Pharmacovigilance Newsletter

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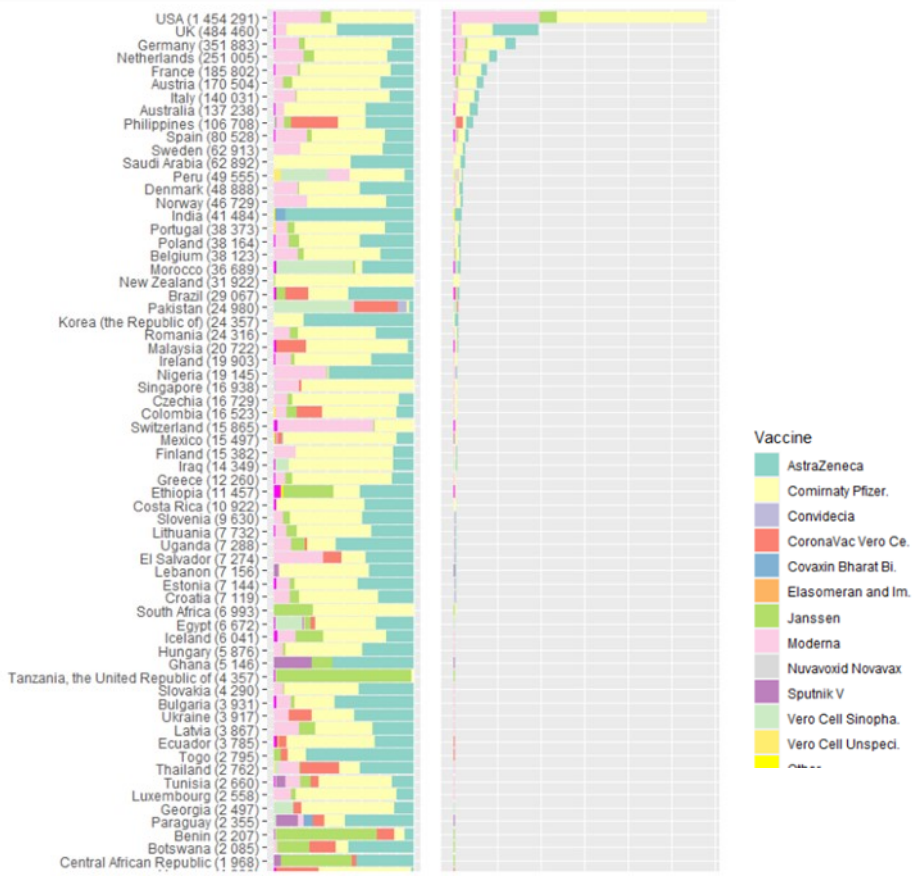
Number of Individual Case Safety reports on COVID-19 vaccine globally

This report presents data on adverse events following immunization with COVID-19 vaccines, based on Individual Case Safety Reports (ICSRs) in VigiBase, the WHO global database of ICSRs. The ICSRs have been submitted by national pharmacovigilance centres which are members of the WHO Programme for International Drug Monitoring (152 countries globally). Uppsala Monitoring Centre (UMC) maintains VigiBase and produces this report to provide aggregated data on ICSRs concerning COVID-19 vaccines, to facilitate identification of any trends in reported events.

This report includes ICSRs added to VigiBase no later than 2022-09-25, where the vaccine is reported as suspected or interacting. Trade and/or manufacturer names of the included vaccines are displayed in the table below, along with the corresponding total number of ICSRs in VigiBase . The graph shows the top 65 member counties that have reported ICSRs to the WHO database/Vigibase. As it can be seen from the following figure, Ethiopia ,out of the 52,000,000 doses that it has been provided to the public, it is found to be 37th/152 member countries in the number of case safety reports it had entered in the global database. *Source(COVID-19 vaccine reporting in VigiBase. Report 20, data extraction date: 2022-09-25. Uppsala Monitoring center)*



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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Results of Active Safety Surveillance of Janssen COVID 19 Vaccine: A National vaccine safety monitoring from Ethiopia

The Janssen (Johnson & Johnson=J&J) COVID-19 vaccine was granted emergency approval by the Ethiopian Food and Drug Authority (EFDA) in May 2021. To ensure that the safety of the vaccine is maintained, ongoing vaccine safety monitoring is important and hence active surveillance was conducted to monitor the safety of J&J COVID-19 Vaccine in the Ethiopian population. The objective of the active safety surveillance was to assess safety of J&J COVID-19 vaccine through evaluating incidence, types and seriousness of adverse events following immunization (AEFIs). The active surveillance was conducted between August 21, 2021 to June 20, 2022 at conveniently selected health facilities from seven regions and two city administrations of Ethiopia. A total of 10,262 adults vaccinated with J&J COVID-19 vaccine were recruited after obtaining their consent. Sociodemographic data and information on comorbidities were collected from participants before vaccination. Participants were observed at the site of vaccination for 30 minutes following immunization. Details about AEFIs occurring within 30 days of follow up period were collected via telephone calls on day 2, 4 and 7 for the 1st week and then weekly on week-2, 3- and 4 by trained data collectors. Data collection process was supervised by experts from the Product Safety Directorate of the EFDA.

The result of the follow up indicated that the overall incidence of AEFIs was 44.51%. 97(2.1%) participants reported encountering immediate AEFIs within 30 minutes of vaccination and injection site pain, headache, fever and nausea/vomiting were the most common immediate AEFIs reported. Of the total 4568 participants who had AEFIs, 4430(97%) reported facing one or more AEFIs after 30 minutes of taking the vaccine. Injection site pain, headache, fever, joint pain and fatigue were the top three types of AEFIs reported. Most of the AEFIs were reported as non-serious. However, 15 AEFI cases were reported as serious. The National pharmacovigilance Advisory Committee reviewed and assessed these serious adverse events reported and classified 8 of them as a vaccine product-related events where immunization with the J&J COVID-19 Vaccine was associated with the occurrence of adverse events in the vaccine recipients.

Based on the result of the assessment it was concluded that the overall incidence of AEFIs with J&J COVID-19 vaccine was 44.51%. Injection site pain, headache, fever,joint pain and fatigue are the most frequent AEFIs reported. As most of the AEFIs were non-serious, based on the available evidence and findings of this active surveillance, the benefits of the J&J COVID-19 vaccine in terms of preventing serious and severe Covid-19 infections and mortality greatly outweigh the rare risk of serious adverse events. However, EFDA is committed to monitor the safety of COVID-19 Vaccines through ongoing review and analysis of all reported adverse events and conducting active surveillances.

Monitoring the safety of vaccines is a process of detecting, reporting ,investigating and analysing adverse events following immunization/AEFI. Using different tools prepared by the EFDA. It s a necessary component towards gaining the confidence of the people so that they could build trust in the immunization programme, get vaccinated and protect their health and that of the society!!!!

So if you are a health care worker, please participate in the process and share your responsibility towards the monitoring of vaccine safety by detecting and reporting AEFI using the tools prepared by EFDA.

If you are a person who has been vaccinated recently by any vaccine and have experienced any side effect, please go to the nearest healthfacility and inform a healthcare worker or report the side effect by using the free toll telephone 8482 that is prepared by EFDA for your use!!!!

Activities performed in the Pharmacovigilance center

Results of Active Safety Surveillance of Pfizer -BioNtech Covid-19 vaccine:A National vaccine safety monitoring from Ethiopia

Vaccines represent one of the greatest public health achievements for combating the COVID pandemic. Although vaccines against SARSCoV-2 have demonstrated excellent safety profiles in clinical trials, realworld surveillance of post-vaccination side effects is an impetus. The Ethiopian Food and Drug Authority (EFDA) is conducting intensive monitoring of COVID-19 vaccine safety using an active and passive surveillance to identify Adverse Events Following Immunizations (AEFIs). EFDA investigates and assesses serious AEFI reports , conducts causality analysis where necessary and take appropriate actions accordingly.

The objective of the active safety surveillance was to investigate the incidence, type and seriousness of adverse event following the administration of the first dose of the Pfizer-BioNTech vaccine in Ethiopia.

A multicenter prospective cohort event monitoring study design was used to collect the data using active surveillance from five regions and two city administrations of Ethiopia. A total of 10,947 were in enrolled with Pfizer vaccine obtaining their consent. Participants were observed at the site of vaccination for 30 minutes following immunization. Details about AEFIs occurring within 30 days of follow up period were collected via telephone calls on every other day (on day 2,4,7) for the first week and then weekly (on week-2, 3 and 4) by 4 trained data collectors from each site. Data collection process was supervised by Experts from the Product Safety Directorate of the EFDA and other exerts from EFDA Branch offices. The data was collected from selected 24 health facilities from November 15, 2021 to March 28,2022.

The result showed that out of a total 10,947 active surveillance participants, 3851 (35.18 %) vaccine recipients reported at least one AEFI symptom following COVID -19 vaccination. The mean (±SD) age of the participants was 16(10.5) years and more than half (56.6 %) of them were females. From the total, only 69 (0.6%) of them had one or more comorbidities. Of which, hypertension (17, 24.6%) and diabetes (15, 21.7%) were the most frequent comorbidities. From a total of 3851 participants with AEFI, the occurrence of AEFI before and after 30minutes of post vaccination were 83 (2.2 %) and 3603 (94.1%), respectively. Of which, injection site pain/redness/swelling (48.68%) and headache (18.62%), were the most frequently reported AEFIs after 30 minutes of vaccination. Out of a total participant who reported experiencing AEFI, a total of 4531 AEFI were reported. The rate of reports of AEFI was 1.26 per person. Injection site pain/redness/swelling (48.02%), headache (17.15 %), fever (9.50%), body weakness/ tiredness/ fatigue (3.14%) and arthralgia/joint pain (2.57 %) were the top five types of AEFIs reported by the active surveillance participants. Among serious AEFIs cases, 7 were requiring hospitalization and then fully recovered, whereas, one AEFI result in death. The National Pharmacovigilance Safety Advisory committee reviewed the serious cases and classify as follows, 4 cases were in consistent/product related, 3 cases were coincidental, and one case was indeterminate (1) to Covid-19 vaccine. Conclusion and Recommendations: More than one-third of the participants experienced one or more AEFIs. Most AEFI were generally mild to moderate and frequently reported after 30 minutes of vaccination. Most of the AEFI encountered were in the age group of 12 to 18. Therefore, these AEFI are not a significant concern in recommending vaccination.

Report adverse events following Immunization/AEFI by using one of the following tools

1. Yellow card reporting form
2. AEFI reporting form
3. E-reporting established by EFDA (available at the website www.fmhaca.gov.et-serivces-e-Reporting ADR)
4. Mobile application (Medsafety mobile app to be downloaded from play store/app store)
5. Email address (e-mail : pharmacovigilance@efda.gov.et)

Activities performed in the Pharmacovigilance center

Training on possible product quality defect detection and reporting of medicines including COVID 19 vaccines through the Passive ADE Reporting System at EFDA

Monitoring the quality of products available in the marketplace should identify products that are defective, deteriorated, or adulterated because of poor manufacturing practices, inadequate distribution, and storage, or tampering. As it stands now, reporting vaccine related quality defects using such system is not being practiced - but can be a very valuable source of information to gather quality related data on regular basis. For this purpose, EFDA in collaboration with USP/PQM+ organized a two-day training programme from August 23-24 /2022 at, Tokuma hotel, Adama. The objective of the programme was to strengthen product defect detection and reporting through the passive/Spontaneous Adverse Drug Event (ADE) reporting system to include COVID-19 vaccine by providing training to selected health workers at COVID-19 active surveillance sites. Training was given to the participants using topics ; Overview of the National Pharmacovigilance system, National AEFI monitoring system- AEFI reporting, Investigation, causality and tools, Results of vaccine active surveillance on AstraZeneca vaccine, Inspection report of cold chain system in selected health facilities in Ethiopia, Cold chain management of COVID-19 vaccine at distribution sites and the supply chain, and Cold chain management at health facility level to ensure their the vaccine quality and safety. The topic presenters were selected from the pharmacovigilance center of EFDA, Facility inspection directorate of EFDA, Maternal and child health directorate of the ministry of Health and the Ethiopian pharmaceutical Supply service.

Some of the questions and suggestions raised during the training were: There is a delay from the Authority in contacting a reporter. We need to obtain timely feedback on the reported PQD from the EFDA; Many of the important information like patient details, vaccine or product batch number are not properly documented at health facilities; Regionals Health bureaus should strengthen Supportive supervision and Immunization should be assessed as one component. It would be useful to be evaluate the cold chain management through a standard checklist, this will solve the problems observed on Documentation, detection, and reporting; Reporting of a PQD on COVID-19 vaccines should be As soon as possible; There is a misunderstanding of the receiver of a PQD report as the immunization programme are also requesting the report to be sent to them; Stakeholders that are involved in the vaccination programme (the Public health emergency programme, the Immunization programme and the regulatory need to integrate to work on the monitoring of PQD of vaccines; There is a difficulty in ensuring the reconciliation of vials after the vaccines are used and so the Ethiopian Pharmaceuticals Supply Service should provide information to all healthcare facilities about vial reconciliation to ensure that empty vials are not used to produce counterfeit vaccines; Calibration of reading of fridge thermometers is not being done for most of healthcare facilities and availability of fridge tags need also be seen; Some facilities will receive vaccines that are beyond the capacity of the cold chain equipment in the health facility; When the vaccines are received, documents with important information like expiry date should be sent from the EPSS to the health facilities. Otherwise, relabelling can be a problem. Below are some pictures from the training programme.