Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Importation of Medicines Under Prescription (Patient-Specific Import)

Version Number	1	
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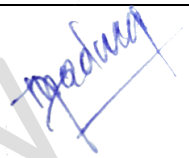
Authorized by	Thooma Adam, Deputy Director General, Laboratory Services (Acting Head of MFDA)	

SUMMARY OF CHANGES

Version No.	Issued Date	Section / Clause	Summary of Change	Changes Made by
1	01.06.2026	-	Creation of the document	Mariyam Laisa, Asst. Medicine Regulatory Officer

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ABBREVIATIONS

MOH	Ministry of Health
MFDA	Maldives Food and Drugs Authority
MTG	Medicines and Therapeutic Goods Division
ADL	Approved Drug List
NCDs	Chronic non-communicable diseases

DEFINITIONS

Term	Definition
Patient-Specific Treatment	Importation of a medicine based on a valid prescription issued for a specific named patient, where the product is intended solely for that individual's treatment and not for stock, resale, or general distribution.
Named Patient	An identifiable individual patient for whom a medicine is prescribed, supported by valid patient details (e.g., name, ID/passport number), and for whom the import approval is exclusively granted.
Clinical Need	A justified medical requirement for a specific medicine, established by a licensed medical practitioner, based on the patient's diagnosis and treatment plan. This includes situations where: • The medicine is essential for treatment, including life-saving or disease-modifying therapy • No suitable registered alternative is available locally, or available options are ineffective, contraindicated, or not tolerated • Patient-specific factors (e.g., age, comorbidities, prior treatment response) necessitate the requested medicine Clinical need shall be clearly documented and supported by appropriate medical justification.
Valid Prescription	A prescription issued by a licensed medical practitioner, containing all required patient, prescriber, and medicine details, and meeting the requirements outlined in Section 5 of this guideline. A valid prescription shall: • Be signed, dated, and stamped • Be issued within three (3) months prior to import • Reflect current clinical need
Licensed Medical Practitioner	A healthcare professional authorized and registered under national regulations to prescribe medicines within their scope of practice.
Suitable Registered Alternative	A medicine that is registered with MFDA and available in the local market, with the same or equivalent therapeutic effect, strength, dosage form, and indication.
Importer	An entity or individual authorized to import medicines into the Maldives in accordance with applicable regulatory requirements.
Bulk Quantity	Any quantity of a medicine that exceeds the amount reasonably required for the treatment of a specific named patient for the prescribed duration of therapy. This includes quantities intended for stock, storage, future use, multiple patients, institutional supply, resale, redistribution, or any purpose other than the immediate treatment needs of the approved patient. For the purpose of patient-specific importation, quantities inconsistent with the prescribed dosage, frequency, and treatment duration shall be considered bulk quantities and shall not be permitted unless specifically justified and approved by MFDA.

Redistribution	The transfer, supply, or provision of a medicine imported for a named patient to any other individual, healthcare facility, or entity.
Traceability	The ability to track and verify the movement of a medicine from importation through storage and final supply to the named patient, including batch number, expiry date, and quantity.
Unregistered Medicine	A medicine that has not been evaluated and approved by MFDA for quality, safety, and efficacy for general use in the Maldives.
Emergency or Compassionate Use	Use of an unregistered medicine in urgent or life-threatening situations where no suitable approved treatment is available, and immediate intervention is required.
Regulatory Authority (MFDA)	The Maldives Food and Drug Authority responsible for regulating the importation, approval, and monitoring of medicines in the Maldives.

1 Introduction

Access to safe, effective, and quality medicines is essential for the protection and promotion of public health. In certain situations, patients may require medicines that are not registered or readily available in the Maldives due to urgent clinical needs, limited market availability, specialized treatment requirements, or the absence of suitable therapeutic alternatives. To address such exceptional circumstances, the Maldives Food and Drug Authority (MFDA) permit the importation of medicines under a patient-specific prescription pathway.

This pathway is intended solely to facilitate access to medicines for an identified individual patient based on a valid prescription issued by a licensed medical practitioner. It is designed as an exceptional and controlled regulatory mechanism to address specific clinical needs where appropriate registered alternatives are unavailable or unsuitable for the patient.

Importation under this pathway shall be subject to regulatory oversight to ensure that the medicines imported maintain acceptable standards of quality, safety, and efficacy, and that adequate traceability and accountability are maintained throughout the importation and supply process. Medicines imported through this mechanism shall not be used for stock purposes, resale, redistribution, or routine commercial supply.

This guideline outlines the requirements, procedures, responsibilities, documentation, labeling, quantity limitations, and compliance measures applicable to the importation of medicines under prescription for patient-specific use. The guideline also aims to ensure consistent implementation, strengthen regulatory control, prevent misuse of the pathway, and safeguard public health while facilitating timely access to clinically necessary medicines for patients in need.

2 Purpose

This guideline outlines the requirements for the importation of medicines based on a valid prescription for individual patient use. It aims to ensure that such medicines are imported strictly for patient-specific treatment, and not for stock, resale, or general distribution.

3 Scope

This guideline applies to:

- Any medicine not in ADL

- Medicines not available in the Maldives
- Emergency or compassionate use medicines
- Special access medicines
- Patient-specific treatment requirements

This pathway shall only be used for named patient importation and shall not be used as an alternative procurement mechanism for routine supply. The medicines imported by this pathway is not evaluated for safety, quality and efficacy by MFDA and hence adherence to the standard practice as mentioned in this guideline is imperative.

This guideline emphasizes the patient specific prescription imports by authorized medicine importers. This guideline does not cover the medicines imported by prescriptions by patients who have undergone treatment abroad.

4 General Requirements

4.1 Importation shall be permitted only for a specific named patient:

4.1.1 Importation under this pathway shall be allowed only for an identified patient with a documented clinical need. The approval shall apply only to that patient, and the medicine must remain traceable to the individual. Transfer to another person is not permitted. A valid prescription (having 3-month validity from the date prescribed) and a copy of the patient's identity card shall be submitted at the port of entry during import.

4.2 Medicines imported under this pathway shall not be used for stock:

4.2.1 Medicines imported under prescription shall not be kept as stock or buffer inventory by importers, pharmacies, or healthcare facilities. The quantity imported must match the specific patient's requirement. Importing additional quantities for future use, emergency stock, or institutional use is not permitted and may result in penalties under the Medicines Regulation.

4.3 Medicines shall not be resold, redistributed, or supplied to other patients:

4.3.1 Medicines imported under this pathway are strictly for the named patient. They shall not be resold, transferred, shared, or supplied to any other patient. Redistribution of unused medicines is prohibited. Any unused medicines (eg: if the patient no longer requires treatment, patient did not want the medicines, etc) should be declared to MFDA in writing and shall take appropriate action as per the written instruction from MFDA.

4.4 Importation shall be supported by a valid prescription issued by a licensed medical practitioner:

4.4.1 Each import request must be supported by a valid prescription issued by a licensed medical practitioner. The prescription shall include indication, medicine details, dosage, and treatment duration. It must be signed, dated, and stamped. Altered, incomplete, expired, or unauthorized prescriptions shall not be accepted. The prescriptions shall be clinically valid at the time of import. Prescriptions submitted after treatment completion or discharge shall not be accommodated unless supported by updated clinical justification or a revised prescription.

4.5 Medicines shall be prescribed by a licensed medical practitioner:

The medical practitioner shall be qualified and trained in the relevant field of practice in accordance with the patient's clinical condition .

4.5.1 This ensures that prescribing decisions are based on specialized knowledge, current clinical guidelines, and safe use of medicines. However, exemptions may be granted on a case-by-case basis for patients requiring lifelong medication. In such cases, renewal of such prescriptions by a general doctor or medical officer can be done along with the attachment of the original or most recent specialist prescription.

4.5.2 Accordingly, prescriptions shall align with the prescriber's area of expertise, as outlined below:

a. **Chronic non-communicable diseases (NCDs):** Medicines for conditions such as diabetes mellitus, hypertension, and dyslipidemia shall be prescribed by a **physician, internal medicine specialist**.
b. **Women's health and obstetrics:** Medicines related to pregnancy, fertility, hormonal therapy, and gynecological conditions shall be prescribed by a **gynecologist / obstetrician**.

c. **Oncology:** Chemotherapy agents, antineoplastic medicines, and supportive cancer therapies shall be prescribed by an **oncologist** due to their complexity and high-risk nature.

d. **Pediatrics:** Medicines for infants and children, particularly dose-sensitive or specialized therapies, shall be prescribed by a **pediatrician**.

e. **Psychiatric conditions:** Psychotropic medicines, including antidepressants, antipsychotics, and mood stabilizers, shall be prescribed by a **psychiatrist** or appropriately trained physician.

f. **Cardiovascular diseases:** Advanced cardiac medicines (e.g., antiarrhythmics, anticoagulants requiring close monitoring) shall be prescribed by a **cardiologist** or physician.

g. **Endocrine disorders:** Complex hormonal therapies (e.g., thyroid disorders, adrenal disorders) shall be prescribed by an **endocrinologist** or physician.

h. **Infectious diseases:** Specialized antimicrobial therapies (e.g., for tuberculosis, HIV, or resistant infections) shall be prescribed by an **infectious disease specialist** or trained physician.

4.5.3 Where specialist care is not readily available, a **general practitioner** may prescribe medicines within their scope of competence, particularly for common and stable conditions, in line with national standard treatment guidelines.

4.6 Quantity imported shall be limited to the duration of treatment:

4.6.1 The quantity for importation shall be based on the prescribed dose and treatment duration. Excess quantities shall not be permitted. For continued treatment, a new prescription or additional justification shall be required.

4.7 Each application shall be assessed and approved on a case-by-case basis:

4.7.1 All patient-specific import requests shall be reviewed individually. Approval shall depend on clinical need (clearly established and supported by the prescribing practitioner), availability of alternatives, and completeness of documentation. Blanket approvals shall not be granted.

5 Prescription Requirements

The prescription submitted shall contain the following information:

5.1 Patient Information

a. Full name of patient

b. National ID / Passport number

c. Age

d. Gender

e. Hospital or Health facility number for the patient

5.2 Prescriber Information

a. Name of licensed medical practitioner

b. Registration number

c. Healthcare facility name

d. Contact details, if feasible

e. Signature and official stamp

f. Date of prescription

5.3 Medicine Details

a. Generic name/Brand name (mandatory)

b. Strength

c. Dosage form

d. Route of administration

e. Dose and frequency

f. Duration of treatment

g. Total quantity required

5.4 Clinical Justification

a. Diagnosis or indication

b. Confirmation of patient-specific use

6 Quantity Limitations

6.1 Quantity Limitation and Justification for Extended Supply:

6.1.1 The quantity of medicine approved for importation shall normally be limited to a maximum of three (3) months based on the prescribed dosage and treatment duration. Requests exceeding this limit may be considered only when supported by clear and adequate clinical justification, such as the need for long-term therapy or challenges in obtaining the medicine. All such requests shall be subject to regulatory review and approval. As per the medicine regulation the maximum duration per prescription is 6 months provided that proof document is submitted for the patient clinical condition. Prescriptions where the treatment duration exceeds 6 months are considered invalid as per the medicine regulation.

6.2 Repeat importation shall require a new prescription:

6.2.1 Each additional import for the same patient shall require a new valid prescription. Previous prescriptions shall not be reused.

6.3 Bulk quantities shall not be permitted under this pathway:

6.3.1 Importation of bulk quantities is not allowed. Medicines shall not be imported for future use, or stock purposes under this pathway.

7 Importer Responsibilities

The importer shall:

7.1 Ensure the import is for a named patient only:

7.1.1 The importer shall ensure the medicine is imported only for the specific patient mentioned in the prescription and approval. It shall not be intended for general use or multiple patients.

7.2 Maintain traceability of product to patient:

7.2.1 The importer shall keep records linking the medicine (batch number, expiry date, quantity, and supplier) to the specific patient to ensure full traceability.

7.3 Not distribute to other patients:

7.3.1 Medicines imported for a named patient shall not be shared, transferred, or supplied to any other patient. Redistribution of unused quantities is not permitted.

7.4 Not hold product as stock:

7.4.1 Medicines imported under this pathway shall not be kept as stock or included in routine inventory. Quantities must match the patient's treatment requirement. If any of these medicines are kept in stock or included in the routine inventory without a corresponding valid prescription, the party shall bare the penalties as defined under the Medicines Regulation.

7.5 Ensure appropriate storage conditions:

7.5.1 The importer shall store the medicines according to the manufacturer's recommended conditions, including temperature and special handling requirements where applicable.

7.6 Maintain documentation for regulatory review:

7.6.1 The importer shall keep all relevant documents, including prescription, approval, procurement, and supply records, and make them available to MFDA upon request. These records shall be kept and maintained for a period of 2 years.

7.7 Justification for importation (e.g., unavailable locally):

7.7.1 The importer shall provide a valid reason for importation, such as unavailability of the medicine locally or specific clinical need for the patient.

If a particular medicine is imported more than 20 times within a single month, for prescription, the importer shall explore the options for registration of this product due to the high demand of it.

8 Labeling Requirements

Medicines imported under this pathway shall:

8.1 Be labeled "For Named Patient Use Only – Not for Sale":

8.1.1 All medicines imported under this pathway shall be clearly labeled "For Named Patient Use Only – Not for Sale" on the outer packaging after the point of import until dispensing to the patient or storage in the pharmacy or warehouse.

8.2 Include patient name on outer label (where feasible):

8.2.1 Where possible, the patient's name shall be included on the outer label to ensure the medicine is linked to the correct individual.

8.3 Retain original manufacturer labeling:

8.3.1 The original manufacturer's label shall remain intact and must not be removed or altered. This includes product name, strength, batch number, expiry date, and storage conditions.

8.4 Not obscure critical product information:

8.4.1 Additional labels shall not cover important information such as product name, strength, batch number, expiry date, or storage conditions.

9 Documentation Required

The following documents shall be submitted:

9.1 Valid prescription meeting requirements in Section 4:

9.1.1 A valid prescription issued by a licensed medical practitioner, from that relevant field, shall be submitted. It must include patient details, medicine information, dosage, and duration, and must be signed, dated, and stamped. Incomplete, altered, illegible, or expired prescriptions shall not be accepted.

9.2 Proforma invoice or procurement documents:

9.2.1 A proforma invoice or procurement document shall be submitted with details such as product name, strength, dosage form, quantity, the batch number, manufactured date, expiry date, unit price and total price, manufacturer, and supplier. The importer shall also submit the Excel sheet of prescription medicine details as required by MFDA. (Refer to Guideline for Health Clearance of Pharmaceuticals at Entry Ports (MTG/QA-HC/GLN-TE 011))

9.3 Product information (if requested):

9.3.1 Product information such as datasheet, package insert, or other quality documents shall be provided when requested by MFDA.

9.4 Importer declaration confirming patient-specific import:

9.4.1 The importer shall submit a signed declaration confirming that the medicine is for a named patient only and will not be used for stock, resale, or distribution. The declaration format is attached in Annex 1 of this document

9.5 Any additional information requested by MFDA:

9.5.1 Any additional documents including the patient Identity card copy, or any other documents or information requested by MFDA shall be submitted promptly to support the clearance of the medicines.

10 Record Keeping

10.1.1 The importer shall establish and maintain comprehensive records for all medicines imported under the patient-specific importation pathway. These records shall be readily retrievable upon request from MFDA during inspections and these records shall ensure traceability, accountability, and facilitate regulatory review.

At a minimum, the importer shall maintain the following:

a. **Copy of prescription:** A clear copy of the valid prescription shall be retained. It must include patient details, medicine information, dosage, duration, and prescriber details, and be available for verification.

b. **Import clearance document:** A proof document of import clearance issued by the regulatory authority shall be retained and kept together with the prescription until the medicine is supplied to the patient.

c. **Product details (batch number and expiry date):** The importer shall record product details including product name, strength, manufacturer, batch number, and expiry date to ensure traceability. The product details shall be cross-referenced with the prescription copy for full traceability.

d. **Quantity imported:** The importer shall document the quantity imported, including pack size, number of packs, and total units, matching the prescribed treatment duration.

e. **Date of supply to patient:** The importer shall record the date the medicine is supplied to the patient and provide this information to MFDA when required. Consider specifying a timeframe for recording

f. **Patient acknowledgement (where applicable):** Where feasible, a signed acknowledgement from the patient confirming receipt of the medicine shall be obtained and retained.

g. **Records retention requirement:** All records shall be kept for at least two (2) years from the date of supply and made available to MFDA upon request.

11 Prohibited Practices

11.1 The following practices are strictly prohibited under the patient-specific prescription importation pathway to ensure regulatory compliance, prevent misuse, and safeguard patient safety. Any such practices shall be penalized under Medicines Regulation and Health services Act accordingly:

a. **Importation for stock purposes:** Medicines shall not be imported for stock, buffer inventory, or future use. Importation is allowed only for the immediate needs of a named patient.

b. **Importation for multiple patients under one prescription:** One prescription shall apply to only one patient. Import requests for multiple patients under a single prescription shall not be accepted.

c. **Importation exceeding prescribed quantity:** The imported quantity shall not exceed the amount stated in the prescription. Any excess quantity may be held by MFDA to prevent misuse.

d. **Use of expired prescriptions:** Only valid prescriptions shall be accepted. Prescriptions are valid for three (3) months from the date of issue. Expired prescriptions shall not be used.

e. **Altered or incomplete prescriptions:** Altered, overwritten, or incomplete prescriptions shall not be accepted. All required details must be clearly provided.

f. **Redistribution of imported medicines:** Medicines imported for a named patient shall not be shared, transferred, or supplied to other patients or facilities.

12 Compliance and Enforcement

12.1 Failure to comply with the requirements outlined in this guideline may result in one or more of the following regulatory actions, depending on the nature and severity of the violation:

a. **Rejection of import application**: Applications that do not meet the requirements, such as incomplete documents or invalid prescriptions, may be rejected. Importation shall not proceed until deficiencies are corrected.

b. **Suspension of import privileges**: Repeated non-compliance or misuse of this pathway may result in suspension of the importer's privilege to import medicines.

c. **Regulatory enforcement action**: Any violations shall lead to regulatory actions such as warning letters, penalties, or other enforcement measures as per applicable regulations.

d. **Confiscation of products**: Medicines imported in violation of this guideline may be detained or confiscated by the regulatory authority. The products will be further subjected to disposal accordingly.

e. **Other actions as deemed appropriate by MFDA**: MFDA may take additional actions, including inspections or corrective measures, to ensure compliance.

13 Declaration (Recommended Format)

The declaration is in the ANNEX 1 of this document

14 Effective Implementation

14.1 This guideline is intended to ensure that patient-specific importation remains a strictly controlled and exceptional pathway, used only when a patient's clinical needs cannot be met by locally registered and available medicines. It is not intended to replace routine medicine registration, standard procurement, or established supply systems.

14.2 This pathway shall be used only where:

- No suitable registered medicine is available locally, and
- There is a clear, justified clinical need for an individual patient.
- It shall not be used to import medicines for stock, routine use, or to bypass regulatory approval processes.

14.3 All stakeholders, including importers and healthcare providers, shall prioritize the use of medicines that are properly registered and supplied through approved channels. Where there is recurring demand for an unregistered medicine, efforts shall be made to register the product or use appropriate regulatory pathways to ensure sustainable access.

14.4 This guideline also ensures proper regulatory oversight, product traceability, and assurance of quality, safety, and efficacy. By limiting this pathway to exceptional cases, MFDA aims to prevent misuse, reduce risks, and promote long-term reliance on approved medicines.

15 REFERENCES

- Health Services Act 29/2015 (Chapter 7)
- Medicine regulation 2014/R-46
- First amendment to medicine Regulation 2016/R-49
- Guideline for Health Clearance of Pharmaceuticals at Entry Ports (MTG/QA-HC/GLN-TE 011)

ANNEX 1

Maldives Food and Drug Authority
Male'
Republic of Maldives

MTG/RE-PS/Re 0144

Official Declaration Statement for Importing Medicines Under Prescription for a Specific Patient

I _____ hereby declare that the medicines imported is prescribed exclusively for a specific named patient based on a valid prescription issued by a licensed medical practitioner. The requested product is intended solely for the treatment of the identified patient and shall not be used for general stock, institutional inventory, emergency reserve, or any other non-patient-specific purpose.

I _____ further confirm that the medicine will not be resold, redistributed, transferred, or supplied to any other patient, healthcare facility, or third party under any circumstances. The importation is strictly limited to addressing the clinical needs of the named patient and will be handled in accordance with all applicable regulatory requirements.

I_____ also certify that the quantity requested for importation corresponds only to the prescribed dosage regimen and duration of treatment. No excess quantities have been requested beyond what is necessary for the patient's therapeutic course. Should additional quantities be required, a new prescription and separate regulatory approval will be obtained prior to any further importation. I_____ have no objections for MFDA to hold excess quantities beyond the prescribed amount in the prescription.

I _____ acknowledge that providing false, misleading, or inaccurate information in this declaration may result in regulatory action, including rejection import, suspension of medicine import or other enforcement measures as deemed appropriate by the Maldives Food and Drug Authority (MFDA).

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority			**Document Created on:** 19.05.2026
Rec. No: MTG/RE-PS/Re 0144	**Rec. Name:** Official Declaration Statement for Importing Medicines Under Prescription for a Specific Patient		
Version No: 01	**Issued Date:** 19.05.2026	**Copy Letter:**	**Page No:** Page 1 of 2

Name of Importer / Authorized Person:	
Designation:	
Organization:	
Signature:	
Date:	
Official Stamp (if applicable):	