Product safety Directorate, Ethiopian Food and Drug Authority

Guidelines for Consumer Reporting of Side effects of medicines

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Foreword

Medicines are chemicals or compounds used to cure, halt, or prevent disease; ease symptoms; or help in the diagnosis of illnesses. Advances in medicines have enabled doctors to cure many diseases and save lives. Medicines are one of the most essential components in the health care system. Worldwide, numerous numbers of drugs are being released into the market every day with incomplete knowledge as to their safety levels when used by wide variety of population category other than the one studied in the limited clinical trials making safety of medicines as one important concern. 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 a great pleasure to present this Guideline for consumer reporting of side effects as they are the main stakeholders of monitoring medicines safety/ pharmacovigilance. I hope consumers will use this guideline effectively as a guide towards detecting and reporting of side effects 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 developing and printing this Consumers reporting of side effects 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., Tel.251-115524122, e-mail contact efda@.efda.gov.et.

Heran Gerba

Director General, EFDA

Abbreviation

ADR- Adverse Drug Reaction

EFDA: Ethiopian Food and Drug Authority

WHO: World Health Organization

Acknowledgment

The Ethiopian Food and Drug Authority would like to extend its gratitude to Tony Blair Institute/ TBI for its technical assistance and ----------for its financial support in meeting all the financial expenses associated with the execution of the revision workshop and printing of this guideline. The Authority also acknowledges and extends its gratitude to all the participants of the workshop for their valuable contribution.

Definitions

Consumer

A consumer in a healthcare is anyone who uses, has used, or may use any health or health related service. It is not limited to those currently using a service. The terms "patients" and "users" generally apply only to those currently undergoing some form of treatment.[3]

Health institution

A health institution is any governmental, non-governmental or private institution that carry 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."[4] (National Coordinating Council for Medication Error Reporting and Prevention)

Medicine

“Medicine means any substance or mixture of substances used in the diagnosis, treatment, mitigation or prevention of a disease in human and includes narcotic drugs, psychotropic substances and precursor chemicals, traditional medicines, complementary or alternative medicine; poisons, blood and blood products, vaccine, radioactive pharmaceuticals, cosmetics, and sanitary items and medical instruments” [5]

Pharmacovigilance

"The science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems." [1]

Product quality defect

Quality problems of products i.e; suspected contamination, questionable stability, defective components, poor packaging or labeling, or unexpected therapeutic ineffectiveness.

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 of the Guideline

The scope of this Guideline is to outline the roles and responsibilities of consumers that are involved in monitoring medicines safety, especially to describe how consumers can detect and report side effects that are encountered after a medicine is taken.

The findings are used to create awareness on and promote rational, safe, and more effective use of medicines.

Activities to monitor medicine safety

Activities to promote medicines safety involve monitoring medicine use in order to detect potential medicine-related problems, further assesses and understand in order to develop prevention strategies to minimize patient harm. 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.

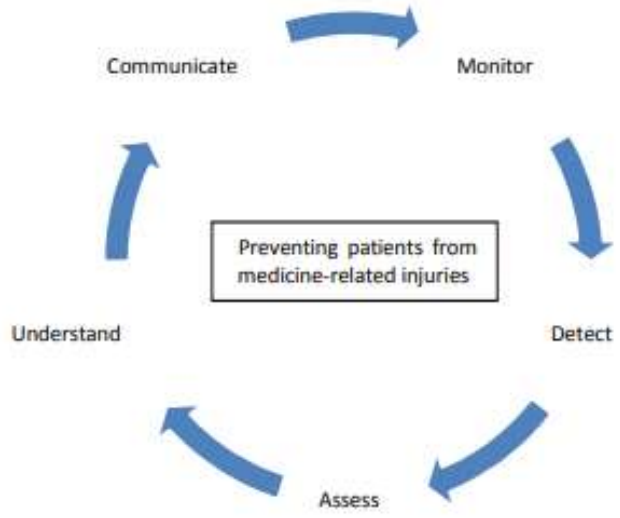


Figure 1. Activities to prevent medicine-related injuries and promote medicines safety

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.

Side effects to be reported are

- 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

Chapter one

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 tasted 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 and all the consumers and patients and consumers should involve in the reporting of the medicine related injuries that they have experienced to the regulatory authority so that 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 Drug Reactions (ADRs) are the cornerstone of pharmacovigilance and adverse drug reactions continue to be a major public health issue as they are a major cause of patient morbidity and mortality [6]. The costs associated with treatment of ADRs are an economic burden on resource-limited health care systems such as those in most African countries [7]. 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

Consumer reporting of adverse drug reactions (ADRs) has existed in several countries for decades, but throughout Europe the role of consumers as a source of information on ADRs has not been fully accepted until recently. In Europe, The Netherlands and Sweden were among the first countries to implement consumer reporting well before it was mandated by law throughout the EU (8).

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 (8).

Though the reporting of adverse drug reactions and pharmacovigilance is known to be necessary, adverse drug reactions are not being reported as expected and there is a huge underreporting in the whole specially in Africa [9]. To address the issue of under-reporting, some countries in Africa, e.g. Ghana and Kenya, have embarked on patient reporting initiatives [9]. Patient reporting is generally seen as a positive development for pharmacovigilance [10]. In the Netherlands, for example, patient reporting has been shown to increase the number of reported ADRs and also provides a new perspective on the experiences of ADRs [11].

Pharmacovigilance in sub-Saharan Africa (SSA) countries typically focus on healthcare workers and rarely on patients. 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 [12].

For patient reporting to work however, it is important for patients to be aware of ADRs and the formal national tools and channels for reporting ADR and to be able to recognize an ADR. They must be able to easily use these tools and channels and should find value in using them.

In the Proclamation 1112/2019 of the Food and Drug Authority, Article 4: Power and duties of the executive organ sub article (9) 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, sub article (10) 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 [5].

Objective:

The objective of this guideline is to enable consumers can understand about medicine related harms and side effects of medicines and involve in the monitoring of medicines safety.

Specific objectives

To enable consumers understand

- What and side effects, medication error and product quality defects are,
- To whom they should report an adverse drug reaction, a medication error and a product quality defect,
- How they could report a side effect, medication error and product quality defect to the EFDA and,
- Which tools to use to report a side effect, a medication error, and a product quality defect whenever they experience one.

Chapter two

What are the types of medicine related harms that need to be reported? (Side effects, medication error and product quality defects)

There are three types of medicine related harms that a consumer should be vigilant, detect and report to the EFDA. These are side effects, medication errors and product quality defects of medicines.

Side effect

Is 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 in addition to its function of curing illness or pain. In other words, it means any bad situation, illness, reaction or harm that resulted after a consumer has taken a medicine whether it is prescribed by a healthcare professional or by self-medication and has resulted in an inconvenience in the consumer's life in addition to the disease

the person had experienced before the medicine was taken. For this guideline purpose we use side effect interchangeably with Adverse Drug Reaction

Medication errors

Medication errors are 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. [4] (National Coordinating Council for Medication Error Reporting and Prevention).

In other words, it means any error committed by the patient while taking the medicine or healthcare professional while prescribing, dispensing and administering a medicine. The error may be harmful and might have been prevented had the proper procedures been communicated and followed both by the consumer and the healthcare professional.

A Product quality defect

Are any quality problems of medicines i.e; suspected contamination, questionable stability, defective

components, poor packaging or labeling, or unexpected therapeutic ineffectiveness.

In other words. It means any visually observable physical defect of a medicine that can be identified by the healthcare professional and the consumer before the medicine is taken.

Hence, a side effect, a medication error and product quality defect are the medicine related harms that should be reported by a consumers or patients to EFDA so that appropriate regulatory measures are taken on the medicine and people are protected from being harmed again.

Chapter three

Roles and responsibilities of consumers in reporting side effects, medication errors and product quality defects

There are many stakeholders who are responsible to monitor medicine related harms and collaborate on the reporting of the data to the EFDA. These are healthcare providers working at medicine manufacturers, wholesale and distributors, retail pharmacies, public health programmes, public and private health care facilities, Universities, professional associations, and the media.

In this Guideline focus is given to the roles and responsibilities of patients and consumers. Hence, the roles and responsibilities of all patients who have taken any medicine and suspect they have been affected by an ADR is to report to the EFDA or any health care professional including the one that had prescribed, dispensed, or administered to them on the drug that has caused the ADR. The health professional will then be able to report the medicine-related problems to the pharmacovigilance center at EFDA.

It should be clear to all consumers or patients that they need to report any observed side effect, 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.

Currently the EFDA uses both the centralized and decentralized approach to collect information on medicine related harm. The centralized pharmacovigilance center is at EFDA, Addis Ababa and consumers can report to the center any time they encounter a side effect, medication error or product quality defect to the center. Consumers can also report to pharmacovigilance experts at the six decentralized pharmacovigilance centers that are established near to their localities at specialized referral hospitals of; Gonder university hospital (Gonder), Jimma University hospital (Jimma), Hawassa university hospital (Hawassa), Blacklion university hospital (Addis Ababa), Dilchora university hospital (Diredawa) and Ayder university hospital (Mekelle). In addition,

consumers can also report to the pharmacovigilance focal persons of branch EFDA offices situated at Bahirdar, Jimma, Hawassa, Diredawa, kombolcha and Mekelle

Chapter four

Tools to be used in reporting side effects, medication errors and product quality defects by consumers (how to report a medicine related harm)

This chapter describes the how a consumer can report a medicine related harm. There are four 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 harms 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

2.Web Based (E-Reporting) System and Mobile Apps

3. Toll free telephone number/8482

4. Email using the address: pharmacovigilance@efda.gov.et

1. Paper based tools

The EFDA has prepared and distributed a standard consumer side effect reporting form that has the necessary features to capture medicine related harms. This yellow form is available at all health facilities and community pharmacies at all localities 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 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 free of charge through a post office, can be given to the health facility or community pharmacy, or any of the offices mentioned above who can then deliver it to the EFDA as mentioned in Chapter two.

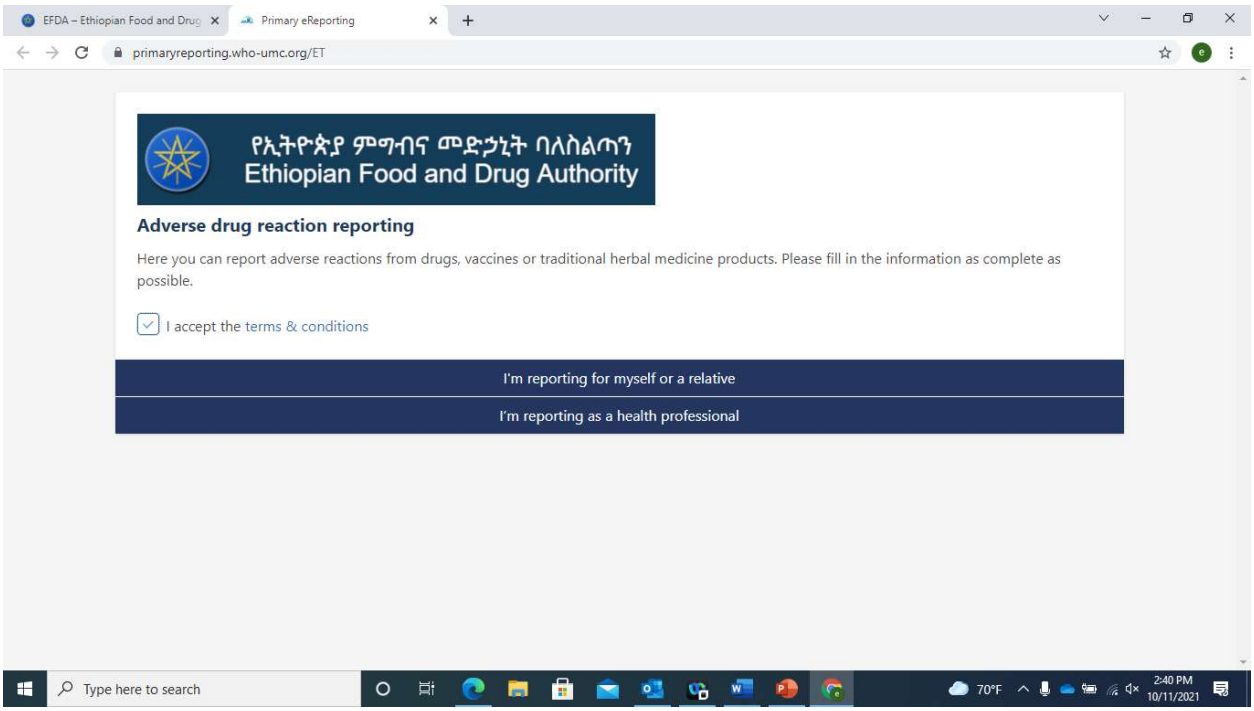
2. Web based reporting (E- reporting) and mobile apps

These tools are used through the use of internet and hence requires the knowledge and understanding of use of online applications. If consumers are able to fully understand and follow on the instructions, then they can report medicine related harms easily. There are two types namely: Web based E- reporting tool and mobile application called Med safety application

A. Web based E- reporting tool

Any consumer or patient who is able to use computer and access internet can report a medicine related harm online through the use of the following link which will take to the following first page of the system at the EFDA website. Thereafter the reporter can enter the necessary data and follow upon the steps by clicking the next buttons until the final submit button is reached. The following is the first page of the e-reporting tool that could be seen when in use.

www.fmhaca.gov.et https://primaryreporting.who-umc.org/ET



B. The other address to report a medicine related harm is through the use of the given link https://med-safety.redant.cloud/login. This link can be used by healthcare professionals after they are informed about the adverse experience that a patient or a consumer experienced and the necessary data are obtained. Using this link requires one to create an account, choose the organization EFDA, add persona details and create a user to use the system always.

C. Medsafety 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)

3.Toll free telephone center

This is the most convenient form of to report on a medicine related harm by a consumer or a patient. The reporter can simply dial the number 8482 which is a toll-free telephone number

prepared by EFDA to receive any medicine related harm experienced by consumers or patients. The reporter can inform to 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.

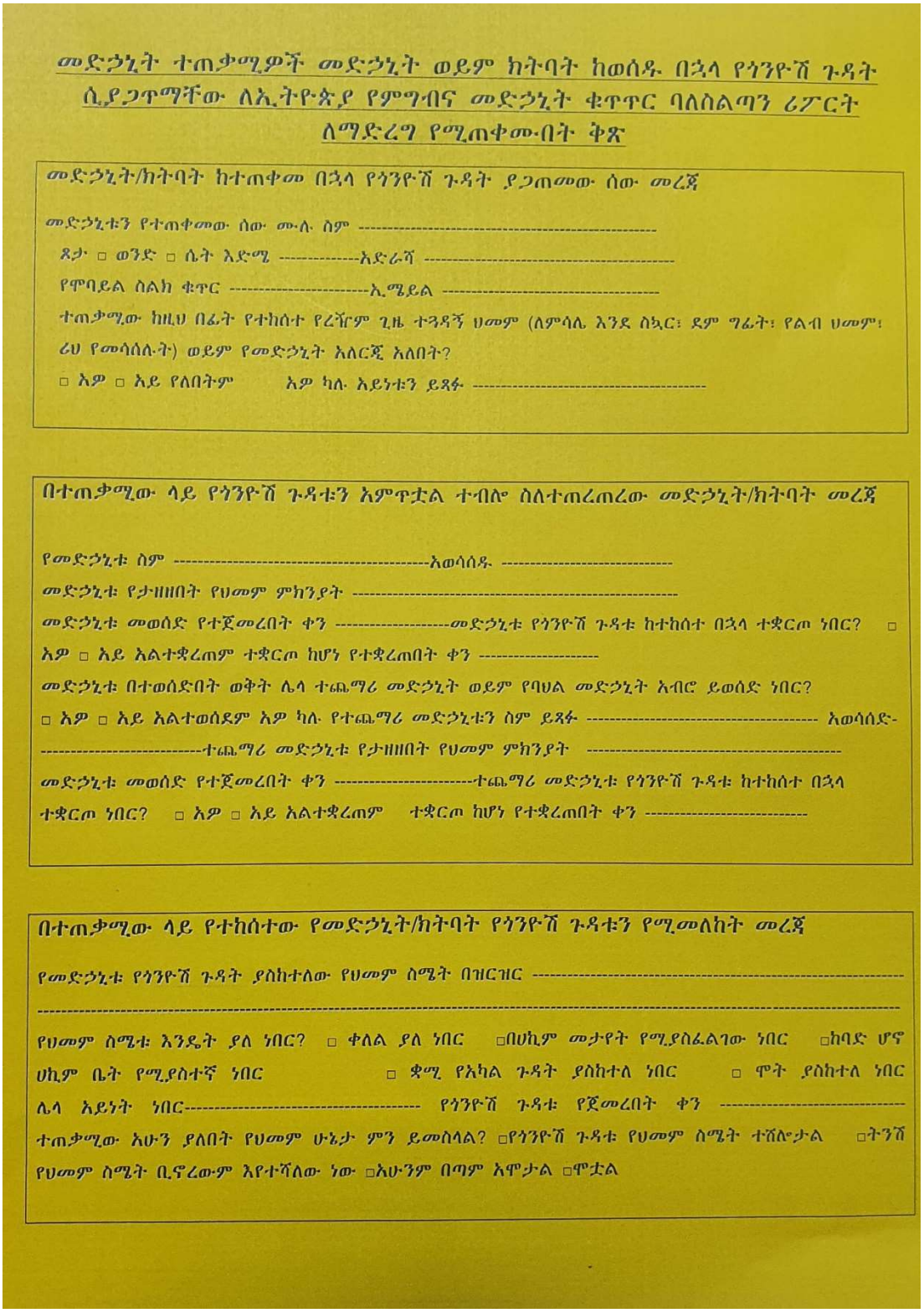
4. Email using the address: pharmacovigilance@efda.gov.et

Consumer reporters can also send a report on a medicine related harm 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 which is the address of the pharmacovigilance center.

Any consumer or patient after having experienced any sideeffect , a medication error or a product quality defect and can choose to report to the EFDA or other branch offices mentioned above by using any convenient one out of the four types of reporting tools described above.

Annexures

Annex 1. The National consumer reporting form



መድኃኒት ተጠቃሚዎች መድኃኒት ወይም ክትባት ከወሰዱ በኋላ የጎንዮሽ ጉዳት ሲያጋጥማቸው ለኢትዮጵያ የምግብና መድኃኒት ቁጥጥር ባለስልጣን ሪፖርት ለማድረግ የሚጠቀሙበት ቅጽ

መድኃኒት/ክትባት ከተጠቀመ በኋላ የጎንዮሽ ጉዳት ያጋጠመው ሰው መረጃ

መድኃኒቱን የተጠቀመው ሰው ሙሉ ስም ----------

ጾታ □ ወንድ □ ሴት እድሜ ----------አድራሻ ----------

የሞባይል ስልክ ቁጥር ----------ኢሜይል ----------

ተጠቃሚው ከዚህ በፊት የተከሰተ የረዥም ጊዜ ተጓዳኝ ህመም (ለምሳሌ እንደ ስኳር፣ ደም ግፊት፣ የልብ ህመም፣ ሪህ የመሳሰሉት) ወይም የመድኃኒት አለርጂ አለበት?

□ አዎ □ አይ የለበትም አዎ ካሉ አይነቱን ይጻፉ ----------

በተጠቃሚው ላይ የጎንዮሽ ጉዳቱን አምጥቷል ተብሎ ስለተጠረጠረው መድኃኒት/ክትባት መረጃ

የመድኃኒቱ ስም ----------አወሳሰዱ ----------

መድኃኒቱ የታዘዘበት የህመም ምክንያት ----------

መድኃኒቱ መወሰድ የተጀመረበት ቀን ----------መድኃኒቱ የጎንዮሽ ጉዳቱ ከተከሰተ በኋላ ተቋርጦ ነበር? □ አዎ □ አይ አልተቋረጠም ተቋርጦ ከሆነ የተቋረጠበት ቀን ----------

መድኃኒቱ በተወሰድበት ወቅት ሌላ ተጨማሪ መድኃኒት ወይም የባህል መድኃኒት አብሮ ይወሰድ ነበር?

□ አዎ □ አይ አልተወሰደም አዎ ካሉ የተጨማሪ መድኃኒቱን ስም ይጻፉ ---------- አወሳሰድ-

----------ተጨማሪ መድኃኒቱ የታዘዘበት የህመም ምክንያት ----------

መድኃኒቱ መወሰድ የተጀመረበት ቀን ----------ተጨማሪ መድኃኒቱ የጎንዮሽ ጉዳቱ ከተከሰተ በኋላ ተቋርጦ ነበር? □ አዎ □ አይ አልተቋረጠም ተቋርጦ ከሆነ የተቋረጠበት ቀን ----------

በተጠቃሚው ላይ የተከሰተው የመድኃኒት/ክትባት የጎንዮሽ ጉዳቱን የሚመለከት መረጃ

የመድኃኒቱ የጎንዮሽ ጉዳት ያስከተለው የህመም ስሜት በዝርዝር ----------

የህመም ስሜቱ እንዴት ያለ ነበር? □ ቀለል ያለ ነበር □በሀኪም መታየት የሚያስፈልገው ነበር □ከባድ ሆኖ ሀኪም ቤት የሚያስተኛ ነበር □ ቋሚ የአካል ጉዳት ያስከተለ ነበር □ ሞት ያስከተለ ነበር ሌላ አይነት ነበር---------- የጎንዮሽ ጉዳቱ የጀመረበት ቀን ----------

ተጠቃሚው አሁን ያለበት የህመም ሁኔታ ምን ይመስላል? □የጎንዮሽ ጉዳቱ የህመም ስሜት ተሸሎታል □ትንሽ የህመም ስሜት ቢኖረውም እየተሻለው ነው □አሁንም በጣም አሞታል □ሞቷል

የመድኃኒት/የክትባት የጥራት ጉድለት ጥርጣሬ ሲያጋጥምዎት መረጃዎችን ከመድኃኒቱ የውጭ ማሸጊያ ላይ በማየት እዚህ ላይ ይጻፉ

የመድኃኒቱ ስም ----------የአገልግሎት ዘመኑ መጀመሪያና መጨረሻ----------
የመገለጫ ቁጥሩ ----------

የታየ የመድኃኒት/የክትባት የጥራት ጉድለት ጥርጣሬ (ለምሳሌ የከለር ወይም የሽታ ለውጥ ፣ መሰባበር፣ መጣበቅ፣ ከእሽጉ የጎደለ፣ አስተሻሸጉ ችግር ያለበት፣እንዲሁም ሌሎች) ----------
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መጀመሪያ እዚህ ላይ እጠፉ

የሚከተሉት ሲያጋጥምዎት ሪፖርት አድርጉ

የመድኃኒት/የክትባት የጎንዮሽ ጉዳት

የመድኃኒት/የክትባት የጥራት ጉድለት

የመድኃኒት/የክትባት አሰጣጥ ስህተት

ቀጥለው እዚህ ይጠፉ

የላኪ አድራሻ ----------

EFDA

የኢትዮጵያ የምግብና መድኃኒት ቁጥጥር ባለስልጣን ፖ.ሳ.ቁ 5681.ስ.ቁ 251-115-524122/5524123. ድህረ ገጽ www.fmhaca.gov.et ኢሜይል contactefda@efda.gov.et

Annex 2. 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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