Guidance for Authorization of Local Agent for the Importation of Medical Products

A. Introduction

In Eritrea, in the arena of trading with medical products, a Local Authorized Agent (LAA) is a company physically located in Eritrea and authorized by the National Medicines and Food Administration (NMFA), Ministry of Health of the State of Eritrea, to deal with the importation, distribution, surveillance and sale of medical products. Foreign establishments who intend to import medical products in Eritrea must, during their registration process, identify and appoint a LAA. The appointment shall be notified to the NMFA by submitting a letter of appointment *(annex 1)* supported by an original copy of power of attorney that complies with the Eritrean laws.

B. Purpose

This document is intended to inform all stakeholders involved in importation activities in general, and the LAA in particular, to adhere to the requirements and responsibilities required during importation of medical products as stipulated in the current Medicines Registration Guideline and Medical Devices Registration Guideline.

C. Requirements for Local Agent Authorization

The NMFA/MOH demands that a firm fulfills a number of requirements before they are granted permit to be a LAA. Accordingly, for the importation of medical products in Eritrea, a LAA should:

1. Have a valid business license issued by the Ministry of Trade and Industry.
2. Have a valid professional license for the import and wholesale of pharmaceuticals and medical devices issued by the NMFA, MOH.

3. Have a qualified pharmacist employed as a professional in-charge. The professional-in-charge should:
    - Be familiar with NMFA's regulatory documents and guidelines related to registration of medicines and medical devices.
    - Be responsible for all communications made during the registration process.
    - Be familiar with post-market surveillance and product recall process.
    - Submit manufacturer's dossier applications for medicines in the Common Technical Document (CTD) format and for medical devices in the Common Submission Dossier Template (CSDT) format.
4. Have a dedicated office equipped with the required communication channels (Internet access, Fax, Telephone, P.O. Box).
5. Have an agency agreement/letter of authorization submitted in line with the requirements indicated in the Medicine Registration Guideline and Medical Devices Registration Guideline.

    The agreement should state that all parties involved (local agent, manufacturer, and/or market authorization holder) will be required to provide risk minimization plans, facilitate product recalls, substantiate any related consequences and be liable for legal action as per articles pertaining to importation of medical products in Proclamation No. 36/1993 *(A Proclamation to Control Drugs, Medical Supplies, Cosmetics and Sanitary Items)*, National Pharmacovigilance Policy or other relevant laws of the country.

D. Responsibilities of an Authorized Local Agent

The LAA shall be responsible for the following activities:

1. Ensuring manufacturer's adherence to product registration as well as GMP inspection requirements. These include activities such as:
    - Facilitating communication with the applicant and submission of dossier applications to the NMFA for review.
    - Facilitating payment of application and registration fees.
    - Facilitating communication of queries and responses related to the submitted application for registration.

- Facilitating submission of Market Authorization Holders' (MAHs) bid documents to procuring entity.
- Assisting the NMFA in scheduling GMP inspections.
- Adhering to regulatory inspection terms during port clearance.

2. Following up issues related to the product once it is marketed in Eritrea. These include activities such as:
    - Product quality and safety monitoring.
    - Whenever any serious quality and/or safety concern is noted, the LAA should assist in conducting investigations and facilitate implementation of corrective and preventive actions (CAPA).
    - Serving as a channel of communication between the NMFA and the MAHs whenever requested by the NMFA.
3. In case of issue of product recall by the NMFA, the LAA should be responsible in clearing issues related to corrective actions such as completing processes of reimbursement, replacement of defective batches and/or return of consignments to the MAH.

Annex 1: Template Letter of Local Agent Authorization

[To be printed on Company Letterhead of Market Authorization Holder]

[Date]

Product Evaluation and Registration Unit
National Medicines and Food Administration (NMFA),
Ministry of Health
Street no. 174-4
P.O Box 212
Asmara, Eritrea.

Subject: Letter of Authorization for *[name of local agent (Company Name)]*

Dear Sir/Madam,

We, *[name of Market Authorization Holder]*, as the *Market Authorization Holder*, hereby authorize *[name of local agent (Company Name)]*, as the local agent for importation, distribution, surveillance and sale of medical products in Eritrea on our behalf.

This authorization shall remain in effect until our notification to the NMFA, in writing by postal mail, that the authorization agreement is terminated. It shall also be effective while the above-mentioned authorized company is in an active state, unless this authorization is earlier withdrawn by their end.

We acknowledge that all the responsibilities for complying with the terms and conditions for registration and marketing of the medical products still resides with the *[applicant/manufacturer name and address]*. We concede that any non-compliance with any registration conditions issued by the NMFA in relation to medical products registered in Eritrea may result in the suspension or cancellation of the medical products marketing authorization.

We undertake to provide post-market support and assistance to the local agent as may be required in relation to any matter involving our medical products. We also agree to assist the NMFA with any request for information in regards to our medical products.

Yours Sincerely,

[Market Authorization Holder signature] *[Full Name and Title of Senior Company Official]* *[Company stamp]*	*[Local agent signature]* *[Full Name and position of the LAA contact person]* *[Company stamp]*

Annex 2: Particulars of a Local Authorized Agent (LAA)

Name and address of the local agent	**Contact person**
Name: Business Address: Postal Address: Country: Phone (Office): Fax: Email: Website (optional):	Name: Position: Phone (Office): Phone (Mobile): Email: