Safe Drugs Save Lives

NATIONAL DRUG AUTHORITY

PHARMACOVIGILANCE BULLETIN

Volume 12 | Issue 1 | **March 2020**

In this issue:

- Safety updates
- Support suppervision report
- Medsafety launch highlights
- Stakeholders involved in medicine safety
- How to distinguish counterfeit from substandard medicines
- Statistical review for quarter 3
- ADR reporting

Editorial

The year 2020 threatens to be phenomenal considering the rate of change in various areas of our lives as a new wave of Covid-19 cases increases across the African continent. Uganda has so far been commended for its handling of the Covid-19 epidemic and we continue to call upon you to observe guidelines from the Ministry of Health so that the gains made are not lost.

The toll of the pandemic on the economy and the already imperfect health care systems in many low and middle income countries like Uganda is increasing. Like many other viral diseases, there is no cure. However, a number of potential remedies have been proposed.

Pharmacovigilance professionals therefore have to be more alert to the likely increased risk and hidden effect of irrational use of medicines and medical products. In this 12th volume of the bulletin, we have included tips on how to identify substandard and counterfeit products.

For close to 14 years, health care professionals have been the pillar of report submission to the NDA database. For the first time ever, consistent reporters and facilities were rewarded, a tradition we hope to continue. This will be done in conjunction with in-person support supervision visits to all facilities.

Worldwide, patients have been recognized as key participants in pharmacovigilance and the first Patient Safety day was celebrated in 2019. We were therefore delighted to launch the Med Safety app in February 2020 in order to also involve patients in pharmacovigilance. Guidance has been provided for the general public and health professionals on what and how to report at the back of the bulletin.

Drug Safety is a global issue and we have shared relevant safety updates from other regulatory agencies.

We wish you happy reading!

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Preview

4 

The National Pharmacovigilance Centre introduces a Mobile App for Reporting of Adverse Events in Uganda

6 

National Drug Authority recognizes perfomance of healthworkers

7 

Pharmacovigilance Sensitization and Support Supervision

8 

Safety Updates

10 Summary of individual Safety Case Reports Reported between January 2020 and March 2020

12 

Distinguishing between Counterfeit and Substandard Medical Products

14 

Drug Safety: Shared Responsibility

17 

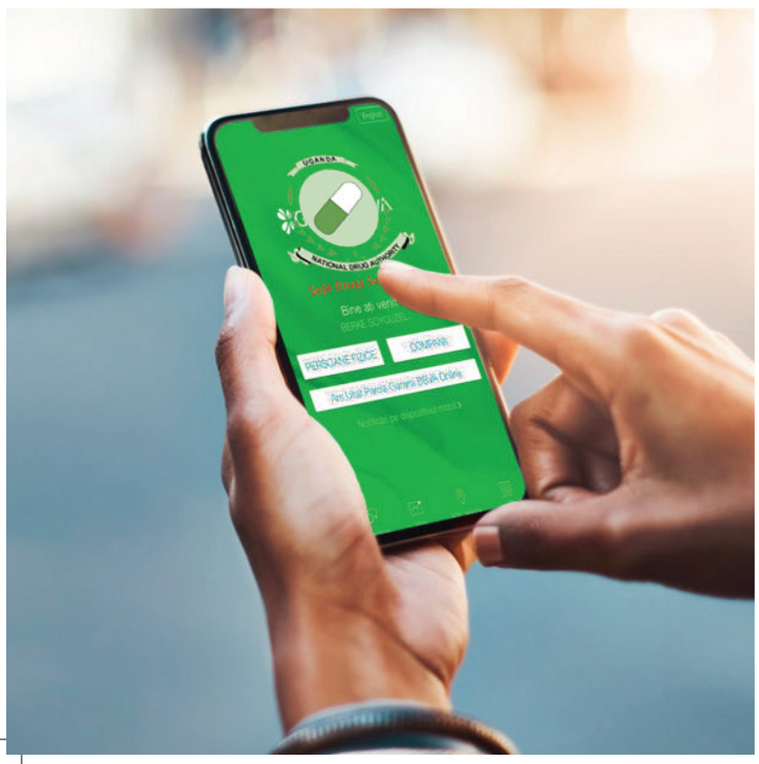
What To Report

Annex I: 18

Annex II: 21

Annex III: 22

The National Pharmacovigilance Centre introduces a Mobile App for Reporting of Adverse Events in Uganda



Since the setting up of the National Pharmacovigilance Centre within the National Drug Authority, suspected adverse drug reaction reports and reports on other drug related problems have been received mainly from health care professionals using the AEFI/ADR reporting form (appendix III). One of the challenges of the reporting form is the delay in relaying information from the reporter to the national centre. This delay hampers timely assessment and feedback on the suspect adverse event especially if it is serious in nature.

In 2015 an e-Reporting platform was introduced to address the shortfalls of paper based reporting. The NPC has subsequently instituted additional electronic reporting platforms including a toll free line, whatsapp and email.

To further embrace technology to ease reporting of adverse drug reactions, the National Pharmacovigilance Centre this year introduced a mobile application (MedSafety app) for use by both health workers and the public.

The app brings mobility and convenience to ADR reporting while completing the feedback loop between users and NDA. The App can be downloaded from Google and Apple app stores. Once installed, the user selects "Uganda" from the country list and follows the easy prompts to start reporting any drug safety information.

Features of the med safety app

- The application has been designed to account for multiple regions, with a planned option for translation into local languages in future.
- News data from NDA are embedded in the app; the app also provides for a personalised Watch List, which enables users to view information that is relevant to them by following products of interest (the NDA register has been integrated into the app).

- Reports can be created and saved for later transmission where low signal prevents sending immediately.
- The app automatically enables users to make use of features on their device such as dictation.
- It is also adapted to iOS and Android platforms making the look and feel familiar to users of both.

The mobile application was launched on 26th February 2020 during the 3rd Annual Pharmacovigilance stakeholders meeting at Golf Course Hotel Kampala. The launch was graced by the commissioner pharmacy Mrs. Oteba Neville and the WHO country representative Dr Yonas Tegegn Woldemariam.

The **Director Product Safety** giving a presentation on the evolution of Pharmacovigilance in Uganda.

Manager Pharmacovigilance demonstrated how the app works.

The Secretary to the Authority giving his speech

The guest of honour, the commissioner pharmacy department, Mrs. Oteba Neville launched the app.

Dr Yonas Tegegn Woldemariam the WHO Country Representative emphasized that the Med Safety app is meant to improve the quality & quantity of adverse drug reaction reporting in countries in real time.

Top reporters displaying their certificates and plaques

National Drug Authority recognizes perfomance of healthworkers

Since 2005, the National Drug Authority ADR database has amassed over 4,800 ADR reports and this has been made possible with the vigilance and diligence of health care workers. 20 health workers and over 20 health facilities (hospitals, health centres IV, III, II and private facilities) were recognized and awarded 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.

We hope to continue appreciating our reporters with these annual awards as well as in all our quarterly bulletins as way of recognizing their efforts towards drug safety. (appendix II shows details of the awards and the categories).

PHARMACOVIGILANCE SENSITIZATION AND SUPPORT SUPERVISION

Participants at Moyo General Hospital taking their pre-test before the Pharmacovigilance training.

Health care professionals constitute the largest proportion of Pharmacovigilance stakeholders and play a very vital role in the documentation and reporting of ADRs. The National Drug Authority therefore, continuously strives to reach

out to the different health care providers in their respective health facilities across the country. The purpose of this is to train them on documentation and reporting of ADRs, sharing medicines safety updates and distribution of the various reporting tools. In the months of January,February and March, 2020, the PV unit has been able to reach out to; over 200 health facilities, sensitizing over 1000 health care workers within 17 districts i.e. Jinja, Kamuli, Isingiro, Buliisa, Masindi, Hoima, Kikuube, Kibaale, Kapchorwa, Sironko, Bududa, Manafwa, Tororo, Nakaseke, Luweero, Kitgum and Lamwo.

In these visits, 100 IEC materials and over 500 ADR booklets amounting to 10,000 individual reporting forms were disseminated. The sensitization program will continue and the goal is to reach each and every health worker and every health facility nationwide. The details of the facilities visited are presented in appendix I.

SAFETY UPDATE

Local safety update(s)

Ocular disorders related to Isoniazid

THE centre has received 7 reports this quarter of visual disturbances potentially associated with Isoniazid from across the country. This is in addition to the 13 reports already documented in previous reporting periods. The cases affected were between 18-44 years (mean-35 years), with 90% being female. The cases reported symptoms including; blurred vision, colour blindness, photosensitivity, and reddening of eyes with an average onset time of 20 days from start of INH treatment. 75% of cases were reported as serious, involving potential disability. These attributes are broadly consistent with the 517 reports documented globally so far. According to the estimates in the WHO-database, this rate of occurrence is 1.7 times higher than expected.

The product labelling has optic atrophy as the only known visual adverse reaction associated with INH. It's noted as a rare (1/10,000) reaction that could manifest with blurred vision, difficulties with peripheral (side) vision, difficulties with colour vision and a reduction in sharpness of vision. The centre is continuing to monitor this adverse reaction and would like to encourage you to look out for and report any cases that may experience visual disturbance whilst on INH.

Global safety updates

Montelukast and serious mental health side effects [1]

The US FDA has included a new requirement for a Boxed Warning stating that serious neuropsychiatric events that may include suicidal thoughts or actions have been reported in patients taking Montelukast. It has been recommended that Montelukast only be used for allergic rhinitis in patients who have an inadequate response or intolerance to alternative therapies.

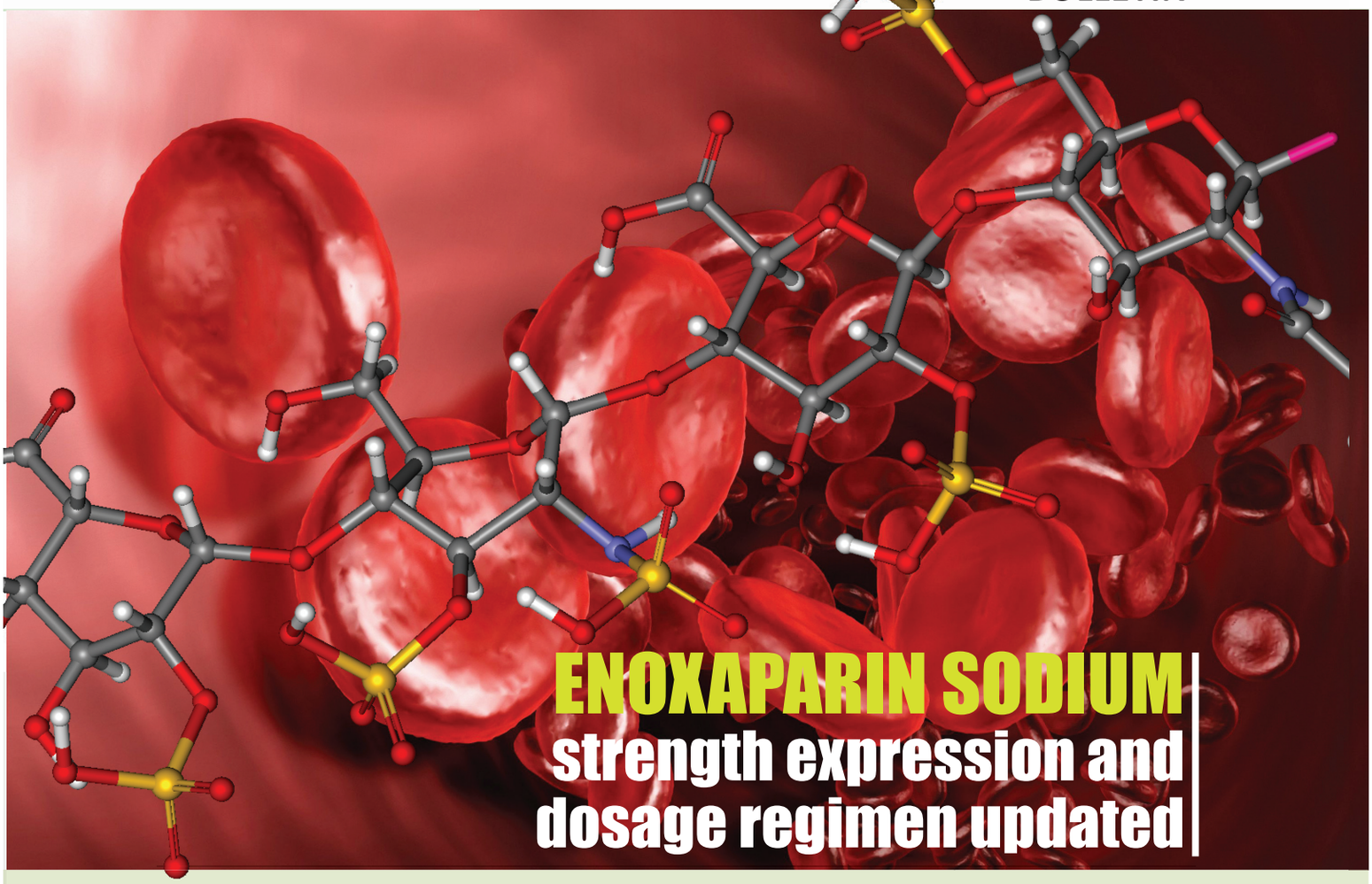
The advice to health- care professionals is:

- Ask patients about any history of psychiatric illness prior to initiating treatment.
- Consider the risks and benefits of Montelukast when deciding to prescribe or continue patients on the medicine.
- Advise all patients of the risk of neuropsychiatric events when prescribing Montelukast. Warnings about these side effects are included in the existing prescribing information; however, many health care professionals and patients/caregivers are not aware of this risk, and suicides and other adverse events continue to be reported.

- Advise patients and parents/ caregivers that the patient should stop taking Montelukast and contact a health care professional immediately if changes in behaviour or new neuropsychiatric symptoms, suicidal thoughts or behaviour occur.
- Monitor all patients treated with Montelukast for neuropsychiatric symptoms. Events have occurred in patients with and without pre-existing psychiatric disease.
- Most reported cases of neuropsychiatric events occurred during Montelukast treatment, but some occurred after discontinuation. In many cases, symptoms resolved after stopping Montelukast; however, in some cases symptoms persisted after discontinuation from therapy or were reported after discontinuation of therapy.
- Encourage patients and parents/caregivers to read the Medication Guide they receive with their Montelukast prescriptions, which explains the safety risks and provides other important information.

Although NDA has not yet received any suspected adverse events related to Montelukast, health care professionals are advised to monitor and report any adverse event using the available reporting platforms.

1 Drug Safety Communication, US FDA, 9 July 2019 (www.fda.gov)



ENOXAPARIN SODIUM strength expression and dosage regimen updated

THE manufacturer (Sanofi) of Clexane (Enoxaparin) is updating the product information regarding the strength expression, dose regimens and guidance for use.

Expressing strength both in IU and mg is to provide healthcare professionals clarity about Enoxaparin doses regardless of which units they are familiar with, and will prevent medication errors potentially leading to thrombosis or major bleeding.

The updates are presented below;

- **Enoxaparin Sodium strength expression and dosage regimen updated**

1 mg of enoxaparin sodium is equivalent to 100 IU of anti-Xa activity

For example, for the 0.4 ml pre-filled syringes, the strength will appear as: <Clexane®> 4000 IU (40 mg) / 0.4 ml solution for injection.

- **Two dose regimens for the treatment of deep vein thrombosis (DVT) and pulmonary embolism have been defined:**

Either as a once daily injection of 150 IU/kg (1.5 mg/kg): used in uncomplicated patients with low risk of venous thromboembolism (VTE) recurrence.

Or as twice daily injections of 100 IU/kg (1 mg/kg): used in all other patients such as those with obesity, with symptomatic PE, cancer, recurrent VTE or proximal iliac vein thrombosis.

The regimen should be selected by the physician based on an individual assessment including evaluation of the thromboembolic risk and the bleeding risk.

- **Contraindication in patients with severe renal impairment (creatinine clearance <30 ml/min) was removed.**
- For patients with **creatinine clearance [15-30] ml/min, dose adjustment** is required

Use in patients with end stage kidney disease **(creatinine clearance < 15 ml/min)** is not recommended outside the prevention of thrombus formation in haemodialysis patients.

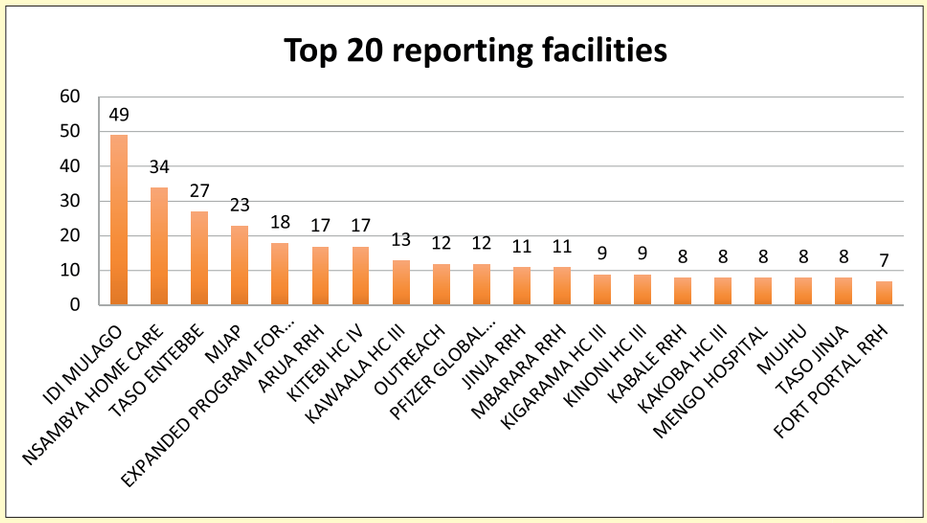
For further information, consult the product label. Any suspected adverse events should be reported to National Drug Authority.

Summary of individual Safety Case Reports

Reported between January 2020 and March 2020

The following is a summary of ADR reports received at the National Pharmacovigilance Centre in the period from January to March 2020. There has been an increase in reports due to active drug safety monitoring, increased sensitization campaigns as well as launch of the Med Safety App.

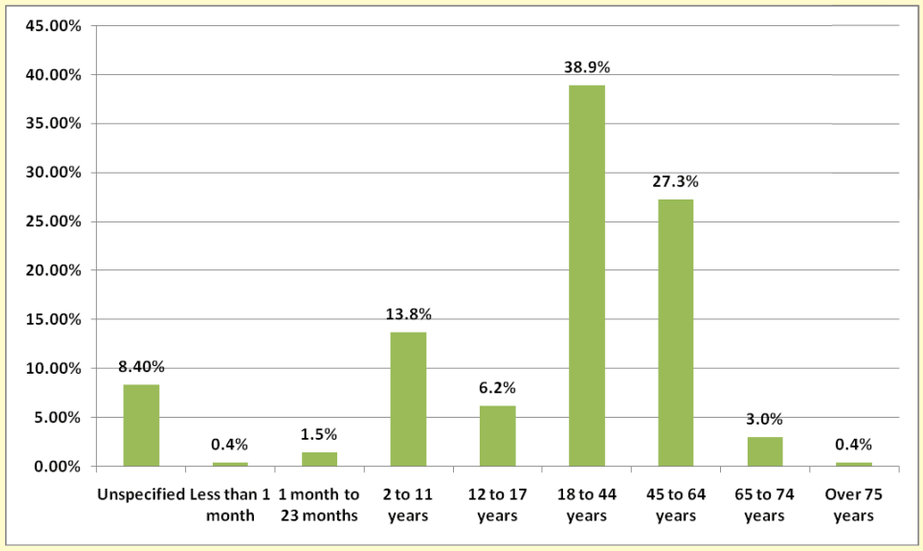
A total of 465 case reports were received, with half of the reports (50%) reported to be serious. Majority of reports were submitted through paper forms (72%), while 17 % was through online platform, 5% through the MedSafety mobile app and 5% via WhatsApp. The figure below shows the top 20 reporting health facilities.



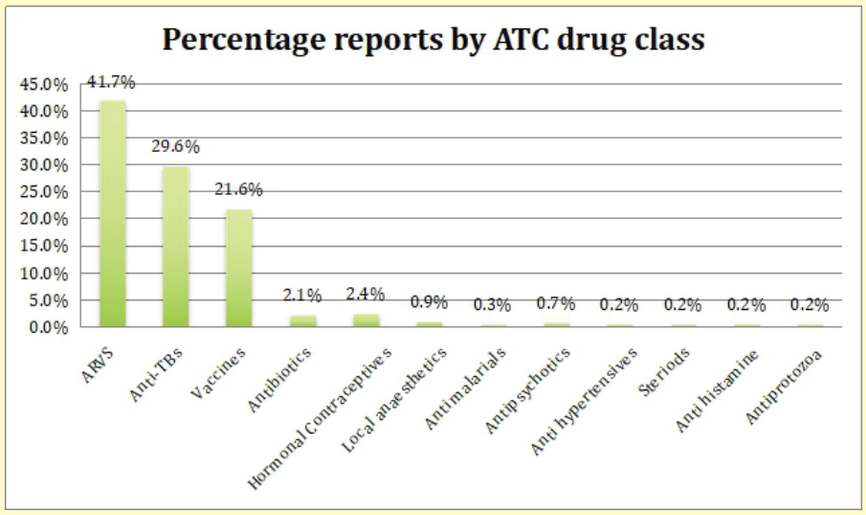
Number of reports from top 20 health facilities

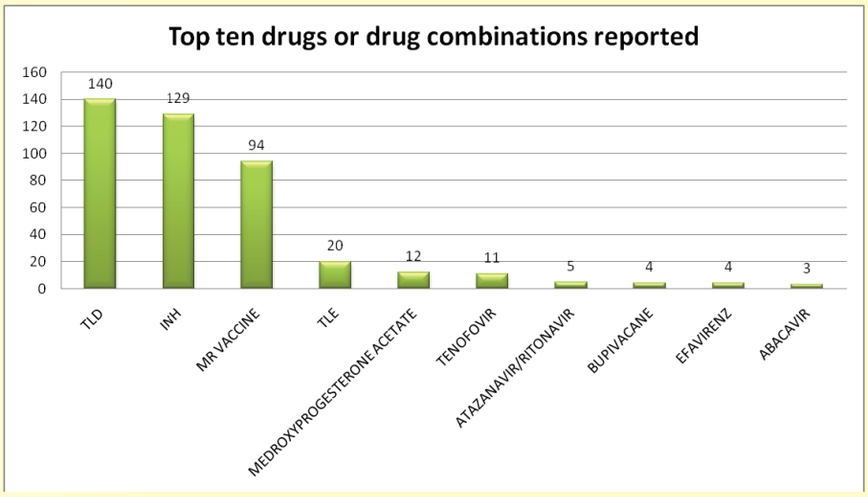
Overall, majority of ADRs (n = 310; 67. %) were reported from females. Stratification by age of patients showed that the highest number of reports were from those aged 18 to 44 years (n =181; 38.9 %) while the reports from the eldest (over 75 years) and the youngest (less than 28 days) were fewer (n=2; 0.4%)

Age categorization of reports received

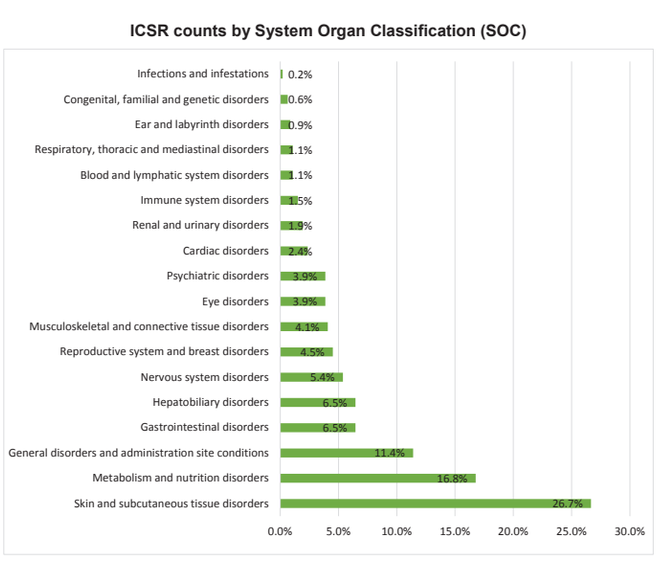


Medicines used in management of HIV (ARVs) were reported most (41.7%; n=104), followed by Anti-TBs (29.6%; n=75) as shown in the graph below. The top 10 drugs with suspected reaction are presented in the next graph.





Based on system organ classification (SOC), most reported reactions were skin and subcutaneous disorders(27%), followed by metabolic and nutrition disorders(17%) and general disorders (11%). Hepatobiliary disorders (6%) and gastrointestinal disorders (6%) are also among the serious and frequent reactions that were reported and led to withdraw of suspected medicines.



NDA officers display counterfeited Quinine Sulphate, Augmentin and Postinor tablets during a crackdown on substandard and illegal medicines in July 2019.

DISTINGUISHING BETWEEN COUNTERFEIT AND SUBSTANDARD MEDICAL PRODUCTS

Section 30 of NDP/Act Cap 206, on supply of impure drugs prohibits sale of any drug which is unwholesome (substandard) or adulterated (counterfeit) or which does not conform to the prescription under which it is supplied.

Over the 2019-20 financial year, National Drug Authority has intensified enforcement operations with a goal to protect the population from substandard, counterfeit, unregistered medicines and quack operators. Nationwide enforcement operations targeted recalled drugs such as Augmentin, Postinor-2 and Quinine Bisulphate in which over 500 drug outlets were inspected.

Substandard medicines are medicines which have failed to pass the quality measurements and standards set for them. They should be distinguished from counterfeit (falsified) medicines which are deliberately and fraudulently mislabeled. Combining the two together however is not helpful. They are different problems that require different solutions. Substandard and counterfeit medicines are a widespread problem in low-income and lower–middle-income countries.

Health professionals need to be aware that medicines like any other product may be substandard. Counterfeit medicines may be recognized by spelling mistakes in the packaging. Recognizing substandard medicines is more difficult. The possibility of a substandard medicine should be considered if: a patient fails to respond to treatment; if several patients who have received the same batch of a particular drug fail to respond to treatment; if an unusual adverse drug reaction occurs. For medicines administered parenterally, unusual appearance or smell should raise suspicion that the medicine may be contaminated. Because of the difficulties in recognizing substandard medicines, it is essential that the pharmaceutical industry does its utmost to minimize substandard medicines.

The World Health Organisation defines a counterfeit medicine as one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Substandard medical products are authorized for market use which post approval fail to meet either their quality standards or their specifications, or both.

Substandard medical products have the following features:

1. Substandard medical products are usually properly packaged,
2. Generally bought through trusted supply chains,
3. Often also contain a percentage of the correct active ingredient.

Substandard medical products reach patients when the tools and technical capacity to enforce quality standards in manufacturing and the supply chain are limited.

What are the risks of counterfeit medicines to the patient?

An individual who receives a counterfeit medicine may risk a number of dangerous health consequences.

The drug may

- contain a different quantity of the original active ingredient
- contain totally different active ingredients
- contain toxic ingredients
- bear forged manufacturer's data on the packaging
- have been completely repackaged
- have been produced under conditions that do not conform with current Good Manufacturing Practice (cGMP)
- I have not been transported and stored properly

You may experience unexpected side effects, allergic reactions, or a worsening of a medical condition. Such unexpected effects must be reported immediately to a physician. Even worse, counterfeited medicines can kill.

How to Identify Counterfeit/fake Drugs

Visual inspection as stated by the World Health Organization (WHO) (1999) still remains the first step in identifying potential fake drug irrespective of the analytical methods used.

This is because such observation serves as a lead to identifying fake products even in the absence of the knowledge of the physical characteristics of a genuine drug product. You are expected to examine carefully both the package and its content before purchase or use.

Visual inspection of the Package

You should

1. Examine the package and check if it appears suspicious or different from what you previously know.
2. Check if the security seal has been tampered with by looking for breaks or tears in the sealing tape and seals.
3. Look for unusual fonts, font sizes, print colour, and spelling errors.
4. Check the legibility of the information on both the primary and secondary packages.
5. Check if the batch number, expiry date and manufacturer's address on the secondary package are the same with that on the primary package.
6. Check if the manufacturer's address is traceable, that is, if it contains the exact location of the company and not just the country address.

Visual inspection of the Dosage form.

At this stage, you are meant to:

A. Check for differences in the physical appearance (colour uniformity, size, shape, consistency etc.) of the drug. As stated by WHO, commonly encountered physical defects that should be looked out for in tablets include:

1. Excessive powder and/or pieces of tablets at the bottom of the container (from abraded, crushed or broken tablets);
2. Cracks or chips in the tablets, swelling, mottling, discolouration, fusion of tablets;
3. Appearance of crystal on the walls of the container or on the tablet.
4. Hardening or softening, cracking, swelling, mottling or discolouration of capsule shell should also be looked out for.

B. Also check the physical properties of the dosage form if you have been using the medication.

DRUG SAFETY:
SHARED RESPONSIBILITY

THE SAFETY OF MEDICINE is a major concern for all stakeholders in healthcare. Numerous factors are usually investigated in medicine safety like rational use, ADR, patient compliance, medication errors and shared across stakeholders. In Uganda the responsibility of individual stakeholders are outlined below;

National Pharmacovigilance Centre (National Drug Authority)

NDA is responsible for the safety of drugs. As a regulatory agency, it is responsible for coordinating the nationwide activities of detection, remediation and communication of risk associated with potential adverse drug effects. It ensures that medical information is correct and updated by the market authorization holders. In the event of any safety relevant findings, NDA must also ensure that healthcare professionals and the public are informed without any delay. In some cases, if necessary the NDA with support from other international agencies can also take safety measures such as restricting the authorized indication, modify the product information, causing labelling changes and in some cases reclassifying drug from OTC to prescription. Through its Pharmacovigilance centre NDA coordinates the collection and reporting of ADRs, analyzes, evaluates and maintains a database of received adverse drug reactions and medicine related problems.

Regional Pharmacovigilance Centres

Regional PV Centres are established in Regional referral hospitals. These centres serve to extend the reporting infrastructure to health facilities within their catchment areas and their specific functions are delineated in specific memorandum of understanding between the centres and the NPC along with the terms of reference therein.

Medical professionals and their professional associations

Healthcare professionals make an important contribution to drug safety depending on their role in each case. The clarification of possible risk factors before prescribing is just important here as providing patients with accurate information.

If notifiable adverse reactions are observed in a patient receiving a drug treatment, these must, despite the extra work for the primary reporter – be reported to the authorities in order to improve drug safety, not just because this is a legal requirement but for ethical reasons as well. Good documentation of drug treatment is also important, particularly at interfaces such as hospital admissions or discharges. Studies have shown a big financial burden due to adverse events and therefore reducing the consequences of adverse drug reactions much as it is not accrued directly, but results in a lowering of the general costs for the insured persons.

Medical professional associations can also make an important contribution to drug safety by alerting their members, as needed, to safety-relevant publications by NDA and other regulatory agencies or authorization holders (multiplier effect). Another very welcome

development is the professional sharing of information on specific issues around identified safety-relevant risks.

Patients and their organizations

In recent years' patients and their organizations are demanding a greater say in their treatment and, as a precondition, greater transparency from the manufacturers and the authorities specifically as regards the safety of "their" medication. Easy to understand package leaflets are important in this context. On the other hand, Patients and their relatives can be assumed to possess a certain amount of self- initiative. Competent patients read the package leaflets for the medicines, often obtain information on the internet and dare to ask their doctor or dispensing professional questions about a particular drug treatment and its risks. In the event of suspected adverse drug reactions, patients should also be encouraged to make use of their reporting right and inform the doctor or pharmacist.

Patient organizations are very important in voicing the concerns of those who are affected, particularly those suffering from rare illnesses. Thanks to their much frequented networks, these organizations can quickly reach those affected and their relatives – and they can also serve as a reliable source of information on drug safety.

Public Health Programs (PHPs)

Public health programmes, like manufacturers and distributors, are legally required to develop and maintain a robust Pharmacovigilance system that ensures a continuous loop of patient safety information is communicated to the National Drug Authority and feedback is provided to the patients on the expected benefits and risks of the programme medications.

Conclusion

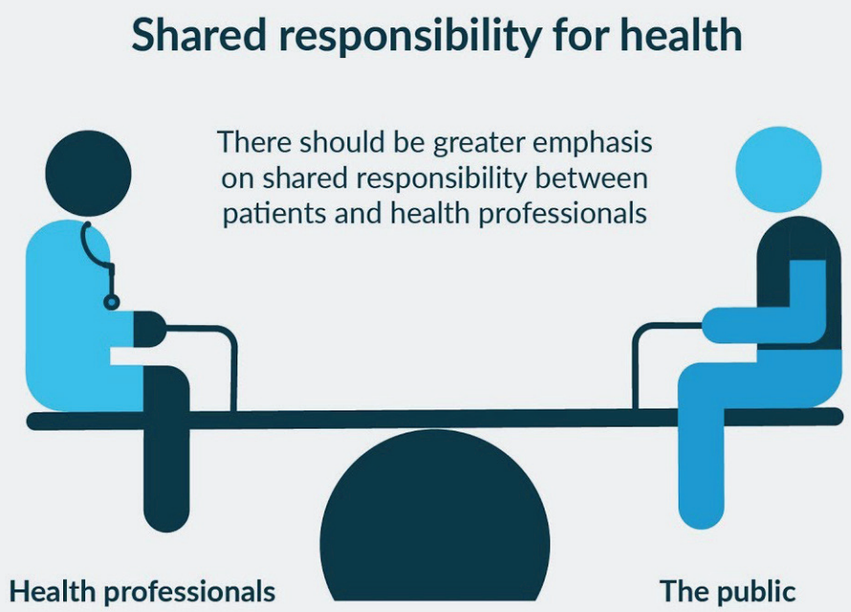
Drug safety is a valuable asset and involves numerous stakeholders. The tasks of the individual stakeholders are known and also clearly regulated. Compliance with the legal obligations, and also quality management, involves effort, but this is essential for ensuring safe drug treatment.

Guidelines for reporting ADRs

Recognizing and reporting of ADR/ADE

Adverse Drug Reactions are difficult and sometimes impossible to distinguish from the disease being treated or prevented since they may act through the same physiological and pathological pathways.

The following step-wise approach may be helpful in assessing possible drug- related Adverse Drug Reactions:



a) Take a proper history

i. A full drug and medical history should be taken

ii. Can this adverse effect be explained by other causes? E.g patient's underlying disease, other drugs, toxins or food etc.

iii. When other causes do not explain patient's condition, do thorough investigation

b) Establish time relationships

The time of start of therapy and time of onset of the suspected reaction should be logical; keeping in mind some reactions start immediately after start of medication while others take time to develop.

c) Do a thorough physical examination with appropriate laboratory investigations

i. Do laboratory test(s) especially if the drug is considered essential for patient care or if the laboratory results will improve management of the patient.

ii. Look out for distinctive physical signs and carefully evaluate the symptoms described by the patient

iii. Try to describe the reaction as clearly as possible and where possible, provide an accurate diagnosis.

iv. Use relevant up-to date literature and personal experience as a health professional on drugs and their ADRs and verify if there are previous conclusive reports on this reaction.

d) Effect of de-challenge and re-challenge should be determined

i. Positive de-challenge means improvement/ remission of the adverse event on withdrawal of the drug

ii. Re-challenge means reintroducing the drug after a de-challenge (re- challenge is not advisable as reactions have the propensity to recur with greater severity)

e) Check the known pharmacology of the medicine

i. Is the reaction known to occur with the suspected particular drug as stated by the package insert or other reference materials?

ii. Note: If the reaction is not documented in the package insert, it does not mean that the reaction cannot occur with that particular medicine.

iii. The National formularies, summary of product characteristics, research publications and international health bodies are very important sources for obtaining information on ADR.

The manufacturer of the drug can also be a resource to consult.

Reporting of adverse events

Reporting of ADRs, ADEs, and AEFIs should be 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. Hotline: +256 800 101 999

ii. WhatsApp: on 079-415 555

iii MedSafety mobile app downloaded from Google Play Store for android or the App store for iOS

b) An online reporting platform available at **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=UG**

All the information required on the form is considered essential; therefore, complete the form to the best of your knowledge. Avoid non standard abbreviations.

A valid report

For the report to be valid, it should have the following minimum information

a) Source of information

b) Patient details

c) Drug details

d) Reaction details

WHAT TO REPORT

REPORT all suspected adverse drug reactions on all drugs including vaccines. Any ADR experienced by a patient should be reported even if you are not certain that the product caused the ADR or even if you do not have all the details.

a) For "new" drug molecules – report all suspected reactions, including minor ones. (For the purpose of this guideline, 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 report; all serious and all unexpected (unusual) suspected adverse drug reactions.

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

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

e) Report adverse drug reactions in special fields of interest such as drug abuse and drug use in pregnancy and during lactation.

f) Report when suspected adverse drug reactions are associated with drug withdrawals.

Therapeutic failure

For all drugs (new or old) with 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.

Products of questionable quality

Report product quality concerns such as:

- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labelling
- Expired drugs

Handling of information from your report

The information obtained from your reports helps to promote safe use of medicines on local, national and international levels. Your reported case will be entered into the National Adverse Drug Reaction database, and analysed by experts to determine possible casual relationships. Feedback will be given on the case as per procedures set by the NPC. A well completed adverse drug reaction reporting form submitted by you may result in one or more of the following:

a) Additional investigations into the medication in Uganda.

b) Educational initiatives to improve the safe use of medicines

c) Initiate a change in the schedule or manufacture of medicines to make them safer.

d) Regulatory and health promotion interventions as the situation may warrant including change in supply status or withdrawal.

Therefore, the purpose of ADR reporting is to reduce the risk associated with drug prescribing and administration and to ultimately improve patient care, safety and treatment outcome.

Annex I: Facilities visited during support supervison between January and March

District	Health Facility Type			
	General Hospital	**Health Centre IV**	**Health Centre III**	**Health Centre II**
Jinja	Al-Shafa		Gaddaffi Barracks	
	Kakira Sugar Ltd		Family Hope Center	
	Buwenge mission		Jinja Islamic	
	Jinja RR		IMC	
			Mpambwa	
			AOET	
			Budima	
			Butagaya	
			St. Camillus	
Kamuli	Kamuli General	Namwendwa	Mbulamuti	
	Kamuli mission	Nankandulo	Balawoli	
			Namasagali	
			Nabirumba	
			Bulopa	
			Kitayunjwa	
			Bugulumbya	
			Lulyambuzi	
			Bupadhengho	
Isingiro		Rugaaga	Kyanywamaizi	Rwantaha
		Kabuyanda	Kashumba	Rabugu
		Rwekubu	Mbaare	Rwakakwenda
			Endiizi	Karama
			Rushasha	Kyamusooni
			Roborogota	Kyezimbire
			Kikagati	Ruyanga
			Nshungyezi	Rulongo
			Mabona	Rubondo
			Nakivale	Juru

District	Health Facility Type			
	General Hospital	**Health Centre IV**	**Health Centre III**	**Health Centre II**
Luweero	Luweero Hospital	Nyimbwa	Bombo	Katuugo
		Kalagala	Nsawo	
			Kikoma	
			Katikamu	
			Butuntumula	
			Kamira	
			Wabusana	
Luweero			Kyalugondo	
			Zirobwe	
			Bamunanika	
Nakaseke	Kiwoko	Ngoma	Kikamulo	
	Nakaseke	Semuto	Bidabuggya	
			Wakyato	
			Kinoni	
			Kinyogoga	
			Bukalasa	
			Mifunya	
			Kapeeka	
Buliisa	Buliisa	Buliisa	Avogera	Kigwera
			Butiaba	Bugoigo
			Biiso	
Masindi	Masindi	Buijanga	Ikoba	Kirasa
		Masindi Kitara	Kinyara	
		TASO	Pakanyi	
			Kyatiri	
			Police Barracks	
			Masindi Prison	
			Kimengo	
Kibaale		Kibaale	St. Luke	Kibaale Police
		Emesco	Maisuka	Bubango
			Kabasekende	St. Denis Nsonga
			Mugarama	
			Kyebando	
			Allustin	
			Matale	
			Busesa	
			Ems	
			Nyamarwa	

District	Health Facility Type			
Kikuube	General Hospital	Health Centre IV	Health Centre III	Health Centre II
			Bugambe	
			Bujugu	
			Bugambe Tea	
Hoima		Kigorobya	Buseruka	St. Jude Tadeo
Kapchorwa	Kapchorwa		Tegeres	Gamatui
			Chebonet	Ngangata
Kapchorwa			Kabeywa	Chepterech
			Sipi	Tumboboi
			Gamogo	Kokwomurya
			Kaserem	
			Cheptuya	
			Chemosong	
			Kaplelko	
Sironko		Budadiri	Bumulisha	Nampanga
		Buwasa	Bulwala	Bundege
			Bunaseke	
			Bumumulo	
			Bulujewa	
			Buwalasi	
			Buteza	
			Sironko	
Bududa	General Hospital	Health Centre IV	Health Centre III	Health Centre II
	Bududa		Bufuma	
			Bulucheke	
			Bukigai	
			Bukibokolo	
			Foundation for Internati onal Medical International Medical Relief of Children (FIMRC) Bushika	
			Bushika	
			Bukalasi	
			Bushiyi	
Manafwa	Butiru Chrisco	Bubulo	Bukimanayi	
		Bugobero	Bukewa	
			Butiru	
Tororo	Tororo	Mukuju	Kirewa	
		Mulanda		
		Nagongera		

Annex II: Details of Pharmacovigilance Awards to Top Reporters and Partners

Plaques:	Personality/Organization
Exceptional,consistent and leading reporter for over 5 years	Habib Hussein
Top implementing partner Top Regional Referral Hospital Top General Hospital Top Health Centre IV Top Health Centre III Top Health Centre II	Infectious Disease Institute Masaka Regional Referral Hospital-Uganda cares Lyantonde General Hospital Kitebi Health Centre IV Kiswa Health Centre III Kyamuyimbwa Health Centre II
Top Reporting Private not for Profit Facilities	First: The AIDS Support Organization (TASO)
	1st runner up: Mildmay Uganda
Top AEFI Reporter Highest active drug safety monitoring reports Highest reports submitted from health centre IV Highest number of reports from a PNFP Most active focal person Highest reports from National Referral Hospital Certificates of Appreciation	2nd runner up: Nsambya Home Care Vicky Nyombi Arnold Arinaitwe Namanda Swalha Rodgers Katwesigye Dr. Musinguzi Patrick Achol James Erienyu
Kauma Sumayah (Jinja)	Most active District Assistant Drug Inspector
Benon Buyinza Medard Arinaitwe Dr. Ambangira Fortunate Hamza Mayanja Dr. Paul Kirumira Dr. Atwiine Martha Mugerwa Moses Dr. Berna Naggirinya Dr. Naiga Fairuzi Musimbaggo Douglas Dr. Arinaitwe Ivan Nakamanya Sharon Kitibwakye Okoth Moses Dr. Abdullah Waigala Dr. Edna Auma Dr. Jacqueline Balungi Namatovu Nuriat	Bundibugyo Hospital Mbarara Regional Referral Hospital Mulago Joint AIDS Programme IDI – Mulago Nsambya Home Care IDI – Mulago IDI – Mulago TASO Masaka Baylor – Uganda Mulago Joint AIDS Programme Kiswa Health Centre III IDI intern pharmacist Uganda Cares – Soroti IDI Mulago Kawaala Health Centre III Baylor – Uganda TASO Entebbe
Dr. Bridget Ainembabazi	IDI
Grace Amuge Dr. Kenneth Christopher Opio	Lyantonde Muslim Health Centre Kiruddu National Referral Hospital
Uganda Medical Association	Partnership with NDA
Shamim Nakade	IDI

Annex III:

NATIONAL DRUG AUTHORITY
Plot No. 19 Lumumba Avenue,
P.O. Box 23096, Kampala, Uganda.
Email: druginfo@nda.or.ug website: www.nda.or.ug
Tel: +256-417-788100 Toll-free: 0800 101999

Safe Drugs Save Lives

Doc. No.: DPS/FOM/313
Revision No.: 0
Effective Date: 11 Mar 2019

SUSPECTED ADR/AEFI REPORTING FORM

Note: Reporters and patients identity are held in strict confidence by NDA and protected to the fullest extent of the law

1.0 Type of Report

Initial ☐ Follow up ☐ | Serious ☐ Not Serious ☐ | Drug ☐ Vaccine ☐

2.0 Patients Information

Patient ID/initials: _____ Gender: Male ☐ Female ☐ Weight (kg)_____ Pregnancy status Yes ☐ No ☐ N/A ☐

Full address_____ Telephone Number _____

Date of birth :_ _/ _ _/ _ _ _ _ *(dd/mm/yyyy) OR Age at onset:*_____ Medical History _____

3.0 Vaccine(s) Information

Vaccine						*Diluent (if applicable)*			
Name of vaccine	Date of vaccination	Time of vaccination	Dose (1st, 2nd, 3rd etc)	Batch/Lot Number	Expiry date	Name of diluent	Batch/Lot Number	Expiry date	Date and time of reconstitution

4.0 Medical Product Details (List of all medicines used in the last 3 month – including herbal medicine)

Generic Name	Brand name	Batch no	Route, Dose and frequency	Date started	Date stopped	Indication	Tick suspected medicine

5.0 Brief description of the ADR/AEFI and any treatment given

5.1 Description of the AEFIs *(for vaccines)*
Severe local reaction > 3 days ☐ Encephalopathy ☐ Toxic shock syndrome ☐ Thrombocytopenia ☐ Anaphylaxis ☐ Generalized urticaria (hives) ☐ Injection site abscess ☐ High fever ≥38 °C ☐
Other (specify) _____

P.T.O

Date of ADR/AEFI onset: _ _/ _ _/_ _ _ _ Time of onset: _____ Date ADR/AEFI stopped: _ _/ _ _/_ _ _ _

6.0 Relevant Laboratory test results

6.1 Reason for seriousness
Prolonged hospitalization ☐ Congenital anomaly ☐ Disability ☐ Death ☐ Life threatening ☐

6.2 Action taken
Drug withdrawn ☐ Dose increased ☐ Dose reduced ☐ Dose not changed ☐ Not applicable ☐ Unknown ☐

6.3 Outcome
Recovered ☐ Recovering ☐ Continuing ☐ Recovered with sequelae ☐ Not recovered ☐ Death ☐ Unknown ☐

6.4 Causality of the ADR/AEFI
Certain ☐ Probable/ Likely ☐ Possible ☐ Unlikely ☐ Unclassifiable ☐

7.0 Reporter details

Name of reporter:	E mail Address/Contact:	Date of reporting
	Designation:	
Institution/Health facility:	Contact/Email:	District:

7.1 Administrative details

Report title:	Form ID number:	Date received:

NOTES

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