

#тс 0312139.11 ЭНН +7 18 NOV 2025

To: All Medicine Market Authorization Holders and/or Manufacturers

Subject: Request for Registration in the EFDA-MVC Traceability Hub

The Ethiopian Food and Drug Authority (EFDA), mandated by law to safeguardpublic health, is responsible for ensuring the safety, quality, and efficacy of medicines. In line with this mandate, The Authority has been using the electronic Regulatory Information System (eRIS) to strengthen and facilitate its regulatory functions.

As part of those efforts, the EFDA is implementing a track-and-trace system designed to combat falsified and substandard medicines, improve integrity and efficiency of the supply chain, and ensureend-to-end visibility throughout the pharmaceutical supply chain. To fully operationalize the traceability system, all Marketing Authorization Holders and/or manufacturers that export medicines to Ethiopia are required to register in the EFDA-MVC Traceability Hub in accordance with the stepsindicated within the system.

Accordingly, all Marketing Authorization Holders and/or Manufacturers are hereby required to complete their registration in the EFDA-MVC Traceability Hub within fifteen (15) working days from the date of issuance of this letter. Failure to comply with this requirement may result in appropriate regulatory and enforcement actions as deemed necessary by the Authority.

Note: Complete your registration using the Sign-Up feature in the EFDA-MVC Traceability Hub.

CC.

Director General

Deputy Director General, Medicine sector

Medicine Manufacturers Inspection and Enforcement Lead Executive Office

Information Communication Technology Executive Office

• MVC, Addis Ababa Office

Addis Ababa

P.O.Box: 5681

Website: www.fmhaca.gov.et E-mail: contactefda@efda.gov.et IN REPLY REFER TO OUR REF. NO.

Regards

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