



**Maldives Food and Drug Authority**

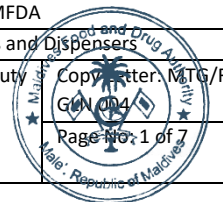
Ministry of Health

Male', Maldives

**Guideline on Registration of Alternative/ Dhivehi Beys Pharmacies and Dispensers**

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<b>Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority</b>		Authorized by: Director General, MFDA	
Doc. No: <b>MTG/RE-AP/GLN-TE 017</b>	Doc. Name: Guideline for Registration of Alternative/Dhivehi Beys Pharmacies and Dispensers		
Issue No: 01	Issue Date: 29.08.2022	Prepared by: Director, Pharmaceuticals	Approved by: Deputy Director General, Pharmaceuticals
Revision No: 00	Revised Date: -	Verified by: Technical Committee of MTG	Copy letter: MTG/RE GLN 014 Page No: 1 of 7





**Guideline on Registration of Alternative/ Dhivehi Beys Pharmacies and Dispensers is released under the authority of**

**Ms. Thooma Adam  
Deputy Director General**

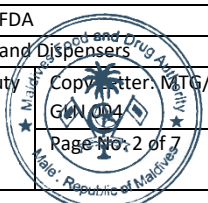
**It is the property of:  
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**Prepared by:  
Mohamed Fazeen  
Director, Pharmaceuticals**

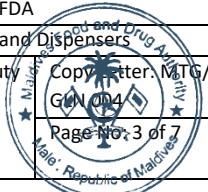
<b>Approved by: Ms. Aishath Mohamed Deputy Director General, Pharmaceuticals Maldives Food and Drug Authority</b>		29.08.2022
<b>Authorized by: Ms. Thooma Adam Deputy Director General, Laboratory Services Maldives Food and Drug Authority</b>		29.08.2022

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# Guideline on Registration of Alternative/ Dhivehi Beys Pharmacies and Dispensers

## 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

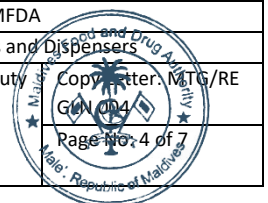
## 3 SCOPE

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 submission

**5.1.1** Request for permit for Alternative/ Dhivehi Beys must submit for the following situations:

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

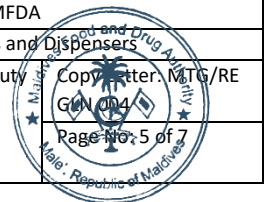
**5.1.2** To register an Alternative/ Dhivehi Beys Pharmacy for dispensing alternative medicines /Dhivehi beys, clients can apply via Dhirithi Portal. (<https://dhirithi.egov.mv/>).

- 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

**5.1.3** 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

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b. Sole proprietor registration certificate

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

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

**5.1.5** 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

## 5.2 Processing of Application

**5.2.1** 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

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

**5.2.3** 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/> .

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

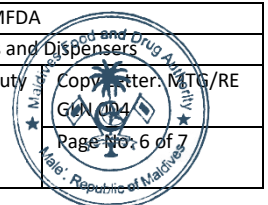
## 5.3 Rejection of request

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

## 5.4 Registration of request

**5.4.1** 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.

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**5.4.2** 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)

**5.5 Re-registration of permit**

**5.5.1** 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

**5.5.2** 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.

**5.6 Who can dispense Alternative Medicines / Dhivehi Beys**

**5.6.1** A registered pharmacist, pharmacy assistant or a person who is registered to manufacture of sell the alternative medicine at Maldives Allied Health Council.

**6 Legal Basis and References**

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

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