



Food Medicine and Health  
Care Administration and  
Control Authority



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Systems for Improved Access  
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# Pharmacovigilance Newsletter

**“Do what you have to do today  
Don't wait for tomorrow”**

*Ato Chalachew Bayu (pharmacist), Debremarkos Referral hospital pharmacy head said.*

He also described that, even though post marketing surveillance is vital and untouched area in developing world, especially in Ethiopia, most health providers participation is very far from what could have been done in practice . In Debremarkos Referral Hospital pharmacy department, knowing that little input is crucial to contribute to the National drug safety monitoring and thereby improve the quality of health care being provided, they are working tremendously by mobilizing all clinical staff. The department assigned

Adverse Drug Event (ADE) focal person and design ADE registration book to document observed ADE to use the information for the facility in addition to primarily reporting it to the Pharmacovigilance center on a regular basis for further investigation and regulatory measure. Doing this is considered as part of their daily activities.



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## Contribute to the National Adverse Drug Monitoring/Pharmacovigilance system by - - - -

1.Reporting the encountered Adverse Drug Events (**Adverse drug reactions, Medication errors and Product quality defects**) that you encountered in your day to day practice at your health facility ( private or public) primarily using

A. **The yellow page reporting**

**form** that is available at all health facilities and sending it to the post office free of charge.

B. **The electronic version** of the reporting form that is uploaded at the website [www.fmhaca.gov.et](http://www.fmhaca.gov.et).

C. **Telephone line**

0115524122 and free call at 8482.

2.Managing the encountered ADE at your facility through the Drug and Therapeutic Committee and using the information from the decision to prevent the drug related injury from happening again.

This news letter is prepared regularly by the **FOOD, MEDICINE AND HEALTHCARE ADMINISTRATION AND CONTROL AUTHORITY** with the objective of providing information to **HEALTH CARE PROVIDERS WORKING AT BOTH THE PUBLIC AND PRIVATE HEALTH SECTORS** on drug safety information and activities that are carried out by the **NATIONAL PHARMACOVIGILANCE CENTER.** Visit us at [www.fmhaca.gov.et](http://www.fmhaca.gov.et)

## Activities performed by the Pharmacovigilance center

### Pharmacovigilance Workshop for Market Authorization Holders (MAH's) (Pharmaceutical Manufacturers ,Importers and distributors)

It has been observed that the involvement of Market Authorization holders in the monitoring of drug safety is very minimal and they are not reporting the safety profiles of their products in the country as required in the National Guideline.

Hence, the Authority conducted a one day workshop on January 10,2013 at Siyonat Hotel ,Addis Ababa with the objective of orienting MAH's with the importance, skills, principles and practices of pharmacovigilance in the nation thereby creating awareness and

ensuring their involvement . The workshop was organized by FMHACA of Ethiopia in collaboration with USAID/SIAPS.

Participants were composed of representatives of seven pharmaceutical manufacturers and fifty two importers

Ato Mengisteab W/Aregay Deputy Director General of FMHACA opened the workshop ,debriefed the participants the national policies and laws on pharmacovigilance.

Following this, participants were provided with information on The importance of Pharmacovigilance; Definitions, adverse drug events, serious adverse drug events, serious unexpected events; the national pharmacovigilance system; partnership in pharmacovigilance; Periodic Safety Updates Reports (PSUR) and Individual Case Safety Reports. Participants raised and discussed various points to have a clear understanding of the roles and responsibilities they are supposed to play in drug safety monitoring.

**As a way forward the participants (pictured right) agreed "To assign a focal person on Pharmacovigilance who will be responsible to follow upon the safety profiles of the drugs they are handling in their organization and work in collaboration with and in accordance with the requirements of the National Pharmacovigilance center"**



### Training of Trainers (TOT) on Pharmacovigilance



TOT was given to thirty experts of regional FMHACA, regional health bureau and regional technical advisors of USAID/SIAPS by FMHACA in collaboration with Global Fund and USAID/SIAPS from February 25-27,2013 at the conference hall of FMHACA. The objective of the TOT was to capacitate the experts at region, so that they could work on drug safety monitoring activities including provision of training to health providers at facilities and execution of other National pharmacovigilance strategies in their regions.

Theoretical and practical aspects of adverse drug event monitoring/ pharmacovigilance were provided together with training skills and methodology . As a way forward, participants have agreed to fulfill their responsibility both as an individual and as a representative of their organizations using the knowledge they gained in the TOT.

## Face to Face discussion on Pharmacovigilance at facilities

Face to a Face discussion on Pharmacovigilance was carried out at Wereda 8 Health Center and Addis Hiwot Private Hospital in Addis Ababa by the Ethiopian Food, Medicine and Healthcare Authority with the technical and financial support of USAID/SIAPS on April 10 and 18, 2013. A total of 45 health providers attended the programme.

An introductory presentation about the need for pharmacovigilance, the National Pharmacovigilance system

and the role of Drug and Therapeutic Committee (DTC) in assessing and managing drug safety was given to the participants in brief.

Participants then discussed on issues and challenges related to adverse drug reporting and monitoring drug safety.



## Summary of Adverse drug Event reports that were sent to the Pharmacovigilance center on the year 2004

The total number of Adverse drug event (ADE) reports received by the Food Medicine and Health Care Administration and Control Authority during the year 2004 E.C were 79 of which 71 are reports of adverse drug reactions (ADR) caused by drugs, 2 are medication errors, 6 are reports of product defect problems .

These reports include 4 reports of Periodic Safety updates from Giant Pharmaceuticals like Roche and Astra Zeneca and 2 reports from Adverse Event Following Immunization programme .This shows that collaborative activity is being carried out between the various partners in the system indicating the widening scope of pharmacovigilance or drug safety monitoring system .

Out of the total 79 individual ADE reported cases, most of the reports (57, 72%) were on females and the age group most cases were reported (37, 46.8%) was ( 15-30) which was contrary to last year's frequency that was (66, 48.5%) in the age group (31-45).

Most of the current reports on adverse drug reactions were on medicines and there were 2 reports on vaccines. 58 of the reported drugs were on oral formulations, 15

were on implants, 3 were on iv fluids and another 3 were on injectables .The majority (41,51.9% )of drugs that were suspected to cause the reported reactions were Antiretrovirals followed by contraceptives (16,20.2%).

One important issue that is observed in this year's reporting but was not observed in the previous year's is that; by including Brands and batch numbers (reported in 25 of the case reports), concomitant drugs (seen in 4 reports) and lab results (seen in 8 of the reports) of specific drugs, health providers have indicated that they understood the necessity of providing additional information that will help for further investigation.

Effects that arise after a long term use of antiretrovirals especially the Nucleoside Reverse Transcriptase Inhibitors like Stavudine that are exhibited in the form of metabolic disorder like Lipodystrophy have been reported with a frequency of (22, 30%).other effects like anemia and generalized skin reactions that are mostly observed early in a treatment are also reported to be (10,14.1%) for each.Also important

was the excessive bleeding which was reported as (15,21.1%).

In the two reports of administration error, reaction observed was injection site bacterial abscess, redness; pain and swelling with discharge .

Most of the reported reactions could be categorized as mild to moderate as only the drugs are discontinued or changed and reactions are managed but ; in the cases of the 21 metabolic disorders, gyneacomastia and the stomatitis where hospitalization was prolonged, severity is clearly observed. There is one fatality case reported after a reactions that arise during the use of an antiretroviral drug combined with an antibiotic.

In this year, six product quality problems were reported using the reporting form as a result of health providers increased awareness that the information is relevant to the maintenance of drug safety of the public. Product defects reported were; caking, color change molding and growth, flocculation, visible solid particles floating, increase in friability, and difficulty in being palatable to the patients.

## **FDA Drug Safety Communication :Azithromycin (Zithromax or Zmax) and the risk of potentially fatal heart rhythms**

**Safety announcement [3-12-2013]** The U.S. Food and Drug Administration (FDA) is warning the public that azithromycin (Zithromax or Zmax) can cause abnormal changes in the electrical activity of the heart that may lead to a potentially fatal irregular heart rhythm. Patients at particular risk for developing this condition include those with known risk factors such as existing QT interval prolongation, low blood levels of potassium or magnesium, a slower than normal heart rate, or use of certain drugs used to treat abnormal heart rhythms, or arrhythmias. This communication is a result of our review of a study by medical researchers as well as another study by a manufacturer of the drug that assessed the potential for azithromycin to cause abnormal changes in the electrical activity of the heart.

The [azithromycin drug labels](#) have been updated to strengthen the *Warnings and Precautions* section with information related to the risk of QT interval prolongation and torsades de pointes, a specific, rare heart rhythm abnormality. Information has also been added regarding the results of a clinical QT study which showed that azithromycin can prolong the QTc interval.

Health care professionals should consider the risk of fatal heart rhythms with azithromycin when considering treatment options for patients who are already at risk for cardiovascular events (see Additional Information for Health Care Professionals below). FDA notes that the potential risk of QT prolongation with azithromycin should be placed in appropriate context when choosing an antibacterial drug: Alternative drugs in the macrolide class, or non-macrolides such as the fluoroquinolones, also have the potential for QT prolongation or other significant side effects that should be considered when choosing an antibacterial drug.

FDA released a [statement on May 17, 2012](#), about a *New England Journal of Medicine (NEJM)* study that compared the risks of cardiovascular death in patients treated with the antibacterial drugs azithromycin, amoxicillin, ciprofloxacin (Cipro), and levofloxacin (Levaquin), or no antibacterial drug.<sup>1</sup> The study reported an increase in cardiovascular deaths, and in the risk of death from any cause, in persons treated with a 5-day course of azithromycin (Zithromax) compared to persons treated with amoxicillin, ciprofloxacin, or no drug. The risks of cardiovascular death associated with levofloxacin treatment were similar to those associated with azithromycin treatment.

Source ,<http://www.fda.gov/Drugs/DrugSafety/ucm341822.htm>

## **Drug safety updates-National**

Following are drugs that regulatory measures have been taken by FMHACA currently

**1. Ivygentacin 0.3% 10ml eye drop.** Batch No- 021177, 021248,021181,021159. Made by Ivee Aquapez Ltd. Kenya.

**Adverse drug reaction** caused is conjunctiva, Chemosis, Redness, Pain ,Tears and Congested Eye lid.

**Local Importer and distributor** is Pharmaceutical Supply and Fund Agency (PFSA).

**Regulatory action taken-**communication has been done through a formal letter to the Importer and distributor to inform the facilities where the drug has been distributed not to use it until further investigations are carried out.

**2.Furesamide 40mg tablet.**  
Batch No 1020833,0031213

**Product quality defect** reported is color change and powdering of the tablet.

**Manufacturer** is Ethiopian Pharmaceuticals Manufacturing Sh. Co (EPHARM)

**Regulatory action taken-**communication to the stakeholder through a formal letter to take action has resulted in the following response.

Retention sample has shown no difference on color change on assessment and the manufacturer has changed the hardness limit for the tablet from 2kp-4kp to 4kp-6kp to solve the problem.

**3.RHZE combination tablet. (Rifampicin 150mg/ Isoniazid 75mg/ Pyrazinamide 400mg/**

You can find earlier issues of this newsletter at [www.fmhaca.gov.et](http://www.fmhaca.gov.et)

**Ethambutol 275mg)** .  
Batch No EFA166A .Macleod Pharmaceuticals ,India.

**Product quality defect reported** is color change

**Local Importer and distributor** is Pharmaceutical Supply and Fund Agency (PFSA).

**Regulatory action taken-**After a laboratory test was carried out by FMHACA the product sample it was found out that the drug does not meet the USP 2011 specification. Communication has been done to the stakeholder through a formal letter to collect the product from the facilities that it was distributed to and inform FMHACA.