ETHIOPIAN FOOD AND DRUG AUTHORITY

PHARMACOVIGILANCE AND CLINICAL TRIAL LEAD EXECUTIVE OFFICE

Guideline for Consumer Reporting of Adverse Event of Medicines

Document No.:	**EFDA/GDL/008**	**Version No:**	**002**
Date of approval:	**12 July 2024**	**Date of First issue:**	**29 July 2024**

Document History

Version No.	Reason for Amendment	Effective Date
001	New version	2020
002	Amended to include all adverse events and safety communication, procedures how to report AE and reporting forms customized to fit for customers.	July, 2024

Asnakech Alemu, Signature

Contents

Foreword

Medicines are chemicals or compounds used to cure, halt, or prevent disease; ease symptoms; or help in the diagnosis of illnesses. Medicines are one of the most essential components in the health care system and advances in medicines have enabled health professionals to cure many diseases and save lives. Worldwide, numerous drugs are released into the market every day with limited information about their safety on larger and diversified populations raising concern about their safety. The large number of populations receiving medicines may come with harm if not monitored properly. This concern calls for a comprehensive pharmacovigilance system.

Hence a complete pharmacovigilance system needs an up to date and practical guideline to provide information and guidance to the various partners of pharmacovigilance as to what their roles and responsibilities should be towards the maintenance of a national drug safety.

It gives me great pleasure to present this Guideline for consumer reporting of adverse events (AE) as they are the main stakeholders of monitoring medicines safety or pharmacovigilance. I hope consumers will use this guideline effectively as a guide towards detecting and reporting adverse drug events and ultimately improve the safety and quality of healthcare they are being provided.

I would like to take this opportunity to thank all those who contributed in revising and printing this Consumers reporting of adverse drug events Guideline. I also call upon interested parties to continue their support by forwarding their comments and suggestions to the Ethiopian Food and Drug Authority P.O. Box 5681 Addis Ababa, Ethiopia. E-mail: pharmacovigilance@.efda.gov.et

Heran Gerba

Director General

Ethiopian Food and Drug Authority

Abbreviations

ADR	Adverse Drug Reaction
ADE	Adverse Drug Event
AE	Adverse Event
EFDA	Ethiopian Food and Drug Authority
NPC	National Pharmacovigilance Centre
UMC	Uppsala Monitoring Center
WHO	World Health Organization

Acknowledgment

The Ethiopian Food and Drug Authority would like to extend its gratitude to USP/PQM+ for its technical and financial support in the revision of this guideline. The Authority also acknowledges and extends its gratitude to all participants for their valuable contribution.

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Definitions

Consumer: a consumer in healthcare is anyone; patient or client or family; who uses, has used, or may use any health or health related service. It is not limited to those currently using a service.

Consumer report: is a report of a suspected adverse event to a medicinal product as initiated by the consumer and without interpretation by a health-care professional.

Health institution: a health institution is any governmental, non-governmental or private institution that carries out promotive, preventive, curative and rehabilitative activities or medicine trade or services.

Healthcare professional: health professional means a person who is registered by the relevant body as a professional to protect human health or provide service.

Medication errors: "A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

Medicine: "means any substance or mixture of substance used in the diagnosis, treatment, mitigation or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof; used in restoring, correcting or beneficial modification of organic or mental functions in human; or articles other than food, intended to affect the structure or any function of the body of human and it includes articles intended for use as a component of any of the above specified articles".

Pharmacovigilance: "The science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine/vaccine related problems."

Product quality defect: means attributes of a medicinal product or component which may affect the quality, safety and /or efficacy of the product, and/or which is not in-line with the approved market authorization. This includes suspected contamination, questionable stability, substandard, defective components, poor packaging, and labeling.

Side effect: any unintended effect of a pharmaceutical product occurring at a dose normally used in man, which is related to the pharmacological properties of the drug. The side-effects of a drug are the effects, usually bad ones, that the drug has on you in addition to its function of curing illness or pain.

Scope

This guideline applies to all pharmaceutical products; conventional medicine, traditional medicine, complementary and alternative medicine, biological products placed in the Ethiopian market. Moreover, this guideline also encompasses the monitoring of adverse events (both minor or serious), medication error and product quality defects, such as counterfeit, falsified and substandard products.

Objective

The objective of this guideline is to enable consumers to understand about medicine related adverse drug events by engaging in medicines safety monitoring systems.

Specific objectives

To enable consumers, understand about: -

- the reasons for reporting of adverse drug reaction, medication error and product quality defects
- what adverse drug reaction, medication error and product quality defects are reported?
- whom and when they should report an adverse drug reaction, a medication error and a product quality defect
- how they could report adverse drug reaction, medication error and product quality defect to the EFDA and
- the tools used to report any adverse drug reaction, medication error, and product quality defect whenever observed.

Introduction

Medicines are essential for individual patients and public health. Medicinal products have undergone thorough studies on animals and also on humans to prove its quality, safety and efficacy before it is allowed to be used for the general public and market authorization is granted. Though the medicine has been tested in various phases, the product has only been tested on a restricted number and type of patients, for a limited length of time and used under strict protocols. Hence the safety profile of every medicine in the market is not fully known and so needs continuous monitoring.

For this purpose, the safety of medicines should be monitored continuously using various systems. All the consumers should be engaged in the reporting of the medicine related adverse events in which they have experienced to the regulatory authority. Therefore, appropriate actions are taken on a timely basis to prevent other users from being harmed.

Both active drug safety reporting and spontaneous reporting of adverse events are the cornerstone of pharmacovigilance. Adverse drug reactions continue to be a major public health issue as they are a major cause of patient morbidity and mortality. The costs associated with treatment of ADRs are an economic burden on resource-limited health care systems such as those in most African countries. An important aim of pharmacovigilance is the detection of signals by timely sharing of data on ADRs to identify previously known and unknown medicines-related safety issues. To facilitate this process, the authority uses a centralized and decentralized drug safety monitoring system. The centralized pharmacovigilance system is a medicine safety monitoring center who receives, analyses, provides feedback, takes necessary action, provides regulatory management of all individual cases safety reports and communicates to the global community. While, the decentralized pharmacovigilance system: This is medicine safety monitoring center who detects, collects/ receives, analyses, implements feedback, manage cases, implements necessary action, enter the AE reports to WHO Uppsala monitoring center database, communicates to consumer and central pharmacovigilance center.

Consumer reporting of adverse drug reactions has existed in several countries for decades. The Netherlands and Sweden were among the first countries to implement consumer reporting. Information from consumer reports may give a new perspective on ADRs via the consumers unfiltered experiences. Consumers' views may change the way the benefit harm balance of drugs

is perceived and assessed today, and, being the ultimate users of drugs, consumers could have a relevant influence in the regulatory decision-making processes for drugs. All stakeholders in pharmacovigilance should embrace this new valuable source of information.

In the Proclamation 1112/2019 of the Food and Drug Authority, Article 4: Power and duties of the executive organ sub article it is stated that the EFDA shall undertake or order post marketing surveillance to ensure safety, efficacy and quality of medicines and take appropriate legal measures. In addition, the sub article states that the EFDA shall ensure that evidence of existing and new adverse events and information about pharmacovigilance of globally monitored products are followed upon and, as appropriate, take the necessary legal measure.

Activities to monitor medicine safety

Activities to promote medicines safety include monitoring safe medicine use in order to detect potential medicine-related problems, further assess and understand in order to develop prevention strategies to minimize patient adverse events. The strategies can then be communicated to all the medicine users to monitor the impact of any action taken. Consumers are one of the stakeholders that need to be involved in monitoring medicine safety or pharmacovigilance.

The core activities that will work in a well- established system are outlined in Figure 1 below.

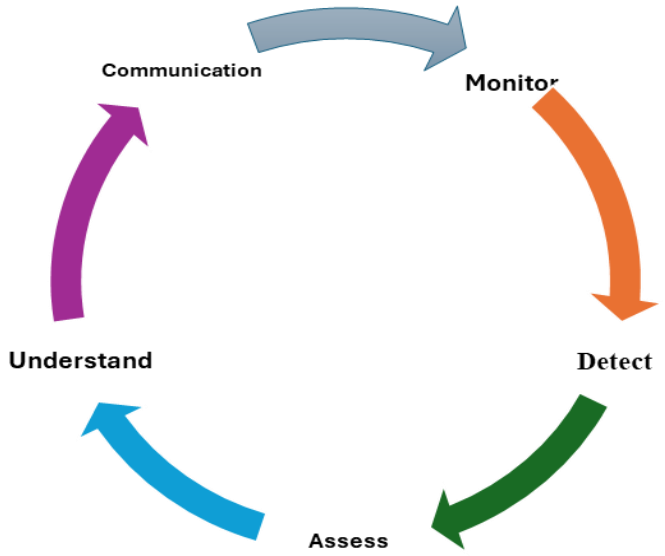


Figure1. Activities to prevent medicine-related injuries and promote medicines safety

Medicines to be monitored

The medicines to be monitored are conventional, herbal, and traditional medicines, vaccines, cosmetics.

Outcome from the activities

Information obtained on medicines safety from Ethiopia and all over the world will be used as the primary basis for decision making and regulatory measures will be taken by the EFDA on the medicines that are causing the drug related harms. Within these activities. The findings can result

in restricted use of the product in certain patient populations, dosage adjustments, added warnings, or withdrawal of the product. Adverse Event (AE) to be reported include

- Any side effects that are experienced after a consumer or patient used a medicine or a vaccine or any medicine-related injuries,
- Medication errors
- Product quality defects
- Therapeutic failure

Why consumers reporting?

Though the reporting of adverse drug reactions (ADR) in pharmacovigilance monitoring systems are necessary, adverse drug reactions are not being reported as expected in Africa. To address the issue of under-reporting, some countries in Africa, such as Ghana and Kenya, have embarked on patient reporting initiatives. Patient reporting is generally seen as a positive development for pharmacovigilance. In the Netherlands, for example, patient reporting has been shown to increase the number of reported ADRs and provide a new perspective on the experiences of ADRs. Pharmacovigilance in sub-Saharan Africa countries typically focus on healthcare workers and rarely on clients. However, it is patients who experience ADRs and are able to give a first-hand account of what they have experienced making them an integral part of any ADR reporting process. Consumer reporting of AEs has existed in several countries for decades, but in Ethiopia, the role of consumers as a source of information on AEs has not been fully established. Consumer reporting should be an integral part of the spontaneous reporting systems to boost AE reports. Though the consumer guideline was developed in 2023 as the first edition, the reporting system by consumer was not activated. Currently, in order to strengthen the pharmacovigilance system, the Ethiopian FDA has planned to closely work with consumers. Among the major sections added in the revision are safety communication, procedures how to report AE and reporting forms customized to fit for customers.

This Guideline shows the EFDA to set up a well-organized and effective consumer reporting within its pharmacovigilance system. Adverse event reports from consumers are the additional source of information on medicine safety. In addition, consumer reporting will tackle the problem encountered with low detection and underreporting. The new and novel adverse reactions can be detected through consumer reporting mechanisms. Hence consumer reports could complement reports received from health-care professionals. The Ethiopian national pharmacovigilance center participates in the WHO Programme for International Drug Monitoring, and it is recommended that ADR reports from consumers be forwarded to the WHO International Individual Case Safety Reports (ICSR) database.

Note: It is important for consumers to be aware of adverse events, the formal reporting tools used and channels for reporting.

What to report

There are different types of ADEs; adverse drug reaction, medication error and product quality defects; of medicine related harms that a consumer should be vigilant, detect and report to the EFDA. These are adverse drug reactions, medication errors and product quality defects of medicines.

An ADR is an unwanted symptom or effect caused by medicines, which can be minor or serious. Experts say that ADR varies for each patient and depends largely on their general health, the state of disease, age, weight, gender and genetic makeup. Patients/consumers cannot always be certain that what they are experiencing is caused by the medicine; but by reporting AE they can help the EFDA in their investigations, which will lead to safer medicines. Therefore, patients/consumers should report all those unusual symptoms or effects (AE) suspected to be caused by the medicines to National pharmacovigilance center (NPC), EFDA.

Necessary information to be included in a report

The patient /consumers of medicine should provide the adequate information in the AE reporting form about the following:

- Information about the person/patient who has experienced an AE or Adverse Event Following Immunization (AEFI) such as age, gender, weight and name etc
- The description of an AE or AEFI including how it happens, what the patient experience, and the onset date of the event
- Information about the medicine such as brand name, generic name, batch number, dose, strength, indication, route of administration, start and stop date etc.
- Information about any other drug or therapeutic good that the patient was taking at the same time
- Information about any other illness or medical condition
- Information about past allergies (if any)

Who and to whom should report

There are many stakeholders who are responsible to monitor medicine related AEs and collaborate on the reporting of the AEs to the EFDA. These are healthcare providers working at medicine manufacturers, wholesale and distributors, retail pharmacies, public health programmers, public (health posts, health centers and any type of hospital), private health facilities, University hospitals, professional associations, and the media.

In this Guideline focus is given to the roles and responsibilities of patients or consumers. Hence, consumers who experienced an AEs should report to the EFDA or to any health care professional including the one that had prescribed, dispensed, or administered to them the drug that has caused the AEs. The health professional will then be able to report the medicine-related problems to the national pharmacovigilance center at EFDA.

It should be clear to all consumers or patients that they need to report any observed adverse drug reaction, medication error, product quality defects and therapeutic failure as soon as possible and they need only suspect the drug related problems and there is no need to worry whether it was caused by the drug or not. Confirmation will only be done at the pharmacovigilance center after different types of additional investigations are carried out.

When to report

The patient should report a serious AEs or AEFI as soon as possible to healthcare professionals, or the National Pharmacovigilance Centre. Sometimes, the AE might be unexpected and might be posing harm to other patients. All serious cases should be reported within 24 hours of detection to the Ethiopian Food and Drug Authority. Be reminded that, earlier reporting by the patient will be helpful to minimize harm to other patients. Further, the non-serious/mild AEs should also be reported at the earliest through all available means of reporting channels.

How to report

Consumers should use either of the following tools (listed below) during reporting side effects, medication errors and product quality defects. There are different types of tools to report medicine related harms that can be used by consumers, disease specific patient associations and consumer associations. The reporting of medicine related AEs will be mandatorily written at the end of all prescription papers so that consumers could be reminded that they can use any of the reporting tools to report medicine related harms.

1. Paper based tools (yellow form)
2. Web Based (e-reporting) System
3. Med safety Mobile App
4. Toll free telephone number: 8482
5. Email: pharmacovigilance@efda.gov.et.

1. Paper based tools-Yello form

The EFDA has prepared and distributed a standard consumer Adverse Event reporting form that has the necessary features. This yellow form is available at all health facilities and community pharmacies and can be obtained easily upon request. The report form has places to fill the data on the information about the person that has experienced the suspected side effect, information on the medicine/vaccine that caused the harm, information on signs and symptoms of the side effect that are suspected to be caused by the medicine taken and information about the person who is reporting the side effect. For a proper investigation this information must be filled as much as possible (Annex 1).

If a consumer is unable to fill the form, support could be requested from any healthcare professional, or the healthcare professional can fill the required data based on the information obtained from the consumer who has encountered a medicine related harm. In addition, a family member/friend could also support the consumer to report a side effect on behalf of the consumer that has experienced the side effect.

The filled report form can then be sent directly or through the health facility or community pharmacy in the vicinity, or any of the offices mentioned above who can then deliver it to the EFDA.

2. **Web based reporting (E- reporting)**

These tools are used through the use of the internet and hence requires the knowledge and understanding of use of online applications. If consumers are able to fully understand and follow the instructions, then they can report medicine related harms easily.

Any consumer or patient who is able to use computers and access the internet can report medicine related adverse events online through the use of the following link (www.efda.gov.et or directly login to https://www.eris.efda.gov.et). Then it will take you to the following first page of the system at the EFDA website. Thereafter the reporter can enter the necessary data and follow the steps by clicking the next button until the final submit button is reached. (See Annex 2)

3**. Med Safety Application**

This online mobile based reporting application can be downloaded from Google play store for Android phones or APP store for IOS users. It requires the reporter to create an account through an email address. Once the account is created the application is entered through the "new report" button and then the required data is entered until the final submit button is reached and the report is sent after a final click. Instructions n how to use this app are obtained at the end of this Guideline (Annex 2)

4. **Toll free telephone call: 8482**

This is the most convenient form of reporting on a medicine related adverse events by a consumer. The reporter can simply dial the number 8482 which is a toll-free telephone number owned by EFDA to receive any medicine related adverse events experienced by consumers. The reporter can inform the expert who will be picking up the telephone the details about the person affected by the medicine, the name and other identifying information of the medicine and the experienced adverse effect as a result of the use of the medicine. The expert will then record the information and transfer it to the pharmacovigilance center who will then take the necessary regulatory action.

5. **Using the email address**: pharmacovigilance@efda.gov.et

Consumer reporters can also send a report on a medicine related adverse event to the EFDA by using the given email address. After filling all the necessary information on a report form and making a scan copy of the report they can send it using the given email.

Note: Any consumer or patient after having experienced any Adverse drug event, a medication error or a product quality defect can choose to report to the EFDA or other branch offices mentioned above by using any convenient one out of the listed reporting tools and means described above.

What happens to report?

National Pharmacovigilance Center (NPC) collects reports of AEs, suspected ADRs and AEFI from healthcare professionals, patients, sub national Pharmacovigilance centers, public health programmes, and pharmaceutical companies having registration of medicines. The staff at NPC, checks the report for mandatory and essentially required information. For consumers' reports, it may be necessary to convert the ordinary terms to medical terminologies for coherence with the reports coming from health professionals. If there is any missing mandatory information, the reporter is contacted. The staff also contacts the reporter for more information about serious adverse events.

NPC compiles the reports received against a medicine via different channels and performs a complete assessment where possible. The reports are checked for new signals by safety experts to determine if there is any new information about the safety of the medicines. After evaluation of the safety signals, NPC//EFDA may issue:

- New warning/ contraindication,
- Remove indication of medicines for specific diseases or age groups,
- Advice on how the medicines should be used, or
- In some cases, even stop the use of medicines.

Communication

Effective medicine safety communication is an important subject for effective implementation of the guideline as clear understanding is enabler for effective implementation, enables for protecting themselves and the society from medicine related adverse events. Based on this, the main communication points that should be considered by health professionals during oral or written communication strategy when providing education to consumers are shown below.

- When health professionals or experts working in the authority provide information about drug safety, it is expected to be presented in short, clear, informative and direct/simple language. It is preferable if it includes practical examples, inviting discussion and attractive ways for better understanding.
- Health professionals or experts from Authority are expected to raise awareness about drug safety to consumers in the ways listed below.
- The approach needs to be:
    - Use of opportunities where communities have gathering for related event
    - Association meetings/platforms

      Disease specific associations like consumers, diabetes, People living with HIV/AIDS (PLWHA), kidney problem, cancer society etc.
    - Health Education in Health Institutions
    - Health extension programs
    - Health professionals' Associations platform
    - Mainstream medias and social media
    - Website
    - Campaign
    - Distribution of fliers and via short messages

Note

- Utilizing different methods and media strategies by repeated and consistent messaging helps to achieve effective communication.
- It is important for consumers to attend drug safety education provided by healthcare professionals
- Messages transmitted by any media require caution and should be approved by the authority.

Annex

Annex 1. Medicine/Vaccine consumer reporting form

Ethiopian Food and Drug Authority (EFDA)

Adverse Drug Event / Adverse Event Following Immunization reporting form for Consumers

Information about affected Consumer/Patient

Patient Name (abbreviation) ----------	Age (date of birth) --------	Sex Male --------- Female ------	Address ----------	Any prior health problems, allergies etc ---------- ----------

Information on suspected drug/vaccine

Drug name	Dose/ dosage form, route, frequency	Batch number	Drug taking started (DD/MM/YYYY)	Reaction started (DD/MM/YYYY)	Drug taking stopped (DD/MM/YYYY)	Reason for drug use

From where did you get this medicine? □ Hospital □ Community pharmacy □ Health center □ Health post □ Other-------

Information about the adverse event

- How long was the medication(s) taken before the adverse event appeared? □minutes/hours/days/months/years (choose)
- Did the adverse event subside when the medication(s) was stopped?□ Yes □ No □ Did not stop taking the medicine
- Did the adverse event reappear when the medication (s) was taken again? □ Yes □ No □ Did not taken again
- Were any treatment given/ medication taken to overcome the adverse event? □ Yes (please specify) □ No
- Describe in detail the damage caused by the medicine/vaccine?

What is the current outcome of the adverse event?

□ Fully recovered □ Getting better □ Adverse event continuing □ Caused death

Relevant medical conditions such as allergies, renal disease, liver disease, other chronic diseases, pregnancy etc

_____

Reported by: Name ----------	Telephone ----------	Date ----------

Product quality problem: Color change, separating of components, powdering, crumbling, caking, molding, change of odor, incomplete pack, suspected contamination, poor packaging/poor labeling, etc. (Write if anything different than given above)

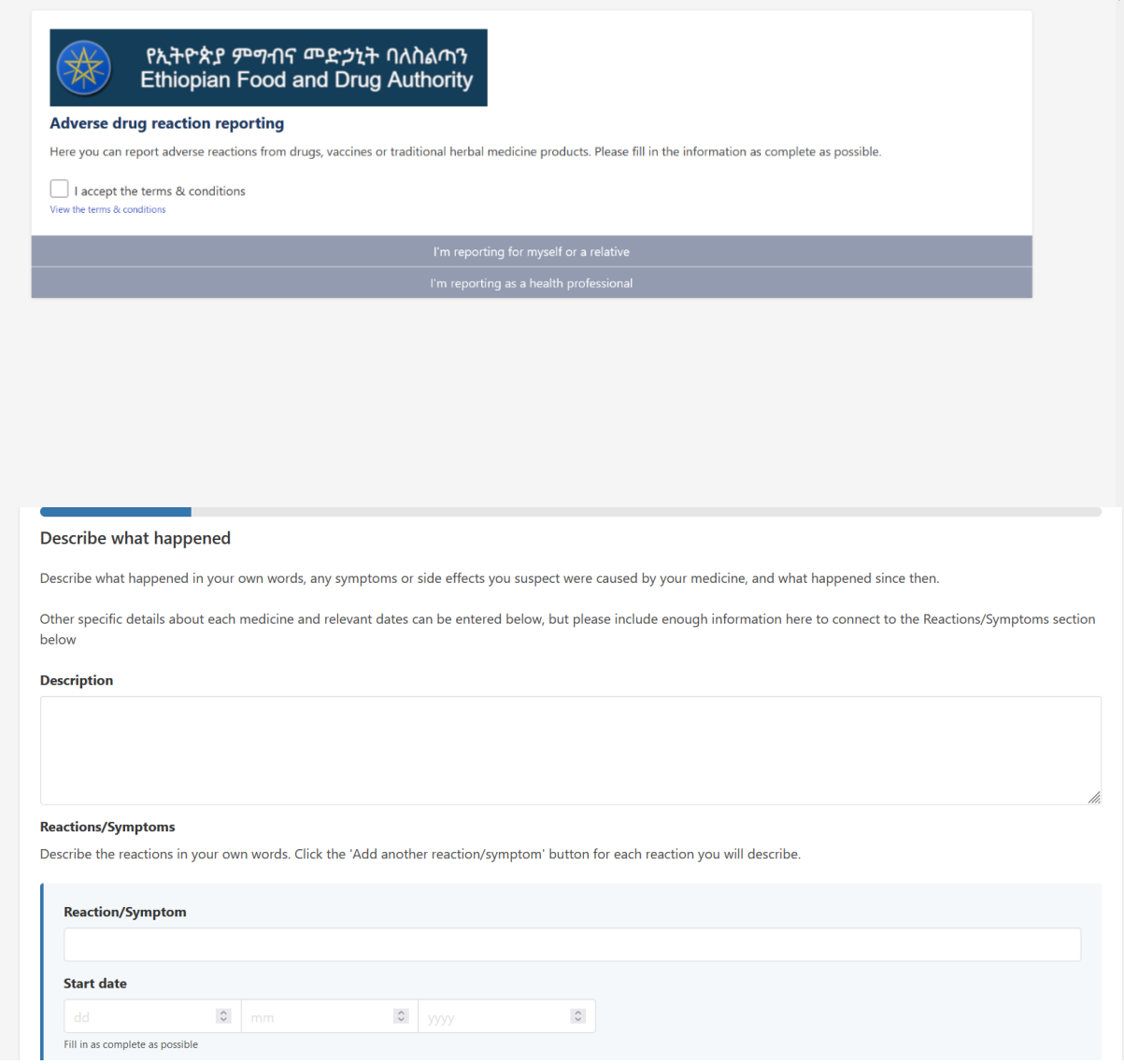
Drug trade name	Batch No	Registration no	Dosage form and strength	Size /type of package

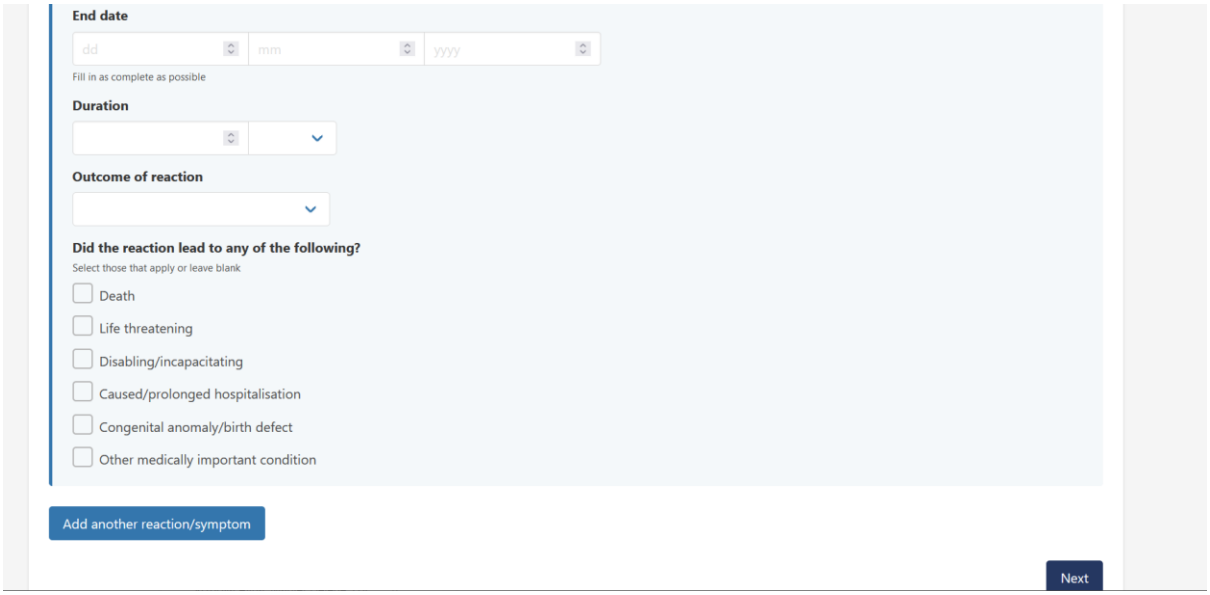
For office use only

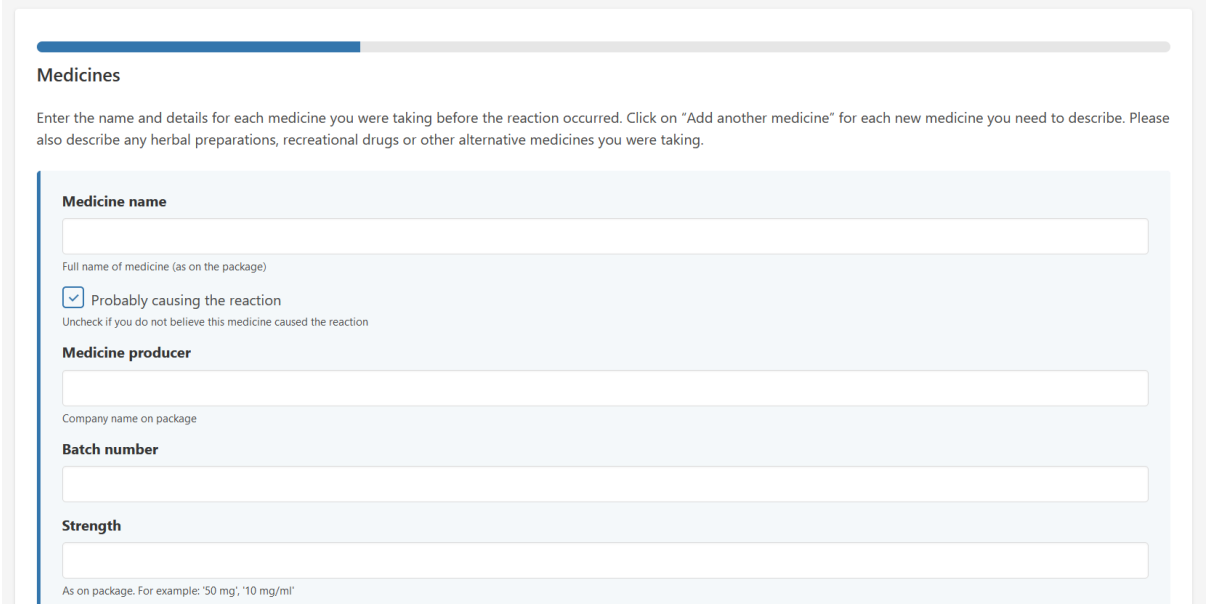
Received on:	Registration no:

For more information
P.O. Box 5681
Toll free call: 8482, Addis Ababa, Ethiopia

Annex 2: Steps in e-Reporting




End date
dd
mm
yyyy
Fill in as complete as possible
Duration
Outcome of reaction
Did the reaction lead to any of the following?
Select those that apply or leave blank
Death
Life threatening
Disabling/incapacitating
Caused/prolonged hospitalisation
Congenital anomaly/birth defect
Other medically important condition
Add another reaction/symptom
Next


Medicines
Enter the name and details for each medicine you were taking before the reaction occurred. Click on "Add another medicine" for each new medicine you need to describe. Please also describe any herbal preparations, recreational drugs or other alternative medicines you were taking.
Medicine name
Full name of medicine (as on the package)
Probably causing the reaction
Uncheck if you do not believe this medicine caused the reaction
Medicine producer
Company name on package
Batch number
Strength
As on package. For example: '50 mg', '10 mg/ml'

Dosage

How much did you take? For example: '2 tablets 3 times a day'

How was the medicine administered

Start date

dd mm yyyy

Fill in as complete as possible

End date

dd mm yyyy

Please leave blank if the medicine is still being taken

Duration

Reason for taking the medicine

Why did you take the medicine? (For example: Diabetes, headache)

Action taken with medicine

Additional information

Please give a short description of your medical history. This is important since some reactions only appear with a combination of previous or ongoing disease, special diets, recreational drugs, smoking habits, alcohol intake or allergies. You can also enter other comments you feel are important.

Current and previous illnesses

Additional comments

Previous

Next

User of the medicine

Initials

Sex

Male Female Unknown

Weight

kg

Date of birth

dd mm yyyy

Complete Date of birth or Age must be entered

Age at time of reaction

Complete Date of birth or Age must be entered

Country where the reaction started

Ethiopia

This is important if the environment has been a trigger for the reaction/symptom

Previous Next

Contact details

Email

Telephone

Previous Next

Review

This is the summary of your report. Please verify that the information is correct. If it's not, use the Edit button to change the information. To send the report, click the Send button.

Send report

Reactions/Symptoms

Description

adr

Annex 3. Instruction on how to use mobile apps to report on medicine related harm

Healthcare professionals can report ADE by using their MOBILE PHONES by following these simple procedures.

1. To access the Med safety app for IOS users go to the APP store for Android users go to google store search for Med safety app in the search bar (found as in the diagram above)
2. Click on the Med safety icon app to select it
3. click install to install the app
4. Once the app has been successfully installed click open on your device
5. Create a user account.
6. once the account has been created you come to the home page where the full page is provided
7. Then You can now report an ADE

Email

Password

LOGIN
Forgotten password?
☐ Keep me logged in

CREATE AN ACCOUNT
CONTINUE AS A GUEST

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