



Food Medicine and Health
Care Administration and
Control Authority



Pharmacovigilance newsletter

Message from Bole Bulbula Health center healthcare providers!

Why is Adverse Drug Event reporting important ?

*The importance of Adverse Drug Event Reporting (ADE) system lies in its objective which is ,the provision of drug safety data to FMHACA pharmacovigilance center .This initial information enriched by further investigation will finally enable the users to prevent the recurrence of the adverse drug event in other patients resulting in the delivery of a better safe and quality health care. **Frehiwot Zerihun*** ➡



*Previously, I didn't know about the ADE reporting system, and the allergy card. But one day I shared the idea from other health center. Now ,when i get ADEs ,I report quickly because by the feedbacks i am receiving from FMHACA, i now understand that my participation in the system will add more knowledge about the effect of drugs, save my clients from drug related injuries and i will also be involved in the reduction of drug resistance. **Dejene Melese*** ↑



*I had no idea about how I can report ADEs but after a get the face to face training, I now understand many things like how to report ,when to report and other important concepts about pharmacovigilance. So when I get the case ,i immediately send the report after filling the form. I am also getting a rapid response from FMHACA. **Abebech Tefera*** ➡



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This news letter is prepared and shared quarterly by the
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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 HEALTH SECTORS.
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Activities of the pharmacovigilance center

Face to face discussions were carried out at 10 health facilities on Pharmacovigilance

Face to face discussions was carried out at Nifas Silk Lafto (NLK) , Wereda 5, Addis hiwot, Hiwot fana, Maichew, Guto meda, Hidasie ,Tibeb bekechene, Addisu Gebeya and Shegole health centers of NLK and Gulele Sub cities of Addis Ababa from June 19 until September 12/2014.

The objective of the training

was to create awareness to health providers on the importance of medicine safety monitoring and the national pharmacovigilance system so that they could contribute to the system and ensure that medicine related injuries are subsequently prevented.

The programmes were organized and carried out in collaboration with the health bureaus of the sub cities and their pharmacy heads. Trainings were provided at the meeting halls of the facilities from 2.pm-4.30pm.

A total of 266 health providers were presented and discussed on the concepts of Adverse Drug Events and the need for monitoring, the principles and tools of the National pharmacovigilance system ,the role of Drug and Therapeutic Committee and the challenges of reporting. Participants then promised to carry out their responsibility of maintaining safety and chose a focal person at each facility to coordinate these activities,



Activities of the pharmacovigilance center

National Pharmacovigilance guideline was revised



Guideline for Adverse Drug Events
Monitoring (Pharmacovigilance)

Third Edition

Food, Medicine and Healthcare
Administration and Control Authority of
Ethiopia

2014

The National guideline for Adverse Drug Event Monitoring was revised for the second time . The current guideline shows that the national pharmacovigilance system is working towards a more broader scope of monitoring medicines safety (by including the monitoring of medication errors and product quality in addition to adverse drug reactions which was the practice previously). The guideline also describes clearly the roles and responsibilities of all the partners involved in pharmacovigilance which are; the patients , consumers, the health care providers, Drug and therapeutic committee at facilities, Market Authorization Holders, Public Health programmes, National Medicine Advisory Committee, Academia and Research Institutions, Professional Associations ,WHO ,the media and others who will be working in collaboration with the pharmacovigilance center at FMHACA towards the same goal of preventing medicine related injuries.

“A complete pharmacovigilance system needs an up to date and practical guideline to provide information and guidance to the various partners of pharmacovigilance ”

Ato Yehulu Deneke Alamneh

Director General, FMHACA

Summary of Adverse Drug Events that were reported in the year 2006 E.C

The total number of ADE reports received by the FMHACA pharmacovigilance center during the year 2006 E.C were 223 of which 179 are reports on Adverse drug reactions (ADR) ,42 on product quality problems and 2 were on medication errors. Out of the adverse drug reactions 36 were reports on periodic safety update reports sent from medicine importers and 3 were on treatment failures. Most of the reports {75, 51.7% (N=140)} were on females and the age group that {57, 39.3% (N=138)} was reported was from(16-30). This year, 12 of the reports were on vaccines and 9 were on diagnostic kits .The majority of the medicines that were suspected to cause the reported events by the reporters were Antibacterials (74,33.2%) followed by Antiretrovirals (54, 24.2%) and (10,4.5%) of the reports were on Antituberculars. Dermatological reactions including Steven Johnson's problem (3 cases) were observed in the majority of the cases (77, 38.9%) to be followed by gastrointestinal reactions (29, 14.6%). As to the medication error reports received, it was burning sensation and Pain upon administration of a medicine that was given in a bolus form instead of being diluted with an iv fluid .The errors have resulted in the prolongation of the hospitalization of the patients. Regarding product quality issues, false positive results after the use of test kits(9 cases), presence of visible floating particulate matter in an iv solution, color change and crumbling were among the most reported quality defects. (138, 61.8%) of the reports were sent from hospitals four of which were private and (49,22%) of the reports were sent from health centers. (36, 16.2%) reports were obtained from importers. Majority of the reports (142, 75.9% %) were sent by pharmacists followed by druggists (14, 7.5%), physicians (13,7%) , Health officers (7 , 3.7%) ,nurses (6, 3.2%) and laboratory technologists (5, 2.7%).Importance of providing complete medicine information by health providers has improved as shown in the reports that were sent by including Brands and batch numbers (reported in 193 of the case reports) and lab results (seen in 23 of the reports) .

Update on medicine safety-International

Testosterone products

Risk of venous blood clots

USA. The US Food and Drug Administration (FDA) notified health professionals and their medical care organizations that it is requiring the manufacturers of all approved testosterone products to include a warning in the drug labelling about the risk of blood clots in the veins, also known as venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE).

The risk of venous blood clots as a possible consequence of polycythemia is already included in the labelling of testosterone products. Because there have been post market reports of venous blood clots unrelated to polycythemia, FDA is requiring a change to drug labelling of all testosterone products to provide a more general warning regarding venous blood clots, to ensure this risk is described consistently in the labelling of all approved testosterone products. This new warning, a class labelling change, is not related to an ongoing FDA evaluation of the possible risk of stroke, heart attack, and death in patients taking testosterone products. FDA is currently evaluating the potential risk of these cardiovascular events, which are related to blood clots in the arteries.

Reference: WHO Pharmaceuticals Newsletter No. 4, 2014 ,page 7.

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Update on medicine safety -Local

Summary of an adverse drug event on the use of Tenofovir/lamivudine drug combination

Three adverse event reports were sent to the pharmacovigilance center by a pharmacist from a referral hospital in Amhara region. The adverse drug reaction reported was observed in three adult males (Age group ranging from (21-56) that were taking the antiretroviral drug combination (Tenofovir/lamivudine 600mg drug combination .

The specific adverse drug reaction encountered in three patients as per the reports was ;Low urine output, high creatinine clearance level, Excessive thirst, high water

intake, Increase urine output both in volume and frequency as much as six times per night.

The outcome of the adverse drug reaction shows that out of the three patients the reaction resolved by itself for the two of them whereas for the other one the situation worsens into renal failure and the patient died. Again for the two patients, in spite of the inconvenience, patients tolerated the adverse reaction after some time and there was no need for discontinuation of therapy.

Supportive information obtained from standard reference books (*American Society of Health system Pharmacists, ASHP drug information*) has indicated that the

suspected drug, in this case the NRTI Tenofovir disoproxil fumarate has renal toxicity. Renal impairment including cases of acute renal failure and Fanconi Syndrome (renal tubular injury with severe hypophosphatemia) has been reported in patients receiving Tenofovir during post marketing surveillance. Although most cases occurred in patients underlying systemic or renal disease or in patients receiving nephrotoxic drugs some cases occurred in patients without identified risks.



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