Food Medicine and Health Care Administration and Control Authority

Pharmacovigilance Newsletter

Advice from our VIGILANT healthcare providers!

Volume 3 Issue 3

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As it is our custom, to publish advice from health providers who are VIGILANT in the monitor ing of drug safety, we have chosen for you in this issue ardent reporters of ADE from Amhara region ,Alem Ketema Enat hospital. Let us hear their personal comments on pharmacovigilance—

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Medications are given to treat a specific disease and as they do so they can result in unwanted effects, one of which is adverse drug reaction. These reactions manifest in different forms. It is the duty of the health professionals to identify and report such events to the responsible body so that the proper measures are taken accordingly. In my experience, most of these events occur in patients who are allergic to a specific group of medication and the patient is not aware of it. It is not a common practice in our health care provision to ask and identify if our patient has an allergy to a medication which leads to facing unnecessary drug reactions. If we do so, we will for sure decrease the event of adverse drug reactions by a substantial amount.

Pre- marketing evaluation of drugs, with its limitations cannot guarantee absolute safety of drugs!

Gizew Dessie (ADE focal person) gizew dessie@gmail.com . Our Drug and Therapeutic Committee (DTC) believes that ADE Report is great input for FMHACA to take regulatory measures in order to safe guard our community. Understanding the magnitude of the problem our DTC assigned a focal person who mobilizes all the clinical staffs in early identifying, reporting and documenting every ADE as a routine activity, ensures reporting formats are available in all clinical areas and all heath care providers are familiar with the form and how to complete it.

With such continuous activities it is possible to detect adverse drug events which were not observed in the clinical trials, to identify counterfeit or substandard medications that entered to the market and to take all the necessary actions before more harmful effects happen on the health of the people.

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Reporting ADR to FMHACA is a Little deed but a great contribution to save the community. In addition to reporting, we health care providers prevent ADE by taking allergy history of patients, by preventing medication errors, by providing allergy card and so on…

This news letter is prepared quarterly by the **FOOD, MEDICINE AND HEALTHCARE ADMINISTRATION AND CONTROL AUTHORITY** with the objective of providing information to **HEALTHCARE PROVIDERS WORKING AT BOTH THE PUBLIC AND PRIVATE HEALTH SECTORS** on drug safety and activities that are carried out by the **NATIONAL PHARMACOVIGILANCE CENTER.**

Visit us at www.fmhaca.gov.et

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Activities performed by the Pharmacovigilance center

Face to Face discussion on pharmacovigilance at health facilities

Awareness creation programmes in the form of face to face discussions were carried out on drug safety monitoring/ pharmacovigilance at various facilities in Addis Ababa by FMHACA the technical and financial support from USAID/SIAPS .

Discussions were carried out with the health providers of Beata, Janmeda, Ras Emiru, Afinchober Meri and Goro health centers on October 2 and 31 ,November 19 and 27, December 18 and 24, 2013 respectively in the meeting halls of the facilities during the afternoons . The programmes were organized and executed together with the Arada and Bole sub city Health bureau's pharmacy heads.

During the events distribution of the ADE report form, allergy cards, the national pharmacovigilance framework and 3 issues of the pharmacovigilance newsletters was carried out.

Discussions were mainly initiated by asking questions like

Do you know what an Adverse Drug Event is?

-Do you think they are problem enough to be monitored?

-Have you ever encountered an ADE in your day to day practice? If so What did you do about it?

-Have you ever heard of the national pharmacovigilance system, what it does and its tools?

-Have you ever reported an ADE, If so, what were your challenges in ADE reporting?

-Do you know about the PV newsletters?

-Do you have a DTC in your facility?

-What does it do in assessing and managing drug safety?

After a common understanding of the need to monitor ADEs, the participants and their medical directors thanked the organizers for their effort and promised to be involved in the activities .They then chose a focal person to facilitate and follow upon the safety monitoring in collaboration with FMHACA. Following are pictures of the discussions at Ras Emiru ,Janmeda ,Afinchober ,Meri and Goro Health centers respectively.

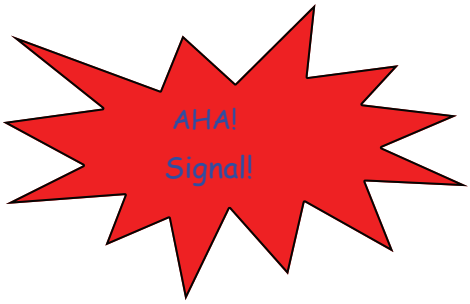
Important terminologies in pharmacovigilance

What is a Signal?

The WHO has defined a signal as

"Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously" An additional note says, usually more than one report is required to generate a signal, depending on the seriousness of the event and the quality of the information.

A signal is therefor a hypothesis together with data and argument. A signal is not only uncertain but also preliminary in nature; the situation may change overtime one way or another. A signal may also be more documentation which further qualifies a simple association of a drug product with an ADR, for examples information on the range of severity of reactions, its outcome; postulating a mechanism; indicating an "at risk" group; a dose range which might be more suspect; or suggesting a pharmaceutical group effect; or indeed a lack of such effect by a particular drug.



Product quality reports received by FMHACA from 11/05-4/06 E.C

Name of the drug	Drug identifying information	Region where the report was sent from	Quality problem observed and reported
1.OMECAP 20mg caps ,blister COTRI 240mg/5ml susp 100ml bot	BN 12295 BN11751	Addis Ababa	Incomplete pack , Incomplete pack and caking
2. Rifampicin/Isoniazid 150mg/75mg	DA995L .Reg No KR/drugs/ KTK/ 28A/472/2001.Exp date12/2014	South Nations Nationalities and Peoples Republic(SNNPR)	Color change and cracking
3.Ringer lactate solution 1000ml	BN A301021, Pharmacure	**Amhara** ***(Action taken and communicated)***	Formation of highly visible particulate matter, color changed to cloudy
4. Ringer lactate I,V infusion 1000ml,USP isotonic solution,	BN B301021 Pharmacure	Addis Ababa	Coagulation and big suspended particles
5. RHZE 150/75/400/275mg	BN EFA129A, EFA214A, EF17A	SNNPR	Change in color
6. RHZE 150/75/400/275mg	BN EFA214A (Macleods)	Addis Ababa	Tablets cracking
7. Tenolam (Tenofovir and lamivudine) 300mg,300mg	BN E120573 Macleods pharmaceuticals	Addis Ababa	Taste difficult bitter severe, nausea vomiting, burning sensation .Tablet cracking 5 cases
8. Tetracycline eye ointment	BN AF11059 Gelantic pharmaceutical, India	Amhara region	Color changed to blue ointment
9. Amoxacillin oral suspension 125mg/ml	BN 1269069 Brand name Medomox	Amhara	Caking of the powder
10. Ringer lactate I, V infusion 1000ml USP isotonic solution.	BN A181022, Pharmacure	Amhara	Color change, debris and contamination of microorganism
11. Multivitamin syrup balanced formula of 120ml	BN 890B,Mfg date 01/2011,Exp date 01/2014 Brand name Mixavit	Addis Ababa	Leakage from the bottle which resulted in a dried brown sugar on the bottle cap and also on container.
12.Phenobarbitone 30mg tab	BN 0120063	Amhara	Cracking and crumbling
13. AVIRANZ 200mg of 90 caps	Reg No 04-6996 BN 2438102	Oromia	Crumbling of capsules,
14.d Best one step HBS Ag test strip pk of 25	BN 201210088,Mf date 10/11/12,Exp date 13/15. Subsidiary plant Ameritech diagnostic reagent co .development zone, Tongxiang, China.Seattle Washington, USA. info@ Ameritech.org	Addis Ababa	Result giving false positive

Drug safety advice– International

Rituximab screening for Hepatitis B Virus before treatment

Screening for Hepatitis B Virus is now recommended in all patients (not only those at risk of this infection) before starting treatment for all indications. A patient with positive serology test for Hepatitis B virus should be referred to a specialist in liver disease before starting treatment with rituximab. During treatment this patients should be monitored and managed to prevent reactivation of the virus.

Rituximab (MabThera) is a treatment for adults with Non Hodgkin's lymphoma; chronic lymphocytic leukaemia; rhuematod arthritis; or granulomatosis with polyangiitis and microscopic polyangiitis. A recent review of all available data has shown that rituximab has been associated with reactivation of hepatitis B virus when used in the indication of cancer and rheumatoid arthritis .This cases included fulminant hepatitis some of which were fatal.

Analysis has shown that rituximab is associated with reactivation of this virus in patient with positive HB surface antigen ,and in those with negative HB surface antigen positive HB core antibody- particularly when given in combination with steroids or chemotherapy.

Advice given for health professionals:

- Screening for Hepatitis B Virus is now recommended in all patients (not only those at risk of this infection)before starting treatment for all indications.
- Patient with active hepatitis B disease shouldn't be treated with Rituximab.
- A patient with positive serology test for Hepatitis B virus should be referred to a specialist in liver disease before starting treatment with rituximab. During treatment this patients should be monitored and managed to prevent reactivation of the virus.

Source ;*Drug safety update December 2013 volume 7,Issue 5:A1.*

Web: www.fmhaca.gov.et.

Drug safety updates-Local

During this quarter ,regulatory decision has been taken on the following drug.

Drug name: Ringer lactate Iv. solution 1000ml

Batch No:301021

Manufactory date ;10/2012.

Expiry date: 4/2015

Manufacturer: Pharmacure plc.

Product defect observed and reported by health providers:

Visible floating particulate matter in the solution.

Action taken; An official letter was written to the manufacturer on 29/2/06 E.C to collect the mentioned batch of the product that the defect was observed from the market or distributed health facilities and to report to the regulatory authority. The letter was copied to the Food and medicine registration and licensing directorate to follow up on the manufacturing process of the manufacturer.