



Food Medicine and Health
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Control Authority



Pharmacovigilance newsletter

Importance of Adverse Drug Event Monitoring and the responsibilities of health care providers.

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Message from Tirunesh Beijing General Hospital healthcare

providers ! (Tsegaye Ababiya B. Pharm, clinical and Nigist Nigussie B. pharm, clinical)

During the course of treatment, drugs prescribed to patients produce certain effects other than the desired or expected effects. These cause concern both to the physician and the patient.

They not only add to spiraling costs of medical treatments, but also cause a great deal of morbidity and mortality. People usually attribute these abnormal effects to either overdose or



inappropriate medications prescribed by the doctor or the attending specialists.

Adverse drugs reactions (ADRs), put simply, are noxious, unintended, and undesirable effects that occur as a result of drug treatment at doses normally used in man for diagnosis, prophylaxis, and treatment.

Although there are many terms indicating the harmful and undesirable effects of drug treatment, the term 'adverse drug reaction' describes them best.

All health professionals and other trained personnel should be educated on the importance and benefit of ADE reporting.

All health professionals and other trained personnel should be encouraged to report ANY suspected ADE (adverse drug reactions, medication errors and product quality defects).

Reporting process should be Simplified for reporting suspected

ADEs .

Program should be ongoing. System should respect the confidentiality of the patient and facility.

ADR reporting should be promoted through an ongoing campaign.

In hospitals where there are trained clinical pharmacists, Their role should be to promote the development, maintenance, and ongoing evaluation of the monitoring program to reduce the risk of ADEs through detecting, reporting and assessing any suspected adverse drug reaction, medication error and product quality defect co-operatively working with physicians, pharmacists, nurses, public health officers and others.



This news letter is prepared and shared

quarterly by the FOOD ,MEDICINE AND HEALTHCARE ADMINISTRATION AND CONTROL AUTHORITY

with the objective of providing MEDICINE

SAFETY information and activities of the pharmacovigilance center to all HEALTHCARE PROVIDERS working at both the

PUBLIC AND PRIVATE HEALTH SECTORS.

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Activities by the Pharmacovigilance center

Face to face discussions at health facilities on Pharmacovigilance

Continuing on its awareness creation programmes, the pharmacovigilance center at the Ethiopian Food, Medicine and Healthcare Administration and Control Authority (FMHACA) organized and provided trainings on pharmacovigilance to 9 health facilities in collaboration with the health bureaus of three sub cities (Bole, Gulele and Nifas silk lafto) and the financial and technical support of USAID/SIAPS .

Discussions were carried out with the health providers of Amoraw , Bulbula, Dilfire, Gerji, Selam, Wereda 2 , Wereda 6 , Wereda 11 health centers of Bole sub city ,Gulele and Nifas silk lafto sub cities and Yekatit 12 hospital., from January 1-May 9 /2014 at the meeting halls of the facilities . A total of 207 health providers were trained on the importance of pharmacovigilance, the tools and principles of pharmacovigilance and the responsibility each health provider have towards the monitoring of medicine safety.

Participants actively discussed on the challenges of monitoring and agreed on a way forward. A focal person was chosen at each facility in order to strengthen the activity and sustainability of the system.

(See some of the attached pictures)



Activities by the Pharmacovigilance center

Consultative workshop to enrich Adverse Drug Event (ADE) Monitoring Guideline, 3rd Edition



Consultative workshop was carried out by FMHACA in collaboration with World Health Organization -Ethiopia at Adama ,Maya Hotel from March 13-14, 2014. The objective of the workshop was to enrich the Adverse Drug Event Monitoring guideline 3rd edition that was drafted by the experts at FMHACA. Participants of the workshop were 25 in number and were composed of representatives from WHO-E, Health facilities, Teaching Institutions, Public health programmes , Professional associations, Regional Health bureaus,

Regional regulatory Authorities, Market Authorization Holders and the Media. The event was opened by Mr. Mengisteab W/Aregay, Deputy General Director of FMHACA who thanked the participants for their attendance and requested their committed participation for the betterment of the Guideline under revision. The National Policy and Regulations with respect to Medicines safety monitoring ,Overview of the National pharmacovigilance monitoring system and contents of the revised guideline were presented for the participants before they were grouped for discussion on the document. Participants then provided their valuable comments to be included in the guideline and this was again discussed together with the whole audience.

The rationale for the revision of the previous guideline among other things was to update and clearly define the roles and responsibilities of stakeholders especially that of market authorization holders which was not clearly stated in the previous edition.

The workshop was finally closed by Mr. Abraham W/Giorgis, representative of WHO-E who thanked the participants for their fruitful deliberation and encouraged them to fulfil their responsibilities in the monitoring system at their respective organizations..



Update on medicine safety -International

Falsified antimalarial medicines in Africa

Quinine sulphate

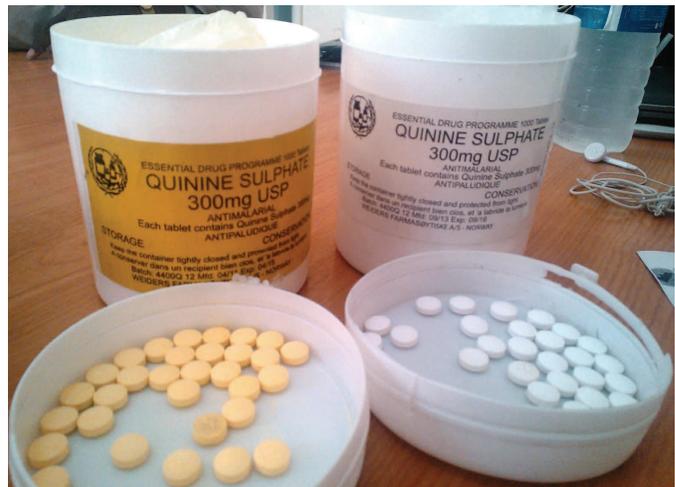
As obtained from WHO Drug Alert 131, In march 2014, the Liberian medicines and Health products Regulatory Authority reported to WHO that they had discovered the following two batches of suspected falsified medicines bearing the same batch number.

Product name : Quinine sulphate 300mg USP., Manufacturer: Weiders farmasotiske, Dosage :300mg, Batch Number : 4400Q1, Expiry dates: 04/15 and 09/16, Manufactory dates: 4/11 9/13. Laboratory results are awaited but enquiry with weiders' parent company confirm that they didn't manufacture these products.

The drug alert summarizes that these products have been intentionally falsified and are circulating within the formal and informal supply chain. National Regulatory authorities are requested to increase vigilance within the supply chain for these specific batches. In addition, vigilance is requested for any medicines bearing the previous WHO Essential drugs programme logo (No longer in use by WHO). If discovered steps should be taken to ensure that they met full -

Specifications .The drug alert also describes that these medicines are contained in tubes of 1000 tablets designed for hospitals and clinics .The labeling's are in English and French languages and contain spelling mistakes. They also show previous WHO Essential Drugs Programme Logo which is no longer in use by WHO.

Source ; Information Exchange system. Drug Alert No.131.Falsified Antimalarial medicines in west and Central Africa. WHO. 25 March 2014.



Update on medicine safety-local

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

Name of the medicine: RHZE (Rifampicin , Pyrazinamide, Isoniazid, Ethambutol) .**Medicine identifying Information; Manufacturer,** MacLeod's Pharmaceuticals Ltd., **Brand name** ,Forecox Trac , **Batch Number** , EFA214A. **Product defect observed and reported by health providers** , Color change in the tablets

Action taken by the regulatory authority

⇒ After receiving the observed product defect report sent by health providers through the yellow page prepaid adverse drug event reporting form, the regulatory authority performed its own investigation and quality test and reached its decision. Then based on the mandate given to the authority, an official letter was written to the importer and distributor of the medicine (The Ethiopian Pharmaceuticals fund and supply agency) to collect the product from the market and report the situation to FMHACA. A reminder was also given to the same stakeholder on a similar product defect reported on another batch of the same product that was observed and communicated to it previously.



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