Pharmacovigilance Newsletter

Quarter 2, Issue 1

January 2025

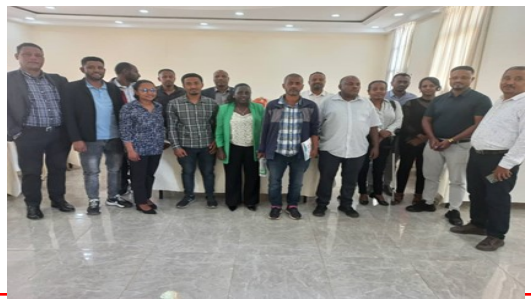
EFDA Participated in Regional Pharmacovigilance Training and Experience Sharing Events

EFD's pharmacovigilance expert participated in the continental and international trainings and experience sharing events held in Ghana, Nigeria and India. These training and events offered a comprehensive global perspective on pharmacovigilance, enabling them to grasp the diverse challenges and opportunities encountered by various countries. Engaged in discussions about efforts in medicine safety monitoring, pharmacovigilance inspection and post-marketing surveillance studies, provided insights into our pharmacovigilance system's structure, functions, and challenges. EFDA's experiences and best practices were also shared with regional and international colleagues' illuminated areas for improvement in pharmacovigilance. These events underscored the importance of harmonization and collaboration among countries within the continent to strengthen pharmacovigilance systems and enhance patient safety.

EFDA Conducted Pharmacovigilance Stakeholders Meeting

This pharmacovigilance stakeholder meeting was conducted on 22 October 2024 as per its establishment TOR to review pharmacovigilance activities and also amend TOR. Different achievements on activities related to medicine safety monitoring during the 2016 Ethiopian Fiscal Year (EFY) were discussed, the challenges encountered were highlighted and key focus areas for the current 2017 EFY were also presented. After both presentations, a thorough questions and discussions conducted.

The final session of the workshop focused on presenting and signing of the revised stakeholders' TOR. The amended sections and their justifications, including changes to the frequency of meetings, the list of pharmacovigilance stakeholders, and the naming of positions within the Desk, were discussed. After the discussions, participants signed the TOR, and it was shared with members.



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

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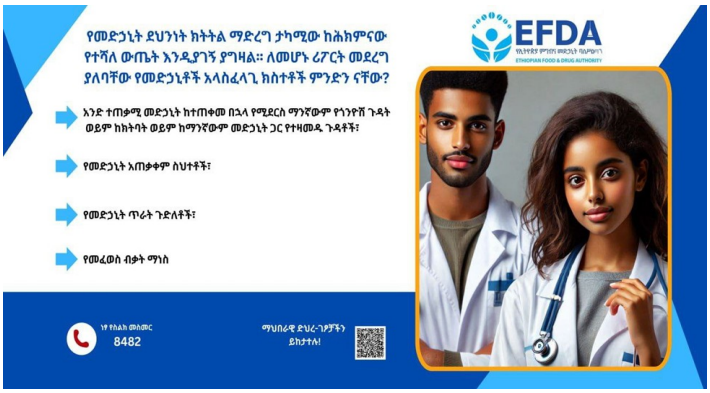
Activities Performed by the Pharmacovigilance Center

EFDA Celebrated Global MedSafety Week

MedSafetyWeek is a global campaign that aims to raise awareness about the importance of reporting suspected side effects from medicines to regulatory authorities, encouraging patients and healthcare professionals to report any adverse reactions they experience while taking medications. EFDA celebrated the 2024 MedSafey week, from November 4–10/204 with the theme of "**Preventing Side Effects**", by conduction different public awareness campaigns in different local languages.

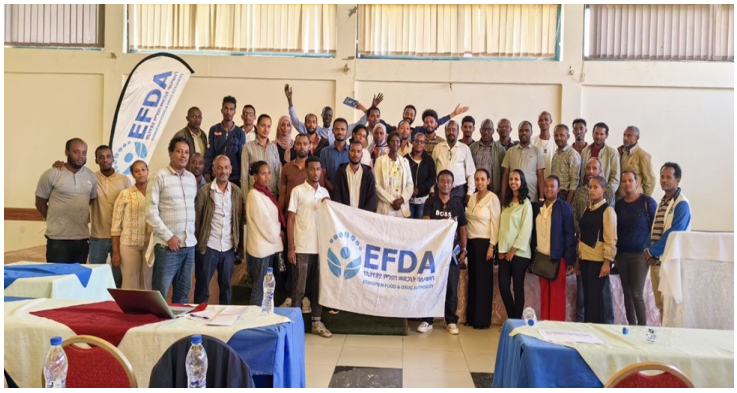


EFDA Provided Vaccine Safety and aDSM Trainings for Healthcare Professionals

The Ethiopian Food and Drug Authority (EFDA) recently conducted a two-days training on monitoring of Adverse Events Following Immunization (AEFI) for 85 health professionals from the Benishangul-Gumuz and Tigray regions. Participants were representatives from Regional Health Bureaus, regulatory bodies, Woreda health offices, hospitals, and health centers. During the training, attendees provided feedback on the challenges, and discussed future steps to enhance vaccine safety and AEFI monitoring.

In addition, the authority organized sensitization workshops on active Drug Safety Monitoring and management (aDSM) for healthcare professionals at MDR TB Treatment Initiation Centers (TICs) in Dessie and Jimma towns. A total of 88 participants (33 from the Amhara and 55 from the Oromia regionS) attended the workshop. The workshops targeted clinicians, nurses, and pharmacists involved in the management of MDR TB. Key topics covered included an overview of pharmacovigilance and the national PV system, updates on MDR TB/Programmatic Management of Drug-Resistant Tuberculosis (PMDT), treatment protocols for MDR TB and patient monitoring, detection, management and reporting of Adverse Drug Events (ADEs). Finally, participants engaged in discussions and experience-sharing sessions and a way for ongoing support to healthcare professionals in enhancing drug safety monitoring.

The training effectiveness assessment indicated both trainings significantly improved participants' awareness of AEFI monitoring, aDSM of MDR-TB treatment and clarified their roles in promoting medicine safety including vaccines.

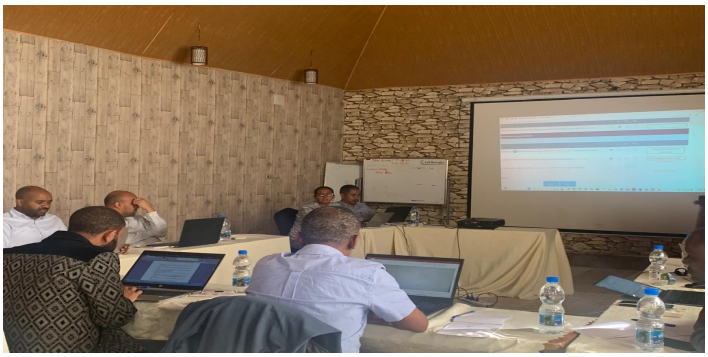


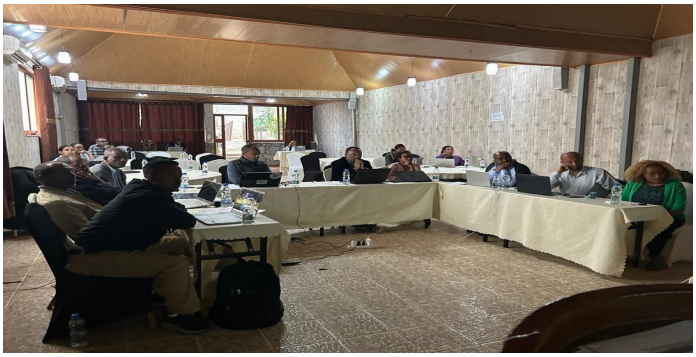
Activities performed in the Pharmacovigilance center

EFDA Conducted Causality Assessment of Serious Adverse Events

The Ethiopian Food and Drug Authority (EFDA) is responsible for ensuring that all pharmaceutical products, including vaccines, used in the country are of high quality, effective, and safe. The national pharmacovigilance center at EFDA coordinates the monitoring of pharmacovigilance activities and Adverse Events Following Immunization (AEFI). EFDA is committed to safeguarding patient safety and fostering trust in medication use. Serious adverse events, cluster adverse events, and unexpected events that deviate from a product's known safety profile are thoroughly investigated and undergo causality assessments.

From January 2 to 3, 2025, the National Pharmacovigilance Advisory Committee (PAC), comprising experts from various specialties, assessed 19 adverse events. The committee issued decisions and recommendations based on the causality assessment findings to enhance pharmacovigilance practices and safeguard public health.





EFDA Took Regulatory Actions on Artemether+ Lumefantrine Dispersible Tablet

Based on the Post Marketing Survey (PMS) result, EFDA has been taking different regulatory actions in order to protect the public from medicine related harms. PMS carried out from July 16 – 25, 2024 identified for batches of Artemether+ Lumefantrine dispersible tablet from different manufacturers (Brand: Artefan 20/120, Batch No: PA04254, Manufacturer: Ajanta Pharma Limited, Brand: LARTEM, Batch No: AR23102, Manufacturer: Skant Healthcare Limited, India, Brand: COMETER, Batch No: 24EY, Manufacturer: KPC pharmaceutical Inc, China, and Brand: CachART20/120, Batch No: CHRT24005E, Manufacturer: Cachet Pharmaceutical PVT. Ltd, India) with substandard active ingredient. EFDA had made a product recall decision with Artemether+ Lumefantrine Dispersible tablet the above mentioned batches and suspension of the market authorization holders for one month.

EFDA Vaccine Safety monitoring in Vaccination Campaigns

The Ethiopian Food and Drug Authority (EFDA) has been actively involved in detecting and reporting Adverse Events Following Immunization (AEFI) to ensure the safety, efficacy, and quality of vaccines. In line with its mandate, EFDA oversaw the safety monitoring of the HPV and nOPV2 vaccination campaigns recently conducted by the Ministry of Health and the Ethiopian Public Health Institute. Adverse event detection and reporting were integrated into the vaccination campaign, with daily feedback provided throughout the campaign to enhance real-time monitoring and response

National and International Medicine Safety Updates

Safety Updates on Prednisolone Misuse

Recent social media trends have dangerously promoted the misuse of prednisolone, falsely claiming it effectively reduces hip and general obesity. The Ethiopian Food and Drug Authority (EFDA) warns that using prednisolone without a doctor's prescription and supervision can lead to severe health complications or even death. These risks are well-documented and scientifically proven. We strongly urge everyone to exercise caution and adhere to the proper use of this medication

Safety Updates on Tegretol® (Carbamazepine) Use

Novartis Pharma Schweiz AG, the market authorization holder/manufacturer, has notified the Ethiopian Food and Drug Authority(EFDA) that Tegretol® (carbamazepine) 100 mg/5ml Oral Suspension (0S), is no longer recommended for neonates (below 4weeks of age for term babies or 44 weeks post-menstrual age for pre-term babies) due to the amount of propylene glycol (PG) in this formulation. Propylene glycol, one of the excipients in this product, is generally recognized as safe by the US Food and Drug Administration (FDA) for uses in food and tobacco products, pharmaceuticals, and cosmetics. However, the amount in this product is beyond the safety limit for neonates mentioned in this alert letter. Therefore, the Authority (EFDA) requests all health professionals to avoid prescribing and dispensing the medicine for neonates.

Safety Updates on Artemether

During a recent market survey, the EFDA identified Artemether80 mg/ml injection (Batch No. 231104SPF, manufactured in November2023 by Shinepharm, China) that was not registered by the authority. Laboratory analysis of a sample taken from the market revealed that the product did not contain the active ingredient, Artemether. In response, the EFDA has advised health professionals and the public to avoid using this medicine the above specified batch No. The authority has also instructed regional inspectors at all levels to take appropriate measures by implementing strict monitoring in their respective areas.

.Safety Updates on "RELIEF"

The Ethiopian Food and Drug Authority (EFDA) would like to alert the public to the circulation of an illegal drug named "**RELIEF**" in the Ethiopian market. This unregistered product is supposed to contain a combination of Diclofenac, Paracetamol, Chlorpheniramine, and Magnesium Trisilicate. Due to its unverified quality, safety, and efficacy, using this drug may pose significant health risks. The EFDA strongly advises against purchasing or using "RELIEF"

.Safety Updates on Immunoglobulina Humana Anti-D (Rho) 5% solution

The Ethiopian Food and Drug Authority (EFDA) has received a market complaint regarding an illegal medicinal product: Immunoglobulina Humana Anti-D (Rho) 5% solution, Batch No. 11369C, manufactured in October 2023 by Pare Medicbai a Hanan, Cuba. Upon assessment, the EFDA found that this product does not meet any established standards, rendering it falsified and substandard. The authority alerts healthcare providers and the public to avoid using this out-of-specification medicinal product and report immediately when encounter.