Pharmacovigilance Newsletter

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EFDA hosted and actively participated in the 6th AU-3S (Africa Union Smart Safety Surveillance) steering committee meeting

Ethiopia joined the Africa Union Smart Safety Surveillance (AU-3S) program to enhance its medicine safety monitoring and pharmacovigilance systems. The program, led by the African Union (AU) and Africa CDC, focuses on ensuring the safety, efficacy and quality of medicines, including vaccines and other medical products.

On March 26–27, 2025, AU-3S member states convened in Addis Ababa for the 6th AU-3S Steering Committee Meeting. The agenda focused on enhancing in-country medicine safety, optimizing AU-3S technology and reviewing the AfriVigilance road-map. Discussions also covered signal management, Validation Hubs and Africa Union Pharmacovigilance Risk Assessment Committee (AU-PRAC).

The Meeting marked a significant step in strengthening medicine safety and advancing AU-3S initiatives and established strategic recommendations and key decisions to effectively operationalize the African Medicines Agency (AMA), strengthen AU-PRAC, and drive technological advancements, ensuring a more resilient and efficient pharmacovigilance system across Africa.

EFDA participated in regional pharmacovigilance workshop and experience sharing

The Medical Dictionary for Regulatory Activities (MedDRA) is a globally recognized system used for coding adverse events and other medical data. Signal management involves identifying and confirming new or emerging safety concerns related to medicines, with signal validation ensuring that detected potential safety signals are credible, relevant, and actionable. Accurate MedDRA coding enables standardized reporting of adverse events, while effective signal validation supports informed regulatory decisions and promotes patient safety. Together, these processes play a critical role in strengthening pharmacovigilance systems, ultimately enhancing drug safety and protecting public health.

EFDA participated in two key continental workshops: one on signal validation, held in Rwanda from February 13–14, 2025, and another on MedDRA coding, conducted in South Africa from February 24–25, 2025. These engagements provided valuable opportunities for knowledge exchange and experience-sharing with regional and international experts. They also contributed to building EFDA's capacity in detecting, assessing, and validating medicine safety signals, as well as improving proficiency in the use of standardized medical terminology for accurate adverse event reporting and evidence-based regulatory decision-making

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

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Activities Performed by the Pharmacovigilance Center

EFDA organized a workshop for Qualified Person for Pharmacovigilance (QPPVs)

Article 39 of the Ethiopian Food and Drug Authority (EFDA) Proclamation No. 1112/2019, Article 31 of EFDA Regulation No. 299/2013, and Article 4 of the Pharmacovigilance Directive No. 932/2022 clearly stipulate that each market authorization holder is responsible for establishing a pharmacovigilance system to continuously monitor the safety of medicines and take corrective actions when safety concerns arise. Specifically, the Pharmacovigilance Directive mandates that all market authorization holders appoint a Qualified Person for Pharmacovigilance (QPPV) for their marketed medicinal products.

In line with this regulatory requirement, the EFDA's Pharmacovigilance and Clinical Trials Lead Executive Office organized an orientation workshop on March 21, 2025, in Addis Ababa for QPPVs designated by their respective market authorization holders. The workshop focused on the Ethiopian pharmacovigilance regulatory framework, emphasizing the roles and responsibilities of market authorization holders and QPPVs, as well as EFDA's Good Pharmacovigilance Practice (GVP) inspection approaches.

Participants engaged in meaningful discussions on best practices for monitoring medicine safety, highlighting the critical regulatory obligations of both market authorization holders and QPPVs. They also shared experiences, addressed current challenges, explored potential solutions, and reaffirmed their commitment to enhancing medicine safety reporting systems. The workshop concluded with a collective pledge to strengthen collaboration with EFDA in ensuring that authorized medicines remain safe and effective for the public.

EFDA conducted causality assessments for Serious Adverse Event(SAE) cases

The Ethiopian Food and Drug Authority (EFDA) plays a vital role in safeguarding the public from unsafe medicinal products by monitoring cluster of adverse events and serious adverse events (SAEs) related to medicines, vaccines, medical devices and other health-related products. EFDA oversees the national pharmacovigilance system, ensuring that all adverse events, including SAEs, are properly identified, assessed and reported. Based on the severity of an SAE, EFDA may take regulatory actions such as issuing safety alerts and warnings, recalling or restricting unsafe products and updating product labels with new safety information.

In the first week of April, the Pharmacovigilance Advisory Committee (PAC)—comprising experts from various disciplines—conducted a detailed causality assessment of 13 serious adverse event cases, 12 of which were associated with nOPV2. Based on the assessment findings, the PAC provided key recommendations aimed at strengthening pharmacovigilance efforts and enhancing public health protection..

National and International Medicine Safety Updates

Safety updates on Mannitol 20% w/v intravenous injection

Product quality defect (large visible crystals forming inside the infusion bags) was reported in Mannitol 20% w/v intravenous injection in a batch (Batch No.: 82SE220601; manufactured in May 2023, expiring in April 2026) produced by Fresenius Kabi India Pvt. Ltd. Upon detailed investigation, EFDA found that the product had been stored below the recommended temperature range for several days, which likely contributed to crystal formation. The primary packaging label and SmPC specify that Mannitol should be stored between 20–30°C, as lower temperatures can lead to crystal deposition. As a result, EFDA has advised the healthcare provider to strictly follow the manufacturer's key recommendations on storage and handling of products, as described on the primary packaging label and summary of product characteristics (SmPC). These include recommendations redissolve by increasing the temperature to 60°C if needed, maintaining its storage conditions, occasionally shake the crystals until it redissolves, cooling to body temperature before use, avoiding use if leakage occurs when squeezed and ensuring no visible particles remain before use.

Safety updates on Cyclophosphamide 1000 mg

A product quality defect was reported in Cyclophosphamide 100 mg, manufactured by Venus Remedies Limited, involving powder sticking to the bottle before reconstitution and a color change to yellow after reconstitution. These issues were reported to the EFDA by three comprehensive hospitals. Following a thorough investigation, the EFDA determined that the product had been stored at room temperature, contrary to the manufacturer's recommendation of keeping it below 15°C. As a result, the EFDA recommended that the affected product batches be identified and disposed of and advised healthcare centers to verify storage conditions upon procurement and must ensure that the product is stored according to the manufacturer's recommendations.

Safety updates on Inmunoglobulina Humana Anti-D (Rho) 5% IV

The EFDA has issued safety alert for falsified Inmunoglobulina Humana Anti-D (Rho) 5% intravenous injection (Batch No.: 11369C, Manufacture Date: October 2023 and Expiry Date: October 2026) which is declared as it is manufactured in **Pare MEDICBAI a Haban**, **Cuba**. Laboratory test results showed that the product did not meet microbiological and physicochemical quality standards. **CECMED**, **Cuba**'s health authority, confirmed that **MEDICBAI** or **MEDICUBA** is not a legitimate drug manufacturer in Cuba. The safety, efficacy and quality of this falsified product cannot be guaranteed and its use may lead to serious health risks, including therapeutic failure or death. Therefore,the EFDA cautions the public against using the product and advises healthcare providers not to administer it under any circumstances.

WHO safety updates in Oxycodone hydrochloride 80 mg

A falsified OxyContin 80 mg (batch no. 262174, exp. 12/2025) was identified in the unregulated Swiss market. Reported by genuine manufacturer Mundipharma A/S, the counterfeit product mimics genuine OxyContin 80 mg which is authorized in Poland. Laboratory tests in Zurich confirmed that the tablets lacked the active ingredient oxycodone. But, it contains undeclared nitazene compounds, which pose a significant risk due to the high likelihood of adverse events, even in small doses. The WHO recommends that the healthcare professionals required to report adverse effects, lack of expected effects, or suspected falsification to the National Regulatory Authorities or National Pharmacovigilance Centre.