



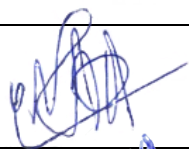
Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

MTG Guideline on Product Labelling

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 11.10.2026	
Doc. No: MTG/RE-PL/GLN-TE 027	Doc. Name: MTG Guideline on Product Labelling		
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Version Number	01	
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Prepared By	MTG Technical Committee	
Approved By	Aishath Mohamed, Deputy Director General, Pharmaceuticals	
Authorized by	Thooma Adam, Deputy Director General, Laboratory Services (Acting Head of MTG)	

SUMMARY OF CHANGES

Version No.	Issued Date	Section/Clause	Summary of Change	Changes Made by
1	11.10.2026	-	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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DEFINITIONS

Medicine Label	Any written, printed or graphic information appearing on, attached to or accompanying a medicine package or container that provides information necessary for identification, storage, handling or use of the medicine.
Original Manufacturer's Label	The label applied to the medicine or its packaging by the manufacturer in accordance with the approved product information.
Dispensing Label	A label applied by a pharmacy or authorized dispenser to a medicine supplied to a patient to communicate the information necessary for its correct and safe use.
Loose Medicine	A medicine that is removed from its original primary packaging, including individual tablets or capsules removed from a blister, strip or bulk container for dispensing.
Long-Term Medication	Medicine supplied for continuous or repeated treatment over an extended period in accordance with a valid prescription or treatment plan.
Antibiotic Label	The specific patient-use label required for an antibiotic under Annex 4 of the Medicine Regulation.

1 INTRODUCTION

Proper medicine labelling is an essential component of the medicine regulatory system and is critical for ensuring the identity, quality, safety, traceability and appropriate use of medicines throughout the medicine supply chain.

Medicine labelling must provide sufficient information to allow medicines to be correctly identified and handled from the time of importation, through transportation and storage, until the medicine is finally dispensed and used by the patient.

Inadequate, incomplete, illegible or misleading labelling can contribute to medication errors, inappropriate use, loss of traceability, incorrect storage, administration errors and difficulties in investigating medicine-related incidents.

Medicine Regulation No. R-64/2026 establishes requirements relating to labelling of medicines at different stages of the supply chain. In particular:

- **Clause 27** establishes requirements for labelling medicines imported into Maldives.
- **Clause 36** establishes requirements relating to dispensing, medicine-use instructions, dispensing records and labelling of medicines supplied to patients.
- **Clause 39** establishes requirements relating to transportation, distribution and movement of medicines.
- **Annex 4** establishes the required format and information for medicine-use labels, including a specific **red label for antibiotics**.

This Guideline emphasizes these regulatory requirements into practical requirements for importers, warehouses, transporters, pharmacies, pharmacists, dispensers and healthcare facilities.

2 PURPOSE

The purpose of this Guideline is to:

1. Establish minimum requirements for medicine labelling during importation, transportation, storage and dispensing.
2. Ensure that every medicine remains identifiable and traceable throughout the supply chain.
3. Prevent medication errors arising from incomplete or unclear labels.

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4. Establish standardized requirements for medicines dispensed from original packaging.
5. Establish specific requirements for loose tablets and medicines removed from their original packaging.
6. Establish requirements for medicines supplied to patients receiving long-term treatment.
7. Establish a standardized patient-use label in accordance with Annex 4.
8. Establish specific requirements for antibiotic labelling.
9. Ensure that medicine labels remain legible, durable and securely attached throughout the intended period of use.
10. Facilitate regulatory inspection, investigation, recall, pharmacovigilance and enforcement activities.

3 SCOPE

This Guideline applies to:

- Manufacturers
- Licensed medicine importers
- Registered medicine suppliers
- Warehouses and distribution facilities
- Transport and logistics providers handling medicines
- Pharmacies
- Pharmacists and authorized dispensers
- Healthcare facilities
- Medicines supplied to patients receiving long-term treatment
- Antibiotics and other medicines requiring specific patient-use labelling

4 LEGAL AND REGULATORY BASIS

This Guideline is in line with:

Medicine Regulation No. R-64/2026

- Clause 27 – Labelling of imported medicines
- Clause 36 – Dispensing of medicines
- Clause 39 – Transportation, distribution and movement of medicines

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- Annex 4 – Required format for medicine-use labels
- Applicable MFDA guidelines and SOPs relating to medicine storage, transportation, dispensing and inspection.

Where there is any inconsistency between this Guideline and the Medicine Regulation, the Regulation shall prevail.

5 GENERAL PRINCIPLES OF MEDICINE LABELLING

5.1 All medicine labels shall be:

- Accurate
- Clear
- Legible
- Durable
- Easily visible
- Unambiguous
- Resistant to normal handling
- In Dhivehi or English
- Consistent with the approved medicine information
- Applied in a manner that does not obscure critical information on the original manufacturer's packaging.

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- 5.2** The label shall not contain information that conflicts with the approved product information, prescription or instructions of the authorized prescriber.
- 5.3** Where a medicine is dispensed into another container, sufficient information shall be transferred to the dispensing label to maintain medicine identity, patient safety and traceability.

6 LABELLING OF MEDICINES DURING IMPORTATION

6.1 General requirement

- 6.1.1** In accordance with **Clause 27**, all medicines imported into Maldives shall have appropriate labelling and shall be accompanied by the required product information/leaflet.
- 6.1.2** The regulation requires all imported medicines to be labelled and requires medicine information to be available with the product.

6.2 Language

- 6.2.1** Medicine labels shall be provided in:
- English
 - Dhivehi
- 6.2.2** Labels shall be sufficiently clear and legible to allow the information to be readily understood.

6.3 Minimum Information on Imported Medicine Labels

- 6.3.1** The label of imported medicines shall contain, as applicable:
- Brand name
 - Generic name/International Nonproprietary Name (INN)
 - Strength
 - Dosage form
 - Active ingredient(s)
 - Non-active ingredients/excipients, where required
 - Manufacturer's name and address; or a barcode or QR code that can traced the manufacturer
 - Country of manufacture

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- Manufacturing date, where applicable
- Expiry date
- Batch/Lot number
- Storage condition
- Directions or relevant precautions for storage and handling
- Product registration/product code, as applicable
- Any other information required by the Authority or approved product information

6.3.2 Clause 27 specifically identifies information including the brand/generic name, manufacturing and expiry dates, strength, manufacturer information, storage instructions, batch number, active and non-active ingredients and reference pharmacopoeia.

7 PRODUCT REGISTRATION/PRODUCT CODE

7.1 Where the Authority has assigned a product registration number or product code, the importer shall ensure that it is clearly identifiable on the medicine packaging if applicable. However, the product registration number or approval number shall be pasted, marked or written on all product packages before the medicine is placed on the shelves for dispensing. This sticker, mark or written code shall be visible on the package.

7.2 The product code shall be displayed in a manner that allows regulatory inspectors, pharmacists and other authorized personnel to readily identify the registered product.

7.3 The product code shall not be altered, concealed or replaced without MFDA authorization.

8 PACKAGE AND LEAFLET REQUIREMENTS

8.1 Every medicine imported into Maldives shall, where applicable:

- Be supplied in its original manufacturer's packaging;
- Have the manufacturer's label intact;
- Be accompanied by the approved product information/leaflet;
- Have labels that are securely attached and legible;
- Have no critical information obscured by additional labels or stickers.

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- 8.2** An importer shall not remove, alter or obscure essential manufacturer information without appropriate regulatory authorization.

9 LABELLING DURING TRANSPORTATION AND DISTRIBUTION

- 9.1** Medicine labels shall remain intact and legible during transportation.

- 9.2** In accordance with Clause 39, medicines shall be transported and distributed in a manner that maintains their quality and safety. The Regulation also requires appropriate arrangements for medicines requiring specific temperature conditions and cold-chain management.

10 Transport requirements

10.1 During transportation:

- 10.1.1** Original medicine labels shall remain attached.
- 10.1.2** Shipping cartons shall be identifiable by medicine name and relevant batch information.
- 10.1.3** Labels shall not be covered or damaged by transport packaging.
- 10.1.4** Medicines shall be protected from heat, moisture, sunlight and physical damage.
- 10.1.5** Temperature-sensitive medicines shall be transported under the required temperature conditions.
- 10.1.6** Cold-chain medicines shall be accompanied by appropriate temperature monitoring where required.
- 10.1.7** Any temperature excursion shall be documented and assessed before the medicine is released for use.
- 10.1.8** Medicines shall remain traceable to the batch and shipment documentation.

10.2 Transport/shipping labels

- 10.2.1** Where a secondary shipping label is used, it should include, as appropriate:

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Information	Requirement
Medicine name	Required
Strength	Required
Dosage form	Required
Quantity	Required
Batch/Lot number	Required
Expiry date	Required
Storage condition	Required
Sender	Required
Recipient	Required
Handling precautions	Where applicable
Cold-chain indication	Where applicable

10.2.2 Secondary transport labels shall supplement and not replace the manufacturer's medicine label.

11 DISPENSING AND PATIENT-USE LABELLING

11.1 Clause 36 requires medicines supplied by pharmacies to be labelled with information necessary for proper use. It also specifically requires the medicine-use information to follow the format in Annex 4.

11.2 Every medicine dispensed to a patient shall therefore have a clear patient-use label unless the medicine is supplied in a manner where the original packaging already provides all required information and the pharmacist determines that an additional label is unnecessary.

11.3 MINIMUM DISPENSING LABEL

11.3.1 The dispensing label shall contain, as applicable:

1. Patient name
2. Medicine name
3. Strength
4. Dosage form, where necessary
5. Directions for use
6. Dose
7. Frequency/time of administration
8. Duration of treatment
9. Route of administration, where applicable
10. Quantity supplied
11. Expiry date, where applicable
12. Batch number, particularly where medicine is removed from its original packaging
13. Relevant storage instructions
14. Appropriate warnings and precautions
15. Pharmacy name/contact details
16. Date of dispensing

11.3.2 The information shall be consistent with the prescription and approved medicine information.

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12 EMPHASIS ON CLAUSE 36 – PATIENT-USE INFORMATION

12.1 The dispensing label should answer the following questions clearly:

What medicine is this?
The patient must be able to identify the medicine by name and strength.
Why am I taking it?
Where appropriate, the pharmacist should communicate the purpose of treatment.
How much should I take?
The dose must be clearly stated.
How often should I take it?
The frequency should be stated clearly rather than using ambiguous abbreviations.
When should I take it?
Where clinically relevant, the label should specify morning, evening, before food, after food, at bedtime, etc.
How long should I take it?
The duration of therapy should be stated.
How should I take it?
The route and method of administration should be stated where necessary.
How should I store it?
Storage conditions shall be communicated when they are important for product stability.

13 PROHIBITION OF UNCLEAR INSTRUCTIONS

13.1 Labels should avoid unclear abbreviations such as:

- "OD"
- "BD"
- "TDS"
- "QID"

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13.1.1 Unless the pharmacy's approved system ensures that the patient clearly understands their meaning.

13.1.2 Instead, instructions should preferably be written as:

Take one tablet once daily.

or

Take one tablet in the morning and one tablet in the evening.

13.1.3 This is particularly important for elderly patients, children, patients with multiple medicines and patients receiving long-term treatment.

14 LOOSE TABLETS AND CAPSULES

14.1 General requirement

14.1.1 Where a medicine is dispensed as loose tablets or capsules, the pharmacy shall ensure that the medicine remains identifiable and traceable until it is consumed.

14.1.2 Loose tablets shall not be supplied to a patient in an unlabeled envelope, plastic bag or container and shall comply with minimum dispensing label requirements as mentioned in this guideline.

14.2 Removal from blister packaging

14.2.1 Where individual tablets are removed from a blister or strip:

- The medicine identity shall be confirmed before dispensing.
- The original packaging shall be retained where practical until the dispensing process is complete.
- The batch number and expiry date shall be verified.
- The medicine shall be placed in a suitable clean container.
- The container shall be labelled appropriately.
- The label shall not be handwritten in a manner that is illegible or ambiguous.
- shall comply with minimum dispensing label requirements as mentioned in this guideline

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14.3 MEDICINES DISPENSED FROM CUT BLISTER STRIPS

14.3.1 When a partial blister strip is supplied:

- The remaining blister should retain the medicine name and strength wherever possible.
- If the original blister does not contain sufficient information after cutting, an additional label shall be applied.
- The patient shall not receive a strip segment that cannot be reliably identified.
- Batch and expiry information shall be maintained through the dispensing record or label.

14.3.2 A pharmacy shall not rely solely on the patient's ability to recognize a tablet by its color, shape or appearance.

15 LONG-TERM MEDICATION

15.1 Clause 36 specifically requires medicines supplied for long-term use to be individually packed and labelled so that the medicines can be readily identified. The Regulation further requires important information such as the medicine name, generic name, strength, formulation, batch number and expiry date to be retained on the individual medicine packages.

15.2 Individual packaging

15.2.1 For patients receiving long-term medication, medicines should be:

- Separately packaged
- Clearly identified
- Labelled according to the prescribed regimen
- Separated by medicine where multiple medicines are supplied
- Packed in a manner that protects the medicine from moisture and contamination

15.3 Long-term medication label

15.3.1 The following information should be provided:

PATIENT: [Name]
MEDICINE: [Brand/Generic Name]

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STRENGTH: [e.g., 500 mg]
FORMULATION: [Tablet/Capsule/etc.]
DOSE: [e.g., 1 tablet]
FREQUENCY: [e.g., once daily]
TIME: [e.g., morning]
DURATION: [e.g., 30 days]
BATCH No.: [XXXX]
EXPIRY: [MM/YYYY]
STORAGE: [Condition]
PHARMACY: [Name/contact]

15.4 MULTIPLE MEDICINES FOR LONG-TERM PATIENTS

15.4.1 Where a patient receives several medicines:

- Each medicine should preferably be packaged separately.
- Medicines should not be placed together without individual identification.
- The patient should be able to distinguish each medicine.
- Similar-looking medicines should be separated.
- LASA medicines should receive enhanced verification.
- The pharmacist should provide counselling on the purpose and administration of each medicine.

15.4.2 Where a compliance/blister-pack system is used, the system shall retain sufficient information to identify each medicine and its administration time.

16 ANTIBIOTIC LABELLING – SPECIAL REQUIREMENT

16.1 Regulatory requirement

16.1.1 Antibiotics are subject to a specific dispensing label requirement under Clause 36 and Annex 4.

16.1.2 Where an antibiotic is dispensed, the pharmacist shall apply the antibiotic-specific label prescribed in Annex 4.

16.2 REQUIRED COLOUR

RED ANTIBIOTIC LABEL

The antibiotic label shall be printed on:

RED PAPER

with:

BLACK TEXT

and:

FONT SIZE 10

as specified in Annex 4.

16.2.1 This color requirement should be standardized nationally to allow patients, pharmacists, healthcare workers and inspectors to immediately recognize the additional counselling requirement associated with antibiotic use.

17 REQUIRED ANTIBIOTIC LABEL INFORMATION

17.1 The red antibiotic label shall include:

1. Medicine name

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2. Strength
3. Directions for use
4. Frequency/time of administration
5. Duration of treatment
6. Expiry date
7. Batch number
8. Antibiotic-use warning
9. Any other information required under Annex 4

17.1.1 The antibiotic warning prescribed in Annex 4 communicates that the patient should use the antibiotic according to the regulation/prescription and complete the prescribed dose/course.

17.2 Recommended presentation:



ANTIBIOTIC MEDICINE

Complete the prescribed course/doses as directed. Do not stop treatment early unless advised by a healthcare professional.

17.2.1 The wording used operationally should remain consistent with the wording approved by MFDA under Annex 4.

17.3 SAMPLE ANTIBIOTIC LABEL

ANTIBIOTIC MEDICINE

Medicine: Amoxicillin

Strength: 500 mg

Dose: Take 1 capsule

Frequency: Take every 8 hours

Duration: 5 days

Route: By mouth

IMPORTANT: Use this antibiotic exactly as directed and complete the prescribed course.

Batch No.: XXXXX

Expiry: XX/XXXX

Pharmacy: XXXXX

Date Dispensed: XX/XX/XXXX

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Printing specification: RED paper + BLACK text + minimum font size 10,

17.4 ANTIBIOTICS DISPENSED AS LOOSE TABLETS

17.4.1 Where antibiotics are dispensed as loose tablets/capsules:

1. **The red antibiotic label is mandatory.**
2. Each container/package shall be clearly identified.
3. The patient shall receive clear dose and frequency instructions.
4. The duration of therapy shall be stated.
5. The batch and expiry shall remain traceable.
6. The pharmacist shall provide appropriate counselling.
7. The pharmacist should reinforce adherence and completion of the prescribed course.

17.4.2 This requirement is particularly important because antibiotic dispensing represents a significant opportunity for antimicrobial stewardship and prevention of inappropriate antibiotic use.

17.5 ANTIBIOTIC ORAL LIQUIDS

17.5.1 For antibiotic suspensions or oral liquids, the label shall additionally include:

- Dose in mL
- Frequency
- Duration
- Reconstitution instructions where applicable
- Storage after reconstitution
- Beyond-use period after reconstitution where applicable
- Requirement to shake well before use, where applicable
- Measuring device instructions

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17.5.2 The pharmacist should provide an appropriate oral syringe or measuring device where necessary.

18 STORAGE AND HANDLING INFORMATION

18.1 Where special storage requirements exist, the dispensing label shall clearly communicate them.

18.2 Examples:

- Store below 25°C
- Store in a refrigerator (2–8°C)
- Protect from light
- Protect from moisture
- Do not freeze
- Keep out of reach of children

18.3 For temperature-sensitive medicines, the pharmacist shall ensure that the patient understands the storage requirement.

19 PATIENT-SPECIFIC LABELS

19.1 For prescription medicines, the dispensing label should be patient-specific and linked to the prescription.

19.2 The label should contain:

- Patient name
- Medicine
- Strength
- Dose
- Frequency
- Duration
- Route
- Quantity
- Relevant precautions.

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19.3 A medicine should not be supplied to a patient with a label intended for another patient.

20 LABELS FOR PEDIATRIC MEDICINES

20.1 For children, the label shall be particularly clear.

20.2 Where weight-based dosing is prescribed, the dispensing process should include verification of:

- Patient age
- Patient weight where relevant
- Dose
- Concentration
- Volume per dos
- Frequency
- Duration

20.3 For liquid medicines, the label should state the dose in mL rather than relying solely on household spoon measurements.

21 LABELS FOR ELDERLY PATIENTS

21.1 For elderly patients, pharmacists should:

- Use clear and sufficiently large text
- Avoid unnecessary abbreviations
- Provide simple instructions
- Clearly identify medicines
- Separate medicines where multiple medicines are supplied
- Provide additional counselling where there is a risk of confusion

22 TRANSPORT OF DISPENSED MEDICINES

22.1 Where medicines are delivered to patients, including through authorized online medicine services:

- The dispensing label shall remain attached

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- The medicine shall be transported in a manner that protects the label
- Temperature requirements shall be maintained
- The package shall remain identifiable
- Patient confidentiality shall be maintained
- Antibiotics shall retain the red antibiotic label
- No transport packaging shall obscure the medicine label

23 LABEL INTEGRITY DURING TRANSPORT

23.1 Transporters shall not:

- Remove medicine labels
- Cover critical information
- Replace labels
- Alter expiry dates
- Alter batch numbers
- Repackage medicines without authorization

23.2 Any damaged, detached or illegible label identified during transportation shall be reported to the responsible pharmacy/importer and assessed before the medicine is supplied.

24 FINAL PHARMACIST CHECK

24.1 Before a medicine is handed to the patient, the pharmacist shall verify:

24.2 The Five Rights

1. Right patient
2. Right medicine
3. Right strength
4. Right dose/instructions
5. Right duration/quantity

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24.3 In addition, the pharmacist shall verify the label and medicine against the prescription.

Dispensing Labelling Checklist:

#	Requirement	Tick if yes
a.	Patient name corrects	☐
b.	Medicine name corrects	☐
c.	Generic name identifiable	☐
d.	Strength corrects	☐
e.	Dosage form corrects	☐
f.	Dose clearly stated	☐
g.	Frequency clearly stated	☐
h.	Duration stated	☐
i.	Route stated where necessary	☐
j.	Quantity corrects	☐
k.	Batch traceable	☐
l.	Expiry verified	☐
m.	Storage instruction provided	☐
n.	Warning/precaution provided	☐
o.	Antibiotic label applied where applicable	☐
p.	Label is legible	☐
q.	Patient counselling completed	☐

25 SPECIFIC REQUIREMENTS FOR ANTIBIOTIC DISPENSING

For every antibiotic dispensed, the pharmacist shall:

1. Verify the prescription.
2. Verify the antibiotic and strength.
3. Apply the red antibiotic label.
4. Ensure black text is used.
5. Use font size 10 or larger as required by Annex 4.
6. Clearly state dose, frequency and duration.
7. Include the antibiotic-use warning.
8. Maintain batch and expiry traceability.

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9. Counsel the patient regarding appropriate use.
10. Reinforce adherence and completion of the prescribed treatment course.
11. Explain what the patient should do if a dose is missed or an adverse reaction occurs, where appropriate.

26 RECORDKEEPING

26.1 Pharmacies shall maintain records sufficient to establish traceability between:

26.2 Manufacturer → Supplier → Importer → Batch → Pharmacy → Prescription → Patient

26.3 For medicines supplied as loose tablets or repackaged medicines, the pharmacy shall maintain sufficient records to identify:

- Original product
- Manufacturer
- Batch number
- Expiry date
- Quantity received
- Quantity dispensed
- Date dispensed
- Patient/prescription
- Responsible dispenser/pharmacist

27 NON-COMPLIANCE WITH PRODUCT LABELLING REQUIREMENTS

27.1 Examples of labelling non-compliance include:

- Missing medicine name
- Missing strength
- Incorrect instructions

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- Illegible label
- Unlabeled loose tablets
- Missing batch/expiry traceability for repackaged medicines
- Antibiotic supplied without the required red label
- Label inconsistent with prescription
- Incorrect patient information
- Obscuring the original manufacturer's information
- Altering or covering expiry/batch information
- Failure to provide required storage instructions

27.2 Such deficiencies shall be managed in accordance with applicable MFDA inspection and enforcement procedures.

28 RESPONSIBILITIES

28.1 Importer

28.1.1 The importer shall:

- Ensure imported medicines meet Clause 27 labelling requirements.
- Ensure labels are not altered or obscured.
- Maintain traceability.
- Ensure product information accompanies the medicine.
- Notify MFDA of significant labelling defects.

28.2 Warehouse

28.2.1 The warehouse shall:

- Maintain label integrity
- Protect labels from damage
- Maintain batch and expiry traceability

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- Apply appropriate shipping/transport identification
- Ensure storage conditions are maintained

28.3 Transporter

28.3.1 The transporter shall:

- Protect medicines and their labels
- Maintain required temperature conditions
- Prevent damage or contamination
- Maintain shipment traceability

28.4 Pharmacist

28.4.1 The pharmacist shall:

- Verify the prescription
- Ensure correct dispensing
- Apply appropriate patient-use labels
- Apply the red antibiotic label where required
- Ensure loose medicines remain identifiable
- Provide appropriate counselling

28.5 Pharmacy

28.5.1 The pharmacy shall:

- Maintain an approved dispensing SOP
- Maintain appropriate labelling materials
- Ensure staff competency
- Conduct periodic audits of dispensing labels
- Correct identified labelling deficiencies

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29 SUMMARY OF PRODUCT LABELLING SYSTEM

Label type	Color	Text
General dispensing label	White	Black
Antibiotic label	 RED	BLACK
Refrigerated/temperature-sensitive warning	White with prominent warning	Black
External-use warning, where required	White with prominent warning	Black
High-alert medicine warning	As specified by MFDA	Black

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ANNEX 1: Schedule 4 of Medicine Regulation R-64/2026 – Product Labelling for Medicines

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