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Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline for Authorization of Medicine Import

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Deputy Director General

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Maldives Food and Drug Authority
Male’
Republic of Maldives

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Guideline for Authorization of Medicine Import

1 INTRODUCTION

Due to inadequate capacity to manufacture, Maldives is a 100% importing country with regard to medicine. Hence to assure the safety, quality and efficacy of the medicines imported is imperative since it directly affect the health of the population. For this purpose, standards and criteria are put in place as per the medicine regulation. One of the criteria and pre requisite for medicine import is to register a medicine warehouse as per the specification highlighted in medicine regulation.

2 PURPOSE

This guideline describes the process of authorizing and issuing the registration of medicine warehouse and license for medicine import. This is to ensure that medicines are imported in compliance to the medicine regulations and stored in a registered medicine warehouse, at appropriate conditions specified for medicines, in order to ensure that medicines used in Maldives are safe, of good quality and is of the required efficacy.

3 SCOPE

This guideline applies to the authorization and issuance of registration and license for medicine import permit from Medicine and Therapeutic Goods Division (MTG) of Maldives Food and Drug Authority (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 medicine import registration and permit

b) Renewal of registration and permit
c) Re-registration of permit
d) Changes to the location or name of the medicine warehouse
e) Change of Ownership of the medicine warehouse or medicine import permit

5.1.2 To register a medicine warehouse for the purpose of medicine import, clients shall 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, Clients have to submit a form "**Dhirithi Portal User Registration Form**" which will be available in Ministry of health (MOH) website and from "publication" section of Dhirithi portal

5.1.3 To register a medicine warehouse for the purpose of medicine import, following supporting documents as mentioned below shall be submitted.

I. Floor plan of the medicine warehouse with the following details:
   a) All Measurements of the warehouse including square feet of the premises
   b) Details of the exact location of the warehouse (example: which floor of the building, which building and located in which area etc.)

The floor area of a medicine warehouse shall be minimum 200 square feet.

II. Copy of a valid business name / business activity registration
III. Authorization issued by a relevant Government authority to use the premises for the proposed purpose.

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

I. A copy of previously issued registration and permit for medicine import, issued by this Authority shall be submit if permit was issued before or if applying for permit renewal

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 medicine warehouse/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 medicine warehouse for the purpose of medicine import 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 application handed to Inspection unit, the inspection of the facility or the premises (medicine warehouse) will be conducted with in 07 (Seven) working days if the premise is located in Male' region

6.1.3 If the facility of the premises (medicine warehouse) 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 from the inspection unit, 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 1200/- will be generated on portal for new /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 medicine import / medicine warehouse 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) Medicine warehouse/ Medicine import permit and approved floor plan (for new warehouse)

8.1.3 After registration, the registered importer and premises details shall be included in "Authorized importers list (MTG/RE-IL/Li 0006)" 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" in Dhirithi portal under "publication"

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

8.1.5 Databases of all licencing applications received and approved are maintained in a excel worksheet "Pharmacy and Medicine Warehouse Registration and Licencing Application worksheet (MTG/RE-WS/Re 0006)" and a master list of all the requested accepted rejected 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, medicine warehouse for the purpose of medicine import shall be removed from the "Authorized Importers List (MTG/RE-IL/Li 0006)"

9.1.2 Importers shall be informed via email that the import licence, warehouse has been removed from the list and if the client intends to continue the services, a new application shall be submitted to re-register the medicine warehouse for the purpose of medicine import.

9.1.3 To register a medicine warehouse for the purpose of medicine import, following documents as mentioned in 5.1.3.and 5.1.4 shall be submitted.

9.1.4 Payment of 1200/- MVR shall be taken.

9.1.5 Permit number shall be in this format (MFDA/MW-AB 0001-1), MW refers to medicine warehouse, AB refers to Owners Code, 0001 is the number allocated to medicine warehouse and -1 refers to the number of times the medicine warehouse/importer has been re-registered.

10 Legal basis and references

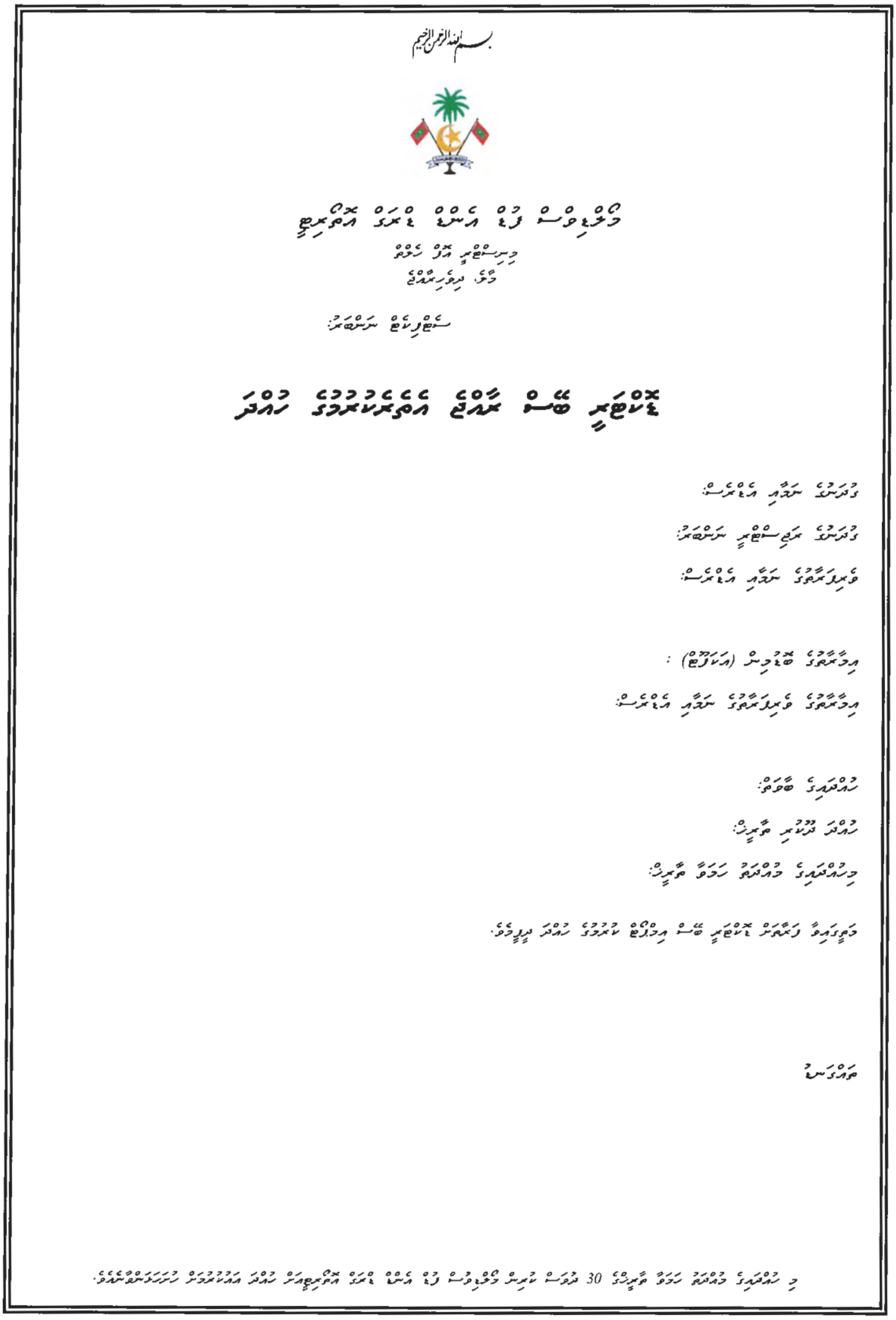
a. Medicine regulation R-46 (2014)

b. Medicine regulation amendment R-49 (2016)

c. Health service act (29/2015)

d. Standard Operating Procedure for medicine import

11 Annex 1



بسم الله الرحمن الرحيم

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މާލެ، ދިވެހިރާއްޖެ

ސްޓިކަރ ނަންބަރު:

ޑޮކްޓަރީ ބޭސް ރާއްޖެ އެތެރެކުރުމުގެ ހުއްދަ

ގުދަނުގެ ނަމާއި އެޑްރެސް:

ގުދަނުގެ ރަޖިސްޓްރީ ނަންބަރު:

ވެރިފަރާތުގެ ނަމާއި އެޑްރެސް:

އިމާރާތުގެ ބޮޑުމިން (އަކަފޫޓުން) :

އިމާރާތުގެ ވެރިފަރާތުގެ ނަމާއި އެޑްރެސް:

ހުއްދައިގެ ބާވަތް:

ހުއްދަ ދޫކުރި ތާރީޚް:

މިހުއްދައިގެ މުއްދަތު ހަމަވާ ތާރީޚް:

މަތީގައިވާ ފަރާތަށް ޑޮކްޓަރީ ބޭސް އިމްޕޯޓް ކުރުމުގެ ހުއްދަ ދިނީމެވެ.

ތައްގަނޑު

މި ހުއްދައިގެ މުއްދަތު ހަމަވާ ތާރީޚުގެ 30 ދުވަސް ކުރިން މޯލްޑިވްސް ފުޑް އެންޑް ޑްރަގް އޮތޯރިޓީއަށް ހުއްދަ އައުކުރުމަށް ހުށަހަޅަންވާނެއެވެ.

بسم الله الرحمن الرحيم

Maldives Food and Drug Authority
Ministry of Health
Malé, Maldives

ނަންބަރު:
Number

ބޭސްގުދަނުގެ ރަޖިސްޓްރީ
MEDICINE WAREHOUSE REGISTRATION

ބޭސް ރައްކާކުރާ ގުދަނުގެ ނަން:
Name and Address of the Warehouse:
ވެރިފަރާތުގެ ނަމާއި އެޑްރެސް:
Name and Address of the Owner:
އިމާރާތުގެ ވެރިފަރާތުގެ ނަމާއި އެޑްރެސް:
Name and Address of Building Owner:
ހުންނަތަން:
Location:
ލިޔުމުގެ މުއްދަތު ހަމަވާ ތާރީޚް:
Expiry date of document:

މަތީގައިވާ ޢިމާރާތް ބޭސްގުދަނެއް ކަމުގައި ރަޖިސްޓްރީކޮށްފީމެވެ.

The referred building is hereby registered as medicine warehouse