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Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Storage and Sale of OTC Medicines in General Stores

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 12.10.2026	
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Summary of Changes

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DEFINITIONS

General Shop/Store	A retail establishment primarily engaged in the sale of general consumer goods and not licensed as a pharmacy.
Selected Medicine	A medicine specifically included in the MFDA Approved List of Medicines Permitted for Sale in General Shops.
Over-the-Counter (OTC) Medicine	A medicine that may legally be supplied without a prescription, subject to applicable regulatory restrictions.
Approved General Shop	A general shop that has obtained prior written authorization from MFDA to sell specified medicines.
Medicine Sales Area	The designated area or shelf within an approved general shop where permitted medicines are stored and displayed for sale.

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1 Introduction

All Medicines shall be supplied in such a way that the quality, safety and efficacy throughout the supply chain is ensured. Although pharmacies remain the primary and preferred premises for the sale and supply of medicines, Clause 40 of Medicine Regulation No. R-64/2026 provides a regulatory basis for permitting certain selected medicines to be sold through general shops, subject to requirements established by the Maldives Food and Drug Authority (MFDA).

The purpose of allowing a limited range of medicines in general shops is to improve public access to selected low-risk medicines, particularly where such products are commonly required for minor and self-limiting conditions. However, such access shall not result in unrestricted or inappropriate medicine sales or undermine the professional role of licensed pharmacies and pharmacists.

Accordingly, general shops shall only be permitted to sell medicines that have been specifically approved by MFDA for sale through general shops. The permission shall be subject to prior approval of the premises, appropriate storage conditions, temperature control, product restrictions, recordkeeping, inspection and compliance with all applicable regulatory requirements.

The fact that a medicine is registered in the Maldives or classified as an OTC medicine shall not automatically authorize its sale in a general shop. Eligibility for sale in general shops shall be determined separately by MFDA based on the medicine's safety profile, therapeutic risk, likelihood of misuse, storage requirements, dosage form, potential for inappropriate self-medication and the availability of appropriate pharmacy services.

2 Purpose

2.1 The purpose of this Guideline is to:

- Establish requirements for the sale of selected medicines through general shops.
- Define the medicines that may be sold in general shops. (Refer to **Authorized OTC Products for Sale in General Stores MTG/RE-OS/Li 0064/2026-001**)
- Ensure that only medicines specifically approved by MFDA are sold in general shops.
- Ensure medicines are stored under appropriate environmental conditions at all times.
- Prevent deterioration of medicines due to excessive temperature, humidity, sunlight or other unsuitable conditions.
- Minimize inappropriate self-medication and misuse of medicines.

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- Prevent the sale of prescription medicines and other higher-risk medicines through general shops.
- Establish minimum requirements for premises, storage, personnel and records.
- Establish a system for MFDA approval, inspection and monitoring of general shops.
- Protect the public while facilitating reasonable access to selected low-risk OTC medicines.

3 Scope

This Guideline applies to:

- General shops seeking approval to sell selected medicines
- Existing general shops currently selling medicines
- Owners and operators of approved general shops
- Medicine importers and distributors supplying medicines to approved general shops
- MFDA inspectors and other personnel responsible for monitoring compliance

4 Legal Basis

This Guideline is issued under Clause 40 of Medicine Regulation No. R-64/2026 and shall be referred together with:

- Medicine Regulation No. R-64/2026
- applicable MFDA medicine registration requirements
- medicine storage and distribution requirements
- applicable labeling requirements
- applicable pharmacovigilance requirements
- applicable product recall and quality-defect requirements
- other guidelines, standards and instructions issued by MFDA from time to time

5 General Regulatory Principles

5.1 Pharmacy as the Primary Medicine Outlet

- 5.1.1** Pharmacies shall remain the primary and preferred premises for the retail sale and supply of medicines.

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5.1.2 The availability of selected medicines in general shops is intended to facilitate access to a limited range of low-risk medicines and shall not be interpreted as permitting general shops to operate as alternative pharmacies.

5.2 Prior MFDA Approval

5.2.1 A general shop shall not sell any medicine unless the shop has obtained prior approval from MFDA.

5.2.2 Registration of the shop as a general business, grocery shop, supermarket, convenience store or other retail establishment shall not constitute approval to sell medicines.

5.3 Product-Specific Authorization

5.3.1 Approval shall apply only to the medicines listed in the authorization issued by MFDA.

5.3.2 A shop shall not introduce additional medicines without obtaining prior approval from MFDA.

5.4 Risk-Based Approach

5.4.1 Authorized OTC Products for Sale in General Stores is developed by MFDA in consideration based on:

1. Therapeutic risk
2. Potential for misuse or abuse
3. Toxicity in overdose
4. Likelihood of inappropriate self-medication
5. Interaction potential
6. Contraindications
7. Need for professional counseling
8. Dosage form
9. Storage requirements

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10. Potential for antimicrobial resistance
11. Age restrictions
12. Frequency of adverse effects
13. Availability of suitable pharmacy services

6 Eligibility of Medicines for Sale in General Shops

6.1 Only medicines meeting the following criteria should ordinarily be considered:

1. Registered and authorized for sale in Maldives
2. Classified as OTC or otherwise legally permitted for non-prescription supply
3. Suitable for self-care of minor and commonly occurring conditions
4. Have a relatively wide therapeutic margin
5. Have a low potential for serious harm when used according to the label
6. Do not normally require diagnosis or professional assessment before use
7. Do not require prescription monitoring
8. Do not require specialized storage that cannot reasonably be maintained in a general shop
9. Have clear and understandable labeling
10. Have a low potential for misuse, abuse or dependence.

6.2 MFDA shall establish and periodically revise an Authorized OTC Products for Sale in General Stores.

7 Medicines That Shall Not Be Sold in General Shops

7.1 The following categories shall generally be prohibited:

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Prescription-Only Medicines	Prescription-only medicines shall not be sold or supplied through general shops.
Controlled and Dependence-Producing Medicines	Controlled medicines, narcotic medicines, psychotropic medicines and medicines with significant dependence or abuse potential shall not be sold.
Antibiotics and Antimicrobials	Systemic antibiotics and other antimicrobial medicines requiring professional assessment shall not be included in the general-shop list unless specifically authorized by MFDA following a formal risk assessment. This restriction is important to minimize inappropriate antimicrobial use and contribute to national antimicrobial resistance control efforts.
High-Risk Medicines	Medicines with a significant risk of serious adverse effects, toxicity, clinically significant interactions or inappropriate use shall not be permitted.
Injectable Medicines	Injectable medicines shall not be sold in general shops.
Temperature-Sensitive Medicines	Medicines requiring controlled refrigeration or specialized cold-chain arrangements shall generally not be permitted unless MFDA has specifically authorized the premises and verified the required storage system.

8 Recommended Categories of Medicines That May Be Considered

8.1 Subject to MFDA assessment and the approved product list, consideration may be given to selected low-risk medicines such as:

- Simple oral rehydration salts
- selected antacids
- selected simple analgesics/antipyretics
- selected topical preparations for minor conditions
- selected lozenges

- selected simple dermatological preparations
- and other low-risk OTC medicines identified by MFDA

9 Application for Approval of a General Shop

9.1 A general shop intending to sell medicines shall submit an application to MFDA before commencing medicine sales.

9.2 The application shall include, at minimum:

1. Business registration details
2. Full name and address of the premises
3. Contact details of the owner/operator
4. Details of the responsible person for medicine-related activities
5. Proposed list of medicines to be sold
6. Proposed storage arrangements
7. Description or photographs of the medicine storage/display area
8. Temperature-control arrangements
9. Temperature-monitoring arrangements
10. Cleaning and pest-control arrangements
11. Proposed medicine purchasing sources
12. Evidence that medicines will be purchased only from authorized suppliers
13. Recordkeeping arrangements
14. Complaint-handling arrangements
15. Recall arrangements

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16. Declaration of compliance with MFDA requirements.

17. Any other information requested by MFDA.

10 MFDA Approval

10.1 Approval shall be granted only where the Authority is satisfied that:

- The premises are suitable
- Appropriate storage conditions are available
- Temperature can be controlled and monitored
- Medicines can be segregated from unsuitable products
- Products can be protected from sunlight, moisture and contamination
- Appropriate records can be maintained
- The shop can comply with the approved medicine list
- There is no significant risk to medicine quality or public safety

10.2 MFDA may:

- Approve the application
- Approve with condition
- Restrict the approved medicine list
- Require corrective actions before approval
- Reject the application

11 Storage Requirements

11.1 Medicine quality shall be maintained from receipt until sale.

11.2 All medicines shall be stored according to:

- The manufacturer's specified storage conditions
- The product labeling
- MFDA requirements
- applicable good storage practices

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11.3 Medicines shall not be stored:

- Directly on the floor
- In direct sunlight
- Next to heat-generating equipment
- In areas exposed to excessive humidity
- Near chemicals or cleaning products
- In bathrooms or other unsuitable areas
- In vehicles for prolonged periods
- In any location where their quality may be adversely affected

12 Temperature Control

12.1 Temperature control shall be maintained at all times

12.1.1 This shall be a fundamental condition for approval.

12.1.2 Where the medicine labeling specifies a storage condition, the shop shall maintain the required temperature continuously.

12.1.3 For medicines permitted under general-shop conditions, the applicable MFDA general storage temperature requirement shall be followed. The temperature shall not exceed 25 degrees in the premises where the medicines are kept and the premises shall have adequate means to ensure that the temperature does not exceed that limit at all times.

12.2 Temperature Monitoring

12.2.1 The shop shall:

- Have a suitable thermometer or calibrated temperature-monitoring device
- Monitor temperature at an appropriate frequency
- Maintain a daily temperature record
- Record minimum and maximum temperatures where applicable
- Maintain records for inspection
- Investigate temperature excursions
- Take corrective action where required

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12.3 Continuous Temperature Control

12.3.1 Where the premises are air-conditioned, the responsible person shall ensure that the air-conditioning system remains operational during the period medicines are stored.

12.3.2 Where feasible, an electronic temperature data logger or continuous monitoring device should be used.

12.4 Power Failure

12.4.1 The shop shall have procedures for dealing with power failures.

12.4.2 Medicines shall not be sold where there is reasonable doubt that their required storage conditions have been maintained.

12.5 Temperature Excursions

12.5.1 Where the required temperature has been exceeded:

- Affected products shall be identified.
- Products shall be segregated from saleable stock.
- The date, duration and maximum temperature reached shall be documented.
- The responsible person shall notify the supplier where necessary.
- MFDA may be consulted for significant excursions.
- Products shall not be returned to sale until their suitability has been established.

13 Medicine Display and Segregation

13.1 Medicines shall be:

- Clearly identified
- Kept in a designated area
- Protected from sunlight and environmental exposure
- Separated from non-medicinal products
- Kept away from chemicals and hazardous materials
- Arranged to minimize selection errors.

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14 Purchasing of Medicines

14.1 Approved general shops shall purchase medicines only from:

- MFDA authorized medicine importers
- Other legally authorized medicine suppliers

14.2 Purchasing medicines from unauthorized sources, informal suppliers or unverified online sources shall be prohibited.

14.3 The shop shall retain purchase invoices and related documentation.

15 Staff Responsibilities

15.1 The shop owner shall ensure that staff responsible for medicine sales receive appropriate basic training on:

- The approved medicine list
- Storage requirements
- Temperature monitoring
- Expiry-date checking
- Recognition of damaged medicines
- Basic product information

Note: Staff shall not present themselves as pharmacists or provide services that require professional qualifications.

16 Recordkeeping

16.1 Approved general shops shall maintain records of:

- medicine purchases
- supplier details
- medicine name and strength
- quantity received
- batch/lot number where available
- expiry date

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- sales when required by MFDA
- temperature records
- temperature excursions
- complaints
- recalled products
- returned products
- disposal of unsuitable medicines

16.2 These records shall be made available to MFDA upon request.

17 Inspection and Monitoring

17.1 MFDA may inspect or request documents from approved general shops at any time in accordance with applicable legislation.

17.2 Inspectors may assess:

- approved medicine list
- actual medicines available for sale
- storage conditions
- temperature records
- expiry control
- purchase records
- supplier details
- product labeling
- medicine display
- complaints
- recalled products
- staff knowledge
- overall compliance

18 Renewal and Continued Approval

18.1 MFDA approval for medicine sales shall be subject to continued compliance.

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18.2 MFDA may review approval periodically or whenever:

- the premises changes
- ownership changes
- the approved medicine list changes
- significant non-compliance occurs
- medicine-related complaints are received
- there is evidence of inappropriate medicine use

19 Rationale for Restricting Medicine Sales to Selected Products

19.1 The Maldives has a relatively extensive network of licensed pharmacies providing access to medicines and professional pharmacy services. Therefore, there is limited regulatory justification for permitting broad categories of medicines to be sold through general shops.

19.2 The general-shop pathway should instead address accessibility of simple, low-risk OTC medicines without creating an uncontrolled parallel medicine-distribution system.

19.3 The availability of pharmacies should therefore be considered when determining which medicines require pharmacy-based supply and which very low-risk medicines may reasonably be made available through general shops.

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