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Health centers of Yeka sub city, Addis Ababa

Awareness creation trainings were provided to 123 health care providers of 4 health centers of Yeka sub city ,Addis Ababa on pharmacovigilance .The trainings were provided to the participants of Aware Health Center (HC), Ankorcha HC, Korea Zemachoch HC, Wereda 11 HC from November 12/2015 until December 24/2015 .

A Presentation that contains topics on the limitations of premarketing evaluations ,the importance of pharmacovigilance, the national pharmacovigilance system mandates and responsibilities, the three types of ADE reporting mechanisms, medication error and prevention mechanisms and the role of Drug and Therapeutic Committee in assessing and managing drug safety was discussed with the participants and they responded with questions and comments on the system. During the sessions the tools used in drug safety monitoring ,i.e; ADE report form, allergy card, and the quarterly newsletters were distributed for the participants to be used. At the end of each session a focal person for the facility was chosen and was given the responsibilities of facilitating the ADE monitoring at the facility. During this sessions refreshments were provided by USADI/SIAPS for the participants.

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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Activities at the pharmacovigilance center

Workshop on the enrichment of the manual for the CEM on Antiretrovirals

FMHACA in collaboration with Global fund and USAID/SIAPS has carried out a workshop that was aimed at enriching the manual prepared to implement the active surveillance planned to be carried out on adverse drug reactions of Antiretrovirals in the form of Cohort Event Monitoring (CEM). The workshop was carried out from December 31,2015-January 1,2016 at Adama Dire international hotel and it was officially opened by Ato Abdulkadir Wolyei (Director of Medicine registration and licensing) who thanked the participants for their attendance and requested for their full commitment on this vital step towards the success of the CEM.

The participants were 31 task force members who are representatives of stakeholders i. e ; Federal ministry of Health, FHAPCO, regional health bureaus, teaching institutions, health facilities, professional associations, pharmaceutical Importers, adherence supporters, FMHACA (facility Inspection directorate , product registration and licensing directorate and quality control directorate).

The objective of the workshop was to enrich the implementation manual , the various tools necessary to carry out the CEM and to review and comment on the Terms of reference (TOR) prepared for the task force to provide technical support for FMHACA towards the execution of the CEM .

Two presentations were done on the Importance of drug safety monitoring and Objectives of the CEM, the Implementation manual , tools for the CEM and the TOR .Task force members were then divided into two groups with a proper balance from each stakeholder for each group and they were provided with the documents of the manual and the TOR. They then discussed thoroughly and provided their comments and suggestions and this was strengthened more by general discussions carried out during the group presentations.

Finally the workshop was closed by Ato Abdulkadir who acknowledged the efforts observed during the workshop and reminded the participants that they are to be part of this great endeavor which is aimed towards the active monitoring of the adverse drug events that the users of Antiretrovirals are facing day to day.

Activities at the Pharmacovigilance center

Product quality defects that were reported in the first 6 months of the year 2008 E.C

A total of 18 reports were received at the pharmacovigilance center during the first 6 months of the current fiscal year on product quality defects. The reports were sent by health providers from allover the country.

The reported defects were described as providing false result, labeled as NPH suspension but has a clear appearance like regular insulin and has also some tiny particle dispersed over all the clear solution, Taking more than 5 minutes to provide the result by the laboratory diagnostic kit (the specification says 5 minutes) ,Incomplete pack, a missed tablet in the blister, Product sealed without the catheter, Insoluble crystals suspend in the solution and after shaking settling immediately ,caking, Two products packed together, Capsule leakage, Contamination, Powdering, Color change, poor packaging, Broken tablets (3 tablets were broken out of 10 tabs of the strip), Difficulty to open the lid of the bottle and once it is opened it is not closed. List of the products and their identifying information are as follows.

1.Alkaline phosphate liquicolor(DEA buffer,DGKC Humazym test)
2.Insulin suspension (Justine N, 100u/m, batch number 0004)
3.HCG Urine test of 50 strips (Wondfo. batch number W001403162)
4. Paracetamol 500mg strip of 10 tablets. (Paramol, batch number 15882)
5. Foley catheter, (batch number 14B22. Size 16FR. Neutral code no 661 CB (H). 30-50 ml.)
6. Pentavalent vaccine {(Dtp, Teta, Pertu, HB, Haem b) batch no 30139E14.Exp date march 2016.Manufacturer Biological E. ltd india.}
7. Diclofenac { Adiflam -50mg of 10 tabs. batch number T-2902HFG.India,Leben laboratories ltd Indomethacin {INDOCAD 25mg of 10 tabs. batch number D14023BX60,Cadilla Ethiopia}
8.Paracetamol 120mg/5ml po syrup { batch number 14020116 and chloroquine phosphate 50 mg/5ml syrup 14001611.Fawes pharmaceuticals .Addis Ababa}
9.Amoxicillin {Amoxi 500mg,50x10, Epharm ,batch number 5020231}
10.Doxycycline 100mg caps {(Lentecline) .batch number MS5GO33E}
11.Ciprofloxacin 500mg .{Ciprodac 500,batch number D14003BY38,Cadillapharmaceuticals }
12.Chloroquine phosphate 50mg/5ml syrup, {batch number 14200116,MFD 9/14.Exp Date 9/16.Manufacturer Fawes Pharmaceuticals}
13.Paracetamol 120mg/5ml {Batch number 14001811.Exp date 01/16} and Dextromethorphan 15mg/5ml syrup. {batch number 14012912.Exp date 4/16 Both from Fawes pharmaceuticals.}
14.Ringerlactate solution 100ml,batch no {B120241,Manufactured by Pharmacure}
15.Amoxicillin 500mg caps, {Manufactured by Addis Pharmaceutical Factory, batch number 17075}
16.Cloxacillin 500mg.{Manufactured by APF, batch number 14441}
17. Ciprofloxacin 0.5% eye drop. {Ciprocin, Batch number 1410985. 332400LBL000004}
18. Chloramphenicol sodium succinate Bp 1gm injection powder.50 vials per package. {Manufactured by Karnataka antibiotics and pharmaceuticals ltd.india. Batch number 4202812.}

Drug safety updates international

In this quarter the pharmacovigilance center has received the following two important information from international sources (Eritrea) and have used them to initiate an investigation of the status of the products in our country.

1.Two WHO-Prequalified Anti TB products manufactured by Svizera, Labs, India and Lupin Ltd, India have failed the quality test as the level of Hydrazone impurity is out of specification. The products are-

A. Rifampicin 150mg/Isoniazid 75mg/Ethambutol 275mg – Tablet, Lot: SL139 and

B. Rifampicin 150mg/Isoniazid 75mg/Pyrazinamide 400mg/Ethambutol 275mg - Tablets, Lot A500071.

The QC Lab strictly advised that the products are "Unfit for Human Use" and may cause serious health problems if used. Based on the seriousness of the defect, the National Medicines & Food Administration has decided to recall the two products from the Eritrean market.

2. The National Medicines and Food Administration/MOH of Eritrea has received a number of quality defect complaint on the currently available lots of malaria RDTs {***Product-Malaria Ag P.f/ P.v (Rapid Diagnostic Test) .Manufacturer-Standard Diagnostics (SD) BIOLINE, S. Korea, Defective lots-All lots currently available in Eritrea (145136-145142; 145145-145147;05DD14007-05DD14011;05DD14013,05DD14014); Catalogue No.05FK80,Exp date Jan.2016,June 2016,Presentation -25 tests/kit }*** and several steps have been undertaken to investigate the problem at internal and external levels. Internal assessments done in comparison with B/F Microscopy positive have shown false negative results even for high parasite density. An opportunity was also given to the Manufacturer (SD BIOLINE, Korea) to investigate the quality complaints by conducting on site self assessment using its retained samples. Like wise all cases tested by the SD retained RDTs for B/F Microscopy positive showed false negative results. Based on this findings and the possible seriousness of the defect the NMFA has decided to institute a product recall and has advised PHARMECOR ERITREA to issue a recall letter to all recipients ,to quarantine the available stock, to receive and quarantine stock retrieved and to submit report which includes reconciliation and communication with the manufacturer. Source ***WHO Pharmacovigilance Programme - Africa***

Drug safety update local

During this quarter The following regulatory measure was taken

Products description-Ringer lactate iv solution 1000ml,batch number 120241 manufactory date 2 /2014 and Expiry date 8/2016. Name of Manufacturer Pharmacure.

Product defect reported-Visible particulate matter inside the iv fluid

Regulatory measure taken-The manufacturer was informed to collect the products from the market and report on the amount collected and its process weekly to the regulatory authority.

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