EFDA
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ETHIOPIAN FOOD & DRUG AUTHORITY

ቁጥር / Ref. No: 02/61/17/03

ቀን / Date: 31 JAN 2024

To: All Local Manufacturers and Importers of Radiopharmaceuticals

Addis Ababa

Subject: Notification to submit application dossier for Evaluation and Marketing Authorization of Radiopharmaceuticals

According to Food and Medicine Administration Proclamation 1112/2019 (Article 20 (1)) any medicine shall not be manufactured, imported, exported, stored, distributed, transported, sold, hold or used without Marketing Authorization. Hence, as part of Medicine, Registration and Marketing Authorization (MA) of Radiopharmaceuticals is crucial to ensure safety, efficacy and quality of Radiopharmaceuticals.

As you are aware, EFDA has been issuing a pre-import permit for the importation and distribution of Radiopharmaceuticals. The authority has now developed and published guidelines for the registration of Radiopharmaceuticals.

Therefore, you are required to compile available information and submit your application for registration and marketing authorization of your product(s) as per the approved guidelines.

With regards

Seble Shambel
Lead Executive Officer,
Medicine Evaluation and
Market Authorization

CC

- Director General
- Deputy Director General, Medicine sector
- Lead executive office, Medicine Manufacturers Inspection and Law Enforcement
- Lead Executive office, Pharmacovigilance and Clinical Trial
- Lead executive office, Medicine Quality Control

Ethiopian Food and Drug Authority (EFDA)

Addis Ababa, Ethiopia

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