بسم الله الرحمن الرحيم

Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline Authorizing Medicine Import and Warehouse Registration

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Authorized by	Thooma Adam, Deputy Director General, Laboratory

SUMMARY OF CHANGES

Version No.	Issued Date	Section/Clause	Summary of Change	Changes Made
1	23.06.2022	-	Creation of the document	Nafha Rasheed, Pharmaceutical Officer
2	13.11.2024	4,5,6.8,6.9,7	Clauses regarding what can be imported, who can import, responsibilities of the importers, location change and health clearance at entry ports	Fathimath Azla, Pharmaceutical Officer
3	08.10.2025	Overall Document	Additional details to procedure, changes to requirements for permit renewal	Aishath Suna, Medicine Regulatory Officer

Contents

ABBREVIATIONS

MOH	Ministry of Health
MFDA	Maldives Food and Drug Authority
MED	Ministry of Economic Development
ADL	Approved Drug List
AIL	Approved Importers List

Definitions

Importer	An authorized person/entity established in Maldives who is authorized by Maldives Food and Drug Authority to import medicines from abroad and place it in the Maldivian Market.
Approved Drug List	List of medicines authorized to be imported, distributed and sold in the Maldives.
Medicines	A medicine is any substance or combination of substances marketed or manufacturerd to be marketed for treating or preventing disease in human beings, or with view to making a medical diagnosis in human beings, or to restoring, correcting or modifying physiological functions in human beings.(WHO PQ definition of medicine)
Pre authorization	Preauthorization is an exemption approval issued after evaluating the minimum safety requirements of the product to ensure availability and accessibility of essential medicines including critical and emergency medicines, antidotes, which are not registered with full dossier submission but are needed for the health care system.
Import License	A permit issued by MFDA for import of medicines into Maldives . A pre-requisite is to have a establsihed storage facility as per the medicine regulation.

1 INTRODUCTION

Due to no manufacturing capacity, Maldives import 100% of all pharmaceuticals. Hence, it is of utmost importance that the medicines imported, stored and distributed in Maldives is regulated to ensure its safety, quality and efficacy.

The Medicine and Therapeutic Division (MTG)of Maldives Food and Drug Authority (MFDA) regulates all medicine imports under the Medicine Regulation R-46/2014 and its amendment Medicine Regulation R-49/2016. Medicine importers are required to have medicine storage facility as per the criteria of these regulations. MTG issues these permits under the same regulation and application requirements for both private and government entities are same correspondingly.

2 Purpose

The purpose of this guideline is to provide guidance on the requirement for importers and warehouse registration and the process conducted by MTG to issues the permits.

3 Stakeholders

Regional Health facilities	Responsible for Providing support in inspection services in islands in collaboration with Enforcement Section of MTG
Ministry of Economic Development	Issue of trading license for all trades.
Councils	Responsible for issuing permits for facilities
Maldives Ports Limited	MTG Port Unit conducts health clearance of medicines at Male' seaport
Maldives Airport Company Limited	MTG Port Unit conducts health clearance of medicines at Velanaa International Airport
Ministry of Health	MOH is responsible for the overall law and regulation for health services
WAMCO	For disposal of damaged and expired medicines
Ministry of finance	All payments are processed through the Ministry's Bandeyri Pay

4 Who can import?

Authorization as a medicine importer is open for any National of 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.

5 What can be imported?

As per the import permit issued by MFDA, the importer can import only medicines in accordance with the published Approved Drugs List(ADL). ADL is the list of medicines authorized to be imported, distributed and sold in the Maldives and is published on a monthly basis. The main purpose of the ADL is to ensure the medicine that are imported in Maldives are all registered and approved medicines with assured safety, quality and efficacy.

Medicine can be imported in the following ways:

- By registering a product available for registration as per the ADL. Samples can be imported for the purpose of this registration process
- Preauthorization: A special import permit issued to ensure the availability of essential 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 the appropriate conditions 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 shall 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

- Premise should be air conditioned and air conditioner should adequate for floor area to maintain temperature below 25°C (twenty-five)
- There must be a functioning thermometer that shows the temperature of the premise.
- It is a must to install a fire extinguisher within the premise and staffs 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 access controlled except for the owner and authorized staff
- Competent personnel to handle and store the medicines

6.2 Inspection of the Warehouse

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 warehouses 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.

6.4 Dhirithi portal registration

6.4.1 Medicine warehouse registration is a pre-requisite for medicine import.

6.4.2 To register as a medicine import and warehouse registration clients shall apply via Dhirithi Portal. (https://dhirithi.egov.mv/). Dhirithi Portal is an online portal that provides MFDA services for the ease of clients. Registration can be done as a company / sole proprietor / partnership / cooperative

6.4.3 To access the portal and request for services the user must have an eFaas login and submit "Dhirithi Portal User Registration Form". With the submission of the form, through e-mail, MTG/MFDA can associate the user to the entity. The form is available in the "Publication" section of the portal.

6.4.4 To register in Dhirithi portal, Clients must submit a form "**Dhirithi Portal User Registration Form**", available in Ministry of health (MOH) website and from "publication" section of Dhirithi portal. Dhirithi Portal Registration shall be completed within 05 working days.

6.4.5 After dhirithi registration, the client shall request to register as a medicine import and medicine warehouse from pharmaceutical section of dhirithi portal.

6.5 Medicine import and warehouse registration.

6.5.1 Medicine Import and Medicine warehouse Registration is issued by MTG/MFDA to allow import of medicine and warehouse in a specific location with the submission of required documents and inspection of the premise to verify all criteria are met. The criteria are based on medicine regulations and are listed in detail in Annex I of this guideline.

6.5.2 The basic criteria of a warehouse include:

- Floor plan of the medicine warehouse with all the Measurements of the warehouse including square feet of the premises and 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 a minimum of 200 square feet.
- Copy of a valid business name / business activity registration

- Authorization issued by a relevant Government authority to use the premises for the proposed purpose.
- Self Inspection Checklist (for new registration - Checklist 1, for renewal - Checklist 2)
- Standard operation procedure for Receiving, storing and distribution (stock records)
- Standard operation procedure for storing and disposing of expired and damaged medicine
- Standard operation procedure for cleaning and pest control
- Standard operation procedure for reporting and handling adverse drug reaction (ADR)

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

6.5.4 The process of applying for medicine import and medicine warehouses will be the same for both private and public parties. In addition, the same criteria are used for processing and issuing approvals for both private and public.

6.6 Processing of Application for New Importers

6.6.1 Application for renewal shall be submitted before 30 working days of the expiry of the registration and license. And the last day for requesting will be the day of expiration.

6.6.2 Once the request is received from the Dhirithi Portal, documents shall be checked and verified by the licensing staff of MTG and if all are complete, the documents will be handed over to the inspection unit within 05 (Five) working day. The status will be updated as Inspection scheduled) in Dhirithi portal for the client to check.

6.6.3 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 must provide the documents or complete the application to process it. The Request will be" rejected**"** if not clarified within 14 (Fourteen) working days.

a. If all requirements are complete, application is handed to Inspection unit, the inspection of the facility or the premises (medicine warehouse) will be conducted within 07 (Seven) working days if the premise is located in Male' region.

b. 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.

c. Once the inspection report is received from the inspection unit, further process will be carried out once the payment has been completed. It will be updated in the portal accordingly.

6.7 Payment procedure and issue of certificate

a. All payments are conducted by MTG through Bandeyri Portal. No other method of payment will be accepted by the authority.

b. The Import licence is issued with a fixed fee of 1200/- Maldivian Rufiyaa.

c. After the completion of inspection, if no issues are found the request will be verified and an invoice of MVR 1200/- will be generated through Dhirithi portal for new and re-registrations. The client will be requested to complete the payment through Bandeyri Portal within 05 (Five) working days. Bandeyri Portal is managed by the Ministry of Finance.

d. Once the payment has been completed, the license will be issued by MTG/MFDA. The following documents will be shared through Dhirithi Portal (No physical copies will be handed over). Status of the application from the portal will be changed to "Registered"

e. Once the payment has been completed the certificate will be issued and the client will be updated as "Registered" in the Dhirithi Portal.

f. The permits are only issued through Dhirithi Portal. The permit authorises the importer to import medicines and to store medicines in the warehouse. The permit consists of:

1. Medicine warehouse registration certificate (Format in Annex 1)
2. Medicine import permit (format in Annex 2)
3. Approved floor plan

6.8 Responsibilities of the Importer

a. Authorized importers are expected to be compliant with the Medicine Regulation R-46/2014 and Amendment of Medicine Regulation R-49/2016.
b. Importers have to conduct the necessary processes for disposal of damaged and expired medicines, conduct recalls when required by MFDA and provide full cooperation in case of recalls conducted by MTG.
c. Cooperate and coordinate with MTG inspectors in the inspection of warehouses.
d. Facilitate the inspection process of MTG.
e. Importers are responsible for importing medicines under the import permit and store this medicine in the registered warehouse and store the medicines as in conditions specified by the manufacturer.
f. Importers must import at least one shipment within the year of registration.
g. If there are any changes to the floor plan or owner of the warehouse, the client shall request through Dhirithi portal and get approval from MFDA before implementing the changes. For the request, shall apply:

- Changes to the floor plan or location change
- Changes to the name of the medicine warehouse
- Change of Ownership of the medicine warehouse or medicine import permit

6.9 Location change

6.9.1 A permit shall be taken before changing the location of the Medicine Warehouse.

6.9.2 An exceptional condition where there is not enough time to take a permit before location change along with the medicine stock, the importer/owner shall request with the details via an email.

6.9.3 When applying for location change of warehouse, it is the owner's to ensure that the medicines are in the right storage conditions.

6.10 Post-Licensure changes

6.10.1 The registered party shall inform via e-mail to the Authority with:

6.10.1.1 Close for Renovation

6.10.1.2 Working hours changed

6.10.1.3 Responsible personal changes

6.10.1.4 Contact information changes

6.10.1.5 Or any other information changes

The Authority shall then respond to them on how to handle the medicine stock, if applicable and shall inform them to proceed with 5.11.2.

6.10.2 An application shall be submitted for any post licensure changes and a permit shall be generated.

7 Health Clearance at Entry Ports

a. To clear imported medicines from the entry ports (airport and seaport), the importer shall have a valid import permit. Alongside the permits, there are other documents that are required to be submitted. (Refer to Guideline on Health Clearance of Medicines at Entry Ports)

b. Without a valid import permit, MTG has the authority to permanently hold the medicines without release. MTG is not liable for any damage caused or sustained by the importer in such situations.

8 Authorized Importers List

a. All registered importers are listed in the "Authorized Importers List (MTG/RE-IL/Li 0006)" with the details of the importer and their respective warehouse.

b. This list is published every other month and will only include importers with a valid import permit. If request for permit renewal has not been submitted before the expiry of permit, medicine import and medicine warehouse permit shall be removed from the AIL.

c. The importer will also be removed from the list in any case where the permit has been revoked by the authority.

9 Renewal and reregistration of Permit

As per the Medicine regulation R-46 (2014) Medicine Import and warehouse registration shall be renewed every 02 years. The client shall submit a request to renew the permit through Dhirithi portal prior to 30 days of expiry of the permit. The application will not be accepted before the given timeframe.

a. Documents are required, same as mentioned for new registrations in points 6.5 and 9.

b. In addition to the documents the client shall submit the following document:

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

   II. Import details of the shipments imported, (at least one shipment must be imported) before the expiry of the permit.

c. The application process will be carried out same as for the registration of new importers. However, there is no payment required for renewal.

10 Re registration of permit

a. If request for permit renewal has not been submitted before the expiry of permit, medicine import and medicine warehouse shall be removed from the "Authorized Importers List (MTG/RE-IL/Li 0006)"

b. Importers shall be informed via email that the import license, 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 import and medicine warehouse permit.

c. To re-register as a Medical Importer, the required documents and the process of application will be same as for a new registration.

d. The same process and payment will be applied for re-registrations as for new applications. (Refer to point 3)

e. 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.

11 Warehousing

a. Clients can also register a premise for the sole purpose of storing medicines in cases such as wholesaling medicines, third party storage for medicine importers, temporary storage for medicines during transportation etc….

b. In this case the client does need to be registered at the warehouse, and it will not be permitted to import any medicines.

c. The same requirements are applicable to the warehouse as described in points 3.1-3.3.

12 Suspension/revoke of permit

12.1.1 Medicine Import license / Warehouse registration shall be suspended / revoked on the following grounds:

12.1.1.1 If various transactions related to medicines in violation of laws and regulations.

12.1.1.2 If the medicines supplied are unapproved and not safe for public health.

12.1.1.3 During the inspection conducted by the Authority, within a period of 2 months, without reasonable cause, 02 consecutive inspection finds that the warehouse is closed and does not provide services or import any medicines.

12.1.1.4 Poor cleanliness of the place where the medicines are kept and therefore doubt about the safety of the medicines in the place.

a. There are several circumstances as per the Medicine Regulation R-46/2014 and its amendment Medicine Regulation R-49/2016 where a permit can be suspended for a defined period or permanently revoked.

b. The action to be taken shall be decided by MTG depending on the severity of the situation and on the advice from the Legal Team of MOH.

c. In such cases inspections may be conducted by MTG to assess and confirm the situation prior to any decisions being made. The final decision will be officially communicated with the permit holder.

d. To reinstate a permit, in case of suspension, a letter shall be submitted by the importer for consideration by the authority.

13 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

14 Annex 1

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ތިލަވަރުގެ ވެހިކަލްގެ ނަމާ ތަޚައްލުސް:

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ފުރަތަމަ ދުވަހުގެ ގަޑި:

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Maldives Food and Drug Authority
Ministry of Health
Malé, Maldives

ނަންބަރު:
Number

ގޯސްވެއަރހައުސް ރަޖިސްޓްރީ

MEDICINE WAREHOUSE REGISTRATION

ގޯސް ހުންނަ ތަނުގެ ނަން:
Name and Address of the Warehouse:
ތަނުގެ ވެރިފަރާތުގެ ނަން ދާއިމީ ލިބޭ ތަން:
Name and Address of the Owner:
ބިލްޑިންގުގެ ވެރިފަރާތުގެ ނަން ދާއިމީ ލިބޭ ތަން:
Name and Address of Building Owner:
ހުންނަ ތަން:
Location:
ލިޔުންތަކުގެ ވަޒަންދާ ތާރީޚު:
Expiry date of document:

ދެކެވަޑައިގަންނަ ބިލްޑިންގ ގޯސްވެއަރހައުސް ގޮތުގައި ރަޖިސްޓަރ ކުރެވިފައިވެއެވެ.

The referred building is hereby registered as medicine warehouse