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**FOOD, MEDICINE AND HEALTH CARE
ADMINISTRATION AND CONTROL AUTHORITY OF ETHIOPIA**

ቁጥር: D2/6.1/17/23
Ref. No.

ቀን: 27 MAY 2015
Date:

TO ALL MARKET AUTHORIZATION HOLDERS

The World Health Organization (WHO) has published a guideline "Stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms" (WHO Technical Report Series, No 863, Annex 5), updated in the Report of the thirty-seventh meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, Geneva, 22-26 October 2001. The WHO guideline describes stability testing recommendations, including storage conditions for all four climatic zones.

Thus Ethiopia is categorized under climatic zone IVA in which the recommended long-term stability study storage conditions is 30ºC±2ºC/65%±5%RH and the more universal condition of 30ºC±2ºC/75%±5%RH as recommended WHO can also be acceptable.

Hence all applicants with previously registered medicines by the authority in which the long-term storage stability was conducted under storage condition 25°C ± 2°C/60% RH ± 5% RH are expected to initiate a stability study as recommended by the WHO (30ºC±2ºC/65%±5%RH and the more universal condition of 30ºC±2ºC/75%±5%RH) ,submit the stability data on a schedule base as per their ongoing stability study protocol and revise their shelf life if there is a need to do so. In the mean time all are required to inform the authority if there is any out of specification while performing their study under the recommended storage condition.

With best regards

for Helen Birhane

DIRECTOR, MEDICINE
REGISTRATION AND
LICENSING DIRECTORATE

C.c

- Product registration and licensing directorate
EFMHACA

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