



**Maldives Food and Drug Authority**

Ministry of Health

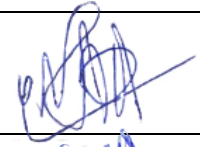

Male', Maldives

**Guideline for Import, Registration of Alternative/  
Dhivehi Beys Pharmacies and Dispensers**

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CONTROLLED COPY

<b>Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority</b>		<b>Document Created on:</b> 29.08.2022	
<b>Doc. No:</b> MTG/RE-AP/GLN-TE 017	<b>Doc. Name:</b> Guideline for Import, Registration of Alternative/ Dhivehi Beys Pharmacies and Dispensers		
<b>Version No:</b> 02	<b>Issued Date:</b> 08.10.2025	<b>Copy Letter:</b>	<b>Page No:</b> Page 1 of 15

<b>Version Number</b>	2	
<b>Issued Date</b>	08.10.2025	
<b>Prepared By</b>	Mohamed Fazeen, Director, Pharmaceuticals	
<b>Approved By</b>	Aishath Mohamed, Deputy Director General, Pharmaceuticals	
<b>Authorized by</b>	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	29.08.2022	-	Creation of the document	Mohamed Fazeen, Director, Pharmaceuticals
2	08.10.2025	Overall document	Addition of clauses in regards to inspection, Details regarding the designated sellers for alternative/ herbal medicines	Mohamed Fazeen, Director, Pharmaceuticals

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## 1 INTRODUCTION

One of the criteria for operating an Alternative/Dhivehi Beys pharmacy is to register the facility as per the specification highlighted in medicine regulation. This pharmacy shall be registered and licensed under the provisions of Medicine Regulation No: 2014/R-46 and first amendment to the Pharmaceutical Regulation No 2016/R-49.

## 2 PURPOSE

This guideline describes the process of authorizing and issuing the registration of a pharmacy. This is to ensure authorized parties sell alternative and Dhivehi Beys medicine in Maldives are, registered, licensed and operates in accordance with the regulation

## 3 SCOPE

This guideline applies to the authorization and issuance of registration, Issuing and renewal of license for an Alternative/Dhivehi Beys pharmacy in the Maldives from MTG.

## 4 RESPONSIBILITY AND ACCOUNTABILITY

1. Pharmaceutical officer/ Public Health Program Officer of Regulation Unit
2. Director, Pharmaceuticals (Regulation)
3. Deputy Director General (Medicine Therapeutic Goods Division)
4. Director General (MFDA)

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## 5 Guideline content

### 5.1 Request for Import of Alternative medicine.

#### 5.1.2 Who can import?

Authorization as an alternative medicine importer is open for any National to Maldives. The following are required for application for import permits.

- a. A valid registration under Ministry of Economic Development (MED) as a Company / sole proprietor / partnership / cooperative etc
- b. A storage facility or warehouse of minimum 200 sq.ft. with the authorization from relevant authorities to use the warehouse for the proposed purpose fulfilling the standard criteria as defined by ANNEX 1 of medicine regulation R-49/2016.
- c. If already registered as a medicine importer for allopathic medicines, the same warehouse may be used to obtain a permit for importing alternative medicines. However, a designated separate area must be allocated to store them, ensuring they are not mixed with allopathic medicines.

## 6 Application and Process for Import Permit

### 6.1 Preparation of warehouse and Process for Warehouse Registration

- a. It is essential that the warehouse is of appropriate condition to store medicines to ensure their safety, quality and efficacy. The warehouse shall have sufficient space, a minimum of 200 sq. ft as stated in the Medicine regulations. The warehouse should have appropriate storage conditions and necessary equipment such as:
  - Lights or bulbs to provide adequate lighting throughout the warehouse
  - Means of preventing entry of rodents such as rat and mice
  - The premise walls, ceiling and floor should be prepared to prevent moisture
  - There must be a functioning thermometer that shows the temperature of the premise.
  - It is a must to install a fire extinguisher within the premises and staff should be trained and documented.

Other conditions for registering a warehouse as specified in the regulations include:

- “No Smoking” sign / notice with act number must be displayed in premise (As per act no 15/2010 (Tobacco Control Act))
- Warehouse shall be fully accessed except for the owner and authorized staff

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- Competent personnel to handle and store the medicines

## 6.2 Inspection of the Warehouse and Pharmacies

- a. For the initial registration of a warehouse, an authorization inspection will be carried out by MTG Inspection Unit to verify whether the warehouse meets all the requirements. The permit will not be issued until all the requirements have been met.
- b. Apart from these other inspections that will be conducted for Alternative warehouses/Alternative Pharmacies can include:
  - **Routine Inspections:** Annually scheduled inspections to monitor the warehouse operations.
  - **Follow up Inspections:** This can be conducted following the authorization inspection or a routine inspection if there are any requirements to be fulfilled in the warehouse.
  - **Spot Inspection:** Spot Inspections are instantaneous inspections conducted without any schedule. These inspections are carried out in conjunction with public complaints or when a problem or irregularity has been spotted.

## 6.3 What can be stored in the warehouse?

- a. MFDA's warehouse registration permit is issued as an authorization to store medicines in the registered warehouse. Hence the approved medicine shall be stored in the warehouse.

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## 6.4 Request submission Pharmacy Permit

**6.4.1** Request for permit for, Pharmacy for Alternative/ Dhivehi Beys must submit for the following situations:

- a. New registration
- b. Renewal of the permit
- c. Registration
- d. Changes to the location or name of the pharmacy
- e. Ownership of the pharmacy
- f. Dispenser/ Pharmacist or any other information

**6.4.2** To register an Alternative/ Dhivehi Beys Pharmacy for dispensing alternative medicines /Dhivehi beys, clients can apply via Dhirithi Portal. (<https://dhirithi.egov.mv/>).

- Company / sole proprietor / partnership / cooperative should first register in Dhirithi portal before requesting to any services.
- To register in Dhirithi portal, have to submit a form named “Dhirithi Portal User Registration Form” which can be download from Ministry of health’s website and in the publication section of Dhirithi portal

**6.4.3** To register an Alternative/ Dhivehi Beys pharmacy, supporting documents as mentioned below shall be submitted.

- I. Floor plan of the pharmacy with the following details:
  - a. All Measurements of the pharmacy including square feet of the premises
  - b. Details of the exact location of the pharmacy (example: which floor of the building, which building and located in which area etc.)
  - c. The floor area of a pharmacy shall be minimum 100 square feet.
    - If the pharmacy is located in a clinical the floor area of a pharmacy, it shall be a minimum 75 square feet
- II. Copy of a valid business name / business activity registration
- III. If application is tendered by a company:
  - a. A copy of company registration certificates issued by relevant authorities
- IV. If application is tendered by an individual.
  - a. A copy of national identity card
  - b. Sole proprietor registration certificate

**6.4.4** In addition to this, the following documents shall be submitted with the request:

- a. A copy of previously issued permit (if any)

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- b. A copy of registration certificate issued by Ministry of Health (Maldives Allied Health Council) of the responsible seller.

**6.4.5** Within the duration of the issued permit, if the location of the facility, dispenser or floor area changed, expiry of the permit will be same as previous permit issued

## 6.5 Processing of Application

**6.5.1** Once received the request from the Dhirithi Portal documents will be checked and documents will be handed over to inspection unit within 03 (Three) working day.

- Need Clarification (If the request is incomplete, Invalid or Incorrect or improper information or any documents are missing)
- Request will be rejected if not clarified within 14 (Fourteen) days
- Inspection duration for Male' area is working 07 (Seven) days, and for regional area working 14 (Fourteen) days

**6.5.2** Once the inspection report is received request will be verified and registered within 05 (Five) working days.

**6.5.3** After verification an invoice of MVR 300/- will be generated on portal for new / re-registrations, which has to be paid via <https://bandeyripay.finance.gov.mv/> .

**6.5.4** Once the payment is completed, it will be updated on portal as payment complete.

## 6.6 Rejection of request

**6.6.1** If the request is rejected, the reason for rejection will be updated on Dhirithi portal logs.

## 6.7 Registration of request

**6.7.1** If no issues are found during inspection and all requirements are fulfilled, after payment verification it will be updated as "Registered" in Dhirithi Portal, and the permit will be uploaded to portal.

**6.7.2** The following documents will be uploaded under "Authorization permit" in Dhirithi Portal along with the permit:

- a. Registration letter and approved floor plan (for new pharmacies)

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## 6.8 Re-registration of permit

**6.8.1** If request for permit renewal has not been submitted before the expiry of permit, the pharmacy shall be removed from the Alternative/ Dhivehi bey pharmacy List

**6.8.2** Owners of the facility shall be informed via email that the pharmacy has been removed from the list and if the client intends to continue the services, a new application shall be submitted to register.

## 6.9 Who can dispense Alternative Medicines / Dhivehi Beys

**6.9.1** A registered pharmacist, pharmacy assistant or a person who is registered in the field of Traditional/Alternative Medicine Practitioners to dispense the alternative medicine at Maldives Allied Health Council.

**6.9.2** These persons must be registered at Maldives Allied Health Council and must have a valid licence.

## 7 Legal Basis and References

- a. Medicine regulation R-46 (2014)
- b. Medicine regulation amendment R-49 (2016)
- c. Health service act (29/2015)

## 8 Annex

Annex 1: Inspection Checklist for Traditional medicine (Dhivehi Beys) manufacturing facilities

Annex 2: Alternative and Herbal Medicine Inspection Report

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## **Inspection Checklist for facilities selling/import of Alternative Medicine and Dhivehi Beys**

**Medicine and Therapeutic Goods Division**

**Maldives Food and Drug Authority**

**Rec Name: MTG/RE-IS/Li 0032/2026-**

### Things to consider when completing this checklist

- ❖ Completing all columns of checklist and writing (N/A) in parts which shouldn't be considered for inspection.
- ❖ If any corrective action taken should specify it in corrective action column.
- ❖ If corrections are made to inspection checklist, inspector sign will be required

### **Inspection Type:**

<input type="checkbox"/>	Initial inspection
<input type="checkbox"/>	Routine inspection
<input type="checkbox"/>	Renewal Inspection

### **Warehouse Information**

Name: .....

Address/Atoll and Island: .....

Phone Number: .....

E-Mail: .....

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 04.09.2018	
Rec Name: MTG/RE-IS/Li 0032	Rec Name: Inspection Checklist for facilities selling/import of Alternative Medicine and Dhivehi Beys		
Version No: 01	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 1 of 3

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 29.08.2022	
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**MFDA Permit Details:**

Permit No: .....

Permit Issued Date: .....

Permit Expiry Date: .....

Requirements Details			
#	Details	(X) (✓) (N/A)	Corrective Actions
1	No changes have been made to floor plan approved by this authority	<input type="checkbox"/>	
2	Warehouse access is controlled.	<input type="checkbox"/>	
3	Warehouse access is controlled and "no admittance without permit" notice is displayed.	<input type="checkbox"/>	
4	Stock retained and stored have the details of the medicines and if sold from the warehouse, are the sales invoices kept for a minimum of 2 years	<input type="checkbox"/>	
5	The following standard operation procedures are monitored. S.O.P for Storing expired and damaged medicine before disposal. <input type="checkbox"/> S.O.P for cleaning and pest control. <input type="checkbox"/>	<input type="checkbox"/>	
6	Designated space is available for Damaged and expired medicine until disposal time and that space is labeled appropriately	<input type="checkbox"/>	
7	Shelves are available for medicine storage and no medicine is kept on the floor.	<input type="checkbox"/>	
8	Medicines kept on the shelves are not touching against walls and ceiling.	<input type="checkbox"/>	
9	Maintenance and renovation are done on warehouse building regularly.	<input type="checkbox"/>	
10	Warehouse floor, walls and ceiling has not been damaged or effected with water	<input type="checkbox"/>	
11	Warehouse building is not accessible to pests	<input type="checkbox"/>	

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 08.10.2025	
Rec Name: MTG/RE-IS/LI 0032	Rec Name: Inspection Checklist for facilities selling/import of Alternative Medicine and Dhivehi Beys		
Version No: 01	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 2 of 3

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12	As per act no 15/2010 (Tobacco control act 15/2010) "No Smoking" sign is displayed in Warehouse	<input type="checkbox"/>	
13	Fire prevention counter measures are established in the warehouses Expiration date:	<input type="checkbox"/>	
14	Appropriate amount of shelves are available to keep medicines and no medicines are kept on the floor	<input type="checkbox"/>	
15	Floor, walls and ceiling has no sign of damage from water	<input type="checkbox"/>	
16	Building shows no signs of pests and is not accessible to pests	<input type="checkbox"/>	
17	Dustbin with lid available and waste disposal is kept separately from medicine stock.	<input type="checkbox"/>	
18	Appropriate measures have been taken to protect medicines on shelves from direct sunlight	<input type="checkbox"/>	

**Additional Findings from Inspection**

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.....

**Inspection carried out by:**

Name	Designation	Signature	Date	Pharmacy Stamp

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 08.10.2025	
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## Alternative Medicine Warehouse Inspection Report

Medicine and Therapeutic Goods Division

Maldives Food and Drug Authority

Report Number: MTG/RE-AL/Re 0146

Date:

### Inspection Type:

<input type="checkbox"/>	Initial inspection
<input type="checkbox"/>	Routine inspection
<input type="checkbox"/>	Renewal Inspection

### Warehouse Information

Name: .....

Address/Atoll and Island: .....

Phone Number: .....

E-Mail: .....

### MFDA Permit Details:

Permit No: .....

Permit Issued Date: .....

Permit Expiry Date: .....

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Record Created on: 30.06.2026	
Rec. No: MTG/RE-AL/Re 0146	Rec. Name: Alternative and Herbal Medicine Inspection Report		
Version No: 01	Issued Date: 30.06.2026	Copy Letter:	Page No: Page 1 of 3

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Requirements Details			
#	Details	(X) (✓) (N/A)	Corrective Actions
1	No changes have been made to floor plan approved by this authority	<input type="checkbox"/>	
2	Warehouse access is controlled.	<input type="checkbox"/>	
3	Warehouse access is controlled and "no admittance without permit" notice is displayed.	<input type="checkbox"/>	
4	Stock retained and stored have the details of the medicines and if sold from the warehouse, are the sales invoices kept for a minimum of 2 years	<input type="checkbox"/>	
5	The following standard operation procedures are monitored. S.O.P for Storing expired and damaged medicine before disposal. <input type="checkbox"/> S.O.P for cleaning and pest control. <input type="checkbox"/>	<input type="checkbox"/>	
6	Designated space is available for Damaged and expired medicine until disposal time and that space is labeled appropriately	<input type="checkbox"/>	
7	Shelves are available for medicine storage and no medicine is kept on the floor.	<input type="checkbox"/>	
8	Medicines kept on the shelves are not touching against walls and ceiling.	<input type="checkbox"/>	
9	Maintenance and renovation are done on warehouse building regularly.	<input type="checkbox"/>	
10	Warehouse floor, walls and ceiling has not been damaged or effected with water	<input type="checkbox"/>	
11	Warehouse building is not accessible to pests	<input type="checkbox"/>	
12	As per act no 15/2010 (Tobacco control act 15/2010) "No Smoking" sign is displayed in Warehouse	<input type="checkbox"/>	
13	Fire prevention counter measures are established in the warehouses Expiration date:	<input type="checkbox"/>	

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Authorized by: Director General, MFDA		
Rec. No: MTG/QA-SP/	Rec. Name: Self-Assessment Checklist - Warehouse			
Issue No: 01	Issue Date:	Prepared by: Director, Pharmaceuticals	Approved by: Deputy Director General, Pharmaceuticals	Page No:
Revision No: -	Revised Date:	Verified by: Technical Committee of MTG		Page 2 of 4

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14	Appropriate amount of shelves are available to keep medicines and no medicines are kept on the floor	<input type="checkbox"/>	
15	Floor, walls and ceiling has no sign of damage from water	<input type="checkbox"/>	
16	Building shows no signs of pests and is not accessible to pests	<input type="checkbox"/>	
17	Dustbin with lid available and waste disposal is kept separately from medicine stock.	<input type="checkbox"/>	
18	Appropriate measures have been taken to protect medicines on shelves from direct sunlight	<input type="checkbox"/>	

**Additional Findings from Inspection**

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**Inspection Team**

Name	Designation	Signature	Date

**Verified by:**

Name	Designation	Signature	Date

**Approved by:**

Name	Designation	Signature	Date

<b>Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority</b>		Authorized by: Director General, MFDA		
Rec. No: MTG/QA-SP/	Rec. Name: Self-Assessment Checklist - Warehouse			
Issue No: 01	Issue Date:	Prepared by: Director, Pharmaceuticals	Approved by: Deputy Director General, Pharmaceuticals	Page No:
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