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ETHIOPIAN FOOD & DRUG AUTHORITY

ቁጥር / REF.NO 02/2/29.1/00

DATE 12 FEB 2025

To: All Local Pharmaceutical Manufacturers

Addis Ababa, Ethiopia

Subject: Notification for Submission of Bioequivalence (BE) Study Reports as Mandatory Requirement

Dear Manufacturers,

The Ethiopian Food and Drug Authority (EFDA) is mandated to ensuring the safety, efficacy, and quality of medicines available in the Ethiopian market, in accordance with the Food and Drug Administration Proclamation No. 1112/2019, Article 20. Bioequivalence (BE) studies serve as a critical surrogate marker for assessing the therapeutic equivalence of multisource (generic) medicines and have always been an essential requirement in the dossier assessment process for pharmaceutical product registration and market authorization.

In line with this mandate, EFDA hereby notifies all local pharmaceutical manufacturers that, effective immediately, the submission of a BE study report is a mandatory requirement for the registration and marketing authorization of pharmaceutical products that require BE studies. Any dossier submitted without the BE study data will not be considered for evaluation.

For further guidance on BE study requirements and dossier submission, manufacturers are encouraged to refer to EFDA's regulatory guidelines or contact the Authority for clarification.

With regards,

Seyoum Wolde
Deputy Director General,
Medicine Sector

CC

- Director General
- Deputy Director General, Medicine sector
- Medicine Evaluation and Market Authorization Lead Executive Office
  Ethiopian Food and Drug Authority (EFDA)

Tel . 251-11-552 4122/552 4123
ፋክስ/Fax: 251-11-552 1392
P.O.Box: 5681
Website: www.efda.gov.et
E-mail: contactefda@efda.gov.et