

بِسْمِ اللّٰهِ الرَّحْمٰنِ الرَّحِیْمِ



Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline for Medicine Disposal

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Authorized by: Director General, MFDA		
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal			
Issue No: 01	Issue Date: 13.02.2020	Prepared by: Director, Pharmaceuticals	Approved by: Deputy Director General, Pharmaceuticals	Copy Letter: MTG/RE GLN 004
Revision No: 01	Revised Date: 15.05.2022	Verified by: Technical Committee of MTG		Page No: Page 1 of 13



Guideline for Medicine Disposal is released under the authority of

**Ms. Thooma Adam
Deputy Director General
Maldives Food and Drug Authority**

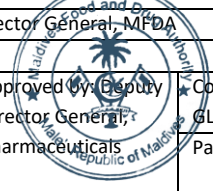
**It is the property of:
Maldives Food and Drug Authority
Male'
Republic of Maldives**



**Prepared by:
Director Pharmaceuticals
Mohamed Fazeen**

Approved by: Ms.Aishath Mohamed Deputy Director General, Pharmaceuticals Maldives Food and Drug Authority		15.05.2022
Authorised by: Ms.Thooma Adam Deputy Director General, Laboratory Services Maldives Food and Drug Authority		15.05.2022

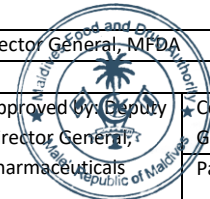
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Guideline for Medicine Disposal

1 INTRODUCTION

Modern medicine has changed our healthcare and allowed us to live longer and healthier lives. However, it also comes with costs and consequences. When medicines are cautiously prescribed, it should also be disposed of carefully. When medicines are unused, expired, or damaged, then how do we get rid of them safely?

Proper disposal helps to prevent overuse, misuse, and damage to environment. Medicines should be disposed in a way that it does not release toxins into the atmosphere or water supply that may adversely affect human and animal health.

The Maldives and Food and Drug Authority (MFDA) is responsible for monitoring the medicine disposal in the Maldives. MFDA follows the Medicine Regulation (Regulation Number: 2014/R-46) and Health Service Act (Law Number: 29/2015) in proper disposal of medicines.

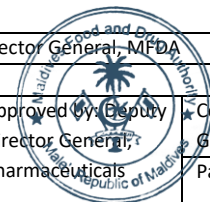
2 PURPOSE

This guideline is aimed at informing the public and other stakeholders on safe disposal of medicines and the established system for medicine disposal in the Maldives.

3 SCOPE

The guideline is applicable for medicines that are leftover, expired, damaged, or withheld at the ports of entry, recalled, etc. in Male' and other islands in the Maldives. Medical waste disposal at health facilities is not covered in the scope of this guideline.

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4 What is the role of government in medicine disposal?

The MFDA is responsible for monitoring and witnessing the safe disposal of medicines in Male'. In other islands, the medicines disposal will be witnessed by the Health Facility and Island/City Council of the island. All medicines disposal records shall be maintained up to 3 years and made available for establishment inspectors when required.

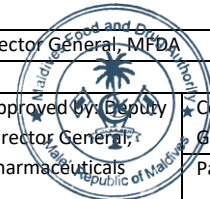
AGENCY	ROLE
MFDA	National overseeing body; Witness and approve medicine disposal in Male' at Thilafushi
HEALTH FACILITIES	Witness and approve medicine disposal in islands other than Male'/Thilafushi
ISLAND/CITY COUNCIL	Witness medicine disposal in islands other than Male'/Thilafushi

5 Why should you safely get rid of the medicines you have purchased?

Unneeded prescription medicines at home pose risk to the consumers and those who possess it and the community. These risks include:

- **risk of accidental use:** All medicines should be kept safe and away from children to prevent accidental use. Hence, it is best to discard these medicines when they are no longer needed.
- **intentional misuse:** Misuse of medicines, especially pain medications and cough medications, is an emerging problem among the youth in the Maldives. These medicines that are unused or leftover can be a source for such misuse.
- **health risks:** keeping leftover medicines can lead to consumption of expired medicines and medicines sharing. Consumption of expired medicines pose health risks, and it will also be ineffective for the ailments. Furthermore, sharing left over medicines can be problematic as the dosage may vary, cause side effects depending on the person and medicine interaction.
- **safety risks:** When medicines are kept for long periods in the homes the safety and quality cannot be assured. In pharmacies and medicine warehouses, the medicines are stored under

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appropriate conditions for storage and the establishments are subject to regulations.

- **environmental damage:** improper disposal of medicines at homes can lead to water supply contamination with toxic chemicals adversely affecting the local human and wildlife.


6 What are the safe ways to dispose medicines?

6.1.1 Medicines can be safely disposed in the following ways depending on the type of medicine.

Table 1 Disposal Methods

Type of medicine	Disposal method		
	Incineration	Burying	Into drains
Antibiotics	✓		
Vaccines	✓		
Vitamins/Minerals	✓	✓	
Cytotoxic	✓		
Liquid vitamins			✓
Others	✓		

6.1.2 Antibiotics and cytotoxic medicines should never be discarded into the sea or onto ground to prevent adverse effects to wildlife.

6.1.3  Apart from the methods described in Table 1, medicines can be crushed with regular waste and incinerated. This method is currently applied for medicine disposal by MFDA.

7 The public or consumers

7.1 What must be disposed?

7.1.1 Medicines including tablets, syrups, capsules, medicine ointments and creams, drops, etc. shall be disposed if they are:

- Unused,
- Leftover,
- Opened,
- Expired,

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- Damaged, or
- Incorrectly stored, etc.

7.2 What has to be done?


7.2.1 Household medicines and personal use medicines can be submitted to MFDA for disposal.


8 Private Pharmacies and Warehouses

8.1 What has to be disposed?

8.1.1 Private pharmacies and warehouses may have damaged, expired, non-conforming or recalled medicines that should be disposed safely. The disposal of these medicines shall be coordinated with MFDA and Waste Management Corporation (WAMCO).

8.2 What has to be done?

8.2.1 Pharmacies/warehouses shall submit a **complete and clearly filled** Medicine Disposal Form (MTG/RE-DF/Fo 0007) (Annex: 01)  **via email: mtg@health.gov.mv**

8.2.2  **The document will be checked and verified within 05 (five) working days and client will be informed if there are any incomplete information via email.**

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8.2.3 ☞ The following information shall be filled:

- a. Brand Name
- b. Generic Name
- c. Batch Number
- d. Strength
- e. Dosage Form
- f. Detail of the Manufacturer
- g. Country of Origin
- h. Volume/Unit
- i. Unit Price MVR (Unit price MVR (per bottle, tube, vial, ampoule)
- j. Total Expired quantity
- k. Total Price
- l. strength per unit
- m. Unit price MVR (per tablet, capsule, suppository)
- n. Total Expired quantity
- o. Total Price
- p. Remarks

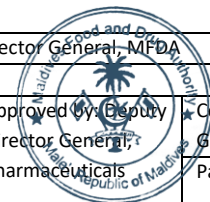
8.2.4 ☞ Once the document verification process is completed, within working 07 (seven) days, client will be issued a letter mentioning a date for physical verification of the expired goods and it will include a direction for the disposal of the medicines with the cooperation from Waste Management Corporation (WAMCO).

8.2.5 Physical verification is conducted to verify if the medicines are consistent with the submitted documents. Once the process is completed, MTG staff will close and seal the boxes with the signature and date.

8.2.6 The client or present client representative will be requested to sign on the Medicine Disposal Form to verify the product verification.

8.2.7 Clients shall proceed with the disposal of the medicines as directed in the letter and submit a confirmation letter to MTG with the date of disposal.

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9 Medicine disposal for Maldives Ports Limited (MPL) and Maldives Airports Company Limited (MACL)

9.1 What has to be disposed?

9.1.1 As the port authorities at Male’ international Airport and Sea port of Male’, MACL and MPL respectively bears the responsibility for disposal of medicines held at the two main ports of entry for medicines. These medicines may include non-conforming, damaged or expired medicines, unapproved or unauthorized medicines, substandard and falsified products, unclaimed medicines, etc.

9.2 What has to be done?

9.2.1 MACL/MPL shall submit a email requesting (mtg@health.govmv) for disposal of medicines held at ports of entry with the list of medicines.

9.2.2 Staff responsible for medicine disposal will complete the Medicine Disposal Form (MTG/RE-DF/Fo 0007) based on the list received. If further information is required, staff will visit and check the medicines to be disposed.

9.2.3 Port pharmaceutical unit will inspect and verify the products according to the Medicine Disposal Form.

9.2.4 Once verified, the boxes will be sealed with the signature of the staff and date of inspection.

9.2.5 Disposal of the medicines will be then conducted with the attendance of Port pharmaceutical unit staff.

9.3 Medicine disposals in Regional Atolls

9.3.1 Private pharmacies and warehouses may have damaged, expired, non-conforming or recalled medicines that should be disposed safely. The disposal of these medicines shall be coordinated with a relevant health facility and MFDA.

9.4 What has to be done?

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- 9.4.1 Pharmacies and warehouses outside greater Male' Area shall complete the Medicine Disposal Form (MTG/RE-MD/Fo 0007) and submit to the relevant health facility.
- 9.4.2 Medicines will be disposed under the supervision of the health facility.
- 9.4.3 Once medicine is disposed, the health facility staff shall sign the form to verify the disposal and the form shall be shared with MTG (via email) by the pharmacy or warehouse.

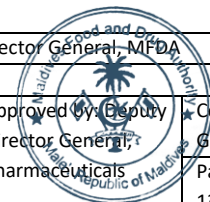
9.5 Other requests for disposal

- 9.5.1 Requests for disposal may be submitted by public, ships etc....
- 9.5.2 Clients will be required to submit a list of the medicines to be disposed along with the medicines.
- 9.5.3 The procedure for disposal will then be conducted by MFDA.

9.6 Disposal of Controlled Drugs (Narcotics and Psychotropics)

- 9.6.1 Disposal of controlled drugs from pharmacies and warehouses will be conducted in the same manner as other medicines.
- 9.6.2 However, when requesting for disposal, pharmacies are required to submit any controlled drugs in a separate list from other medicines.

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10 ANNEX

- Annex 01: Medicine Disposal Form (MTG/RE-DF/Fo 0007)

11 REFERENCE

- Medicine Regulation 2014/R-46
- Health Service Act 29/2015

Contact

- Hotline Number: 7200321
- E-mail: mtg@health.gov.mv

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Annex 1 – Medicine Disposal Form

MEDICINE DISPOSAL FORM

Maldives Food and Drug Authority
Ministry of Health
Male' Maldives

Form number: MTG/RE-DF/FO 0007/...../.....

Client Reference Number:...../202
Name of the Applicant :
Name of the pharmacy :
Location of the pharmacy:
Location of where the Expired/Damaged medicines are kept:

#	Brand Name	Generic Name	Batch number	Strength	Dosage form	Detail of the Manufacture	country of origine	Expiry Date	For liquid and Semi Solid medications (Oral liquids / Injection / Cream / Ointment /Gels/ Inhalations etc)				For Solid Medications (Tablet /Capsule / suppositories etc)				Remarks	
									Volume / Unit	Unit price MVR (per bottle, tube, vial, ampule,etc)	Total Expired quantity	Total Price	streight per unit	Unit price MVR (per tablet, capsule, suppository)	Total Expired quantity	Total Price		

ON behalf of the client:		Prepared by:	
Name:			
Signature:			
Name of the Organisation or Pharmacy:			
Contact Number :	Date:	Stamp	

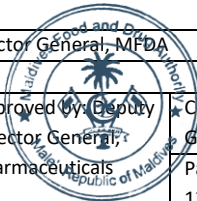
For official/MFDA use ONLY:			
List Checked and Verified by:		Products inspected and verified by:	
Name/s:		Name/s:	
Designation		Designation	
Signature		Signature	
Date :		Date :	

MTG/MFDA
Doc No: No: MTG/RE-DF/FO 0007
Issue No: 04
Rev No: 03

Fac. Name: Me Dis form

Authorised by: DG, MFDA
Approved by: DDG, Pharma
Verified by: Technical Committee, MTG
Prepared by:

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Office Stamp		Office Stamp	
Medicine Disposed by:			
Disposed by:			
Name			
Designation			
Signature		Date:	Office Stamp

NOTE: This form shall be submitted through e mail in excel format to mtg@health.gov.mv
A sample template is attached to the form to facilitate in filling the form accurately

MTG/MFDA
 Rec No: No: MTG/RE-MD/TE-0007
 Issue No: 04
 Rev No: 03

Rec Name: Me Dis form

Authorised by: DG, MFDA
 Approved by: DDO, Pharma
 Verified by: Technical Committee, MTG
 Prepared by:

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