Pharmacovigilance Newsletter

Ethiopian Food Medicine and Health Care Administration and Control Authority

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Message from a committed drug safety advocate!

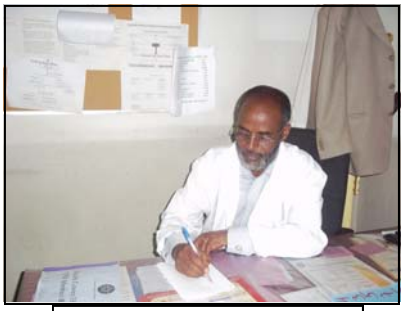
The day I was called to participate in the launching of the establishment of drug safety monitoring center of the Ethiopia Food, Medicine and Health Care Administration and Control Authority, I started to understand and visualize the magnitude of the problem, felt impressed and vowed to do my share of responsibility . Afterwards appreciation of the effort put on my continued adverse drug event (ADE) reporting was my only motivation.

Continuing on his words of advice; Dr Kebede Gunjo, a highly devoted pharmacovigilante (one who is involved in drug safety monitoring activities) mentioned the following points.

Despite they know that medicines have risks which calls for constant monitoring, health providers in the country are not fully participating in ADE reporting for so many reasons. Some of this are uncertainty in what to report and reluctance in reporting.

To help alleviate this uncertaininity, awareness creation programmes targeting the health provider should be constantly carried out. Facility specific morning sessions could be one opportunity for this purpose. Also if available, live demonstration of an ADE victim in health facilities could sensitize all those concerned on the significance of the situation and initiate them to be involved.

Reporting an Adverse Drug Event and getting a feedback on it could help us save our people from injuries which is the sole purpose of our respected profession.



Dr Kebede Gunjo Yeka HC

As to the reluctance observed by many , much attitude change is expected with the understanding that getting good therapeutic outcomes and maintaining patient safety is a collaborative approach and hence the part played by the health provider is the major one.

Also use of printed materials, adequate education and information transmission using the media are important methods that could help in reaching the public.

Dr Kebede wisely concluded by stressing the importance of continuous supervision and follow up of the interventions the Authority has carried and provision of support as needed

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.

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Basic information needed to be put on during Adverse Drug Event reporting

1.Patient Information Patient name (abbreviation), Card No, Age, Sex, Weight, Ethnic group , substance abuse (if any).

2.Drug Information Suspected drug **(S),** Concomitantly used drug **(C)** Drug Name (Brand, Batch No, Manuf date, Exp.date, Manufacturer, country of origin, Dose, Dosage from, route &frequency of administration, Date drug taking was started, Date Drug reaction started, Date drug taking was stopped and Indication.

3.Adverse drug event Information Detail Narrative Description of the event (Adverse drug reaction, Medication error, Product quality problem) including laboratory results, what the Reaction (rxn) necessitated (discontinuation of drugs, prolongation of hospitalization) ,rxn subsided after discontinuation ,rxn reappeared after restart of the drug (if any), treatment of rxn. outcome , sequelae, other medical conditions.

4.Reporter information Name, Profession, Telephone, Email, Name of Health facility ,Date of reporting.

Consultative Workshop on the development of the National Pharmacovigilance Framework

Consultative workshop on the development of the National Pharmacovigilance Framework was carried out on June 20, 2011 at MSH/SPS Head office Lalo building by The Food, Medicine and Health Care Administration and Control Authority (FMHACA) in collaboration with Management Sciences for Health/ Strengthening Pharmaceutical Systems (MSH/SPS). A total of 26 participants from the various partners of pharmacovigilance (7 from Importers and wholesalers,4 from Health facilities,2 from Professional organizations,1 from Pharmaceutical manufacturer,5 from Universities and colleges,2 from the Inspection and registration directorate of FMHACA,5 from Regulatory Information Development and Dissemination of FMHACA) attended the workshop. The Programme was officially opened and the objective introduced by Ato Kidanemariam G/Michael, the Regulatory Standard Setting and Information Delivery Directorate Director of FMHACA. After presentations about the pharmacovigilance system and the draft document, the participants were grouped and discussed on the draft pharmacovigilance Framework. Discussion was carried out on the raised comments and suggestions of each group. The participants appreciated the initiative taken to strengthen the Pharmacovigilance system by developing a National framework and wished for its successful implementation. The workshop was closed by Ato Mengisteab W/Aregay,Deputy Director of FMHACA who thanked the participants for their active participation.

Participants discussing on the draft framework at MSH/SPS Head office Lalo building on June 20,2011.

Consultative Workshop on the standardization of course contents

Participants at the workshop on June 22,2011

Consultative Workshop on Standardization of course content was organized and carried out by FMHACA in collaboration with MSH/SPS .The objective of the workshop was to standardize the course contents of the teaching institutions in the nation with regard to the information they are delivering on Adverse event monitoring to their students during pre service training. Then the students will be equipped with the knowledge and would be able to participate in drug safety monitoring while they are in practice. The participants were instructors from both governmental (13) and private (4) medical faculties and pharmacy colleges and 3 from Regulatory Information Development and Dissemination team of FMHACA. The workshop was officially opened by Ato Mengisteab W/Aregay, Deputy Director of FMHACA who reminded the participants that teaching institutions are the main partners in maintaining drug safety and have the responsibility of training their students with the necessary information about the National Pharmacovigilance system. After a brief introductory presentation the participants were grouped and discussed on the draft document prepared for the purpose. and forwarded their comments. Participants believed the importance of the inclusion of the various points described in the daft and discussion was active especially where to include it (which course) and the amount of time needed as their syllabus allows it. Finally, Ato Hailu Tadeg, MSH/SPS Institutional Capacity Building Team Leader thanked the participants for their active participation and also reminded them of their responsibility to facilitate and lobby this inclusion in their respective Teaching Institutions.

Face to Face discussions at facilities

Face to face discussions on Adverse drug event and their monitoring were carried out by the collaborative activities between FMHACA ,Regional Health Bureaus, Pharmaceutical Fund and Supply Agency and MSH/SPS at 38 Health facilities in the Nation (15 in Addis Ababa,2 in Tigray region,11in Oromia ,3 in SNNP,6 in Amhara and 1 in Diredawa region).

The aim of the programme was to create awareness on the importance of drug safety monitoring and discuss challenges encountered by the health providers at each health facility so that strategies were designed to overcome them by the participants themselves. A minimum of 20 participants were available at each programme who promised to work actively in the future and chose a focal person to coordinate the activity.

Summary of Adverse events that were reported to FMHACA in 2003 E.C

Fig 1.Total Number of ADEs and the types of drugs reported to FMHACA during the year 2003 E.C(2010/2011G.C)

Total ADE reports	Reports on Adverse reactions	Reports on Product quality
123	114	9
	88 Antiretrovirals	2 Antibiotics
	16 Anti tuberculars	2 Antihypertensives
	2 Antipsychotics	2 Injectable contraceptives
	2 Antihelmenthics	1 Antitubercular
	2 Analgesics	1 obstetric drug
	1 Anticonvulsant	1 Analgesic
	1 Cardiac drug	
	1 Antiasthmatic	
	1 Vaccine	

What is an adverse drug event?

It is any untoward medical occurrence that may be present during treatment with a medicine. It could arise as a result of known or unknown Adverse drug reactions, medication errors or poor quality products.

All Adverse drug events (ADE) observed are reported to FMHACA using

1.The yellow page prepaid adverse event reporting form

2.Telephone 0115523142/3205

3.website www.daca.gov.et , email: daca@ethionet.et

As shown in this 3rd summary above, there were a total of 123 ADE reports of which 114 were reports of adverse drug reaction (ADR) caused by various drugs

Most of the offending drugs(88,77%) were drugs of antiretroviral therapy, followed by antitubercular drugs (16,14%).others reported were antipsychotics, antihelmenthics and analgesics. An ADR caused by a vaccine was also reported by a health provider showing un understanding of the fact that reactions to vaccines are also reportable.

Product quality defect reports on 9 drugs were also reported once again showing that concerns over drug safety also arise as a result of use of poor quality product.

The reported adverse drug reactions caused by this drugs were; lipodystrophy (37), Skin reactions (23),Anemia (17), Peripheral Neuropathy (15), Lipoatrophy (8),Skin color change(3), Liver toxicity(3), Psychosis (3), Steven's Johnson syndrome(1) and others(8).

As to the product quality defects ,that were reported are ;capsule cracking, treatment failure, color change and reconstitution problem.

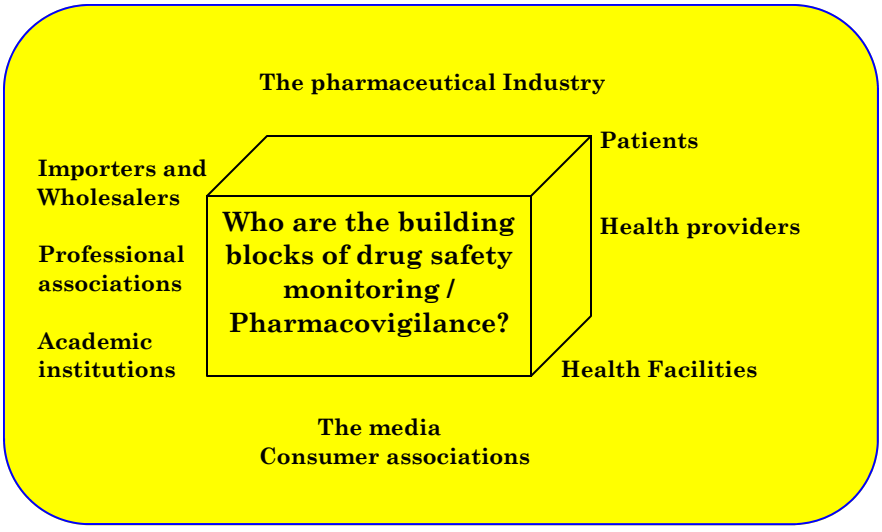
These reports were sent to the regulatory Authority by 34 health providers from 30 health facilities all over the nation who had reported their observation because of their concern .

The majority of people(67,59%) affected by the adverse drug reactions were women and the age group most of the reaction observed(57,56%)was among 21-40.This could be explained by the fact that most of the reactions reported are as a result of use of the ART drugs indicated for HIV/AIDS which mostly affects women and the productive age group among the whole population.

Partnership in pharmacovigilance

In a health care delivery, monitoring drug safety and securing the public from drug related hazards is a collaborative activity between various partners and a pharmacovigilance center.

The industry, importers and wholesalers should create a system to follow on the drugs they have manufactured or imported. Patients and health providers should be involved in reporting observed ADEs. Academic institutions and professional associations should be involved in training ,research and policy development. The media and consumer associations should be active in inquiring and disseminating proper safety information to the public



Drug safety Updates-Local

Following batch of drugs were found to be unfit for use as a result of product quality problem observed after a post marketing surveillance done by FMHACA. Official letter was sent to the importers and manufacturer (local) to recall their products.

1.AMYN 500mg
Amoxicillin 500mg capsule, Batch No 53659034,Manf. date October 2009,Exp date Sep 2012, Importer and distributor-KERTINA PHARMA, Manufacturer-KOPRAN LIMITED(INDIA).

2.KANAPRIM 480mg
Cotrimoxazole 480mg tablet, Batch No 8002,Exp date Dec. 30/2013,Importer and distributor-BEKER GENERAL BUSINESS, Manufacturer- HOUNS CO.LTD,KYUNGGI(SOUTH KOREA).

Others. **DEPRIM** (Batch No 40157),**LAGATRIM** (Batch No 7438),**COTRIECH** (Batch No 490058) ,**RIVAMOX** (Batch No 080912A),**AMOXID** 500 (Batch No 6266),**ASMOX** 500 (Batch No B113M),**ORIPRIM** (Batch No 1810),**DEPRIM** (Batch No 39682),**AMOXICILLIN** EPHARM (Batch No 0030291),**BISEPTON** 480mg(Batch No 373)

FOOD, MEDICINE AND HEALTHCARE ADMINISTRATION AND CONTROL AUTHORITY OF ETHIOPIA.
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Drug safety Updates-International

FDA Drug Safety Communication: Safety Review of possible increased risk of blood clots with birth control pills containing drospirenone.

Drospirenone is a type of female sex hormone called a progestin. Most birth control pills contain two types of hormones--estrogen and progestin. Birth control pills work by preventing the release of eggs from the ovaries (ovulation) and changing the cervical mucus and the lining of the uterus to prevent pregnancy. All birth control pills pose a risk of blood clots.
Several epidemiological studies have reported that the risk of blood clots for women who use birth control pills containing drospirenone is higher than that for women who use birth control pills containing the progestin levonorgestrel. A blood clot that forms in a deep vein in the body is called a deep vein thrombosis (DVT). A DVT is a rare side effect of taking birth control pills. A blood clot can break loose from the vein, move through the body to the lung, and cause a serious problem in the lung, called a pulmonary embolism (PE). This can lead to death.
Two recently published studies reported a greater risk of blood clots for women taking birth control pills containing drospirenone as compared to the risk in women taking birth control pills containing another progestin known as levonorgestrel.
An additional large study exploring the association of blood clots with hormonal contraception has been commissioned by FDA, and results of that study are currently being finalized and reviewed.
The European Medicines Agency (EMA) announced on May 27, 2011, that it is updating the product information on oral contraceptives containing drospirenone and ethinyl estradiol regarding the risk of venous thromboembolism after review of all available data, including the same newly published data FDA is reviewing *(Source FDA Drug Safety Communication September 26,2011).*