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ETHIOPIAN FOOD & DRUG AUTHORITY

Reference No: 02/2/29.1/213

Date: 09 OCT 2025

To All Marketing Authorization Holders (MAHs)

Subject: Final Reminder to Assign a Local Qualified Person for Pharmacovigilance

As per Proclamation No. 1112/2019 and the Pharmacovigilance Directive No. 932/2022, every Marketing Authorization Holder (MAH) is legally required to establish a pharmacovigilance system and appoint a Qualified Person for Pharmacovigilance (QPPV) residing in Ethiopia.

The Authority acknowledges and appreciates those MAHs who have already assigned their Local QPPV within the requested period and continue to demonstrate commitment to strengthening pharmacovigilance systems.

However, despite repeated communications, including the recent orientation held on March 21, 2025, a number of MAHs remain non-compliant. In addition, the Guideline to Conduct Good Pharmacovigilance Practice (GVP) Inspection, officially endorsed by EFDA in April 2025, now provides a clear and enforceable framework for compliance monitoring.

Accordingly, this serves as a final reminder that all remaining MAHs must designate and officially notify the Authority of their Local QPPV (including name, qualifications, contact information, and letter of appointment) by October 31, 2025.

The Authority strongly urges all MAHs to give this matter utmost priority. Ensuring the safety, quality, and efficacy of medicines is a shared responsibility, and the QPPV is central to fulfilling this obligation. Failure to comply within the stated deadline will result in regulatory enforcement actions.

With Regards,

Seyoum Wolde
Deputy Director General,
Medicine Sector

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- Medicine Sector, Deputy Director General
- Pharmacovigilance and Clinical Trial Executive Office