



Pharmacovigilance newsletter

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Message from vigilant health providers !



After I participated in the workshop on Pharmacovigilance which was organized by SIAPS/ USAID in collaboration with PFSA at Jimma some eight months back, I started to understand and visualize the magnitude of the problem and its importance as well. Thereafter, I became very interested and vowed to report ADE whenever I come across and encourage my colleagues do the same. We, health providers, well know that medicines have risks of adverse effects which need to be monitored. Though we are many in the country, we do not report adverse drug events

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.

(ADE_s) when we encounter them. The reasons may be knowledge gap, uncertainty, fear of disclosing the patient's history, not understanding its importance, carelessness etc.. But, if we do so there will be good therapeutic outcome (or the events get resolved) and patient safety will be maintained. Health care provision requires collaborative approach and hence the part played in reporting ADE by the health care providers is crucial. Moreover, workshops, printed materials, adequate and persistent education, information transmission and reporting ADE whenever encountered may reduce problems that may arise due to ADE. Above all, I want to thank the continuous and stringent supervision and follow up that SIAPS/USAID-Ethiopia has provided to us.) *Wondimu Gichile, Pharmacist, Nekemt referral hospital.*

Adverse drug event (ADE) reporting is health professional's responsibility. The ADE we come across whether product defect, treatment failure, drug resistance or unexpected or expected drug adverse effects may seem minor and we may leave them without reporting to the concerned body. However this may have disasters effect on our nation, in particular and to the glob in general. Hence each and every health professional should play his part in reporting ADE, which may be minor or gross to safe guard our people from drug related problems. *Demiss Mohammed ,Pharmacist, Dessie referral*



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Activities done by the pharmacovigilance center

Face to face discussions were carried out on pharmacovigilance at 12 health facilities

Trainings in the form of face to face discussions were carried out at 13 health facilities (Efoyta HC, Hiwot Amba HC ,Feresmeda HC, Saris HC ,Gotera meshualekia HC, Serti HC, Gelan HC, Selam Fire HC, Wereda 12 HC, Wereda 9 HC , Mikilieland HC, and Lomi meda HC) during this quarter. The trainings were performed at the meeting halls of the facilities during the afternoon hours and a total of 308 health providers participated during the discussions.



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 collaborate and work with the center and ensure that medicine related injuries are prevented from harming the public.



The trainings were organized by the pharmacovigilance center and SIAPS in collaboration with the pharmacy heads of the sub cities .Refreshments were provided during the events by USAID/SIAPS.

Presentation was given on the need for pharmacovigilance, the tools for spontaneous reporting, what to report, how to report and the activities of the national pharmacovigilance system.

The participants eagerly discussed the challenges encountered in ADE monitoring and a focal person was chosen at each facility to communicate with the national center and facilitate the monitoring activity . (Attached are some pictures of the events).



Activities done by the pharmacovigilance center

Acknowledgment sent to health providers through email

The Ethiopian pharmacovigilance center has started providing acknowledgment letters to health care providers using the email address they are writing in the report form. This means of feedback was introduced in addition to sending the acknowledgment letters hard copy to the reporters through their postal address. This new system has helped to ensure that healthcare providers receive their motivational letters on time. More than 40 ADE reporters have received their letters through the new system in this quarter. The center would like to encourage the ADE reporters to send their email addresses correctly so that they could receive their acknowledgments by email.

Summary of ADE reports that were sent to FMHACA during the half year of 2007 E.C

The total number of ADEs reported received by the **FMHACA pharmacovigilance center** during the first half year of 2007 E.C. were 197 of which 159 are reports on adverse drug reactions (ADR) caused by medicines, 30 are reports on product quality defect problems, and 8 are on treatment failure. Out of the ADRs 13 are periodic safety update reports sent from various medicine importers in the country. Most of the ADR reports {62, 52.5% } were on females and age group that most cases {49, 41.5%} were reported was (16-30). Most of the reports on ADRs were on medicines for treatment, 4 reports on vaccines, 4 reports on diagnostic kits and one report on X-ray film. The majority (68, 44.1%) of medicines that were suspected to cause the reactions by the reporters were Antibacterials followed by Antiretrovirals (29, 18.8%). Various types of dermatological reactions including various types of rash, swelling, redness of the skin, itching and Steven Johnson's problem (2 cases) were observed in the majority of the cases (72, 33.3%). Peripheral Neuropathy (burning sensations...) were the second most reported reactions (38, 17.6%). 30 product quality problems were sent 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. Incomplete pack, false positive and negative results after the use of test kits, presence of visible floating particulate matter in a solution, color change and crumbling were among the most reported quality defects. Most of the adverse drug event reports (117, 59.4%) were sent from hospitals, (five from private) and (41, 20.8%) were sent from health centers, (26, 13.2%) reports were sent from clinical trial sites and the rest (13, 6.7%) reports were obtained from importers. The majority of the reports (89, 56.3%) were reported by pharmacists followed by druggists (22, 14%), physicians (15, 9.5%), Health officers (4, 2.5%), nurses (11, 7%) and lab technologists (2, 1.3%). Amhara region health providers sent (68, 45%) of these reports, Addis Ababa (53, 35%), SNNPR (7, 4.6%), Oromia (10, 6.6%), and Tigray (13, 8.6%).

Drug safety updates International

Combined hormonal contraceptives

Difference in risk of thromboembolism between products and the importance of individual risk factors

Egypt. Egyptian Pharmaceutical Vigilance Center (EPVC) has informed about the differences in risk of thromboembolism between products and the importance of individual risk factors with combined hormonal contraceptives (CHCs). EPVC has recommended:

- When prescribing CHCs, careful consideration should be given to the individual woman's current risk factors, particularly those for venous thromboembolism (VTE), and the difference in risk of VTE between products.
- A woman who has been using her combined contraceptive without any problems does not need to stop using it.
- The importance of an individual woman's risk factors should be emphasized and the risk factors need to be regularly reassessed.
- Signs and symptoms of VTE and arterial thromboembolism (ATE) should be described to women when a CHC is prescribed.
- The possibility of a CHC associated thromboembolism should be considered when a woman presents with the symptoms.

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Drug safety updates-local

In this period regulatory measures were taken o by FMHACA on the following products.

1.Ringer lactate iv solution 1000ml

Manufacturer -Pharmacure private limited company, **Batch number** 170441,**manuf. date** April 2014,**exp. Date** October 2016.**Batch number** A040342

Product quality defect reported-Floating particles

Regulatory measure taken-The market authorization holder was informed by letter to collect the mentioned batches from the market ,investigate on the root cause of the problem and provide an action plan for a solution.

2.Alcohol denatured 70% of 1 liter. Manufacturer-Fine chemicals general trading, **Batch number** 016157,7 **manuf. date** 7 Aug 2014,**exp. Date** 6 Aug 2016 ,**Batch number** 012106 **manuf. date** 12 dec 2014 **exp. date** dec 2016.

Product quality defect reported-permanent staining of color.

Regulatory measure taken-The market authorization holder was informed by a letter to stop production temporarily, to investigate on the root cause of the problem and provide an action plan for solution and to collect all the mentioned batch products from the market



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