is a welcome addition to the electronic platforms that NDA has instituted. The mobile application that was launched on 26th February 2020 during the eighth annual pharmacovigilance stakeholder meeting is believed to bring mobility and convenience to ADR reporting by both health workers and the public. Prior to this, reports have been submitted to NDA mainly using the paper form and other electronic reporting platforms including a toll-free line, whatsApp, email, and a web portal.

Dr Helen Ndagije at a radio talk-show a week before the launch of the Med Safety application

One month of intensive mass media campaigns on the television, radio, local newspapers and a press conference on the eve of the launch were held. The launch attracted 200 stakeholders from the Ministry of Health Uganda (MoH), health professional associations, hospitals, health centers, patient representative organisations, academia, local governments and the pharmaceutical industry. The event was officiated by the Commissioner Pharmacy department, MoH Dr. Neville Okuna Oteba, the National Drug Authority Head Dr. David Nahamya and WHO country representative Dr Yonas Tegegn Woldemariam.

David Nahamya, welcomed guests, highlighted the contributions of stakeholders and appreciated WHO for its technical and financial support and Medicines and Healthcare Products Agency (MHRA) for supporting the development and customization of the application for Uganda. In his speech Dr Yonas Tegegn Woldemariam, emphasized that the Med Safety app is meant to prove the quality & quantity of adverse drug reporting in countries.

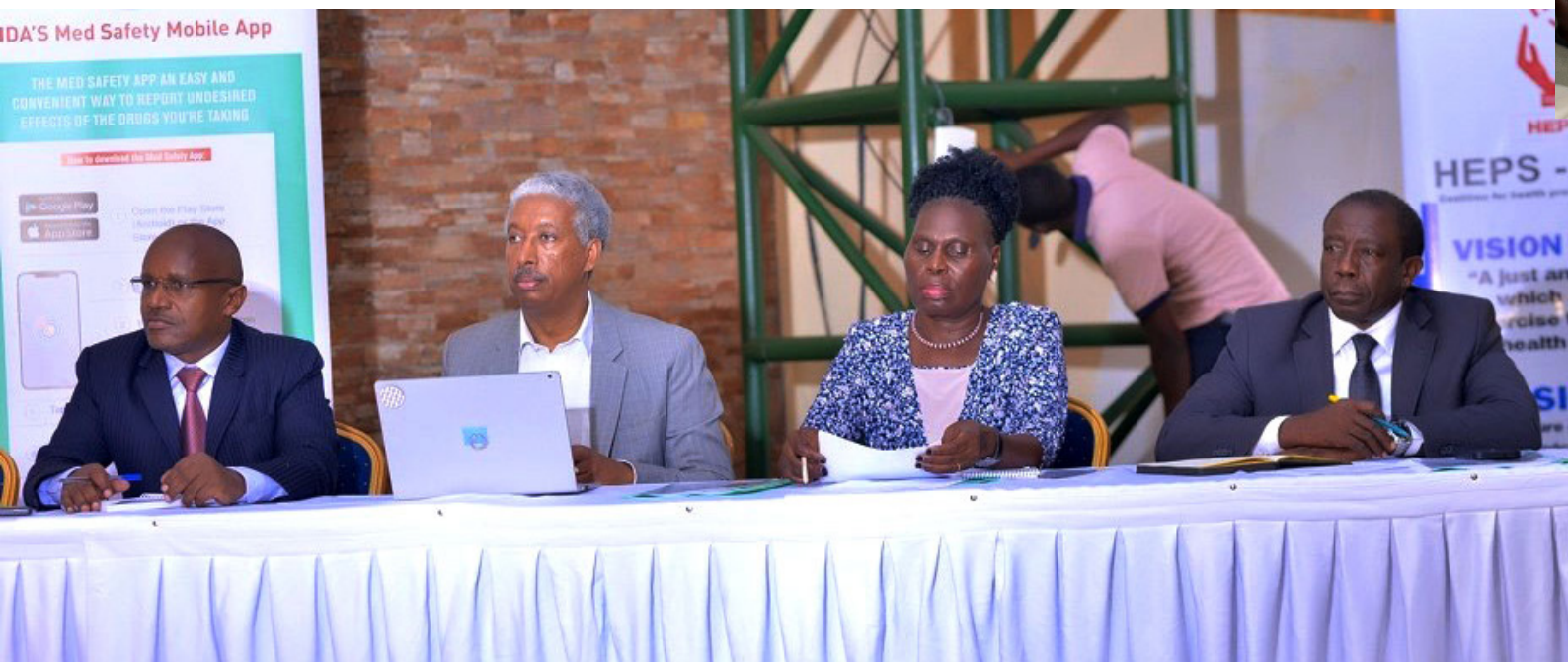


Figure 6 L-R Dr David Nahamya, Dr Yonas Tegegn Woldemariam , Dr Neville Okuna Oteba and Dr Fred Sebisubi listening to the Director Product Safety at the Med Safety app launch event.

Dr. Helen Ndagije, the Director of Product Safety presented an overview of pharmacovigilance activities in Uganda in which she also reported on the progress of implementation of stakeholder recommendations from the previous annual meeting. The demonstration of the application was made by Miss Victoria Nambasa and finally Dr. Oteba reiterated the ministry of health commitment to support pharmacovigilance.

The launch ended on a high note when 20 health workers and over 10 health institutions were recognized and awarded with certificates or plaques of excellence. The recognition was based on commitment to reporting ADRs consistently not only in terms of quantity but also quality of reports.

A number of activities following the launch have been undertaken, including sensitization and training of 118 health facilities on how to use the application.

CIOMS patient safety meeting

The National Drug Authority hosted a workshop titled,' Opportunities and Challenges on Drug Development and Safe use of Medicines in Resource Limited Settings' on 29th August 2019.

The meeting brought together health workers, patient representative organisations, as well as organisations that are responsible for Patient healthcare.

The patient representative organisations in attendance included: Uganda Young Positives, Sickle Cell Association of Uganda, CEHURD, Positive Men's Union, Thrive a woman Uganda, HEPS Uganda, Server Support services, Epilepsy Support organisation (ESAU), Golden Center for Women's Rights Uganda, Community Health And Information Network (CHAIN), Uganda Alliance of Patients Organisations (UAPO), National Association of People Living with Hepatitis B, Rakai Health Sciences Program.

The other institutions that were represented included: The Medical Conceierge Group, Infectious Diseases Institute, Makerere University College of health sciences, Mulago National Referral hospital, Ugandan Academy for Health promotion-IDI MUK, Uganda Christian University school of Medicine, Medical Access, United health Care Distributors Ltd, Mengo hospital.

Dr. Frederick Nakwagala, the chair of the Federation of Research Ethics Committee Chairpersons of Uganda explained the drug development cycle to the participants. He explained therapeutic misconception and vulnerability among patients *when it comes to drug related studies.*

The attendees expressed some concern regarding guidelines being developed in Geneva whereas the circumstances in Africa are different. There was need to domesticate the issues such as having a balance between the medical and social model. The participants were educated about their choices on studies.

Participants recommended the following about how they can get involved in the development of drugs and safe use of medicine in the following ways:

a) There should be community participation in the registration of drugs
b) There should be active patient participation in the monitoring of drugs.
c) Community Advisory Boards should be made more relevant and the recommendations they make should be taken into consideration.
d) It is important for NDA to always get feedback from the patients on the pharmacological effects patents suffer.

There was a discussion on priority areas in which patients can be involved in the development of drugs and safe use of medicine and these were suggested:

a) Access to information by patients should be made clear and such information should also be disseminated.
b) It should be conducive for communities to participate at all levels of drug development.
c) Ethical standards have to be followed at all levels.
d) Policy and decision makers should be involved as well
e) At all times patients at the clinics and health workers should be informed about the benefits and harmful effects of drugs.
f) There should be a patient communication package especially whenever a new drug is introduced in the market.
g) Patient-focused organizations should be involved to inform their stakeholders with knowledge on the drugs that are available.
h) Educate patients and users of health services about their rights, regulatory frameworks, ethical aspects of participation in development and research, treatment literacy and advocacy to promote access.
i) Support engagement, adherence and retention by peer-to-peer interventions.

COLLABORATIONS (UMA and Nurses council)

Uganda Medical Association

The Uganda Medical Association and the National Drug Authority have had a long-standing relationship. The Directorate of Product Safety committed some of its budgeted funds towards the 3rd Grande Doctors conference in November 2018 where they sensitized over 500 doctors about pharmacovigilance. It was at this time that the Pharmacovigilance champions group between NDA and UMA came into place.

During the 2019-20 financial year, the Directorate of Product Safety committed funds towards the sensitization of Medical Doctors on Pharmacovigilance.

Pharmacovigilance sensitizations happened. Dr. Obuku, the 2016-2019 UMA president led the UMA secretariat in organising the sensitizations at the different UMA branches across the country which included: Buddu branch, Kigezi branch, Ankole branch, elgon branch, and the Central Branch. These were possible because they took place in the first quarter of the year. A Memorandum of Understanding between NDA and UMA on Pharmacovigilance was finalized and signed off in November 2019.

During the COVID lockdown, UMA was able to hold a virtual CPD meeting where the NDA was invited to speak about the COVID-19 pharmacovigilance plan as well as the licensing of hand sanitizers. This online CPD was attended by over 150 Doctors and it generated a lot of informative feedback for the authority. Dr. Helen Ndagije gave a presentation on PV in COVID while Solomon Onen gave a presentation on the guidelines for licensing of hand sanitizers.

The Directorate of Product Safety continues to work with the UMA in the 2020-21 financial year.

The Uganda Nurses and Midwives Council (UNMC)

In March 2019, Dr. Helen Ndagije and a PV team member visited the Uganda Nurses and Midwives Council with the objective of engaging the council about promoting pharmacovigilance sensitization amongst the nursing fraternity. The UNMC registrar Angellah Ilakut and the other officers of the council attended. After Dr. Ndagije's presentation, the registrar expressed that the council was ready to collaborate with the NDA in pharmacovigilance and there was a recommendation of Trainer of Trainers approach as the best way to achieve this.

In July 2019, there were further engagements and discussions on the ways to advance this mutual partnership. The NDA team was advised to submit the course content for review by the committee responsible for Continuing Professional Development. A CPD accreditation application was submitted to the UNMC council and is currently under review.

Publication

Nambasa, V.; Ndagije, H.B.; Serwanga, A.; Manirakiza, L.; Atuhaire, J.; Nakitto, D.; Kiguba, R.; Figueras, A. Prescription of Levofloxacin and Moxifloxacin in Select Hospitals in Uganda: A Pilot Study to Assess Guideline Concordance. Antibiotics 2020, 9, 439.

Abstract

Background: In Uganda, national tuberculosis (TB) treatment guidelines were revised to include the newer generation fluoroquinolones among the second-line treatment options for multidrug-resistant TB. This study was designed to analyze if the prescription of these quinolones is compliant with country recommendations. Methods:

This was an observational retrospective study of consumption data for 2017 and 2018 across four selected regional referral hospitals. The sources of consumption data were hospital pharmacy stock cards and the dispensing register. The medical files of patients who had been prescribed fluoroquinolones were also assessed to study compliance with the Uganda Clinical Guidelines and the British National Formulary (BNF). Results: None of the 371 levofloxacin prescriptions analyzed complied with the Uganda Clinical Guidelines, although 250 (67.3%) were prescribed for indications included in the BNF. According to WHO prescription indicators, only 220 (59.3%) prescriptions were appropriate. Conclusion: The prescription of levofloxacin and moxifloxacin increased in the hospitals studied, but in a high proportion of cases, they were not compliant with country recommendations. The findings call for the strengthening of national antimicrobial stewardship programs

Action Plan 2020-2021

1. Conducting Community engagements on pharmacovigilance in collaborations with consumer groups.
2. Increase pharmacovigilance training coverage for health centres III and below
3. Conduct GVP Inspections for local pharmaceutical companies.
4. Joint CPDs with professional associations on Pharmacovigilance
5. Development of online pharmacovigilance training modules
6. Hosting the annual meeting of the International Society of Pharmacovigilance –African Chapter
7. Organism the annual Pharmacovigilance stakeholder feedback meeting

Annex 1

Distribution of health facilities that submitted ADRs in the index year

Facility	Count
IDI MULAGO	180
MJAP MULAGO	124
BAYLOR	95
KITEBI HC III	86
NSAMBYA HOME CARE	77
EXPANDED PROGRAM FOR IMMUNIZATION	64
MBARARA RRH	58
TASO ENTEBBE	46
SOROTI RRH	42
MYLAN LABS	40
KAWAALA HC III	37
KISWA HC III	37
MILDMAY COE	33
KIRUDDU NATIONAL REFERAL HOSPITAL	31
IGANGA HOSPITAL	30
ARUA RRH	29
MENGO HOSPITAL	27
KABALE RRH	25
OUTREACH	24
JINJA RRH	23
UG CARES SOROTI	21
UG CARES MASAKA	20
FORT PORTAL RRH	19
PFIZER GLOBAL PHARMACEUTICALS	17
KINONI HC III	14
MASAKA RRH	14
KAYUNGA HOSPITAL	12
LIRA RRH	12
TASO MASAKA	12
LUWEERO HOSPITAL	11
MUJHU ART CLINIC	11
TASO MBARARA	11
VIIV HEALTH CARE LIMITED	11
TASO JINJA	11
KAMYOKYA CHRISTIAN CARING CLINIC	10
KIGARAMA HC III	10
MITYANA HOSPITAL	10
NYENGA HOSPITAL	10
CIPLA LTD	9
KAWEMPE HOME CARE	9
KIBAALE HC IV	9
TASO MASAKA	9
KAKOBA HC III	8
LYANTONDE HOSPITAL	8
MBALE RRH	8
TASO MASINDI	8
UGANDA CARES SOROTI	8
BUGIRI HOSPITAL	7
KOBOKO HOSPITAL	7
MUKONO HOSPITAL	7
ST BALIKUDDEMBE UG CARES	7
AYIPE HC III	6
IDC MBALE	6
KATAKWI GENERAL HOSPITAL	6
LEFORI HC III	6
MUBENDE RRH	6
NAKASERO HOSPITAL	6
REACH OUT KINAWATAKA	6
REACH OUT MBUYA	6
UGANDA CARES	6
CUF HOSPITAL NAGURU	5
GLAXOSMITHKLINE	5
GULU RRH	5
HOIMA RRH	5
KITYERERA HC IV	5
KYAMUYIMBWA HC II	5
MULAGO NATIONAL REFERRAL	5
UNKNOWN	5
VIIV HEALTHCARE LIMITED	5
ADJUMANI HOSPITAL	4
BUSIA HC IV	4
BUSIU HC IV	4
BWIZIBWERA HC IV	4
KASAMBYA HC III	4
KIDERA HC IV	4
KIHEFO CLINIC	4
KITAGATA HOSPITAL	4
KOMAMBOGA HC III	4
KUMI HOSPITAL	4
KYABAKUZA HC II	4
LACOR HOSPITAL	4
LWALA HOSPITAL	4
MOYO GENERAL HOSPITAL	4
CONSUMER	4
AYIRI HC III	3
BUKEDEA HC IV	3
BUTABIKA NR HOSPITAL	3
HOLY INNOCENTS HOSPITAL	3

KALAGALA HC IV	3
KAMULEGU HC III	3
KAMULI HOSPITAL	3
KILEMBE MINES HOSPITAL	3
KINONI HC IV	3
KYANAMIRA HC III	3
LAROPI HC III	3
LUBAGA HOSPITAL	3
MABAALE HC III	3
OMBACHI HC III	3
RHSP-KALISIZO	3
UNICHEM LABS	3
VIRIKA HOSPITAL	3
AMBROSOLI MEMORIAL HOSPITAL AGAGO	2
BETHANY WOMENS AND FAMILY HOSPITAL ENTEBBE	2
KRED PHARMACY	2
BUKULULA HC IV	2
BUNDIBUGYO HOSPITAL	2
BUSESA HC IV	2
JOHN PAUL II CHILDREN´S HIV/AIDS CLINIC BUIKWE (HEALTH INITIATIVE ASSOCIATION)	2
ISHAKA ADVENTIST HOSPITAL	2
KAMUGANGUZI HC III	2
KIGATA HC II	2
KIYUNGA HC IV	2
KYANAMUKAKA HC IV	2
LWEBITAKULI HC III	2
MASAKA MUNICIPAL CLINIC HC II	2
NAMATALA HC IV	2
NAMAYUMBA HC IV	2
NAMBALE HC III	2
NEBBI HOSPITAL	2
ST PADRE PIO HC III	2
UG CARES MASAKA	3
ABBVIE	1
AGAGO HC	1
AHF SOROTI	1
AIDS INFORMATION CENTER	1
AMUCU HC III	1
ARIGLE HC III	1
AUROBINDO	1
AYAGO HC IV	1
AZUR CHRISTIAN CLINIC	1
BAYER HEALTHCARE, PHARMACEUTICALS	1
BENEDICTS HOSPITAL LUZIRA	1
BUDOMERO HC II	1

BUKOTO HC II	1
BULIISA HC IV	1
BUNYIRO HC III	1
BUSHENYI MEDICAL CENTER	1
BUSIA HOSPITAL	1
BUSODWA HC III	1
BUTOOLO HC III	1
BUYINJA HC IV	1
BWINDI COMMUNITY HOSPITAL	1
BYAMAKA PHARMCY	1
BYANSI CLINIC	1
CHIDRENS CLINIC KAMPALA	1
CPHL	1
DEVIC MEDICAL CLINIC	1
ENTEBBE HOSPITAL	1
ERIA HC III	1
GBOROKOLONGO HC III	1
GOBORO HC II	1
IKONIA HC III	1
KABAROLE RRH	1
KABERAMIDO HOSPITAL	1
KANJOBE HC II	1
KAPTUM HC IV	1
KASAALI HC III	1
KASENSE HC	1
KATOVU HC II	1
KIBAALE HOSPITAL	1
KIBUKU HC IV	1
KIGOROBYA	1
KITOVU HOSPITAL	1
KAYUNGA HOSPITAL	1
KYAMPISI HC III	1
LAROO HC III	1
LHC III	1
LUZINGA PRIVATE CLINIC	1
MADINA PRIVATE CLINIC	1
MAYLAN	1
MAYUGE HC III	1
MBARARA MUNICIPAL CLINIC HC IV	1
MIDAS PHARMACY	1
MIITYANA HOSPITAL	1
MIJHU ART CLINIC	1
MOYO MISSION HC IV	1
MPIGI HC	1
MPUMUDE HC III	1
MRC KYAMULIMBWA	1
MULAGI HC III	1
MUNGULA HC IV	1

MYENGA HOSPITAL	1
NALINYA NDAGIRE HC III	1
NAPRORON HC IV	1
NAWAMPI HC II	1
NOVO NORDISK	1
NTWENTWE HC IV	1
OGUR HC IV	1
RAKAI HOSPITAL	1
SANOFI	1
ST ELIZABETH KIJJUKIZO	1
ST FRANCIS HOSPITAL NSAMBYA	1

ST STEPHENS HOSPITAL MPERERWE	2
TASO GULU	1
UGANDA CARES KAMPALA(AHF)	3
VICTORIA HOSPITAL	2
YOYO HC III	1
UNKNOWN	13
VICTORIA HOSPITAL	1
VICTORIA MEDICAL CENTER	1
YOYO HC III	1
UNKNOWN	12

Annex 2

Reported suspected Drug - Reaction Pairs

Drug –reaction pairs	Count of Reports
Abacavir	**10**
Decreased appetite	1
Diarrhoea	2
Oedema	1
Pruritus	1
Pyrexia	1
Rash pruritic	2
Swelling face	1
Vomiting	1
Abacavir;Dolutegravir;Lamivudine	**7**
Abdominal distension	1
Hyperglycaemia	1
Hyperphagia	1
Muscular weakness	1
Polydipsia	1
Polyuria	1
Pyrexia	1
Abacavir;Lamivudine	**3**
Drug-induced liver injury	1
Hypersensitivity	1
Renal impairment	1
Acetylsalicylic acid;Caffeine;Paracetamol	**1**
Rash	1
Albendazole	**3**
Lip ulceration	1
Pruritus	1
Tongue ulceration	1
Amikacin	**1**
Rash	1
Amlodipine	**5**

Gravitational oedema	1
Oedema peripheral	2
Peripheral swelling	1
Shock	1
Amoxicillin	**4**
Rash	1
Rash pruritic	3
Amphotericin b	**2**
Confusional state	2
Ampicillin	**1**
Skin reaction	1
Artemether	**3**
Eye pruritus	1
Rash pruritic	1
Swelling	1
Artemether;Lumefantrine	**5**
Nausea	1
Rash	1
Shock	1
Skin reaction	1
Vomiting	1
Artesunate	**9**
Diarrhoea	1
Dizziness	2
Hypersensitivity	2
Nausea	1
Rash pruritic	1
Skin ulcer	1
Swelling	1
Atazanavir;Ritonavir	**26**
Abdominal pain upper	2
Ageusia	1
Aphthous ulcer	1

Conjunctivitis	1
Diarrhoea	3
Dizziness	1
Eye pruritus	1
Hepatitis	1
Jaundice	4
Malaise	1
Ocular icterus	2
Photophobia	1
Rash pruritic	3
Skin wound	1
Swelling face	1
Vomiting	2
Atorvastatin	**1**
Myopathy	1
Bcg vaccine	**2**
Injection site reaction	1
Pyrexia	1
Bendroflumethiazide	**2**
Burning sensation	1
Lipodystrophy acquired	1
Benzylpenicillin	**5**
Drug reaction with eosinophilia and systemic symptoms	1
Hypoaesthesia	1
Loss of consciousness	1
Shock	1
Skin reaction	1
Bisoprolol	**1**
Hypotension	1
Blood, whole	**4**
Chills	1
Pruritus	1
Rash	1
Urticaria	1
Bupivacaine	**17**
Aggression	2
Confusional state	2
Depressed level of consciousness	1
Dizziness	1
Generalised tonic-clonic seizure	1
Headache	1
Hyperhidrosis	1
Irritability	1
Mental status changes	1
Neck pain	1
Psychotic disorder	1
Restlessness	1
Seizure	1
Shared psychotic disorder	1
Vomiting	1
Carbamazepine	**13**
Angioedema	1
Hypersensitivity	1
Muscle atrophy	1
Pruritus	1
Rash	3
Rash macular	2
Rash pruritic	2
Stevens-Johnson syndrome	1
Wound	1
Cefixime	**1**
Swelling face	1
Ceftriaxone	**7**
Angioedema	1
Dyspnoea	1
Hyperhidrosis	1
Hypotension	1
Incoherent	1
Loss of consciousness	1
Urticaria	1
Chloroquine	**2**
Pruritus	1
Shock	1
Chlorpromazine	**1**
Angioedema	1
Clofazimine	**8**
Conjunctival hyperaemia	1
Conjunctivitis	1
Eye pain	1
Haemoptysis	1
Mucosal inflammation	1
Ocular hyperaemia	1
Skin exfoliation	1
Visual impairment	1
Cycloserine	**12**
Amnesia	1
Anaemia	1
Arthralgia	2
Dizziness	1
Myalgia	1
Oedema peripheral	1
Seizure	1
Tachycardia	1
Tinnitus	2
Vision blurred	1

Dapsone	3
Asthenia	1
Blister	1
Decreased appetite	1
Darunavir	2
Blood pressure increased	1
Hyperglycaemia	1
Darunavir;Ritonavir	**1**
Rash pruritic	1
Dexamethasone	**1**
Pruritus	1
Diclofenac	**4**
Confusional state	1
Headache	1
Neck pain	1
Skin ulcer	1
Dihydroartemisinin;Piperaquine	**6**
Anaemia	1
Dizziness	1
Face oedema	1
Malnutrition	1
Periorbital oedema	1
Skin ulcer	1
Diphtheria vaccine;Hepatitis b vaccine;HIB vaccine;Pertussis vaccine;Tetanus vaccine	**5**
Abscess	1
Injection site reaction	1
Nodule	1
Pyrexia	2
Diphtheria vaccine;Tetanus vaccine	**1**
Pruritus	1
Dolutegravir	**179**
Abdominal discomfort	3
Abdominal distension	3
Abdominal pain upper	3
Abnormal weight gain	1
Ageusia	1
Allergic cough	2
Arthralgia	2
Asthenia	7
Back pain	1
Birth mark	1
Blindness	1
Blister	1
Blood glucose increased	1
Blood pressure increased	1
Burning sensation	1

Chest pain	1
Chills	2
Deafness	1
Decreased appetite	3
Dermatitis allergic	1
Diabetes mellitus	6
Diabetic ketoacidosis	1
Diarrhoea	5
Dizziness	2
Dizziness postural	1
Drug-induced liver injury	2
Dry mouth	1
Dry skin	1
Dyspnoea	1
Early satiety	1
Erectile dysfunction	3
Extrapyramidal disorder	1
Foetal death	1
Gastritis	1
Gynaecomastia	2
Hallucination, tactile	1
Headache	4
Hepatic enzyme increased	1
Hot flush	1
Hyperglycaemia	8
Hyperhidrosis	1
Hyperphagia	2
Hypersensitivity	2
Hypertension	1
Hypoaesthesia	2
Increased appetite	2
Insomnia	2
Ischaemic stroke	1
Jaundice	2
Lipodystrophy acquired	1
Liver injury	1
Loss of consciousness	1
Loss of libido	1
Malaise	4
Measles	1
Micturition urgency	1
Myalgia	3
Nausea	1
Nephropathy toxic	1
Neuritis	1
Neuropathy peripheral	1
Nocturia	3
Ocular hyperaemia	1

Oedema peripheral	2
Opportunistic infection	1
Palpitations	1
Paraesthesia	2
Pigmentation disorder	1
Pneumonia	1
Pollakiuria	2
Polydipsia	4
Polyuria	2
Premature delivery	1
Pruritus	7
Pruritus genital	1
Pyrexia	2
Rash	4
Rash maculo-papular	1
Rash pruritic	2
Salivary hypersecretion	1
Seizure	1
Skin discolouration	1
Skin hyperpigmentation	2
Skin reaction	1
Swelling face	1
Thirst	2
Tinnitus	1
Type 2 diabetes mellitus	1
Unevaluable event	1
Upper respiratory tract infection	1
Vaginal haemorrhage	1
Vision blurred	4
Visual impairment	1
Vitreous opacities	1
Vomiting	3
Weight decreased	3
Weight increased	1
Wound sepsis	1
Dolutegravir;Lamivudine	2
Chronic kidney disease	1
Pulmonary tuberculosis	1
Dolutegravir;Lamivudine;Tenofovir	176
Abdominal pain	2
Abdominal pain lower	1
Abdominal pain upper	2
Aggression	1
Anosognosia	1
Anxiety	1
Appetite disorder	1
Arthralgia	4

Asthenia	7
Back pain	1
Birth mark	1
Blood creatinine increased	1
Blood glucose increased	2
Blood pressure increased	1
Burning sensation	1
Cachexia	1
Chills	1
Chromaturia	1
Congenital umbilical hernia	1
Cough	2
Death	1
Decreased appetite	3
Diabetes insipidus	1
Diabetes mellitus	2
Diabetic ketoacidosis	1
Diarrhoea	6
Dizziness	2
Dry mouth	1
Dyspnoea	1
Erectile dysfunction	3
Eye pruritus	1
Eye swelling	1
Fatigue	2
Gait disturbance	1
Gynaecomastia	2
Haemorrhage	1
Hallucination	1
Headache	2
Hepatic failure	1
Hepatomegaly	1
Hepatotoxicity	1
Hunger	1
Hyperglycaemia	7
Hyperhidrosis	2
Hyperphagia	1
Hypersensitivity	1
Hypertension	1
Hypertonia	1
Hypoaesthesia	2
Increased appetite	1
Insomnia	3
Jaundice	2
Libido decreased	2
Lip pain	1
Lip swelling	1

Liver injury	1
Loss of consciousness	1
Loss of libido	2
Macular pigmentation	1
Malaise	3
Muscular weakness	1
Myopia	1
Nausea	1
Nephropathy toxic	1
Neuropathy peripheral	2
Neuropsychiatric syndrome	1
Nightmare	1
Nocturia	3
Ocular hyperaemia	2
Ocular icterus	1
Oedema peripheral	2
Osteoporosis	1
Palpitations	1
Papular pruritic eruption of HIV	1
Paraesthesia	1
Partial seizures	1
Peripheral swelling	1
Photosensitivity reaction	1
Pollakiuria	4
Polydipsia	2
Polyuria	2
Pruritus	4
Psychotic disorder	1
Pyrexia	2
Rash	1
Rash maculo-papular	1
Rash papular	1
Rash pruritic	1
Seizure	3
Skin burning sensation	1
Skin reaction	1
Somnolence	2
Starvation	1
Stevens-Johnson syndrome	1
Swelling	1
Swelling face	3
Syncope	1
Thirst	2
Thrombocytopenia	1
Type 2 diabetes mellitus	1
Urticaria	2
Vertigo	1
Vision blurred	3
Visual impairment	1
Vomiting	2
Vulvovaginal dryness	1
Weight decreased	2
Weight increased	2
Doxorubicin	6
Alopecia	1
Dry mouth	1
Dry skin	1
Neutropenia	1
Onycholysis	1
Photophobia	1
Doxycycline	1
Headache	1
Drug name/s under assessment for who-dd	16
Asthenia	1
Burning sensation	1
Decreased appetite	2
Dizziness	1
Eye pain	1
Headache	1
Hypotension	1
Malaise	1
Neuropathy peripheral	2
Paraesthesia	1
Pruritus	2
Rash	1
Unevaluable event	1
Ebastine	4
Abdominal pain upper	1
Chest pain	1
Dizziness	1
Palpitations	1
Efavirenz	62
Abdominal pain	2
Abdominal pain upper	1
Abnormal behaviour	1
Abnormal dreams	1
Aggression	1
Amnesia	1
Arthralgia	1
Asthenia	2
Blister	1
Burning sensation	2
Deafness	1
Depression	1

Disorganised speech	1
Dizziness	2
Dizziness postural	1
Drug eruption	1
Gynaecomastia	4
Haemoglobinuria	1
Hallucination, visual	1
Headache	1
Hepatotoxicity	1
Hypersomnia	1
Irritability	1
Jaundice	2
Liver function test abnormal	1
Malaise	1
Mania	1
Mental disorder	1
Mental impairment	1
Neuropathy peripheral	1
Nightmare	3
Ocular hyperaemia	1
Pain in extremity	1
Pruritus	2
Psychiatric symptom	1
Psychotic disorder	1
Pyrexia	1
Rash	4
Rash maculo-papular	1
Rash pruritic	1
Skin reaction	2
Somnolence	1
Tinnitus	1
Unevaluable event	1
Urinary incontinence	1
Vision blurred	1
Weight decreased	1
Efavirenz;Emtricitabine;Tenofovir	2
Measles	1
Premature rupture of membranes	1
Efavirenz;Lamivudine;Tenofovir	96
Abdominal discomfort	1
Abdominal pain	3
Arthralgia	1
Asthenia	4
Birth mark	2
Chills	1
Chromaturia	1
Confusional state	2
Congenital umbilical hernia	2
Decreased appetite	1

Delivery	1
Diarrhoea	3
Dizziness	2
Drug-induced liver injury	2
Dysphagia	1
Dyspnoea	1
Dysuria	1
Feeling hot	1
Hallucination	1
Headache	2
Hepatitis	1
Hyperglycaemia	1
Hypersensitivity	2
Insomnia	2
Jaundice	1
Live birth	1
Malaise	3
Mouth ulceration	1
Nasal congestion	1
Nausea	1
Neuropathy peripheral	1
Neurotoxicity	1
Nightmare	1
Ocular hyperaemia	2
Ocular icterus	1
Oedema peripheral	1
Oral disorder	1
Palpitations	1
Peptic ulcer	1
Periorbital disorder	1
Photophobia	1
Premature baby	1
Pruritus	6
Psychotic disorder	1
Pyrexia	2
Rash	3
Rash erythematous	1
Rash pruritic	2
Restlessness	1
Sedation	1
Skin discolouration	2
Skin exfoliation	1
Skin hyperpigmentation	1
Skin reaction	1
Sleep disorder	1
Slow speech	1
Somnolence	1
Stevens-Johnson syndrome	1
Stillbirth	1

Stomatitis	1
Swelling face	1
Tinnitus	1
Unevaluable event	1
Vision blurred	2
Vomiting	2
Weight decreased	1
Efavirenz;Lamivudine;Zidovudine	**2**
Headache	1
Lipodystrophy acquired	1
Emtricitabine;Tenofovir	**2**
Acute kidney injury	1
Psychotic disorder	1
Ethambutol	**1**
Haemoptysis	1
Ethambutol;Isoniazid;Pyrazinamide;Rifampicin	**6**
Hypoaesthesia	1
Liver injury	1
Neuropathy peripheral	1
Paraesthesia	1
Pruritus	1
Unevaluable event	1
Ethionamide	**11**
Breast pain	1
Dizziness	1
Goitre	1
Gynaecomastia	2
Haemoptysis	1
Neuropathy peripheral	1
Pruritus	1
Skin exfoliation	1
Tuberculosis	1
Vomiting	1
Fluphenazine	**2**
Muscle atrophy	1
Skin reaction	1
Folic acid	**3**
Birth mark	1
Congenital umbilical hernia	1
Skin reaction	1
Folic acid;Iron	1
Abdominal pain	1
Gentamicin	34
Abdominal pain	1
Abdominal pain upper	1
Asthenia	2
Burning sensation	1

Chest pain	1
Chills	1
Dizziness	3
Dry throat	1
Dyspnoea	1
Headache	2
Hyperhidrosis	2
Hypotension	1
Injection site pain	1
Loss of consciousness	2
Muscular weakness	1
Nausea	1
Palpitations	2
Pyrexia	1
Rash	1
Shock	1
Syncope	1
Undersensing	1
Unevaluable event	1
Vertigo	1
Vision blurred	1
Vomiting	2
Griseofulvin	**1**
Rash	1
Haloperidol	**2**
Mucocutaneous ulceration	1
Skin ulcer	1
Iopamidol	**3**
Headache	1
Infusion related reaction	1
Vomiting	1
Isoniazid	**229**
Abdominal discomfort	1
Abdominal distension	2
Abdominal pain	3
Abdominal pain upper	2
Abdominal tenderness	1
Abnormal faeces	1
Acute hepatic failure	1
Acute kidney injury	1
Anaemia	1
Arthralgia	4
Ascites	1
Asthenia	7
Ataxia	1
Back pain	2
Burning sensation	1
Chest pain	2

Chromaturia	2
Cough	2
Decreased appetite	5
Dermatitis	1
Dermatitis bullous	1
Diarrhoea	4
Diplopia	1
Dizziness	3
Drug-induced liver injury	6
Dyspnoea	1
Eczema	1
Erythema	1
Eye irritation	1
Eye pruritus	1
Eye swelling	2
Fatigue	2
Flatulence	1
Gait disturbance	1
Gynaecomastia	1
Haemoglobinuria	1
Haemoptysis	1
Hallucination	1
Headache	3
Hepatic cirrhosis	1
Hepatic enzyme increased	2
Hepatic failure	1
Hepatitis	1
Hepatomegaly	2
Hepatotoxicity	2
Hyperbilirubinaemia	1
Hypersensitivity	4
Hypersomnia	1
Hypoaesthesia	6
Hypoaesthesia oral	1
Impaired work ability	1
Increased appetite	1
Insomnia	1
Jaundice	2
Lacrimation increased	1
Lethargy	1
Lip exfoliation	1
Lip swelling	1
Liver injury	2
Loss of consciousness	2
Loss of libido	1
Malaise	2
Mood altered	2
Mood swings	1

Mouth ulceration	2
Muscular weakness	1
Nausea	2
Neck pain	2
Nephropathy toxic	1
Neuritis	1
Neuropathy peripheral	5
Nicotinic acid deficiency	1
Ocular hyperaemia	2
Ocular icterus	3
Oedema	2
Oedema peripheral	1
Oral candidiasis	1
Oropharyngeal pain	1
Ototoxicity	1
Pain	2
Pain in extremity	4
Palpitations	2
Paraesthesia	3
Peripheral swelling	1
Photosensitivity reaction	1
Pigmentation disorder	1
Polyuria	1
Pruritus	6
Psychotic disorder	2
Pyrexia	3
Rash	6
Rash erythematous	1
Rash maculo-papular	3
Rash pruritic	2
Restlessness	1
Seizure	2
Septic rash	1
Sideroblastic anaemia	1
Sight disability	2
Skin burning sensation	4
Skin discolouration	1
Skin exfoliation	5
Skin hyperpigmentation	3
Skin reaction	3
Somnolence	3
Splenomegaly	1
Stevens-Johnson syndrome	3
Stomatitis	3
Sunburn	1
Swelling face	1
Thirst	1
Tongue eruption	1

Transaminases increased	1
Tremor	1
Urticaria	2
Vision blurred	4
Visual impairment	1
Vomiting	2
Weight decreased	1
Yellow skin	1
Isoniazid;Pyridoxine	**1**
Hypersensitivity	1
Isoniazid;Pyridoxine;Sulfamethoxazole;Trimethoprim	1
Death	1
Kanamycin	**16**
Abdominal pain upper	1
Arthralgia	1
Balance disorder	1
Deafness	3
Deafness bilateral	1
Dizziness	1
Haemoptysis	1
Headache	1
Hypoacusis	1
Hypoaesthesia	1
Visual impairment	1
Vomiting	1
Wheezing	2
Lamivudine	**7**
Asthenia	1
Drug-induced liver injury	1
Gait disturbance	1
Muscular weakness	1
Paraesthesia	1
Rash	2
Lamivudine;Nevirapine;Stavudine	**2**
Eye pruritus	1
Pyrexia	1
Lamivudine;Nevirapine;Zidovudine	**17**
Anaemia	1
Diarrhoea	1
Dizziness	1
Dyspnoea	1
Headache	1
Hepatotoxicity	1
Lipoatrophy	1
Malaise	1
Pallor	1
Palpitations	1

Paraesthesia	1
Rash	2
Skin reaction	2
Stevens-Johnson syndrome	1
Vomiting	1
Lamivudine;Tenofovir	**9**
Anaphylactic reaction	1
Arthralgia	1
Birth mark	1
Congenital umbilical hernia	1
Nocturia	1
Paralysis	1
Polyuria	1
Renal impairment	1
Weight decreased	1
Lamivudine;Zidovudine	**16**
Anaemia	1
Arthritis	1
Dizziness	1
Gynaecomastia	1
Headache	1
Lipodystrophy acquired	1
Muscular weakness	1
Nausea	1
Pallor	1
Pyrexia	1
Rash	1
Skin discolouration	1
Skin reaction	1
Swelling face	1
Tachycardia	1
Vomiting	1
Levofloxacin	**16**
Arthralgia	2
Burning sensation	1
Chills	1
Decreased appetite	1
Dizziness	1
Headache	1
Myalgia	1
Pain in extremity	2
Palpitations	1
Pruritus	1
Rash	1
Seizure	1
Tachycardia	1
Vomiting	1
Levonorgestrel	**3**

Abdominal distension	1
Headache	1
Unevaluable event	1
Linezolid	**1**
Anaemia	1
Lopinavir	**1**
Dizziness	1
Lopinavir;Ritonavir	**5**
Decreased appetite	1
Diarrhoea	1
Drug-induced liver injury	1
Lipodystrophy acquired	1
Vomiting	1
Losartan	1
Hyperglycaemia	1
Lumefantrine	**1**
Pruritus	1
Measles vaccine;Rubella vaccine	**82**
Abdominal pain	2
Anaemia	1
Anaphylactic reaction	1
Arthralgia	2
Asthenia	2
Blister	1
Bullous impetigo	1
Chest pain	1
Conjunctivitis	1
Cough	3
Crying	1
Dehydration	1
Dermatitis allergic	2
Diarrhoea	1
Dizziness	2
Dysphagia	1
Dyspnoea	2
Eye pruritus	1
Fatigue	1
Headache	2
Hypersensitivity	1
Influenza	1
Influenza like illness	2
Injection site abscess	1
Injection site reaction	1
Lip swelling	1
Local reaction	1
Loss of consciousness	1
Lymphadenopathy	1
Malaria	1

Mucosal inflammation	1
Nasal congestion	1
Ocular hyperaemia	3
Oropharyngeal pain	2
Penile swelling	1
Pneumonia	1
Pyrexia	2
Rash	5
Rash maculo-papular	6
Rash pruritic	6
Rhinorrhoea	1
Skin exfoliation	1
Skin irritation	1
Skin reaction	1
Skin swelling	2
Stevens-Johnson syndrome	2
Swelling	1
Swelling face	3
Toxic epidermal necrolysis	1
Urticaria	2
Vaginal haemorrhage	1
Vomiting	2
Meclozine;Pyridoxine	2
Dizziness	1
Malaise	1
Medroxyprogesterone	4
Congenital anomaly	1
Pregnancy	1
Rash pruritic	1
Vomiting	1
Meningococcal vaccine	5
Asthenia	1
Inflammation	1
Pyrexia	1
Skin lesion	1
Somnolence	1
Metronidazole	5
Confusional state	1
Headache	1
Neck pain	1
Rash	1
Swelling face	1
Morphine	1
Injection site pain	1
Moxifloxacin	**2**
Haemoptysis	1
Nausea	1
Nevirapine	**37**

Abdominal distension	1
Abdominal pain	1
Abdominal pain upper	1
Anaemia	1
Arthritis	1
Asthenia	1
Blister	1
Burning sensation	1
Cough	1
Decreased appetite	1
Dermatitis bullous	2
Dizziness	1
Drug-induced liver injury	1
Eye discharge	1
Gynaecomastia	1
Headache	1
Hepatotoxicity	1
Jaundice	1
Liver injury	1
Lymphadenopathy	1
Rash	5
Rash erythematous	1
Rash maculo-papular	1
Rash pruritic	1
Skin reaction	2
Stevens-Johnson syndrome	2
Swelling face	1
Toxic epidermal necrolysis	1
Unevaluable event	1
Vomiting	1
Nifedipine	**2**
Headache	1
Lipodystrophy acquired	1
Oxytocin	2
Psychotic disorder	1
Shared psychotic disorder	1
Paracetamol	**4**
Asthenia	1
Decreased appetite	1
Pruritus	2
Phenoxymethylpenicillin	**3**
Nausea	1
Rash	1
Vomiting	1
Phenytoin	5
Gingival hypertrophy	1
Headache	1
Photophobia	1

Rash vesicular	1
Stevens-Johnson syndrome	1
Piroxicam	**3**
Pain	1
Pruritus	1
Skin burning sensation	1
Polio vaccine	**1**
Anaemia	1
Promethazine	**1**
Urinary retention	1
Pyrazinamide	**25**
Amnesia	1
Anaemia	1
Arthralgia	4
Chest pain	1
Confusional state	1
Decreased appetite	1
Haemoptysis	1
Headache	2
Loss of consciousness	1
Myalgia	1
Oedema peripheral	1
Pain in extremity	1
Peripheral swelling	1
Pruritus	2
Rash	1
Seizure	1
Skin exfoliation	1
Tachycardia	1
Vomiting	2
Pyridoxine	**7**
Asthenia	1
Cachexia	1
Decreased appetite	1
Hyperglycaemia	1
Pain in extremity	1
Urticaria	1
Vomiting	1
Pyrimethamine;Sulfadoxine	**7**
Anaemia	1
Malnutrition	1
Pruritus	1
Rash	1
Thrombocytopenia	1
Toxic epidermal necrolysis	1
Vomiting	1
Quinine	**3**
Hypersensitivity	1

Injection site injury	1
Visual impairment	1
Raltegravir	**3**
Aphthous ulcer	1
Rash	1
Rash macular	1
Rifabutin	2
Abdominal distension	1
Jaundice	1
Rifampicin	**1**
Anaemia	1
Ritonavir	**1**
Dizziness	1
Rivaroxaban	**3**
Antiphospholipid syndrome	1
Ischaemic stroke	1
Pneumonia aspiration	1
Secnidazole	**4**
Blister	1
Lip swelling	1
Rash pruritic	1
Tongue erythema	1
Sildenafil	**2**
Cardiac discomfort	1
Neck pain	1
Sodium stibogluconate	**1**
Blood creatinine increased	1
Stavudine	**1**
Neuropathy peripheral	1
Sulfamethoxazole;Trimethoprim	**45**
Alanine aminotransferase increased	1
Anaemia	1
Aspartate aminotransferase increased	1
Asthenia	1
Burning sensation	1
Death	1
Decreased appetite	1
Dizziness	1
Electrolyte imbalance	1
Eye discharge	1
Headache	1
Hepatitis	1
Hyperhidrosis	1
Hypersensitivity	1
Lymphadenopathy	1
Malaise	1
Malnutrition	1
Nausea	1

Neuropathy peripheral	1
Ocular hyperaemia	1
Oropharyngeal pain	1
Pneumonia	1
Pruritus	4
Psoriasis	1
Rash	3
Rash maculo-papular	2
Rash pruritic	1
Scrotal pain	1
Shock	1
Skin burning sensation	1
Skin hyperpigmentation	1
Skin reaction	1
Skin ulcer	2
Stevens-Johnson syndrome	2
Stiff tongue	1
Thrombocytopenia	1
Toxic epidermal necrolysis	1
Tenofovir	34
Arthralgia	3
Asthenia	1
Back pain	1
Blood creatine increased	1
Blood creatinine increased	2
Bone density decreased	1
Bone pain	2
Chronic kidney disease	1
Decreased appetite	1
Dizziness	1
Generalised oedema	1
Malaise	1
Nephropathy toxic	3
Oedema	1
Osteoarthritis	1
Osteoarthropathy	1
Osteomalacia	1
Osteoporosis	2
Pain in extremity	1
Papular pruritic eruption of HIV	1
Peripheral swelling	1
Polyarthritis	1
Pruritus	1
Rash	2
Skin hyperpigmentation	1
Vomiting	1
Tramadol	**1**
Epigastric discomfort	1

Trifluoperazine	**7**
Decreased appetite	1
Lip discolouration	1
Mouth ulceration	1
Rash	1
Skin discolouration	1
Weight decreased	1
Wound sepsis	1
Zidovudine	**22**
Anaemia	3
Anaemia macrocytic	1
Arthritis	1
Asthenia	1
Dizziness	1

Hypersensitivity	1
Hypoaesthesia	1
Lipoatrophy	1
Lipodystrophy acquired	2
Loss of consciousness	1
Muscle atrophy	1
Nausea	1
Neuropathy peripheral	1
Neutropenia	1
Palpitations	2
Peripheral swelling	1
Pigmentation disorder	1
Unevaluable event	1

Annex 3:

Product Label changes effected by the different pharmaceutical companies

Month	Company	Label Changes
Jul-19	Johnson & Johnson	Benylin
Aug-19	Sanofi Pasteur	Vaxigrip
	Denk Pharma	Gran-denk
	Sanofi Aventis	Maalox
	Sanofi Aventis	Lantus
	Aurobindo	Tenofovir, Lamivudine, Dolutegravir
	Pfizer Laboratories	Nimenrix
	Intracin	Bupacin
	GlaxoSmithKline	Zentel
Sep-19	Abbvie	Aluvia
	Denk Pharma	Nifedi-Denk
	Novartis	Coartem
Oct-19	Bayer	Secta Insecticidal Shampoo
	Mylan	Acriptega
	Aurobindo	Lamivudine and Zidovudine
	Pfizer Laboratories	Sayana Press
	Gilead Sciences	Truvada
	GlaxoSmithKline	Synflorix
	Denk Pharma	Deslora-Denk
	Hetero labs	Monast
	Cipla	Tenvir Em
	GlaxoSmithKline	Actifed
Nov-19	Bayer	Mirena

	Bayer	Aspirin Cardio
	Glaxo Wellcome	Zinacef
	Glaxo Wellcome	Lamictal
Dec-19	GlaxoSmithKline	Synflorix
	Strides Arcolab	Emtricitabine and Tenofovir
	MSD	Januvia
	MSD	Isentress
	Sanofi Aventis	Maalox
	Sanofi Aventis	Lantus
	GlaxoSmithKline	Piriton
	GlaxoSmithKline	Proximera
Jan-20	Sanofi Pasteur	Vaxigrip
	Martindale	Magnesium Sulphate Injection
	Martindale	Pethidine
	Medreich Sterilab	Norfloxacin and Tinidazole
	International Dispensary Association	Oxytocin
	Denk Pharma	On.setron-denk
	Bliss GVS Pharma	P-alaxin
	Denk Pharma	Deslora-Denk
	Sanofi Aventis	Epilim
	Martindale	Pethidine
	Gilead Sciences	Viread
	Ajanta	Kamagra
	Medreich Sterilab	Zeben
	Martindale	Ephedrine
	Abbvie	Aluvia
	Abbvie	Norvir
	Unique	Rantab
	GlaxoSmithKline	Alben
	GlaxoSmithKline	Clavulin
Feb-20	Bayer	Xarelto
	MSD	Atripla
	Cipla	Beclate
	Sanofi Aventis	Maalox
	Gilead Sciences	Epclusa
	MSD	Stocrin
	Novartis	Certican
	Ajanta	Kamagra
	Cipla	Tenvir
	Martindale	Fentanyl
	Sanofi Aventis	Clexane

	GlaxoSmithKline	Augmentin
	GlaxoSmithKline	Clavulin
	MSD	Aerius
Mar-20	MSD	Atripla
	Sanofi Aventis	Typhim VI
	GlaxoSmithKline	Priorix vaccine
	MSD	Stocrin
	Ajanta	Kamagra
	Sanofi Aventis	Clexane
	Johnson & Johnson	Sinutab 3-way
	Johnson & Johnson	Benylin Four Flu
	Johnson & Johnson	Benylin Dry Cough
	Sanofi Aventis	Amaryl
	Remedica	Quetra and Acetazolamide
Apr-20	Gilead Sciences	Descovy
	Bayer	Levitra
	Abbvie	Aluvia
	Medreich Sterilab	Fleming
	Medreich Sterilab	Amedin
	Bayer	Claritine
	Sanofi Aventis	Cordarone
	AstraZeneca	Brilinta
	Novartis	Tobrex
	GlaxoSmithKline	Piriton
	Gilead Sciences	Vemlidy
	Novartis	Cataflam, Voltaren, Ultibro
	Abbvie	Norvir
	Virchow Biotech	Osteotide
	Bayer	Jadella
May-20	Sandoz NVS	Tasigna
	GlaxoSmithKline	Triumeq
	Novartis	Isopto Carpine 2%
	GlaxoSmithKline	Tivicay
	GlaxoSmithKline	Amoxil, Penamox
	GlaxoSmithKline	Clavulin, Augmentin
	Martindale	Morphine
	Gilead Sciences	Genvoya
	Novartis	Asunra
Jun-20	Ajanta	APDYL-H
	MSD	Rotateq
	AstraZeneca	Forxiga

	AstraZeneca	Zestoretic
	Sanofi Pasteur	Epilim
	Sanofi Pasteur	Shanchol Cholera Vaccine
	Abbvie	Aluvia
	Bayer	Levitra
	Medreich Sterilab	Fleming
	Sanofi Aventis	Cordarone
	Bayer	Xarelto

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

Further information about adverse reactions may be obtained from;
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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

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