

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ



## Maldives Food and Drug Authority


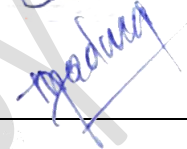
Ministry of Health

Male', Maldives

### Guideline for Medicine Disposal

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Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 1 of 29

<b>Version Number</b>	04	
<b>Issued Date</b>	08.10.2025	
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### SUMMARY OF CHANGES

Version No.	Issued Date	Section/Clause	Summary of Change	Changes Made by
1	13.02.2020	-	Creation of the document	Mohamed Fazeen, Director, Pharmaceuticals
2	26.05.2023	Overall Document	Additional details of procedure	Mohamed Fazeen, Director, Pharmaceuticals  Zeenath Rasheed, Senior Public Health Officer
3	30.09.2023	Overall Document	Addition of disposal methods and expansion on current procedure	Mohamed Fazeen, Director, Pharmaceuticals  Zeenath Rasheed, Senior Public Health Officer

4	08.10.2025	Overall Document	Addition of quarterly declaration procedure, Random verification of disposal per quarter	Aishath Suna, Medicine Regulatory Officer
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## ABBREVIATIONS AND DEFINITIONS

<b>Brand Name</b>	A drug manufactured and sold by a manufacturer under a specific name or trademark is called brand name or trade name.
<b>Controlled Drugs (CD)</b>	The medicines fall under Narcotic controlled law no 17/2011 is classified as controlled drugs.
<b>Country of Origin</b>	The country of origin is the country where the medicine was produced or manufactured.
<b>Dosage Form</b>	Dosage form is the way the final medicinal product is presented for usage.
<b>Generic Name</b>	This is the shortened chemical name of the actual drug. Sometimes it is known as the international name of the drug.
<b>Manufacturer</b>	A company who manufactures medicines for trade use.
<b>Medicine and Therapeutic Goods Division (MTG)</b>	The medicine regulatory division of Maldives Food and Drug Authority.
<b>Medicine Importers</b>	The register and licensed party to import the medicines by Maldives Food and Drug Authority.
<b>National Program (NP)</b>	The National Program is special programs run by the Health Protection Agency and provide the medication to the patients free of cost. (such includes TB, HIV and Reproductive Health).
<b>Pharmacies</b>	This is the registered retail medicine shops where they can store and sell medicines.
<b>Prescription Only Medicine (POM)</b>	This is a category of medicine which can be sold only for a valid prescription only.
<b>Strength</b>	The strength is the amount of drug in the dosage form or a unit of the dosage form
<b>Waste Management Corporation Limited (WAMCO)</b>	Mandated to provide a sustainable waste management solution throughout the country.
<b>World health organization (WHO)</b>	The United Nations agency working to promote health, keep the world safe and serve the vulnerable.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 4 of 29

<b>Health Protection agency (HPA)</b>	The Health Protection Agency (HPA) is a governmental organization dedicated to safeguarding public health and preventing the spread of infectious diseases. It focuses on disease surveillance, control, and prevention measures to minimize health risks and protect the well-being of the population
<b>Ministry of health (MOH)</b>	Ministry of Health, Government of Maldives is the apex body providing leadership and guidance to protect health and wellbeing of the citizens of Maldives. It promotes health through a high quality and comprehensive health care system which is effective, efficient, responsive, affordable, equitable and accessible to all in the country. It regulates and provides policy guidance in matters of health, setting norms and standards for service delivery and coordinate with other national and international stakeholders."
<b>Maldives Food and drug authority (MFDA)</b>	Competent Authority which is under the Ministry of health to regulate the Food and Medicines.
<b>Maldives ports limited (MPL)</b>	MPL is the sole authority on port related businesses in the Maldives
<b>Maldives Airports Company Limited (MACL)</b>	Leading airport operator in the Maldives with the largest International Airports in the country under its management.
<b>Sorting of Medicines</b>	Separating different categories of medicines
<b>Expired Medicines</b>	Drug expiration is the date after which a drug might not be suitable for use as manufactured.

## 1 INTRODUCTION

Since Maldives is not a medicine manufacturing country, it relies on 100 percent on imports. In this regards, several million Maldivian Rufiyaa (MVR) worth of medicines are imported into the Maldives every year. In addition, medicines are imported as donations.

Therefore, the number of medicines that must be disposed of due to expiration, damage or other reasons is increasing year by year.

Medicines can take many years to degrade and persist for a long time in the environment. Many medicines are now detectable at low levels in the environment. Improper disposal may be hazardous if it leads to contamination of water supplies or local sources used by communities.

To prevent unnecessary environmental contamination, medicines should not be treated as general waste. They are not suitable for an insecure landfill and should not be poured down the sink, flushed down the toilet or otherwise permitted to enter the water table.

The Maldives Food and Authority Act No. 05 of 2015 empowers the National Medicines Regulatory Authority (NMRA) to recall and dispose of medicine, medical devices, borderline products, or investigational medicinal products. Disposal of pharmaceuticals should be carried out under the supervision of an Authorized Officer appointed. And, prior approval should be obtained from the authority before disposing of items. Information on pharmaceutical disposal must be carefully handled as it may be politicized and sensationalized. If the public and media are not kept judiciously informed of the efforts to dispose of expired pharmaceuticals safely, the disposal work may be severely hampered by misinformation propagated by uninformed journalists and politicians. Several methods for safe disposal of unusable and unwanted pharmaceuticals.

When a medication is no longer suitable or safe to be used, it has turned into waste. Medications contain active ingredients (otherwise known as chemicals). When unused medications are discarded into the landfill or sewage, these active ingredients may eventually leak into surface water and contaminate the environment.

Therefore, it is very important to dispose of the drug in the most appropriate manner. If the drugs are not disposed in the most appropriate manner, they may be relabeled and come back on the market.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 6 of 29

Therefore, MFDA is working with other institutions involved in the disposal of drugs to resolve such issues.

## 2 PURPOSE

The purpose of this guideline is to guide the medicine importers, pharmacy owners and the relevant stake holders and the public on the disposal of expired and damaged medicines in the most appropriate manner using available resources to prevent the expired and damage medicines from being relabeled and brought to market.

## 3 SCOPE

This guideline is intended to applies health care providers, pharmacies, medicine importers, individuals and other stake holders (Health Protection Agency, National Drug Agency, Ministry of Health) to dispose the expired and unwanted medicines in most appropriate manner by using resources to ensure and prevent the expired and damage medicines from being relabeled and brought to market.

## 4 RESPONSIBILITY AND ACCOUNTABILITY OF AGENCIES

AGENCY	ROLE
MFDA	National overseeing body; Oversee and approve medicine disposal process in Male area
MEDICINE AND THERAPEUTIC GOODS DEVISION	Issuance of permits for disposal of medicines and verification before of medicines prior to disposal of drugs Maintain records of disposable medicines
HEALTH FACILITIES	Approve and oversee medicine disposals in the islands and resorts. After disposal of the medicines it is a responsibility of the health facilities to share the Medicine Disposal Form in PDF and Excel format with the MFDA along with signature, name and date of disposal
ISLAND/CITY COUNCIL	Overseeing the medicine disposal in islands other than Male'
PHARMACIES AND MEDICINE IMPORTERS	Complete and submit the required form for disposal of expired medicine. The authorized person preparing and submitting the form

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 7 of 29

	<p>shall be responsible for the accuracy of the data and must be available during random MFDA verification inspections.</p> <p>Sort the disposal medicines and pack and prepare for verification.</p> <p>Coordinate with WAMCO and arrange the disposal sessions.</p>
<b>HEALTH PROTECTION AGENCY</b>	<p>Complete and submit the Medicine Disposal Form in accordance with the procedure for disposal of expired and unwanted medicines brought to the National Program.</p> <p>Advice and Guidance on safe disposal of handling, storage, transport and treatment of cytotoxic waste</p>
<b>WASTE MANAGEMENT CORPORATION LIMITED (WAMCO)</b>	<p>Once the drugs submitted for disposal and are verified and sealed by the MFDA, WAMCO shall dispose it in front of the MFDA staff upon request of the client.</p> <p>After disposal of the medicine, sign and seal the medicine disposal form and hand it over to the MFDA.</p>

### RESPONSIBILITY AND ACCOUNTABILITY OF STAFF

Staff	Responsibility and Accountability
Medicine Regulatory Officer	<ul style="list-style-type: none"> <li>Check for completion of Medicine disposal form (MTG-RE/FO0007/Year/0000) upon receive.</li> <li>Share the document with the main entry of MFDA if the form is complete.</li> <li>Issue a number for the form from the numbering Sheet (MTG/RE-DN/Re0095/year/0000)</li> <li>Fill the check list and issue number for the check list from Numbering sheet for check list (MTG/RE-DP/Li0053/year/0000)</li> <li>Fill the medicine disposal summary sheet (MTG/RE-DD/Re0028/year/0001)</li> <li>Email the client informing them of the</li> </ul>

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 8 of 29



	<p>date and time of the verification inspection.</p> <ul style="list-style-type: none"> <li>• Conduct verification inspections</li> <li>• Attend the sessions of medicine disposal</li> </ul>
Director, Pharmaceuticals	<ul style="list-style-type: none"> <li>• Verification of all documents before emailing the client informing them of the date and time of the verification inspection</li> <li>• Verify the check list and sign on the required areas prior to emailing the client informing them of the date and time of the verification inspection.</li> </ul>
Deputy Director General, Pharmaceuticals	<ul style="list-style-type: none"> <li>• Approval and authorization of the check list and sign on the required areas.</li> <li>• Approved to send the email to the client informing them of the date and time of the verification inspection.</li> </ul>

## 5 General Procedure for Medicine Disposal

The following procedure shall apply to all parties submitting medicines for disposal, including pharmacies, warehouses, importers, health facilities, resorts, ports, and other organizations.

### 5.1 Submission of Disposal Form and Declarations

All facilities submitting medicines for disposal shall complete and submit the Medicine Disposal Form (Excel version: MTG/RE-DF/Fo0007) via email to [medicine.disposal@mfa.gov.mv](mailto:medicine.disposal@mfa.gov.mv).

#### 5.1.1 Forms will be accepted on a quarterly basis:

- January–March: between 1st and 10th of April
- April–June: between 1st and 10th of July
- July–September: between 1st and 10th of October
- October–December: between 1st and 10th of January

#### 5.1.2 The following information must be filled in the form:

- Serial No.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 9 of 29

- ADL Product No.
- Generic Name
- Product Name
- Manufacturer / Company Name
- Dosage Form
- Strength
- ADL Category
- Batch Number
- Expiry Date
- Total Expired Quantity
- Total Price
- Remarks (e.g., Brand Name)

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 10 of 29

- 5.1.3** MFDA staff shall check the submitted forms for completeness within seven (07) working days of submission.
- 5.1.4** If the form is complete, the client will be emailed within ten (10) working days to inform them of the date and time of the pre-disposal verification inspection, if required.
- 5.1.5** If incomplete, the client will be notified within seven (07) working days, and the corrected form must be resubmitted.
- 5.1.6** All facilities (including pharmacies, warehouses, health facilities, etc.) must submit a Quarterly Declaration Form (MTG/RE-QC/Fo 0070) before 10<sup>th</sup> of the month for each quarter.
- 5.1.7** If no medicines are to be disposed of in the particular quarter, a declaration stating “No Disposal” must still be submitted.
- 5.1.8** MFDA staff shall maintain a Quarterly Declaration Checklist (MTG/RE-QC/Re 134) recording receipt of each facility’s form Each declaration must be ticked, dated, and filed for record keeping.
- 5.1.9** If a facility fails to submit the declaration form by the due date, MFDA staff shall send an email reminder within five (05) working days, keeping a copy of the follow-up email with the checklist.
- 5.1.10** All forms and verification records should also be maintained digitally (scanned or electronic copies) for audit and regulatory purposes

## **5.2 Sorting of Medicines**

- 5.2.1** Medicines must be sorted prior to inspection according to categories (Prescription Only, Over-the-Counter, Controlled Drugs, Antineoplastic Drugs, etc.).
- 5.2.2** Controlled drugs and other high-risk medicines must be clearly separated and secured for full verification.
- 5.2.3** Protective equipment (gloves, masks) should be used during handling of expired or high-risk medicines to ensure staff safety.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 11 of 29

### 5.3 Verification Inspection

- 5.3.1 MTG staff shall conduct verification inspections of the medicines with the submitted forms.
- 5.3.2 Physical verification will be conducted for randomly selected two (02) places within per quarter.
- 5.3.3 After scheduling the inspection, the date and time will be informed to the client via email at least one (01) day in advance.
- 5.3.4 As inspections are conducted randomly, the person responsible for completing and submitting the Medicine Disposal Form shall be accountable for the accuracy and completeness of all details entered.
- 5.3.5 The verification authority therefore includes both the MFDA officials conducting the verification and the authorized person who prepared and submitted the disposal form.
- 5.3.6 The submitting officer must be present or contactable during the verification process to clarify any discrepancies found during inspection.
- 5.3.7 For controlled drugs, a 100% verification inspection shall be carried out.
- 5.3.8 For other medicines, 50% to 100% will be verified depending on the quantity and category.

### 5.4 Authorization for Disposal

- 5.4.1 If the submitted form is complete, the relevant MTG staff shall sign and return the form via email, to the client, authorizing to process for disposal by coordinating with WAMCO.
- 5.4.2 If incomplete, the form will be returned for correction and resubmission.

### 5.5 Disposal with WAMCO

- 5.5.1 Disposal shall be carried out in the presence of WAMCO officials.
- 5.5.2 WAMCO staff must complete, sign, and seal the designated section of the form and email it to [medicine.disposal@mfd.gov.mv](mailto:medicine.disposal@mfd.gov.mv).

### 5.6 Completion of Disposal Process

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 12 of 29

**5.6.1** Upon receipt of the WAMCO-confirmed form, MTG staff will apply the official “Disposed” seal.

**5.6.2** The finalized form will be returned to the relevant party, completing the disposal process.

## **5.7 Compliance and Non-Compliance**

**5.7.1** Repeated failure to submit forms or follow procedures may result in regulatory actions, including warnings or fines.

**5.7.2** This General Procedure applies uniformly to all medicine disposal cases. Any additional requirements specific to an agency or facility are described in their respective sections of this guideline.

## **6 CONSEQUENCES OF IMPROPER DISPOSAL OR NON-DISPOSALS**

**6.1.1** Improper disposal may be hazardous if it leads to contamination of water supplies or local sources used by nearby communities.

**6.1.2** Expired drugs may come into the hands of scavengers and children if a landfill is insecure. Pilfering from a stockpile of waste drugs or during sorting may result in expired drugs being diverted to the market for resale and misuse.

**6.1.3** Most pharmaceuticals past their expiry date become less efficacious and may develop a different adverse drug reaction profile.

**6.1.4** There are some categories of expired drugs or defective disposal practices that carry a public health risk.

**6.1.5** The main health risks are summarized below.

- If the drugs are not disposed in the most appropriate manner, they may be relabeled and come back on the market.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 13 of 29

- Contamination of drinking water must be avoided. Landfills must be sited and constructed in a way that minimizes the possibility of leachate entering an aquifer, surface water or drinking water system.
- Non-biodegradable antibiotics, antineoplastics and disinfectants should not be disposed of into the sewage system as they may kill bacteria necessary for the treatment of sewage. Antineoplastics should not be flushed into watercourses as they may damage aquatic life or contaminate drinking water. Similarly, large quantities of disinfectants should not be discharged into a sewerage system or watercourse but can be introduced if well diluted.
- Burning pharmaceuticals at low temperatures or in open containers results in release of toxic pollutants into the air. Ideally this should be avoided.
- Inefficient and insecure sorting and disposal may allow drugs beyond their expiry date to be diverted for resale to the public. In some countries scavenging in unprotected insecure landfills is a hazard.

## 7 RECOMMENDED DISPOSAL METHODS OF MEDICINE

### 7.1 Solids, semi-solids, and powders Anti-infective drugs, controlled drugs, and antineoplastics

- It must be disposed of for landfill. Also, it is recommended to inertization is recommended before discharge to a landfill.
- Anti-infective drugs and antineoplastics are encapsulated to delay release to the environment and avoid high concentrations.
- Controlled drugs should be immobilized under the supervision of the pharmacist, the police or a judicial representative, depending on the local regulations.

### 7.2 Liquids Pharmaceuticals with no or low toxicity.

- Pharmaceuticals that can be classed as readily biodegradable organic material include liquid vitamins that may be diluted and flushed into a sewer.
- Harmless solutions of different concentrations of certain salts, amino acids, lipids, or glucose may also be disposed of in sewers.

### 7.3 Ampoules

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 14 of 29

- a. These can be crushed on a hard impermeable surface (e.g. concrete) or in a metal drum or bucket using a stout block of wood or a hammer.
- b. Workers doing this should wear protective equipment, such as eye protection, boots, clothing, and gloves.
- c. The crushed glass should be swept up, placed in a container suitable for sharp objects, sealed and disposed of in a landfill. The liquids released from the ampoules should be diluted and disposed of as described above.
- d. Ampoules should not be burnt or incinerated as they will explode, possibly causing injury to operators and damage to the furnace or incinerator. Melted glass will also clog up the grate of a furnace or incinerator if the operating temperature is above the melting point of glass. Volatile liquids in small quantities can be allowed to evaporate in the open air.
- e. Ampoules of antineoplastics or anti-infective drugs must not be crushed, and the liquid discharged to sewers. They should be treated using the encapsulation or inertization disposal methods described above.

#### 7.4 Anti-infective drugs

- a. Anti-infective drugs should not be discarded in an untreated form. Generally, they are unstable and are best incinerated, and if that is not possible encapsulated or inertized. Liquid anti-infective drugs may be diluted in water, left for two weeks, and disposed to the sewer.

#### 7.5 Controlled substances

- a. Controlled substances must be destroyed under supervision of a pharmacist or the police depending on national regulations. Such substances must not be allowed into the public domain as they may be abused.
- b. They should either be rendered unusable, by encapsulation or inertization, and then dispersed among the municipal solid waste in a landfill or incinerated.

#### 7.6 Antineoplastics

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 15 of 29

- a. Antineoplastic drugs, previously called cytotoxic or anti-cancer drugs, can kill or stop growth of living cells. They are used in chemotherapy for cancer which is usually performed in specialized treatment centers. It is extremely unlikely that they would form part of an aid donation in emergencies. However, if unwanted and discharged into the environment they can have very serious effects, such as interfering with reproductive processes in various life forms. Their disposal must therefore be handled with care.
- b. Antineoplastics should be segregated from other pharmaceuticals and kept separately in clearly marked containers with rigid walls. They should ideally be safely packaged and returned to the supplier for disposal. If this option is not possible, they must be destroyed in a two-chamber incinerator which operates at a high temperature of at least 1200°C in the secondary chamber and is fitted with gas cleaning equipment. An after-burner (i.e. the secondary chamber) is important for the destruction of cytotoxic waste, as it is possible that antineoplastic solutions could become aerosolized following the initial combustion in the primary chamber.
- c. As a result, without a higher temperature secondary chamber, degraded antineoplastic material may be emitted from the chimney.
- d. The secondary combustion chamber consequently ensures that such antineoplastic substances are fully incinerated. Antineoplastic drugs/waste should never be disposed of in a landfill other than after encapsulation or inertization.
- e. Work teams handling these drugs must avoid crushing cartons or removing the product from its packages. They may only be discharged in a sewerage system after chemical decomposition and must not be discharged untreated into surface water drains or natural watercourses.
- f. Although the above methods are the best methods for drug disposal, not all of these methods are currently used in Maldives. However, the drugs are being disposed of using the best available resources.

## 8 DISPOSAL OF EXPIRED OR UNWANTED PHARMACEUTICALS

### 8.1 Pharmaceuticals that should never be used and should always be considered pharmaceutical waste are:

- a. All expired pharmaceuticals
- b. All unsealed syrups or eye drops (expired or unexpired)

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 16 of 29



- c. All cold chain damaged unexpired pharmaceuticals that should have been stored in a cold chain.
- d. All bulk or loose tablets and capsules. If unexpired these should only be used when the container is still sealed, properly labelled or still within the original unbroken blister packs.
- e. All unsealed tubes of creams, ointments, etc. (expired or unexpired).

## 9 Who should request for disposal of medicines?

- a. Medicine Importer (Warehouses) and Pharmacies
- b. Health Facilities
- c. Maldives Airport Company Limited (MACL)
- d. Maldives Ports Limited (MPL)
- e. Other Organizations (World Health Organization (WHO), Health Protection Agency (HPA) and Ministry of Health (MOH)
- f. Resorts
- g. Households
- h. Ships

## 10 Medicine Importer (Warehouses) and Pharmacies

### 10.1 What must be disposed?

- 10.1.1** Private pharmacies and warehouses may have expired or unwanted medicines that should be disposed of safely.

### 10.2 What Shall be done?

- 10.2.1** Pharmacies and warehouses shall follow the **General Procedure (Section 5)**.
- 10.2.2** No additional requirements beyond those in Section 5.

## 11 Disposal of Medicines

- 11.1** Disposal with WAMCO shall follow Section 5.5 and 5.6.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 17 of 29

- 11.2** WAMCO must confirm disposal by signing/sealing the form.
- 11.3** Upon completion of the verification inspection, the client shall arrange for the disposal of the drug in collaboration with WAMCO.
- 11.4** The drug should be disposed in the presence of WAMCO officials, and they are to confirm if all the boxes which were sealed and signed during the verification process were disposed completely.
- 11.5** Once completed the session, the document shall be signed and sealed by the WAMCO officials who were present at the session and share it with the client.
- 11.6** Client shall share the signed document with MFDA Via email within five (05) working days.

## **12 Self-disposal of Medicines**

- 12.1** Pharmaceuticals that can be classed as readily biodegradable organic material include liquid vitamins that may be diluted and flushed into a sewer. Harmless solutions of different concentrations of certain salts, amino acids, lipids or glucose may also be disposed of in sewers. Small quantities of other liquid pharmaceuticals, which are not controlled substances, anti-infective drugs, or antineoplastics, can be flushed into sewers.

### **12.2 What Shall be Done?**

- 12.2.1** Self-disposal is allowed only for small quantities of readily biodegradable medicines (e.g., vitamins, oral rehydration salts, amino acids, glucose).
- 12.2.2** These must be diluted in water and flushed into sewers.
- 12.2.3** Documentation of self-disposal must be prepared and submitted to MFDA/Public Health Unit.

## **13 Medicine disposals in Regional Atolls**

- 13.1.1** Private pharmacies and warehouses may have expired unwanted and recalled medicines that should be disposed of safely.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 18 of 29

**13.1.2** The disposal of these medicines shall be coordinated with the closest relevant health facility and MFDA.

### **13.2 What has to be done?**

**13.2.1** Regional health facilities must coordinate with the nearest Public Health Unit for disposal.

**13.2.2** All other steps follow Section 5.

## **14 Medicine disposals in resort clinics/ pharmacies**

**14.1.1** The tourist resorts may have expired and unwanted or recalled medicines that should be disposed of safely. The disposal of these medicines shall be coordinated with a relevant health facility close by and MFDA.

### **14.2 What has to be done?**

**14.2.1** Resort pharmacies and clinics must submit disposal forms to MFDA.

**14.2.2** The Public Health Unit (PHU) must be informed before disposal is carried out.

**14.2.3** All other steps shall follow the General Procedure (Section 5).

## **15 Disposal of Controlled Drugs**

**15.1.1** Controlled drugs must follow the **General Procedure (Section 5)**.

**15.1.2** Additional requirements:

- 100% verification inspection is mandatory.

## **16 Medicine disposal for Maldives Ports Limited (MPL) and Maldives Airports Company Limited (MACL),**

### **16.1 What has to be disposed?**

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 19 of 29

**16.1.1** As the port authorities at Male' international Airport (MACL) and Sea port of Male' (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 unapproved or unauthorized medicines, substandard and falsified products, unclaimed medicines, etc.

## **17 Pre-Disposal Verification**

**17.1** Physical verification will be conducted by the officials of Maldives Food and Drug Authority (MFDA), on the prescheduled date and time to verify if the medicines are consistent with the submitted documents.

**17.2** MTG staff shall conduct random physical verification inspections at two (2) pharmacies per quarter.

**17.3** For all controlled drugs, a full (100%) physical verification inspection must be conducted prior to authorizing disposal, regardless of the quantity.

**17.4** For non-controlled medicines, between fifty percent (50%) and one hundred percent (100%) shall be checked depending on the quantity and associated risk category.

**17.5** The submitted form set will be taken by MFDA officials for the verification inspection.

**17.6** During this inspection fifty percent (50%) to one hundred percent (100%) will be checked depending on the quantity of the products.

### **17.7 How to differentiate Percentage by Physical Inspections:**

**17.7.1** All expired medicines should be sorted according to the approved drug list categories, such as prescription-only medicine (POM), Over-the-counter Medicine (OTC), etc.

**17.7.2** Based on these categories, we will identify two groups: high-risk and low-risk.

**17.7.3** High-risk categories include prescription-only medicine (POM) and hospital-use medications, while low-risk categories include Over-the-Counter Medicine (OTC).

**17.7.4** For high-risk categories, we will calculate 80% to 50% of the total, and for low-risk categories, 20% to 10%.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 20 of 29

- 17.7.5** We will concentrate only on large quantities and will not address the smaller quantities listed in the forms.
- 17.7.6** The recommended procedure will be followed, and records will be kept.
- 17.7.7** Once the process is completed, MFDA staff will close and seal the boxes with the signature and date.
- 17.7.8** The form set shall be shared with the client via email within seven (03) working days.
- 17.7.9** The client or client representative present during the verification process will be requested to sign the Medicine Disposal Form to verify the product verification.
- 17.7.10** If for any reason the scheduled time for the verification inspection needs to be changed, the client shall be notified by email by rescheduling it to another time of the day.
- 17.7.11** If for any reason the date of verification inspection must be changed, the inspection shall be rescheduled within the next 02 days and inform the client via email.

## **18 Disposal of Medicines**

- 18.1** Upon receipt of the Medicine Disposal Form, MTG staff shall check the accuracy and completeness of the form.
- 18.2** If all information is correct, the form shall be signed within 5 working days by MTG staff and returned to the relevant pharmacy via email, granting permission to proceed with disposal through WAMCO.
- 18.3** Upon completion of the verification inspection, the client shall arrange for the disposal of the drug in collaboration with WAMCO.
- 18.4** The drug should be disposed in the presence of WAMCO officials, and they are to confirm if all the boxes which were sealed and signed during the verification process were disposed of completely.
- 18.5** After disposal, the designated section of the form must be filled, signed, and sealed by WAMCO staff. The completed form shall then be emailed to [medicine.disposal@mfd.gov.mv](mailto:medicine.disposal@mfd.gov.mv) within 14 days.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 21 of 29

**18.6** Upon receipt of the WAMCO-signed form, MTG staff shall apply the official “Disposed” seal and send the finalized form back to the relevant pharmacy within working 5 days.

**18.7** This process will serve as the official completion of the medicine disposal procedure.

## **19 Medicine disposal for Maldives Food and Drug Authority**

**19.1.1** Maldives Food and Drug Authority may have samples received for registration that are no longer in use and other medicines collected for testing purposes.

**19.2** The samples which are to be disposed of shall be listed by the medicine’s registration staff including the below information.

- a. Brand Name
  - a. Serial No
  - b. ADL Product No
  - c. Generic Name
  - d. Product Name
  - e. Manufacture / Company Name
  - f. Dosage form
  - g. Strength
  - h. ADL Category
  - i. Batch Number
  - j. Expiry Date
  - k. Total Expired quantity
  - l. Total Price
  - m. Remarks Brand Name

**19.3** The list shall be emailed to the division email (medicine\_disposal@mfa.gov.mv) and the samples shall be handed over in written form by taking the signature, name, and date from the received staff who is responsible of the disposal process

**19.4** The samples should be easy to count, and the list of medicines must correspond with the samples provided. If they do not match, the Disposal Team will reject the form

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 22 of 29

- 19.5** Upon receive of the list and the medicines, medicines shall be kept in the appropriate boxes and sealed labelling as samples for disposal.
- 19.6** Once the list is received with the medicines the Medicine Disposal Form (MTG/RE-DF/Fo0007) (Annex: 01) shall be filled by the relevant staff who is responsible for the process and send it to the main entry with in working ten (10 days).
- 19.7** Upon receiving the form from the entry, the form number shall be given and shall be entered to the medicine disposal summary within seven (07) working days.
- 19.8** Within the next ten (10) working days, the relevant staff shall write a memo to the MFDA admin and share it via email, requesting to arrange the vehicle to take the medicines to the disposal site at Male.

## **20 Other requests for disposal**

- 20.1** Requests for disposal may be submitted by general public (house hold medicines) , ships, passenger lines and others.
- 20.2** The general public (households), ships and passenger lines may have small quantity of expired and unwanted medicines.
- 20.3** For disposal of such small quantity medicines the client shall email the list of medicines to be disposed including the below information.
- a. Serial No
  - b. ADL Product No
  - c. Generic Name
  - d. Product Name
  - e. Manufacture / Company Name
  - f. Dosage form
  - g. Strength
  - h. ADL Category
  - i. Batch Number
  - j. Expiry Date

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 23 of 29

- k. Total Expired quantity
- l. Total Price
- m. Remarks Brand Name

- 20.4** The list shall be emailed to the MTG division email (medicine\_disposal@mfa.gov.mv) and the samples shall be handed over in written form by taking the signature, name, and date from the received staff who is responsible of the disposal process.
- 20.5** Upon receiving the list and the medicines, medicines shall be kept in the appropriate boxes and sealed labeled as samples for disposal.
- 20.6** Once the list is received with the medicines the Medicine Disposal Form (MTG/RE-DF/Fo0007) (Annex: 01) shall be filled by the relevant staff who is responsible for the process and sent it to the main entry within working ten (10) days).
- 20.7** Upon receiving the form from the entry, the form number shall be given and shall be entered to the medicine disposal summary within ten (10) working days.
- 20.8** Within next ten (10) working days, the relevant staff shall write a memo to the MFDA admin and share it via email, requesting to arrange the vehicle and vessels to take the medicines for the disposal. The disposal of relevant samples, including ship samples, household samples, and registration samples, should be coordinated with the Procurement Unit at the Ministry of Health.
- 20.9** Once the administrative work is completed, the relevant staff shall write to WAMCO requesting to arrange a disposal session for these medicines. The designated staff should prepare all medicines for disposal. After completing the necessary administrative tasks, the medicines should be packed in plastic bags, labeled as "Dispose," and placed in the Medicine Therapeutic Unit (MTG).

## 21 PUBLICATION AND AWARENESS

- 21.1** If any changes are brought to the guideline, they have to be published and shared with the importers. Additionally, awareness sessions on appropriate medicine disposal shall be conducted once in every year.

## 22 REFERENCE

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 24 of 29



- Medicine Regulation 2014/R-46
- Health Service Act 29/2015
- Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies (WHO)

## 23 ANNEX

- Annex 1: Medicine Disposal Process Timeline
- Annex 2: Summary of pharmaceutical categories and disposal methods
- Annex 3: Medicine Disposal Form
- Annex 4: Medicine Disposal Declaration Form

### Contact

- Hotline Number: 7200321
- E-mail: [medicine.disposal@mfa.gov.mv](mailto:medicine.disposal@mfa.gov.mv)

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 25 of 29

## Annex 1

### Medicine Disposal Process Timeline

⌚ Medicine Disposal Process Timeline			
Step	Process Description	Responsible Party	Timeframe
<b>Form Submission</b>	Submit the Medicine Disposal Form for each quarter <b>before the deadline.</b>	Health Facilities Pharmacies Warehouse	<b>On or before the 10th of each quarter</b>
<b>Form Review</b>	Review and check submitted disposal forms.	MTG	<b>Within 7 working days</b>
<b>Verification Notice</b>	Notify the client regarding the <b>verification schedule.</b>	MTG	<b>Within 10 working days from the date of form submission</b>
<b>Verification Inspection Notice</b>	Inform the client of the <b>verification inspection date.</b>	MTG	<b>1 day prior to verification inspection</b>
<b>Verified Form Issuance</b>	Share the <b>verified, signed, and stamped form</b> with the client.	MTG	<b>Within 2 working days from the date of inspection</b>
<b>Medicine Disposal with WAMCO</b>	Dispose of verified medicines with <b>WAMCO</b> and submit <b>WAMCO-signed disposal forms</b> to MFDA.	Health Facilities Pharmacies Warehouse	<b>Within 14 working days from the date verified forms are shared by MFDA</b>
<b>Finalization of Disposal Form</b>	Apply <b>"Disposed"</b> seal and return the <b>finalized form</b> to the client.	MTG	<b>Within 2 working days of receiving WAMCO-signed forms</b>

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 26 of 29

## Annex 2

### Summary of pharmaceutical categories and disposal methods

Category	Disposal methods	Comments
<b>Solids</b>	Landfill	No more than 1% of the daily municipal waste should be disposed of daily in an untreated form (non-immobilized) to a landfill.
<b>Semi-solids</b>	Waste encapsulation	
<b>Powders</b>	Waste inertization Medium and high temperature incineration (cement kiln incinerator)	
<b>Liquids</b>	Sewer High temperature incineration (cement kiln incinerator)	Antineoplastics not to sewer.
<b>Ampoules</b>	Crush ampoules and flush diluted fluid to Sewer	Antineoplastics not to sewer.
<b>Anti-infective drugs</b>	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Liquid antibiotics may be diluted with water, left to stand for several weeks and discharged to a sewer.
<b>Antineoplastics</b>	Return to donor or manufacturer Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator) (chemical decomposition)	Not to landfill unless encapsulated. Not to sewer. No medium temperature incineration.
<b>Controlled drugs</b>	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Not to landfill unless encapsulated.
<b>Aerosol canisters</b>	Landfill Waste encapsulation	Not to be burnt: may explode.
<b>Disinfectants</b>	Use To sewer or fast-flowing watercourse: small quantities of diluted disinfectants (max. 50 litres per day under supervision)	No undiluted disinfectants to sewers or water courses. Maximum 50 litres per day diluted to sewer or fast-flowing watercourse. No disinfectants at all to slow moving or stagnant watercourses.

## Annex 3

### Medicine Disposal Form

Page 1 of 1

#### MEDICINE DISPOSAL FORM

Maldives Food and Drug Authority  
Male' Maldives

OFFICE USE ONLY

Form number: MTG/ RE-DF/10-0007/2024-

Client Reference Number:																		
Name of the Company :																		
Name of the pharmacy/Warehouse / Health Facilities :																		
Direct Contact Number of the Indebtor :																		
Location of the pharmacy/Warehouse / Health Facilities :																		
Location of where the Expired/Damaged medicines are kept:																		
										For liquid and Semi Solid medications( Oral liquids / Injection / Cream / Ointment / Gels/ Inhalations etc)				For Solid Medications (Tablet/Capsule / suppositories etc)				
Serial No	ADL Product No	Generic Name	Product Name	Manufacture / Company Name	Dosage form	Strength	ADL Category	Batch Number	Expiry Date	Volume / Unit	Unit price MVR (per bottle, tube, vial, ampoule, etc)	Total Expired quantity	Total Price	Weight per unit	Unit price MVR (per tablet, capsule, suppository)	Total Expired quantity	Total Price	Remarks

Prepared by:	
Name:	
Signature:	
Name of the Pharmacy / Warehouse / Health Facility	
Direct Contact Number :	Date:
For official / MFDA use ONLY:	
List Checked and Verified by:	
Name:	
Designation:	
Signature:	
Date:	
For WAMCO/Health Facilities/Pharmacies and Warehouse Use Only	
WAMCO/Health Facilities/Pharmacies and Warehouse:	
The Medicines in this form has disposed under our supervision	
Name and Designation of the staff attended the disposal session	
Organization	
Signature	Date : office Stamp

NOTE: This form shall be submitted through e mail In excel format to [medicinedisposal@health.gov.mv](mailto:medicinedisposal@health.gov.mv)  
A sample template is attached to the form to facilitate in filling the form accurately

MTG/MFDA  
Rev.No.: 10: MTG RE-DF/10-0007  
Issue No.: 01  
Rev No.: 4

MD Rule  
ID: 21.02.19  
RD :28.12.23

Auth: by DG, MFDA  
App: by Pharmas Specialist  
Verified by: Technical Core, MTG  
Prepared by:

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority			Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal			
Version No: 04	Issued Date: 08.10.2025	Copy Letter:		Page No: Page 28 of 29

## Annex 4

### Medicine Disposal Declaration Form

To be completed by all Pharmacies / Warehouses / Health Centers  
(Even if no disposal form is submitted for the quarter, this checklist must still be filled and emailed to:  
medicine.disposal@mfa.gov.mv)

#### Disposal Declaration Form

Name of Pharmacy / Warehouse / Health Center: \_\_\_\_\_

Address: \_\_\_\_\_

Responsible Person (Name & Contact): \_\_\_\_\_

Email Address: \_\_\_\_\_

#### Quarter (tick one):

- ☐ Q1 (Jan – Mar) – Submission by 10 April
- ☐ Q2 (Apr – Jun) – Submission by 10 July
- ☐ Q3 (Jul – Sep) – Submission by 10 October
- ☐ Q4 (Oct – Dec) – Submission by 10 January (following year)

#### Disposal Form Submission Status

☐ Yes – Disposal form(s) for this quarter have been submitted.

• Form Reference Number(s): \_\_\_\_\_

• Date(s) Submitted: \_\_\_\_\_

☐ No – No disposal form for this quarter.

#### Declaration

I hereby confirm that the above information is true and accurate.

Name & Designation: \_\_\_\_\_

Signature & Date: \_\_\_\_\_

#### Note

1. This checklist must be completed every quarter by all pharmacies/warehouses/health centers.
2. Submit the completed checklist (signed and dated) to medicine.disposal@mfa.gov.mv by the due date.
3. Retain a copy for your own records.

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideline for Medicine Disposal		
Version No: 04	Issued Date: 08.10.2025	Copy Letter:	Page No: Page 29 of 29