FOOD MEDICINE AND HEALTH CARE ADMINISTRATION AND CONTROL AUTHORITY OF ETHIOPIA

Pharmacovigilance Newsletter

Face to face training on pharmacovigilance at six health centers of Yeka sub city

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Training was given to six health centers of yeka sub city on pharmacovigilance from January 22 to the end of March 2016. Wereda 8/Chefe Health center (HC), Wereda 12 HC, Entoto no 2 HC, and Ferensay Akababi HC.

A total of 176 health providers were trained 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 its prevention mechanisms and the role of Drug and Therapeutic Committee in assessing and managing drug safety.

ADE reporting form, newsletters and an allergy card was distributed during the discussions to be used during and after the training.

Detail explanation of what to report ,how to report ,when to report and to whom to report an adverse event was discussed with the participants. Different varieties of challenges encountered in reporting were raised and discussed by the participants.

Each facility assigned a focal person after the trainings for further follow up and strengthen the relation ship between the facility and the pharmacovigilance center in the country.

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

Inside this issue:

Activities at the pharmacovigilance center

Training of Implementers of the Cohort Event Monitoring on Antiretroviral drugs that is planned to be carried out at Addis Ababa

A two days training was provided to the implementers of the Cohort Event Monitoring/CEM on Antiretrovirals that is planned to be carried out in Addis Ababa. The training was given to participants that were derived from the 20 health facilities in the city that were selected to be the sites for the CEM. From each facility ,three health providers who are directly involved in the service delivery and can carry out the CEM (ART prescriber, ART dispenser and medical director/ART focal person were provided the training from February 25-26/2016 at Dire international hotel Adama. The objective of the event was to train the participants on the manual for implementation and the different tools(6 questionnaires, consent forms and CEM participant ID card) so that they could use the tools when the CEM gets carried out at their facilities.

The training was opened officially by Ato Abdulkadir Welyei ,former Director, Medicine Registration and Licensing Directorate on behalf of the Regulatory Authority who welcomed the participants ,thanked them for their full attendance and requested for their full commitment towards understanding the manual and the tools for implementation.

Presentations were given on the introduction to pharmacovigilance ;ART and Assessment ,Identification and management of their Adverse drug reactions ;objective of the CEM, the implementation manual and tools for the CEM. Participants were then grouped into three to discuss on the tools of the CEM and to provide their comments for the better outcome of the cohort. Then they presented their findings and provided their comments and suggestions to the general audience by their group secretaries .

The workshop was finally closed by Ato Abdulkadir who thanked the participants and informed them that those comments and suggestions provided would be considered .He also reminded the participants that they would be the focal persons and implementers of the CEM which is planned to be carried out at each of the 20 facilities and hoped for major collaborative action for a good result in the cohort.

Do you know what Medication error is?

It is "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use." (US NCCMERP).

Do you know what Product quality defect is ? It is– a quality problem of products with suspected contamination, questionable stability, defective components, poor packaging and labeling and therapeutic failure.

Activities at the pharmacovigilance center

Number of Adverse drug Events that were reported to the pharmacovigilance center from December 2015-February 2016.

	Name of health facility	Number
1.	Debretabor hospital	1
2.	Beata HC	1
3.	Kolfe keranio HC	3
4.	Mekaneselam hospital	4
5.	Debre markos hospital	6
6.	Meshualekia HC	1
7.	Kazanchis HC	1
8.	Debrebirhan hospital	5
9.	Nekemte referral hospital	6
10.	DSMB	8
11	Pfizer	4
12	Glenmark	6
13	Novonordisk	1
14	Sanofi	2
15	Novartis	11
16	Astrazeneca	3
17	Sandoz	6
18	GSK	10
19	Alcon	4
20	MSD	1
	Total	74

21	Motta referral hospital	2
22	Dessie tossa pharmacy	1
23	Wereda 8 HC	1
24	Tazma cardiac center	15
25	Akaki HC	1
26	Kolfe keranio HC	2
27	Hawassa FMHACA	1
28	Enat hospital	1
29	Abebe bikila HC	4
30	Hawasa University hospital	1
31	Debremarkos HC	2
32	Kirkos HC	1
33	St Paul hospital	1
34	Gonder university hospital	8
35	Menagesha HC	1
36	Bole 17 HC	13
37	Finoteselam hospital	1
38	Hidar 11 hospital	1
39	Carter center	8
40	Shegole HC	1
	Total	76
	Overall total 74+76 =	**150**

As it can be observed from the above tables a total of 150 ADE reports were sent to the pharmacovigilance center at FMHACA. Out of this reports 56 were received from Market Authorization Holders in the form of Periodic Safety Update reports (PSUR). It is understandable that for a comprehensive monitoring of drug safety it is necessary that all the partners(health providers at public /private health facilities, Pharmaceutical manufacturers, Importers and distributors ,professional associations, consumer associations, health teaching institutions and the general public need to be involved in the reporting and monitoring of drug safety problems. They need to report on adverse drug event (adverse drug reactions, medication errors and product quality defects)that they observe in their day to day practice .

To report and ADE all the partners can use the yellow page prepaid reporting form which is available at all health facilities and regional branches of EFMHACA and send it via post mail, the various telephones of EFMHACA {0115524122,0115523205, 8482 (free toll)}, and the online reporting tool that is newly prepared and is deployed at the website of EFMHACA ; www.fmhaca.gov.et .All partners can enter through the gates at the end of the left hand corner of the home page of the website where features for reporting Adverse drug reaction, medication error and product quality defect are available. All ADE reporters have to register first to have a user name and password which they can use always to enter and post a new report or update an old one.

Drug safety updates international

Dipeptidyl peptidase-4 (DPP-4) Inhibitors

Risk of severe joint pain

Egypt. Egyptian Pharmaceutical Vigilance Center (EPVC) recommends the addition of a warning label to products containing dipeptidyl peptidase-4 (DPP-4) inhibitors, to include Joint Pain (Arthralgia).

DPP-4 inhibitors (e.g. sitagliptin, saxagliptin, linagliptin, and alogliptin) combined with diet and exercise are used to lower blood sugar in adults with type 2 diabetes. These medicines are available as single-ingredient products and in combination with other diabetes medicines such as metformin.

This recommendation was based on the US FDA warning of severe and disabling joint pain associated with the use of DPP-4 inhibitors.

Reference:

Newsletter, EPVC, Volume 6, Issue 11, November 2015 *(See WHO Pharmaceuticals Newsletter No.5, 2015: DPP -4 inhibitors for Type 2 diabetes may cause severe joint pain in the United States of America)*

Drug safety update local

During this quarter The following regulatory measures were taken on the following products as a result of reports sent by healthcare providers from health facilities.

1.Hydrogen peroxide 3% -batch number 075022,Expiry date 20/10/2016,batch number 072271,Expiry date 10/11/2017

Product quality defect reported

Poor quality and lesser volume than the standard.

Manufacturer-

Fine chemicals general trading

Regulatory measure taken-

Products was tested in the quality control laboratory of the EFMHACA and it failed the tests. So the manufacturer was informed to stop production and to recall the products from the market and report about the quantity recalled.

2.Iodine tincture-

Product quality defect reported

Intolerable burning sensation on the skin

Manufacturer-

Fine chemicals general trading

Regulatory measure taken-

The manufacturer was informed to refrain from distributing those products that are available in the store and to investigate on the root cause of the problem .

3.Paracetamol syrup125md/5ml

Product quality defect reported

The cup on the bottle is difficult to open and once it is opened it doesn't close properly

Manufacturer-

Fawes Pharmaceuticals

Regulatory measure taken-

To correct the frequently reported defect and report to the authority.

4. Chloroquine phosphate and paracetamol syrup

Product quality defect reported

Color and size of the labeling material of both products is similar which can lead to error both during production and dispensing.

Manufacturer

Fawes Pharmaceuticals

Regulatory measure taken

The manufacturer was informed to change and differentiate the size and color of the labeling of the two products.

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