

# PHARMACOVIGILANCE NEWSLETTER



Food Medicine and Health  
Care Administration and  
Control Authority

INSIDE THIS ISSUE:

History of ADR monitoring	2
Functions of the WHO ADR monitoring center	2
Why is ADR Monitoring necessary?	2
The National ADR monitoring center	3
Major activities performed by the center	3
Activities continued	3
Updates on some medicines As obtained from WHO	4

This newsletter is prepared by FMHACA on a monthly basis

The aim of this newsletter is to disseminate information about the drug safety activities of the EFMHACA, to communicate with health providers any safety concerns on drug safety both local and as obtained from international WHO drug monitoring center.

Website [www.daca.gov.et](http://www.daca.gov.et)

Coming soon will be—

[www.fmhaca.gov.et](http://www.fmhaca.gov.et)

## ADVERSE DRUG REACTION (ADR) REPORTING NEEDS COMMITMENT

The only thing that remains between an adverse drug reaction observed in a drug treatment and the help that the user of the drug gets as a result is the will and commitment of the health provider to report the situation to the regulatory authority.

There are many health providers who have been reporting an ADR and one of whom has given us his comments as follows- Ato Adissu Tolena who is a pharmacist working at Bole 17 health center told Ethiopian Food Medicine and Health care Administration and Control Authority (EFMHACA) that reporting an ADR that occurred during a drug use benefits the patient and the health care system as a whole. He also mentioned that filling the simple yellow



Ato Addisu Tolena, Pharmacist at Bole 17 Health center

colored prepaid ADR reporting form and sending it to the post office or returning it to the pharmacy department of the health facility is not a difficult or an additional task for a health provider who really stands for the

good of the patient care. Ato Addisu has been known to work with EFMHACA to support the pharmacovigilance system of the country and has reported various number of ADRs encountered .

## IN OUR COUNTRY ADVERSE DRUG REACTION REPORTING IS POSSIBLE

**Using a yellow colored prepaid ADR reporting form** available at all health facilities

- Fill it to the best of your ability seal it and Send it to the post office or return it to pharmacy dept in your health facility.

**Using INTERNET** –The yellow ADR report form is also available in the website of the regulatory authority.

- [www.daca.gov.et](http://www.daca.gov.et) ,so fill the form online and mail it to [riddteam@gmail.com](mailto:riddteam@gmail.com)

**Using TELEPHONE** you can report an ADR through this telephone

- 0115523142 is the direct number of the team that is working on pharmacovigilance.

## What is Pharmacovigilance?

It is the science and activity related to the detection, assessment, understanding and prevention of adverse drug reactions and any other drug related problems

## Who should report an ADR?

- All health professionals who are involved in prescribing, dispensing and administering a drug are voluntarily required to report an observed ADR

Physicians  
Health officers  
Pharmacy—  
professionals  
Nurses  
Dentists

# HISTORY OF ADVERSE DRUG REACTION MONITORING

**Historically** the origin of adverse drug reaction monitoring lies in often-cited thalidomide catastrophe, which initiated a new perception of drug control in many countries.



The drug thalidomide which was then marketed produced birth defect in children after it was taken by several number of pregnant women. A total of 10,000 children were born with a defective limb. The World Health Organization reaction in 1967, to these events resulted in the setting up of a project on the international monitoring of adverse reaction to drugs. With time the project developed into WHO program on International Drug monitoring which at present has a number of members from developed and developing countries. The Ethiopian ADR Monitoring center is the 88th member of this center.

## FUNCTIONS OF THE WHO ADR MONITORING CENTER

**All member countries** collect reports from health professionals and pass them on for entry into the WHO database (vigiflow) housed at the center

for international Drug Monitoring in Uppsala, Sweden. The center then monitors the sent reports from the database and generates potential signals of severe Adverse

drug reactions and provide confirmation of these signals generated in respective countries or regions which will then be communicated back to all members.

## WHY IS ADR MONITORING NECESSARY?

**Monitoring of drugs** after they are put into market is necessary because there are limitations in the preclinical and clinical stages of the drugs during the drug development process before they are marketed. **What are**

**these limitations?**

- 1.Number of people participating in this studies is too few.
- 2.People with medical histories or who are taking other drugs are excluded from this studies.
- 3.Population group

exposed has too narrow range. Children, pregnant mothers and geriatrics are excluded. **4.**A drug is investigated only for a single use. **5.**Study has short duration and hence problems with long term use cannot be detected.

# THE NATIONAL ADR MONITORING (PHARMACOVIGILANCE) CENTER

**The National ADR Monitoring system of Ethiopia** was first established in 2002 G.C after a kick off workshop by concerned stakeholders and partners who are responsible for the maintenance of drug safety . This establishment created the center at the Drug Administration and Control Authority. The authority then marched actively by preparing the

necessary monitoring tools (Guideline and reporting form) and performed various awareness creation activities like giving trainings to health providers and also preparation of Educational materials (posters) both for the provider and the public . Communication with the WHO ADR monitoring programs were also



The new building of EFMHACA

started which had further paved the way for various activities to be performed.

## What are the major aims of Pharmacovigilance ?

- Early detection of unknown reactions and interactions.
  - Detection of increase in ADRs frequency.
  - Identification of risk factors.
  - Quantification of risks.
  - Preventing patients from being affected unnecessarily.
- Rational and safe use of drugs.

## MAJOR ACTIVITIES PERFORMED BY THE CENTER AT EFMHACA

**Currently** the center is focused on strengthening of its monitoring activities in collaboration with an international NGO Management Sciences for health/ Strengthening pharmaceutical systems. Hence;

**1.Assessment** of knowledge Attitude and Practice of health providers was carried out and a report was generated and disseminated .

i.e. ADR Guideline and reporting form and also printing was carried out and both are now distributed and are being in use by all health facilities of all regions.

**2.Revision** of the basic Pharmacovigilance tools

**3. A Brochure** on ADR Monitoring was prepared and is distributed to health providers.

ing of Trainers (TOT ) and basic advocacy trainings on pharmacovigilance were given on various rounds to the health providers of the public and private health facilities of all the regions in the country. Other trainings on ADR were also provided on related trainings like during Drug and Therapeutic Committee trainings, malaria control

and ACT (Coartem) Pharmacovigilance trainings ,Training on Known ADRs of ART ,Anti TB and Antimalarial drugs and trainings on Antimalarial drug management and Pharmacovigilance.

**4.Summary** of the 249 reports that were reported by health providers was prepared and was disseminated at various trainings and workshops.

**6.Eleven rounds** of Face to face discussions with health providers of 6 health facilities were carried out.

**5.Two rounds** of Train-

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address

[riddteam@gmail.com](mailto:riddteam@gmail.com)

about any  
information,  
comment or  
suggestions on drug  
related injuries  
(Adverse drug  
reaction, Medication  
error or product  
quality problems).



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## Updates on some medicines as obtained from WHO

- 1.Ceftriaxone,(Rocephin)–( Canada,2008, Malaysia and USA 2009)** this antibiotic shouldn't be mixed or co administered with calcium containing solutions. Also in Malaysia it is contraindicated to use the two together in infants(<28days) because of the risk of dangerous precipitation.
- 2.Clopidogrel,(Plavix)(European Union, Malaysia and Newzealand,2009)** concomitant use of this drug with Proton pump inhibitors is discouraged.
- 3.Desmopressin, (Minirin)(Iraq,2008)** lingual tablet is restricted to be used in primary enuresis, central diabetes insipidus, and enuresis in adults. Also not to be used by patients over 65 years.
- 4.Isotretinon,(Accutane,Amnesteem,oratane)(newzealand2009, Switzerland 2008)** is contraindicated and is restricted for use in women of childbearing age due to its risk of teratogenecity.
- 5.Ivermectin,(Stromectol)(Iraq2008)** restricted to be used in hyperkeratosis crusted lesions only.
- 6.Metoclopramide,(Reglan,primperan) (USA,2009)** FDA has required manufacturers to add boxed warnings their label about the risk of its long term or high dose use. It is recommended that treatments not exceed three months due to the risk of tardive dyskinesia.
- 7.Nimesulide,(Aldoron,Nisulid,redaflam,scafan) Argentina 2009**-ordered the prohibition of all medical specialties containing the NSAID nimesulide as the only active pharmaceutical ingredient or in combination products. **,Bhutan 2008**,sale and use was suspended, **Egypt 2009**-use is contraindicated in children under 12 years, **Malaysia 2008**,registration of all products containing it were cancelled and new product registration containing nimesulide were prohibited. **Singapore 2008** benefit risk analysis is unfavorable due to the risk of liver toxicity, sale of its oral preparation is suspended. **Thailand 2008** use is restricted in hospitals with continuous liver toxicity monitoring, suspension and 50mg tablet are withdrawn, **Ukraine 2008** use has been restricted to the treatment of acute pain, symptomatic

treatment of acute osteoarthritis and primary dysmenorhea and is contraindicated in children under 12 years of age, in patients with fever or flulike syndromes and for use together with other hepatotoxic drugs, other NSAIDs .

**8.Piroxiciam,(Feldene) (Canada,2009)** recommended that it should no longer be used to treat acute or short-term pain and inflammation due to an increased risk of serious skin reactions and gastrointestinal problems relative to other similar drugs. It can still be prescribed for the symptomatic relief of chronic pain and inflammation in patients suffering from certain types of chronic arthritis (osteoarthritis,rhematoid arthritis and ankylosing spondylitis).

Reference (WHO ,Update of the 14th issue,2010)

Update will continue in next issue