



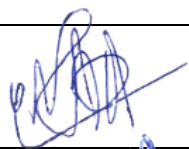
Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

**MTG Guideline for the Registration and Qualification of
Medicine Suppliers**

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 06.10.2026	
Doc. No: MTG/RE-SR/GLN-TE 025	Doc. Name: MTG Guideline for the Registration and Qualification of Medicine Suppliers		
Version No: 01	Issued Date: 06.10.2026	Copy Letter:	Page No: Page 1 of 29

Version Number	1	
Issued Date	06.10.2026	
Prepared By	MTG Technical Committee	
Approved By	Aishath Mohamed, Deputy Director General, Pharmaceuticals	
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SUMMARY OF CHANGES

Version No.	Issued Date	Section/Clause	Summary of Change	Changes Made by
1	06.10.2026	-	Creation of the document	MTG Technical Committee

Definitions

Medicine Supplier	A medicine supplier means an individual, company, organization or other legal entity that supplies medicines to a licensed medicine importer in the Maldives. A supplier may include a wholesaler, distributor, marketing authorization holder, contract manufacturing organization or other legally authorized entity involved in the commercial supply of medicines.
Manufacturer	An entity responsible for manufacturing, processing, packaging, testing, releasing or otherwise producing a medicine.
Contract Manufacturer	A manufacturer that produces a medicine on behalf of another company or product owner under a contractual manufacturing arrangement.
Supplier Registration	The formal approval by MTG of a supplier following assessment of its legal status, legitimacy, quality systems, manufacturing/supply arrangements and other applicable regulatory requirements.
Importer	A person or entity licensed by MTG to import medicines into the Maldives.

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1 Introduction

The Maldives Food and Drug Authority (MTG), through its Medicine and Therapeutic Goods Division (MTG), is responsible for regulating medicines throughout their lifecycle to ensure that medicines available in the Maldives meet the required standards of quality, safety, and efficacy.

As medicines are predominantly imported into the Maldives, the reliability, competence and regulatory compliance of overseas medicine suppliers are critical components of the national medicine regulatory system. Appropriate oversight of suppliers is therefore necessary to ensure that medicines supplied to licensed importers originate from legitimate and suitably qualified sources and are manufactured, stored, handled and supplied in accordance with applicable quality standards.

This Guideline establishes the requirements and procedures for the registration, assessment, monitoring and continued oversight of medicine suppliers supplying medicines to the Maldives.

For the purpose of this Guideline, “Medicine Supplier” means any person, company, organization, distributor, wholesaler, procurement agent, trading company, marketing authorization holder, or other third party that supplies or arranges the supply of medicines to an importer, but is not the actual manufacturer of the medicine.

A supplier may procure medicines directly from the manufacturer or through another authorized supply chain entity and may act as an intermediary between the manufacturer and the importer. The term includes, but is not limited to, medicine supply agents, distributors, wholesalers, trading companies, procurement agencies, and other third-party entities involved in the commercial supply of medicines.

For the avoidance of doubt, a company shall be considered a supplier under this Guideline where it supplies a medicine manufactured by another entity, even if the supplier owns, markets, distributes, or holds rights to the brand under which the medicine is supplied.

The registration of a supplier with the Authority shall not replace or exempt the requirement to identify and provide information on the actual manufacturer and manufacturing site of the medicine. The importer shall remain responsible for ensuring that the supplier and the manufacturer meet all applicable regulatory, quality, safety, and compliance requirements established by the Authority.

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Clause 13 of medicine Regulation No. R-64/2026 should be read together with this guideline. The Regulation establishes a broader framework covering medicine registration, manufacturer registration, supplier registration, storage, importation, distribution, dispensing, quality assurance and inspection.

2 Purpose

The purpose of this Guideline is to:

1. Establish a standardized system for the registration of medicine suppliers.
2. Ensure that medicines imported into the Maldives are sourced from legitimate and appropriately qualified suppliers.
3. Ensure that suppliers have adequate systems for maintaining the quality, safety and efficacy of medicines throughout the supply chain.
4. Establish minimum documentation and information requirements for supplier registration.
5. Define the responsibilities of medicine importers and suppliers.
6. Establish mechanisms for monitoring supplier performance and compliance.
7. Facilitate effective regulatory oversight, inspections, quality investigations, complaints and recalls.
8. Minimize the risk of substandard, falsified, contaminated, deteriorated or otherwise unsuitable medicines entering the Maldivian market.

The overall regulatory objective is consistent with the Medicines Regulation's requirement to ensure that medicines supplied for use in the Maldives are of appropriate quality and safe for use.

3 Scope

This Guideline applies to:

- All medicine suppliers (except manufacturers) supplying medicines to the Maldives;
- Wholesalers and distributors supplying medicines to Maldivian importers;
- Marketing authorization holders or product owners acting as suppliers;
- International procurement organizations supplying medicines to the Maldives;
- Suppliers involved in the supply of prescription, OTC, controlled and hospital-use medicines, where applicable; and

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- Licensed medicine importers applying to register or use an overseas supplier.

The requirements may be applied proportionately according to the nature of the supplier, the type of medicine supplied and the associated quality and safety risks.

4 General Requirement for Supplier Registration

- 4.1.1** It's the medicines importers responsibility to ensure that every supplier from whom they import medicines is registered or otherwise approved by MTG in accordance with the applicable regulatory requirements.
- 4.1.2** The responsibility for ensuring that the supplier is appropriately registered rests with the medicine importer intending to source medicines from that supplier.
- 4.1.3** An importer shall not source medicines from an unregistered supplier.

5 Responsibilities of the Importer

The registered importer shall:

1. Conduct appropriate due diligence on the proposed supplier.
2. Submit complete and accurate supplier registration information to MTG.
3. Ensure that the supplier is legally authorized to supply medicines.
4. Ensure that medicines supplied by the supplier are registered/approved for importation where required.
5. Maintain a valid written agreement or contract with the supplier.
6. Ensure that the supplier maintains appropriate quality management systems.
7. Ensure that the supplier provides all documents and information required by MTG.
8. Monitor supplier performance.
9. Notify MTG of significant changes affecting the supplier or medicines supplied.
10. Maintain records of purchases and supplies from each registered supplier.
11. Cooperate with MTG during inspections, investigations, recalls and quality-related activities.
12. Ensure that medicines supplied are transported and handled under appropriate conditions.

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6 Supplier Registration Requirements

- 6.1** Supplier registration from (ANNEX1) shall be completed by the importer and submitted for approval before importing medicines from this specific supplier.

Application can be submitted to MTG Registration Unit using the following link: [Medicine Supplier Registration Application Form – Fill out form](#)

- 6.2** An application for registration of a medicine supplier shall include, at a minimum, the following information and documentation:

6.3 Supplier–Importer Agreement

- 6.3.1** The importer and supplier shall have a written and valid contractual agreement governing the supply of medicines. Refer to ANNEX 2 for the Supplier-importer agreement.

- 6.3.2** The agreement should clearly define the responsibilities of both parties

6.4 Product Information to be Maintained by the Supplier

- 6.4.1** For each medicine supplied, the importer shall maintain sufficient information to establish traceability.

- 6.4.2** At minimum, records should include:

No.	Information
1	Generic/INN name
2	Brand name
3	Active ingredient(s)
4	Strength
5	Dosage form
6	Pack size/volume
7	Product registration/authorization number, where applicable
8	Manufacturer name
9	Full manufacturing-site address
10	Batch/lot number
11	Manufacturing date

12	Expiry date
13	Quantity supplied
14	Unit price and total value, where applicable
16	Shipping/consignment information

6.4.3 This is particularly important for ensuring traceability during quality investigations, recalls and post-market surveillance.

6.5 Verification of Product Quality

6.5.1 The supplier shall demonstrate that the medicines supplied meet applicable quality requirements.

6.5.2 MTG may require evidence such as:

- Certificate of Analysis
- GMP certificate

6.5.3 Where this documentation is not available or cannot be provided, a written declaration from the supplier shall be submitted, confirming that the medicines and other regulated products supplied meet applicable quality, safety, and efficacy requirements and are suitable for their intended use. The supplier shall accept responsibility for any quality defects, safety concerns, non-conformities, or other deficiencies attributable to the products supplied and shall cooperate fully with the importer and the MTG in investigating and addressing any such concerns.

6.6 Validation of the Supplier

6.6.1 MTG requires the importer to provide following documentation to verify the supplier's legal status, legitimacy, and authorization to export, import, supply, or trade in medicines and other regulated pharmaceutical products. Such documentation may include, but is not limited to:

- A valid pharmaceutical export, import, wholesale, or trading license
- OR Registration or authorization issued by the relevant national regulatory or government authority
- OR equivalent evidence of authorization to procure, store, handle, distribute, supply, or sell pharmaceutical and healthcare products

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6.6.2 The MTG may verify the authenticity and validity of submitted documents with the issuing authority or through other appropriate means. Where the required evidence cannot be satisfactorily verified, the MTG may withhold, suspend, or refuse the relevant import authorization or take other regulatory action in accordance with the applicable requirements.

7 Storage and Handling Requirements

7.1 The supplier shall ensure that medicines are stored and handled in accordance with the manufacturer's specified conditions and applicable Good Distribution Practice (GDP) principles.

7.2 The supplier should have appropriate systems for:

- Temperature control
- Humidity control, where applicable
- Stock rotation
- FEFO/FIFO
- Pest control
- Cleaning
- Security
- Segregation of rejected, recalled and expired products
- Prevention of contamination and cross-contamination
- Handling of temperature excursions
- Documentation and recordkeeping

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- 7.3** The Regulation separately establishes requirements concerning medicine storage, distribution and transportation.

8 Transportation and Cold Chain

- 8.1** Where medicines require controlled temperature conditions, the supplier shall demonstrate that appropriate transportation systems are available.

- 8.2** For temperature-sensitive products, the importer may require:

- Validated or qualified transportation arrangements
- Temperature monitoring devices
- Temperature records
- Cold-chain procedures
- Excursion management procedures
- Emergency arrangements
- Evidence of appropriate handling during transportation

9 Supplier Audit and Inspection

- 9.1** MTG may require a supplier to undergo an inspection or audit were considered necessary.

- 9.2** Such inspections may be conducted to assess:

- Legitimacy of the supplier
- Manufacturing or distribution facilities
- Quality management systems
- Storage conditions
- Traceability
- Documentation
- Complaint management
- Recall systems
- Compliance with applicable pharmaceutical standards

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- 9.3** The Regulation provides MTG with inspection and assessment powers and establishes inspection procedures and sampling/testing provisions.
- 9.4** Where an inspection is required, the importer shall cooperate with MTG and facilitate access to the relevant supplier and premises.

10 Supplier Performance Monitoring

- 10.1** The importer shall establish a system for periodically evaluating the performance of registered suppliers.
- 10.2** Supplier performance may be assessed based on:
- Number and severity of quality complaints
 - Number of defective batches
 - Delivery performance
 - Product shortages
 - Temperature excursions
 - Documentation deficiencies
 - Regulatory compliance
 - Recall history
 - Responsiveness to quality issues
 - Compliance with contractual requirements
 - Results of inspections or audits

11 Annual Supplier Performance Record

- 11.1** For suppliers supplying medicines to Maldives, the importer should maintain an annual supplier performance record.
- 11.2** The assessment should include:

Area	Assessment
Product quality	Satisfactory/Unsatisfactory

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Delivery performance	Satisfactory/Unsatisfactory
Documentation	Satisfactory/Unsatisfactory
Complaints	Number and severity
Quality defects	Number and severity
Recalls	Yes/No and details
Regulatory issues	Yes/No and details
Temperature excursions	Number and outcome
CAPA	Required/Not required
Overall supplier status	Approved/Conditional/Suspended

11.3 MTG may request these records during inspection or when conducting regulatory assessment.

12 Notification of Changes

12.1 The importer shall notify MTG of significant changes involving a registered supplier.

12.2 These may include:

- Change of company name
- Change of ownership
- Change of address
- Change in manufacturing site
- Change in distribution site
- Change in pharmaceutical license
- Suspension or cancellation of authorization
- Significant regulatory action
- Major GMP deficiency
- Product recall
- Change in quality management system
- Any other change that may affect the quality, safety or supply of medicines
- Addition of manufacturing site following addition of product

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13 Supplier Suspension or Cancellation

13.1 MTG may suspend or cancel supplier registration where there is evidence that the supplier:

1. Has supplied substandard or falsified medicines;
2. Has provided false or misleading information;
3. Is no longer legally authorized to supply medicines;
4. Has serious or repeated quality deficiencies;
5. Has failed to cooperate with regulatory investigations;
6. Has failed to comply with applicable regulatory requirements;
7. Has failed to provide requested documentation;
8. Has been subject to significant regulatory action in another jurisdiction; or
9. Presents an unacceptable risk to the quality, safety or efficacy of medicines supplied to Maldives.

14 Reinstatement of a Suspended Supplier

14.1 A suspended supplier may be considered for reinstatement following satisfactory completion of corrective and preventive actions and submission of appropriate supporting evidence.

14.2 MTG may require:

- CAPA documentation
- Updated licenses/certificates
- Inspection reports
- Evidence of regulatory compliance
- Quality-control documentation
- Independent laboratory results
- A follow-up inspection

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15 Complaints and Quality Defects

- 15.1** The importer shall maintain an effective system for receiving, investigating and documenting complaints related to medicines supplied by registered suppliers.
- 15.2** The supplier shall cooperate with investigations and provide relevant information within the timeframe specified by the importer or MTG.
- 15.3** Serious quality defects that may affect patient safety shall be reported to MTG without undue delay.

16 Product Recall

- 16.1** The supplier shall have an effective recall and traceability system.
- 16.2** Where a product recall is initiated, the supplier and importer shall cooperate with MTG to:
1. Identify affected batches
 2. Determine quantities supplied
 3. Identify affected healthcare facilities/pharmacies
 4. Stop further distribution
 5. Recover affected stock
 6. Maintain appropriate records
 7. Investigate the root cause
 8. Implement CAPA
- 16.3** The Regulation separately establishes requirements for medicine recalls under Clause 55.

17 Blacklisting / Regulatory Alert

- 17.1** If a supplier is found to present a significant regulatory risk, MTG may place the supplier under regulatory alert or restrict further sourcing from that supplier.
- 17.2** The importer shall immediately notify MTG if it becomes aware that a supplier:
- Has been suspended by another regulatory authority
 - Has been identified as supplying falsified medicines

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- Has had a major GMP certificate withdrawn
- Has been subject to a serious regulatory warning
- Has been involved in a major product recall
- Has otherwise become unsuitable to supply medicines

24. Supplier Documentation Checklist

Supplier registration application should include, where applicable:

- ☐ Completed supplier registration application
- ☐ Importer–supplier agreement/contract
- ☐ Company registration certificate
- ☐ Pharmaceutical wholesale/distribution license
- ☐ Manufacturing license, where applicable
- ☐ GMP certificate, where applicable
- ☐ Evidence of product authorization/registration
- ☐ Full supplier address and contact details
- ☐ Manufacturing-site details
- ☐ Distribution/storage-site details
- ☐ Quality management system information
- ☐ Complaint-handling procedure
- ☐ Product recall procedure
- ☐ Storage and transportation procedures
- ☐ Cold-chain arrangements, where applicable
- ☐ Supplier quality assurance declaration
- ☐ Regulatory history
- ☐ Details of previous regulatory sanctions, recalls or major quality defects
- ☐ Product list

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- ☐ Relevant quality certificates
- ☐ Other documents requested by MTG

18 Risk-Based Assessment

18.1 MTG may apply a risk-based approach when assessing suppliers.

18.2 Factors that may increase the regulatory risk include:

- Supplier's regulatory history
- Type of medicines supplied
- Criticality of medicines
- Biological or sterile products
- Controlled medicines
- Temperature-sensitive products
- High-risk medicines
- Previous quality defects
- Recalls
- GMP deficiencies
- Lack of regulatory authorization
- Poor supplier performance
- Inadequate quality systems

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18.3 Lower-risk suppliers may be subject to proportionate documentary assessment, while higher-risk suppliers may require enhanced documentation, inspection or other regulatory controls.

19 Validity and Renewal

19.1 Supplier registration shall remain valid for the period specified by MTG.

19.2 The importer shall ensure that the supplier's registration and all supporting licenses and certificates remain current.

19.3 An application for renewal should be submitted sufficiently in advance of expiry and should include updated information and documentation.

19.4 Any material change occurring during the validity period shall be reported to MTG rather than waiting until renewal.

20 Record Retention

20.1 Importers shall maintain complete records relating to each registered supplier, including:

- Registration documents
- Contracts
- Product lists
- Purchase records
- Batch records
- Certificates of Analysis
- Complaints
- Quality investigations
- Recall records
- Regulatory communications
- Supplier performance assessments
- CAPA records

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20.2 Records shall be retained for the period prescribed by applicable legislation or MTG requirements.

21 Regulatory Compliance

21.1 Failure to comply with this Guideline may result in regulatory action, including:

- Request for additional information
- Rejection of supplier registration
- Suspension of supplier registration
- Restriction of products supplied
- Suspension of importation
- Product detention
- Product recall
- Cancellation of applicable approvals
- Other enforcement action provided under the Medicine Regulation

21.2 The Regulation contains specific provisions relating to prohibited activities, penalties, suspension/cancellation and enforcement.

22 Legal Basis

- Medicine Regulation R-64/2026

23 Annex

- ANNEX 1 - Medicine Supplier Registration Application Form
- ANNEX 2 - Importer–Supplier Agreement for the Supply of Medicines

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ANNEX 2 - Medicine Supplier Registration Application Form

Please note that the following form is a sample for reference only. The actual form is available in an online form ([Medicine Supplier Registration Application Form – Fill out form](#)) and is subject to changes.

Declaration form is available through Ministry and MFDA website, and through Dhirithi Portal Publications.

Application type: ☐ New registration ☐ Renewal ☐ Change/Update

Important: The application is submitted by the licensed Maldivian importer. Supplier registration does not replace identification/approval of the actual manufacturer and manufacturing site.

A. Applicant / Importer Details

Importer legal name	
MTG importer license/registration no.	
Registered address	
Contact person	
Telephone	
Email	

B. Supplier Details

Full legal name	
Registered/trading name (if different)	
Country of registration	
Country of operation	
Registered address	
Website	
Primary contact person/title	
Telephone	
Email	

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Legal status of the supplier:	
Authorization to wholesale/distribute /export/supply medicines	
Validity of the authorization mentioned above	

C. Supplier Business Activities

- ☐ Wholesaler
- ☐ Distributor
- ☐ Trading company
- ☐ Procurement agent
- ☐ Marketing authorization holder/product owner
- ☐ Other (specify): _____

Does the supplier store medicines? ☐ Yes ☐ No

Does the supplier arrange transportation? ☐ Yes ☐ No

D. Manufacturing and Supply Chain Information

Does supplier source directly from manufacturer?	☐ Yes ☐ No
If no, describe supply chain/intermediaries	
Number of manufacturers covered by this application	
Manufacturing-site details attached	☐ Yes ☐ No
Distribution/storage-site details attached	☐ Yes ☐ No

E. Product Information

Attach a list of products that will be supplied by the supplier in the given format below (The product list can be updated as required)

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No.	Generic Name	Brand name	Strength	Dosage form	Manufacturer	Manufacturing site	Registration/authorization number of MTG
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F. Quality and Regulatory Information

Quality management system available? ☐ Yes ☐ No

Complaint-handling procedure available? ☐ Yes ☐ No

Recall procedure available? ☐ Yes ☐ No

Storage/transport procedures available? ☐ Yes ☐ No

Cold-chain arrangements available, where applicable? ☐ Yes ☐ No ☐ N/A

Supplier subject to regulatory sanctions in the last 5 years? ☐ Yes ☐ No

Major recalls in the last 5 years? ☐ Yes ☐ No

Major GMP deficiencies/regulatory warnings? ☐ Yes ☐ No

If Yes to any regulatory history question, provide details and supporting documents.

G. Declaration by Supplier

I declare that the information provided is complete and accurate and that the supplier is legally authorized to supply medicines. I undertake to notify the importer of significant changes affecting licenses, regulatory status, manufacturing/distribution arrangements, product quality, recalls or other matters that may affect the quality, safety or efficacy of medicines supplied to Maldives.

Supplier authorized representative – name/title	
Signature	
Date	
Company stamp, where applicable	

H. Declaration by Importer

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I confirm that, as the importer, I have conducted appropriate due diligence, will maintain a valid written agreement with the supplier, and will ensure compliance with MTG requirements, including traceability, quality monitoring, complaints, recalls and notification of significant changes.

Importer authorized representative – name/title	
Signature	
Date	
Company stamp	

I. Supporting Document Checklist

- ☐ Completed Supplier Registration Application
- ☐ Importer–Supplier Agreement/Contract
- ☐ Company registration certificate
- ☐ Pharmaceutical wholesale/distribution license of the supplier
- ☐ Manufacturing license, where applicable
- ☐ GMP certificate, where applicable
- ☐ Evidence of product authorization/registration
- ☐ Supplier address and contact details
- ☐ Manufacturing-site details
- ☐ Distribution/storage-site details
- ☐ Quality management system information
- ☐ Complaint-handling procedure
- ☐ Product recall procedure
- ☐ Storage and transportation procedures
- ☐ Cold-chain arrangements, where applicable
- ☐ Supplier quality assurance declaration
- ☐ Regulatory history and sanctions/recalls/major quality defects
- ☐ Product list
- ☐ Relevant quality certificates
- ☐ Other documents requested by MTG

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ANNEX 2 - Importer–Supplier Agreement for the Supply of Medicines

This Agreement is designed to satisfy the minimum supplier–importer contractual requirements set out in the MTG supplier guideline. Parties should obtain legal review before execution.

1. Parties

Importer legal name	
MTG license/registration no.	
Registered address	
Supplier legal name	
Supplier registration/license no.	
Registered address	

Effective date: _____

Agreement expiry/review date: _____

2. Purpose and Scope

The Supplier agrees to supply, or arrange the supply of, medicines to the Importer in accordance with this Agreement, applicable MTG requirements, applicable laws in the supplier's jurisdiction, and the approved product/manufacture arrangements.

3. Supplier Authorization and Legitimacy

The Supplier shall maintain all licenses and authorizations necessary to supply medicines and shall only source medicines from legitimate and appropriately authorized sources. The Supplier shall provide evidence of such authorization when requested.

4. Product Quality

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The Supplier shall ensure that medicines supplied are legally manufactured and/or sourced, authorized for supply where applicable, meet approved quality specifications, are within approved shelf-life, are appropriately packaged and labelled, and are stored and transported under required conditions.

5. Manufacturer and Manufacturing Site

The Supplier shall identify the actual manufacturer and manufacturing site for each medicine and shall not change the approved manufacturer or manufacturing site without prior notification to the Importer and, where required, MTG approval.

6. Product Documentation

The Supplier shall provide Certificates of Analysis and GMP documentation or supplier declaration confirming that the medicines and other regulated products supplied meet applicable quality, safety, and efficacy requirements and are suitable for their intended use. Certificates of Analysis or batch certificates shall be provided for all biologicals and IV preparations. The required DEG/EG report shall be provided for cough and cold preparations.

7. Storage and Transportation

The Supplier shall maintain appropriate storage, handling and transportation conditions consistent with the manufacturer's requirements and applicable GDP principles. Temperature-sensitive medicines shall be transported using appropriate qualified/validated arrangements, temperature monitoring and excursion-management procedures.

8. Traceability and Records

The Supplier shall maintain records sufficient to trace medicines from source to the Importer, including product, manufacturer, manufacturing site, batch/lot, manufacturing and expiry dates, quantities and shipping/consignment information. Records shall be made available to the Importer or MTG when lawfully requested. To ensure full traceability in accordance with Section 9 of the MTG Guideline for the Registration and Qualification of Medicine Suppliers, such records shall, in respect of each medicine supplied, also include the generic/INN name, brand name, active ingredient(s), strength, dosage form, pack size/volume, product registration/authorization number (where applicable), and unit price and total value

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(where applicable), in addition to the manufacturer, manufacturing site, batch/lot number, manufacturing date, expiry date, quantity supplied and shipping/consignment information referred to above.

9. Complaints and Quality Defects

The Supplier shall promptly investigate and respond to complaints and quality defects. The Supplier shall cooperate with investigations and provide requested information and samples/documents. Serious defects that may affect patient safety shall be communicated to the Importer without undue delay so that MTG notification can be made as required.

10. Suspected Falsification

The Supplier shall immediately notify the Importer of any suspected falsified, counterfeit, tampered, contaminated or otherwise unsuitable medicine and shall cooperate in investigation, segregation, detention, notification and disposition.

11. Recalls

The Supplier shall maintain an effective recall and traceability system and shall cooperate with the Importer and MTG in recalls. Cooperation shall include identifying affected batches, quantities and recipients, stopping distribution, recovering stock, maintaining records, root-cause investigation and CAPA.

12. Regulatory Changes and Notifications

The Supplier shall promptly notify the Importer of significant changes, including company name/ownership/address, manufacturing or distribution site, license or authorization status, suspension/cancellation, regulatory restrictions, major quality defects, recalls, significant GMP findings, or other changes that may affect medicine quality, safety, efficacy or supply.

13. Quality Management System

The Supplier shall maintain a quality management system proportionate to its activities, including appropriate controls for document management, change control, deviations, CAPA, complaints, recalls, training, storage/distribution, temperature management and record retention, as applicable.

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14. Audit and Inspection

The Supplier shall cooperate with reasonable quality audits by the Importer and with MTG inspection or assessment where required. The Importer shall facilitate MTG access to relevant supplier premises and records. Overseas inspection costs may be borne by the Importer as determined by MTG.

15. Supplier Performance

The Importer may periodically assess Supplier performance based on product quality, delivery, documentation, complaints, defects, recalls, temperature excursions, regulatory compliance and responsiveness. Poor performance may result in corrective actions, suspension of purchasing or other measures. The Supplier shall provide such information and records as the Importer may reasonably request to complete these assessments, including for the purpose of the Importer's Annual Supplier Performance Record maintained in accordance with the MTG Guideline.

16. Subcontracting and Intermediaries

The Supplier shall disclose relevant intermediaries or other entities involved in sourcing or arranging supply. The Supplier remains responsible for ensuring that medicines and services provided through such entities meet this Agreement.

17. Non-conforming Products

The Importer may reject or quarantine medicines that are damaged, falsified, expired, incorrectly labelled, outside specification, subject to unresolved temperature excursions or otherwise non-conforming. Disposition shall be agreed and documented in accordance with applicable requirements.

18. Confidentiality

Each party shall protect confidential commercial and quality information received from the other party, except where disclosure is required by MTG, law, regulatory authorities or necessary for patient safety and product-quality investigations.

19. Termination

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Either party may terminate this Agreement in accordance with its commercial terms. The Importer may suspend sourcing immediately where there is a serious quality, safety, regulatory or legal concern. Termination shall not prevent either party from fulfilling recall, investigation, record-retention or regulatory obligations. Without limiting the foregoing, the Importer may immediately terminate or suspend sourcing under this Agreement where the Supplier's registration with MTG is suspended or cancelled, or where the Supplier is placed under regulatory alert or otherwise restricted by MTG.

20. Regulatory Compliance

The parties shall comply with applicable Maldives medicine regulation and other applicable laws. Where an MTG requirement conflicts with a commercial term of this Agreement, the parties shall take the necessary steps to comply with the applicable regulatory requirement.

21. Product Schedule

Products proposed to be imported shall be annexed to this document and shall be in this given format

No.	Generic Name	Brand name	Strength	Dosage form	Manufacturer	Manufacturing site	Product registration/authorization number
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22. Signatures

For the Importer – name/title	
Signature	
Date	
Company stamp	
For the Supplier – name/title	
Signature	
Date	
Company stamp	