Quarter 4
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Pharmacovigilance Newsletter

INSIDE THIS ISSUE

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 Conducts Training on AEFI Causality Assessment and nOPV2 Case Review for Enhanced Vaccine Safety Monitoring

From June 9–11, 2025, the Ethiopian Food and Drug Authority (EFDA), in collaboration with The Ohio State University – Global One Health initiative (OSU-GOHi) and Akros Research, held a high-level training workshop on Adverse Events Following Immunization (AEFI) causality assessment and review of nOPV2 cases. The training, hosted in Hawassa, brought together Pharmacovigilance Advisory Committee (PAC) members and Experts from Medicine Safety and Post-Marketing Surveillance of EFDA, Ethiopia Public Health Institute (EPHI) and Ministry of Health (MOH). The event aimed to build national capacity in conducting evidence-based vaccine safety assessments and to review reported AEFI cases linked to the novel oral polio vaccine type 2 (nOPV2).

Over the course of three days, participants engaged in comprehensive sessions covering: introduction to vaccine safety and AEFI principles, steps in conducting causality assessments, application of Brighton collaboration criteria, utilization of verbal autopsy in case investigations and learning f rom Uganda's experience in AEFI causality assessment. The training was led by distinguished experts from the U.S. Centers for Disease Control and Prevention (CDC) – Global Immunization Safety Team, who shared global best practices and case-based approaches for effective AEFI evaluation

EFDA Signal Review Team Conducts Critical Assessment of Adverse Events to Enhance Medicine Safety

The Ethiopian Food and Drug Authority (EFDA) has undertaken a critical review of reported adverse events through its dedicated Signal Review Team as part of its commitment to protecting public health from medicine-related harms.

The signal review process involves a rigorous assessment of pharmacovigilance data to identify potential safety signals (new or known adverse events that may be linked to specific medical products).

The team's review aims to generate evidence-based safety signals that guide timely regulatory actions, minimize risks, and enhance the safe use of medicines in Ethiopia. The outcome of the review will contribute to strengthened safety monitoring and regulatory decision-making,

Pharmacovigilance Advisory Committee (PAC) Meeting Held in Bishoftu

The PAC meeting was convened on April 29–30, 2025, at Bin International Hotel in Bishoftu City. The committee reviewed 18 serious adverse event (SAE) cases related to vaccines and conventional medicines using the WHO standardized causality assessment tool.

Of the cases assessed, 14 SAE reports were classified—12 reports were on vaccines whereas the remaining 2 were on conventional medicines—while 4 remained unclassified pending because it required additional information.

Key recommendations included avoiding house-to-house administration of injectable vaccines, ensuring availability of vaccination records, and managing adrenaline supply during every immunization activity.

The PAC continues to support the regulatory authority by providing expert guidance and recommendations on medicine and vaccine safety, efficacy, and quality.

Training for Regional Investigation Task Forces conducted

Investigation of serious Adverse Events Following Immunization (SAEFIs) and other eligible cases is a critical element of the pharmacovigilance system in identifying & correcting the problem(s) related to the use of medicines or vaccines as well as taking appropriate regulatory action based on the findings to ensure trust among clients, immunization programs, and other actors.

To strengthen the Regional Investigation Task Force members, the Ethiopian Food and Drug Authority, in collaboration with Ohio State University/Global One Health and Akros Research, provided training on the investigation of serious adverse events for South and East Ethiopia Investigation Task Force members.

The training was carried out from May 8-10, 2025, parallelly in Shashemene, Oromia Region and Harere city, Harere Region, and a total of 37 investigation task force members participated from six regions, who were representatives of regional EPI, regulators, PHEM, Pharmacy services, experts from EFDA branch offices and health facilities.

Pharmacovigilance Training Empowers 980 Healthcare Professionals Nation wide

The Ethiopia Food and Drug Authority (EFDA) successfully conducted a series of pharmacovigilance training sessions for healthcare professionals from May 21 to June 25, 2025. The training aimed to strengthen the capacity of healthcare professionals working in the detection, assessment, reporting, and prevention of adverse drug reactions and medicine-related problems.

Covering more than ten separate rounds, each lasting three days, the sessions brought together a total of 980 participants.

Attendees represented a diverse group of institutions, including kenema pharmacies, private and public hospitals, and the regulatory sector all over Ethiopia. EFDA reiterated its commitment to improving public health by building a robust pharmacovigilance system at all levels of healthcare service.

Guideline on Good Pharmacovigilance Practice (GVP) Inspection

EFDA has officially issued a new Guideline for the Conduct of Good Pharmacovigilance Practice (GVP) Inspections, aimed at strengthening the safety monitoring of medicines circulating in the Ethiopian market.

This critical regulatory document provides a structured framework to ensure that all Marketing Authorization Holders (MAHs) fulfill their legal and ethical obligations in implementing Good Pharmacovigilance Practices. It also guides both the pharmaceutical industry and regulators on the expectations, processes, and responsibilities related to pharmacovigilance inspections.

The development process was formulated through stakeholder consultations with relevant actors, a validation workshop that ensured alignment with contextual realities and practical implementation and incorporation of global best practices to elevate the national pharmacovigilance system to internationally accepted standards.

The guideline becomes effective from April 2025 and applies to all Marketing Authorization Holders whose medicinal products are placed on the Ethiopian market, regardless of whether they are locally manufactured or imported.

National Active Safety Surveillance on Cabotegravir Long-Acting (CAB-LA)

EFDA has commenced a nationwide active safety surveillance initiative on Cabotegravir Long-Acting (CAB-LA), starting in June 2025. Cabotegravir is a long-acting injectable indicated for HIV prevention in at-risk individuals and for HIV treatment in virologically suppressed adults and adolescents aged 12 and older.

This proactive surveillance aims to systematically monitor, evaluate, and characterize the safety profile of CAB-LA in real-world settings across Ethiopia. The surveillance is being conducted at selected 12 health facilities and six drop-in centers, with a target sample size of 1,250 participants.

EFDA Establishes Four New Pharmacovigilance Centers at University Hospitals

The Ethiopia Food and Drug Authority (EFDA) has taken a significant step in strengthening the country's pharmacovigilance system by establishing four new sub-national pharmacovigilance centers at major university hospitals. This milestone initiative, conducted in June 2025, aims to enhance the monitoring of the safety, quality, and efficacy of medicinal products across different regions of the country. The newly inaugurated centers are located at Madda Walabu University Goba Referral Hospital, Bahir Dar University Tibebe Ghion Comprehensive Specialized Hospital, Arba Minch University Teaching and Comprehensive Specialized Hospital and Jigjiga University Sheikh Hassen Yabare Comprehensive Specialized Hospital.

Bahir Dar University comprehensive specialized Hospital

Maada Walabu university Goba Referral Hospitals

During the inauguration, EFDA engaged in face-to-face discussions with the staff of these university hospitals, focusing on the importance of pharmacovigilance, and the specific roles and responsibilities of healthcare professionals in medicine safety surveillance. The interactive sessions fostered a shared understanding of the vital collaboration needed between Ethiopia Food and Drug Authority and university hospital institutions. Academic institutions, through their dual role in education and service delivery, are uniquely positioned to contribute to pharmacovigilance. They can support medicine safety through teaching and training of health professionals, conducting clinical and policy-relevant research, and generating scientific evidence that informs regulatory decisions.

Jigjiga University Sheik Hassen Yabare comprehensive specialized Hospital

In addition, these newly formed sub-national pharmacovigilance centers will serve their respective catchment areas, supporting the national pharmacovigilance system by collect-

ing , analysing, and reporting adverse drug events, and promoting rational medicine use in the healthcare system.

Arbaminch University Teaching and Comprehensive Specialized Hospital

National and International Medicine Safety Updates

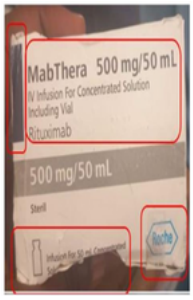
Safety update on bromocriptine: Need for blood pressure Monitoring

The Medicines and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom has announced that blood pressure monitoring of patients prescribed with bromocriptine is essential especially during the first days of treatment. Bromocriptine is a dopamine agonist and is indicated for the prevention or suppression of postpartum physiological lactation only where medically indicated. Hence, EFDA also would like to highlight the need for blood pressure monitoring during bromocriptine treatment, especially during the first days of therapy. Health-care professionals should, when prescribing bromocriptine for any of its indications, carefully monitor for an increase in blood pressure, especially during the first days of therapy and with any subsequent dose increases. If patients prescribed bromocriptine present with signs and symptoms of hypertension, treatment should be discontinued, and the patient evaluated promptly

Safety update on oral anticoagulants: Potential risk of mood changes

The Medsafe of New Zealand is reviewing the risk of mood changes in individuals taking direct acting oral anticoagulant medicines following receiving a small number of reports of psychiatric changes associated with rivaroxaban use. Oral anticoagulants (apixaban, dabigatran and rivaroxaban) are referred to as 'blood thinners' and are prescribed to treat and/or prevent blood clots. Hence, EFDA is encouraging reporting to obtain more information on this potential safety signal. Although the signal was identified with rivaroxaban, reporting of mood disorders with other direct acting oral anticoagulants is also encouraged.

Medical product alert: a falsified batch of MabThera 500mg/50ml



The Ethiopian Food and Drug Authority (EFDA) has been notified by the marketing authorization holder, F. Hoffmann-La Roche Ltd, regarding a suspected falsified batch of MabThera® 500mg/50ml concentrate for solution for infusion. Following this notification, EFDA conducted a thorough investigation to verify the authenticity of the batch. The investigation confirmed that the product is falsified, having been deliberately misrepresented in terms of its identity, composition, or source. The falsified batch details are as follows: Product name: MabThera® 500mg/50ml concentrate for solution for infusion, batch number: N2110A09, expiry date: 09-10-2026 and Stated manufacturer: F. Hoffmann-La Roche Ltd (as labeled on secondary packaging)
EFDA strongly advises all healthcare professionals not to prescribe, dispense, or administer this batch. Consumers are also urged not to use the identified product. If this product is found on the market, please report it immediately to EFDA through the appropriate channel

Medical product alert: a falsified HEALMOXY (Amoxicillin) Capsules 500mg

The World Health Organization (WHO) was identified a Falsified HEALMOXY (Amoxicillin) Capsules 500mg in Cameroon (Batch no: 023011 023011, H02605 and expiry dates 18/07/2025 10/01/2027 02/27 respectively, stated manufacturer MAXHEAL PHARMACEUTICALS (India) Limited) and Central African Republic (Batch no: H026051, Expiry date 01/26 and stated manufacturer MAXHEAL PHARMACEUTICALS (India) Limited. The active pharmaceutical ingredient in genuine HEALMOXY capsules is amoxicillin: it is an antibiotic used to treat a variety of bacterial infections, including middle ear infections, pneumonia, skin infections, dental infections, and urinary tract infections.

Therefore, the Ethiopia Food and Drug Authority would like to inform all healthcare professionals not to prescribe, dispense and administer, and consumers also not to use this falsified medicine batch. In addition, if such stated medicine is/are found in the market, please report immediately to EFDA.

Medical product alert: a falsified IMFINZI (durvalumab) injection 500mg/10ml

A Falsified IMFINZI (durvalumab) injection 500mg/10ml was identified by the World Health Organization in the Eastern Mediterranean and European Regions. The details of the Product are Lot: BAZR, BBEG and AVZT, Expiry date 03-2025 12-2025 12-2026 and Stated manufacturer: AstraZeneca. IMFINZI is a sterile concentrate for infusion. It contains the active pharmaceutical ingredient durvalumab, which is a monoclonal antibody. As monotherapy, it is indicated for the treatment of Non-Small Cell Lung Cancer (NSCLC) in adults. Therefore, the Ethiopia Food and Drug Authority would like to inform all healthcare professionals not to prescribe, dispense and administer, and consumers also not to use this falsified medicine batch. In addition, if such stated medicine is/are found in the market, please report immediately to EFDA.

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Addressed up-update regulatory information about the safety,quality,efficacy, rational use and performance of regulated health product. Follow us on all social media links below for all the latest updates.

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