



GUIDELINE FOR EXEMPTION FROM
**THE TWO-THIRD (2/3) REMAINING
SHELF LIFE REQUIREMENT FOR
IMPORTED MEDICAL PRODUCTS**

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1. Legal Authority



This Guideline is issued pursuant to the applicable provisions of the national pharmaceutical laws and regulations of the State of Qatar and falls under the regulatory mandate of the Pharmacy and Drug Control Department (PDCD), Ministry of Public Health.

2. Purpose



The purpose of this Guideline is to define the exceptional and controlled circumstances under which medicinal products with less than two-thirds (2/3) remaining shelf life at the time of arrival in the State of Qatar may be permitted for importation, while ensuring:

- Patient safety and product quality
- Continuity of medical care
- Rational supply chain management
- Prevention of waste and misuse

3. Scope



This guideline shall apply to:

- All licensed importers, local agents, and authorized distributors in the State of Qatar.
- All public and private healthcare institutions that import or procure medicines through official channels.
- All registered medicinal products authorized for distribution in the State of Qatar, unless otherwise specified by PDCD.

4. Definitions



For the purposes of this Guideline, the following definitions shall apply:

- 4.1. Total Shelf Life: The period between the date of manufacture and the labelled expiry date.
- 4.2. Remaining Shelf Life (RSL): The period remaining until expiry at the point of arrival in the State of Qatar.
- 4.3. Two-Thirds (2/3) Rule: The regulatory requirement that medicinal products must have at least two-thirds of their total shelf life remaining upon arrival.
- 4.4. Short-Dated Shipment: Any shipment of medicinal products with remaining shelf life of less than two-thirds (2/3) of total shelf life.
- 4.5. Exemption: A formal, written, case-specific approval issued by PDCD allowing deviation from the 2/3 rule.
- 4.6. Hospital-Controlled Outpatient Dispensing: Dispensing under hospital governance whereby only the prescribed quantity is supplied to patients using unit-dose or split packs with full traceability and appropriate labelling.

5. General Regulatory Principle



- 5.1. Importation of medicinal products that do not comply with the 2/3 remaining shelf-life requirement is prohibited, unless an exemption is formally granted by PDCD in accordance with this Guideline.
- 5.2. Exemptions shall be exceptional, justified, time-limited, and non-commercial in nature.
- 5.3. Under no circumstances shall exemptions be granted for the purpose of commercial clearance, promotional activities, or dumping of near-expiry products.

6. Eligibility Criteria for Exemption



An exemption may be considered only under one or more of the following conditions:

6.1. Critical Drug Shortage

Where a documented national or regional shortage exists for an essential medicinal product, and no suitable registered alternative is available.

Required justification shall include objective evidence such as:

- Inventory and consumption data
- Manufacturer or supplier shortage notifications
- Clinical demand forecasts

6.2. Public Health Emergencies or Government Stockpiles

During officially declared public health emergencies, pandemics, disasters, or government-mandated stockpiling initiatives requiring immediate availability of medicinal products.

6.3. Immediate Life-Saving or Urgent Therapeutic Use.

For medicinal products required for urgent or life-saving intervention where no compliant alternative is available, including but not limited to:

- Epinephrine auto-injectors
- Nitroglycerin preparations

6.4. Hospital-Specific Controlled Use (Inpatient and Outpatient)

For public or private hospitals with demonstrated capacity for controlled utilization, including:

- Data-based consumption forecasting
- Defined clinical protocols
- Robust inventory management systems

Outpatient dispensing under this category shall be restricted to unit-dose or split-pack dispensing and shall not involve full commercial retail packs.

7. Application and Approval Process



7.1. All exemption requests shall be submitted formally to PDCD by the licensed importer or healthcare institution prior to shipment arrival.

7.2. Each request shall include, at minimum:

- Product and batch details
- Total and remaining shelf life
- Justification under Section 6
- Utilization and distribution plan
- Supplier undertaking (where applicable)

- 7.3. PDCD shall review applications on a case-by-case basis and may approve, reject, or request additional information.
- 7.4. Emergency requests may be subject to expedited review at the discretion of PDCD.

8. Control and Acceptance Conditions



8.1. General Conditions

Approved short-dated shipments shall comply with the following:

- Clear utilization plan ensuring full use before expiry
- Accurate expiry labelling on all packaging levels
- Written supplier commitment to replace expired quantities or cover disposal costs

8.2. Hospital-Controlled Use

Hospitals shall demonstrate:

- Effective stock rotation systems
- Traceable dispensing records
- Compliance with internal SOPs for split-pack dispensing

9. Monitoring and Reporting



9.1. Approved entities shall submit monthly reports detailing:

- Quantities received, dispensed, and remaining
- Expiry status of each batch
- Wastage and disposal records

10. Record Retention and Audit



- 10.1. All records related to exemption approvals and utilization shall be retained for a minimum period determined by PDCD.
- 10.2. PDCD reserves the right to conduct inspections, audits, and post-approval reviews at any time.

11. Enforcement and Sanctions



- 11.1. **Any misuse, misrepresentation, or non-compliance with this Guideline may result in:**
 - Suspension or revocation of exemption approvals
 - Regulatory corrective actions
 - Enhanced inspections or audits
- 11.2. Further regulatory measures may be applied in accordance with applicable laws and regulations.

12. Effective Date and Review



- 12.1. This Guideline shall enter into force on the date of issuance.
- 12.2. PDCD may amend or review this Guideline periodically based on regulatory needs, market dynamics, and public health considerations.



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