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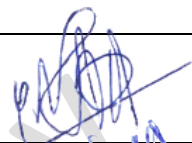
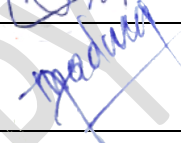
Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

MTG Guideline for Transport of Medicines, Vaccines and Biological

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 12.10.2026	
Doc. No: MTG/RE-TR/GLN-TE 029	Doc. Name: MTG Guideline for Transport of Medicines, Vaccines and Biologicals		
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Version Number	1	
Issued Date	12.10.2026	
Prepared By	MTG Technical Committee	
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Summary of Changes

Version No.	Issued Date	Section/Clause	Summary of Change	Changes Made by
1	12.10.2026	-	Creation of the document	MTG Technical Committee

DEFINITIONS

Cold Chain	A temperature-controlled supply chain used to maintain medicines, vaccines or biological products within their specified temperature range from the point of manufacture or dispatch until the point of use.
Temperature Excursion	Any exposure of a medicine or vaccine to a temperature outside the approved/manufacturer-specified temperature range.
Temperature-Sensitive Medicine	A medicine for which exposure to temperatures outside a specified range may adversely affect its quality, safety or efficacy.
Transport Container	A container specifically designed or qualified for the transportation of medicines under specified environmental conditions.
Passive Cold-Chain Container	An insulated container that maintains the required temperature using conditioned coolant packs or another passive cooling system without continuous mechanical refrigeration.
Data Logger	An electronic device used to continuously or periodically record temperature during storage or transportation.
Vaccine Vial Monitor (VVM)	A temperature-sensitive indicator attached to applicable vaccine containers to indicate cumulative exposure to heat.
Consignor	The party responsible for preparing and dispatching a medicine shipment.
Consignee	The party designated to receive the medicine shipment.
Transport Provider	A person or organization contracted to transport medicines from one location to another.

1 INTRODUCTION

The quality, safety and efficacy of medicines, vaccines and biologicals can be adversely affected by inappropriate transportation, handling, storage conditions, exposure to excessive heat or cold, light, humidity, physical damage, contamination, delays and other environmental or operational factors.

Medicine Regulation No. R-64/2026 places responsibility on persons and entities involved in the medicine supply chain to ensure that the quality and safety of medicines are maintained throughout all stages of handling and movement.

Clause 38 establishes the responsibility to maintain the safety and quality of medicines from manufacture until use and requires medicines to be stored under appropriate conditions. It also establishes specific requirements for temperature-controlled medicines, vaccines and injections.

Clause 39 further requires medicines to be transported, distributed and moved between locations in accordance with standards issued by MFDA. It specifically requires cold-chain management and documentation when medicines or vaccines requiring specific temperature conditions are transported.

This Guideline operationalizes these requirements and establishes minimum standards for the transport, loading, unloading, handling, temporary holding and receipt of medicines and vaccines within the Maldives.

2 PURPOSE

The purpose of this Guideline is to establish minimum requirements to ensure that:

1. Medicines, vaccines and biologicals remain safe, effective and fit for use throughout transportation
2. Required storage and transportation temperatures are maintained
3. Medicines and vaccines are protected from physical, chemical and environmental damage
4. Cold-chain integrity is maintained for temperature-sensitive products
5. Transportation risks are identified and appropriately controlled

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6. Medicines transported between Malé and the atolls are handled appropriately
7. Temperature excursions and other transport incidents are identified, documented, investigated and managed
8. Transportation activities are traceable through appropriate documentation
9. Third-party transport providers operate according to approved requirements
10. Responsibilities of importers, distributors, pharmacies, health facilities and transport providers are clearly established

3 SCOPE

This Guideline applies to all persons and organizations involved in the transportation or handling of medicines and vaccines, including:

- Medicine importers
- Medicine suppliers and distributors
- Wholesalers
- Pharmacies
- Hospitals and health facilities
- Government medicine supply programmes
- Vaccine programmes
- Logistics and courier companies
- Shipping companies
- Airlines and air-cargo handlers
- Transport contractors
- Drivers and delivery personnel
- Persons responsible for loading and unloading

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- Persons receiving medicines
- And any other party involved in transporting medicines within the Maldives
- It applies to:
 - Imported medicines
 - Medicines transported from ports to warehouses
 - Medicines transported between warehouses
 - Medicines transported from warehouses to pharmacies
 - Medicines transported to hospitals and health facilities
 - Inter-island transportation
 - Vaccines
 - Biological products
 - Temperature-sensitive medicines
 - Refrigerated medicines
 - Frozen products where applicable
 - Controlled medicines
 - Medicines returned, recalled, rejected or transported for disposal

4 REGULATORY BASIS

4.1 This Guideline shall be inconsistent with Medicine Regulation No. R-64/2026.

4.2 The principal relevant provisions include:

Regulation	Relevance to this Guideline
Clause 30	Importation, handling and temperature control of vaccines and biologicals
Clause 38	Responsibility for maintaining medicine quality and safety and appropriate storage conditions
Clause 39	Movement, distribution and transportation of medicines and vaccines

Clause 40	Restrictions concerning storage of medicines in ordinary commercial premises
Clause 47	Complaints and incident management, including quality/safety incidents involving transport
Clause 30	Requires imported vaccines and biological products to be registered and to comply with the storage conditions specified by the manufacturer. It also places responsibility on the importer to establish arrangements to maintain the required temperature during importation, distribution and storage.
Clause 39	Requires MFDA standards to be followed for movement, distribution and transportation and specifically requires cold-chain management and documentation for medicines and vaccines requiring specific temperature conditions.

5 GENERAL PRINCIPLES

5.1 All medicines, vaccines and biologicals shall be transported and handled in a manner that prevents:

1. Exposure to temperatures outside approved limits
2. Excessive heat
3. Freezing where freezing is not permitted
4. Direct sunlight
5. Excessive humidity
6. Water exposure
7. Contamination
8. Pest exposure
9. Physical damage
10. Tampering
11. Unauthorized access
12. Loss or theft
13. Mix-up of products
14. Deterioration of packaging
15. Loss of traceability

5.2 The transport conditions shall be based on the approved product information and manufacturer's specified storage requirements.

5.3 A single temperature requirement shall not automatically be applied to all medicines or vaccines.

6 RESPONSIBILITIES

6.1 Importer

1. Ensure all imported vaccines and biologicals are registered and approved to be imported.
2. Ensure all imported vaccines and biologicals are packed and stored as per the manufacturer's storage condition

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3. Ensure that all cold chained items including injectable, vaccines and biological are imported, transported and distributed while maintaining the manufacturer specified temperature for that product and under appropriate conditions
4. Ensure that all documentation requirements are fulfilled during import for injectables, vaccines and biologicals specifically the batch certificates or batch analysis report.
5. Ensure that during import and transport and distribution the cold chain is properly managed, maintained and documented and conditions maintained as per the manufacturer's specification
6. Ensure to prevent the import, distribution and use of cold chain abuse products
7. Establish written transportation procedures
8. Assess transportation risks and Qualify transport providers
9. Ensure temperature-sensitive medicines are transported using appropriate cold-chain arrangements;
10. Ensure data logger or vial monitor is kept inside the carrier during import and distribution and transporting cold chain items like injections, vaccines and biologicals and also a data logger or vaccine vial monitor is kept inside the fridge if these products are store in that fridge.
11. Ensure to maintain transport records
12. Ensure to Investigate temperature excursions
13. Ensure to Maintain emergency arrangements
14. Ensure personnel are appropriately trained
15. Ensure medicines are protected from unauthorized access
16. Establish procedures for damaged, rejected, recalled and returned products
17. Report relevant quality and safety incidents to MFDA.

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6.2 Transport Provider

1. Comply with the requirements specified by the consignor
2. Maintain required environmental conditions
3. Protect medicines from damage and contamination
4. Prevent unauthorized access
5. Avoid unnecessary delays
6. Maintain chain of custody
7. Ensure appropriate loading and unloading
8. Immediately report accidents, delays, damage, temperature excursions and security incidents
9. Maintain required records
10. Ensure personnel handling medicines are appropriately trained.

6.3 Receiving Facility

1. Ensure to receive medicines only at an appropriate location
2. Ensure to inspect shipments upon arrival
3. Ensure to verify quantities and product identity
4. Ensure to inspect packaging
5. Ensure to review temperature records
6. Ensure to check the working condition and records of Data Logger or Vaccine Vial Monitor
7. Ensure to identify damaged or compromised products

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8. Ensure to immediately quarantine products suspected of being compromised and maintain receiving records.

6.4 TRANSPORT RISK CLASSIFICATION

6.4.1 Medicines should be classified according to their transport requirements.

Category A – Ambient Medicines	Medicines that may be transported under controlled ambient conditions according to the approved product specification.
Category B – Temperature-Sensitive Medicines	Medicines requiring a specified temperature range.
Category C – Refrigerated Medicines	Medicines requiring refrigerated transportation, commonly 2–8°C where this is the approved product requirement.
Category D – Vaccines and Biological Products	Vaccines and biological products requiring controlled temperature conditions according to the approved product information.
Category E – Frozen Products	Products requiring frozen conditions, where specifically indicated by the manufacturer.
Category F – High-Security Medicines	Controlled medicines, high-value products and other products requiring enhanced security and chain-of-custody controls.

6.5 TRANSPORT PLANNING

- 6.5.1 Before transportation, the responsible person shall assess Product type, required temperature, Quantity, Route, estimated journey time, Mode of transport, Number of transfers, Expected weather conditions, Availability of cold storage at transfer points, Destination storage capacity, Security requirements, Emergency arrangements and Potential delays.
- 6.5.2 For inter-island transportation, additional consideration shall be given to Vessel availability, flight schedules, weather conditions, sea conditions, port delays, transfer between vessels and vehicles, overnight storage, electricity availability at destination, and availability of qualified cold-chain equipment.

6.6 TRANSPORT VEHICLES

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6.6.1 Vehicles used for transporting medicines shall be clean, dry, maintained in good condition, free from pests, free from strong odors or contaminants, capable of protecting medicines from environmental exposure, secure against unauthorized access and appropriate for the type and quantity of medicines being transported.

6.6.2 Medicines shall not be transported in vehicles where they may be exposed directly to sunlight, rain, excessive heat, contaminated materials, chemicals, food, animals or other goods that may adversely affect product quality.

7 TEMPERATURE CONTROL

7.1 General Requirement

7.1.1 The temperature requirements stated on the approved product label, package insert or other approved product information shall strictly be followed throughout the supply chain.

7.1.2 Where the manufacturer specifies a temperature condition, the product shall remain within that condition during:



7.2 Ambient Medicines

7.2.1 Medicines that do not require refrigeration shall nevertheless be protected from excessive heat, direct sunlight and other adverse environmental conditions.

7.2.2 Where medicines are required to be stored at a temperature not exceeding 25°C, appropriate controls shall be established to maintain that condition.

7.3 Refrigerated Medicines

7.3.1 Where a product requires refrigeration:

1. Qualified cold-chain equipment shall be used
2. The transport container shall be capable of maintaining the required temperature
3. Temperature monitoring shall be performed

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4. The product shall be protected from freezing where freezing is not permitted
5. Coolant packs shall be appropriately conditioned
6. Products shall not be placed directly against frozen coolant packs unless the validated packing configuration permits it
7. All temperature records shall be retained.

7.4 VACCINE TRANSPORT

- 7.4.1 Vaccines shall receive enhanced temperature-control measures.
- 7.4.2 Clause 30 specifically requires vaccines and biologicals to be maintained according to the conditions specified by the manufacturer.
- 7.4.3 For applicable vaccines, the transport system shall include qualified vaccine carriers or cold boxes, appropriate coolant packs, temperature monitoring, data loggers where required, VVM monitoring where applicable, appropriate packing configuration, protection from freezing, protection from excessive heat, secure handling and documented chain of custody.
- 7.4.4 For vaccines requiring refrigeration, **2–8°C shall be used only where this is the specified product requirement.**

7.5 VACCINE VIAL MONITORING (VVM)

1. The VVM shall be checked at receipt
 2. The VVM status shall be documented where required
 3. Vaccines with an unacceptable VVM status shall not be administered
 4. The affected stock shall be quarantined
 5. The responsible authority shall be notified according to applicable procedures.
- 7.5.1 The Regulation specifically recognizes the use of a data logger or VVM for monitoring temperature conditions for applicable vaccines and temperature-sensitive injections.

7.6 PACKING OF TEMPERATURE-SENSITIVE MEDICINES

- 7.6.1 The packing procedure shall ensure:
 1. Adequate insulation

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2. Appropriate coolant quantity
3. Correct placement of coolant
4. Separation of products from frozen coolant where required
5. Minimal empty space where this is relevant to the validated configuration
6. Protection against crushing
7. Prevention of movement inside the container
8. Appropriate temperature-monitoring device placement
9. Secure closure.

7.6.2 Transport containers shall be used according to their qualified capacity and configuration.

8 TEMPERATURE MONITORING

8.1 Temperature monitoring equipment shall be:

1. Suitable for the intended temperature range
2. Maintained in good working condition
3. Appropriately calibrated or verified
4. Positioned appropriately
5. Protected against damage
6. Capable of producing records where continuous monitoring is required.

8.2 For higher-risk shipments, continuous temperature monitoring using a data logger should be the preferred method.

8.3 Temperature records shall identify, where applicable the product details, batch/lot, date and time, origin, destination, transport container, monitoring device, temperature readings, excursion details and receiving status.

9 INTER-ISLAND TRANSPORT

9.1 The Maldives presents specific transportation challenges due to the geographic distribution of islands and dependence on sea and air transport.

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9.2 Accordingly, every organization transporting medicines, vaccines and biologicals between islands shall establish documented procedures for:

1. Route planning
2. Departure and arrival times
3. Cold-chain requirements
4. Transfer points
5. Temporary storage
6. Delays
7. Missed vessels or flights
8. Adverse weather
9. power failure
10. Equipment failure
11. Damaged containers
12. Emergency return or alternative transportation.

9.3 Clause 39 specifically requires standards for sending medicines and vaccines to atolls by sea and air to be established by MFDA.

10 SEA TRANSPORT

1. products shall be protected from seawater and humidity;
2. temperature-controlled products shall remain within their required range;
3. cold-chain containers shall remain closed during transit;
4. products shall not be exposed to direct sunlight;
5. loading shall be performed as close as practicable to departure;
6. unloading shall occur promptly after arrival;
7. and contingency arrangements shall be available for delays.

10.1 For long-duration sea transportation, the transport provider shall assess whether passive cold-chain capacity is sufficient for the maximum anticipated journey duration.

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11 AIR TRANSPORT

1. Medicines shall be appropriately packed
2. Temperature-sensitive products shall be transported in qualified temperature-control systems
3. Unnecessary exposure to airport ambient conditions shall be avoided
4. Transfer time shall be minimized
5. Temperature monitoring shall be maintained
6. Responsibility during transfer between air cargo handlers and medicine importers/distributors shall be clearly documented

12 TEMPORARY HOLDING DURING TRANSIT

- 12.1** Where medicines cannot immediately continue their journey, they shall be transferred to appropriate storage.
- 12.2** Temperature-sensitive medicines shall not be left in vehicles, at ports, on docks, in airport areas, in uncontrolled warehouses or in other unsuitable locations.
- 12.3** Where temporary storage is unavoidable, the required temperature shall be maintained and documented.

13 TEMPERATURE EXCURSION MANAGEMENT

- 13.1** Any temperature excursion shall be treated as a quality incident.
- 13.2** The responsible person shall:
1. Immediately identify the affected product
 2. Stop distribution/use where appropriate
 3. Quarantine the affected batch
 4. Download or obtain temperature records
 5. Document duration and extent of excursion
 6. Identify the cause

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7. Assess the product against available stability information
8. Consult the manufacturer/marketing authorization holder where necessary
9. Consult MFDA where required
10. Determine disposition
11. Document the decision
12. Implement corrective and preventive action.

14 HANDLING OF FROZEN-SENSITIVE PRODUCTS

14.1 Where a product must not be frozen:

1. It shall not be placed directly against frozen coolant packs
2. The packing configuration shall protect the product from freezing
3. Temperature monitoring shall be used
4. Suspected freezing shall be treated as an excursion
5. Affected products shall be quarantined pending assessment.

15 DAMAGED MEDICINES

15.1 Medicines with broken containers, cracked vials, damaged blister packs, leaking containers, damaged labels, wet packaging, evidence of contamination, evidence of tampering, or other physical damage shall be segregated and assessed before being released for use or distribution.

16 SECURITY AND CONTROLLED MEDICINES

16.1 Controlled medicines and other high-risk medicines shall be transported using enhanced security measures.

16.2 These shall include restricted access, documented chain of custody, secure packaging, authorized personnel, appropriate delivery documentation, investigation of losses or discrepancies, and immediate notification of suspected theft or diversion.

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17 RECEIPT OF MEDICINES

17.1 The receiving person shall verify the following information and document any discrepancies:

Product	Name
	Strength
	Dosage form
	Quantity
	Batch/lot number
	Expiry date
Packaging	Integrity
	Cleanliness
	Tamper evidence
	Labelling
Temperature	Transport temperature record
	Data logger
	VVM where applicable
	Evidence of excursion.
Documentation	Invoice
	packing list
	relevant transport records
	delivery documentation

18 QUARANTINE

1. Temperature exposure is uncertain
2. A temperature excursion occurred
3. Packaging is damaged
4. Product identity cannot be confirmed

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5. Tampering is suspected
6. Documentation is incomplete
7. A recall has been initiated
8. Quality is otherwise in doubt

18.1 Quarantined medicines shall be clearly identified and physically or electronically segregated from saleable stock.

19 RETURNS

19.1 Returned medicines shall not automatically be returned to saleable stock.

19.2 The responsible person shall assess, reason for return, product identity, batch, expiry, storage history, transport conditions, packaging integrity, evidence of tampering, and temperature history where applicable.

20 RECALLS

20.1 When a medicine is recalled, transportation of recalled stock shall be controlled to ensure:

1. Traceability
2. Secure handling
3. Segregation
4. Prevention of accidental redistribution
5. Documentation of quantities
6. Confirmation of receipt at the designated location

20.2 This shall be implemented together with the MFDA medicine recall requirements under Clause 55.

21 TRANSPORTATION RECORDS

21.1 The following records shall be maintained where applicable:

1. Dispatch record
2. Delivery record

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3. Transport manifest
4. Invoice
5. Packing list
6. Batch/lot information
7. Temperature records
8. Data logger records
9. VVM records
10. Transport deviation report
11. Damage report
12. Incident report
13. Proof of delivery
14. Return records
15. Recall transportation records
16. Vehicle cleaning records
17. Transport provider qualification records.

22 THIRD-PARTY TRANSPORT PROVIDERS

22.1 An importer or distributor outsourcing medicine transportation remains responsible for ensuring that the contracted service is suitable.

22.2 A written agreement shall specify:

1. Responsibilities
2. Temperature requirements
3. Security requirements
4. Handling requirements
5. Documentation
6. Incident reporting
7. Excursion management

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8. Confidentiality
9. Subcontracting controls
10. Inspection rights
11. Corrective actions

23 TRAINING

- 23.1** Personnel involved in transportation and handling shall receive training appropriate to their responsibilities.
- 23.2** Training shall include medicine handling, vaccine handling, cold-chain principles, temperature monitoring, packing, loading/unloading, security, documentation, temperature excursions, emergency procedures, damaged products, recalls and incident reporting.
- 23.3** Training records shall be maintained.

24 QUALITY MANAGEMENT SYSTEM

- 24.1** Organizations involved in medicine transportation shall establish written procedures covering transportation planning, vehicle qualification, cold-chain management, temperature monitoring, equipment calibration, packing, loading, unloading, receipt, excursion management, incident management, complaints, recalls, returns, cleaning, training and record management.

25 EQUIPMENT QUALIFICATION

- 25.1** Where temperature-controlled equipment is used, appropriate qualification shall be undertaken.
- 25.2** This may include:
1. Cold-box qualification
 2. Vaccine carrier qualification
 3. Refrigerated vehicle qualification
 4. Temperature logger verification
 5. Refrigerator qualification

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6. Freezer qualification
7. Thermal mapping where appropriate

25.3 Equipment shall be requalified following significant changes, repair or other events that may affect performance.

26 INCIDENT AND COMPLAINT REPORTING

26.1 Transport-related incidents affecting medicine quality or safety shall be reported through the applicable complaint and incident management system.

26.2 Clause 47 explicitly identifies medicine registration, importation, distribution/retail, supply and transportation parties among those responsible for reporting quality- and safety-related complaints and incidents.

Examples include:

1. Temperature excursion
2. Damaged shipment
3. Suspected counterfeit
4. Suspected tampering
5. Lost medicine
6. Stolen medicine
7. Incorrect delivery
8. Contamination
9. Cold-chain failure
10. Any incident that may affect medicine quality or patient safety.

27 CORRECTIVE AND PREVENTIVE ACTION

27.1 Repeated transport failures shall trigger a documented investigation.

27.2 CAPA may include:

1. Retraining

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2. Equipment replacement
3. Route modification
4. Transport-provider reassessment
5. Revised packing configuration
6. Additional monitoring
7. Equipment qualification
8. Revised sops
9. Or termination of a transport contract

28 MFDA INSPECTION

28.1 MFDA may inspect vehicles, warehouses, pharmacies, transport facilities, cold-chain equipment, records, temperature monitoring systems, transport procedures and third-party transport arrangements.

28.2 Inspection shall assess compliance with the Regulation and this Guideline.

28.3 The Regulation gives MFDA authority to inspect medicine-related activities and premises and to take samples where appropriate.

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