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ETHIOPIAN FOOD & DRUG AUTHORITY

07 SEP 2023

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Ref. No. Date

**To all marketing Authorization Holders**

Subject: -Submission of summary of any variation to the registered product.

It is known that the submission (in Tabular form) of summary of any variations notified, accepted, and pending with the Authority since the grant of marketing authorization, if any is one of the regulatory requirements during renewal of the marketing authorization as provided in Appendix 4 of the registration guideline and section 2 of the guideline for Renewal of Medicines Marketing Authorization First Edition by December, 2022

However, some of the recent renewal application coming in to the EFAD are not fulfilling this requirement, though we have a filledvariation application that have been submitted and approved and/or waiting for approval within the authority. Furthermore, variations are being identified by the authority during the assessment of renewal application

Therefore, this is to kindly remind all the marketing authorization holders to submit a tabular summary of any variations notified, accepted, and pending with the Authority since the grant of marketing authorization

Please also note that if variation is identified by the authority during assessment of renewal application the Authority may impose administrative measures or revoke the marketingauthorization certificate as per Medicine Marketing Authorization Directive and other relevant law of the Country based on the potential impact of the changes on the product quality, safety and efficacy.

With best regards

Hadgamu Beyene Guluma
Medicine Registration and Licensing Directorate Director

CC//

- Medicine Registration and Licensing Directorate
- EFDA

Tel .251-11-552 4122/552 4123 P.O.Box: 5681 Website: www.efda.gov.et ፋክስ/Fax: 251-11-552 1392
E-mail: contactefda@efda.gov.et
መልስ በሚሰጡበት ጊዜ የእኛን ደብዳቤ ቁጥር ይጥቀሱ IN REPLY REFER TO OUR REF. NO.