



Pharmacovigilance Newsletter

Medication Errors!!!!!!

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Medication error is one of the main causes of drug related injury or Adverse drug event. It is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

Medication errors consist of the administration of medicine or dose that differs from written order and includes—

- Medicine prescribed but not given
- Administration of a medicine not prescribed
- Medicine given to the wrong patient
- Wrong medicine or IV fluid administered
- Wrong dose or strength given
- Wrong dosage form given
- Medicine given for wrong duration
- Wrong preparation of a dose (e.g., incorrect dilution)
- Incorrect administration technique



- Medicine given to a patient with known allergy
- Wrong route of administration used
- Wrong time or frequency of administration

The National Pharmacovigilance center monitors medication errors in addition to Adverse drug reactions and product quality defects through the help of reports obtained from health providers.

© This news letter is prepared periodically by the **FOOD, MEDICINE AND HEALTHCARE ADMINISTRATION AND CONTROL AUTHORITY** with the objective of providing information **TO HEALTH PROVIDERS WORKING AT BOTH THE PUBLIC AND PRIVATE HEALTH SECTOR** on drug safety information and activities that are carried out by the **NATIONAL PHARMACOVIGILANCE CENTER**.

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The Ethiopian Pharmacovigilance Center

Where is it located?

The Ethiopian Pharmacovigilance center is found in the Food, Medicine and Healthcare Administration and Control Authority under the regulatory standard

Setting and Information Delivery Directorate.

What does it do?

It works towards the monitoring of drug safety through advocacy and collecting reports from health providers using

the national reporting forms, it analyzes the data, consults with experts and takes appropriate regulatory measures together with its partners in the various sectors of drug supply and management



Launch of a pharmacovigilance database

A pharmacovigilance database that was developed with the objective of storing, and analysis of drug safety information sent from health providers was launched at Siyonat Hotel on April 23, 2012. Participants present were stakeholders from regional Health bureaus, teaching institutions, professional associations health facilities and partners (WHO). The programme was officially opened by Ato Mengisteb Woldearegay, Deputy Director of Standards and Licensing of the Ethiopian Food, Medicine and Health Care Administration and Control Authority (FMHACA). The development and launch of this database was possible through the collaborative activity of strengthening the National pharmacovigilance system between FMHACA and Management

Sciences for Health System for Improved Access to Pharmaceuticals and Services (MSH/SIAPS).

The database Pharmacovigilance data management system (PVDMS 1.0) was developed by the IT Unit of MSH/SIAPS according to the Scope of work specified by the National Pharmacovigilance center experts at FMHACA. The database captures all kind of necessary information i.e. data on Adverse drug reaction, medication error, product quality defect including safety reports obtained from Adverse Events following Immunization (AEFI) and Market Authorization holders (MAH) needed for a comprehensive monitoring and analysis of drug related reactions using user friendly and consistent input



taking interfaces. The Information stored in the appli-

cation can be accessed only by authorized personnel and the drug safety Information stored in the application can be exported to different data analysis tools. During pilot testing, it has accommodated 25+ reports from which analysis could be generated using few clicks.

According to the WHO drug safety monitoring center, one of the minimum requirement for a comprehensive pharmacovigilance system that determines the level of the National Pharmacovigilance centers' capacity and performance is the capacity regarding signal generation and data management .This requires the availability and use of a National pharmacovigilance database; hence this requirement is now met for the Ethiopian Pharmacovigilance center. Drug safety data properly collected, entered and analyzed using this data base will be subjected to the necessary recommendations and regulatory measures will be taken accordingly.



Familiarization of the National Pharmacovigilance Framework at regions

Familiarization of the national Pharmacovigilance Framework was carried out at three regions; on June 5, 2012 at Siyonat Hotel, Addis Ababa; July 30, 2012 at Lewi Garden restaurant, Hawassa and August 28, 2012 at EthioStar Hotel, Bahirdar for the health providers of Addis Ababa, Oromia, Diredawa, Afar, Somali, SNNP, Amhara and Tigray region. The



Familiarization at Addis Ababa

objective of the programme was to introduce the National strategic document which was developed and printed with the technical and financial support of MSH/SIAPS. The national framework aims at strategical interventions to be implemented in the pharmacovigilance system of the country regarding capacity building, coordination of all Pharmacovigilance efforts among all partners, introduction of active surveillance system, managing drug safety information as a result of adverse drug reactions, medication errors and product quality problems, use and involvement of the public health programmes in the system and appropriate communication of drug safety measures to the public. Familiarization of this important document to the part-

ners of drug safety monitoring is the first step towards its implementation.



Familiarization at Hawassa (above) and at Bahirdar (below)



Face to Face discussions were carried out at Private hospitals

Face to face discussions were carried out on pharmacovigilance with the health providers of selected private hospitals namely Denberua hospital, Zenbaba hospital, St Yared hospital, Bethel General hospital, Tezena hospital and St Gabriel hospital. 77 participants of different professions attended the discussion programmes that were aimed at

giving orientation about the importance of drug safety monitoring, the national pharmacovigilance system, the tools to be used for reporting an observed Adverse event, partners involved, the importance of prevention of adverse effects and the role of Drug and Therapeutic Committee (DTC) in managing drug safety.



Face to Face discussion at St Gabriel private hospital



Adverse Event Following Immunization Monitoring Training

A training was carried out on strengthening Adverse Event Following Immunization (AEFI) Monitoring and causality assessment by FMHACA in collaboration with WHO from 29 October-02 November 2012 at Dreamliner Hotel, Addis Ababa. 32 Participants were derived from Immunization experts of Tanzania, Tanzania MOHSW and WHO Tanzania; WHO Ethiopia, UNICEF Ethiopia, CHAI, representatives from FMHACA, Regional FMHACA, Regional Health Bureau, ministry of Health, and EHNRI. Training was given in the form of presentations and group discussions regarding the National Pharmacovigilance system, methods of monitoring, investigation of AEFIs, analysis of vaccine safety data, Causality assessment, global initiatives to support causality assessment, strengthening the AEFI surveillance and causality assessment and vaccine risk communication.



Participants at the AEFI training

Drug safety measures update -Local

1. Niclosamide 500mg tabs Manufacturer-Addis Pharmaceuticals factory PLC

Product quality problem -Therapeutic effectiveness

In response to a report from various health providers, the Ethiopian Food, Medicine and Healthcare Administration and Control Authority has carried out an investigation and the manufacturer has provided the following response on 22/10/2004 E.C. They have understood the problem and are performing a research and development activities that would result in a formulation change, they are planning to carry out a study regarding the therapeutic effectiveness in collaboration with Mekelle University and they have stopped producing the tablet temporarily.

2. Ringer lactate 1000ml iv fluid, Manufacturer-Addis Pharmaceuticals factory PLC

Batch No- 120034/35/40/41/43-50/53/59/65-68/71/72/74/76/77/80/93

Product quality problem -Solid particle floating in the iv fluid

Based on an initial report from a health provider and further investigation about a product quality problem, on 10/07/2012; the Ethiopian Food, Medicine and Healthcare Administration and Control Authority urgently requested the manufacturer to notify the problem to each health facility, pharmaceutical distributor and retail outlets the product was dispatched ASAP and report the means of communication followed upon, to closely follow other batches of these products from the retention samples because of suspicion of the problem, to revise and report their compliant handling Standard Operating procedure (SOP) with respect to compliant recording, to revise their recall SOP with respect to method/means of recall notification and the channel of recall within their department, to halt manufacturing of ringer lactate until full investigation of the compliant is carried out and reported.