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Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Pharmacy Registration and Medicine Dispensing Approval

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Guideline for Pharmacy Registration and Medicine Dispensing Approval is released

under the authority of

Ms. Thooma Adam
Deputy Director General

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Maldives Food and Drug Authority
Male'
Republic of Maldives

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CONTENTS

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1 INTRODUCTION

To ensure that medicines imported, distributed and sold are safe, of good quality and efficacious, the outlets where medicines are sold shall be fully regulated and monitored.

By registering the pharmacies, the facilities where the medicines are kept is monitored, the storage conditions of the medicines are monitored, and the person who is dispensing the medicine is monitored.

Hence as per the medicine regulation, to operate pharmacies and dispense medicine a pharmacy has to be registered as per the criteria defined in the medicine regulation.

It is vital to note that by simply registering a pharmacy you cannot dispense medicine or operate the pharmacy. For operation of pharmacy, medicine dispensing approval has to issued, in addition to pharmacy registration, and upon fulfilling the requirements as defined the medicine regulation

2 PURPOSE

This guideline describes the process of authorizing and issuing the registration and medicine dispensing approval for pharmacy operations. The main purpose is to ensure authorized parties operate pharmacies, qualified and competent personnel sell medicines, medicines are kept and stored at the specified conditions and the pharmacies in Maldives operates in accordance with the medicine regulation

3 SCOPE

This guideline applies to the registration and issuance of medicine dispensing permit, Issuing and renewal of the permit as issued from Medicine and Therapeutic Goods Division of MFDA.

4 RESPONSIBILITY AND ACCOUNTABILITY

1. Pharmaceutical officers of Regulation Unit
2. Director, Pharmaceuticals (Regulation)
3. Deputy Director General (Medicine Therapeutic Goods Division)
4. Director General (MFDA)

5 Guideline content

Request submission

5.1.1 Request must be submitted for the following situations:

a) New Pharmacy registration and medicine dispensing permit
b) Renewal of the permit
c) Re registration of the permit
d) Changes to the location or name of the pharmacy
e) Changes in the Ownership of the pharmacy
f) Changes in Pharmacist or any other information

5.1.2 To register a pharmacy for dispensing medicine, clients shall apply via Dhirithi Portal. (https://dhirithi.egov.mv/):

- Company / sole proprietor / partnership / cooperative shall first register in Dhirithi portal before requesting to any services.
- To register in Dhirithi portal, Clients have to submit a form "**Dhirithi Portal User Registration Form**" which can be download from Ministry of health's website and from "publication" section of Dhirithi portal

5.1.3 To register a pharmacy for dispensing medicine, following 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 identifying particulars like location of the counter, AC, main door, windows, partitions etc

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. However, if the pharmacy is located inside the premises of a health facility, the floor area of a pharmacy shall be minimum 75 square feet

II. Copy of a valid business name / business activity registration

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

I. A copy of previously issued permit for dispensing medicine in pharmacy if permit was issued before or if applying for permit renewal

II. A copy of registration certificate issued by Maldives Allied Health Council for the responsible pharmacist /pharmacy assistant /dispenser who will be working in the pharmacy

III. A copy of ALL Pharmacists ID cards who are currently employed.

5.1.5 Documents to be submitted will be available in Dhirithi portal as "**Documents to be submitted**" in the "Publication" as a guidance for clients

5.1.6 Within the duration of the issued permit, if the location of the pharmacy / pharmacist and any changes to floor area, expiry of the new permit will be same as previous permit issued with no additional fee.

5.1.7 The process of applying for pharmacy registration and medicine dispensing approval will be same for both private and public parties. In addition, the same criteria are used for processing and issuing the approvals for both private and public.

6 Processing of Application

6.1.1 Once the request is received from the Dhirithi Portal, documents will be checked and verified and if all are complete, the documents will be handed over to inspection unit within 05 (Five) working day. The status will be updated accordingly in Dhirithi portal for the client to check.

- If the status indicates **"Need Clarification"** that means the request is incomplete, Invalid or Incorrect or improper information or any documents are missing, and the client has to provide the documents or complete the application to process it. The Request will be**" rejected"** if not clarified within 14 (Fourteen) working days.

6.1.2 Once completed applications are handed to Inspection unit, the inspection of the facility or the premises (Pharmacy) will be conducted within 07 (Seven) working days, if the premise is located in Male' region.

6.1.3 If the facility of the premises (Pharmacy) is located in islands, after receiving the inspection slip, inspection request letter shall be submitted within 05 (Five) working days to the relevant island to conduct inspection, Inspection shall be conducted within 20 (Twenty) working days.

6.1.4 Inspection assessment report shall be shared annually with the client via email and published on annual report & MTG annual newsletter.

6.1.5 After receiving the inspection checklist from the relevant unit, report to be completed within 5 (Five) working days, report shall be submitted to Dhirithi portal.

6.1.6 Once the inspection report is received request will be verified and registered within 05 (Five) working days and it will be updated in the portal accordingly.

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

6.1.8 Once the payment is completed, it will be updated on portal as "Paid". New and re-registration requests will be registered after receiving the payment.

7 Rejection of request

If the application has been rejected, the reason for rejection will be mentioned and can be checked from logs.

8 Registration and issuing pharmacy permit.

8.1.1 If no issues are found during inspection and all requirements are fulfilled, after payment verification it will be updated as "**Registered**" in Dhirithi Portal

8.1.2 The following documents will be uploaded under "**Attachment section**" in Dhirithi Portal:

a. Pharmacy registration permit
b. Registration letter and approved floor plan (for new pharmacies)
c. Essential medicine list to be kept in the pharmacies
d. If pharmacist documents submitted, medicine dispensing approval will also be uploaded.

8.1.3 If a valid pharmacist or pharmacy assistant or a dispenser's document is applied with the request, **pharmacy registration letter and permit** shall be issued.

8.1.4 The letter shall include the following.

a) That Pharmacy operation shall be started within one month. And if operation cannot be started within one month the client shall inform MFDA in writing.

b) Pharmacist can dispense medicine only after they have been registered in MFDA and have a valid pharmacist Id card for the respective pharmacy.

c) Registration will be cancelled if pharmacy service does not commence within 6 months.

8.1.5 If a valid pharmacist or pharmacy assistant or a dispenser document is **NOT** applied with the request, **only the pharmacy registration letter** shall be issued.

8.1.6 Letter shall mention that permit will be issued once the client submits the documents of a registered pharmacist or pharmacy assistant or a dispenser within 6 months. If the documents cannot be submitted within 6 months registration will be cancelled.

8.1.7 After registration, the registered pharmacy details shall be included in “Authorized Pharmacy list (MTG/RE-PL/Li 0007)” which is monitored by MFDA through routine inspection and it is updated after issuing of every permit. This list shall be published every 04 (Four) months. This will be available at MOH website under “downloads” and in Dhirithi portal under “publication”

8.1.8 Once a month a performance indicator shall be generated, which contains the total requests received, rejected and processed.

8.1.1 A database of all licencing applications received and approved is maintained in a worksheet “Pharmacy and Medicine Warehouse Registration and Licencing Application worksheet (MTG/RE-WS/Re 0006)” and a master list can be view from Dhirithi portal as well.

9 Re registration of permit

9.1.1 If request for permit renewal has not been submitted before the expiry of permit, the pharmacy shall be removed from the Pharmacy Register (MTG/RE-PL/Li 0007).

9.1.2 Pharmacy owners 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 the pharmacy.

9.1.3 Relevant authorities such as Aasandha shall be informed about the removal of the pharmacy from the Pharmacy register.

9.1.4 To re-register a pharmacy for dispensing medicine, following documents as mentioned in 5.1.3.and 5.1.4 shall be submitted.

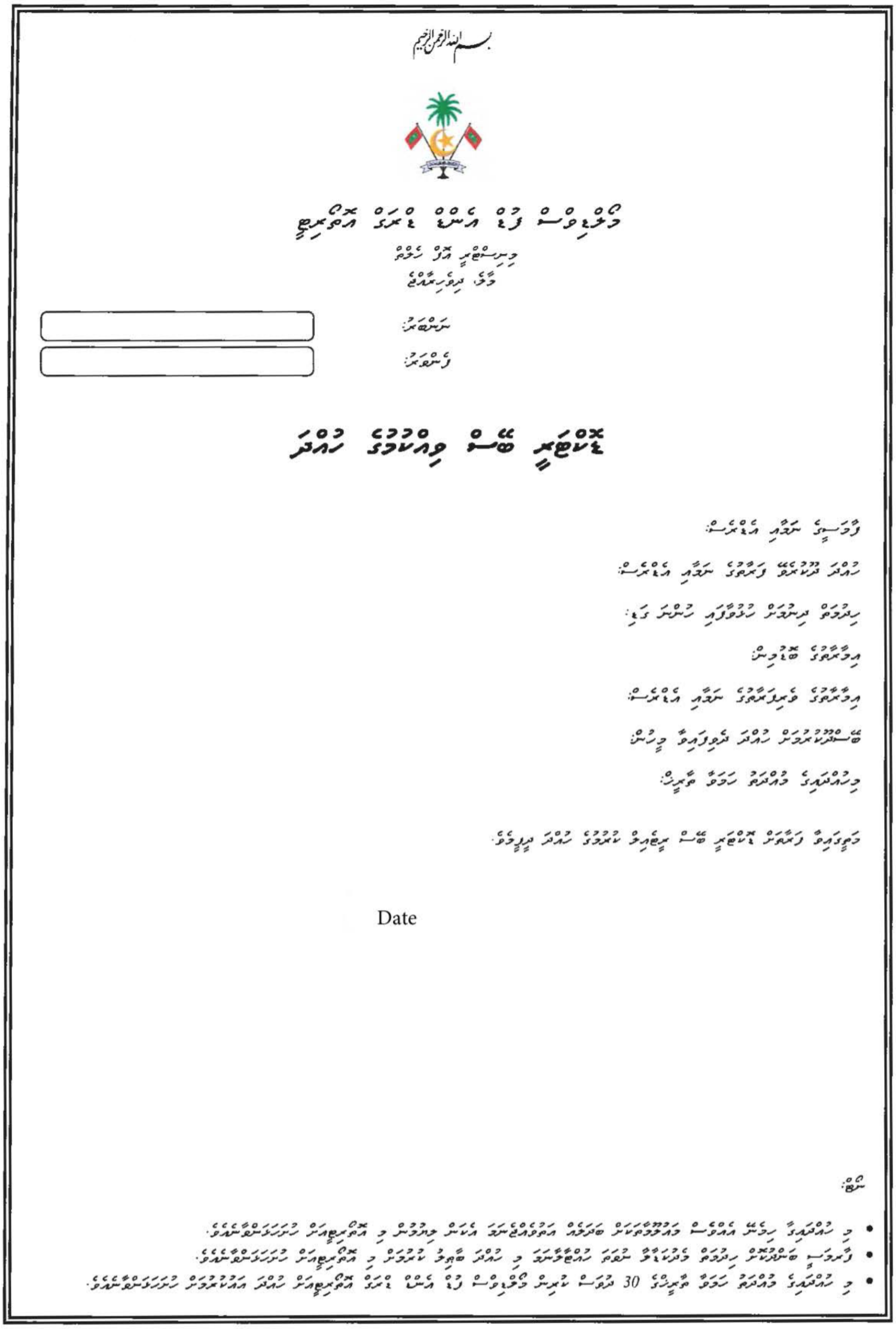
9.1.5 Payment of 300/- MVR shall be taken.

9.1.6 Permit number shall be in this format (MFDA/PH-AB 0001-1), PH refers to pharmacy, AB refers to Owners Code, 0001 is the number allocated to pharmacy and -1 refersto number of times the pharmacy has been re registered

10 Legal basis and references

- **a.** Medicine regulation R-46 (2014)
- **b.** Medicine regulation amendment R-49 (2016)
- **c.** Health service act (29/2015)
- **d.** Standard Operating Procedure for registration of Pharmacies

11 Annex 1



بسم الله الرحمن الرحيم

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Date

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