



FOOD MEDICINE AND
HEALTH CARE
ADMINISTRATION
AND CONTROL
AUTHORITY OF
ETHIOPIA



Pharmacovigilance newsletter

**"We don't see things as they are, we see them specially-
as a health care provider!"**

Use of medicines is associated with risks that include occurrence of adverse drug reactions, treatment failure and /or, medication error. Adverse drug events may be seen in clinical trials, but this effect becomes clearly seen only when the medicines are widely prescribed. Safe medicine use requires patient education about the proper use of medicines, adverse drug reactions, drug interaction, and treatment failure that could arise as a result of improper use, and so it requires health provider's commitment to review patient drug therapy and ensure minimum risk for the individual patient.

Adverse drug reaction is unexpected, un intended, undesired or excessive response to drug with sequelae and so, we should participate in mechanisms that monitor the safety drug use in high risk populations (e.g. older people, children, HIV/AIDS patient, pregnant women). We should lead education of individual patients regarding potential adverse drug reactions.

Hence - We health providers should be part of the solution by reporting adverse drug events that we encounter in our daily activity at health facilities to the concerned body , FMHACA, to prevent the occurrence of adverse drug reactions, medication errors and use of poor quality and effective products on other patients.



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This newsletter is prepared and shared quarterly by FMHACA with the objective of providing Medicine safety information and sharing the activities of the pharmacovigilance center at FMHACA to healthcare providers working at both the public and private sectors.

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Reporting an adverse drug event !

What do you report ?

All suspected reactions to drugs
Unknown or unexpected reactions
All suspected drug interactions
Product quality problems
Medication errors
Treatment failures

How do you report ?

By using a yellow page adverse drug event report form that is available at all facilities and sending this filled prepaid form through the postal address of FMHACA ,5681.
By using the toll free direct telephone line 8482 that the regulatory center has installed.
By using internet -through the email address regulatory @fmhaca.gov.et

Activities at the pharmacovigilance center

Product quality problems reported during the year 2007 E.C

During the year 2007 E.C, 68 products with 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. As shown in the following table, false positive results after the use of diagnostic test kits, presence of visible floating particulate matter in a solution, color change and crumbling were among the most reported quality defects.

Table 1. Description of the drugs and product quality problems reported in the year 2007 E.C

Quality problem reported	Frequency
1. Giving false positive results	14 19%
2. Color change ,Visible floating particulate matter	10 13.5%
3. Incomplete pack	6 8%
4. Poor packaging	4 5.3%
5. Caking	4 5.3%
6. Cup is not easily openable and it doesn't close afterwards	3 4%
7. Cracking	2 2.75%
8. Empty tube	2 2.75%
9. Contamination	2 2.75%
10. Suspending particles	2 2.75%
11. Poor adhesive ability	2 2.75%
12. Easily friability	2 2.75%
13. Inability to disperse upon shaking	2 2.75%
14. Inability Crystal doesn't melt upon heating	2 2.75%
9. Others*	11 22.9%
Total	68 100%

Others light sensitive x ray film and gets so dark to read, empty blister, Inhaler inability to dispense, fragile, Improperly short and sharp needle, powdering on the capsule, tablet weight variation and deformity, easily friable, bag leaks urine, powder at the bottom, crumbling, sedimentation at the bottom of the bottle, easily detachable labeling, highly staining GV, too much powder on the glove, volume smaller than the specified, batch number cut off from the package,*

Revision of the National Adverse Event Following Immunization Guideline

The National AEFI guideline was revised and enriched in a workshop carried out from July 8- 9, 2015 at Adama Dire International Hotel .Participants were derived from health facilities all over the nation (Immunization and Pharmacovigilance focal persons of health facilities), teaching institutions (AAU pharmacy department), Ministry of Health (PHEM), and partners (WHO, USP,CHI) making a total number of 25.

The workshop was officially opened by Ato Habtamu Beyene ;Director, medicine registration and licensing ,FMHACA who appreciated the commitment of the participants and wished a fruitful deliberation. After a brief guiding presentation of the guideline the Participants were divided into three groups to discuss, comment and provide their suggestion for the betterment of the document. In the second day each group presented its findings and discussions were made on the points raised. The workshop was closed by the WHO representative (Dr Ayeshshum.....) who thanked the participants for their unreserved effort.

Activities at the pharmacovigilance center

Face to Face discussion on pharmacovigilance at regions

Trainings in the form of face to face discussions were carried out on pharmacovigilance at 14 health facilities at regions. 255 Health providers at **Agaro hospital (H) , Karamara H, Jugal H, Hiwot Fana University Specialized H, Sabian Primary H, Haramaya Primary H,Chiro Zonal H, Adama H, Ejaji Health center (HC) , Meki HC, Bulbula HC, Adama HC, Boku HC and Modjo HC** participated in the discussions that were carried out at each of facilities from June 10 up to September 18/2015. The trainings were organized and

carried out by FMHACA pharmacovigilance center and regional SIAPS in collaboration with the heads of the facilities. The objective of the trainings was to raise awareness of the health providers at regions on the importance of pharmacovigilance ,the national system and its tools of reporting an adverse drug event and the challenges they encountered towards the maintenance of drug safety. Participants raised and discussed questions on the relevance of reporting a known adverse drug event, follow up reports, availability and access of reporting tools,

susceptible of their area for illegal trade of medicines and the challenges they are facing, consumers awareness regarding the purchase of drugs from illegal markets, timely receiving information on regulatory actions taken, reporting of vaccines, illegal marketing of laboratory regents, reporting of medication errors, challenges of not reporting an observed event, and access to current information. On the overall discussions ,the participants raised lack of their awareness on the topic and understood the significance of their participation on national medicine safety monitoring program. Pharmacovigilance focal persons were chosen at each facility for further follow up and communication.



Drug safety updates International

Non-steroidal anti-inflammatory drugs and diclofenac

Cardiovascular risks

Australia. The TGA has informed health professionals of changes in PI and labels for non-steroidal anti-inflammatory drugs such as diclofenac, naproxen, ibuprofen, celecoxib, etoricoxib, indomethacin, meloxicam and piroxicam, to include cardiovascular risks. Diclofenac, naproxen and ibuprofen are available as OTC oral dosage forms (in lower doses). Diclofenac ibuprofen and piroxicam are also available as an OTC topical gel.

The changes follow a review of approximately 200 publications, information from companies, reports collected by TGA and expert advice obtained from the Advisory Committee on the Safety of Medicines. In addition, a full safety review of diclofenac was considered. The reviews found that OTC NSAIDs were safe if used according to the recommended doses for short durations, as instructed on the label. However, inappropriate use or overuse of these medicines could pose a significant risk of cardiovascular events and, in the case of diclofenac, hepatotoxicity.

Product labelling for OTC diclofenac, naproxen and ibuprofen did not carry strong enough warnings regarding these risks for all patients, or adequate advice for people with cardiovascular disease or risk factors.

TGA has advised health professionals to:

- avoid using prescription NSAIDs in patients who have previously had myocardial infarction, angina, cardiac failure, hypovolemia, significant peripheral vascular disease or pre-existing significant renal/hepatic dysfunction.

- use these medicines with caution in patients with identifiable risks factors for cardiovascular disease, undertaking individual assessment of each patient to ensure the benefits outweigh the risks.

- consider advising patients of the increased cardiovascular risks of using NSAIDs, including OTC products, and educating them regarding the signs and symptoms of serious cardiovascular events. Instruct them to seek medical attention immediately if they experience any.

- be aware that, in rare cases, diclofenac has been associated with a risk of hepatotoxicity and should be used at the lowest effective dose for only short periods of time.

WHO Pharmaceuticals Newsletter No. 3, 2015 .12

Reference:



check us at www.fmhaca.gov.et

Drug safety update local

During this quarter, the following product was recalled from market at the initiation of the importer itself after a product quality complaint was obtained. The stakeholder have submitted a recall progress report after collecting the product from pharmacies and wholesalers.

Product-RB tone capsule, batch number D40286.

Importer-Caroga pharma Eth. Pvt. ltd.co

Based on repeated product quality defect reports sent by health care providers, preliminary investigation was done and information was provided to the Medicine facility inspection directorate and quality control directorate on the following products of local manufacturers.

1. Product quality defects on Tetracycline eye ointment 1%
2. Product quality defects on Diagnostic kits (HCG test, H Pylori Ag Rapid test , Widal Antigen set O&H ,d Best one step HBS Ag test
3. Product quality defects of tablet and capsule preparations obtained from local manufacturers
4. Product quality defects of pediatric formulations obtained from local manufacturers (Amoxicillin 125,250mg syrup, Paracetamol syrup, Cotrimoxazol suspension). Based on this reports the medicine facility inspection directorate has carried out a full inspection on site and have provided their feedbacks on the major and minor deficiencies observed.



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