Pharmacovigilance Newsletter

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EFDA established its seventh sub-national pharmacovigilance center at Wachamo University Nigist Eleni Hospital

The proper implementation of pharmacovigilance requires the engagement of different stakeholders and centers to coordinate and synergize the contributions at different levels. For this reason it is essential to establish a decentralized sub-national pharmacovigilance center at different geographic locations in the country. Starting from 2019 EFDA has established six sub-national pharmacovigilance centers in selected University hospitals, considering these hospitals as pivots for reaching the existing and future health professionals as well as clients in large for better medicine safety monitoring. Expanding this great initiative, on January 2024, EFDA established its seventh sub-national pharmacovigilance center at Nigist Eleni Hospital of Wachamo University. During the launching of the center MOU was signed by higher officials of the hospital and EFDA. In addition, the top officials from EFDA and the hospital delivered speech on the importance of the newly established center and expressed their commitment for its proper functioning.

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

Pharmacovigilance strengthening workshop was Conducted with selected Universities providing master of science in clinical pharmacy

Representatives of school of pharmacies from six Universities namely Addis Ababa University, Haramaya University, University of Gondar, Wollo University, Wolayita Sodo University and Jimma University were participated in this workshop. Two staffs from each university hospital and one participant from each hospital drug information center were represented for the workshop. Additionally, representatives from regional health bureau pharmacy service were also participated in the workshop. The main goal of the workshop was to discuss on strategies for strengthening medicine safety monitoring and emphasis on the role of academicias involved in teaching clinical pharmacies. During the workshop overview of the national pharmacovigilance system was presented and followed by participants discussion. During the discussion the participants raised ways of bringing the ADEs detected by MSc in Clinical Pharmacy students to EFDA as well as timeline for sending the report and assigned responsible persons for this activity. After the discussion the participants were divided into groups to prepare strategies, action plan and suggested the following strategies for boosting ADE detection and reporting: Making ADE detection and report part of key performance indicator (KPI), assigning PV focal persons and continues follow up, organizing PV awareness creation workshops, providing PV trainings to students before graduation as well to staff, creating ways of incentivizing those reporting ADE and clarifying the route of reporting.

Inside this issue:

Activities Performed by the Pharmacovigilance Center

Induction training provided for newly joined pharmacovigilance staff's on AEFI and pharmacovigilance

EFDA recently underwent a restructuring process, resulting in the assignment of new staff members to pharmacovigilance and the clinical trial lead executive office. These new staff members are unfamiliar with the department's activities, particularly in the areas of pharmacovigilance and AEFI monitoring. To address this, EFDA organized a staff induction training on basic pharmacovigilance and AEFI monitoring. The training was conducted in collaboration with the Ethiopian Pharmaceutical Association and GHSC-PSM from February 13th to 16th, 2024, in Adama. A total of 25 participants (16 males and 9 females) attended the four-day training.

During the training, various topics were covered, including the basics of pharmacovigilance, the national PV system and reporting tools (with demonstrations), the fundamentals of vaccines and AEFI, the AEFI surveillance system, ADE investigation and causality assessment, and the role of PV in public health programs such as HIV, TB, MDA, MCH, NCD, and malaria. At the end of the training, a discussion session was held between the participants and the head of the department, Asnakech Alemu. During this session, the participants were provided with guidance, their expectations were clarified, the routine activities of the team were explained, and common challenges and coping mechanisms were discussed.

National Pharmacovigilance Advisory Committee (PAC) Conducted Causality Assessment of Serious Adverse Events

Mr. Seyoum Wolde, the Deputy Director-General of the Medicine Sector at the Ethiopian Food and Drug Authority, extended a warm welcome to the committee members on behalf of the Authority. He emphasized that Ethiopia is leading among African countries in submitting a high number of AEFI reports, according to the latest data from the World Health Organization database. This highlights the urgent need for a thorough investigation and assessment of AEFI cases. It is crucial to provide feedback to program owners and the community regarding these cases. Mr. Seyoum also noted that the frequency of conducting causality assessments falls short of the required standards for timely recommendations. The Authority is committed to taking the necessary actions to improve this situation. The advisory committee's continued dedication is highly valued, and Mr. Seyoum expressed his gratitude for their unconditional assistance to the Authority. He also extended his thanks to the partners, USAID/USP-PQM+, and OSU-GOH Programs, for their financial and technical support.

Following the welcoming remarks, Mr. Teshita, the Head of the Medicine Safety and Post Marketing Surveillance Desk, highlighted that the committee would review a total of thirteen serious ADE/AEFI cases. Among these cases, three were related to Anti-TB medicines, one to the HPV vaccine, three to the Johnson COVID-19 vaccine, one to the Pfizer-BioNTech COVID-19 Vaccine, two to the oral cholera vaccine (OCV), two to Intravenous immune globulin (IVIG), and one to the Rabies Vaccine.

The investigation report and other relevant documents of each serious cases were presented to the committee by experts medicine safety and post marketing surveillance experts. The committee thoroughly reviewed and assessed the causalities of events after discussing in detail. Finally, 13(5 female and 8 male) cases were reviewed, classified and appropriate recommendations were provided for better patient management and program improvement.

Activities performed in the Pharmacovigilance center

Sub-National Pharmacovigilance Centers Advocacy Meeting

(*March 05, 2024 - Ramada Hotel, Addis Ababa)*

The Sub-national Pharmacovigilance (PV) Centers Advocacy Meeting was successfully held on March 5, 2024, in Ramada hotel, Addis Ababa. This pivotal event brought together 37 key stakeholders from seven sub-national pharmacovigilance centers; Black Lion Hospital, Ayider Hospital, Gondar University Hospital, Hawasa Referral Hospital, Jima University Hospital, Wachamo University Hospital and Haromaya University Hospital. pharmacovigilance focals, pharmacy heads, and medical directors from each hospitals were participated in the meeting. Additionally, branch heads from EFDA, representatives from USP/PQM+, GHSC-PSM, and other relevant EFDA staff members contributed to the workshop's success.

The meeting aimed to discuss the assessment report from centers, chart the way forward, and witness the signing of Memorandums of Understanding (MOU) from the six participating sub-national pharmacovigilance centers. A significant focus was placed on the decentralization of Pharmacovigilance centers to selected health facilities, such as university hospitals.

The advocacy meeting continued with invaluable insights from EFDA experts, addressing the critical issue of underreporting in adverse drug events. The ;sub-national pharmacovigilance focals outlined that a model Standard Operating Procedure (SOP) for Adverse Drug Event (ADE) reporting could be prepared and shared by EFDA to streamline the process across all health facilities. EFDA experts provided guidance on the importance of conducting onsite face to face discussions wit healthcare professional on pharmacovigilance and stressed the need for PV centers to have a clear work plan. They also highlighted the importance of acknowledging the original reporters and ensuring that PV work is internalized within the health system. EFDA also highlighted that medicine safety will be included with the ongoing revision of the national medicine policy to include product safety, and PV is set to become a regular agenda item in Joint Steering Committee (JSC) meetings. The meeting concluded with the signing of Memorandums of Understanding (MOU) between hospital medical directors and D/D/G representative Mr. Getachew Genete, representative of EFDA, sealing a promise.

Sensitization meeting on surveillance of adverse events following immunization (AEFI)

OHIO STATE GLOBAL ONE HEALTH IN COLLABORATION WITH EFDA TIKUR ANBESSA SPECIALIZED HOSPITAL (TASH) CPD CENTER March 25, 2024

A one day sensitization meeting on surveillance of AEFI was provided to healthcare professionals working at Tikur Anbesa Specialized hospital and Yekatit 12 medical college hospitals by EFDA in collaboration with OSU-GOHi. Participants from emergency, inpatient, and pharmacy departments of each hospital attended. The primary aim of the meeting was to enhance awareness among healthcare professionals about the importance of monitoring and reporting Adverse Events Following Immunization (AEFI) and Adverse Drug Events. This initiative seeks to bolster the active participation of medical staff in identifying and communicating any adverse events that occurred after drug or vaccine administration.

The sensitization session commenced with insights from the Deputy Director General of EFDA, who emphasized the critical need for vigilant safety monitoring of medicines and vaccines. He highlighted the existing under reporting of adverse drug events and AEFI by healthcare professionals and called for their increased cooperation and involvement in pharmacovigilance activities. Experts from EFDA provided comprehensive presentation on the national AEFI surveillance system and the broader scope of pharmacovigilance. Discussions was held on the current state of national pharmacovigilance system and its associated challenges. Additionally, an update on the progress of the "Hospital Based Sentinel Surveillance" project, focusing on "Adverse Events of Special Interest post-Vaccination at Tikur Anbessa Specialized and Yekatit 12 Hospital Medical College," was shared with the attendees.

A total of 25 clinical staff members from Tikur Anbessa Specialized and Yekatit 12 Hospital Medical College, along with representatives from the Ministry of Health and the World Health Organization (WHO) attended the meeting.

International Medicine Safety Updates

Safety Alert on BENYLIN PAEDIATRIC 100ml Cough Syrup

The Benylin pediatric cough syrup manufactured by JOHNSON & JOHNSON (PTY), South Africa with batch numbers of 329304 & 329303 has been recently recalled by five regulatory Authorities in Africa namely National Agency for Food and Drug Administration and Control (NAFDAC) of Nigeria , South African Health Products Regulatory Authority (SAHPRA) , Rwanda Food and Drug Authority (Rwanda FDA), The Medicines Control Authority of Zimbabwe (MCAZ) and Pharmacy and Poisons Board (PPB)/Kenya due to safety and quality concerns. The syrup with 329304 batch was initially tested by the NAFDAC and found to have unacceptably high level of Diethylene glycol, a contaminant toxic chemical which can result in fatal outcomes if consumed by humans. EFDA confirms that this syrup is not registered for use in our country and no pre import permit was given so far. However, though it is not registered and imported legally, the syrup might end up in our market through other means. Therefore, the Authority would like to alert all healthcare professionals about this syrup with the following immediate actions.

1. To immediately to notify the Authority if they found,
2. To stop distributing it to the public for use and
3. To segregate the product

Safety Alert on Fluoroquinolones

Fluoroquinolones are a class of antibiotics that include ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, and ofloxacin. These antibiotics have been reported to cause serious side effects involving tendons, muscles, joints, nerves, or mental health and in some patients, these side effects have caused long-lasting or permanent disability. Thus,

- Patients should stop taking fluoroquinolone antibiotic and contact you're their prescriber or pharmacist immediately if they have any of the following signs of a side effect:

⇒ tendon pain or swelling,

⇒ pain in joints or swelling in joints such as in the shoulders, arms, or legs abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning),

⇒ weakness in the legs or arms, or difficulty walking severe tiredness,

⇒ depressed mood, anxiety, problems with memory or severe problems sleeping,

⇒ changes vision, taste, smell or hearing.

- Systemic fluoroquinolones should only be used when other commonly recommended antibiotics are inappropriate. Situations where other antibiotics are considered to be inappropriate are where:
  - ⇒ there is resistance to other first-line antibiotics recommended for the infection
  - ⇒ other first-line antibiotics are contraindicated in an individual patient
  - ⇒ other first-line antibiotics have caused side effects in the patient requiring treatment to be stopped
  - ⇒ treatment with other first-line antibiotics has failed

Advice for healthcare professionals:

- systemic (by mouth, injection, or inhalation) fluoroquinolones can very rarely cause long-lasting (up to months or years), disabling, and potentially irreversible side effects, sometimes affecting multiple systems, organ classes, and senses
- advise patients to stop treatment at the first signs of a serious adverse reaction, such as tendinitis or tendon rupture, muscle pain, muscle weakness, joint pain, joint swelling, peripheral neuropathy, and central nervous system effects, and to contact their doctor immediately for further advice
- do not prescribe fluoroquinolones:
  - ⇒ for non-severe or self-limiting infections, or non-bacterial conditions
  - ⇒ for some mild to moderate infections (such as in acute exacerbation of chronic bronchitis and chronic obstructive pulmonary disease; please refer to revised indications in the Summary of Product Characteristics) unless other antibiotics that are commonly recommended for these infections are considered inappropriate
- ciprofloxacin or levofloxacin should no longer be prescribed for uncomplicated cystitis unless other antibiotics that are commonly recommended are considered inappropriate
- avoid use in patients who have previously had serious adverse reactions with a quinolone or fluoroquinolone antibiotic