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Ethiopian Food and Drug Authority

Electronic adverse drug event reporting/ADE (e-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 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.

What are the simple procedures of e-reporting of ADE that is just added today in addition to the available reporting mechanisms?

1.Go to the website of EFMHACA
www. fmhaca.gov.et
2. Enter services, click on the link
3. Enter your email address
4. Click on the Adverse drug reaction reporting button and start filling the information on the adverse drug event that you want to report. Please look into the reporting page at the back of this brochure for further information

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.

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.

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 affected so that the evidence obtained can be used to prevent the public from harm.