



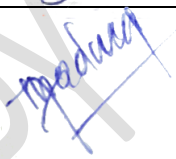
Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Exceptional Import of Medicines Not Available in Maldives

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority			Document Created on: 15.10.2026
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Version Number	1	
Issued Date	15.10.2026	
Prepared By	MTG Technical Committee	
Approved By	Aishath Mohamed, Deputy Director General, Pharmaceutical	
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SUMMARY OF CHANGES

Version No.	Issued Date	Section / Clause	Summary of Change	Changes Made by
1	15.10.2026	-	Creation of the document	MTG Technical Committee

Definitions

Medicine Not Available in the Maldives	A medicine that is not currently available through the normal legal supply system in the Maldives and is required for the provision of healthcare services. For the purposes of this Guideline, lack of availability may include situations where: • The medicine is not registered in Maldives • The registered product is temporarily unavailable • There is no suitable registered alternative • The required strength, dosage form or formulation is unavailable • A specialized medicine is required for a particular clinical condition • A medicine is required for a specific patient or defined patient group and cannot reasonably be obtained through the normal registered supply system
Healthcare Facility	A hospital, healthcare center or other facility legally authorized to provide healthcare services.
Special Import Authorization	A specific authorization issued by MFDA permitting the importation of a medicine that is not available in the Maldives for use at an identified healthcare facility.
Applicant	The entity submitting the application for special authorization. This may be an authorized medicine importer or another party specifically permitted by MFDA.
Intended Healthcare Facility	The healthcare facility at which the medicine imported under Clause 41 is authorized to be used.

1 Introduction

The Maldives relies substantially on imported medicines to meet the healthcare needs of its population. Due to the relatively small market size, limited local demand for certain specialized medicines, and the availability of medicines through international supply channels, there may be circumstances in which a medicine required for the treatment of patients is not registered or otherwise not available in the Maldives.

Clause 41 of the Medicines Regulation No. R-64/2026 establishes a specific regulatory mechanism to permit the importation of such medicines where they are required for use by a healthcare facility.

The purpose of this mechanism is to ensure that patients can obtain necessary treatments when an appropriate medicine is not available through the normal registered-product supply system, while ensuring that such medicines remain subject to appropriate controls relating to quality, safety, efficacy, traceability, storage, use, pharmacovigilance and accountability.

Under Clause 41, a medicine imported through this mechanism is permitted only for use in the healthcare facility for which the special authorization has been granted and only for the treatment provided by that facility. It should not be treated as an alternative route for placing an unregistered medicine generally on the Maldivian market.

Furthermore, this is a conditional and temporary authorization under an agreement signed by both the importer and MFDA.

In addition to addressing the critical unavailability of essential medicines, the regulatory authority may issue conditional, temporary import authorizations to state-owned importing entities. These authorizations are contingent upon full compliance with regulatory standards that ensure patient safety and product quality. A key mechanism under this framework is the provision for temporary import approvals specifically for medicines procured from accredited international healthcare institutions.

2 Purpose

The objectives of this Guideline are to:

1. Establish a clear and consistent procedure for the importation of medicines that are not available in the Maldives.

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2. Facilitate timely access to medically necessary medicines for patients where registered alternatives are unavailable or unsuitable.
3. Ensure that medicines imported under Clause 41 meet appropriate standards of quality, safety and efficacy.
4. Establish clear responsibilities for healthcare facilities, importers and MFDA.
5. Ensure appropriate laboratory testing of imported medicines where required.
6. Establish appropriate post-importation monitoring and reporting requirements.
7. Ensure traceability of medicines from the manufacturer/supplier to the healthcare facility and ultimately to the patient.
8. Prevent unauthorized distribution, sale or diversion of medicines imported under this mechanism.
9. Establish a structured system for periodic reporting to MFDA.
10. Ensure that the special authorization mechanism is used only when justified by a genuine healthcare need.

3 Scope

This Guideline applies to:

- Healthcare facilities requiring medicines that are not available in the Maldives
- State owned medicine importers
- Authorized medicine importers
- Pharmaceutical suppliers or other entities supplying such medicines
- Pharmacists and other healthcare professionals involved in receiving, storing, dispensing or administering such medicines
- MFDA officers responsible for assessment, authorization, inspection, quality monitoring and enforcement

The process described in this guideline does not replace the normal medicine registration and importation requirements applicable to medicines that are routinely available in the Maldives.

4 Section A: The Importation and Use of Medicines Not Available in Maldives For Use at Healthcare Facilities

4.1 Legal Basis

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4.1.1 Clause 41 establishes that where a medicine required for services provided by a healthcare facility is not available in the Maldives, MFDA may issue a special authorization for its importation.

4.1.2 Medicines imported under this special authorization shall be restricted exclusively to be used in healthcare facilities and administered solely for treatments conducted within that institution. To ensure strict compliance, a standardized operational framework shall be established through a Memorandum of Understanding (MOU) between the importer and the Maldives Food and Drug Authority (MFDA), establishing explicit criteria to guarantee the safety, quality, and efficacy of all products imported under this mechanism

4.2 Background

4.2.1 The Maldives Food and Drug Authority (MFDA) recognizes that certain medicines required for the diagnosis, treatment, or management of patients may not be routinely available or registered in Maldives.

4.2.2 In exceptional circumstances, a medicine that is not available in Maldives may therefore be imported under a Special Import Authorization for use at a healthcare facility where there is a demonstrated clinical need.

4.2.3 Clause 41 of the Medicine Regulation R-64/2026 permits the Authority to authorize the importation of such medicines where they are required to provide healthcare services and are not otherwise available in Maldives.

4.2.4 This guideline establishes the requirements and procedures for:

- Requesting authorization to import medicines not available in Maldives
- Assessing the need for such medicines
- Evaluating the quality, safety and suitability of the proposed products
- Approving the healthcare facility and importer
- Importing, receiving, storing and using the medicines
- Monitoring the use and safety of the medicines
- Reporting adverse events and other quality concerns
- maintaining records and submitting periodic reports to MFDA

4.2.5 The purpose of this is to ensure that access to medically necessary medicines is facilitated while maintaining appropriate regulatory control over their quality, safety, efficacy and appropriate use.

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4.3 General Principles

- 4.3.1 Exceptional Use:** The Special Import Authorization pathway shall be used only where the medicine is not reasonably available through the normal registered supply system.
- 4.3.2 Clinical Need:** The request shall be supported by a legitimate clinical or public-health need.
- 4.3.3 Restricted Use:** Medicine imported under this pathway shall be used only at the healthcare facility specified in the authorization.
- 4.3.4 Quality Assurance:** The applicant/importer shall be responsible for ensuring that the medicine meets applicable quality and safety requirements throughout the supply chain.
- 4.3.5 Traceability:** Complete records shall be maintained to enable MFDA to trace the medicine from the manufacturer/supplier through importation, storage and use.
- 4.3.6 No Commercial Distribution:** Medicines imported under this pathway shall not be:
- Sold to pharmacies
 - Transferred to another healthcare facility without approval from MFDA
 - Distributed to another importer
 - Supplied to retail outlets
 - Commercially marketed

4.4 Eligibility for Special Import Authorization

- 4.4.1** A medicine may be considered for authorization where:
- The medicine is not currently available through the normal authorized supply system in Maldives.
 - There is a demonstrated clinical need.
 - The medicine is required for treatment provided by a healthcare facility.
 - There is no suitable registered alternative available, or the available alternative is clinically unsuitable or unavailable.
 - The proposed product can be adequately evaluated for quality, safety and efficacy.
 - The proposed manufacturer and supplier can provide adequate supporting documentation.
 - The healthcare facility has appropriate arrangements for receiving, storing and using the medicine.
 - The applicant agrees to comply with all MFDA requirements and conditions.

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4.5 Application Requirements

4.5.1 The applicant shall submit an application to MFDA containing, at minimum:

4.5.1.1 Healthcare Facility Information

1. Name of healthcare facility
2. Registration/authorization number
3. Complete address
4. Contact details
5. Name and designation of responsible healthcare professional
6. Contact details of the responsible person

4.5.1.2 Medicine Information

- For each medicine, the following information shall be provided to MFDA before import:
 1. Generic name
 2. Brand/trade name, where applicable
 3. Strength
 4. Dosage form
 5. Route of administration
 6. Therapeutic indication
 7. Therapeutic class
 8. Manufacturer name
 9. Complete manufacturer address
 10. Country of manufacture
 11. Supplier name and address
 12. Product registration/authorization number in the country of origin, where applicable
 13. Quantity requested
 14. Proposed frequency of importation
 15. Estimated duration of use
 16. Storage requirements
 17. Shelf life
 18. Proposed use at the healthcare facility
- Medicine list which the importer proposed to import shall be submitted and it shall be annexed to the agreement. This list shall be updated as requested by the importer.

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4.6 Criteria for products to be imported:

- 4.6.1** Products to be imported from countries in the category of reference NRAs, eg: Stringent regulatory authorities, WHO-listed regulatory authorities, ML 3 and 4 (list attached in annex 2), and from PIC/s certified manufacturers (<https://eudragmdp.ema.europa.eu/inspections/displayWelcome.do>).
- 4.6.2** Importers shall submit proof documents of this and during import MFDA.
- 4.6.3** If any safety documents mentioned in point 1 not available, products are to be tested by a WHO-prequalified laboratory or an accredited laboratory (except the manufacturer lab), before import, and the reports shall be submitted during import for each batch imported.
- 4.6.4** In cases where the requirements outlined above in 1 and 2 of this document cannot be fulfilled, the Maldives Food and Drug Authority shall, on an exceptional and temporary basis, extend regulatory leniency by permitting the importation of medicines manufactured at sites compliant with current Good Manufacturing Practices (cGMP) as certified by the Central Drugs Standard Control Organization (CDSCO), India. The list of such approved manufacturing sites is attached for reference.
- 4.6.5** Mentioned in point 3 above, the importer shall ensure that the product is sourced from the exact manufacturing site approved by CDSCO. The manufacturing site details indicated on the product label must correspond precisely with the site information provided in the CDSCO-approved list. Any discrepancy between the labeled manufacturing site and the approved site shall render the product ineligible under this leniency pathway.
- 4.6.6** For products imported under the criterion mentioned in clause 3, the importer shall be required to submit quality testing reports obtained from an accredited independent laboratory (other than the manufacturer's laboratory) within one (1) year from the date of importation. These testing reports shall demonstrate compliance with applicable quality specifications to ensure continued assurance of the safety, quality, and efficacy of the imported medicines

4.7 Evaluation of the Application

- 4.7.1** MFDA shall evaluate the application based on:
1. Clinical need
 2. Availability of alternatives

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3. Product quality
4. Manufacturer and supplier reliability
5. Regulatory status in the country of origin
6. Manufacturing standards
7. Product documentation
8. Proposed quantity
9. Intended use
10. Storage requirements
11. Safety considerations
12. Previous compliance history, where applicable

4.7.2 MFDA may consult relevant clinical, technical or regulatory experts when necessary.

4.8 Verification Against the Approved Drug List

4.8.1 Where applicable, the submitted product information shall be checked against the MFDA Approved Drug List (ADL).

4.8.2 Where the product is not listed on the ADL, the importer shall facilitate in submitting clinicians requisition forms to include the product in ADL for further processing.

4.9 Importer Requirements

4.9.1 The medicine shall be imported by:

- a. An MFDA-authorized medicine importer
- b. Another party specifically authorized by MFDA for the particular importation

4.9.2 The importer shall ensure that:

- a. The approved product is imported
- b. The approved manufacturer/supplier is used
- c. Shipment documentation is complete
- d. The product is transported under appropriate conditions
- e. Temperature requirements are maintained where applicable
- f. Batch and expiry information are recorded
- g. The medicine is delivered to the approved healthcare facility
- h. Complete import records are maintained

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4.10 Special Import Authorization

4.10.1 MFDA may issue a Special Import Authorization through the signed MOU

4.10.2 The authorization shall apply only to the medicine and conditions specified in the authorization.

4.11 Quality Testing

4.11.1 In accordance with Clause 41, and clause 5.4 point 2 and point 5, the imported medicine may be required to undergo testing by a laboratory designated by MFDA.

4.11.2 The applicant/importer shall bear the cost of testing.

4.11.3 Testing may include, as appropriate:

- Identification
- Assay/content
- Dissolution
- Sterility
- Microbial limits
- Particulate matter
- Physical characteristics
- Other relevant quality parameters

4.11.4 MFDA may determine whether testing is required based on the nature and risk of the medicine

4.12 Responsibility for Product Quality

4.12.1 The applicant/importer shall bear responsibility for ensuring the quality and safety of the medicine throughout all stages of:

- Procurement
- Transportation
- Importation
- Receipt
- Storage
- Handling
- Supply to the healthcare facility

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4.12.2 Use of a reputable manufacturer or supplier does not remove the applicant's responsibility for compliance with MFDA requirements.

4.13 Storage Requirements

4.13.1 The healthcare facility shall maintain appropriate storage conditions in accordance with:

- Product labeling
- Manufacturer requirements
- Applicable MFDA requirements
- Good storage practices

4.13.2 Particular attention shall be given to:

- Temperature
- Humidity
- Light protection
- Security
- Segregation of unsuitable or expired products
- Cold-chain requirements
- Stock rotation

4.14 Use of Authorized Medicines

4.14.1 Medicines imported under Clause 41 shall:

1. Be used only for the approved clinical indication.
2. Be used only at the healthcare facility specified in the authorization.
3. Not be transferred to another healthcare facility without prior MFDA approval.
4. Not be sold or commercially distributed.
5. Be administered by appropriately qualified healthcare professionals.
6. Be maintained under appropriate professional and institutional controls.

4.15 Records and Traceability

4.15.1 The healthcare facility and importer shall maintain records sufficient to trace every imported batch.

4.15.2 Records should include:

- Medicine name

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- Strength
- Dosage form
- Manufacturer
- Supplier
- Batch/lot number
- Expiry date
- Quantity received
- Quantity used
- Quantity remaining
- Patient/use records where appropriate
- Date of receipt
- Storage records
- Disposal records
- Any adverse-event or quality reports

4.15.3 Records shall be made available to MFDA upon request.

4.16 Adverse Drug Reaction and Safety Reporting

4.16.1 The healthcare facility shall establish a mechanism for identifying and reporting suspected adverse drug reactions and other medicine-related safety concerns.

4.16.2 Any serious or unexpected adverse event associated with a medicine imported under this pathway shall be reported to MFDA in accordance with applicable pharmacovigilance requirements.

4.16.3 The healthcare facility shall also:

- investigate suspected medicine-related incidents
- preserve relevant product and batch information
- cooperate with MFDA investigations
- implement corrective measures where necessary

4.17 Quality Defects and Complaints

4.17.1 Any suspected quality defect shall be reported promptly to MFDA.

4.17.2 Examples include:

- Discoloration

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- Unusual appearance
- Broken tablets
- Damaged packaging
- Contamination
- Incorrect labeling
- Missing information
- Suspected counterfeit product
- Suspected falsification
- Inadequate potency
- Any other defect that may affect product quality or patient safety

4.17.3 The affected batch shall be appropriately quarantined where necessary pending further assessment.

4.18 Periodic Reporting Requirements

4.18.1 In accordance with Clause 41, the importer/authorized healthcare facility shall submit the required information to MFDA periodically.

4.18.2 The report shall include, as applicable:

- Medicine Information:** Information on all medicines imported under the authorization.
- Safety Information:** Reports of adverse drug reactions and other safety concerns.
- Utilization Information:** Detailed information on how the imported medicines were used.

4.18.3 The reporting frequency shall be as specified by MFDA and may be adjusted based on the risk and nature of the medicine.

4.19 Inspection and Monitoring

4.19.1 MFDA may conduct inspections:

- Routinely
- Based on risk
- Following a complaint
- Following a quality defect
- Following an adverse event

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- Where there is concern regarding unauthorized use or distribution

4.19.2 The areas inspected can include:

- The healthcare facility
- Storage areas
- Records
- Medicine stocks
- Dispensing/use records
- Temperature records
- Quality-management systems
- Any other relevant location or documentation

4.19.3 The healthcare facility and importer shall provide full cooperation during inspections.

4.20 Non-Compliance

4.20.1 Non-compliance may include:

1. Importing without valid authorization
2. Importing an unauthorized product
3. Importing quantities exceeding the approved quantity
4. Using the medicine outside the approved healthcare facility
5. Transferring the medicine without MFDA approval
6. Selling or commercially distributing the medicine
7. Failure to maintain records
8. Failure to submit required reports
9. Failure to report adverse events
10. Failure to maintain appropriate storage conditions
11. Submitting false or misleading information
12. failure to comply with conditions imposed by MFDA

4.20.2 MFDA may take appropriate regulatory action in accordance with Medicine Regulation R-64/2026.

4.21 Cancellation or Suspension of Authorization

4.21.1 MFDA may suspend, restrict or cancel a Special Import Authorization where:

- the medicine is no longer required

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- an appropriate registered alternative becomes available
- the medicine is found to present unacceptable safety or quality risks
- the medicine is being used outside the approved healthcare facility
- the applicant fails to comply with reporting requirements
- required information is not submitted
- the applicant provides false or misleading information
- unauthorized distribution occurs
- other regulatory non-compliance is identified

4.21.2 Failure to submit the information required under Clause 41 may result in cancellation of the relevant authorization.

4.22 Responsibilities of the Healthcare Facility

4.22.1 The healthcare facility shall:

1. Demonstrate the clinical need for the medicine
2. Ensure that the medicine is used only for the approved purpose
3. Ensure that the medicine is used only within the authorized facility
4. Maintain appropriate storage conditions
5. Maintain complete records
6. Monitor medicine safety
7. Report adverse events and quality defects
8. Submit periodic utilization reports
9. Cooperate with MFDA inspections
10. Ensure appropriate disposal of unused or expired medicines
11. Prevent unauthorized access or diversion

4.23 Responsibilities of the Importer

1. Obtain the required MFDA authorization before importation
2. Import only the approved product and quantity
3. Procure from the approved manufacturer/supplier
4. Ensure appropriate transportation conditions
5. Maintain complete import documentation

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6. Ensure batch traceability
7. Facilitate laboratory testing when required
8. Bear applicable testing costs
9. Report quality defects and safety concerns
10. Provide information requested by MFDA
11. Ensure delivery to the authorized healthcare facility

4.24 Responsibilities of MFDA

1. Receive and evaluate applications
2. Assess the clinical and regulatory justification
3. Evaluate product quality and safety information
4. Determine whether additional documentation is required
5. Issue or refuse special import authorization
6. Specify appropriate conditions
7. Arrange or require laboratory testing where necessary
8. Monitor compliance
9. Conduct inspections
10. Review adverse-event and quality information
11. Review periodic reports
12. Take appropriate regulatory action where necessary

4.25 Disposal of Unused Medicines

4.25.1 Unused, expired, damaged or rejected medicines imported under this pathway shall not be sold, transferred or otherwise distributed without MFDA authorization.

4.25.2 Disposal shall be conducted in accordance with applicable MFDA requirements.

4.25.3 The healthcare facility/importer shall maintain disposal records including:

- Medicine name
- Strength
- Quantity
- Batch number
- Expiry date
- Reason for disposal
- Date of disposal

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- Method of disposal

4.26 Review and Renewal

4.26.1 A new application or renewal request shall be submitted where continued use of the medicine is required beyond the period specified in the authorization.

4.26.2 The applicant shall provide updated:

- Clinical justification
- Utilization data
- Safety information
- Quality information, where applicable
- Consumption information
- Justification for continued importation

4.26.3 Previous compliance with the authorization may be considered when assessing subsequent requests.

4.27 Key Regulatory Restrictions

4.27.1 Medicines imported under Clause 41 shall not be treated as generally registered medicines in Maldives.

4.27.2 Unless specifically authorized by MFDA, they shall not be:

- Marketed
- Advertised
- Sold through retail pharmacies
- Supplied to other healthcare facilities
- Transferred to another importer
- Commercially distributed
- Used for purposes other than those approved

4.27.3 The authorization is specifically linked to the approved medicine, healthcare facility, importer and intended use.

5 Section B: The Importation of Medicines from Accredited Hospitals

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- 5.1** To ensure the continuous availability of essential medicines required to meet the healthcare needs of the population, the Maldives Food and Drug Authority (MFDA), in consultation with the Ministry of Health (MOH), shall designate a state-owned importer to facilitate the temporary importation of essential medicines that are unavailable or in insufficient supply in the Maldives. Such importation shall be permitted only where necessary to address an identified public health need, prevent or mitigate medicine shortages, and ensure uninterrupted access to essential treatments.
- 5.2** The designated state-owned importer shall comply with the conditions, procedures, documentation requirements, and quality assurance measures specified in the “Guideline for Approving Import of Medicine from Accredited Hospitals” (MTG/RE-AC/GLN-TE 022)
- 5.3** Temporary importation shall be subject to MFDA authorization and appropriate regulatory oversight to ensure that the medicines imported meet acceptable standards of quality, safety, and efficacy. This mechanism shall serve as an exceptional and time-limited measure to safeguard public health and maintain the availability of essential medicines until a sustainable supply arrangement can be established.

6 Legal Bais

- a. Health Services Act 29/2015
- b. Medicine Regulation R-64/2026

7 References

- a. Guideline for Approving Import of Medicine from Accredited Hospitals (MTG/RE-AC/GLN-TE 022)

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