Ethiopian Food and Drug Authority

Pharmacovigilance Directive

September 2020

WHEREAS, It is neccessary to ensuring good Pharmacovigilance practice for the regulation of safety, quality and efficacy of medicines

WHEREAS, the activities incurred in the system need to be regulated by clear law for effective and efficient meet of the objectives of the system;

WHEREAS, It is neccessary to ensuring patient care and paramedical interventions and improving public health and safety in relation to the use of medicines ;

WHEREAS, It is neccessary to early detecting of problems related to the use of medicines, through undergoing investigations and analysis according to a standard and communicating findings and the resulting regulatory measures to all stakeholders involved in a timely manner ;

WHEREAS, encouraging the safe,rational, effective and costeffectiveuse of medicines is necessary;

WHEREAS, to Promote understanding,education and training in Pharmacovigilance and the generation of safety information and contribution to the available knowledge of medicines safety, quality and effectiveness is necessary;

WHERAS, it is necessary to install a Pharmacovigilance scheme that is compatible with the country's expanding medicine demand and the implementation of technologically advanced regulatory systems;

WHERAS, the absence of a Pharmacovigilance directive in the system which has created a gap in the benefit risk analysis of medicines used in the country previously has demanded the development and implementation of a clear direction;

NOW, THERFORE, this directive is issued in accordance with Article 71 sub article (2) of the Ethiopian Food and Medicine Adiminstration Proclamation No 1112/2019

PART ONE

GENERAL

1. Short Title

This directive may be cited as 'Pharmacovigilance Directive No……/2020'

2. Definitions

Without prejudice to the definition provided under Ethiopian Food and Medicine Administration Proclamation No. 1112/2019:

1) **"Pharmacovigilance (PV)"**means a science and activity concerned with the detection, assessment understanding and prevention of adverse effects and other problems related to medicines.

2) **"Adverse DrugEvent (ADE)"means** 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 out come that occurs while the patient is taking the medicine but is not, or not necessarily, attributable to it.

3) **"Adverse drug reaction (ADR)"**means 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.

4) **"Unexpected ADR"**-means any reaction,the nature or severity of which is not consistent with domestical labeling or market authorization,or is unexpected from characteristics of the medicine.

5) **"Serious Adverse Event (SAE)"—means** 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.

6) **"Severity of adverse drug reactions"**–means a classification of the magnitude of the effects of the adverse drug reactions encountered and are classified into four-
   A. Mild-where the effects are tolerated and no antidote or prolongation of hospitalizations required;
   B. Moderate – where a change in drug therapy with or without cessation of the drug is required. Hospitalization is usually prolonged and special treatment may be required.
   C. Severe – which is life threatening and requires drug discontinuation and specific therapy and-
   D. Lethal – the patient has died as a result of ADR from the medicine /s.

7) **“Medication error”**—means 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.Sucheventsmayberelated to professional practice,healthcare products,procedures,and systems,including prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.Medicationerrorsincludes;

   A. Medicine prescribed but not given
   B. Administration of a medicine not prescribed
   C. Medicine given to the wrong patient
   D. Wrong medicine or 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 (e.g., incorrect dilution)
   I. Incorrect administration technique
   J. Medicine given to a patient with known allergy
   K. Wrong route of administration used
   L. Wrong time or frequency of administration

8) **“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 mental functions in human;or particles other than food,intended to affect the structure or any function of the body of human and it includes particles intended for use as a component of any of the above specified particles.

9) **“Productquality defect”**means attributes of a medicinal product or component which may affect the quality, safety and /or efficacyof the product, and/or which are not in-line with the approved market authorization. This includes suspected contamination, questionable stability, substandard, ,defective components, poor packagingand labeling.

10) **“Signal”**meansany Reported information on a possible causal relationship between an adverse event and a medicine,the relationship being previously unknown or incompletely documented where it is necessary to have more than one report to generate a signal, depending on the seriousness of the event and the quality of the information.

11) **“Periodic Safety Update Report/ Periodic Benefit Risk Evaluation Report PSUR-/PBRER”**means a Pharmacovigilance document intended to provide an evaluation of the risk-benefit balance of a medicinal product

at defined time points post-authorization and present a comprehensive and critical analysis of the risk-benefit balance of the product taking into account new or emerging safety information in the context of cumulative information on risk and benefits.

12) **"Individual Case Safety Report (ICSR)"** meansa report providing the most complete information related to an individual adverse drug event case at a certain point of time

13) **"Market Authorization Holder (MAH)"** means a company, firm or non-profit organization that has been granted a marketing authorization. The marketing authorization allows the holder to market a specific medicinal product.

14) **"Passive surveillance"-**means 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.

15) **"Active surveillance"-**means a systems or situations in which adverse events are purposely sought in the postmarketing 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.

16) **"Qualified Person responsible for Pharmacovigilance"**-meansan individual, usually an employee of a pharmaceutical company, who is personally responsible for the safety of the human pharmaceutical products marketed by that company

17) ""**Healthcare facility"-**meansplaces that provide health care that are involved in health promotion, disease prevention, treatment and rehabilitation,laboratory services.

18) **"Causality"-means** The probability that a particular medicine or substance is responsible for an isolated effect or ADR.

19) **"Authority"** means the Ethiopian Food and Drug Authority

20) **"Executive organ**" means a body which is empowered to administer this proclamation and other laws issued to implement this proclamation at the federal government level.

Any expression in the masculine gender shall also apply to the feminine gender

21) **"Regulatory bodies"**-Means governmental entities, which are responsible for formulating and enforcing laws that protect the safety of patients and set basic quality standards.

22) **"Healthcare Professionals"** means any person that is a member of the medical, dental, pharmacy, laboratory, nursing professionals or any other

person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product. They can be any official or employee of a government agency or other organization (whether in the public or private sector.

23.**"Adverse Even following Immunization/AEFI"** means anymedical incident that takes place after an immunization, causes concern, and is believed to be caused by immunization but not necessarily caused by immunization.The adverse event following immunization may be any

Unfavorable or unintended sign,

Abnormal laboratory finding,

Symptom or

Disease

3.SCOPE

This directive shall be applicable for all the Pharmacovigilance activities that are carried out on medicines that are manufactured locally or are imported from foreign countries and are circulating in Ethiopia.

4.OBJECTIVE

The objectives of this directive shall be:

1) To set legal binding framework on how the Authority should perform Pharmacovigilance and to overcome the existing problems that are associated with the execution of the activities
2) To provide specific direction on how to accept adverse drug event reports and process them further so that analysis ,investigation are performed and regulatory actions are taken on a timely manner.
3) To provide specific directions on how to communicate risk findings obtained through the Pharmacovigilance process.
4) To prevent inappropriate practices of monitoring of medicine safety and quality thereby protect the public from drug related harms

PART TWO

ADVERSE DRUG EVENT REPORTS

5.RECIEVING AN ADVERSE EVENT REPORT

1) Any adverse drug eventreport whether is individual Safety report, Periodic Safety Update report including all suspected reactions, unknown or unexpected reactions, serious/non serious adverse drug reactions, unexpected therapeutic effects, all suspected drug interactions, product quality problems, medication errors and treatment failures shall be reported to EFDA Pharmacovigilance center with the following required data as its contents .

a. **Patient information** (Patient name in abbreviation, card No. , Age /date of birth, ,Weight, Height, Ethnic group, Substance of abuse;
b. **Drug information on suspected and concomitantly used drug**(drug specific description including batch number brand name, manufacturing date, Expiry date and manufacturer, dose/dosage form, route. frequency, date drug taking was started/date drug reaction started, date drug was stopped, indication and product quality information if it is a quality issue);
c. **Adverse drug event information**Clear and brief description about the nature of adverse event symptoms experienced, duration, time course and laboratory test results including “negative” and normal results of any relevant test performed; Severity of the reaction includingnecessitated prolonged hospitalization or not, discontinuation of the medicine or not, reaction subsided after the drug was discontinued or not, reaction reappeared after the restart of the drug or not for causality assessment purposes; treatment of reaction; outcome; squeal and relevant medical conditions
d. **Reporter’s information**(Name, Profession, email address, telephone, name of health institution,p. o. box No. and date) as requested in the report form.

2) Any adverse drug event shall be reported to EFDA immediately.

a.Serious Adverse event shall be notifiedwith in 24 hours and shall be

reported witihin 48 days

b.Non-serious adverse events shall be reported within 7 working days

c.Without prejudice to the above article any HCP who failed to report

serious ADE’s shall be liable for accountability by law

3) Any adverse drug event report shall be reported by using at least one of the following reporting mechanisms that are made available by EFDA

a. Using the standard yellow page reporting form that is available in hard copy at health care facilities(Annex1).
b. Using the toll free telephone number 8482.
c. Using the Mobile application Medsafety that can be downloaded from Google store for Android mobiles and App store for Iphones

d. Using the e-reporting that is available on the EFDA website www.efmhaca.gov.et/services/e-reportingADR or use link https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=ET

e.Using any other means of reporting that the authority may avail.

4) In any report all the required Information shall be completely filled.

5)Any report that is going to be sent to the Authority shall not contain non-standard abbreviations of drugs.

6)Use a single report form for each single ICSR whether adverse drug reaction, Medication error or Product quality defect that is observed and is going to be reported.

7)Reporting an adverse drug event does not constitute an admission that the health care professional or the drug contributed to or caused the event in any way and shall have no negative consequences on the reporter in whatever way

8) In order to report an adverse drug event, only a suspicion that the drug might have caused the adverse drug event is enough and there is no need to confirm it.

9) The confidentiality of all the information regarding the adverse event and the reporterin the report shall be highly maintained and the information will not be used for any other purpose

6) INVESTIGATING ON ADVERSE DRUG EVENT

1) Investigations on serious adverse drug event shall begin with in seven days from the day the report was being received by the Pharmacovigilance center

2)All serious adverse drug event reports, any known or unknown cluster of events or adverse drug events of community concern need to be investigated to establish a diagnosis and identify the cause of the adverse drug event.

3) Without prejudice to the above article, any safety concern that the Authority believes requires investigation may be investigated

4) Any adverse drug event report investigation should be performed according to the following steps

a. Confirm the information received in the report by-

i. Obtaining patient's medical file (or other clinical record)
ii. Check details about patient and event from medical file and document the information.
Iii. Obtaining any details missing from report.

b. Investigate and collect data about the patient's

i. Previous medical history, including prior history of similar reaction or other allergies
ii. Family history of similar events
iii.Other concomitant medications taken including traditional medicines and food

c. Investigate and collect data about the adverse drug event

i. History, clinical description, any relevant laboratory results about the adverse drug event and diagnosis of the event
ii. Treatment, whether hospitalized and outcome

d. Investigate and collect data about the suspected medicine(s)

i. Conditions under which the medicine was purchased or obtained, its present storage condition.
Ii. Storage condition of the medicine at all levels before it arrived at health facility.
Iii. The date of manufacture, expiry ,batch number and manufacturer and distributor

e. Investigate about other people whether others have received the same medicine and developed similar adverse drug event and whether they need to be included in the investigation

f. Assess the service provided and observe the service in action about
i. The medicine handling during prescribing, dispensing and administration
ii. If it is injectable investigate about the reconstitution,diluents used

g. Formulate a working hypothesis on the likely/possible cause(s) of the event

h. Test working hypothesis If the case distribution match working hypothesis and occasionally,laboratory tests may help.

7) ANALYZING ON ADVERSE DRUG EVENT

1) The Pharmacovigilance center staff shall assess the causal association of the suspected drug/s and the Individual case safety report based on the collected information and prepare a preliminary report for the safety advisory comittee.
2) Signal detection shall be performed through quantitative and qualitative methods using WHO Vigilyze system
3) Further signal validation and analysis/prioritization shall be carried out to identify the signals appropriately
4) All the available scientific evidence will be evaluated

5) Conclusion and recommendation on a signal detected shall be reached by the safety advisory committee which could be

a. new potentially causal drug and event associations, or a new aspect of a known association
b. Previously unknown ADRs
c. Increases in frequency of known ADRs
d. Risk groups,risk factors and possible mechanisms underlying ADRs.

8)Regualtory actions to be taken

Based on the obtained recommendation the authority shall take regulatory actions with respect to the seriousness of the adverse drug events and shall include;

1) Letters to health care providers by the authority about the safety concern describing how it may affect present patients on the medicine and future prescribing.

2) Package insert revisions – when safety concerns become significant, manufacturers must change the label of the product in the summary of product characteristics. This action requires changing the official labeling and changing the package insert to reflect the new safety concern. The Authority should approve the change.

3)Modifying inadequate designs of product labeling, packaging, product formulation, medical device, orproduct/technical information by the manufacturer of the medicine to be authorized by the Authority.

4) Medicine recalls – When the risk of ADRs or product quality issues outweighs the benefits, withdrawing the medicine from the market might be necessary. Medicine recall can be voluntaryorimposed by the authority

5)Suspension and cancelation

6)Legal proceeding (Medico-legal issues or further legal proceeding should be cleared for sevire consequences such as death, disability)

PART THREE

ROLES AND RESPONSIBILITES OF PHARMACOVIGILANCE PARTNERS

9) Healthcare facilities

1) All health facilities shallestablis and run a pharmacovigilance system as part of their routine practice including organizing awareness creation programmes.

2) In any Healthcare facility there shall be apharmacovigilance focal person who will be assigned to coordinate adverse drug event monitoring and reporting in collaboration with other healthcare professionals and the Drug

and Therapeutic Committee and Drug Information center in the facility and EFDA.

3) The adverse drug event monitoring activity shall include detection,reporting and prevention of adverse drug events.

4) The Management of the healthcare facility shall facilitate on the provision of education on medicines safety to patients on a scheduled programmes.

5) Health facilities shall ensure all ADEs are reported, obtain feedback given from responsible bodies, implement the regulatory decision on the problems identified and maintain all records related to reported ADEs

6) Refrain from dispensing the medicines with suspected products quality defects under investigation

10) Regulatory bodies

Regulatory bodies :

1) shall ensure that establishing a pharmacovigilance system should be a licensing requirement for all health care facilities.

2)Shall establish a strong collaboration and communication mechanism with EFDA and healthcare facilities.

3) Shall strongly collaborate with the EFDA in organizing and implmenting capacity building activities

4) Shall strongly collaborate with the EFDA in the implementation process of regulatory measures.

11) The pharmacovigilance focal person

1) The focal person should be a part of the Drug Information provision service in the health facility

2) The focal person shall ensure that all health professionals are involved in detecting, assessing, managing, reporting and preventing potential adverse drug eventsand get awareness creation on medicine safety

3) Ensure that adverse drug event report forms and other reporting mechanisms are readily available and are known in all clinical areas and that health professionals are familiar with how to use them.

4) The focal person shall participate in investigating on potential adverse drug events that will serve the healthcare facilitiy purpose.

5) The focal person shall analyze adverse drug event data and compile reports for the use of the healthcare facility.

6) The focal person shall provide regular reports to the Drug and therapeutic committee and Hospital Management on encountered adverse drug events in the healthcare facility regularly and provide the necessary directions..
7) The focal person shall report adverse drug event reports whenever they are available and other PV activitiesto the authority monthly and encourage all the other healthcare professionals to report too.

12) Healthcare professionals

1) As part of their professional duty,all healthcare professional shall be involved in patient counseling about ADRs and monitoring of adverse drug events including proper documentation and reporting of an encountered or observed adverse drug event during their day to day service whether they are working in public or private healthcare facilities in accordance with the Article 5(3) of this directive.

2) Inorder to prevent unnecessary drug related harm, all heath care professionals shall follow a safe and basic principles of rational use of medicines listed as follows

a. Use as few drugs, whenever possible
b. Use drugs that are wellknownunless otherwise justified
c. Do not change therapyfrom known drugs to unfamiliar one without good reasons
d. Use text books and other reference material providing information on drug reactions and interactions
e. Take extra care when prescribing drugs known to exhibit a large variety of interactions and adverse reactions(anticoagulants, hypoglycemic and drugs affecting the CNS) with careful monitoring of patients with such reactions.
f. Beware of the interactions of drugs with certain food stuffs, alcohol and even with house hold chemicals
g. Review all the other drugs used by the patient regularly, taking special notice with those bought without prescription and herbal drugs.
h. Be particularly careful when prescribing, dispensing or administering to children, the elderly, the pregnant and nursing women, the seriously ill and patients with hepatic and renal diseases.
i. Carefully monitor patients for previously identified hypersensitive medicines

13) Patients/Consumer

1) Patients who have experienced an adverse drug event or suspect are action to a medicine or other substance shall report to the nearest health care provider or return back to the health care facility that they were provided with the medicine to get the appropriate management and enable the reporting of the event

2) Patients or medicine users that have experienced an adverse drug event could also use the toll free number 8482 to report an adverse drug eventor use any other consumer reporting tool that the EFDA may avail

14)Pharmacovigilance Advisory Committee

1) The Pharmacovigilance advisory committee shall be established with members being composed of different health professionals.

2)The composition of the committee includes multidisciplinary professions that will be governed by the Terms of reference

3) The Pharmacovigilance Advisory Comitteeshallmeet regularly and upon adhoc meetings to support the Pharmacovigilance system in causality assessment, risk benefit assessment and evaluation.

15)Market Authorization Holders/MAH

1) In accordance with article 38,2 of the proclamation, amarket authorization holders shall establish a Pharmacovigilance system to monitor the safety of its medicines

2) In accordance with article 38,2 of the proclamation,anymarket authorization holder (manufacturer, importer) shall have a Qualified person responsible for Pharmacovigilance/QPPV resident in Ethiopia to monitor the safety and quality defects of the medicine under its authorization status.The roles and responsibilities of QPPV shall be clearly indicated by the upcoming updated guideline.

3) Every MAH shall identify high risk medicines and plan risk mitigation plans and submit for the regulatory authority.

4) In accordance with article 38,2 of the proclamation any MAH shall report periodic safety update report, Individual case safety report and establish Risk management plans for its products in line with the national standardsas follows

a. Serious adverse drug eventsshould be reported within /**48** hours and, unexpected and expected must be reported as soon as possible but no later than 15 calendar days of initial receipt of the information by the MAH. Efforts must be taken to send a report that is complete.
b. Non-serious adverse drug events must be sent within 90 days after the granted knowledge of the event.
c. All suspected serious adverse drug events in post-registration studies should be reported according to the timelines given in this article sub article a & b of the previous section
d. For new medicines that are registered and placed in the market in the country, a Periodic Safety Update Report should be submitted to the authority**every 6 months for** the first two years after market approval and thereafterannually for three years. If no adverse drug events have been received by the market authorization holder, it is obliged to submit

a “Null” report, i.e., a report stating that it hasnotreceivedany adverse drug event reportsontheirmedicinal product.Can we follow the International Birth date (IBD) and also follow ICH guidelines for PSUR/PBER submission Aida’s comment

e. The market authorization holder should also inform the Authority of any significant safety issue (from other than single case reports) or action taken by foreign agency, including the bases for such action within 3 working days days of first knowledge by the market authorization holder.
f. Information on withdrawal of the registration status in any country because of safety issue must be noted to the Authoritywithin 24 hoursofthefirstknowledgebythe market authorization holder.
g. For every ICSR, MAH should report a fully completed data

5) Every market authorization holder shall perform post authorization safety studies related to newly identified signals and upon request by the Authority as stated in Proclamation Number 38,3

6) Based on the results obtained from article 6(3) of this directive every market authorization holder shall establish a Risk management plan for their medicines to prevent the ADE’s from harming the public.The market authorization holder should prepare and submit a Risk Management Plan at the time of

a. New drug application
b. Significant change in marketing authorization (new dosage form, route of administration, indication)
c. Significant new safety concern
d. Request by EFDA

7) When executing the activity stated on the article 14(5) of this directive,the fund shall be covered by the manufacturer or importer responsible for the authorization and distribution of the medicine in accordance with article 38(3) of the proclamation

8)The market authorization holder shall Investigate on the detail of the damage caused by its medicine together with EFDA legal directorate and pharmacovigilance center based on a direction provided in the article 38(4) of the proclamation.

9)Based on the result obtained as per the article 14(5) of this directive, the market authorization holder shall compensate for the damage occurred for the public appropriately.

16)Academic institutions

1) Academic centers of medicine,pharmacy and other related schools shall involve in the monitoring of drug safety through teaching,training,research, policy development, clinical research,ethics committees and the clinical service they provide.

2)Topics about the monitoring of drug safety including about the National Pharmacovigilance system shall be incorporated in the medical and pharmacy and other health professionals teaching curricula

17) Public Health Programmes/PHP

1) The regulatory authority jointly with the PHP shall decide priorities regarding the monitoring of medicines to be conducted by the public health programmes including
   a. how the medicines should be monitored,
   b. the duration of the monitoring
   c. when adverse reactions should be reviewed
   d. the time frames for reporting and actions if a safety concern emerges
2) Therapeutic guidelines used in the public health programmes shall include instructions on reporting. If the programmes independently detect safety issues, these should be communicated to theauthority.

18) Immunization programmes

1) Any healthcare professional at the lowest possible level of immunization shall complete an AEFI reporting form(Annex 5) and report an AEFI with in 24 hours of occurrence to the wereda level of EPI officer
2) Reportable AEFI's include

a. Serious AEFI,

b. AEFI as a result of potential immunization errors,

c. Clusters,

d. AEFI causing parental or community concern resulting in the family notifying the case back to the healthcare system,

e. Those that are unexpected, and

f. Those that are known but occur with unexpected frequency.

3) All Zonal and regional level healthbureaus should submit a monthly AEFI report in a line listing form

4) Investigation of a received AEFI report

Based on the AEFI report :

1)The wereda EPI officer shall review the AEFI report form and decide on

investigation after consultation with experts

2) The wereda EPI officer shall initiate investigation and complete all the details using the investigation form with in 7 days and email to the next Zonal/ regional EPI structure

3) While investigating the AEFI, the wereda EPI can ask for help from the regional/ National EPI focal persons and regional regulators

4) The wereda EPI shall initate collection of medical reports,vaccine,logistic samples,laboratory report or other biological products

5) The Zonal/ regional EPI officer shall review the completed AEFI investigation form and share the information obtained with the branch EFDA Pharmacovigilance focal person and EPI team leader at National level

6) The Zonal/regional EPI officer upon request by wereda team for support, shall conduct a regional level planning meeting on the investigation with the regional regulatory body

7))The Zonal/regional EPI officer together with the wereda team shall investigate the AEFI case and further complete the investigation with in 7 days

8) The National EPI focal person shall review the received report form and see if additional cases occurred in other places of the country

9) The National EPI focal person shall send reporting and investigation form to EFDA and support field investigation

10) EFDA Pharmacovigilance center shall coordinate the investigation of the AEFI,analyze the data obtained and consult with AEFI expert committee if necessary to reach a conclusion and recommendation for action

11) EFDA pharmacovigilance center shall assign a code number,create national line list and database and share the data with WHO/UNICEF in JRF

12)EFDA pharmacovigilance center shall work together with National/Zonal/wereda level EPI to ensure that cases are appropriately detected, reported and investigated and recommendation for actions are implemented at the programme level.

19)World Health Organization/WHO and other international organizations

The authority should collaborate with WHO and other organizations to:

1) Identify early warning signals of serious adverse reactions to medicines
2) Evaluate the hazard
3) Undertake research into the mechanisms of action to aid the development of safer and more effective medicines
4) Obtaining expert advice on all matters relating to the safety of medicine.
5) Exchange safety information
6) Conduct various capacity buidlign activities

20)Professional Associations

Professional Associations such as Medical, pharmaceutical and other professional associations :

1) Shall design trainings on pharmacovigilance and continuing education programmes so that members become aware ofthe importance of pharmacovigilance and understand their roles and responsibilities towards the monitoring of medicine safety.
2) Shall establish a communication channel to avail safety information to their members.

21) Other partners in drug safety including the media,consumer association ,and lawyers shall directly or indirectly facilitate the development of new and robust drug policies and decisions, while highlighting deficiencies and weaknesses in existing drug safety policies.

PART FOUR

CAPACITY BUILDING

22)Capacity building

1) Healthcare providers working at both the public and private healthcare facilities shall be trained and be aware of the basic principles of medicine safety monitoring , develop the necessary skills and change their attitude towards the importance of safety monitoring system.

2) The activity stated in the article 22 (1) of this directive shall be facilitated through the professional associations, health facilities, regualtory authorities, PHPs and academic institutions and MAHs in the form of Continuing professional development and trainings.

3) The curriculum necessary to provide training on Pharmacovigilance shall be inline with the National Pharmacovigilance healthcare professionals training manulas.

4) Decentralized Pharmacovigilance centers shall be established at regions and university hospitals tobuildthe capacity of healthcare professionals at all levels and enable them contribute to the activities of monitoring of medicine safety.

5) The established centers shall be continuously monitored regularly by the authorithy.

PART FIVE

ACTIVE SURVEIALLANCE SYSTEM

23)ACTIVE SURVEIALLANCE SYSTEM

EFDA in collaboration with other partners shall perform, active surveillance activities in the form of observational studies, sentinel sitesmonitoring, use of different registries, databases and Cohort event monitoring activities on selected public health programme and other prioritized safety concern medicines.

PART SIX

COLLABORATION,COORDINATION AND COMMUNICATION ON PHARMACOVIGILANCE

24)Collaboration and coordination

1) Any monitoring of drug safety activity in the country shall be coordinated by the Ethiopian Food and Drug Authority.

2) A stakeholder's collaboration and coordination platform shall be established to facilitate the activity stated in the article 22(1) of the directive.

3) All the stakeholders and Partners including safety advisory committees, Drug and therapeutics Committees, Public health programmes, health facilities, pharmaceutical procurement agency, health bureau's , health care professionals, professional associations, academic institutions, manufacturers, importers and wholesalers, consumers and the media shall collaborate to perform pharmacovigilance activities according to the article 22 (1) of the directive

25) Content and target of communication

1) Depending on the safety issue; safety concerns and regulatory measures taken, recommended preventive actions and Risk management plans shall be communicated.
2) Communication by EFDA shall be targeted to include the general public, government and non-government partners, health facilities, health professionals, importers, manufacturers and distributors of medicines, , as well as other stakeholders

26)Responsible body for communicating safety information

1) The Ethiopian Food and Drug Authority Pharmacovigilance centershall communicate any safety information accordingly.
2)Following the notification stated in the above article 23 (1) ; the regional Health bureaus, the EFDA branches and regional regulatory bodies should disseminate the information to the healthcare facilities as soon as possible by using their own

mechanism
3)All market authorization holders and public health programmes shall transfer any new safety knowledge about their products/products in use to the authority so that collaborative actions couldbetaken on time.

27) Means of safety information communication

Communication on drug safety issues shall be carried out through

1) Print media; Quarterly Pharmacovigilance newsletter and Information, Education and Communication (IEC) materials
brochure, magazine (annual), flyers media toolkits
2) Formal letters to the concerned organization, the regional Health bureaus, the EFDA branches
3) The EFDA webpage including the e-reporting information provision page
4) On a scheduled occasion through the media TV, Radio, press release
5) Through social media face book, twitter and on the Medsafety application information page
6) Campaigns, public events on specific days
7) Tel. line 8482
8) Documentaries developed on special occasions
9) Presentations on various events

PART SEVEN

OTHERS

28) COLLABORATION

All organizations working on Pharmacovigilance shall have the obligation to collaborate on the execution of the articles stated here in this directivewhenever required.

29) ANNEXURES

The Annexures attached in this directive shall be used to implement the activities described in the directive

1) ADE report form
2) Instructions on how to use the e-reporting system
3) Instructions on how to use the Medsafety application on Mobile
4). Allergy card

30) Laws that are not applicable in this directive

Any directives, implementation practices or circulars that are against the articles stated in this directive are not applicable on the items included here in this directive.

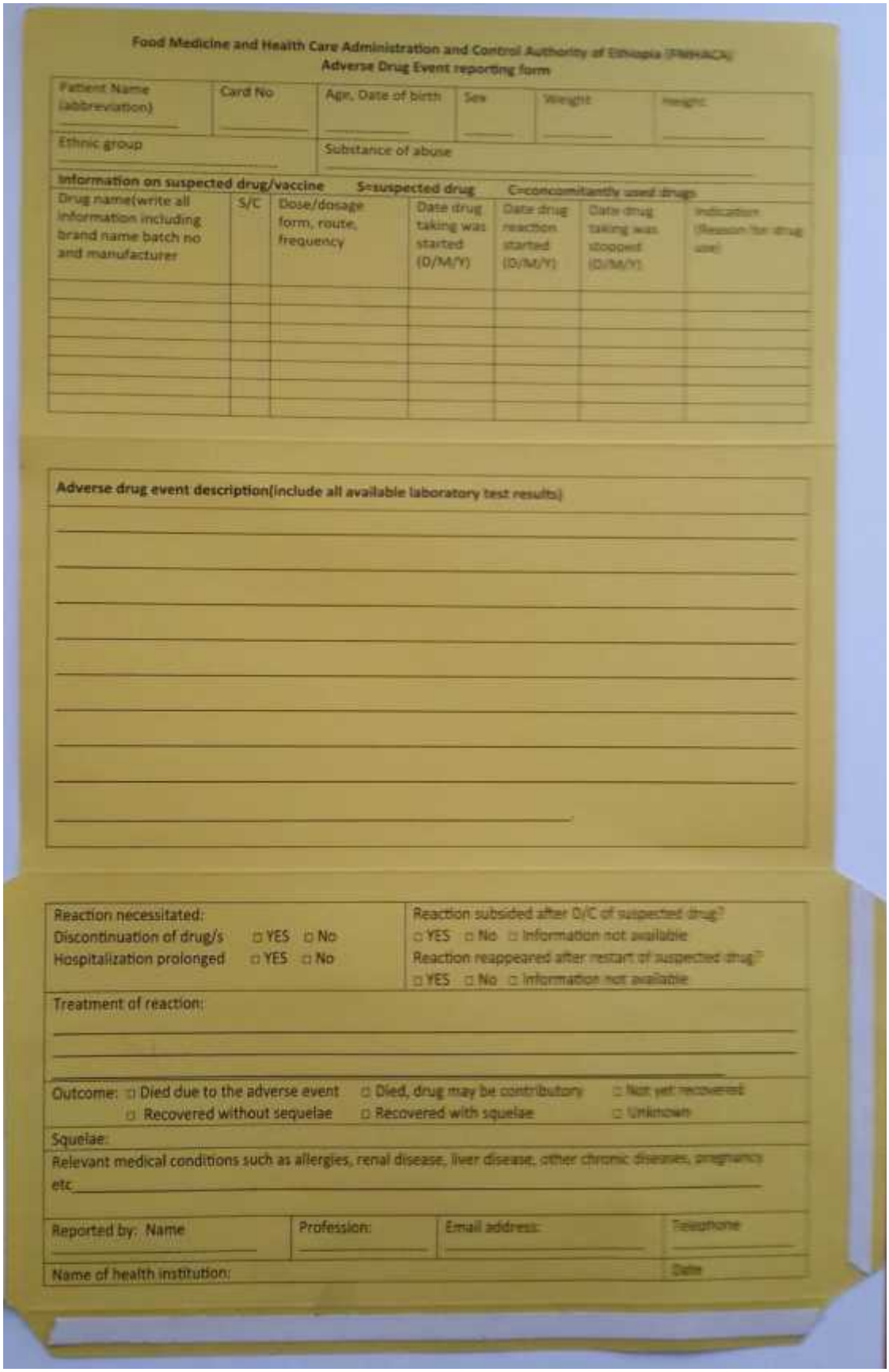
31) Period that the directive shall be effective

This directive shall be effective starting from ----------2020

Heran Gerba

Director General ,Ethiopian Food and Drug Authority

1. Annex 1 ADE Report form



Food Medicine and Health Care Administration and Control Authority of Ethiopia (FMHACA)
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(write 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 drug 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:

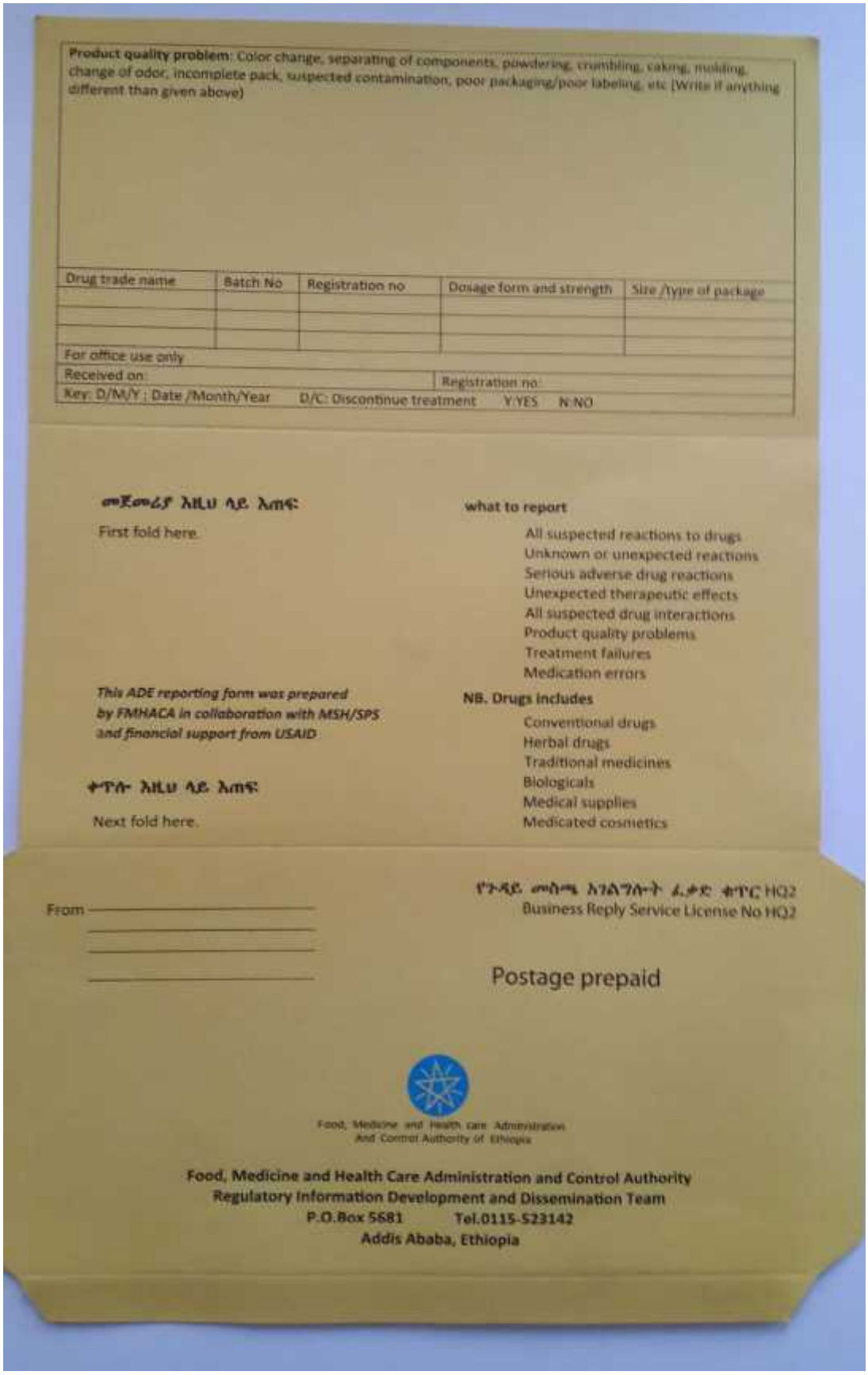
Outcome: ☐ Died due to the adverse event ☐ Died, drug may be contributory ☐ Not yet recovered
☐ Recovered without sequelae ☐ Recovered with sequelae ☐ Unknown

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



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:

Key: D/M/Y : Date /Month/Year D/C: Discontinue treatment Y:YES N:NO

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First fold here

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

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

NB. Drugs includes

Conventional drugs
Herbal drugs
Traditional medicines
Biologicals
Medical supplies
Medicated cosmetics

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From _____

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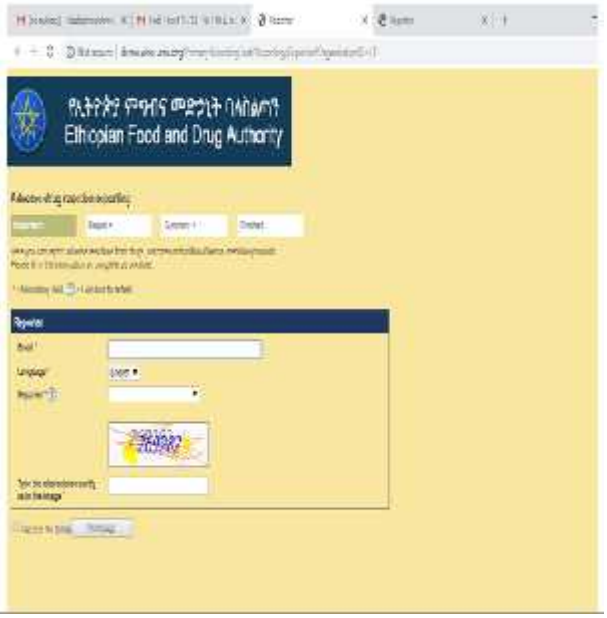
Food, Medicine and Health care Administration And Control Authority of Ethiopia

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 2: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 3:Instructions on how to use the mobile app of Medsafety to report an adverse event

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

Annex 4: Allergy card

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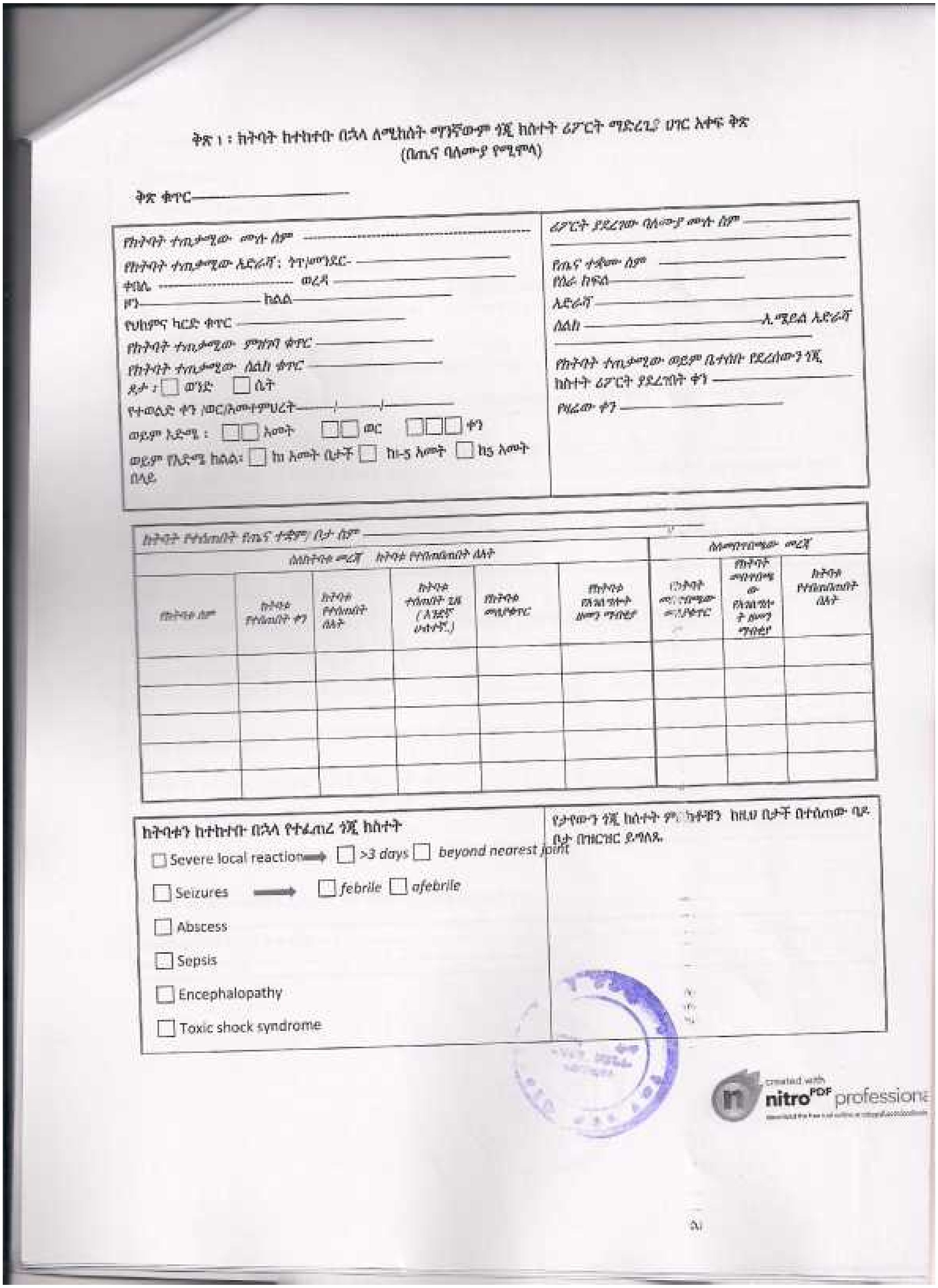
Annex 5 AEFI reporting form


☐ Severe local reaction → ☐ >3 days ☐ beyond nearest joint

☐ Seizures → ☐ febrile ☐ afebrile

☐ Abscess

☐ Sepsis

☐ Encephalopathy

☐ Toxic shock syndrome