



GUIDELINE ON IMPORTING MEDICINES FOR PERSONAL USE.

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NATIONAL MEDICINE REGULATORY AUTHORITY
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1. INTRODUCTION

This document on “Importing Medicines for Personal Use” will serve as the reference guide for the importing of medicine for personal use, as defined in the NMRA Act 2015, in Sri Lanka.

This documentation shall be read in conjunction with the current laws and regulations controlling medicines in Sri Lanka. The written laws shall take precedence over this guidance document in any event of discrepancy. Applicants shall familiarize with the contents of this document and the governing legislations before they submit applications for importing medicines for personal use.

Personal user licence issued for a patient who need a Medicine for his personal use, may import the limited quantity of such medicine on a valid prescription issued by medical practitioner or dental surgeon registered under medical ordinance treating him.

2. SCOPE

Issuance of personal user an authorization for medicine which shall be responsible based on the requirement of the particular patient and shall be in accordance with section 112 of the NMRA Act.

3. ABBREVIATIONS AND DEFINITIONS

PULA	Personal User Letter of Authorization
NMRA	National Medicines Regulatory Authority
CEO	Chief Executive Officer
MEDICAL PRACTITIONER	A person registered as a medical practitioner under section 29 or section 41 of the Medical Ordinance
DENTAL SURGEON	A person registered as a dental surgeon under Medical Ordinance (Chapter 105)
PRESCRIPTION	An authorization in writing to a Pharmacist from a person authorized by law to prescribe medicine to dispense a specified medicine for use by a designated individual.

4. REQUIRED DOCUMENTATION

- Valid prescription issued by a medical practitioner or dental surgeon, registered under medical ordinance treating him within 6 months of period
- Requested letter from the patient or guardian of the patient addressed to CEO/NMRA
- Copy of the NIC/Passport/Driving licence of the patient or the guardian
- Application (Section C in the online application) signed by the Prescriber

- Custom requesting letter if product is held by the customs

The general public can apply for a personal user authorization by logging into www.enmra.gov.lk furnishing required details or handing over the documents directly to NMRA during working hours.

5. QUANTITY

A maximum of 100 doses can be imported by using PULA

6. FEES

No fee is charged by NMRA for this purpose.

7. INSTRUCTION FOR TRAVELERS

A person travelling to Sri Lanka can carry medicine for his personal use, without prior approval of the NMRA under the following conditions.

The quantity of any single medicine required for the duration of his stay in Sri Lanka or the quantity required up to ninety days whichever is less. Prior approval of the NMRA should be obtain for quantities exceeding 90-day requirement. The medicine administered through intramuscular or intravenous route is not permitted. The medicine specified in Schedule III is not permitted

The medicine should be packed in the original container, if it is not in the original container, it should be appropriately labelled to identify the name and strength of the medicine with usage instructions
Medical records or prescription should be produced when necessary.

10. REFERENCES

1. Supply unlicensed medicinal products- Medicines and Healthcare products Regulatory Agency - Gov.uk
2. Personal Import Regulations-Bringing Personal Medications into Singapore-HSA

11. FEEDBACK

- a. Staff and customers may provide feedback about this document by emailing info@nmra.gov.lk