



# Pharmacovigilance Newsletter



## INSIDE THIS ISSUE

page

**EFDA Hosts Pharmacovigilance Training and Recognizes Top Reporters**

1

**EFDA Launches Active Safety Monitoring for Key Vaccines and Treatments Nationwide**

2

**EFDA Establishes 12th Regional Pharmacovigilance Center at Mizan-Tepi University Teaching Hospital**

3

**EFDA Convenes High-Level Advocacy Meeting to Bolster National Pharmacovigilance**

4

**National Pharmacovigilance Advisory Committee (PAC) Reviews Serious Adverse Events in Bishoftu**

5

**Ethiopia Celebrates MedSafety Week, 2025**

5

**National and International Medicine Safety Updates**

6

**Medical product alert: Falsified Medicines**

7

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

### **EFDA Hosts Pharmacovigilance Training and Recognizes Top Reporters**

The Ethiopian Food and Drug Authority (EFDA), in collaboration with its partners, successfully conducted a two-day capacity-building training and recognition program for top reporters from December 17 to 21, 2025, in Adama. The event gathered high-performing adverse event reporters from all regions and city administrations.

The program aimed to recognize outstanding contributions to adverse drug reaction (ADR) and adverse events following immunization (AEFI) reporting during the 2017 Ethiopian Fiscal Year (EFY), while strengthening technical capacity and sustaining motivation for high-quality reporting.



A total of 94 reporters participated across two rounds. The program enabled participants to share experiences, discuss challenges, and develop action plans.

The training concluded with a certification ceremony and a strong commitment to improve PV reporting nationwide.

### **EFDA Launches Active Safety Monitoring for Key Vaccines and Treatments Nationwide**

On September 18, 2025, the Federal Ministry of Health (FMoH) launched the R21 malaria vaccine in malaria-endemic areas of the country to complement existing prevention and control efforts. Although the vaccine demonstrated a strong safety profile during clinical trials and pilot programs in other African countries, it is a new introduction to the Ethiopian population. Therefore, rigorous monitoring through both active safety monitoring programs and routine pharmacovigilance systems is critical. To this end, the Ethiopian Food and Drug Authority (EFDA) has launched a malaria vaccine safety monitoring program in 16 health facilities across endemic regions.

The Ministry recently introduced the HepB zero dose vaccine into the routine immunization program in various parts of the country. Data collectors and supervisors have been trained on the relevant data collection tools and processes.

Additionally, a third active safety monitoring initiative has begun for treatment and prophylaxis medications used during the current Marburg outbreak. Monitoring has commenced at Jinka Hospital for both monoclonal antibody treatments and Remdesivir. This program will continue until the target sample size is reached.

The EFDA has also initiated active safety monitoring in selected health facilities regarding Hepatitis B "zero dose" vaccinations.

## EFDA Establishes 12th Regional Pharmacovigilance Center at Mizan-Tepi University Teaching Hospital

To enhance the accessibility and efficiency of medicine safety monitoring, the EFDA has been establishing pharmacovigilance centers at major university teaching hospitals across the country. These centers serve as regional hubs coordinating pharmacovigilance activities, collecting and analyzing reports of adverse drug reactions (ADRs), and promoting rational medicine use.

The official launching ceremony for the Pharmacovigilance Center was held on October 21, 2025, at Mizan-Tepi University Teaching Hospital, located in Mizan-Aman City, South West Ethiopia Peoples' Region.

The event included a face-to-face discussion session with healthcare professionals and hospital management, followed by an official launching ceremony. A total of 60 participants attended the event, including experts from EFDA, the South West Ethiopia Peoples' Region Health Bureau, Mizan-Tepi University Teaching Hospital management, physicians, pharmacists, nurses, and other healthcare professionals.



## EFDA Convenes High-Level Advocacy Meeting to Bolster National Pharmacovigilance

A high-level advocacy meeting aimed at strengthening the national pharmacovigilance (PV) system was held from November 13 to 14, 2025, in Adama. Participants included heads of regional health bureaus, regional regulatory bodies, EFDA branch directors, and representatives from professional associations and non-governmental organizations.

The primary focus of the meeting was to identify regional challenges in pharmacovigilance activities and formulate strategic recommendations. The meeting was officially opened by Mr. Seyoum Wolde, Deputy Director General of the EFDA.

In his opening remarks, Mr. Seyoum emphasized that regional health bureaus and regulatory bodies must take ownership of PV activities and allocate the necessary resources. He acknowledged the significant contributions of regional partners in helping Ethiopia achieve WHO Maturity Level 3 (ML3) in regulatory performance. Mr. Seyoum noted that while formal pharmacovigilance efforts began in 2008, the transition from EFMHACA to the current EFDA structure marked a pivotal shift in oversight. He further highlighted that through consistent evolution and successful audits in 2023 and 2025, the national system has reached a high level of technical maturity.



## National Pharmacovigilance Advisory Committee (PAC) Reviews Serious Adverse Events in Bishoftu

The National Pharmacovigilance Advisory Committee (PAC) met from November 25 to 26, 2025, in Bishoftu. The committee reviewed 16 serious adverse events linked to various conventional medicines and vaccines using the WHO standardized causality assessment methodology.

A total of 14 cases were successfully classified. The remaining two cases involving conventional medicines could not be categorized due to insufficient or incomplete information.

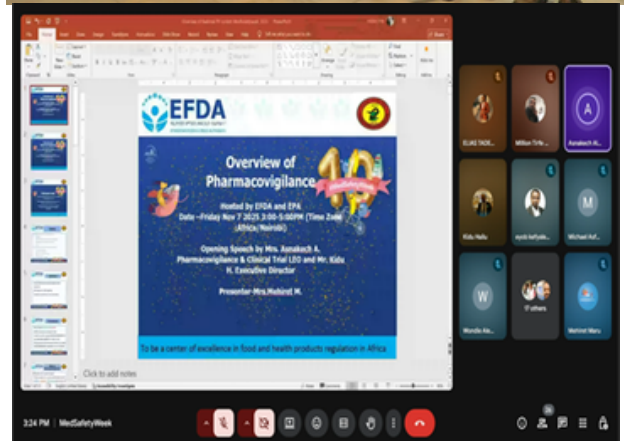
Among the seven vaccine-related cases, six were determined to be vaccine product-related, and the remaining case was found to be coincidental.

The PAC recommended that the Authority publish analysed trends and active surveillance data for all four COVID-19 vaccines. The committee also recommended developing or adopting a standardized Drug-Induced Liver Injury (DILI) classification algorithm for use in Ethiopia. Additionally, the PAC suggested revising the current WHO-UMC causality assessment tool to better accommodate the classification of procedural errors in vaccine administration.

## Ethiopia Celebrates MedSafety Week, 2025

The World Health Organization (WHO) Programme for International Drug Monitoring and the Uppsala Monitoring Centre (UMC) collaborate to organize MedSafety Week, a global awareness campaign.

As the national regulatory body, the Ethiopian Food and Drug Authority (EFDA) effectively observed MedSafety Week from November 3–9, 2025, in accordance with this international movement by organizing a number of coordinated communication, advocacy, and capacity-building events.



# National and International Medicine Safety Updates

## Safety update on Amphotericin B (lipid formulations): Risk of Hyperkalaemia



The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicine Agency (EMA) has recommended updating the product information for amphotericin B (lipid formulations, AmBisome® and Abelcet®) to include the risk of hyperkalaemia. PRAC has also agreed that no further action is deemed warranted at this stage for non-lipid amphotericin B, of which product information already includes the risk of hyperkalaemia.

## Potential Safety Signal: Use of Bisoprolol and Potential risk of hyperkalaemia



The Saudi Food & Drug Authority (SFDA) has released a safety signal concerning use of bisoprolol and potential risk of hyperkalaemia. The SFDA has detected this signal and reviewed all the evidence available. The SFDA's investigation concluded that the current available evidence from assessment of the ICSRs, data mining and literature might support a relationship between bisoprolol and hyperkalaemia. This signal needs further investigation to confirm the risk, and health-care professionals should be aware of this potential adverse reaction.

## Potential Safety Signal: Use of Testosterone and Potential risk of atrial fibrillation



The SFDA has released a safety signal concerning use of testosterone and potential risk of atrial fibrillation. The SFDA initiated this investigation after detecting a published article linking atrial fibrillation to testosterone. The SFDA also looked into the WHO VigiBase to find related cases of atrial fibrillation, which resulted in 330 ICSRs reported internationally. Additionally, atrial fibrillation is listed in the section of reported adverse reactions in the Canadian product monograph. The SFDA's investigation concluded that the current available evidence might support a relationship between testosterone and atrial fibrillation. This signal needs further investigation to confirm the risk; however, health-care professionals should be aware of this potential adverse reaction.

## Regulatory Action: Recall of Pantoprazol Denk 20 mg gastro-resistant tablet



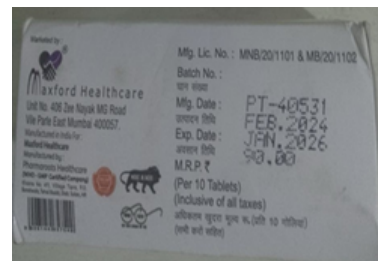
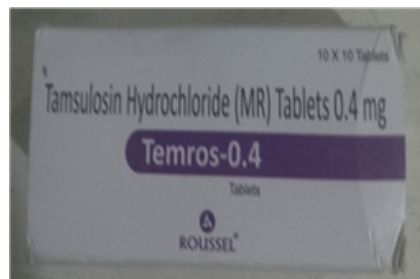
As part of its core mandate, the Ethiopian Food and Drug Authority (EFDA) ensures that all medicinal products in the country are safe, effective, and of assured quality to protect public health. Based on this, a report was received from the World Health Organization's Rapid Alert System indicating that an Out-Of-Specification (OOS) result was found on batches number 5383, 5452, 5381, and 5599 of the medicine Pantoprazol Denk 20 mg gastro-resistant tablet (INN: Pantoprazole Sodium Sesquihydrate). This finding was based on laboratory testing conducted by the Marketing Authorization Holder following an ongoing stability test at the 24-month time point (T24) under storage conditions of 30°C / 75% relative humidity. Consequently, EFDA has announced the recall of this product for the above-mentioned batches with Denk Pharma GmbH & Co. as the Market Authorization Holder and allphamed PHARBIL Arzneimittel GmbH 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.

- Temros (Tamsulosin hydrochloride 0.4mg tablet , Batch number PT-40531, Manufacturing date Feb/2024, Expiry date Jan/2026 and manufactured by Pharma roots Health care India.
- Topme-XL25 (Metoprolol Succinate)extended- release 25 mg tablet extended- release 25 mg tablet, batch number 40921, manufacturing date 12/2024, expiry date 11/2026 and manufactured by UNIZA LIFE CARE PVT.LTD India.

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.