



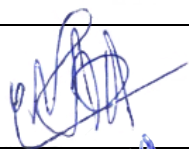
Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

**MTG Guideline on Medicine Delivery and Online Sales of OTC
and Nutraceuticals**

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 08.10.2026	
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Version Number	1	
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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	08.10.2026	-	Creation of the document	MTG Technical Committee

Definitions

Authorized Online Service Provider	A person or entity registered and authorized by MFDA to conduct an online sale activity covered by this guideline.
Authorized Pharmacy	A pharmacy holding a valid MFDA registration/permit and meeting applicable requirements for operation and dispensing of medicines.
Authorized Medicine Warehouse	A medicine storage/distribution facility holding valid MFDA authorization for the relevant activities.
Selected OTC Medicine	An OTC medicine specifically assessed and permitted by MFDA for online sale under Section I of this guideline.
Nutraceutical	A product falling within the applicable MFDA nutraceutical requirements and authorized for the relevant sale or supply activity.
Delivery Provider	A person or company transporting medicines from an authorized pharmacy or medicine warehouse to an intended recipient.
Responsible Pharmacist	A pharmacist designated by the authorized pharmacy or service provider to provide professional oversight where required.
Online Sale	Offering, ordering, selling, or arranging the sale of an eligible product through an electronic platform.
Medicine Delivery	The transport of medicines from an authorized pharmacy or medicine warehouse to an intended recipient in accordance with this guideline.
Traceability	The ability to identify the product, source, batch/lot where applicable, recipient/order, and relevant storage and delivery events.

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1 Introduction

Clause 37 of Medicine Regulation No. R-64/2026 provides that medicines may be sold or delivered through the internet or online platforms only by a service provider registered for the activity and authorized by the Authority. The Regulation also limits online supply to medicines permitted under the applicable requirements.

This guideline establishes two distinct regulatory pathways:

- (1) the online sale of selected over-the-counter (OTC) medicines and nutraceuticals
- (2) the delivery of medicines through authorized pharmacies and medicine warehouses.

The purpose is to facilitate appropriate use of online services and delivery while maintaining the same standards of medicine quality, safety, efficacy, security, traceability, storage, dispensing, and regulatory oversight applicable to conventional supply. Clause 13 of medicine Regulation No. R-64/2026 should be read together with this guideline. The Regulation establishes a broader framework covering medicine registration, manufacturer registration, supplier registration, storage, importation, distribution, dispensing, quality assurance and inspection.

2 Purpose

The purpose of this Guideline is to:

- Ensure that online sale of selected OTC medicines and nutraceuticals is conducted only by appropriately authorized persons or entities.
- Ensure that medicines supplied through online channels are approved, eligible for the relevant pathway, and sourced through lawful supply channels.
- Ensure that medicine delivery services operated by or on behalf of authorized pharmacies and medicine warehouses do not compromise medicine quality, safety, efficacy, or integrity.
- Prevent the supply of falsified, substandard, expired, damaged, recalled, quarantined, or otherwise unsuitable products.
- Ensure appropriate pharmacist oversight and prescription controls where applicable.
- Protect medicines from unsuitable environmental conditions, contamination, damage, tampering, and unauthorized access during storage, packing, transport, and delivery.
- Maintain adequate records and traceability from the authorized source to the recipient.

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- Establish clear responsibilities for authorized pharmacies, medicine warehouses, online service providers, and delivery providers.
- Enable MFDA inspection, surveillance, complaint investigation, recall, and enforcement.

3 Scope

This guideline applies to websites, mobile applications, online marketplaces, social-media pages, messaging platforms, and other electronic systems used to advertise, offer, order, sell, arrange, or facilitate the supply or delivery of products covered by this guideline.

It applies to authorized pharmacies, authorized medicine warehouses, eligible online service providers, medicine importers where applicable, and third-party technology or delivery providers involved in the relevant activity.

The guideline is divided into two sections:

- Section I – Online Sale of Selected OTC Medicines and Nutraceuticals.
- Section II – Delivery of Medicines through Authorized Pharmacies and Medicine Warehouses.

4 General Regulatory Principles

- 4.1** Online sale and delivery are regulated supply activities and shall not be used to bypass requirements applicable to medicines.
- 4.2** Only an MFDA-authorized entity may conduct an activity requiring authorization under this guideline.
- 4.3** Only products legally permitted for the relevant pathway may be offered, sold, supplied, or delivered.
- 4.4** The physical premises from which medicines are stored, dispensed, packed, or dispatched shall be appropriately authorized.
- 4.5** The product owner/seller remains responsible for the quality, safety, efficacy, integrity, and traceability of medicines even where technology or delivery services are outsourced.
- 4.6** Patient safety and medicine quality shall take priority over convenience or speed of delivery.

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- 4.7** All applicable requirements concerning storage, dispensing, labelling, prescription control, records, complaints, recalls, and pharmacovigilance shall continue to apply.
- 4.8** Third-party service providers shall not perform activities requiring professional or regulatory authorization unless separately authorized.

5 Section I - Delivery of Medicines Through Authorized Pharmacies and Medicine Warehouses

5.1 Scope and Eligibility

- 5.1.1** This section applies to delivery of medicines supplied by an MFDA-authorized pharmacy or medicine warehouse to an intended recipient. Delivery may be arranged directly by the authorized establishment or by an authorized delivery provider. This section does not by itself authorize online sale, dispensing, importation, wholesale distribution, or any other activity for which separate authorization is required.
- The pharmacy or medicine warehouse shall hold a valid MFDA authorization for the relevant activity of medicine delivery.
 - The medicines supplied shall be legally approved and authorized and available for supply through the relevant establishment.
 - The pharmacy or the medicine warehouse shall remain responsible for product quality, traceability, storage, packing, and appropriate release for delivery.
 - Delivery arrangements shall be governed by a documented agreement defining responsibilities.

5.2 Delivery Authorization

- 5.2.1** The authorized pharmacy or medicine warehouse shall maintain documented arrangements with delivery provider.
- 5.2.2** The agreement shall define responsibilities for collection, transport, security, temperature control, delivery, failed delivery, incidents, and records.
- 5.2.3** Delivery personnel shall not open, alter, substitute, dispense, or otherwise manipulate medicines unless separately authorized.
- 5.2.4** The authorized establishment shall assess and monitor the performance of the delivery provider.

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5.2.5 MFDA may require details of delivery providers, routes, vehicles/containers, training, and records during inspection.

5.2.6 The medicine delivery to the client shall be only done by an authorized pharmacist as approved by MFDA for the delivery services.

5.3 Prescription and Dispensing Controls

5.3.1 Delivery shall not be used to bypass prescription or professional dispensing requirements.

5.3.2 Prescription medicines shall be dispensed only by an appropriately authorized pharmacy and in accordance with applicable prescription requirements.

5.3.3 Where a prescription is required, it shall be clear, complete, valid, and appropriately verified before dispensing.

5.3.4 Prescription verification shall include the prescriber, patient, medicine, strength, dosage, quantity, and date as applicable.

5.3.5 Suspicious, altered, incomplete, or inappropriate prescriptions shall be referred for clarification.

5.3.6 Dispensing and pharmacist interventions shall be documented where applicable.

5.3.7 The delivery pharmacist, if different from the dispensing pharmacist, shall not make clinical decisions, substitute medicines.

5.4 Packaging and Labelling for Delivery

5.4.1 Medicines shall be packed in a manner that protects them from damage, contamination, tampering, moisture, heat, direct sunlight, and other adverse conditions.

5.4.2 Dispensed medicines shall bear all legally required patient-specific labelling as per the requirements of medicine regulation.

5.4.3 Packages shall be sealed or otherwise secured against tampering.

5.4.4 Packaging shall protect patient confidentiality and minimize unnecessary disclosure of personal or medical information.

5.4.5 Each delivery shall be traceable to the authorized source and relevant order/dispensing record.

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5.5 Storage and Transport Conditions

- 5.5.1 Medicine storage before dispatch shall comply with MFDA requirements and manufacturer-specified conditions.
- 5.5.2 Transport conditions shall maintain the required temperature and other environmental conditions.
- 5.5.3 Transport containers and vehicles shall be clean, suitable, secure, and capable of protecting medicines from environmental exposure.
- 5.5.4 Medicines shall be protected from heat, sunlight, moisture, contamination, pests, damage, and unauthorized access.
- 5.5.5 Temperature monitoring shall be used where required by the product or MFDA.
- 5.5.6 Temperature excursions shall be documented, assessed, and managed before the affected product is supplied.
- 5.5.7 Medicines shall not be transported together with materials that may contaminate, damage, or adversely affect them.

5.6 Delivery Handover and Recipient Verification

- 5.6.1 The recipient or authorized person shall be identified sufficiently to prevent delivery to the wrong person.
- 5.6.2 Proof of delivery shall be obtained and retained where required.
- 5.6.3 Medicines shall not be left unattended in locations where the quality, security, or confidentiality may be compromised.
- 5.6.4 Delivery pharmacist shall follow instructions for safe handover and handling.
- 5.6.5 Failed deliveries shall be managed through a documented return procedure.
- 5.6.6 Medicines returned following failed delivery shall be segregated and assessed before any decision to resupply.

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5.7 Inter-Island Delivery

- 5.7.1 Sea or air transportation shall maintain required medicine storage conditions throughout the journey as per the requirements of medicine regulation.
- 5.7.2 Dispatch, transport, receipt, and delivery events shall be documented sufficiently to establish traceability.
- 5.7.3 Packaging shall be suitable for the expected duration and environmental conditions of transport.
- 5.7.4 Temperature-sensitive products shall be transported using appropriate cold-chain arrangements.
- 5.7.5 Temperature excursions or delays shall be assessed before the product is released for supply.
- 5.7.6 Any product with uncertain storage conditions shall be quarantined pending assessment by an appropriately authorized person.

5.8 Returns, Undelivered Medicines and Damaged Products

- 5.8.1 Returned or undelivered medicines shall be segregated from saleable stock.
- 5.8.2 The reason for return or failed delivery shall be documented.
- 5.8.3 An authorized pharmacist or designated quality personnel shall assess package integrity and, where relevant, storage and transport history.
- 5.8.4 Products with evidence of damage, tampering, contamination, inappropriate temperature exposure, or uncertain storage history shall not be resupplied.
- 5.8.5 Where required, affected products shall be handled as rejected, quarantined, recalled, or otherwise unsuitable stock.
- 5.8.6 Return and disposition records shall be maintained.

5.9 Complaints, Quality Defects and Adverse Events

- 5.9.1 An effective documented complaint-handling system shall be maintained with in the pharmacy or medicine warehouse for medicine delivery activities.

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- 5.9.2** Wrong medicine, wrong strength, damaged packaging, suspected falsification, temperature excursion, delayed delivery, or other quality/safety concerns shall be investigated promptly and reported to MFDA
- 5.9.3** Serious quality or safety concerns shall be reported to MFDA without undue delay.
- 5.9.4** Adverse drug reactions shall be managed through the applicable pharmacovigilance system and report to MFDA
- 5.9.5** Investigations shall use order, batch, supplier, dispensing, storage, and delivery records where relevant.
- 5.9.6** Corrective and preventive actions shall be implemented for systemic deficiencies.

5.10 Traceability and Records

1. The following records shall be retained in a traceable manner:
2. Order or dispensing reference number and date/time.
3. Patient/recipient information as legally required.
4. Medicine name, strength, dosage form, pack size, and quantity.
5. Batch/lot and expiry information where applicable.
6. Manufacturer and supplier/importer information where applicable.
7. Prescription and pharmacist verification records where applicable.
8. Dispatch and delivery information, including delivery provider.
9. Temperature records and excursion records where applicable.
10. Return, complaint, incident, recall, and corrective-action records.
11. Records shall be retained for the period prescribed by law or MFDA requirements and shall be available for inspection.

5.11 Data Protection and Confidentiality

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- 5.11.1 Patient and prescription information shall be accessed only by authorized personnel.
- 5.11.2 Electronic systems shall use appropriate access controls and maintain auditable records.
- 5.11.3 Records shall be protected against unauthorized alteration, deletion, disclosure, or loss.
- 5.11.4 Appropriate backup and recovery arrangements shall be maintained.
- 5.11.5 Information shall be retained and disposed of in accordance with applicable legal and regulatory requirements.

6 SECTION 2 – ONLINE SALE OF SELECTED OTC MEDICINES AND NUTRACEUTICALS

6.1 Eligibility and Authorization

- 6.1.1 Online sale under this section shall be permitted only following MFDA assessment and authorization of the applicant, the proposed platform, the responsible premises, the proposed product categories, and the arrangements for storage, order fulfilment, customer communication, and delivery.
 - 1. Hold the relevant MFDA license, permit, registration, or authorization applicable to the products and activity.
 - 2. Identify the authorized premises from which products will be stored, prepared, packed, or dispatched.
 - 3. Identify a responsible pharmacist where pharmacist oversight is required.
 - 4. Identify the legally responsible seller where a third-party online platform is used.
 - 5. Obtain separate authorization where required for different premises, activities, or product categories.
 - 6. Submit any additional information or documents requested by MFDA.

6.2 Application and Supporting Documents

- 6.2.1 The following information is required when applying for authorization
 - 1. Valid company or business registration.

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2. Valid pharmacy, importer, medicine, nutraceutical, or other relevant authorization, as applicable.
3. Details and evidence of authorization of the storage/dispensing premises.
4. Responsible pharmacist details where applicable.
5. Description of the online platform, including screenshots and proposed customer journey.
6. Proposed list/category of OTC medicines and nutraceuticals.
7. SOPs covering product listing, ordering, customer communication, storage, dispensing/packing, delivery, complaints, returns, recalls, and incident management.
8. Details and agreements for third-party delivery providers, where applicable.
9. Record-retention, data protection, and system-access arrangements.
10. Business continuity and system failure arrangements.
11. Any additional documentation required by MFDA.

6.3 Products Permitted for Online Sale

- 6.3.1** A product shall not be eligible for online sale solely because it is registered or legally imported. MFDA shall assess whether the product and proposed mode of supply are appropriate for online sale. Only OTC medicines listed in “Authorized OTC Products for Online Sale (MTG/RE-OS/Li 0064)” shall be permitted for online sales.

6.4 Selected OTC Medicines

- 6.4.1** The medicine is legally authorized for importation and sale in Maldives.
- 6.4.2** Only those OTC medicines in the list Authorized OTC Products for Online Sale (MTG/RE-OS/Li 0064)”
- 6.4.3** The medicine is classified as OTC and is specifically permitted by MFDA for online sale.
- 6.4.4** The medicines shall be sourced from a registered importer in Maldives and such supply records shall be retained.

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- 6.4.5** The product has no current MFDA restriction, suspension, recall, or other regulatory alert preventing sale.
- 6.4.6** Required storage and delivery conditions can be maintained throughout the transaction.
- 6.4.7** The product can be supplied without compromising applicable professional or safety requirements.
- 6.4.8** The product information presented online is consistent with the approved product information.

6.5 Nutraceuticals

- 6.5.1** The nutraceutical shall be registered under the authority of MFDA.
- 6.5.2** The nutraceuticals shall be sourced from a registered importer in Maldives and such supply records shall be retained.
- 6.5.3** The product complies with applicable safety, quality, labelling, and claims requirements.
- 6.5.4** The product is not subject to a regulatory restriction, suspension, recall, or safety alert.
- 6.5.5** Storage and delivery conditions specified for the product can be maintained.
- 6.5.6** Only authorized product claims and approved information are displayed online.
- 6.5.7** If the product is not registered in Maldives, online sale shall only be conducted by registering the product in MFDA under the applicable requirements. (Refer to Guideline on Registration of Nutraceuticals MTG/RE-NC/GLN-TE 011)

6.6 Products Not Eligible for Online Sale under this Section

1. Controlled medicines and other specially regulated medicines.
2. Prescription-only medicines.
3. Biological products and vaccines.
4. Temperature-sensitive or cold-chain medicines unless specifically authorized under another MFDA pathway.
5. Sterile or other high-risk medicines requiring special handling or restricted distribution.

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6. Medicines requiring specialized storage or restricted supply where the online pathway cannot adequately control the risk.
7. Unregistered, unauthorized, falsified, expired, damaged, recalled, quarantined, or otherwise unsuitable products.

6.7 Applicable Requirements for the Online Platform

1. Display the legal name of the authorized seller and relevant MFDA authorization information.
2. Display the physical address and contact details of the responsible business.
3. Identify the responsible pharmacist/contact where applicable.
4. Use an MFDA-approved or authorized product catalogue.
5. Display accurate product name, strength, dosage form, pack size, manufacturer/importer information where required, and other legally required information.
6. Prevent listing or sale of products that become suspended, recalled, restricted, expired, or otherwise ineligible.
7. Maintain an auditable history of product-listing and material content changes.
8. Provide a clear complaint and customer-support mechanism.
9. Ensure product information is consistent with approved information.
10. Maintain appropriate system controls to prevent unauthorized modification of product information.

6.8 Advertising and Promotion

- 6.8.1 Advertising shall be truthful, accurate, evidence-based, and not misleading.
- 6.8.2 Advertising and promotion of medicines shall comply with the current Medicine Regulation and applicable MFDA requirements.

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- 6.8.3** Only OTC medicines permitted for promotion by MFDA may be advertised, and prior MFDA approval shall be obtained where required.
- 6.8.4** Evidence-based product safety information required by MFDA shall be presented with the product where applicable.
- 6.8.5** No unsupported claims, guarantees, or statements implying MFDA endorsement shall be made.
- 6.8.6** Advertising shall not encourage inappropriate self-medication or unsafe use.
- 6.8.7** Prescription-only and otherwise prohibited products shall not be advertised or promoted through the online service.

6.9 Ordering, Customer Information and Product Supply

- 6.9.1** Order records shall contain sufficient information to establish traceability.
- 6.9.2** The product name, strength, dosage form, quantity, and order date/time shall be recorded.
- 6.9.3** The customer's delivery address and contact information shall be verified.
- 6.9.4** Only products approved for online sale shall be accepted through the platform.
- 6.9.5** Orders shall be reviewed for quantity, product suitability, and any relevant restrictions.
- 6.9.6** Where pharmacist intervention is required, the order shall not be completed until the pharmacist has assessed it.
- 6.9.7** Customers shall be provided with appropriate directions for use, storage, warnings, and other approved product information.

6.10 Storage, Packing and Dispatch

- 6.10.1** Products shall be stored only at an authorized premises and under manufacturer-specified and MFDA-required conditions.
- 6.10.2** Temperature and humidity shall be monitored where required.
- 6.10.3** Saleable, quarantined, recalled, expired, rejected, and returned products shall be segregated.

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6.10.4 FEFO shall be applied where appropriate.

6.10.5 Products shall be protected from sunlight, moisture, contamination, pests, damage, and unauthorized access.

6.10.6 Packaging shall protect the product from damage, contamination, tampering, and unsuitable environmental exposure.

6.10.7 Products shall remain in their approved/original packaging unless repackaging is specifically permitted and controlled.

6.10.8 Dispatch checks shall confirm the correct product, strength, dosage form, quantity, batch/lot where applicable, and expiry.

6.11 Delivery

6.11.1 Where delivery is arranged as part of an online sale, the seller remains responsible for ensuring that delivery arrangements preserve product quality, safety, and integrity.

6.11.2 Delivery providers shall be appropriately qualified for the activity and trained in basic medicine handling.

6.11.3 Products shall be protected from heat, direct sunlight, moisture, contamination, damage, tampering, and unauthorized access.

6.11.4 Delivery timeframes and routes shall minimize exposure to unsuitable conditions.

6.11.5 Products shall not be left unattended where quality or security may be compromised.

6.11.6 Undelivered products shall be returned to an authorized premises and assessed before any further sale.

6.11.7 Products with uncertain storage conditions shall be quarantined pending assessment.

6.11.8 Proof of delivery or equivalent delivery records shall be maintained where required.

6.12 Records, Complaints, Returns and Recalls

6.12.1 Maintain order number/date/time and customer details as legally required.

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- 6.12.2** Maintain product, batch/lot, expiry, supplier/importer, dispatch, and delivery information as applicable.
- 6.12.3** Maintain records of complaints, returns, incidents, temperature excursions, and recalls.
- 6.12.4** Returned products shall be segregated and assessed before any decision to resupply.
- 6.12.5** Suspected falsified, damaged, tampered, defective, or unsafe products shall be immediately segregated and investigated.
- 6.12.6** Recall or regulatory alerts shall result in immediate blocking of affected products from online sale.
- 6.12.7** Serious quality or safety concerns shall be reported to MFDA without undue delay.
- 6.12.8** Records shall be retained for the period prescribed by law or MFDA requirements and made available for inspection.

7 Responsibilities

7.1 Authorized Pharmacy

1. Maintain valid authorization and comply with pharmacy requirements.
2. Supply only eligible and legally authorized medicines.
3. Ensure appropriate pharmacist oversight and dispensing controls.
4. Maintain compliant storage, packing, and delivery arrangements.
5. Maintain traceability and required records.
6. Manage complaints, returns, recalls, and quality defects.
7. Train relevant staff and delivery personnel.
8. Notify MFDA of significant changes, incidents, or serious quality/safety concerns.

7.2 Authorized Medicine Warehouse

1. Maintain valid authorization for storage and relevant supply activities.

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2. Maintain required storage, security, temperature, hygiene, and stock controls.
3. Release only eligible medicines for delivery.
4. Maintain dispatch and traceability records.
5. Ensure appropriate transport and delivery arrangements.
6. Manage incidents, recalls, returns, and temperature excursions.

7.3 Responsible Pharmacist

1. Oversee dispensing and professional aspects of medicine supply where applicable.
2. Verify prescriptions where required.
3. Identify unsafe or inappropriate orders.
4. Provide appropriate medicine information or referral.
5. Support complaint, recall, quality, and incident investigations.

7.4 Delivery Provider

1. Maintain medicine integrity and security during transport.
2. Follow specified environmental and temperature requirements.
3. Prevent unauthorized access, tampering, opening, substitution, or misuse.
4. Maintain delivery and incident records.
5. Immediately report damage, delay, tampering, failed delivery, or temperature excursion.

7.5 MFDA

1. Authorize and monitor activities covered by this guideline.
2. Establish product eligibility and authorization controls.
3. Inspect and conduct regulatory surveillance.

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4. Investigate complaints and quality/safety concerns.
5. Require corrective and preventive actions.
6. Coordinate recalls and regulatory alerts.
7. Restrict, suspend, or cancel activities where necessary to protect public health.

8 Inspection and Compliance Monitoring

- 8.1 MFDA may inspect authorized premises, online platforms, records, storage arrangements, delivery systems, and relevant personnel.
- 8.2 Authorized entities shall provide access to relevant records, systems, premises, and personnel as required for regulatory inspection.
- 8.3 MFDA may conduct test purchases, transaction reviews, or other surveillance activities where appropriate.
- 8.4 MFDA may request product, order, prescription, dispensing, delivery, temperature, complaint, and recall records.
- 8.5 Identified deficiencies shall be risk-assessed and corrective action may be required.

9 Incident Management

- 9.1 The authorized entity shall maintain a written incident-management procedure appropriate to its activities. The procedure shall cover, where applicable, wrong medicine or recipient, suspected falsification, damaged or tampered products, temperature excursions, delivery failures, unauthorized product listings, recalls, data incidents, and serious adverse events.
- 9.2 The procedure shall define containment, assessment, notification, investigation, corrective and preventive action, and documentation requirements.

10 Training

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- 10.1** Relevant personnel shall receive role-appropriate training before undertaking assigned activities and at appropriate intervals thereafter.
- 10.2** Training shall cover medicine/product eligibility, storage, handling, packing, delivery, cold chain where applicable, complaints, recalls, falsified medicines, confidentiality, and incident reporting.
- 10.3** Delivery personnel shall receive appropriate training on medicine handling and the limitations of their role.
- 10.4** Training records shall be maintained and made available during inspection.

11 Quality Management System

- 11.1** Authorized entities shall maintain documented procedures proportionate to the activities conducted. Procedures shall include, as applicable, product eligibility and listing control, order processing, dispensing and pharmacist intervention, storage, packing, delivery, cold chain, returns, complaints, recalls, suspected falsified medicines, adverse-event escalation, change control, data access, records, training, third-party management, self-inspection, and CAPA.

12 Supplier and Product Qualification

- 12.1** Medicines and nutraceuticals shall be sourced only through authorized and traceable supply channels.
- 12.2** Manufacturer and supplier/importer shall be identifiable.
- 12.3** Product quality and supplier performance shall be monitored.
- 12.4** Products with repeated defects, recalls, regulatory restrictions, or other concerns shall be reviewed.
- 12.5** Supplier restrictions or regulatory alerts shall trigger immediate review and, where necessary, suspension of affected products or activities.

13 Changes, Renewal, Suspension and Cancellation

- 13.1** Authorization shall be renewed in accordance with MFDA requirements.

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- 13.2** Material changes to ownership, premises, responsible pharmacist, online platform, product categories, delivery arrangements, or third-party providers shall be notified to MFDA as required.
- 13.3** MFDA may require prior approval for significant changes.
- 13.4** MFDA may suspend or cancel authorization where the activity presents unacceptable risk or does not comply with applicable requirements.
- 13.5** During suspension, the activities specified by MFDA shall stop immediately.

14 Enforcement

- 14.1** Non-compliance with this guideline, the Medicine Regulation, or conditions of authorization may result in warning or corrective action, restriction or removal of products, suspension of online sale or delivery activities, detention or quarantine of products, recall, suspension or cancellation of relevant authorization, or other enforcement action available under the applicable legislation and regulatory requirements.

15 Required SOPs, Forms and Records

1. SOP – Online Sale of Selected OTC Medicines and Nutraceuticals
2. SOP – Product Eligibility and Online Product Listing
3. SOP – Online Order Processing
4. SOP – Pharmacist Review and Intervention, where applicable
5. SOP – Packaging and Labelling for Online Orders
6. SOP – Medicine Delivery and Transportation
7. SOP – Cold Chain and Temperature Excursion Management
8. SOP – Returns and Undelivered Medicines
9. SOP – Complaints and Quality Defects
10. SOP – Recall and Regulatory Alerts
11. SOP – Suspected Falsified Medicines
12. SOP – Data Protection and System Access
13. SOP – Incident Management
14. SOP – Record Retention and Traceability

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15. Application Form – Authorization for Online Sale of Selected OTC Medicines and Nutraceuticals
16. Delivery Provider Qualification/Agreement
17. Online Transaction/Order Register
18. Prescription Verification Record, where applicable
19. Delivery Record/Proof of Delivery
20. Delivery Incident Report
21. Returned Medicine Assessment Form
22. Online Medicine/Nutraceutical Complaint Form
23. Recall Tracking Register
24. Temperature Monitoring and Excursion Record, where applicable

16 Transitional Arrangements

- 16.1** Existing online sellers or service providers conducting activities covered by this guideline shall apply for the relevant MFDA authorization within the transition period specified by MFDA. Patient-safety, product-quality, and other immediate regulatory requirements shall apply during the transition period. After the applicable transition period, no person or entity shall conduct an activity requiring authorization under this guideline without valid MFDA authorization.

17 Assessment for the Authorization of Online Sale

Assessment Area	Evidence
Legal authorization	Licence/registration/authorization
Responsible pharmacist	Registration/appointment, where applicable
Premises	Inspection/authorization
Product eligibility	Approved/authorized product list
Online platform	Screenshots/system demonstration
Advertising	Approved materials/evidence
Storage	Inspection/temperature records
Order controls	Sample transaction/order records
Delivery	SOP/qualification/records

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Traceability	Sample transaction and batch records
Complaints/recalls	SOP/test evidence
Data protection	System/process evidence
Training	Training records

18 Assessment for the Authorization of Medicine Delivery

Assessment Area	Evidence
Source authorization	Valid pharmacy/warehouse authorization
Storage conditions	Inspection/temperature records
Dispensing controls	Prescription/pharmacist records, where applicable
Packaging	Packaging demonstration/SOP
Delivery provider	Agreement/qualification/training
Transport conditions	Vehicle/container/SOP/records
Cold chain	Monitoring and excursion records, where applicable
Handover	Proof-of-delivery/recipient verification
Returns	Return and assessment records
Traceability	Dispatch/order/delivery records
Complaints/incidents	SOP and sample records
Recall	Recall procedure and test evidence

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