Product safety Directorate,

Ethiopian Food and Drug Authority

Pharmacovigilance Guidelines for Antitubercular medicines

EFDA/GDL/001

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Contents

Safety monitoring or Pharmacovigilance of the medicines used to treat TB

I. Overview of safety, efficacy and quality assurance of medicine and medical device

According to the National tuberculosis Guideline 6th edition 2017, Ethiopia is among the 30 High TB, HIV and MDR-TB Burden Countries, that accounted for 80% of all estimated TB cases worldwide, with annual estimated TB incidence of 207/100,000 populations and death rate of 33 per 100,000 populations for 2014.

Continuous availability of needed anti-tubercular and related medical supplies and devices of proven safety, efficacy/performance and quality and their appropriate use are indispensable for diagnosis, prevention, and treatment of tuberculosis. The safety, efficacy /performance and quality of such products shall be assured throughout their life cycle starting from innovation, manufacturing until they are used by patients. Thus, assuring safety, efficacy and quality of such products is the responsibility of manufacturers, importers, distributers, retail out-lets, public health programs, health institutions, health professionals and patients. The responsibility of assuring of safety, efficacy/ performance and quality of such medicinal products and diagnostic devices is not left only to these stakeholders. Hence countries shall establish national medicine regulatory authorities that are legally mandated for ensuring safety, efficacy and quality as well as appropriate use of such products assured by the above-mentioned stakeholders before and after they are made available in the market. .

Accordingly, the Ethiopian Food and Drug Control Authority (EFDA), a national regulatory agency, is established and mandated as per the proclamation 1112/2019, to ensure the safety, quality and efficacy of medicines and medicine devices by undertaking the major regulatory functions including market authorization, quality testing/, regulatory inspection (Good manufacturing practice and supply chain inspection), pharmacovigilance, market surveillance and control and clinical trial monitoring.

No medicine and medical devices, obtained either from locally manufacturers or foreign source, can be marketed and made available for use in the country without market authorization or permission from EFDA. EFDA is authorizing marketing or availability for use of medicine and medical devices in the country after ensuring the safety, efficacy, and quality of medicines and medical devices through dossier evaluation, Good Manufacturing Practice Inspection, and Laboratory Quality testing, as well as issuing pre-import approval and port clearance permit. EFDA also undertakes and coordinates post-market or use surveillance: including undertaking regulatory inspection, marketing surveillance and control, and pharmacovigilance to ensure safety, efficacy and quality of medicine and medical device after are made available for use in the country.

II. The National Pharmacovigilance system

EFDA is mandated to establish and coordinate a pharmacovigilance system to make follow up of adverse drug events both from global and local evidences and then undertake appropriate regulatory measures. The country has a pharmacovigilance system since 2002, and has: organizational structure for Pharmacovigilance; national and sub-national Pharmacovigilance centers; national directives and guideline for Pharmacovigilance; Adverse Drug Reaction Reporting tools including pre-paid yellow paper, electronic and MEDSAFETY ADE /ADR reporting; a national Pharmacovigilance advisory

committee, launched Active Pharmacovigilance on HIV and MDR TB medicines in collaboration with HIV/TB programs; has become the member of WHO UPSALLA drug monitoring center and is reporting ADR to the WHO drug monitoring center; undertake signal detection and risk – benefit management and had carried out regulator measures on such basis.

III. Rationale

It is evidenced that during the premarketing clinical trial evaluations the safety profiles of medicines is not fully identified and understood because of the limited size and profile of participants and the duration of the clinical trial. Hence it is necessary to undergo post marketing safety monitoring or Pharmacovigilance of medicines while they are in the market being used by the users. In addition, TB patients take more than one anti-TB medicine simultaneously and regimens last from many months to 2 years or more resulted an increased ADR; 2/3rd of patients have had at least one medicine stopped temporarily or permanently as a result of ADR; Co-morbidities and other treatments, drug-drug interactions & overlapping toxicities, use of novel regimens (STR) and new medicines (bdq, Lzd, Cfz, Dlm); teratogenicity (DR-TB); MDR TB more number of drugs predisposes to more ADRs. ADRs can lead a DR-TB patient to interrupt treatment before completion, contribute to avoidable morbidity, drug resistance, treatment failure, reduced quality of life, death, transmission of the disease etc. Meta-analysis on Serious Adverse Events in patients on longer MDR TB regimens has shown significant SAEs (Annex II).

The rationale behind adding this Pharmacovigilance specific content on this TB guideline is to enable the users of the guideline understand the importance of Pharmacovigilance, the types safety surveillance systems, the available reporting tools, what adverse events to report, to whom to report and what happens after reporting an adverse drug event encountered in the monitoring of safety of the specific medicines used to treat TB.

IV. Important terminologies in Pharmacovigilance

Pharmacovigilance means-a science and activity concerned with the detection, assessment understanding and prevention of adverse effects and other problems related to medicines.

Major aims of pharmacovigilance:

- Early detection of hitherto unknown adverse reactions and interactions.
- Detection of increases in frequency of (known) adverse reactions.
- Identification of risk factors and possible mechanisms underlying adverse reactions.
- Estimation of quantitative aspects of benefit/risk analysis and dissemination of information needed to improve drug prescribing and regulation.

The scope of pharmacovigilance:

- To improve patient care and safety in relation to the use of medicines, and all medical and paramedical interventions
- To improve public health and safety in relation to the use of medicines.
- To detect problems related to the use of medicines and communicated the findings in timely manner.

- To contribute to the assessment of benefit, harm, effectiveness, and risk of medicine, encouraging their safe, rational and more effective use and
- To promote understanding, education, and clinical training in pharmacovigilance and its effective communication to health professionals and the public

Pharmacovigilance may also aid in identifying medication errors, substandard and falsified medicinal products, therapeutic failure and adverse drug reactions.

Adverse Drug Event(ADE)—Any untoward medical occurrence that may be present during treatment with a medicine but does not necessarily have a causal relationship with this treatment, that is, an adverse outcome that occurs while the patient is taking the medicine but is not, or not necessarily, attributable to it.

Adverse drug reaction (ADR)—any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

An unexpected ADR –Any reaction, the nature or severity of which is not consistent with domestic labeling or market authorization or is unexpected from characteristics of the medicine.

Serious Adverse Effect—Any untoward medical occurrence that at any dose results in death, requires hospital admission or prolongation of existing hospital stay, results in persistent or significant disability or incapacity, or is life threatening.

Medication error—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, nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use."

Medication errors include;

a. Medicine prescribed but not given	b. Administration of a medicine not prescribed
c. Medicine given to the wrong patient	d. Wrong medicine/ IV fluid administered
e. Wrong dose or strength given	f. Wrong dosage form given
g. Medicine given for wrong duration	h. Wrong preparation of a dose
i. Incorrect administration technique	j. Medicine given to a patient with known allergy
k. Wrong route of administration used	l. Wrong time/ frequency of administration

Market authorization holders:

Product quality defect- is quality problem of products with suspected contamination, questionable stability, defective components, poor packaging and labeling and therapeutic failure.

Passive surveillance-is a system in which regulatory authorities and pharmaceutical companies wait for healthcare professionals, patients, or consumers to make the effort to contact the authority or

company to spontaneously report an encountered adverse drug event. It is also called voluntary reporting.

Active surveillance- systems or situations in which adverse events are purposely sought in the post marketing setting by a health authority's request to all physicians to report an adverse drug event of a particular drug or class of drugs in the form of prompted reporting or stimulated reporting or observational studies to more closely follow, identify and investigate on a potential or weak signal

Signal- Reported information on a possible causal relationship between an adverse event and a medicine, the relationship being previously unknown or incompletely documented. Usually more than one signal report is required to generate a signal, depending on the seriousness of the event and the quality of the information.

V. The varieties of ADEs of TB medicines to be reported (What to report)

The following varieties of adverse drug events, i.e. medicine-related injuries, with at least a reasonable possibility to be caused by anti TB medicines need to be reported to EFDA during the use of a spontaneous reporting or passive surveillance system. Peculiarities and reporting mechanisms may differ during the execution on an active surveillance system of a particular drug or disease.

- An individual's particular vulnerability
- Drug interactions
- Unexpected therapeutic ineffectiveness (e.g. resulting from drug interactions, product quality problems or antimicrobial resistance)
- All suspected reactions to the drugs
- Serious adverse drug reaction
- Unknown or unexpected reaction

In addition to the above, adverse drug events to be reported include medication errors, treatment failures and product quality defects independent of whether the action or medicine reached or injured the patient.

VI. National Adverse Drug Reaction Report

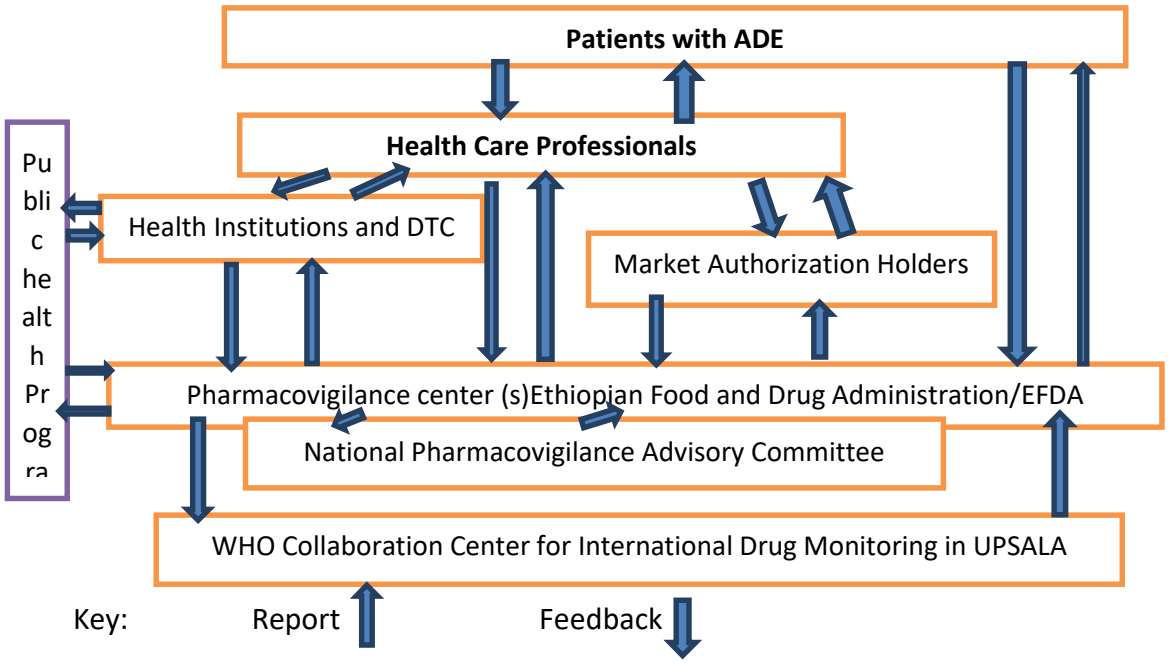


Figure I: Schematic Presentation of the National ADR reporting system

VII. Roles and responsibilities of stakeholders in pharmacovigilance

The following section describes the roles and responsibilities for the different stakeholders involved in activities to minimize the risk of medicine-related injuries or Pharmacovigilance.

1. Patients and Consumers-

Patients who suspect they have been affected by an ADE should report to any health care professional including the one that had prescribed, dispensed or administered the drug that has caused the ADE .This will then enable the health care professional to report the medicine-related problems to the University hospital based regional Pharmacovigilance centers at regions or the Pharmacovigilance center at EFDA.

2. Healthcare professionals-

All healthcare professionals in the nation have a very important role to highlight problems occurring when a marketed medicinal product is used. They need to alert the Ethiopian Food and Drug Administration (EFDA) about suspected ADRs, medication errors and product quality problems in order for the authority to take action in preventing or minimizing the occurrence of the medicine-related injury for other patients in the future.

The activities that healthcare professional need to perform when encountering an ADE should include:

a) Being vigilant and detecting adverse drug events-

Patients and healthcare professionals have the challenging task to monitor and be alert for possible medicine-related problems. It is important that clinicians are vigilant and perceptive towards any

unexpected sign, symptom or complaint voiced by patients taking medicines, particularly in the early phases of treatment.

Distinguishing between the natural progression of a disease and an adverse effect by a medicine can be difficult. When an unexpected event, for which there is no obvious cause, occurs in a patient taking a medicine, the possibility that it is caused by the medicine or its use must always be considered.

Healthcare professionals should monitor for medication errors whilst prescribing, transcribing dispensing and administering medicines to patients.

Health professionals should make physical inspections of the medicinal product to be dispensed or administered. Pharmacy professionals have an important role in the work of detecting product quality defects. Color changes, separating components, powdering, crumbling, caking, molding, change of odor, incomplete pack, suspected contamination, poor packaging/poor labeling should be acknowledged.

b) Have Knowledge of adverse drug reactions of drugs for MDR TB

Health care professionals shall have adequate knowledge of common ADRs of the anti-TB medicines that are in the Ethiopian National essential medicine list and standard treatment guidelines for TB. Health care professionals need to be vigilant and detect them when the events occur and should be able to report whenever they are encountered (ANNEX I).

c) Assessing the patient

When a medicine-related problem is suspected, the clinician should carry out a thorough physical examination with appropriate laboratory tests and consider:

- The patient's medical history, including history of a similar reaction or allergy
- The existence of any potential risk factors, such as hepatic or kidney insufficiency
- The existence of risk groups such as pediatric, elderly, pregnant and lactating patient.

d) Managing the encountered adverse event-

If an ADR is suspected, the health care professional should treat the patient and considerto adjust the dose or replace the medicine or withdraw the medicine.

The patient should be informed about the suspicion of the ADR and what actions are planned. Careful documentation of the ADE in the patient's medical records should take place. Documenting and informing the patient is important to avoid future problems.

If a medicine has caused an allergy, the EFDA "Allergy card" is recommended to be used (see attached below).

The purpose of the Allergy card is to prevent patients from being prescribed again the medicines for which they are allergic in the first encounter. Patients should then carry the card with them and present it to any health facility at upcoming visits.

If the event is believed to be caused by a medication error, action should be taken according to the hospital or healthcare facility routines in order to avoid similar problems in the future. Accordingly, the ADR, medication error or product quality defects encountered should be reported to EFDA immediately as described below.

e) Reporting and adverse drug event (How to report)

Suspected ADEs (ADRs, detected medication errors or product quality defects) should be reported to the Pharmacovigilance center at EFDA. Reporting can be done using any of the four available mechanisms described below:

- The yellow, prepaid report form available at the facility (Annex III)
- 8482 (toll free line) or Telephone 01115523142(direct) or 0115524122(via operator)
- Using online reporting system available from the website www.fmhaca.gov.et-serivces-e-Reporting ADR, creating an account using an email address and then entering the required information in the reporting page (See instructions on Annex IV).
- Using a mobile application Medsafety that can be downloaded from Google play store for Android phones or and **the APP store for IOS users,** creating an account using an email address and then entering through the "new report" button and filling the information on the adverse drug event that is going to be reported (See instructions on Annex V).
- Using a monthly line listing excel sheet to report the monthly encountered adverse drug events. The excel sheet contains all the necessary data that is necessary to report an adverse event (Name of the patient in abbreviation, Identification number, Age, card no, name of drugs taken, name of suspected drug causing the adverse drug event, all the dates of drug start, reaction start, drug discontinued, grading of causality and severity, other medically important conditions, outcome, treatment and measures taken (Annex VI)

All ADEs ranging from minor reactions to disability or death should be reported. However, there is a need to emphasize the reporting of suspected ADRs to new medicines, serious ADRs, unexpected reactions and drug interactions. If the event occurred in a university hospital Pharmacovigilance center it is very important to communicate with the pharmacovigilance focal person available to get the necessary support in the reporting process. These focal persons are also available in other health facilities and are designated by the facility to support Pharmacovigilance activities.

The reporter does not need to prove that there is a causal association between drug and adverse reaction. Therefore, uncertainty of the cause and effect relationship should not be a reason for not reporting. In addition, as stated in the National Pharmacovigilance Guideline of Ethiopia, it should be understood that reporting an ADR will not lead to any blame on the reporters and will not be used for any legal action

f) Timelines of reporting (when to report)

Any suspected ADR; medication error or quality defect should be reported as soon as possible after all relevant information is compiled. Delay in reporting will make reports inaccurate and unreliable. Reporting while the patient is still in the health institution will give chance to the reporter to clear any ambiguity by re-questioning or examining the patient. When the reports have been received by EFDA, an acknowledgement letter will be sent to the reporter and follow-up questions might need to be answered.

Any follow-up information for an event that has already been reported can be sent on a new ADE report form to EFDA. Clearly indicate that the report concerns:

- Follow-up information
- The report case number, (available on the acknowledgement letter), so that this information can be matched with the original report.

It is very important that follow-up reports are identified and linked to the original report to avoid duplications of reports in the Pharmacovigilance database.

3. Health care facilities

All Health care facilities should promote pharmacovigilance and ADR reporting by health care professionals to ensure patient safety and better TB treatment outcome. They should assign a focal person for pharmacovigilance to coordinate ADE monitoring activities, ensure regular availability of ADR reporting tools and ADR reporting, and to serve as a link between the facility medicine safety monitoring activities and national and sub-national pharmacovigilance center.

4. Drug and Therapeutic Committee/DTC at healthcare facilities

The Drug and Therapeutic Committee is a technical working group established at healthcare facilities with representative members from each department with the aim of managing medication use problems. Using the information on medicine safety, the DTC should revise the facility specific medicine list and promote rational use of medicines.

The DTC should also implement programs to track ADRs, medication errors and product quality defects and use the information to improve healthcare. Programs could involve review of adverse drug events, medication errors or near misses, patient chart review, or physical inspection of products. It needs the involvement of all health professionals as a team to identify problems with medicines, setting standards and monitoring practice. The facility should also assign a focal person to coordinate all ADE monitoring activities in the facility and serve as a link between the facility safety monitoring activities and the national Pharmacovigilance center.

5. TB health program

The monitoring of the safety of medicines of public health programs like HIV, Malaria, TB, family planning, Neglected Tropical Diseases ,Non communicable diseases is crucial for the successful implementation of the programs. Hence TB health program should collaboratively work with EFDA starting from the inception of the specific program and throughout the implementation period by

encouraging the users of the Anti-TB medicines and healthcare professionals to report any ADEs encountered using the available reporting mechanisms of the national Pharmacovigilance system.

Through the use of the passive and active surveillance systems, the EFDA Pharmacovigilance center has received adverse drug reports on the public health programs. The summary of these ADEs in the previous calendar year (2018/2019) indicates that out of the total number of reports received 56.9% were on antihelmenthics,7.5% on contraceptives,7.3% on anti-tubercular, 4.2% on NCD's,0.6% on ARV's and 0.1% on anti-malarial.

6. Pharmacovigilance centers at Teaching University Hospitals

Currently there are five decentralized Pharmacovigilance centers in five specialized referral hospitals throughout the country at Hawassa university hospital (Hawassa), Aider university hospital(Mekelle), Gondar university hospital(Gondar), Addis Ababa university Black lion hospital (Addis Ababa), Jimma university hospital (Jimma).

These centers are empowered to promote pharmacovigilance and provide training to healthcare providers in their catchment area to enable them report ADEs. Any ADE report on medicines of health care programs like TB could also be reported to these centers which will then analyze and send the report to EFDA.

7. Branch EFDA, and regional regulators

The role of the six EFDA branches that are available in the country at Jimma, Komblocha, Bahirdar, Hawassa ,Dire Dawa and Mekelle and the regulators that are available at each of the nine regional and two city administration health bureaus in the monitoring of safety of medicines of public health programs is significant. Most importantly, as they are closer to the health facilities, their role in promoting pharmacovigilance, inspection, investigation and sampling of medicines that have adverse events is vital.

8. Pharmacovigilance Center /EFDA /what happens after a report are sent to the EFDA?

As the primary role and mandate of EFDA is to ensure that marketed medicines are safe, effective and of quality, the experts at the Pharmacovigilance center perform the necessary data management activities after an ADR report is received.

These activities are-

a) Report entry

Pharmacovigilance experts at the center enter the incoming reports into the national Pharmacovigilance database which is vigiflow. Each report is classified as an ADR, medication error or a product quality problem. The recipient of the report will carefully review the report for the quality and completeness of the filled information obtained in the report form.

The center then provides an acknowledgment feedback to the reporter and might request information in case of missing pertinent data.

b) Causality assessment

Causality assessment is performed, and the report is classified according to the WHO causality criteria. Causality assessment can also be performed at the regional Pharmacovigilance centers which who are sending reports to the national center. The assessment can then be verified and finalized to be sent to Uppsala monitoring center of WHO

The outcome of the report, together with any important or relevant information relating to the reaction will be communicated to the appropriate stakeholders including TB program coordinators.

c) Analyzing to detect signals.

The Pharmacovigilance experts at the EFDA review each incoming report (ADR, medication error, product quality defect) individually to detect any medicine-related problems that need immediate action.

The authority works towards detecting new potentially causal drug and event associations, or a new aspect of a known association, i.e. a signal which could be-

- Previously unknown adverse drug reactions
- Increases in frequency of known adverse drug reactions
- Risk groups, risk factors and possible mechanisms underlying adverse drug reactions.

A signal can initially be detected in a single incoming report. The literature, the WHO Signal document and the WHO Pharmaceutical Newsletter should be regularly screened to detect medicine-related problems relevant for the nation. Each year, a summary of the reports received during the past year is produced and evaluated.

In addition, post marketing surveillance to detect product quality defects is performed by the EFDA. Samples of any product in the market are collected from various premises in a determined frequency per year. The samples are tested in the EFDA laboratory. Regulatory inspection is also carried out by regional responsible offices to detect product quality defects.

d) Assessing for potential signals

Each detected potential signal will undergo further evaluation. The WHO database published literature and information from the market Authorization Holder are reviewed for similar cases. The National Pharmacovigilance Safety Advisory Committee is provided summary information for evaluation. The committee recommends what action needs to be taken, i.e. if it is a signal that needs to be acted upon, it is not signal, or if further monitoring is needed.

e) Taking regulatory measures

Based on the result of the different evaluations carried out and if necessary, using the quality control laboratory investigation results, and the recommendation obtained from the Pharmacovigilance advisory committee, regulatory measures will be taken on the specific medicine used in the public health program so that appropriate actions are taken. The regulatory actions might range from warnings on the use of the specific medicine to the withdrawal or recall of the medicine and suspension from use by the program.

ANNEXURES

Annex I Known adverse drug reactions of drugs for MDR TB

Bedaquline- nausea, vomiting, diarrhea, joint pain, headache, coughing up blood, chest pain, weight loss, rash, increased transaminases and blood amylase.

Kanamycin; changes in hearing; spinning sensation, problems with balance; ringing or roaring sound in ears; numbness or tingling of skin; muscle twitching, seizure (convulsions); or urinating less than usual or not at all electrolyte disturbance, renal toxicity

Moxifloxacin; nausea; diarrhea; headache; vomiting; dizziness; nervousness; agitation; nightmares, liver toxicity, seizures, psychosis; arrhythmia and QTc prolongation

Prothionamide; nausea and vomiting, depression and hallucinations, jaundice, menstrual disturbances and peripheral neuropathy, liver toxicity, hypothyroidism, psychosis, teratogenicity

Clofazimine;loss of appetite, diarrhea, nausea, vomiting, arrythmia and QTc prolongation, dry skin and discoloration (from pink to brownish-black) of the skin, stools, urine, saliva, sweat, tears or lining of the eyelids

Pyrazinamide; nausea, upset, stomach, vomiting, loss of appetite, mild muscle or joint pain and fatigue, arthralgia /arthritis

Isoniazid; numbness and tingling in the extremities, hepatitis (symptoms include loss of appetite, nausea, vomiting, fatigue, malaise, and weakness), nausea, vomiting, upset stomach, fever, psychosis and rash.

Ethambutol; itching or rash; joint pain; headache, dizziness; nausea, vomiting, stomach pain, indigestion, loss of appetite. And vision impairment

Fluroquinoline; nausea, dyspepsia, vomiting, dizziness, insomnia and headache, arthralgia/arthritis, liver toxicity, arrythmia and QTc prolongation, psychosis, seizures

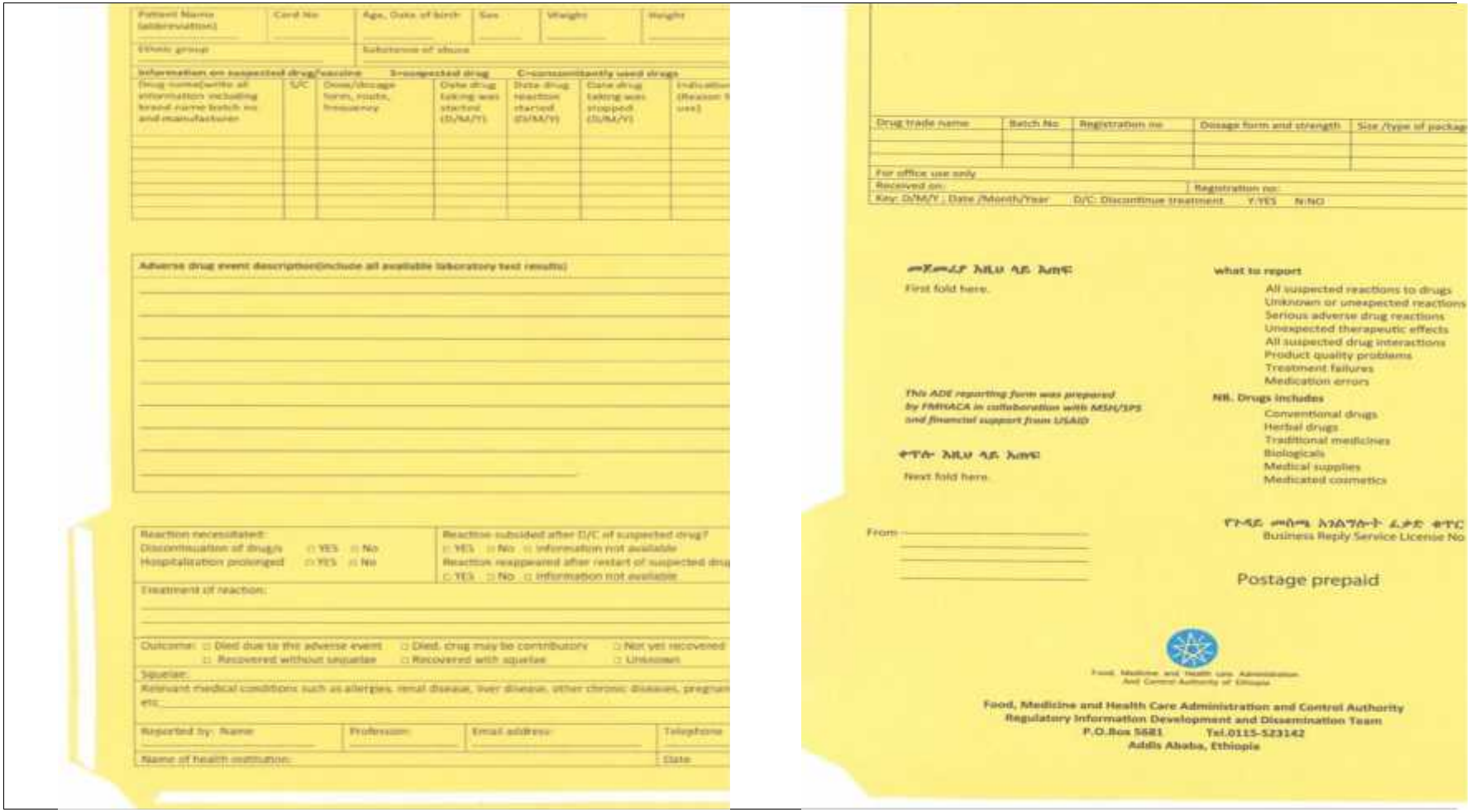
Delamanide; nausea, vomiting, dizziness, low potassium levels in the blood; and. paresthesia (a pricking or tingling sensation), anxiety, and tremor (shaking)

Linezolid; diarrhea, nausea, vomiting, headache, sleep problems (insomnia), constipation, dizziness, discolored tongue, peripheral neuropathy and vision problems

Annex II Serious Adverse Events in patient on longer MDR TB regimens- Meta analysis- WHO DR TB guidelines 2018

Medicine	Absolute Serious Adverse Events (SAE)	
	Median (%)	95% credible Interval
Bedaquiline	2.4	[0.7,7.6]
Moxifloxacin	2.9	[1.4, 5.6]
Amoxicillin-clavulanic acid	3.0	[1.5, 5.8]
Clofazimine	3.6	[1.3, 8.6]
Ethambutol	4.0	[2.4, 6.8]
Levofloxacin	4.1	[1.9, 8.8]
Streptomycin	4.5	[2.3, 8.8]
Cycloserine/ terizidone	7.8	[5.8, 10.9]
Capreomycin	8.4	{5.7, 12.2]
Pyrazinamide	8.8	[5.6, 13.2]
Ethionamide/ prothionamide	9.5	[6.5, 14.5]
Amikacin	10.3	[6.6, 17.0]
Kanamycin	10.8	[7.2, 16.1]
p-amino salicylic acid	14.3	[10.1, 20.7]
Thioacetazone	14.6	[4.9, 37.6]
Linezolid	17.2	[10.1, 27.0]

Annex III. Prepaid Postage Yellow paper Adverse drug event reporting form



Patient Name (abbreviation) | Card No | Age, Date of birth | Sex | Weight | Height

Ethnic group | Substance of abuse

Information on suspected drug/vaccine S=suspected drug C=concomitantly used drugs

Drug name(s)with all information including brand name batch no and manufacturer	S/C	Dose/dosage form, route, frequency	Date drug taking was started (D/M/Y)	Date drug reaction started (D/M/Y)	Date drug taking was stopped (D/M/Y)	Indication (Reason for use)

Adverse drug event description(include all available laboratory test results)

Reaction necessitated:
Discontinuation of drug/s ☐ YES ☐ No
Hospitalization prolonged ☐ YES ☐ No

Reaction subsided after D/C of suspected drug?
☐ YES ☐ No ☐ Information not available
Reaction reappeared after restart of suspected drug
☐ YES ☐ No ☐ Information not available

Treatment of reaction:

Outcome: ☐ Died due to the adverse event ☐ Died, drug may be contributory ☐ Not yet recovered
☐ Recovered without sequelae ☐ Recovered with sequelae ☐ Unknown

Sequelae:

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

Reported by: Name | Profession | Email address | Telephone

Name of health institution | Date

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

For office use only
Received on: | Registration no:
Key: D/M/Y ; Date /Month/Year D/C: Discontinue treatment Y:YES N:NO

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This ADE reporting form was prepared by FMHACA in collaboration with MSH/SPS and financial support from USAID

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what to report

All suspected reactions to drugs
Unknown or unexpected reactions
Serious adverse drug reactions
Unexpected therapeutic effects
All suspected drug interactions
Product quality problems
Treatment failures
Medication errors

NB. Drugs includes

Conventional drugs
Herbal drugs
Traditional medicines
Biologicals
Medical supplies
Medicated cosmetics

From:

የኮሚሽኑ መለያ ኦንሲማሉት ፈቃድ ቁጥር
Business Reply Service License No

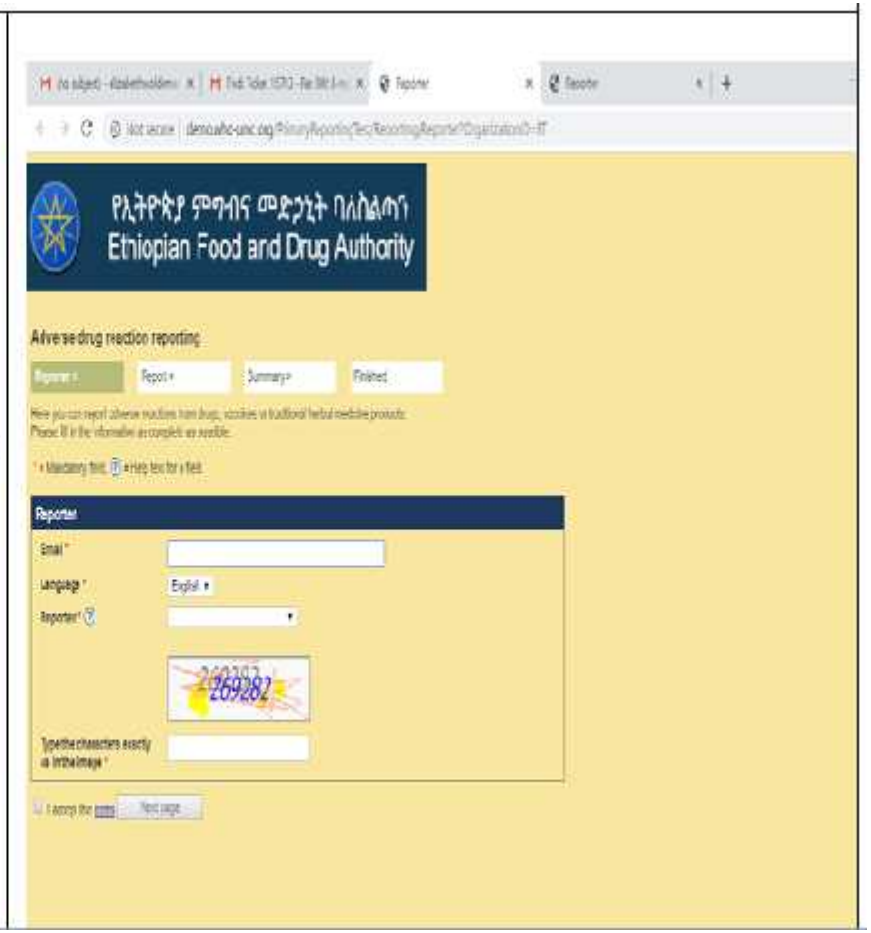
Postage prepaid

Food, Medicine and Health Care Administration and Control Authority
Regulatory Information Development and Dissemination Team
P.O.Box 5681 Tel.0115-523142
Addis Ababa, Ethiopia

Annex IV. Instructions on how to use the e-reporting system to report an adverse drug event

Healthcare professionals can report ADE by using e-reporting by following the procedures.

- Go to EFMHACA website www.fmhaca.gov.et
- click on service
- click on the link e-reporting of ADE then you will find the page page that is attached here
- fill the information required by moving from Reporter → and the rest information necessary for the report
- Submit the filled report to EFDA and protect the public from unnecessary drug related harms caused by Adverse Drug Event's



Annex V. Instructions on how to use the mobile application of Medsafety to report an ADE

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

Annex VI Monthly line listing excel sheet to report the monthly encountered adverse drug events.