



# Pharmacovigilance newsletter

## Importance of Active surveillance and Cohort Event monitoring on ARV medicines in Ethiopia

The cornerstone of any pharmacovigilance system is Spontaneous reporting system which is a passive surveillance system that uses voluntary reporting of an adverse drug reaction by a health professional or a patient with the main objective being able to provide signals with marketed drugs. This passive surveillance system has got various limitations in identifying and assessing drug related injuries. Some of this are; lack of denominator making it impossible to calculate rates and also assess risk factors, Only suspected reactions are reported and death is usually not reported, there is a huge Under-reporting [A meta-analysis showed that the median under-reporting rate for all adverse drug reactions ADRs was 95% (i.e. 5 % of all ADRs are reported) and 80% for serious ADRs (20% reported)].

For this purpose various countries are employing other additional active surveillance methods that could compliment the drug safety information obtained from the passive surveillance system to obtain a high quality data and result into proper decision making. One of these efficient methods is Cohort Event Monitoring (CEM) which is a time-limited, targeted programme and a prospective, observational, study of adverse events associated with one or more monitored medicines. It is advantageous over others in that early detection of signals of unsuspected ADRs is possible, denominator information allows incidence rates of ADRs to be calculated, risks and risk factors could be assessed; comparisons between drug, Pregnancy outcomes and deaths are obtained.

Ethiopia is one of the countries with a high prevalence of HIV/AIDS in sub-Saharan Africa. This safety of the ARV medicines follow up has been carried out in the country by the National pharmacovigilance centre at FMHACA using a passive surveillance spontaneous reporting system . According to a summary of this spontaneous reports from 2001-2003 E.C, (205, 77%) of the adverse drug events were caused by drugs of antiretroviral therapy followed by Antitubercular drugs (37,14%). The most observed reactions as reported by the health providers were; Lipodystrophy (65, 32%), Various skin reactions (41, 20%), Anemia (31, 15%), Peripheral Neuropathy (27, 13%) .Also current reports showed similar patterns for the years 2005-2007 E.C with specific drug reactions of Tenofovir (renal tubulopathy) and ZDV based fixed dose combination .

The primary data obtained through this system needs to be strengthened by an active follow up in the form of Cohort Event monitoring (CEM) and the obtained data translated for the better and safer use of the ART drugs by the public. Hence for this purpose the Ethiopian Food, Medicine and Health care Administration and Control Authority (FMHACA) has planned to carry out Cohort Event monitoring (CEM) on antiretroviral drugs in collaboration with Stakeholders and partners and has undergone various preparatory steps for the successful implementation of the active safety surveillance on ARV medicines.

Volume 6 Issue 3

September 2016

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

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Inside Story

# Activities at the pharmacovigilance center

## Face to face training on pharmacovigilance at five health centers of Addis Ababa

In service training on pharmacovigilance was given to 154 participants of 5 health centers i.e ; Wereda 3 Health center (HC) , Kolfe HC, kotebe HC, yeka HC, wereda 7 health center) in Addis Ababa from August 11-25/2016.

Participants were trained on medicine related adverse drug events, adverse drug reaction, medication error, product quality defects, limitation of premarketing safety evaluations, the importance of pharmacovigilance, important terminologies in adverse drug event monitoring/ADE , Mandates , responsibilities, principles and tools of the national pharmacovigilance system, procedures of ADE processing, the contents of the national ADE reporting form, the role of Drug and therapeutic committee on assessing and managing drug safety, Prevention of an ADE, the types of adverse events to be reported, when to report an ADE, the three types of reporting mechanisms (*the yellow form hard copy which is available at each health facility to be filled and sent to the post office to reach EFMHACA, the different telephones including the toll free line 8482, the internet based online reporting system*), when to report, to whom to report and what happens after an ADE is reported to the pharmacovigi-

lance center at EFMHACA.

The national ADE reporting form, different editions of the quarterly prepared pharmacovigilance newsletters and an allergy card to be given to patients who have experienced an allergy were distributed during the discussions to be used after the training.

The medical directors of the facilities welcomed the EFMHACA pharmacovigilance team and USAID/ SIAPS for the effort shown to create awareness of drug safety monitoring to healthcare providers by the regulatory authority and informed the importance of the training to the participants before the trainings begun .They also reminded them to implement the knowledge provided during the training by reporting an encountered ADE and also to share the knowledge obtained at the events to their colleagues who were not able to attend the programme.

At the end of each session, all the health facilities selected ADE focal persons for the sustainability of the monitoring programme and also to serve as a liaison for collaboration between EFMHACA and the facilities. (*Some Pictures attached below*)



# Activities at the pharmacovigilance center

## Training of Implementers of the Cohort Event Monitoring and discussion on the progress of the pretest of the tools

A training was given to the implementers of the Cohort event monitoring that is designed to be carried out by the EFMHACA on ARV medicines at Adama from September 20-21/2016. The training was given to the team composed from each of the 20 health facilities (11 hospitals and 9 health centers) representing the ARV dispensary, ARV clinic, pediatrics ARV clinic and PMTCT who will be involved in the collection of ADE data at their facilities. The training was provided with the aim of achieving two objectives the first one being the awareness creation of the health providers about the manual that is prepared to execute the CEM activity. The second objective was to discuss on the challenges encountered during the pretesting of the tools of the CEM for those facilities who have started the process.

During the two days event, participants were presented with Introduction to pharmacovigilance, ART and Assessment, Identification and management of their Adverse drug reactions, Objectives of the CEM, the Implementation manual and tools for the CEM. Participants were then grouped and discussed on general issues regarding the implementation, the challenges they faced during the pretesting of the different questionnaires, the consent forms and other challenges that are spe-

cific to their facilities.

The training was then concluded by a discussion on possible solutions and recommendations obtained from the participants themselves and some major challenges were advised to be solved by the EFMHACA.



## Summary of ADE reports from each region in the year 2008 E.C

In the year 2008 E.C, out of the total 683 Adverse drug event/ADE reports sent to the pharmacovigilance center at FMHACA, Addis Ababa region health providers sent (563, 82.4%) of which 304 reports were periodic safety update reports (PSUR) of market authorization holders and 130 were from clinical trials. Amhara region sent (86, 12.6%) ADE reports, Oromia (12, 1.8%), SNNPR (12, 1.8%), Tigray (6, 0.8%), Afar (3, 0.4%) and Harari

region sent (1, 0.2%) ADE report.

Most (317, 46.4%) of the adverse drug events reports obtained this year were sent from medicine importers who have sent both periodic safety update reports and individual case reports. (247, 36.2%) of the reports were received from hospitals whereas health centers have sent (111, 16.3%) of the ADE reports. In this year, a private pharmacy from Amhara region ( Dessie ) has also sent 6

ADE reports and 2 of the reports were obtained from the branches of FMHACA. Categorization by profession shows that the majority of the reports {N=212, (127, 60 %)} were reported by pharmacists (46 reports were by clinical pharmacists). The rest reports were sent by druggists (39, 18.4%), physicians (30, 14.1%), health officers (11, 5%), nurses (4, 1.8%) and one report was sent by a lab technologist.

## Drug safety updates , International-

### Fluconazole

#### Risk of miscarriage in pregnancy: under investigation

**USA.** The US FDA is investigating results from a Danish study which suggests that there is an increased risk of miscarriage with the use of oral fluconazole (Diflucan®) during pregnancy.

Oral fluconazole is used to treat yeast infections of the vaginal area, mouth and esophagus.

It is also used to treat *Cryptococcal*/meningitis and is often used prophylactically in immunocompromised patients.

The FDA advises cautious prescribing of oral fluconazole in pregnancy, until the FDA reviews this study and other available data. **Reference:** WHO Pharmaceuticals Newsletter No.3 2016.14



## Drug safety updates- National

During this quarter the following regulatory measures were taken on medicines that an adverse drug event was reported from healthcare providers at health facilities to the pharmacovigilance center .Further investigations and laboratory analysis were carried out by the pharmacovigilance team, facility inspection and quality control directorates and frequent follow up of the process at the pharmacovigilance forum.

**1.Description of the product:** Methyl prednisolone acetate sterile BP 40mg aqueous suspension. Batch number 5EB01068 , Manufacture date 5/2015 ,Expiry date 1/2017.**Manufacturer** : Ciron Drugs and pharmaceuticals Pvt. Ltd ,India

**2.Description of the product:** Multivitamin syrup 100ml Batch number 5139966,Manufacture date 9/2014, Expiry date 9/2017 .**Manufacturer** : Purna Pharmaceuticals NV, Belgium

**Reason for measure:** Both these medicines did not meet the quality standards as observed by the results of laboratory tests done.

**Regulatory measures taken** : Official letter was written to all stakeholders involved to recall the products from the market and report frequently to EFMHACA.

**3.Description of the product** :Ringer lactate solution IV infusion 1000ml. Batch number B200341 Manufacture date 3/2014, Expiry date 9/2016..**Manufacturer** ,PHARMACURE plc Ethiopia.

**Reason for measure:** The iv solution didn't meet the quality standards it is supposed to have.

**Regulatory measure taken** :Official letter was written to the distributor of the iv fluid ( Pharmaceuticals Fund and Supply Agency ) to recall the products from the facilities where it has distributed to and report the recall process at a certain frequency to EFMHACA.



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