

# PHARMACOVIGILANCE NEWSLETTER

Volume 1 Issue 2

June,2011



## Beletshachew Health center

According to a recent survey carried out by the Food Medicine and Health Care Authority (FMHACA) and MSH/SPS, health providers practice with Adverse drug Reaction (ADR) showed that ( 225, 56.25%) of the participants had encounter with an ADR in their practice during the last 12 months in their day today activities but out of the total of ADRs encountered only 5% was reported to FMHACA.

In order to overcome this challenge ,One important intervention is to train health providers with the right knowledge about the ADR monitoring system in the country and help them see how much their involvement in this important system means towards the betterment of the quality of health care they are giving. This knowledge and involvement would be fruitful when it is combined with a constant commitment and follow up from the management in a health facility.

One good example of this the improved awareness and participation of a Health

center by the Name Beletshachew which is found in Addis Ababa around Lideta. The Medical director of the health center Ato Solomon is so keen on providing drug safety information to the Authority and encouraged and reminded his colleagues to report that 2 health providers from the TB Clinic& Pharmacy department (Tigest Getachew &Senait Mitiku)had reported an observed Adverse Drug Reaction.

Accordingly ,FMHACA has acknowledged the reporters through an acknowledgment package and has entered the reported ADR into its data base for further analysis as well as shared the drug safety information to the world through the use of the WHO database vigibase.



## What to report, to whom to report and when to report?

**According to the National guideline all health providers in the country are required to report-**All Suspected reactions to drugs, Unknown or unexpected reactions, serious adverse drug reactions, unexpected therapeutic effects, all suspected drug interactions, product quality problems, treatment failures and medication errors.

**All suspected and observed drug related reactions are required to be reported to** Food, Medicine and Health Care Administration and Control Authority Adverse drug event Monitoring center using yellow page pre-paid form ,telephone or website.

**All suspected and observed drug related reactions are to be reported immediately** as encountered because delay in reporting will benefit neither the user nor the health provider who has spent his/her invaluable time .

### Inside this issue:

Updates on activities face to face discussions	2
Follow up on facilities	3
Allergy card distribution	3
Preparation of plan	3
Drug safety updates	4

### Special points of interest:

The aim of this newsletter is to disseminate information about the drug safety activities of FMHACA, to communicate with health providers any concern on drug safety both local and as obtained from other international drug monitoring centers.

**Ethiopian Food, Medicine and Health Care Administration and Control Authority.**

**Tel.0115523142/3205 P.o.box 5681**

**Website [www.daca.gov.et](http://www.daca.gov.et) email: [daca@ethionet.et](mailto:daca@ethionet.et)**

## Updates on activities - Face to Face discussions at facilities

The first round of face to face discussion on adverse event monitoring was carried out at 5 facilities in Addis Ababa region by the Food, Medicine and Health care Administration and Control Authority and Addis Ababa Regional Health Bureau (AARHB) with the technical support of MSH/SPS from January 25 to February 8, 2011. The facilities chosen were Ras desta hospital, Menelik II hospital, Bella referral hospital; Federal Police hospital and Gandhi Memorial hospital. Participants involved were 32 physicians (16 GP and 16 Specialists), 9 Pharmacists, 5 Druggists, 54 Nurses, 7 Health Officers, 7 GP interns and 2 HO interns making a total of 117 health providers. All the sessions and the objective of the programme was officially introduced and opened by the representative from the Addis Ababa Regional Health Bureau.



**Ras Desta Hospital**

After a 15 minute presentation on introduction to ADR and facility experience by representatives from the facility, the activity at the National drug safety monitoring center was described to the health providers. Then a WHO Film about the importance of ADR monitoring activity in Philippines was shown so that the participants could learn from other countries experience. Copy of the WHO, USAID and MSH prepared Drug and Therapeutic Committee(DTC) training course participant guide i.e Assessing and managing drug safety, and the National ADR guideline including the ADR report form obtained was distributed to assist the providers in their endeavor towards participating in managing drug safety .

The majority of the session was spent discussing and clearing on challenges and various issues. some of which were; the difference or similarity between side effects and ADRs, what, how ,when and to whom to report, availability of the reporting forms, what happens after reporting ,product quality problems and measures taken, use of herbal drugs in the country ,post marketing surveillance, counterfeit and sub-standard drugs in the market, feedback and communication between the various partners in pharmacovigilance, the importance of using DTC in the prevention of adverse drug events at facilities.

The participants appreciated the programme, forwarded their recommendation, indicated a strong commitment and elected an ADR focal person who will coordinate the overall activity from their staff.



**Gandhi Memorial Hospital**



**Menelik II Hospital**



**Bella referral Hospital**



**Federal Police Hospital**



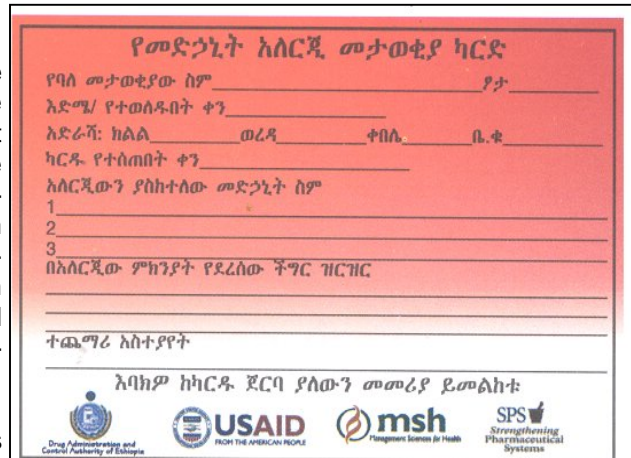
## Updates on Pharmacovigilance activities

### Follow up at facilities on activities of adverse drug monitoring was carried out on December,2010.

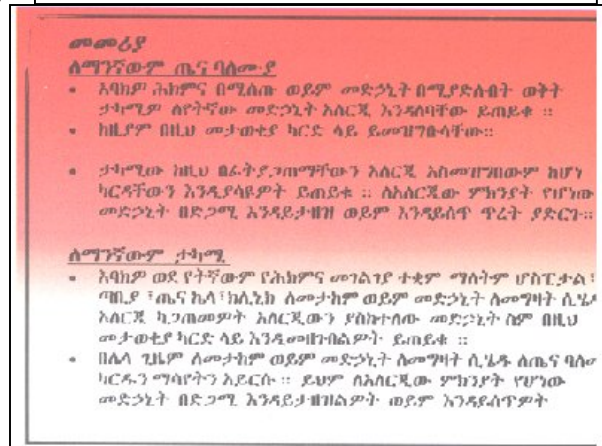
Follow up on adverse drug monitoring at facilities was carried out on December,2010 at 12 Health centers situated in Addis Ababa namely Aakaki , Kaliti ,Saris No 1,Saris No 2, Beleshachew , Kotebe, Kazanchis , Gulele , Entoto, Addis Ketema , Lideta , Shiromeda.This facilities were checked upon their activities including the availability of the reporting forms and guidelines, whether they have ever reported any adverse drug event , the type of support they needed from the national center, awareness level and number of the staff at each facility, whether sensitization sessions were carried out by the health providers who have been trained on Adverse event monitoring on various programmes organized by the regulatory Authority and other related activities. A report was prepared and feedbacks and recommendations were setup on how to further support the facilities according to their needs.

### Allergy Card distribution

Red colored allergy cards that were prepared with the objective of serving as an identification card for people who had suffered from one episode of allergy as a result of a drug taken was prepared and distributed to private and public health facilities at all regions. The 57, 000 allergy cards were prepared with the support obtained from MSH/SPS and distributed to facilities together with a written information on the purpose of the card .So any health provider in contact with a patient who has encountered an allergy for the first time will give the red card after recording the patient name ,address and drug identifying information of the allergy causing drug on the provided space on the card .Thereafter the patient will always carry the card with him/her and show to any health provider who is going to prescribe /dispense a drug and this will prevent the allergy from affecting the patient again.



Front and back page of the allergy card



### Preparation of plan of activity

Preparation of plan of activities that will be carried out to strengthen the pharmacovigilance system in the current fiscal year was carried out at FMHACA. Some of the activities that were planned to be performed were

1. Sensitization sessions aimed at the strengthening of the collaboration between the various partners of drug safety monitoring i.e the involvement of academic institutions and Market Authorization Holders (local drug manufacturers and importers).
2. Use of the national public health programmes of ART, TB and Malaria treatments to serve as an important source of drug safety information as this programmes have a major epidemiological significance resulting in the use of large number and variety of drugs by the population.

## Drug safety updates- local

Following batch of drugs were obtained to have significant drug safety problem as a result of a product quality problem observed by the authority and also information obtained from the importer. Official letters were sent to regional health bureaus, regional FMHACA branch, the importers and the agents to take actions to prevent the drug from being used BY THE PUBLIC.

### 1. Medomox 125mg

Amoxicillin 125mg/5ml, 100ml suspension (Batch No 1069014, 1069012, 1069011, 1069013)

Official Letter has been sent for the supplier to stop distributing the particular batches of the drug and also inform health facilities not to use the drug for treatment

### 2. Euglucon 5mg tablet

Glibenclamide 5mg (Batch No M007301, M007401, M0080B01, M0082B01, M0087B01)

Official letter has been sent for the supplier, regional Food medicine and Health care administration and Control Authority offices and all regional health bureaus to recall the particular batches from the market so that they shouldn't be used by the public.

### 3. Vitamin B Complex injection

(Shangi Pharmaceutical industries Co.LTD, No 107, FUZHOU Rd Shangji PR, China,

Batch No CH0806032, CH078012)

Official letter was sent to the supplier regarding the problem observed on the particular batches

Visit us at our website [www.daca.gov.et](http://www.daca.gov.et)

## Drug safety updates- International

### FDA begins Process to remove breast cancer indication from Avastin label

The U.S. Food and Drug Administration announced that the agency is recommending removing the breast cancer indication from the label for Avastin (bevacizumab) because the drug has not been shown to be safe and effective for that use.

**ISSUE:** FDA notified healthcare professionals and patients that it is recommending removing the breast cancer indication for Avastin (bevacizumab) because the drug has not been shown to be safe and effective for that use. The drug itself is not being removed from the market and today's action will not have any immediate impact on its use in treating breast cancer. Today's action will not affect the approvals for colon, kidney, brain, and lung cancers.

**BACKGROUND:** FDA is making this recommendation after reviewing the results of four clinical studies of Avastin in women with breast cancer and determining that the data indicate that the drug does not prolong overall survival in breast cancer patients or provide a sufficient benefit in slowing disease progression to outweigh the significant risk to patients. None of the studies demonstrated that patients receiving Avastin lived longer and patients receiving Avastin experienced a significant increase in serious side effects. These risks include severe high blood pressure; bleeding and hemorrhage; the development of perforations (or "holes") in the body, including in the nose, stomach, and intestines; and heart attack or heart failure.

### AFSSAPS (Agence française de sécurité sanitaire des produits de santé)

Has informed the quality assurance and safety medicines and pharmaceutical policies of WHO, Geneva Switzerland that it has decided to withdraw the marketing authorization of all products containing dextropropoxyphene and also on the same day in agreement with the concerned laboratories has decided to the recall of the batches present on the market of the product