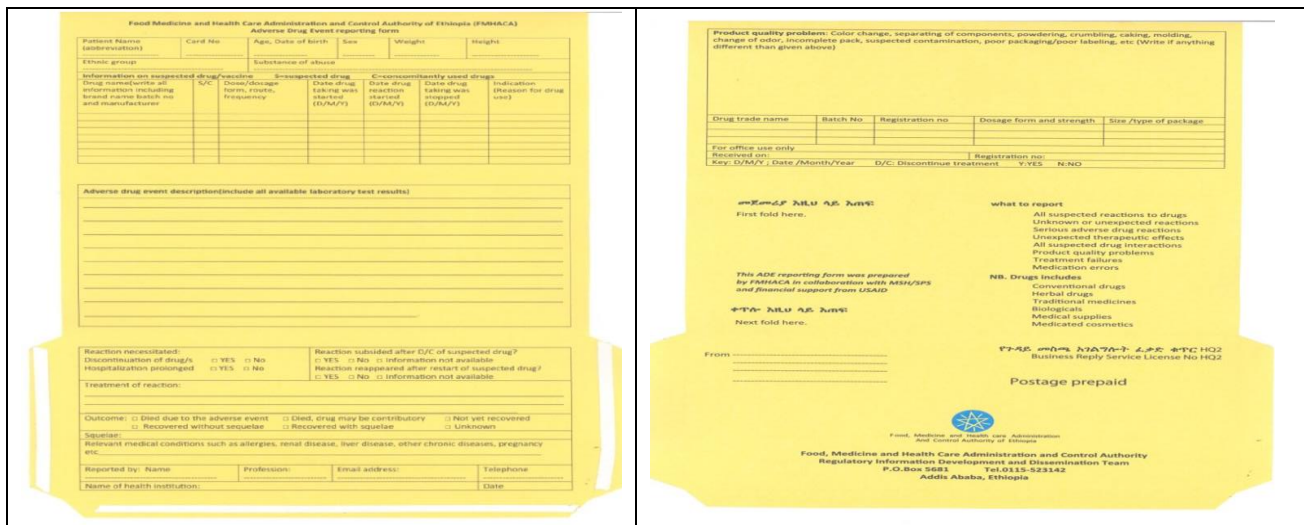


The National Pharmacovigilance system

The Ethiopian Pharmacovigilance system is established in 2002. Currently under the new Proclamation 1112/2019, Article 4: Sub article (9) of the Ethiopian Food and Drug Authority/EFDA, it is mandated to undertake or order post-marketing surveillance to ensure safety, efficacy and quality of medicines and take appropriate legal measures for patient safety and better treatment outcome.

The activities of the Pharmacovigilance center: builds the capacity of healthcare professionals, collects **adverse drug event/ADE** information from all the health care facilities in the country using ADE reporting tools, investigates further, analyzes the evidence and takes appropriate regulatory measures . As the Number of reports obtained yearly for this purpose is very small healthcare professionals need to be aware of the importance of reporting. **Please report Adverse Drug Event (ADE) to EFDA to maintain quality and safety and prevent drug related harms which will then ensure better treatment outcome for patients.** Health Care Professionals should report ADE using the following reporting tools:

1. Prepaid Postage Yellow card



Food, Medicine and Health Care Administration and Control Authority of Ethiopia (FMHACA)
Adverse Drug Event reporting form

Product quality problems: Color change, separating of components, powdering, crumbling, caking, molding, change of color, incomplete pack, suspended 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

የምግብና ሕክምና ወኪልነት ስልጠና
First fold here.

የምግብና ሕክምና ወኪልነት ስልጠና
Next fold here.

what to report
All suspected reactions to drugs
Known 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

የምግብና ሕክምና ወኪልነት ስልጠና
Business Reply Service License No HQ2

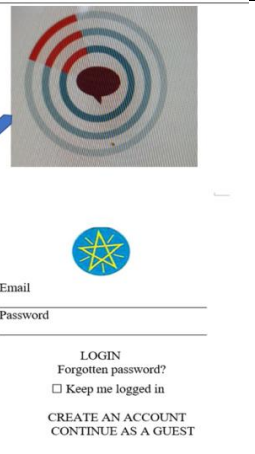
Postage prepaid

Food, Medicine and Health Care Administration and Control Authority of Ethiopia
Regulatory Information Development and Dissemination Team
P.O.Box 5683 Tel.0115-523142
Addis Ababa, Ethiopia

2 Instruction on how to use mobile app Medsafety Tool to report ADE

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

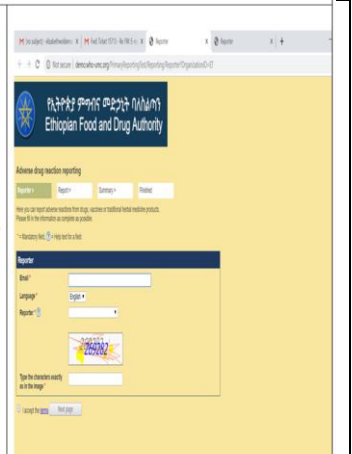
1. To access the Med safety app for **IOS users go to the APP store** for **Android users go to google store** search for **Med safety** app in the search bar (found as in the diagram above)
2. Click on the Med safety icon app to select it
3. click install to install the app
4. Once the app has been 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**



3. Instruction on how to use electronic ADE Reporting tool

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**



4. Using toll free telephone number: Hot number; 8482

For additional explanatory information on the National Pharmacovigilance system please click on the link inside and read on the **important notes on adverse drug event reporting**

