So what are the available reporting mechanisms of ADE in Ethiopia?

ADE can be reported through the use of the yellow form available at health facilities, the toll free telephone number 8482, the Mobile application system (Medsafety) that is just added starting from today.

What are the simple procedures of reporting of ADE through Mobile application (Medsafety)?

- 1.Download the application Medsafety from google store for android mobiles and the APP store for IOS users.
- 2. Create your own account
- 3. Click on the new report button and start filling the information on the adverse drug event that you want to report.

Please look into the first page of the mobile application and the login page attached in this brochure for your information.





Email

Password

LOGIN Forgotten password?

☐ Keep me logged in

CREATE AN ACCOUNT CONTINUE AS A GUEST





EFDA

Mobile application system
(Medsafety) reporting of ADE in
the Pharmacovigilance system
of Ethiopia!!!!!

Do You Know About Pharmacovigilance?

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.

In addition to adverse drug effects it is also concerned with-

- Substandard medicines
- Medication errors
- Product quality defects
- Lack of therapeutic efficacy
- Use of medicines for indications that are not approved and for which there is inadequate scientific basis
- •Acute and chronic poisoning.
- Abuse and misuse of medicines
- Adverse interactions of medicines with chemicals, medicines, and food.

What are the specific aims of Pharmacovigilance?

The specific aims of pharmacovigilance are to:

- Improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions,
- Improve public health and safety in relation to the use of medicines,
- Contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use, and
- Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.

Hence, Pharmacovigilance (monitoring of medicines safety and quality is necessary in our country too. It has been established in a study that 45% of healthcare providers that are prescribing, dispensing and administering medicines have an encounter of ADE in Ethiopia

Do you think Pharmacovigilance is needed in every country?

Yes indeed there are differences in every country with respect to-

- Drug production
- Distribution and use (e.g. indications, dose, availability)
- Genetics, diet, traditions of the people
- Pharmaceutical quality and composition (excipients) of locally produced pharmaceutical products
- The use of non-orthodox drugs (e.g. herbal remedies) which may pose special toxicological problems, when used alone or in combination with other drugs

All this aims ultimately add up to the Goal of providing safe and quality medicines to the public!!

So how is Pharmacovigilance being performed in Ethiopia?

The Ethiopian Pharmacovigilance system has been carrying out various activities in this regard.

Following are the procedures implemented in this system

- 1. ADE(Adverse drug reaction, medication error or product defect) are detected by a healthcare provider who is working at any public or private healthcare facility or manufacturer, importer or distributor.
- 2. The necessary information is filled by the reporter **using one of the available reporting mechanisms** and is sent to EFDA
- 3.Reportsare collated, analyzed, further investigated and if necessary samples of the medicine are assessed by laboratory
- 4. Based on the results of the investigation and the recommendation of the National safety advisory committee the necessary regulatory measure is taken
- 5. The regulatory measure is communicated to the market authorization holder of the medicine and all the stakeholders so that the evidence obtained can be used to prevent the public from drug related harm .