بسب المنالزم الزخيم



Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline for Medicine Disposal

Medicine and Therapeutic Goods Div	ision, Maldives Food	and Drug Authority Authorize	ed by: Director General, MFDA
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideli	ine for Medicine Disposal	1 6 6 C 1 5.5
Issue No: 01	Issue Date: 13.02.2020	Prepared by: Director, Pharmaceuticals	Approved by: Deputy Copy Letter: MTG/RE Director General, GLN 002
Revision No: 00	Revised Date: -	Verified by: Technical Committee of MTG	Pharmaceuticals. Page No: Page 1 of 9

CONTROLLED COPY

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	JA .	13.02.2020
Authorised by: Ms.Thooma Adam Deputy Director General, Laboratory Services Maldives Food and Drug Authority	Mograny	13.02.2020

Medicine and Therapeutic Goods Div	ision, Maldives Food	and Drug Authority Authorize	d by:	Director General, MFDA	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideli	ne for Medicine Disposal	200		
Issue No: 01	Issue Date: 13.02.2020	Prepared by: Director, Pharmaceuticals	13	Approved by: Deputy Director General,	Copy Letter: MTG/RE GLN 002
Revision No: 00	Revised Date: -	Verified by: Technical Committee of MTG	1	Pharmaceuticals	Page No: Page 2 of 9

CONTENTS

1	INT	RODUCTION	- 4
2	PUI	RPOSE	- 4
3	sco	DPE	- 4
4	Wh	at is the role of government in medicine disposal?	- 5
5	Wh	y should you safely get rid of the medicines you have purchased?	- 5
6	Wha	at are the safe ways to dispose medicines?	- 6
7	The	public or consumers	- 6
	7.1	What has to be disposed?	- 6
	7.2	What has to be done?	- 7
8	Priva	ate Pharmacies and Warehouses	. 7
	8.1	What has to be disposed?	
	8.2	What has to be done?	. 7
9	Med	licine disposal for Maldives Ports Limited (MPL) and Maldives Airports Company Limited (MACL)	8
	9.1	What has to be disposed?	8
9	9.2	What has to be done?	8
10	ANN	EX	9
l1	REFE	RENCE	9

Medicine and Therapeutic Goods Div	ision, Maldives Food	and Drug Authority Authori	ized by: Director General, MFDA
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideli	ine for Medicine Disposal	1 2 1 () C. 2
Issue No: 01	Issue Date: 13.02.2020	Prepared by: Director, Pharmaceuticals	Approved by Deputy Copy Letter: MTG/RE Director General, GLN 002
Revision No: 00	Revised Date: -	Verified by: Technical Committee of MTG	Pharmaceuticals Page No: Page 3 of 9



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.

Medicine and Therapeutic Goods Div	ision, Maldives Food	and Drug Authority Authorized b	y: Director General, MFD	r =
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guidel	ine for Medicine Disposal	हुनी (क्रिकेट)	0
Issue No: 01	Issue Date: 13.02.2020	Prepared by: Director, Pharmaceuticals	Approved by: Deputy Director General,	Gopy Letter: MTG/RE GLN 002
Revision No: 00	Revised Date: -	Verified by: Technical Committee of MTG	Pharmaceuticals	Page No: Page 4 of 9



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. When controlled drugs/medicines are disposed, in addition to the above mentioned parties, a staff from Maldives Police Service shall be present at the site for disposal.

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
MALDIVES POLICE SERVICE	Witness disposal of controlled drugs/medicines

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, specially 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

Medicine and Therapeutic Goods Div	ision, Maldives Food	and Drug Authority Authorized	by: Director General, MFDA	9
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideli	ne for Medicine Disposal		
Issue No: 01	Issue Date: 13.02.2020	Prepared by: Director, Pharmaceuticals	Approved by: Deputy Director General	Copy Letter: MTG/RE GLN 002
Revision No: 00	Revised Date: -	Verified by: Technical Committee of MTG	Pharmaceuticals	Page No: Page 5 of 9



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 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.

T	Disposal method					
Type of medicine	Incineration	Burying	Into drains			
Antibiotics	√		tol Harantako eta en 180a x			
Vaccines	V					
Vitamins/Minerals	1	1				
Cytotoxic						
Liquid vitamins	State Control of the		✓			
Others	1					

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

7 The public or consumers

7.1 What has to be disposed?

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

Unused,

Medicine and Therapeutic Goods Div	ision, Maldives Food	and Drug Authority Author	ized by:	Director General, MFDA	
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guidel	ine for Medicine Disposal	1	1 10	W E-6(2-21
Issue No: 01	Issue Date: 13.02.2020	Prepared by: Director, Pharmaceuticals	Majo.	Approved by: Deputy Director General,	Copy Letter: MTG/RE GLN 002
Revision No: 00	Revised Date: -	Verified by: Technical Committee of MTG		Pharmaceuticals	Page No: Page 6 of 9



- Leftover,
- Opened,
- Expired,
- 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** To initiate the disposal process, pharmacies/warehouses shall submit written request with a letter along with Medicine Disposal Form (MTG/RE-DF/Fo 0007) (Annex: 01).
- 8.2.2 If documents are incomplete, MFDA will reject and inform the client within working 2 days. If documents are complete, MFDA will send a letter to the client within working 3 days, to process the disposal of medicine in collaboration with Waste Management Corporation (WAMCO). Medicine disposal takes place during the 1st and 3rd week of every month.
- **8.2.3** Client shall inform MFDA in writing a confirmed date and time for medicine disposal. According to the date and time client has confirmed, the MFDA staff will visit the disposal area, and check and approve the disposal of medicines if medicines and documents are consistent. A copy of the Medicine Disposal Form will be given to the client.

Medicine and Therapeutic Goods Div	ision, Maldives Food	and Drug Authority Auth	orized by: Director General, MFDA
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideli	ne for Medicine Disposal	2.1 6 62/0)
Issue No: 01	Issue Date: 13.02.2020	Prepared by: Director, Pharmaceuticals	Approved by: Deputy Copy Letter: MTG/RE
Revision No: 00	Revised Date: -	Verified by: Technical Committee of MTG	Pharmaceuticals Page No: Page 7 of 9



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 To initiate the disposal process, MPL/ MACL shall submit a written request letter for disposing medicines held at ports of entry. This request shall be submitted to Maldives Food and Drug Authority (MFDA) main counter.
- **9.2.2** Port Pharmaceutical Unit staff will inspect the medicines to be disposed and complete the Medicine Disposal Form (MTG/RE-DF/Fo 0007).
- 9.2.3 MFDA will write a letter to MPL/MACL about processing the disposal of medicines in collaboration with Waste Management Corporation (WAMCO). Medicine disposal takes place during the 1st and 3rd week of every month.
- 9.2.4 MPL/MACL shall inform MFDA in writing a confirmed date and time for medicine disposal. Port Pharmaceutical Unit staff will visit the disposal area, and check the disposal of medicines; And, if medicines are consistent with the submitted documents, the staff will approve disposal of the medicines.

Medicine and Therapeutic Goods Div	ision, Maldives Food	and Drug Authority Au	uthorized by: Director General, MFDA
Doc. No: MTG/RE-MD/GLN-TE 004	Doc. Name: Guideli	ine for Medicine Disposal	11.0. 11.1
Issue No: 01	Issue Date: 13.02.2020	Prepared by: Director Pharmaceuticals	Approved by: Deputy Copy Letter: MTG/RE
Revision No: 00	Revised Date: -	Verified by: Technical Committee of MTG	Pharmaceuticals Page No: Page 8 of 9



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

Medicine and Therapeutic Goods Div	ision, Maldives Food	and Drug Authority Authori	ized by:	Director General, MEDA	2//
Doc. No: MTG/RE-MD/GLN-TE 004		ine for Medicine Disposal	lio!	ACUP	
Issue No: 01	Issue Date: 13.02.2020	Prepared by: Director, Pharmaceuticals	Me	Approved by: Deputy Director General	Copy Letter: MTG/RE
Revision No: 00	Revised Date: -	Verified by: Technical Committee of MTG		Pharmaceuticals	Page No: Page 9 of 9