Pharmacovigilance Newsletter

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Training was given on applying the Brighton collaboration Case definition for causality assessment

Applying standardized case definitions are crucial to enhance the ability to accurately assess the causality of Adverse Events Following Immunizations (AEFIs) and contribute to vaccine safety monitoring. The Ethiopian Food and Drug Authority (EFDA) in collaboration with Global One Health initiative (GOHi) recently provided two (2) days of training on the Brighton Collaboration case definitions (BCCDs) to members of the national pharmacovigilance advisory committee (PAC) and experts from the EFDA. Twenty-six (26) participants attended the training. The necessary topics on the need for standardized case definition in the assessment of AEFIs and how to access as well as apply the BCCDs in day-to-day clinical care and causality assessments were addressed by an invited expert who is a member of the Brighton Collaboration Science Board. It is expected that trainees will correctly apply the skills attained in ascertaining the diagnosis of reported AEFIs and also while conducting causality assessment of AEFI.

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 to healthcare providers

Figure 1: Picture taken during BCC training for Pharmacovigilance Advisory Committee

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Activities Performed by the Pharmacovigilance Center

Pharmacovigilance Inspection Training was given

It is known that Market Authorization Holders (MAH) are one of the stakeholders for pharmacovigilance and they are responsible to monitor their products on regular basis to ensure that the safety, quality and efficacy of products are acceptable. The Ethiopian Food and Drug Authority is mandated by proclamation No.1112/2019 to conduct pharmacovigilance inspections on MAH holders to ensure the proper execution of their responsibilities in safety monitoring. In developed countries with robust pharmacovigilance system, the MAHs contribute a considerable amount of safety reports to the national regulatory Authorities. In our country, the reports received from MAH are very low and the Authority is not properly monitoring the MAHs until now. This is mainly because of lack of adequate capacity of the human resources to do pharmacovigilance inspections. With the objective of building the capacity, the US PQM PLUS in collaboration with Ghana Food and Drug Authority has provided pharmacovigilance inspection trainings for medicine safety and post marketing team staffs for five days in May 2024. The training was given by trainers from Ghana Food and Drug Authority and US – CDC. During the training the Ghana Food and Drugs Authority pharmacovigilance experts shared their experiences for the trainees and guidelines and operating procedures were also benchmarked. Finally, a detailed plan of action was prepared by the participants which will guide the Authority in conducting pharmacovigilance inspection on MAHs.

Figure 2. Picture showing Pharmacovigilance inspection training

Pharmacovigilance Training was given for Health Professionals providing Chemotherapy service

The Ethiopian Food and Drug Authority provided a capacity building training about safety monitoring for health professionals providing chemotherapy services. The training was given for two days on May 29 and 30 2024 and participants were selected from health facilities providing oncology services in the country. The objective of the training was to create awareness about the national pharmacovigilance systems, reporting tools and the importance of reporting Adverse Events (AE) to EFDA. The strengths and challenges in detecting and reporting AEs were discussed during the training. Future priority activities were identified to improve the detection and reporting of AEs on chemotherapy medicines.

Figure 2. Picture taken during PV training for health professionals on Chemotherapy

Activities performed in the Pharmacovigilance center

Causality Assessment on Serious Adverse Events was conducted

The national Pharmacovigilance Safety Advisory Committee has conducted causality assessment on serious adverse events. The committee convened a meeting in Bishoftu town on May 21 and 22, 2024. A total of 18 investigated serious cases were presented and reviewed by the committee. From the 18 cases, 11 (9 AEFI & 2 ADEs) were classified based on the WHO causality assessment algorisms. The remaining 7 cases were not classified because additional information were needed and the committee gave directions to conduct additional investigations and present the completed investigation report for the next meetings. Based on the assessment, the committee has provided recommendations to EFDA and other relevant stakeholders to enhance services provided to the public.

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Pharmacovigilance training was provided for sub national pharmacovigilances centers and health professionals

To keep an eye on the quality, safety, and efficacy of medications, effective pharmacovigilance systems are essential. The sub-national pharmacovigilance centers that participate in ADE monitoring can enhance the detection and management of drug-related issues. Decentralized PV systems are crucial for the implementation of medicine safety monitoring. EFDA has established seven (7) sub-national PV centers in university hospitals in Gonder, Mekelle, Hawassa, Haromaya, Jimma, Addis Ababa and Hossana. It is anticipated that these centers would be of paramount importance in augmenting regional safety surveillance and enhancing the comprehensive execution of the national pharmacovigilance system.

In order to enhance the awareness of health professional about safety monitoring, training was provided in several regions. The training was organized by Ethiopian Food and Drug Authority in partnership with USAID/PQM+ and a total of 180 health professionals from seven subnational PV centers and their catchment areas participated. The trainees were selected from Woreda Health Office, hospitals, health centers, regional health bureaus, and/or regulatory agencies. During the training discussion was held regarding the next stages in medicine/vaccine safety monitoring, and participants forwarded their opinions on the training and problems they had encountered. The training sessions were effective overall, raising the trainees' knowledge on medicine and vaccine safety monitoring which will enable them to comprehend their roles in medicine and vaccine safety monitoring.

Figure 3: Mekell University Hyder Comprehensive Teaching Hospital and Jimma University Comprehensive Teaching Hospital Sub national PV centers

Pseudo Pseudoephedrine

Risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

The European Medicine Agency (EMA) is reminding health-care professionals by issuing a Direct Health-care Professional Communication (DHPC) that cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS), which are serious conditions affecting the cerebral blood vessels, have been reported in patients taking pseudoephedrine-containing medicines. Most reported cases resolved following discontinuation and appropriate treatment. No fatal cases of PRES or RCVS have been reported. Pseudoephedrine is authorized, alone or in combination with other substances, for short-term symptomatic relief of nasal or sinus congestion caused by the common cold or allergic rhinitis, vasomotor rhinitis, aerotitis.

Following an EU-wide review of reported cases and other available data to evaluate the risks of PRES and RCVS with pseudoephedrine-containing medicines, it has been concluded that pseudoephedrine is associated with risks of PRES and RCVS and that the product information should be updated to include information on these adverse reactions and measures to reduce the risks.

Topiramate

Risk of neurodevelopmental disorders in children exposed in-utero

The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicine Agency (EMA) has recommended new measures to avoid exposure of children to topiramate in the womb due to the increased risk of neurodevelopmental disorders after exposure during pregnancy.

Topiramate is indicated for the treatment of epilepsy and prevention of migraine. Topiramate is already known to cause serious birth defects when used during pregnancy. Its use for prevention of migraine during pregnancy is already contraindicated.

The PRAC reviewed three recent observational studies. Two of these studies, which used largely the same datasets, suggest that children born to mothers with epilepsy and who were exposed to topiramate in the womb may have a two- to three-fold higher risk of neurodevelopmental disorders, in particular autism spectrum disorders, intellectual disability or attention deficit hyperactivity disorder (ADHD), compared with children born to mothers with epilepsy not taking antiepileptic medication. The third study did not show an increased risk of these outcomes

The PRAC recommends that the medicine should not be used for the treatment of epilepsy during pregnancy unless there is no other suitable treatment available. The PRAC also recommends additional measures, in the form of a pregnancy prevention programme, to avoid exposure of children to topiramate in the womb. The programme includes the following measures:

⇒ A pregnancy test before starting treatment;

⇒ Counselling about the risks of topiramate treatment and the need for highly effective contraception throughout treatment;

⇒ A review of on-going treatment at least annually by completion of a risk awareness form;

⇒ Topiramate treatment of patients of childbearing potential initiated and supervised by a physician experienced in the management of epilepsy or migraine.