بسم الله الرحمن الرحيم

Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline for Medicine Disposal

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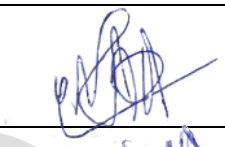
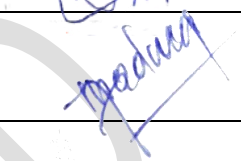
Approved By	Aishath Mohamed, Pharmaceutical Specialist	
Authorized by	Thooma Adam, Deputy Director General, Laboratory Services (Acting Head of MFDA)	

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, Senior Pharmacist
2	15.05.2022	Overall Document	Changes to overall procedure	Mohamed Fazeen, Senior Pharmacist
3	02.12.2023	Overall Document	Changes to timelines and updates to procedure	Mohamed Fazeen, Senior Pharmacist
4	24.01.2025	Overall Document	Changes to overall procedure and timelines	Zeenath Rasheed, Senior Public Health Officer

ABBREVIATIONS AND DEFINITIONS

Brand Name	A drug manufactured and sold by a manufacturer under a specific name or trademark is called brand name or trade name.
Controlled Drugs (CD)	The medicines fall under Narcotic controlled law no 17/2011 is classified as controlled drugs.
Country of Origin	The country of origin is the country where the medicine was produced or manufactured.
Dosage Form	Dosage form is the way the final medicinal product is presented for usage.
Generic Name	This is the shortened chemical name of the actual drug. Sometimes it is known as the international name of the drug.
Manufacturer	A company who manufactures medicines for trade use.
Medicine and Therapeutic Goods Division (MTG)	The medicine regulatory division of Maldives Food and Drug Authority.
Medicine Importers	The register and licensed party to import the medicines by Maldives Food and Drug Authority.
National Program (NP)	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).
Pharmacies	This is the registered retail medicine shops where they can store and sell medicines.

Prescription Only Medicine (POM)	This is a category of medicine which can be sold only for a valid prescription only.
Strength	The strength is the amount of drug in the dosage form or a unit of the dosage form
Waste Management Corporation Limited (WAMCO)	Mandated to provide a sustainable waste management solution throughout the country.
World health organization (WHO)	The United Nations agency working to promote health, keep the world safe and serve the vulnerable.
Health Protection agency (HPA)	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
Ministry of health (MOH)	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."
Maldives Food and drug authority (MFDA)	Competent Authority which is under the Ministry of health to regulate the Food and Medicines.
Maldives ports limited (MPL)	MPL is the sole authority on port related businesses in the Maldives
Maldives Airports Company Limited (MACL)	Leading airport operator in the Maldives with the largest International Airports in the country under its management.
Sorting of Medicines	Separating different categories of medicines

Expired Medicines	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.

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 The role of Maldives Food and Drug Authority (Medicine and Therapeutic Goods Division) in medicine disposal.

Maldives Food and Drug Authority mandated to monitor and oversee that expired and unwanted medicines are disposed in the most appropriate manner by the pharmacies, medicine importers, Health Facilities and other stake holders.

5 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 which is to be disposed. Sort the disposal medicines and pack and prepare for verification. Coordinate with WAMCO and arrange the disposal sessions.
HEALTH PROTECTION AGENCY	Complete and submit the Medicine Disposal Form in accordance with the procedure for disposal of expired and unwanted medicines brought to the National Program. Advice and Guidance on safe disposal of handling, storage, transport and treatment of cytotoxic waste
WASTE MANAGEMENT CORPORATION LIMITED (WAMCO)	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. After disposal of the medicine, sign and seal the medicine disposal form and hand it over to the MFDA.

6 RESPONSIBILITY AND ACCOUNTABILITY OF STAFF

Staff	Responsibility and Accountability

Pharmaceutical Officer	• Check for completion of Medicine disposal form (MTG-RE/FO0007/Year/0000) upon receive. • Share the document with the main entry of MFDA if the form is complete. • Issue a number for the form from the numbering Sheet (MTG/RE-DN/Re0095/year/0000) • Fill the check list and issue number for the check list from Numbering sheet for check list (MTG/RE-DP/Li0053/ year/0000*)* • Fill the medicine disposal summary sheet (MTG/RE-DD/Re0028/year/0001 • Email the client informing them of the date and time of the verification inspection. • Conduct verification inspections • Attend the sessions of medicine disposal
Senior Public Health Regulation Unit (MTG)	• Check all documents before emailing the client informing them of the date and time of the verification inspection. • Conduct verification inspections • Check 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. Attend the sessions of medicine disposal
Senior Pharmacist Regulation Unit (MTG)	• Verification of all documents before emailing the client informing them of the date and time of the verification inspection • 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.
Pharmaceutical Specialist (MTG)	• Approval and authorization of the check list and sign on the required areas. • Approved to send the email to the client informing them of the date and time of the verification inspection.

7 CONSEQUENCES OF IMPROPER DISPOSAL OR NON-DISPOSALS

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

7.1.2 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.

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

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

7.1.5 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.
- 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.

8 RECOMMENDED DISPOSAL METHODS OF MEDICINE

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

a. It must be disposed of for landfill. Also, it is recommended to inertization is recommended before discharge to a landfill.

b. Anti-infective drugs and antineoplastics are encapsulated to delay release to the environment and avoid high concentrations.

c. Controlled drugs should be immobilized under the supervision of the pharmacist, the police or a judicial representative, depending on the local regulations.

8.2 Liquids Pharmaceuticals with no or low toxicity.

a. Pharmaceuticals that can be classed as readily biodegradable organic material include liquid vitamins that may be diluted and flushed into a sewer.

b. Harmless solutions of different concentrations of certain salts, amino acids, lipids, or glucose may also be disposed of in sewers.

8.3 Ampoules

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.

8.4 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.

8.5 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.

8.6 Antineoplastics

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.

9 DISPOSAL OF EXPIRED OR UNWANTED PHARMACEUTICALS

9.1 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)

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).

10 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

11 Medicine Importer (Warehouses) and Pharmacies

11.1 What must be disposed?

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

11.2 What Shall be done?

11.2.1 Pharmacies/warehouses shall submit a complete and clearly filled editable (Excel version of) Medicine Disposal Form (MTG/RE-DF/Fo0007) (Annex: 01) via email: medicinedisposal@health.gov.mv.

11.2.2 Forms will be accepted quarterly.

11.2.3 The forms for January, February and March will be accepted between 1st to 10th of April.

11.2.4 The forms for April, May and June will be accepted between 1st to 10th of July.

11.2.5 The forms for July, August and September will be accepted between 1st to 10th of October.

11.2.6 The forms for October, November and December will be accepted between 1st to 10th of January.

11.2.7 The following information shall be filled:

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

11.2.8 The form will be checked for its completion within seven (07) working days of submission.

11.2.9 If all the information on the form has been completed, the client will be emailed within 10 working days to inform them of the date and time of the pre-disposal verification inspection. If the form is incomplete, the client will be notified within 07 working days and the form shall be filled and resubmitted.

11.3 Preparation for verification inspection

11.3.1 Before attending the verification inspection by the MFDA, the clients shall prepare the stock for disposal by sorting the various categories and kept it in separate boxes for its easy traceability.

11.4 Sorting

11.4.1 The objectives of sorting

- The objective of sorting is to separate the pharmaceuticals into categories that require different disposal methods.
- The appropriate safe disposal method recommended will depend principally on the pharmaceutical dosage form of the drugs. Segregated temporary storage areas or receptacles must be provided for each sorted category.

11.4.2 Practical advice on sorting

- Sorting involves an initial overall evaluation of the stockpile and subsequent division of pharmaceuticals into those suitable for use and those to be discarded.

- For those to be discarded a decision is made on the best method of disposal.
- To be efficient items should only be handled once.
- Pharmaceuticals suitable for use should remain in their packaging.
- The pharmaceuticals to be discarded should, when necessary, be separated from their packaging as late in the process as possible.

11.4.3 The sorting process includes:

- identifying each item; ·
- deciding on whether it is usable; ·
- if usable, leaving packaging intact; ·
- if not usable, making a judgement on the optimal method of disposal and sorting accordingly.
- Leaving packages and boxes intact until reaching their location, prior to definitive disposal or transport to an institution for use.

11.4.4 Optimum conditions for sorting

- Sorting should be done in the open or in a well-ventilated and, if necessary, heated covered structure designated by the local authority.
- Sorting should be done as close as possible to the stockpile in an orderly way, with all sorted material clearly labelled and always separated.
- Staff supplied with protective equipment (gloves, boots, overalls, dust masks, etc.), should work under the direct supervision of a pharmacist.
- They should receive training on the sorting criteria, and health and safety risks associated with handling the materials.

- Once sorted, the pharmaceuticals should be carefully put into containers such as sturdy cardboard boxes, with the contents clearly indicated on the outside of the containers.

- The materials should be kept in a dry, secure and preferably separate room to avoid being confused with in–date pharmaceuticals, until disposal is carried out.

11.4.5 Sorting categories

- The top priority of the sorting process is to separate out the pharmaceuticals that are categorized as controlled substances (e.g. narcotics), antineoplastic (cytotoxicanti–cancer) drugs and any other hazardous non-pharmaceutical products that may have been mixed among the pharmaceuticals.

- These must all be stored in separate, secure designated areas prior to their separate, safe disposal.

- The remaining unwanted pharmaceuticals must be further sorted into different categories by dosage form, (capsules, powders, solutions, suppositories, syrups, tablets).

11.5 Pre-Disposal Verification

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

11.5.2 These sessions will be conducted on working Wednesdays of every week. (REMOVE)

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

11.5.4 During this inspection sixty percent (60%) to one hundred percent (100%) will be checked depending on the quantity of the products.

11.5.5 Once the process is completed, MFDA staff will close and seal the boxes with the signature and date.

11.5.6 The form set shall be shared with the client via email within seven (07) working days.

11.5.7 The client or client representative present during the verification process will be requested to sign the Medicine Disposal Form to verify the product verification.

11.5.8 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.

11.5.9 If for any reason the date of verification inspection has to be changed, the inspection shall be rescheduled within the next 02 days and inform to the client via email.

12 Disposal of Medicines

12.1.1 Upon completion of the verification inspection, the client shall arrange for the disposal of the drug in collaboration with WAMCO.

12.1.2 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.

12.1.3 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.

12.1.4 Client shall share the signed document with MFDA Via email within five (05) working days.

13 Self-disposal of Medicines

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.

13.1 What Shall be Done?

13.1.1 May follow 11.2.1 to 11.5.9.

13.1.2 Upon completion of the verification inspection, the client shall dispose of these medicines.

13.1.3 It can be mixed or diluted in a large quantity (A big Bucket) of water by diluting and flush it to sewer.

13.1.4 Once completed the session, the document shall be signed and sealed by the staff who disposed of the medicines.

13.1.5 Client shall share the signed document with MFDA Via email within five (05) working days.

14 Medicine disposals in Regional Atolls

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

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

14.2 What has to be done?

14.2.1 Pharmacies and warehouses outside the greater Male' area shall complete the Medicine Disposal Form (MTG/RE-MD/Fo 0007) and submit to the relevant public health unit. The staff of the public health unit shall check for the completion of the form within working three (03 days).

14.2.2 If the form is complete the public health unit shall arrange the disposal session within seven (07) working day and inform the client via email or in written.

14.2.3 Client or a representative shall be presented during the disposal session.

14.2.4 Upon disposal, the staff of public health unit who have attended the session shall sign and date on the form mentioning as disposed and handover the form to the client within working three (03 days)

14.2.5 The client shall email the form to the MTG email (medicinedisposal@heath.gov.mv) in three (03) days.

14.2.6 MFDA staff shall check and verify if the form is complete and necessary sign and date are mentioned within two (03) working days. If complete, MFDA staff shall email the form for main entry immediately.

14.2.7 Upon receiving from the main entry, a number shall be given to the form the medicine disposal form numbering sheet (MTG/RE-DN/Re0095/year-0000) and enter to the medicine disposal summary sheet (MTG/RE-DD/Re0023/year/0000) within working ten (10) days.

14.2.8 If the form is incomplete, it must be informed via email to the client within two (02) working days with the details.

15 Medicine disposals in resort clinics/ pharmacies

15.1.1 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.

15.2 What has to be done?

15.2.1 Resort clinics/ pharmacies shall complete the Medicine Disposal Form (MTG/RE-MD/Fo 0007) and submit to the relevant public health unit for disposal.

15.2.2 Forms will be accepted quarterly.

15.2.3 The forms for January, February and March will be accepted between 1st to 10th of April.

15.2.4 The forms for April, May and June will be accepted between 1st to 10th of July.

15.2.5 The forms for July, August and September will be accepted between 1st to 10th of October.

15.2.6 The forms for October, November and December will be accepted between 1st to 10th of January.

15.2.7 The staff of the public health unit shall check for the completion of the form within working three (03 days).

15.2.8 If the form is complete the client shall be informed by public health unit in writing to bring the medicines for disposal within working three (03days).

15.2.9 The client shall submit the medicines for disposal within seven (07) days.

15.2.10 Upon receipt of the medicines, the public health unit staff shall arrange the disposal session within seven (07) working days and inform the client via email or in writing.

15.2.11 A client or a representative shall be present during the disposal session.

15.2.12 Upon disposal, the staff of public health unit who have attended the session shall sign and date on the form mentioning as disposed and handover the form to the client within working three (03 days).

16 Self-disposal of Medicines

16.1.1 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.

16.2 What Shall be Done?

16.2.1 Upon completion of the verification inspection, the client shall dispose of these medicines.

16.2.2 It can be mixed or diluted in a large quantity (A big Bucket) of water by diluting and flush it to sewer.

16.2.3 Once completed the session, the document shall be signed and sealed by the staff who disposed of the medicines.

16.2.4 Client shall share the signed document with Public Health Unit (05) working days.

16.2.5 Public Health Unit shall share the signed document with MFDA Via email within five (05) working days.

16.2.6 The client shall email the form to the MTG email (**medicinedisposal@heath.gov.mv**) in three (03) days.

16.2.7 MFDA staff shall check and verify if the form is complete, and the necessary sign and date are mentioned within five (05) working days. If complete, MFDA staff shall email the form for main entry immediately.

16.2.8 Upon receiving from the main entry, a number shall be given to the form the medicine disposal form numbering sheet (MTG/RE-DN/Re0095/year-0000) and entered to the medicine disposal summary sheet (MTG/RE-DD/Re0023/year/0000) within working ten (10) days.

16.2.9 If the form is incomplete, it must be informed via email to the client within five (05) working days with the details.

17 Disposal of Controlled Drugs

17.1.1 Controlled drugs are the drugs that are controlled under chapter 02 of the Narcotic Drugs Act (Act No. 17/2011).

17.1.2 For the disposal of this category of medicines, the client shall fill a separate form from the other medicines.

17.1.3 The procedure for disposal of control drugs will be conduct as mentioned in 11.2.1 to 12.1.3.

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

18.1 What has to be disposed?

18.1.1 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.

18.2 What has to be done?

18.2.1 MACL/MPL shall submit an email (medicinedisposal@health.govmv) requesting for disposal of medicines held at ports of entry along with the list of medicines to be disposed.

18.2.2 The staff of MFDA shall attend to the email and check the list of medicines and send it to the mail entry within working five (05) days.

18.2.3 Upon receiving from the entry, the client shall be informed a date and a time for the verification of the goods with in working ten (days).

18.2.4 Once verified the medicines shall be disposed in the presence of the MFDA staff. After disposal, the form shall be signed, dated and medicine disposed and send it to MFDA via email (medicinedisposal@health.gov.mv) within three (working days).

18.2.5 Upon receipt of the form, MFDA staff shall sign and seal and share it with the client within three (03) working days.

19 Medicine disposal for Ministry of Health, World Health Organization (WHO), and Health Protection Agency (HPA)

19.1.1 These organizations may have expired and unwanted medicines and vaccines brough for national program and donations.

19.2 What has to be done?

19.2.1 These organizations shall submit a complete and clearly filled editable (Excel version) Medicine Disposal Form (MTG/RE-DF/Fo0007) (Annex: 01) via email: medicinedisposal@health.gov.mv.

19.2.2 The following information shall be filled:

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

19.2.3 The form will be checked for its completion within seven (07) working days of submission.

19.2.4 If all the information on the form has been completed, the client will be emailed within 10 working days to inform them of the date and time of the pre-disposal verification inspection. If the form is incomplete, the client will be notified within 07 working days and form shall be filled and resubmitted.

19.3 Preparation for verification inspection

19.3.1 Before attending the verification inspection by the MFDA, the clients shall prepare the stock for disposal by sorting the various categories and keeping it in separate boxes for its easy traceability.

19.4 Practical advice on sorting

19.4.1 Sorting involves an initial overall evaluation of the stockpile and subsequent division of pharmaceuticals into those suitable for use and those to be discarded.

19.4.2 For those to be discarded a decision is made on the best method of disposal.

19.4.3 To be efficient items should only be handled once.

19.4.4 Pharmaceuticals suitable for use should remain in their packaging.

19.4.5 The pharmaceuticals to be discarded should, when necessary, be separated from their packaging as late in the process as possible.

19.5 The sorting process includes:

19.5.1 Sorting categories

- The top priority of the sorting process is to separate out the pharmaceuticals that are categorized as controlled substances (e.g. narcotics), antineoplastic (cytotoxic) drugs and any other hazardous non-pharmaceutical products that may have been mixed among the pharmaceuticals.
- These must all be stored in separate, secure designated areas prior to their separate, safe disposal.
- The remaining unwanted pharmaceuticals must be further sorted into different categories by dosage form, (capsules, powders, solutions, suppositories, syrups, tablets).

20 Pre-Disposal Verification

20.1.1 Physical verification shall 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.

20.1.2 These sessions shall be conducted on working Wednesdays of every week. Physical inspections are carried out in accordance with the receipt of the disposal forms.

20.1.3 The submitted form set shall be taken by MFDA officials for the verification inspection.

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

20.2 How to differentiate Percentage by Physical Inspections:

20.2.1 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.

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

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

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

20.2.5 We will concentrate only on large quantities and will not address the smaller quantities listed in the forms.

20.2.6 The recommended procedure will be followed, and records will be kept.

20.2.7 Once the process is completed, MFDA staff will close and seal the boxes with the signature and date.

20.2.8 The form set shall be shared with the client via email within seven (07) working days.

20.2.9 The client or client representative present during the verification process will be requested to sign the Medicine Disposal Form to verify the product verification.

20.2.10 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.

20.2.11 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.

21 Disposal of Medicines

21.1.1 Upon completion of the verification inspection, the client shall arrange for the disposal of the drug in collaboration with WAMCO.

21.1.2 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.

21.1.3 21.1.3 Once the session is completed, the allocation for each form (indicating that the medicines in this form have been disposed of under our supervision) should be filled out by the WAMCO officials present at the session and shared with the client. Additionally, the WAMCO seal must be applied to each form for the designated area.

21.1.4 Client shall share the signed document with MFDA Via email within five (05) working days.

22 Medicine disposal for Maldives Food and Drug Authority

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

22.1.2 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

22.1.3 The list shall be emailed to the division email (medicine. disposal@health.gove.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

22.1.4 The samples should be easy to count, and the list of medicines must correspond with the samples provided. If they do not match, the form shall be rejected.

22.1.5 Upon receive of the list and the medicines, medicines shall be kept in the appropriate boxes and sealed labelling as samples for disposal.

22.1.6 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).

22.1.7 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.

22.1.8 Within the next ten (10) working days, the relevant staff shall write a memo to the MFDA Administrative Unit and share it via email, requesting to arrange the vehicle to take the medicines to the disposal site at Male.

23 Other requests for disposal

23.1.1 Requests for disposal may be submitted by general public (house hold medicines) , ships, passenger lines and others.

23.1.2 The general public (households), ships and passenger lines may have small quantity of expired and unwanted medicines.

23.1.3 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
k. Total Expired quantity
l. Total Price
m. Remarks Brand Name

23.1.4 The list shall be emailed to the MTG division email (medicine. disposal@health.gove.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.

23.1.5 Upon receiving the list and the medicines, medicines shall be kept in the appropriate boxes and sealed labeled as samples for disposal.

23.1.6 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).

23.1.7 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.

23.1.8 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.

23.1.9 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).

24 PUBLICATION AND AWARENESS

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.

25 REFERENCE

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

26 ANNEX

- Annex 1: Summary of pharmaceutical categories and disposal methods

Contact

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

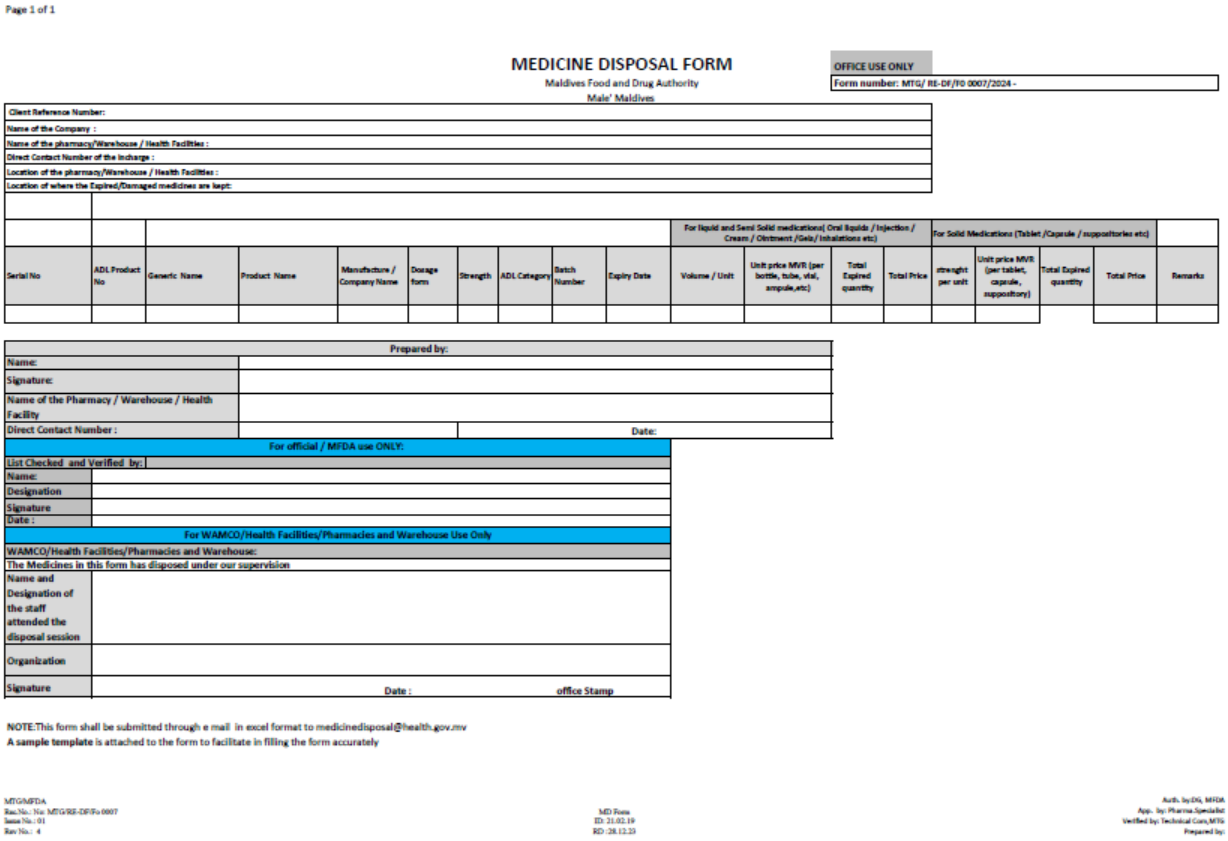
Annex 1

Summary of pharmaceutical categories and disposal methods

Category	Disposal methods	Comments
Solids **Semi-solids** **Powders**	Landfill Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	No more than 1% of the daily municipal waste should be disposed of daily in an untreated form (non-immobilized) to a landfill.
Liquids	Sewer High temperature incineration (cement kiln incinerator)	Antineoplastics not to sewer.
Ampoules	Crush ampoules and flush diluted fluid to Sewer	Antineoplastics not to sewer.
Anti-infective drugs	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.
Antineoplastics	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.
Controlled drugs	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Not to landfill unless encapsulated.
Aerosol canisters	Landfill Waste encapsulation	Not to be burnt: may explode.
Disinfectants	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 2

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/Fo 0007/2024 -

Client Reference Number:	
Name of the Company :	
Name of the pharmacy/Warehouse / Health Facilities :	
Direct Contact Number of the Incharge :	
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	Manufacturer / Company Name	Dosage form	Strength	ADL Category	Batch Number	Expiry Date	Volume / Unit	Unit price MVR (per bottle, tube, vial, ampule,etc)	Total Expired quantity	Total Price	strenght 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
A sample template is attached to the form to facilitate in filling the form accurately

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

MD Form
ID: 21.02.19
RD: 28.12.23

Auth. by:DG, MFDA
App. by: Pharma.Specialist
Verified by: Technical Com./MTG
Prepared by: