Quarter 1
SEPTEMBER 2025

Pharmacovigilance Newsletter

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 & other stakeholders

INSIDE THIS ISSUE

EFDA Strengthens Pharmacovigilance Capacity Through Data Management and Analysis Training

The Ethiopian Food and Drug Authority in collaboration with its partners, successfully conducted a four-day Pharmacovigilance Data Management and Analysis Training from July 17–20, 2025, in Adama Town, Ethiopia. The training brought together Pharmacovigilance experts working at the national centre to enhance their technical capacity in monitoring medicine and vaccine safety.

The program addressed a critical need to strengthen national capacity in managing vaccine safety and adverse drug reaction (ADR) data. It focused on building participants' skills in systematic data collection, accurate documentation, and the effective utilization of safety data to support evidence-based regulatory and public health decision-making.

Throughout the training, participants gained both theoretical and practical experience in data cleaning, validation, and analysis using R, an open-source statistical software. By the end of the program, they were equipped to identify and document adverse events following immunization (AEFI) using standardized tools, conduct trend analyses, and provide timely feedback to reporting sites. These enhanced competencies are expected to significantly improve Ethiopia's Pharmacovigilance system by enabling early detection of safety signals, strengthening data-driven decision-making, and supporting the national immunization program and medicine safety monitoring efforts.

EFDA Holds Consultative Forum to Strengthen Management of Medicinal Product Quality Defect Reports

The Authority held a consultative forum on September 5, 2025, in Addis Ababa, bringing together key stakeholders to discuss strategies for improving the management of medicinal product quality defect reports. The event aimed to raise awareness of EFDA's post-market surveillance processes and responsibilities while fostering stronger collaboration among regulators, manufacturers, importers, distributors, and healthcare providers. A total of 40 participants representing medicine manufacturers, importer-distributors, and relevant EFDA departments attended the forum.

During the session, participants were briefed on various types of medicine quality defects and the associated public health risks, including treatment failure, patient harm, and loss of confidence in the healthcare system.

Presentations titled "Overview of Product Quality Defect" and "SOP for the Management of Complaints Related to Quality Defects of Medicines" highlighted EFDA's risk-based investigation approach, which encompasses laboratory testing, market surveillance, and regulatory measures such as product recalls and suspensions. The forum also featured a review of past complaint cases and current regulatory guidelines, followed by open discussions on best practices and areas for improvement.

In conclusion, participants expressed strong support for EFDA's leadership in ensuring product quality and emphasized the need for continuous stakeholder engagement. Key recommendations included conducting regular awareness and training programs on quality defect reporting, appointing focal persons

at health facilities to facilitate prompt reporting, and encouraging timely submission of reports through Qualified Persons Responsible for Pharmacovigilance (QPPVs) at Marketing Authorization Holders (MAHs).

EFDA was encouraged to incorporate these recommendations to further strengthen regulatory oversight and ensure that all medicines circulating in Ethiopia meet the highest standards of quality, safety, and efficacy.

EFDA Experts participated in Signal Detection and Multi-Country Data Validation

Two pharmacovigilance experts from EFDA participated in a Signal management training workshop held from September 2-4, 2025, in Nairobi, Kenya. The workshop, organized under the African Union Smart Safety Surveillance (AU-3S) program, brought together representatives from 21 African countries to strengthen regional cooperation in medicine safety surveillance. The training focused on adopting a decentralized approach to signal detection and validation for priority medical products, aiming to enhance the timeliness and effectiveness of pharmacovigilance activities across the continent.

Participants engaged in both theoretical sessions and practical exercises on identifying and validating safety signals using the AU-3S Safety Connect data management system, a platform designed to facilitate cross-country data sharing and analysis. EFDA's participation in this regional initiative demonstrates its ongoing commitment to advancing national pharmacovigilance capacity while contributing to continental collaboration in medicine safety monitoring. Strengthening such partnerships is vital to improving public health outcomes and ensuring the quality, safety, and efficacy of medicines across Africa.

Ethiopia achieves World Health Organization Maturity Level 3 Status for National Medicines Regulatory System

Ethiopia has reached a significant public health milestone by achieving Maturity Level 3 (ML3) in the World Health Organization's (WHO) global classification of national regulatory authorities, a recognition awarded to countries with stable, well-functioning, and integrated regulatory systems.

This designation follows a comprehensive assessment by WHO using its Global Benchmarking Tool, which evaluates regulatory performance across more than 250 indicators. With this achievement, Ethiopia becomes one of only nine countries in Africa to attain ML3 status,

reflecting the Ethiopian Food and Drug Authority's (EFDA) strong commitment to regulatory excellence and public health. It confirms that the country has the capacity to effectively authorize medical products, conduct market surveillance, and monitor safety events in line with international standards.

Reaching ML3 brings wide-ranging benefits for Ethiopia's health system and its people.

It strengthens public confidence in the safety, quality, and efficacy of medicines and vaccines available in the country. It also positions Ethiopia to expand local pharmaceutical production and participate more actively in regional and global regulatory initiatives. Moreover, this progress supports the broader African agenda of improving access to essential, quality-assured medical products and building self-reliant, resilient health systems across the continent.

Pharmacovigilance Advisory Committee (PAC) Meeting Held at Bishoftu

The national Pharmacovigilance Advisory Committee meeting was held from August 5 to 6, 2025. During the two-day session, the committee reviewed 20 serious adverse events associated with various conventional medicines and vaccines using the WHO standardized causality assessment tool. Out of the reviewed cases, 18 were classified, with 13 related to vaccines and the remaining 5 linked to medicines.

The committee emphasized the importance of experience sharing with other countries regarding assessment and causality a classification, particularly for cases submitted with limited information.

To address the challenge of incomplete documentation, PAC also recommended the development of a well-designed verbal autopsy tool to supplement cases lacking adequate medical records and detailed reports. These recommendations aim to strengthen the accuracy and reliability of Ethiopia's pharmacovigilance system and enhance national capacity in monitoring medicine and vaccine safety.

Pharmacovigilance Training Empowers 240 Healthcare Professionals at three regions

The Ethiopia Food and Drug Authority (EFDA) successfully conducted pharmacovigilance training sessions for healthcare professionals from August 7 to 23, 2025.

The initiative reflects EFDA's strong commitment to safeguarding public health by building a robust pharmacovigilance system across all levels of healthcare.

The trainings, held in 5 separate sessions across 3 regions lasting three days, the sessions brought together a total of 240 participants from pharmacovigilance center, public hospitals and health centers in selected zones.

The training focused on capacitating health professionals in the detection, assessment, reporting and prevention of adverse events.

By equipping front line healthcare workers with essential skills, EFDA aims to enhance timely and accurate adverse event reporting and improve patient safety nationwide

National and International Medicine Safety Updates

Safety update on Cetirizine, levocetirizine: Risk of severe itching after discontinuation of long-term use

The US-FDA has warned that patients stopping the oral allergy medicines cetirizine (Zyrtec®) or levocetirizine (Xyzal®) after long-term use may experience rare but severe itching, also called pruritus. The itching has been reported in patients who used these medicines daily, typically for at least a few months and often for years. Reported cases were rare but sometimes serious, with patients experiencing widespread, severe itching that required medical intervention.
Therefore, EFDA also would like to emphasize the need for health care professionals to advice patients to contact health-care professional immediately if developing severe itching after stopping cetirizine or levocetirizine.

Safety update on Carbamazepine: Potential risks of born small for gestational age or with microcephaly

The Medsafe of New Zealand has updated the product information for carbamazepine (Tegretol®) to include the risks of the baby being born small for gestational age or with microcephaly (baby's head is smaller than expected). The risks of microcephaly and small for gestational age were recently noted in an observational study using registry data from the Nordic countries.
Hence, healthcare professionals are required to advice patients who could get pregnant to use effective contraception while taking carbamazepine and for two weeks after the last dose.

Safety update on Sulfamethoxazole, trimethoprim: Risk of circulatory shock

Cases of circulatory shock, often accompanied by fever and not responding to standard treatment for hypersensitivity, have been reported with the use of combination products of sulfamethoxazole and trimethoprim (also called as cotrimoxazole), mainly in immuno-compromised patients. The Pharmacovigilance Risk Assessment Committee (PRAC) of EMA has recommended to update the product information to include the risk of circulatory shock. Hence, EFDA strongly recommends healthcare professionals to advice patients to immediately visit healthcare facilities
If experiencing multiple symptoms such as fever, very low blood pressure or increased heart rate after taking this medicine as it may be a sign of shock.

Regulatory Action: Recall of Oxytocin solution for injection

As part of its core mandate, the Ethiopian Food and Drug Authority (EFDA) ensures that all medicinal products in the country are safe, effective, and of assured quality to protect public health. In line with this mission, EFDA conducts routine risk-based post-market quality surveillance to monitor medicines throughout their lifecycle. During recent surveillance, laboratory testing of oxytocin injection samples revealed that a specific batch failed to meet required quality standards. Consequently, EFDA has announced the recall of Oxytocin Solution for Injection, batch number 1721222 (manufacturing date: 12/2022; expiry date: 12/2025), with JSC Grindeks as the Market Authorization Holder and UAB Santonika, Lithuania as the manufacturer. Regional regulators were immediately communicated to ensure implementation of the recall, Health professionals and institutions were urgently advised to stop using and dispensing this batch, quarantine any remaining stock, and follow EFDA's guidance to ensure patient safety.

Medical product alert: Falsified Medicines

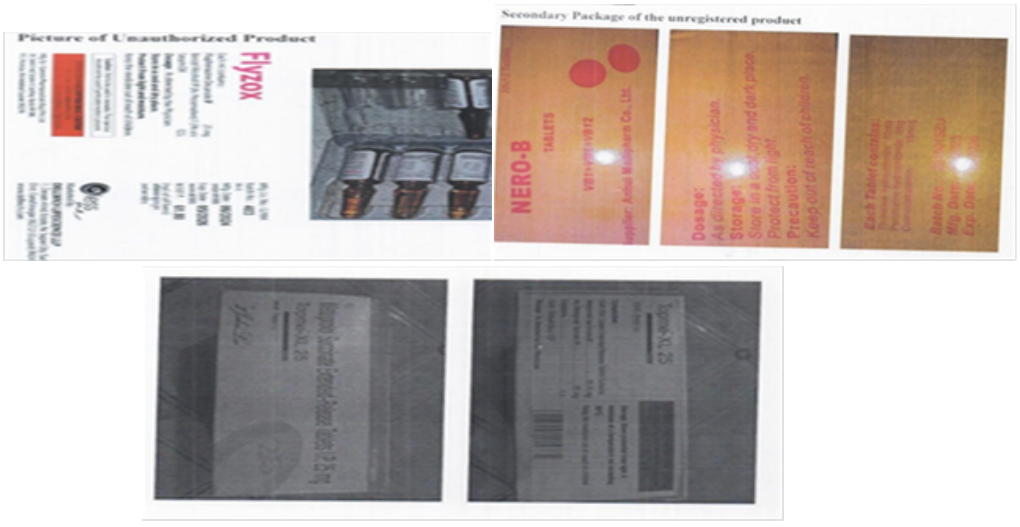
The Ethiopian Food and Drug Authority (EFDA) conducted market surveillance following product quality defects (PQD). The Authority assessed complaints, investigated and did market surveillance to confirm the circulation of the products in the market. The investigation indicated the Products are unauthorized to market by the Ethiopian Food and Drug Authority.

- Fluphenazine Decanoate (Flyzox) 25mg/ml injection,

Batch number: 403, Manufacturing Date: 06/2024, Expiry Date 05/2026, Stated Manufacturers, Care Win Pharmaceuticals PVT. Ltd. India, Marketed by: DELLWICH LIFESCIENCE LLP

- NERO-B (VB1+VB2+VB12; Thiamine 10mg + pyridoxine Hydrochloride 3 mg + Cyanocobalamin 15mcg) tablet, Batch number: 23100ISZU, Manufacturing date 13/2023, Expiry Date 13/2026, Manufacturer not stated, Supplier Anhui Medipharma C. Ltd.
- Metoprolol Succinate (Topme-XL25) extended- release 25mg tablet, batch number: 40921, Manufacturing date 12/2024, Expiry date 11/2026 and manufactured by IUNIZA LIFE CARE PVT.LTD

The listed products are not effective and should not be used.



The Authority intends to Alert healthcare providers to detect and remove circulation and administration of unauthorized products. The regional regulatory authority needs to monitor the circulation and use of unauthorized and substandard products. By searching for the specific product on eRIS and contacting the medicine Evaluation and Market Authorization LEO to inquire about its market authorization status.