FOOD MEDICINE AND HEALTH CARE ADMINISTRATION AND CONTROL AUTHORITY OF ETHIOPIA

Pharmacovigilance Newsletter

VOLUME 2 ISSUE 1 SEPTEMBER 2012

This Newsletter is prepared by FMHACA with the following aims

- To disseminate information about the drug safety monitoring activities of the Authority
- To communicate with health providers on any safety concerns and regulatory measures taken both from local and international sources.

INSIDE THIS ISSUE

Face to Face discussion on Pharmacovigilance

Face to a Face discussion on Pharmacovigilance was carried out at 5 Health Centers in Addis Ababa by the Ethiopian Food, Medicine and Healthcare Administration and Control Authority (FMHACA) with the technical support from MSH/SIAPS. Those present in the half day programmes were a total of 125 health providers (2 Physicians, 12 Health officers,86 Clinical and BSC Nurses, 5 Pharmacists and 11druggists) from Gulele Health Center, Teklehaimanot HC, Kazanchis HC, Shiromeda HC and Bole 17/20(two rounds).

Participants discussing on Pharmacovigilance

During the sessions discussions focused on data to be filled during the reporting, frequently observed medication errors, reasons for their occurrence and practical ways to prevent them from happening again, reporting concomitantly taken drugs and the uncertainty to include them, involvement of private facilities in drug safety monitoring, reporting an outcome on follow up, regulatory measures taken so far and their means of communication to the health provider. Participants also indicated their need for trainings on the known ADRs and safety concerns of the drugs used for the epidemiologically significant diseases like HIV, Malaria and TB.

Heads of the facilities and participants appreciated what has been done by the authority and promised to share the knowledge obtained to their colleagues. They also added that they would carry out their responsibility towards monitoring drug safety and thereby improve the quality of health care given to their patients.

There are 3 ways of reporting an observed Adverse Drug Event

1.Using the yellow page ,prepaid report form that is available at all facilities (wards, examination room, pharmacy department). You can contact the focal person at the facility.

2.Using a telephone number of FMHACA, Regulatory Information development and dissemination team (through the tele. operator 0115524122, direct 0115524118).

3.Using the website of the authority www.daca.gov.et/adr/reportform (the report form is uploaded there you can fill on it and send it through the email address riddteam@gmail.com.

Current activities- - - -

FMHACA developed the National Strategic Framework on the Monitoring of Drug Safety, Pharmacovigilance

The Ethiopia Food, Medicine and Healthcare Administration and Control Authority developed a National strategic framework on the monitoring of drug safety, Pharmacovigilance.

The document contains information on why there is a need for pharmacovigilance, pharmacovigilance at different levels, partnership in pharmacovigilance, current status of the National system and also the rational for the development of the strategies.

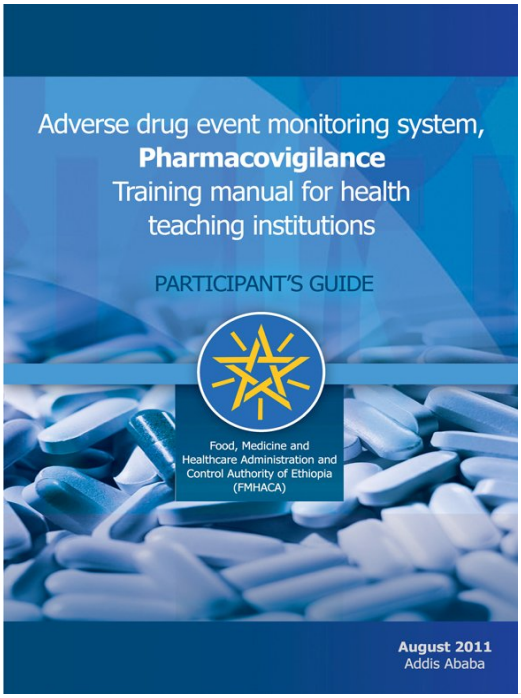
The main objective for the development of the Framework was to put the National strategies for the monitoring of drug safety. Hence the strategies ,the detailed activities and the Stakeholders/ partners that will carry out the systematic implementation are described clearly in the document. As stated in the framework, the 7 strategies that will enable the strengthening of monitoring drug safety in the country are; Capacity building, Collaboration and coordination of efforts, Introduction of Active surveillance system, Use of public health programmes, Communication, Research and Education. This National Framework was familiarized in three rounds to the relevant partners of drug safety monitoring in the country.

Monitoring drug safety/ Pharmacovigilance is a collaborative activity between

- The public
- The health care providers
- The drug manufactutrers
- Professional associations
- The media

and the Pharmacovigilance center in the country at FMHACA

FMHACA developed Training Manual for Health Teaching Institutions



The Ethiopian Food, Medicine and Healthcare Administration and Control Authority developed a Training manual for health teaching institutions on pharmacovigilance . The objective of the manual is standardizing the course contents on the information given on pharmacovigilance and delivered to the students of health science during their pre service training at the institutions. It was believed during the manuals enrichment workshop with stakholdes that using the manual and teaching the students about the adverse event monitoring system in the nation will help them to be involved in the maintenance of drug safety while they perform their practical day today activities in facilities in the future. The manual is currently being distributed to all public and private health teaching institutions at all regions.

Have you encountered the following product quality problems at the health facility you are currently working?

Health providers from various health facilities in Ethiopia have participated in the monitoring of drug safety by reporting about Adverse drug reactions, medication errors and product quality defects of medicines they have encountered during their practice.

Following are some of the product quality defects reported.

1.Medroxyprogesterone actetate (pentogen) vial 150mg/ml suspension for injection/, Batch No 90BG177E, registration no BOD/SA/001.

Quality problem observed

- **Caking**

2.Glucose 5% 1000ml IV infusion ,Batch No 100551.

Quality problem observed

- **Color change, Molding**

3.Insulatard,human insulin suspension for injection
Batch No YS64325. RN, 8-0227-00-201-1.Exp date 03/2013.

Quality problem observed

- **Flocculated solution**

4.Dextrose 5% 100ml IV infusion Batch No 9010594,Exp date 15/01/12.

Quality problem observed

- **Growth**

5.Tenofovir 300mg + Lamivudine 300mg, TENOLAM Batch No E110726A,Heterolab limited ,India. Mfg date 07/2012 , Exp date 06/2013

Quality problem observed

- **10 Patients complained about its palatability.**

6.Nevirapine 200mg of 60 (Nevilsa), Batch No E100631,Exp date 10/13

Quality problem observed

- **High friability**

Have you encountered similar product quality problems during your practice?

If so please report to the Pharmacovigilance center situated at the Food Medicine and Healthcare Administration and Control Authority so that investigations could be carried out regarding the reported drug and the necessary regulatory measure is taken .

Through your vigilance and participation the public would be saved from facing unwanted drug related injuries!!!!!

Please report

- **All suspected reactions to drugs**
- **Unknown or unexpected reactions**
- **Serious adverse drug reactions**
- **Unexpected therapeutic effects**
- **All suspected drug interactions**
- **Product quality problems**
- **Treatment Failures**
- **Medication errors**

Drug safety updates -International

FDA Restricts Use of Simvastatin 80 mg

The Food and Drug Administration is recommending that physicians restrict prescribing high-dose simvastatin (Zocor, Merck) to patients, given an increased risk of muscle damage [1]. The new FDA drug safety communication, issued today, states that physicians should limit using the 80-mg dose unless the patient has already been taking the drug for 12 months and there is no evidence of myopathy.

"Simvastatin 80 mg should not be started in new patients, including patients already taking lower doses of the drug," the agency states.In addition, the FDA is requesting that additional changes be made to the drug's label. The label will be changed to include the new dosing recommendations, as well as warnings not to use the drug with various medications, including itraconazole (Sporanox, Jannsen Pharmaceutica), ketoconazole (Nizoral by Ortho-McNeil Pharmaceutical), posaconazole (Noxafil, Merck), erythromycin, clarithromycin, telithromycin (Ketek, Sanofi-Aventis), HIV protease inhibitors, nefazodone, gemfibrozil, cyclosporine, and danazol.In addition, the 10-mg dose should not be exceeded in patients taking amiodarone, verapamil, and diltiazem, and the 20-mg dose should not be exceeded with amlodipine (Norvasc, Pfizer) and ranolazine (Ranexa, Gilead).The changes to the label are based on the Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine (SEARCH), a study reported by heart*wire* . In that trial, 52 patients taking the 80-mg dose developed myopathy compared with one patient treated with the 20-mg dose. In addition, 22 patients treated with the high dose of simvastatin developed rhabdomyolysis compared with none treated with the 20-mg dose.The FDA notes that the risks of myopathy and rhabdomyolysis were highest in the first year and that older age and female sex increased the risks.

FDA Safety updates accessed on 5/1/2012

Drug safety updates local

Prednisolone 5 mg tab
Brand Name PREDCIP 5mg,
CIPLA Ltd India, B. No. X05827
Date received 5/4/2004 E.C

An individual case report was received on this medicine from a health facility. The reaction observed was ,Rash on face , hands& face swelling and also therapeutic failure.

After receiving this report, the Pharmacovigilance centre at FMHACA acknowledged the reporter and requested to collect further information on the matter. With a positive response from the health care team, the following data was obtained after an investigation was carried out . The investigation on the observed adverse drug event includes Patient clinical record review, interview with health providers and interview with one of the victims who was available on that day.

Clinical card review of 5 patients (among all the patients who have used the drug) showed that the patients complained of symptoms as mentioned above and also for some of them The medication no longer alleviates the symptoms for which it was prescribed .one patient complained of difficulty in swallowing and facial pain after few minutes of swallowing, rheumatism, head ache, blurred vision and suffered from hypertension.

In addition to this, interview with health care providers has shown the amount of the medicine dispensed, the difficulty to tapper the dose as in other steroids and the encounter of the reaction in patients with or without concomitant drugs. They also mentioned that the reaction was observed in patients who are a long term users of the same drug but there was no problem in the previous brands of the same medicine

Interview with one victim also indicates that he has suffered the reaction for a week after taking the drug and so he informed his health care provider and got relief after the drug was discontinued and changed by other brand.

This information was provided to the Inspection and surveillance directorate at FMHACA and afterwards a recommendation was made together to stop the further use of the drug by the facility. Further measures will be communicated after the investigation is complete by the authority.