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ETHIOPIAN FOOD & DRUG AUTHORITY

ቁጥር / ቀን: 02/1/29.1/200

DATE / REF.NO: 13 NOV 2023

To: All Marketing Authorization Holders, Applicants, and Manufacturers

Subject: Clarification on Amendment of Renewal Processing Timeline under Directive No. 963/2023

The Ethiopian Food and Drug Authority (EFDA), in line with its mandate under **Proclamation 1112/2019**, to ensure the availability of safe, efficacous and quality medicines in Ethiopia, issues this official notification regarding the regulatory timeline for renewal applications.

The Ethiopian Food and Drug Authority (EFDA), in accordance with its statutory mandate under **Proclamation No. 1112/2019**, is entrusted with ensuring the safety, efficacy, and quality of medicines, as well as with the development and implementation of science-based regulatory tools, including directives and guidelines. Pursuant to the Medicine Market Authorization Directive No. 963/2023, the stipulated timeline for the processing of renewal applications was indicated as thirty (30) working days. However, it has been noticed that this was a typographical error.

Accordingly, the EFDA hereby issues this formal notification to clarify that the correct timeline for the processing of renewal applications is ninety (90) working days. This correction shall be deemed effective as of **November 2023** and shall remain in force until the relevant directive and associated guidelines are formally amended or revised in accordance with applicable legal procedures.

EFDA kindly requests all applicants and manufacturers to take due note of this correction and govern themselves accordingly.

Best regards

Heran Gerba
Director General

CC
- Director General
- Deputy Director General, Medicine Sector
- Medicine Quality Control Lead Executive Office
- Medicine Evaluation and Market Authorization Lead Executive Office
- Medicine Manufacturers Inspection and Enforcement Lead Executive Office

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