بسم الله الرحمن الرحيم

Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Approving the Import of Medicines from Accredited Hospitals

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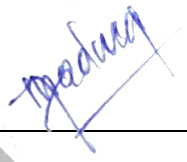
Authorized by	Thooma Adam, Deputy Director General, Laboratory Services (Acting Head of MFDA)	

Summary of Changes

Version No.	Issued Date	Section/Clause	Summary of Change	Changes Made by
1	13.02.2025	-	Creation of the document	Mohamed Fazeen, Senior Pharmacist
2	05.03.2025	-	Correction in overall document	Mariyam Laisa, Assistant Pharmaceutical Officer
3	22.05.2025	10.1	Elaboration on validity period	Mariyam Laisa, Assistant Pharmaceutical Officer

1 INTRODUCTION

As a country dependent on 100% import of pharmaceuticals, Maldives faces shortage and supply interruption of medicines especially critical essential medicines. One of the challenges reoccurring is obtaining the necessary documents for registration of medicines.

To mitigate these challenges MFDA provides different pathways which offer varying levels of lenience.

a. For registration of medicines, the market authorization procedure has been reviewed to add reliance pathways in order to minimize the required documentation and utilize the maximum use of available resources.

b. Preauthorization approvals: This procedure is comparatively more lenient than the registration procedure and also applies reliance mechanism for the approval of medicines.

c. MoU with Hospitals: Another more lenient approach established is MoU agreements with hospitals for the import Hospital Use Only (HU) medicines.

Despite the different pathways and leniencies, the unavailability of medicines is an ongoing and critical issue in the Maldives healthcare system. To overcome this and ensure availability of medicines MoH Policy with MFDA has decided to grant approvals for purchasing medicines from accredited hospitals in the region to designated importers.

These medicines shall be procured and used under the scope of the quality management/accreditation system of the accredited hospital. This is to ensure the quality, safety and efficacy of medicines imported.

2 SCOPE

This is a guidance document detailing the process for importing quality assured medicines from accredited hospitals by importers designated by MoH Policy with MFDA.

3 PURPOSE

- Ensure that medicines are available uninterruptedly.

- Minimize roadblocks in procuring medicines while ensuring their quality, safety and efficacy.
- Ensure compliance with regulatory standards.

4 ROLES AND RESPONSIBILITIES

Maldives Food and Drug Authority	• Evaluate and approve requests for import • Conduct post market surveillance on imported medicines
Importer	• Request for import as per this guideline • Provide data as required in the procedure • Ensure proper storage and handling of medicines • Maintain stock and distribution data • Apply for registration of products as mentioned in this guideline

5 REQUIRED DOCUMENTS

5.1 To ensure the safe and efficient importation of medicines from accredited hospitals, the following standards and documentation are required:

a. Valid Hospital Accreditation Document or Certificate of the procuring Hospital

- A valid and current accreditation document or certificate from the relevant healthcare or regulatory authority. This document certifies that the hospital is authorized to procure and administer medicines within its accredited practices. The certificate must be from a recognized and relevant accrediting body.

b. Letter from Procuring Hospital with Detailed List of Medicines

- Procuring Hospitals shall provide a letter with the list of medicines indicating that the medicines are procured and used in that hospital and these medicines are exported as per the requesting importer.
- This list must include, at a minimum, the following details for each product:

1. **Brand Name**: The registered brand name of the medicine.
2. **Generic Name**: The active ingredient or substance.
3. **Strength**: The concentration or dose of the active ingredient.
4. **Dosage Form**: Whether the medicine is a tablet, injection, liquid, topical, or any other form.
5. **Full Manufacturer Address**: The complete address of the manufacturer, including the site and country of origin. The manufacturer's details must match the product packaging.
6. **Volume of the Product**: For liquid and semi-solid preparations, the volume (e.g., milliliters, grams, or other relevant measurement) of the product.
7. **Quantity of medicines to be imported from the hospital to Maldives**

c. Accredited Hospital's Procedure to Ensure Quality, Safety, and Efficacy

- A detailed description of the procedures followed by the hospital to assure the quality, safety, and efficacy of the medicines it procures and uses. This includes:

    1. **Medicine Procurement Policy:** Steps taken to verify the authenticity and reliability of the source.

    2. **Storage and Handling Procedures:** How medicines are stored, maintained, and protected from temperature fluctuations or contamination.

    3. **Quality Control and Testing:** Internal practices for testing and inspecting medicines.

    4. **Post-purchase Monitoring:** Procedures for tracking the safety and effectiveness of medicines once administered to patients.

Note: Any documents submitted from the accredited hospital must be in the accredited hospital's official letterhead.

6 REQUIRED DOCUMENTATION FOR SPECIFIC PREPARATIONS DURING IMPORT

6.1 For certain medicinal preparations, the following additional documentation must be submitted to ensure safety and compliance during import:

a. **Tested Reports on DEG/EG:** Test results for Diethylene Glycol (DEG) and Ethylene Glycol (EG) content in cold and cough preparations and any other medicines as indicated by the Medicines and Food Directorate Authority (MFDA).

b. **NDMA Reports for Ranitidine:** Test results and reports from the National Drug Monitoring Authority (NDMA) regarding Ranitidine and its formulations, confirming their safety and compliance.

c. **Batch Certificates for IV Fluids and Biological Preparations:** Batch certificates, including detailed information on quality control and compliance, for all intravenous (IV) fluids and biological preparations being imported.

d. **Export License for Controlled Medicines:** A valid export license for all controlled medicines being imported, ensuring they comply with national and international regulatory standards for controlled substances.

7 APPROVAL PROCESS

7.1 Documents shall be sent to MTG@health.gov.mv and shared to relevant individuals as communicated by the authority.

7.2 Once MFDA receives the complete required information (Refer to point 5 and 6), MFDA shall proceed with the evaluation and approval process.

7.3 Evaluation and approval shall be completed within working 03 (days) and the importer shall be notified on how to proceed with any necessary comments.

7.4 The importer must review and fulfill these requirements and proceed with procurement. The reviewed documents shall be verified during the post market surveillance process. (refer to point 9)

7.5 This approval is given separately for individual shipments, and it is mandatory to apply and obtain a permit prior to import for each new shipment.

7.6 If any clarification is required by MFDA for quantity requested, justification shall be provided with evidence from relevant organizations prior to approval. This data can be taken for the past 12 months.

7.7 For products previously approved under this procedure, for new approvals of such products the stock status and distribution data shall be provided.

7.8 Once the approval is given, the list of medicines shall be added to the Approved Drug List under a special category.

8 INSPECTION UPON ARRIVAL AT PORT OF ENTRY:

8.1 Importer shall notify MFDA 24 hours before the arrival of shipment and submit the required documents for port clearance as per the given time frame (Guideline for Health Clearance of Pharmaceuticals at Entry Ports)

8.2 Health clearance shall be given at port of entry after necessary inspection for clearance.

8.3 Information on the imported products shall be recorded by MFDA Port staff alongside the clearance.

8.4 After clearance, usage of the medicines can be commenced.

9 POST MARKET SURVEILLANCE

9.1 Within working 07 (seven) days of arrival, MFDA shall conduct an inspection on the imported products for the following areas:

a. Storage and handling of the products

b. Verifying the labeling

c. Cross checking the product information with the medicine list

9.2 If any discrepancies or quality issues are identified during the inspection, necessary corrective action shall be taken by MFDA.

9.3 The importer shall provide market safety data every 6 (six) months.

10 VALIDITY AND REGISTRATION OF THE PRODUCTS

10.1 The validity of this approval is for a period of one (01) year, starting from the date of approval of the first request submitted by the designated importer. This same validity period applies to all subsequent product approvals under the same importer, regardless of their individual approval dates.

10.2 Within this period the importer shall explore other pathways for the registration of the products. (Guideline for Product Registration and Emergency Approval of medicines, Guidelines for Preauthorization Approval for Medicines)

10.3 Further regulatory measures shall be taken case-by-case based on availability and consumption data.

11 SUPPLIER MONITORING AND EVALUATION

11.1 MFDA shall conduct an annual audit of the accredited hospital's supply chain.

11.2 The expenses incurred for conducting this audit shall be covered by the importer.

12 References

a. Guideline for Pre-Authorization Approval for Medicines (MTG/RE-PA/GLN-TE 010)

b. Guideline for Product Registration and Emergency Approval of Medicines (MTG/RE-RP/GLN-TE 001)

c. Guideline for Health Clearance of Pharmaceuticals at Entry Ports (MTG/QA-HC/GLN-TE 011)