NMRA

NATIONAL MEDICINES REGULATORY AUTHORITY

Guidelines for Registration of Importers of Medicines

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National Medicines Regulatory Authority (NMRA) – Sri Lanka

1. INTRODUCTION

The National Medicines Regulatory Authority (NMRA) regulates the importation of medicines in Sri Lanka to ensure their quality, safety, and efficacy. All entities intending to import medicines into Sri Lanka other than for the purposes of test examination, analysis or clinical trial must obtain a License to Import Medicines from the NMRA prior to importing.
This guideline sets out the requirements, procedure, and responsibilities for obtaining and maintaining a license for importer registration.

2. LEGAL BASIS

This guideline is issued under the National Medicines Regulatory Authority Act, No. 5 of 2015 and the regulations made thereunder, in particular Part III – Import of Medicines (Gazette Extraordinary No. 2145/34 of 14 October 2019). Applicants must comply with the relevant regulations, including but not limited to Regulations 44 to 58

3. ELIGIBILITY

3.1 Basic Entity Requirements

An importer registration may be granted to:
-Companies registered in Sri Lanka
-Sole proprietorships
-Partnerships or other corporate entities legally authorized to conduct importation
The applicant must possess a valid business registration and comply with all relevant national laws.

3.2 Prerequisite

Authorization from Overseas Manufacturer (Only an approval or authorization appointing as a local agent by the relevant overseas manufacturer.

3.3 Regulatory Affairs Officer (Regulation 45)

Every applicant for a license to import medicines (other than for test, examination, analysis or clinical trial) shall employ a Registered Pharmacist, who is registered in SLMC, as the Regulatory Affairs Officer (RAO).

The RAO shall be responsible for:

- Documents for the registration of medicines
- Import licenses
- Correspondence with the Authority regarding technical matters

Exemption: Applicants seeking a license to import medicines solely for testing, examination, analysis, or clinical trials are exempt from the requirement to employ a Registered Pharmacist.

4. SCOPE

This Guideline applies to applicants seeking a license to import medicines manufactured by overseas manufacturers into Sri Lanka. The applicant shall have an approval or authorization from the relevant overseas manufacturer appointing the applicant as the local agent.

The Guideline covers the requirements for application, appointment of the Regulatory Affairs Officer, inspection and suitability of the premises for storage of medicines, fulfillment of the conditions for issuance of the license, and issuance of the license in the prescribed form.

This Guideline does not apply to applicants seeking to import medicines for test, examination, analysis or clinical trial.

Obtaining an importer registration license does not replace the requirement for individual product registration and import licenses. Each medicine shall be separately registered with the NMRA before it is imported into Sri Lanka.

5. APPLICATION PROCEDURE

Applicants shall submit an Application for License to Import Medicines to the Market Control Division of the NMRA, together with the required documents and prescribed fees.

The application form (as determined by the Authority – Schedule X) must be completed in full and submitted in person to the MCD (or as directed by NMRA).

6. REQUIRED DOCUMENTS

The applicant shall submit the following documents and information together with the application

1. Duly completed Schedule X application form – *Application for Renewal of License for a Licensed Importer of Medicines.*
2. Declaration by the Responsible Officer certifying that the information furnished in the application is true and accurate.
3. Copy of the Business Registration Certificate including Forms 1, 6 and 20
4. List of company Directors, indicating the following details for each person:

a. Name of Director/Partner
b. Designation/Position
c. Residential/Official Address
d. NIC/Passport No

5. List of key persons employed by the company, indicating the following details for each person:
   a. Name
   b. Designation
   c. Qualification
   d. Experience

6. Appointment letter of Registered Pharmacist as Regulatory Affairs Officer (RAO) – unless exempted under Regulation 45
7. RAO's SLMC registration certificate
8. RAO's National ID Card / Passport
9. Duties and Responsibilities of the RAO
10. Post-Marketing Surveillance (PMS) Plan of the company
11. Recall Procedure of the company.
12. Complaint Handling Procedure
13. Details of the Warehouses indicating the following details
    Wholesale License No of medicine
    Name of the wholesale establishment
    Name of the third party warehouse when applicable
    Address of the wholesale premises
    Name of the responsible Pharmacist
    Storage conditions of the warehouse
    Validity of wholesale license
14. Copy of wholesale licenses of medicine
15. List of manufacturers by whom the applicant has been appointed as the authorized importer in Sri Lanka.
16. Letters of Authorization as a local agent from overseas manufacturer
17. Any additional documents requested by NMRA

7. EVALUATION

Upon receipt of the application to the Market Control Division, the MCD will compliance with valid wholesale licenses and other regulatory requirements.

Note: Inspection exception due to the valid Wholesale License (WL) being issued by the Pharmacy Division after the inspection

7.1 License Issuance Conditions

A license will be issued only if all conditions for issuing the license have been complied with, including holding the required manufacturer authorization and, where applicable, employing a Registered Pharmacist as the Regulatory Affairs Officer.

7.2 Rejection (Regulation 46(2))

If the application is rejected, the NMRA will inform the applicant of the reasons for rejection.

7.3 Discretionary Provision – Shareholding (Regulation 46(3))

The NMRA may, at its discretion, refuse to issue a license to a company that does not hold more than fifty per centum (50%) shares owned by citizens of Sri Lanka.

8. ISSUANCE OF LICENCE

Upon satisfactory evaluation by the Market Control Division, and payment of the applicable fee, the NMRA will issue a License to Import registration of Medicines in the form determined by the Authority (Regulation 47(1)).
The license authorizes the holder to import medicines subject to the conditions specified in the license and the regulations.

9. APPLICATION PROCESSING FEES

Fees are determined in accordance with the Fees Regulations made under the NMRA Act (Regulation 47(2)).
Fees are determined in accordance with the Extraordinary Gazette No. 2452/39 issued on 04 September 2025 (or as amended by fee regulations).
Note: Applicants must refer to the current NMRA Fee Gazette or contact the NMRA directly for the exact fee amounts. Fees are non-refundable and shall be paid in the manner specified by the NMRA.

10. VALIDITY, RENEWAL AND AMENDMENT OF LICENSE

Validity of License
The license shall be valid for five years or for the period specified in the license, as applicable.

Renewal of License
A renewal application shall be submitted before the expiry of the 6-month current license, accompanied by the renewal fee and any updated documentation required by the NMRA. Failure to renew the license before its expiry may result in the lapse of the license and may require a fresh application.

Amendment of License

Where an amendment is required due to any change in the information specified in the license, the license holder shall submit an application for amendment together with the relevant supporting documents.
The relevant documents shall be submitted in accordance with the applicable amendment application (Annexure 1) specified by the NMRA.

11. RESPONSIBILITIES OF THE LICENCE HOLDER

The license holder shall:

— Import only NMRA-registered medicines;

Maintain proper records of all imports, sales and supplies of medicines and make such records available for inspection by an officer nominated by the NMRA. The records shall be submitted to the Market Control Division (MCD) upon request.

— Provide and maintain adequate staff, premises, equipment and facilities for the handling, storage and distribution of medicines imported under the license and use only premises approved by the NMRA for such purposes;
— Allow any officer nominated by the NMRA to enter, with or without notice, any premises where imported medicines are stored for the purpose of inspection and taking samples for test, examination or analysis, where necessary;
— Furnish to the NMRA such samples of medicines imported under the license as the Authority may consider adequate for test, examination or analysis;
— Furnish full particulars of the quality control tests carried out by the manufacturer of a particular batch of any medicine, when required by the NMRA;
— Not release any vaccine or sera to the market except under the authority of a Lot Release Certificate issued by the Medical Research Institute in accordance with the applicable regulations;
— On being informed by the NMRA that any part or any batch of an imported medicine has been found not to conform to the standards approved by the NMRA, withhold or withdraw such batch from sale;
— Adhere to the guidelines issued by the NMRA on Good Storage Practices, Good Distribution Practices and Good Pharmacovigilance Practices;
— Notify the NMRA forthwith in writing of any circumstance or event which may affect the accuracy of any particulars stated in the application or license and furnish the license to the NMRA where required;
— Ensure that the Regulatory Affairs Officer, where applicable, fulfills the responsibilities specified under Regulation 45;
— Comply with all conditions of the license and any directives issued by the NMRA; and
— Furnish to the NMRA such information, including quantities of medicines imported or supplied and purchasing prices of medicines imported, when directed by the Authority.

12. SUSPENSION OR CANCELLATION

The NMRA may suspend or cancel a license to import medicines if:

- False or misleading information was provided in the application;
- Any condition of the license or applicable regulatory requirement is not complied with;
- The company ceases to meet the eligibility criteria;
- The license holder fails to rectify any identified non-compliance within the period stipulated by the NMRA; or
- The license holder has acted in contravention of the NMRA Act or any regulation relating to the importation and distribution of medicines.
- The NMRA may, after giving the licensed importer an opportunity to show cause why such action should not be taken, by an order in writing stating the reasons:
  suspend the license for such period as may be determined by the Authority; or
  Cancel the license in respect of all or some of the medicines relating to such license.
- The NMRA may revoke a license issued to a Licensed Importer of Medicines if the Authority is satisfied that the license holder has acted in contravention of any regulation relating to the importation and distribution of medicines.

13. APPEALS

An applicant aggrieved by a decision of the NMRA may appeal in accordance with the provisions of the National Medicines Regulatory Authority Act, No. 5 of 2015. An appeal must be filed within one month from the date of communication of the NMRA decision.

14. CONTACT INFORMATION

National Medicines Regulatory Authority (NMRA)
State Engineering Corporation Building (2nd Floor)
No. 130, W.A.D. Ramanayaka Mawatha
Colombo 02
Sri Lanka
Telephone: +94 11 269 8896 / +94 11 269 8897
Email: pa28@nmra.gov.lk

Regulation 52(3)
SCHEDULE X
APPLICATION FOR RENEWAL OF LICENCE FOR A LICENCED IMPORTER OF MEDICINES

I/We ..... of
..... hereby apply for renewal of license for a licensed importer of medicines.

1. GENERAL INFORMATION
1.1 Particulars of the Company/Organization
1.1.1 Name of applicant company/organization
1.1.2 Business model of the company/organization
(e.g. private limited company, public limited company, joint venture, sole proprietorship, partnership etc.)
1.1.3 Postal address (registered office)
1.1.4 Postal address (operational office)
1.1.5 E-mail address
1.1.6 Telephone number(s)
1.1.7 Fax number(s)
1.1.8 Address(es) of Warehouse(s)
1.2 Particulars of Key Personnel of the Company
1.2.1 Names and addresses of Board of Directors/Partners of the company etc. as applicable
1.2.2 Name of the regulatory pharmacist responsible for liaising with NMRA
1.2.3 Sri Lanka Medical Council (SLMC) registration number of the regulatory pharmacist
1.2.4 Telephone number(s) (mobile) of the regulatory pharmacist
1.2.5 Email address of the regulatory pharmacist
1.2.6 Name of the pharmacist responsible for pharmacovigilance/post marketing surveillance
1.2.7 SLMC registration number of the pharmacist responsible for pharmacovigilance/post marketing surveillance
1.2.8 Telephone number(s) (mobile) of the pharmacist responsible for pharmacovigilance/post marketing surveillance
1.2.9 Email address of the pharmacist responsible for pharmacovigilance/post marketing surveillance

Annexure 1

APPLICATION FOR AMENDMENT OF LICENCE TO IMPORTER OF MEDICINES

1. DETAILS OF THE LICENCE HOLDER
Name of the Company:
Business Registration No.:
Registered Address:
Telephone:
Email:

2. DETAILS OF THE EXISTING LICENCE
License No.:
Date of Issue:
Date of Expiry:

3. TYPE OF AMENDMENT REQUESTED

No.	Type of Amendment	Present Information	Proposed Information
1	Change of Company Name		
2	Change of Registered Office / Business Address		
4	Change of Regulatory Affairs Officer		
9	Other Amendment		

4. REASON FOR THE AMENDMENT

5. SUPPORTING DOCUMENTS

The following documents shall be submitted, as applicable to the proposed amendment:

— Copy of the existing License to Import Medicines.

— Relevant document supporting the proposed amendment.
— Updated Business Registration Certificate or relevant company registration documents, where applicable.
— Appointment letter of the new Regulatory Affairs Officer, SLMC Registration Certificate and NIC/Passport, where applicable.
— Valid wholesale licenses
— Revised Letter of Authorization from the relevant overseas manufacturer, where applicable.
— Updated list of overseas manufacturers, where applicable.
— Relevant documents relating to the change of Responsible Pharmacist, where applicable.
— Any other documents requested by the NMRA.
— Prescribed amendment fee.

6. DECLARATION

I hereby declare that the information provided in this application and the documents submitted in support of the proposed amendment are true, accurate and complete.
Name of Responsible Officer:
Designation:
NIC/Passport No.:
Signature:
Date:
Company Seal:

7. FOR OFFICIAL USE

Application Received Date:
Application No.:
Remarks: