Pharmacovigilance Newsletter

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Capacity building activities on Vaccine Pharmacovigilance.

Ethiopia has started providing COVID-19 vaccine since March 13, 2021 and hence the monitoring of the vaccine safety has gone parallelly. For this purpose healthcare providers who are going to be involved in the detection, reporting and investigation were provided with the necessary training by the EFDA so that they would be better equipped for the detail tasks. In doing so , a total of 4000 participants were capacitated on the Adverse event following Immunization system including all the tools available so that they could use them to detect ,report encountered adverse events and investigate all the serious ones. The capacity building activities were carried out in a cascading form after a TOT was given to trainers and a special training was also prepared for the regional AEFI investigation taskforces.

Topics presented and discussed during the events that covered participants from all the regions in the country were as follows. Additional Adult learning methodology topic was added for the TOT participants.

- ⇒ Overview of National Pharmacovigilance system
- ⇒ Overview of national EPI program
- ⇒ Vaccine and AEFI Concepts and Definitions
- ⇒ National AEFI surveillance system
- ⇒ Investigation of AEFIs and causality assessment

- ⇒ Action and response to serious AEFIs

AEFI monitor-

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 EFDA to healthcare providers working at both the public and private sectors.

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Activities performed in the Pharmacovigilance center

Causality assessment of Serious Adverse Events of Vaccines

Causality assessment is the systematic review of data about a serious adverse event/SAE. It decides the likelihood of a causal association between the SAE and the drug/s or vaccines received.

In Ethiopia, causality assessment of AEFIs is conducted by pharmacovigilance advisory committee that encompasses a broad range of expertise including infectious diseases, pediatrics, epidemiology, microbiology, pathology, immunology, neurology and forensics. The committee is supported by a secretariat which is the pharmacovigilance center of the Ethiopian Food and Drug Authority/EFDA that provides findings of investigations on each case to enable causality to be determined. In the case of SAE after vaccination, the WHO causality assessment categorization system guides a systematic, standardized causality assessment process. At the end of the assessment, cases are classified as follows-

I. Case with adequate information

A. Consistent with causal association to immunization

A1. Vaccine product-related

A2. Vaccine quality defect-related

A3. Immunization error-related

A4. Immunization anxiety-related

B. Indeterminate

B1 Consistent temporal relationship but insufficient definitive evidence for vaccine causing the event

Causality assessment meetings

B2. Reviewing factors result in conflicting trends of consistency and inconsistency with causal association to immunization

C. Inconsistent with causal association to immunization (coincidental)

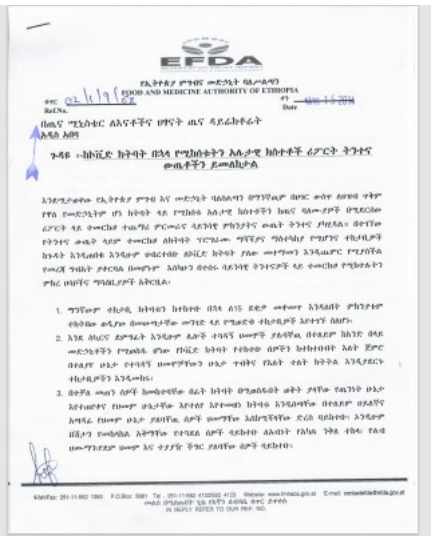
Underlying/emerging condition (s) or condition (s) caused by exposure to something other than vaccine

II. Case without adequate information

It is categorized as “unclassifiable” since it requires additional information to determine causality. Hence until now ,causality assessment was performed on 40 cases of on COVID -19 (28) and Nopv2 vaccine (12) SAEs and classifications were done accordingly. Recommendations were provided by the committee members accordingly.

Recommendations provided after causality assessment meetings

After the causality assessments were done on each of the presented cases, recommendations were provided in an official letter (attached) to the MOH EPI programme for the betterment of the vaccination programmes and the subsequent increase in the public trust on vaccines . Some of the points in this official letter are as follows-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1. Mandatory watching of the vaccinees for 15 mins after vaccination to prevent immediate reactions
2. Strong follow up of vaccinees with chronic diseases.
3. Strong pre-screening
4. Use of appropriate vaccination sites specially for adolescents to prevent vaccination anxiety
5. Health facilities should ask any patient coming for treatment for history of vaccination and act on it

Activities performed in the Pharmacovigilance center

Sensitization workshop on active TB drug-safety monitoring and management (aDSM)

Ethiopia has introduced aDSM as part of the introduction of new TB drugs and novel MDR TB regimens. The implementation of the intermediate package of aDSM and topics related to aDSM are included in the MDR TB management guidelines and training materials. To strengthen aDSM implementation regular discussions among the National TB Program (NTP), Armauer Hansen Research Institute (AHRI), the national Pharmacovigilance center (NPVC), and technical partners (especially the PAVIA project) is ongoing and coordinated support is being provided to Treatment initiating centers/TICs . Despite these efforts,the follow up of drug safety issues include detecting, managing and reporting of adverse events is not adequately practiced at most of the MDR TICs. There exists mainly negligence and skill gapin detecting and reporting o f ADEs related to the use of new TB drugs. Since there is no proper documentation and reporting of ADEs encountered, the overall burden of adversity directly attributable to anti-TB medicines is poorly quantified and it is not usually well profiled in individual TB control programmes. For this purpose, the sensitization programmes were planned.

Sensitization workshops on the implementation of active TB drug-safety monitoring and management (aDSM) were organized on March 29-30/2022 and March 30-April 01/2022 at Robi international and Eftah Hotel, Adama town. A total of (124) participants attended the events including 30TIC's, 12 regional TB programs focal persons, relevant staff members of Ethiopian Food and Drug Authority (EFDA), and focal persons of the national TB Program.

The workshops were officially opened by the Deputy Director of product safety directorate of EFDA, Mr. Teshita Shute. In his speech, he delivered a message on the rationale for active drug safety monitoring for new and repurposed TB drugs. He emphasized that activities on monitoring safety data of these drugs is inadequate and focal persons, especially from MDR TB TICs should be the main players in detecting and reporting those safety data.

During the workshop, presentations on relevant topics were provided with discussions with the participants. In addition, participants practiced on how to record and report data with the existing (paper-based) forms and the newly launched tools (Med safety mobile app and e-reporting).

During the general discussion, participants mainly raised issues related to the shortage of drugs such as RHZE, cycloserine, and the general supply system of TB medicines and ancillary medicines, and supportive supervision of TICs and investigation of the reported SAEs. Finally, reflections on issues raised were given by representatives from EFDA, NTP& EPSA, and general directions given by the representatives of the director of product safety directorate of EFDA W/ro Tigist Dires. She underscored that MDR TICs should focus on identifying and detecting of ADEs, especially for those of new and repurposed MDR TB drugs. She added the national PV center will provide the possible and needed support in this regard.

Some pictures of the programmes are attached below.

National safety update reports

Dissemination of findings on safety monitoring of medicines to stakeholders

A one-day event with a theme: My Medicine, My Vaccine, My safety was organized by EFDA in collaboration with GHSC-PSM to disseminate the findings of medicines safety monitoring on January 2022. The event was attended by 90 participants high and mid-level managers from MOH, EFDA and Regions as well as the national safety advisory committee members. Opening speech was delivered by HE. Dr. Dereje Duguma State Minister, MOH and closing was done by MS. Heran Gerba, DG/EFDA.

1. Summary report of Astrazeneca /Covishield Vaccine-The report provided summary of AEFIs that occur after receiving Covishield Covid-19 vaccine. A total of 15,490 vaccinated individuals were enrolled in the active surveillance and 11476 participants data were eligible for analysis. Majority was from AA, while Harai, Oromia and Amhara share small amount of sample. From these, 4970 (43.3%) Vaccine recipients developed AEFI, 51% are male and 49% female, most of the AEFIs were minor. A total of 29 cases were reported as a serious AEFIs. Twenty-eight of the reported cases were carefully investigated (One become incomplete). 10 were considered as Non-Serious AEFIs, 18 were considered as Serious AEFIS (e.g. hospitalization). causality assessment was done for the remaining 10 serious AEFI cases and categorized as coincidental (4), indeterminate (5) and one was found to be consistent to immunization.

2. Summary report of HPV vaccine. Ethiopia introduced HPV vaccine on Dec. 2018 only to 14 years old adolescent girls. A total of 3064 adolescent girls in 54 selected schools in AA were involved in an Active surveillance where AEFIs were recorded at three follow up periods: 30 minutes, Day 7 and Day 30. Results of AEFIs at three follow up periods; 30 minutes, Day 7 and Day 30 and the AEFI's encountered were 23 (0.8%), 1504 (49%) and 642 (24%) after 30 min, Day 7 and Day 30 follow ups respectively. Most of the observed AEFIs were systemic reactions: headache, fever, fatigue, muscle pain and dizziness. The majority of AEFIs which occurred following the administration of HPV vaccine are mild and transient.

3. Summary report of Medicines for DR-TB management. The safety profiles of new (Bedaquiline and Delamanid) and repurposed (Clofazimine and Linezolid) drugs are not well established and not yet fully understood when used in the MDR-TB regimen for a longer period. Hence, Ethiopia has introduced 'active TB drug-safety monitoring and management' (aDSM) as part of the introduction of new TB drugs and novel MDR-TB regimens. This report presents the description of the national ADE data received by EFDA between 2017-2020. Since 2017, EFDA received a total of 392 valid ADE reports from Treatment centers/ TICs throughout the country. More than 35% (138) of ADEs were GI problems (Nausea & Vomiting, Diarrhea, Epigastric pain, Abdominal pain and cramp) while 14.5% (57) were Neurological problems (Seizure, peripheral neuropathy, numbness, paresthesia, headache & burning sensation). The common comorbidity was RVI, the concomitant medication was ART regimen and the common suspected drug related with ADE are Linezolid, Cycloserine, and all regimens in a proportion of 16.3%, 9.2% and 8.1%. Majority (48%) of the reported cases were mild in severity, with prolonged hospitalization being the most common SAE followed by death (3.8%).

4. Summary report of the ARV medicine Dloutegravir. Since 2019, DTG, class of integrase inhibitors, has been used in Ethiopia as the preferred first line ARV. Since the introduction of DTG, ADE reports experienced by HIV patients have been received by EFDA from health facilities. Until May 2021, a total of 417 ADEs ADE reports were received through the spontaneous reporting from 357 patients taking DTG. Types common ADE include: Insomnia 32.9% (137), Hyperglycemia 20.9% (87), Peripheral neuropathy 9.6% (40), weight gain 8.9% (37), Skin rash/Stephenson Johnson reaction 5.3% (22) and Weight Loss 4.6% (19),