



Food Medicine and Health
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Control Authority



Pharmacovigilance Newsletter

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Advice to all health providers in the country is.....

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Nigst Eleni Mohammed Memorial Hospital is situated in Hadiya zone at Hosanna town in the South Nations Nationalities and Peoples Republic. It is a known fact that drugs are important for disease prevention as well as curative purpose and hence saves life. But this indispensable remedy by its nature has unwanted adverse effect. Knowing this nature of drugs, all health providers should participate in preventing & managing undesirable adverse drug events (ADE).

Nigst Eleni Mohammed Memorial Hospital has assigned an ADE focal

person to promote drug safety and are also reporting Adverse drug events to FMHACA. As the focal person said; In the hospital, they have an experience of preventing unwanted drug effects by designing channels. By identifying and reporting adverse drug events they are minimizing hospital

stay, reducing patient and hospital related cost and also rearranging patient drug choice or regimen. Similarly, they are providing the Allergy Identification card which was prepared and distributed by FMHACA. Their advice to all health providers in the country is to participate in preventing & managing undesirable drug effects.



Do you know that Product quality defects are also monitored by the Ethiopian Pharmacovigilance center?

True! Products quality defects that are encountered during the drug supply management cycle are also monitored through the spontaneous reporting system of the National Pharmacovigilance system.

How? After reports are sent by using the three methods of ADE reporting (back page of the yellow prepaid reporting form, telephone and via internet) further investigation including sampling and la-

boratory analysis are carried out. This will finally result into a recommendation for action and an official letter will be communicated to the responsible organization for action.

So be part of this!!!!!!

This news letter is prepared quarterly 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**.
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Activities performed by the Pharmacovigilance center

Face to Face discussion on pharmacovigilance at health facilities

Face to a Face discussion on Pharmacovigilance was carried out at Yordanos hospital, International Cardiac hospital and Summit health center in Addis Ababa by the Ethiopian Food, Medicine and Healthcare Authority (FMHACA) with the technical and financial support of USAID/SIAPS on May 25, 29 and August

19 2013. A total of 58 health providers attended the sessions. The discussion was carried out from 2-4pm in the afternoon.

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 actively discussed on issues related to monitoring drug safety. Reporting of reactions to laboratory diagnostic chemicals, experiencing treatment failures in the use of drugs currently available for treating chronic diseases and the need to know the resistance profile of these drugs in a documented form, abundant availability of defective products in the market and the action being taken by the regulatory authority to routinely follow on products that are in the supply chain in their post market life, the need to report



Or not report the already documented adverse drug reactions ,the availability and accessibility of the reporting form at every facility every time, the increasing potential for error in dispensing as a result of illegible handwriting of prescribers ,the quality and safety of herbal and cultural medicines being used by the public, and FMHACAs responsibility were some of the points raised and discussed during the programmes.

Finally the medical directors of the facilities thanked FMHACA and SIAPS for the training and promised to carryout their share of responsibility in the drug safety monitoring.





Activities performed by the Pharmacovigilance center

Consultative workshop with health teaching institutions on the inclusion of pharmacovigilance in the respective curriculum

A one day consultative workshop was organized and carried out by FMHACA on June 20, 2013 with 25 representatives of health teaching institutions both private and public of all regions at FMHACA head office. The workshop was financially supported by Global fund and technically supported by USAID /SIAPS. The objective of the workshop was to sensitize the participants on pharmacovigilance, discuss on the challenges faced by the teaching institutions regarding the implementation of the inclusion of the topic in their teaching and to decide on the way forward to overcome the difficulty. It is to be remembered that the material for this purpose was developed and provided by FMHACA in the form of a manual in 2012 but most of the institutions were not using it to deliver information on the national safety

monitoring to their students as observed in an assessment .

The programme was officially opened by Ato Kidanemariam G/michael, Director of Regulatory Standard Setting and Information Delivery, (FMHACA).

Sensitization was provided to the participants in the form of presentations on the topics; Pharmacoepidemiology and pharmacovigilance, the national pharmacovigilance system and The Pharmacovigilance Training manual .

Participants raised various points to the presenters and discussed together.

In the afternoon session, challenges were specifically pointed and consensus on the way forwards were reached for the implementation of teaching on pharmacovigilance. And responsibility was shared between the representatives and FMHACA pharmacovigilance center.

Way forwards were-

1. Communication with the Ministry of Education curriculum development center should be reinstated.

2. Communication with the TVET agency should be done so that final COC exams could be included regarding the national system.

3. Options like reading assignment and demonstration should be taken to overcome the time limitations that is experienced in the curriculum of nursing training and others.

4. Currently there is an involvement of health bureaus in the development and implementation of modular approach of teaching. So it would be wise to include this important partner.

Lastly participants insisted on the involvement of the quality assurance department at each institutions and collaborative activity between the various partners is vital.





Drug safety updates -International

FDA Drug Safety Communication: FDA requires label changes to warn of risk for possibly permanent nerve damage from antibacterial fluoroquinolone drugs taken by mouth or by injection. Safety Announcement

[8-15-2013] The U.S. Food and Drug Administration (FDA) has required the drug labels and Medication Guides for all fluoroquinolone antibacterial drugs be updated to better describe the serious side effect of peripheral neuropathy. This serious nerve damage potentially caused by fluoroquinolones may occur soon after these drugs are taken and may be permanent. The risk of peripheral neuropathy occurs only with fluoroquinolones that are taken by mouth or by injection. Approved fluoroquinolone drugs include levofloxacin (Levaquin), ciprofloxacin (Cipro), moxifloxacin (Avelox), norfloxacin (Noroxin), ofloxacin (Floxin), and gemifloxacin (Factive). The topical formulations of fluoroquinolones, applied to the ears or eyes, are not known to be associated with this risk.

If a patient develops symptoms of peripheral neuropathy, the fluoroquinolone should be stopped, and the patient should be switched to another, non-fluoroquinolone antibacterial drug, unless the benefit of continued treatment with a fluoroquinolone outweighs the risk. Peripheral neuropathy is a nerve disorder occurring in the arms or legs. Symptoms include pain, burning, tingling, numbness, weakness, or a change in sensation to light touch, pain or temperature, or the sense of body position. It can occur at any time during treatment with fluoroquinolones and can last for months to years after the drug is stopped or be permanent. Patients using fluoroquinolones who develop any symptoms of peripheral neuropathy should tell their health care professionals right away. FDA will continue to evaluate the safety of drugs in the fluoroquinolone class and will communicate with the public again if additional information becomes available.



Drug safety updates -local

Following is the drug that regulatory measure have been taken by FMHACA in this quarter

Name of the drug

Dextromethorphan Hydrobromide potassium +Guaiacol sulphonate syrup ,125ml (APHADEX),

Batch number 11015 ,Manufactured by Addis Pharmaceutical Factory PLC .

Manufacturing date 05/12 Expiry date 05/14.

Product quality defect reported -Suspending particle through visual inspection.

Regulatory action taken-Communication has been done to the responsible organization through a formal letter to collect the product from health facilities where it has been distributed and report to the Inspection and surveillance directorate at FMHACA.



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