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ETHIOPIAN FOOD AND DRUG AUTHORITY

Pharmacovigilance Newsletter

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What is the role of academic institutions in Pharmacovigilance?

The drug delivery process is dependent on patients' and health professionals' vigilance in real-life settings to detect potential problems that need to be communicated to the national drug authority in order for preventative actions to be taken. Wherever medicines are being used there should be a readiness to monitor and report unwanted and unexpected medicine-related problems.

Pharmacovigilance is implemented in a collaborative activity between multiple partners among which are the academic institutions, healthcare facilities public health programmes, manufacturers, importers wholesalers and drug outlets, consumer associations the media and healthcare providers.

The expansion of scientific knowledge in drug safety is attributable to greater awareness and academic interest in this field. **Academic institutions** can play an important role through **teaching, training, research, policy development, clinical research, and the clinical services they provide.** In many medical institutions, particularly in the developed world, ADR monitoring is recognized as an **essential quality assurance activity. In addition,** greater integration of Pharmacovigilance into clinical practice is still needed.

In Ethiopia , activities like the inclusion of topics on Pharmacovigilance in the curriculum of health teaching institutions have been implemented in universities both public and private after a collaborative activity carried out with the ministry of Education. Though the activities need to be followed up on to ensure their sustainability and intervene on challenges encountered in the process, the initiative have proved to be a milestone activity to ensure the training of healthcare students so that they could be involved in the monitoring of medicine safety with the knowledge they obtained during their pre service trainings.

This initiative and academic institutions nature of involvement of quest for further knowledge and research has led EFDA to strengthen its collaborative activity through the establishment of decentralized Pharmacovigilance center at selected referral teaching hospitals in the country Namely Gonder University, Ayder University, Jimma University, Hawassa University and Blacklion University hospitals.

Please look into the inside pages of the newsletter for more information on this

This newsletter is prepared and shared quarterly by EFDA with the objective of providing Medicine safety information and sharing the activities of the pharmacovigilance center at FMHACA to healthcare providers working at both the public and private sectors.

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What is the importance of establishing decentralized Pharmacovigilance centers?

Safety monitoring activities will not be effectively conducted by one centralized center situated at the federal level alone and hence, creating pool (increased number) of health care professionals (physicians, pharmacists, nurses…) who are trained on PV and are aware of the importance of regional collaborating center is very important. Hence a decentralized Pharmacovigilance system will create the sense of the monitoring of medicine safety at regions through the provision of trainings, supporting the increase in number of ADE reporting by local healthcare providers in the area, performing various medicine safety researches and providing real time solutions to the drug related problems. In addition the establishment of decentralized Pharmacovigilance centers at teaching hospitals will also create sense of ownership that the institution are responsible and accountable, understand the safety monitoring of medical products used in their overall health care system and will also contribute to their institutions quality assurance system as one important complementary activity.

Underlining the above objective, the EFDA planned to establish six decentralized centers with full support of establishment costs for office furnitures, technical support in the form of training and provision of access to the international WHO drug safety database vigiflow so that the focal person selected to be responsible for Pharmacovigilance center at the Drug Information centers of the teaching institutions could directly enter ADE data into vigiflow.

As the monitoring of medicine safety activities are collaboratively implemented by the federal level EFDA Pharmacovigilance center and the hospital based decentralized centers ,responsibilities were shared among each party so that effective collaboration, coordination and communication activities are executed.

Following are the responsibilities shared between EFDA and the six decentralized centers

	ETHIOPIAN FOOD, MEDICINE AND HEALTH CARE ADMINISTRATION ANDCONTROL AUTHORITY	**_____UNIVERSITY HOSPITAL**
1	Provision of office equipments, resource materials, guidance documents, reference materials, SOPs and ADE reporting tools which will be used for regional Pharmacovigilance centers	Allocation of sufficient/appropriate office, finance and staffs for the establishment of the center
2	Provision of continuous supportive supervision, feedback and directions to regional Pharmacovigilance centers	Provision of capacity building and awareness creation programmes of other selected health institutions health professionals that are located near to the hospital on Pharmacovigilance
3	Preparing training materials and delivering capacity building trainings, dissemination of national and international updates on safety areas	Provision of regular support on the success of the regional Pharmacovigilance center activities
4	Facilitation of new approaches and New strategies (including global community of safety monitoring)	Facilitation for conduct of researches on both undergraduate and Msc students, initiation of new strategies and approaches for strengthening safety monitoring
5	Establishment of National Pharmacovigilance Database and availing it to the regional Pharmacovigilance centers	Promotion of Pharmacovigilance for all university hospital community (health professionals administrative staff and patients)

Activities performed in the Pharmacovigilance center

Launch of decentralized Pharmacovigilance centers

The Ethiopian Food and Drug Administration in collaboration with selected teaching university hospitals at regions established and launched decentralized Pharmacovigilance centers . The centers are situated at the Drug Information centers of the hospitals .The launches were carried out during the months of October and November 2019.

All the decentralized centers were provided with office furniture's including computer and printer and an access and training to the global drug safety database of WHO International drug monitoring (vigiflow) as per the collaborative agreement obtained from the office. During the launching ceremony, trainings were provided to more than 500 healthcare providers on the importance of Pharmacovigilance, the National Pharmacovigilance system and the different ADE reporting systems available in the country. Details of the roles and responsibilities of the decentralized centers and the support that they would obtain from the EFDA National Pharmacovigilance center were discussed. In each launch, the necessity of joint efforts for the increasing of the number of reports and the resulting strengthening of the system were also seriously agreed upon so that the public could be protected from unnecessary drug related harms. The launches were officiated by the Heads of the Hospitals, the Pharmacy services and the branch EFDA and other invited stakeholders in the area.

Launching at Gonder University, Gonder

Launching at Ayder University,Mekelle

Launching at Balcklion Hospital,Addis Ababa

Launching at Jimma University

Launching at Hawassa University

International regulatory updates:

Proton pump inhibitors (PPIs) Risk of acute kidney injury India.

The NCC-PvPI has made a recommendation to CDSCO requesting that the PIL for proton pump inhibitors (PPIs) marketed in India should be revised to incorporate acute kidney injury as a clinically significant adverse drug reaction. PPIs are used to treat gastric ulcers, duodenal ulcers, gastrooesophagal reflux disease and Zollinger Ellison syndrome. Between July 2011 and July 2019, the NCC-PvPI has received 23 ICSRs of PPI associated acute kidney injury. The cases were carefully reviewed by SRP at NCC-PvPI, IPC, and a strong causal relationship between PPIs and acute kidney injury was concluded. Reference WHO Pharmaceuticals Newsletter .*(WHO pharmaceuticals Newsletter. No 6,2019)*

National Regulatory updates

Product quality defects during the first half year of 2012

During the first half of the year 2012 E.C 64 product quality defects were reported by health care providers on different medicines . This product quality defects were observed in different formulation types including tablets, Injectables, Iv fluids, suspensions, test kits and disinfectants. Details of the types of the defects observed and the frequency of the reports received are summarized in the following table. Investigations are being carried out on the defects reported so that the appropriate regulatory measures are taken.

Type of formulation	Rep .No	Reported quality defect	Frequency
Tablets	18	Easily breaking and crumbling	13
Test kits	12	Color change	12
Injectables	9	False result	9
Suspensions	9	Sedimentation, caking and crystallization	9
Iv fluids	5	Packaging and labeling problem	7
Capsules	4	Separation of components	7
Surgical sutures	2	Incomplete pack	5
Glove	1	Powdering	5
H_2O_2	1	Contamination	3
Gimsa stain	1	Odor change	3
Eye drop	1	Wet tab,turbidity,No powder,No foam,diluted soln,No staining, different amount in each bottle	7
Syrup	1		
Total	64		70