وزارة الصحة
Ministry of Health

DSC
مركز سلامة الدواء
Drug Safety Center

Guideline on Good Storage and Distribution Practices (GSDP)

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Acronyms:

API	Active Pharmaceutical Ingredient
CAPA	Corrective and Preventive Actions
DSC	Drug Safety Center
FEFO	First Expiry/First Out
GDP	Good Distribution Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GSP	Good Storage Practices
HVAC	Heating, Ventilation, and Air Conditioning
MAH	Marketing Authorization Holder
SOP	Standard Operating Procedure
WHO	World Health Organization
QMS	Quality Management System
QRM	Quality Risk Management
SF	Substandard and Falsified

12 Definitions

Medical Products	In this guideline, medical products refer to medicines, vaccines and biological products, excluding medical devices unless otherwise specified.
Quality Management System	The organizational structure, procedures, processes, resources and systematic actions required to ensure that products and services meet quality requirements.
Quality Risk Management	A systematic process for the assessment, control, communication and review of risks to the quality of medical products in the supply chain.
Batch Number	A unique combination of numbers/letters that identifies a specific batch.
Consumer	is defined as a primary source who is not a healthcare professional. Examples include a patient, patient representative, caregiver, or relative of a patient.
corrective and preventative actions	A system for implementing corrective and preventive actions resulting from an investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings and trends from process performance and product quality monitoring.
cross-contamination	Contamination of a starting material, intermediate product or finished pharmaceutical product or medicines with another starting material or product, during production, storage and transportation
distribution	The procuring, purchasing, holding, storing, selling, supplying, importing, exporting or movement of medicines, with the exception of dispensing or providing medicines directly to a patient or his or her agent
excipient	A substance, other than the active ingredient, which has been appropriately evaluated for safety and is included in a drug delivery system, to aid in the processing of the drug delivery system during its manufacture; protect, support or enhance stability, bioavailability, or patient acceptability; assist in product identification; or enhance any other attribute of the overall safety and effectiveness of the drug during storage or use
expiry date	The date given on the individual container (usually on the label) of a medical product, up to and including the date on which the product is expected to remain within specifications if stored correctly. It is

	established for each batch by adding the shelf-life to the date of manufacture
Falsified Medical Product	Medical products that deliberately or fraudulently misrepresent their identity, composition or source.
first expiry/first out	A distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used
forwarding agent	A person or entity engaged in providing, either directly or indirectly, any service concerned with clearing and forwarding operations in any manner to any other person; this includes a consignment agent
Good Distribution Practices	Part of quality assurance that ensures the quality of medical products is maintained through adequate control during trade and distribution.
good pharmacy practice	The practice of pharmacy aimed at providing and promoting the best use of medicines and other health-care services and products by patients and members of the public. It requires that the welfare of the patient is the pharmacist's prime concern at all times
good practices	The group of good practice guides governing the preclinical, clinical, manufacture, testing, storage, distribution and post-market activities for regulated medicines, such as good laboratory practices (GLP), good clinical practices (GCP), good manufacturing practices (GMP), good pharmacy practice (GPP), good distribution practices (GDP) and other good practices.
Good Storage Practices	Part of quality assurance that ensures the quality of medical products is maintained through adequate control throughout storage.
Heating, Ventilation and Air Conditioning (HVAC)	Systems used to control heating, ventilation and air conditioning, also referred to as environmental control systems.
importation.	The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).
intermediate product	Partly processed product that must undergo further manufacturing steps before it becomes a bulk finished product
Medicine Recall	A process for removing a medicine from the distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/or concerns that the product is or may be falsified.
pedigree.	A complete record that traces the ownership of, and transactions relating to, a medicine as it is distributed through the supply chain.

production	All operations involved in the preparation of a medical product, from receipt of materials through processing, packaging and repackaging, labelling and relabeling, to completion of the finished product
quality assurance	A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that medicines are of the quality required for their intended use
quality risk management	A systematic process for the assessment, control, communication and review of risks to the quality of medicines in the supply chain
quality system	An appropriate infrastructure, encompassing the organizational structure, procedures, processes, resources and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality
Quarantine	Status of medicine physically or administratively isolated pending decision on their release or rejection.
retest date	The date when a material should be re-examined to ensure that it is still suitable for use
pharmaceutical establishment	A licensed establishment authorized to manufacture, import, export, store, distribute, sell or otherwise handle medical products in accordance with applicable legislation and regulatory requirements.
Substandard Medical Product	An authorized medical product that fails to meet either its quality standards or specifications, or both.
Returned Goods	Medical products returned after distribution from customers, health institutions, distributors or other entities.

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CHAPTER ONE

Introduction

Storage and distribution are critical activities in the supply chain management of medical products. Various stakeholders may be responsible for the handling, storage and distribution of medical products. Medical products may be exposed to different risks at various stages of the supply chain, such as purchasing, storage, repackaging, relabeling, transportation and distribution.

This document sets out steps to assist in fulfilling responsibilities at different stages of the supply chain and to prevent the introduction and proliferation of unauthorized, unregistered, substandard and falsified medical products in the market. The relevant sections should be considered in relation to the particular roles that stakeholders play in the storage and distribution of medical products.

This guideline applies to all stakeholders involved in any aspect of the storage and distribution of medical products, from the manufacturer's premises to authorized agents and to persons dispensing or supplying medical products directly to patients, where applicable. This includes all parties involved at different stages of the supply chain, such as manufacturers, medical stores, suppliers, distributors, logistics providers, transport companies, forwarding agents and their employees.

This guideline establishes the principles of Good Storage and Distribution Practices (GSDP) in accordance with WHO Technical Report Series No. 1025, Annex 7: Good Storage and Distribution Practices for Medical Products.

Legal Basis:

This guideline is issued in accordance with the Law Regulating the Practice of the Pharmacy Profession and Pharmaceutical Establishments issued by Royal Decree No. 35/2015 and its Executive Regulation issued by Ministerial Decision No. 113/2020, including Articles 34, 37 and 38, as applicable.

Purpose

The purpose of this guideline is to:

1. Establish minimum requirements for the proper storage and distribution of medical products.
2. Ensure that medical products are handled in a manner that maintains quality, safety and efficacy.
3. Define the responsibilities of the Drug Safety Center and regulated entities.

4. Promote compliance with GSP, GDP and relevant national regulatory requirements.

5. Support inspection, licensing, monitoring and enforcement activities.

6. Prevent the entry of substandard and falsified medical products into the supply chain.

7. Ensure effective systems for complaints, returns, recalls, documentation and quality risk management.

Scope

This guideline applies to all stakeholders involved in the storage and distribution of medical products. It does not cover direct dispensing to patients where such activity is governed by separate pharmacy practice requirements.

Structure

This document is structured into four chapters:

- Chapter One: Introduction, Purpose, Scope, and Structure
- Chapter Two: Procedures for storage and distribution practices
- Chapter Three: Responsibilities of key stakeholders
- Chapter Four: Document history and version control, References, Annexes, and Appendices

CHAPTER TWO

2.1 General Principles

- All entities involved in the storage and distribution of medical products shall comply with applicable legislation, regulations, licensing conditions and this guideline.
- Medical products shall be stored, handled, transported and distributed in a manner that preserves their quality, safety and integrity.
- All supply chain activities shall be performed only by authorized personnel and authorized entities.
- Medical products shall be protected from contamination, mix-ups, deterioration, damage, theft, diversion, unauthorized access and falsification.
- The Drug Safety Center may inspect storage and distribution facilities to verify compliance with GSP, GDP and national requirements.

2.2 Quality Management System

- Each regulated entity shall establish, implement and maintain a documented Quality Management System.
- The QMS shall include an approved quality policy, organizational chart, defined responsibilities, approved SOPs, quality risk management, complaint handling, return and recall procedures, deviation and CAPA system, change control, self-inspection, training, document control and supplier/customer qualification.
- Senior management shall ensure that the QMS is adequately resourced, implemented, maintained and reviewed.
- The entity shall appoint a responsible person with appropriate qualification, experience, authority and independence to oversee GSP and GDP compliance.

2.3 Quality Risk Management

- A documented risk management process shall be implemented to identify, assess, control, communicate and review risks related to storage and distribution activities.
- Risk assessment shall be based on scientific knowledge, product characteristics, storage requirements, distribution route, historical data and potential impact on patient safety.
- Risk controls shall be implemented and periodically reviewed for effectiveness.
- Risk management shall be applied to temperature-sensitive products, cold-chain distribution, returned goods, recalls, outsourced transport, supplier qualification, computerized systems, storage segregation and handling of suspected falsified products.

2.4 Management Review

- Management review shall be conducted periodically to evaluate the effectiveness of the quality system.

- The review shall include quality objectives, inspection outcomes, complaints, recalls, deviations, CAPA, temperature excursions, returns, rejected products, supplier performance, customer performance, training effectiveness and self-inspection results.
- Minutes of management review meetings shall be documented, approved and retained.

2.5 Personnel

- The entity shall have an adequate number of qualified and trained personnel.
- Personnel shall have appropriate education, experience and training relevant to their assigned duties.
- Initial and continuous training shall cover GSP, GDP, product handling, temperature control, documentation, detection of substandard and falsified products, complaint and recall procedures, hygiene, safety and security.
- Training records, attendance sheets and competency assessments shall be maintained.
- Personnel shall follow hygiene and safety requirements appropriate to the activities performed.

2.6 Premises and Storage Areas

- Premises shall be suitably located, designed, constructed, maintained and secured.
- Storage areas shall provide sufficient space, lighting, ventilation, cleanliness and segregation.
- Access to storage areas shall be restricted to authorized personnel.
- Receiving and dispatch areas should be separated where possible to prevent mix-ups.
- Premises shall be protected from insects, rodents, birds and other animals through an effective pest control programme.
- Eating, drinking and smoking shall be prohibited in areas where medicines are handled.
- Separate and clearly identified areas shall be provided for quarantined, released, rejected, returned, recalled, expired, damaged and suspected falsified products.

2.7 Storage Conditions and Temperature Control

- Storage conditions shall comply with the approved product label and manufacturer requirements.
- Temperature and humidity shall be monitored and recorded at defined intervals.
- Temperature mapping shall be performed for warehouses, storage rooms, refrigerators, freezers and cold rooms, where applicable.
- Monitoring devices shall be calibrated at defined intervals and records shall be reviewed regularly.
- Any temperature excursion shall be documented, investigated, risk-assessed and managed through CAPA.
- Products affected by temperature excursions shall remain under quarantine until a documented quality decision is made.

2.8 Receiving of Medicines

- All incoming consignments of medical products shall be received according to an approved SOP.

- Each delivery shall be checked against relevant documentation, including purchase order, supplier details, product name, batch number, expiry date, quantity, storage condition, certificate of analysis and import permit where applicable.
- Products shall be inspected for damage, contamination, tampering, broken seals, incorrect labelling, missing information and temperature deviation where applicable.
- Suspected, damaged or nonconforming products shall be quarantined and investigated.
- Cold-chain products shall be handled as a priority and transferred immediately to the required storage condition after verification.

2.9 Stock Control and Rotation

- Stock records shall be maintained in paper or electronic format and updated after each receipt, issue, return, rejection, destruction or adjustment.
- Periodic stock reconciliation shall be performed and discrepancies shall be investigated.
- The FEFO principle shall be applied.
- Products close to expiry shall be identified and managed according to approved procedures.
- Expired products shall be removed from usable stock, segregated, labelled and disposed of according to approved procedures and national requirements.

2.10 Distribution and Transport

- Medical products shall be distributed only to authorized persons or entities and according to documented procedures and valid orders.
- Distribution records shall be sufficiently detailed to allow full traceability and effective recall.
- Medical products shall be transported according to the storage conditions stated on the label or specified by the manufacturer.
- Vehicles and containers shall be suitable, clean, secure and capable of maintaining required conditions.
- Temperature-controlled transport shall be monitored, recorded and qualified where applicable.
- Transport deviations, damage, theft or suspected tampering shall be recorded, reported, investigated and managed through CAPA.

2.11 Complaints

- A written procedure shall be established for handling complaints related to product quality, packaging, storage, distribution or suspected falsification.
- All complaints shall be recorded, reviewed and investigated, and the root cause shall be identified where possible.
- The impact on other batches, products or customers shall be assessed.
- Appropriate CAPA shall be implemented.
- Product quality complaints shall be communicated to the manufacturer, MAH, supplier and Drug Safety Center, where applicable.
- Where the complaint indicates a serious quality defect or safety concern, recall action shall be considered.

2.12 Returned Goods

- Returned medical products shall be handled according to an approved written procedure and placed in quarantine immediately upon receipt.
- Returned products shall not be returned to saleable stock unless a documented assessment confirms that their quality has not been compromised.
- The assessment shall consider product nature, required storage conditions, packaging condition, product history, time elapsed since distribution, transport condition during return, evidence of tampering or damage and temperature records where applicable.
- If there is any doubt regarding product quality, the product shall not be reissued.
- Records of returned, rejected, reissued or destroyed products shall be maintained.

2.13 Recalls

- A written recall procedure shall be established and maintained to allow prompt and effective withdrawal of affected products from the market.
- Recall arrangements shall be tested periodically, at least annually.
- Recalled products shall be secured, segregated, clearly labelled, stored under appropriate conditions and prevented from re-distribution.
- Distribution records shall be readily available to support recall actions.
- Recall records shall include product name, batch number, quantity distributed, quantity recovered, customers notified, date of notification, reconciliation and final recall report.
- The Drug Safety Center shall be notified of recalls in accordance with national requirements.

2.14 Substandard and Falsified Medical Products

- The entity shall establish procedures for identifying and handling suspected substandard or falsified medical products.
- Suspected products shall be immediately segregated, secured and clearly labelled.
- Access to suspected products shall be controlled.
- The Drug Safety Center, manufacturer, MAH, supplier and other relevant authorities shall be informed as applicable.
- Suspected falsified products shall not be returned to the market.
- Investigation records and actions taken shall be documented and retained.

2.15 Documentation and Records

- All activities related to storage and distribution shall be documented.
- Documents shall be approved, controlled, reviewed, updated and protected from unauthorized changes.
- Records shall be accurate, legible, traceable, attributable, complete and readily retrievable.
- Electronic records shall be backed up according to approved procedures.
- Records shall include SOPs, training records, receiving records, dispatch records, stock records, temperature records, calibration records, cleaning records, pest control records, complaint records, return records, recall records, deviation records, CAPA records and destruction records.
- Records shall be retained for a defined period in accordance with national requirements.

2.16 Equipment and Computerized Systems

- Equipment shall be suitable for its intended use and shall be installed, qualified, calibrated, cleaned and maintained according to approved procedures.
- Computerized systems used for stock control, traceability, temperature monitoring or documentation shall be controlled and protected from unauthorized access.
- Access rights shall be defined according to user responsibilities.
- Electronic data shall be backed up and recoverable.
- Calibration and maintenance records shall be maintained.

2.17 Qualification and Validation

- Qualification and validation activities shall be performed based on documented risk assessment.
- Qualification may apply to warehouses, cold rooms, refrigerators, freezers, temperature monitoring systems, transport vehicles, HVAC systems and computerized systems.
- Qualification and validation activities shall be conducted according to approved protocols and results shall be documented in reports.
- Deviations identified during qualification or validation shall be investigated and resolved.

2.18 Outsourced Activities

- Outsourced activities related to storage, transport, distribution or handling of medicines shall be controlled through written agreements.
- The contract shall define the responsibilities of each party and include requirements for GSP and GDP compliance, product security, temperature control, training, documentation, subcontracting restrictions, deviation reporting, complaints, recalls and audit rights.
- The contract giver shall assess the contract acceptor before approval and periodically thereafter.
- Outsourced activities shall not compromise product quality or regulatory compliance.

2.19 Self-Inspection

- The entity shall establish a self-inspection programme to verify compliance with GSP, GDP, SOPs and regulatory requirements.
- Self-inspections shall be performed according to an approved annual schedule.
- Inspectors shall be independent, trained and competent.
- Self-inspection reports shall document observations, deficiencies and required corrective actions.
- CAPA shall be implemented within defined timelines and effectiveness shall be reviewed and documented.

2.20 Regulatory Inspection by Drug Safety Center

- The Drug Safety Center may conduct inspections of storage and distribution facilities according to national legislation and regulatory procedures.
- Inspections may be routine, follow-up, complaint-based, risk-based or for licensing purposes.

- Inspections may cover premises, equipment, personnel, documentation, quality system, storage conditions, distribution records, transport arrangements, complaints, returns, recalls, substandard and falsified product controls and outsourced activities.
- Inspection observations may be classified based on risk.
- The inspected entity shall submit CAPA within the timeframe specified by the Drug Safety Center.
- The inspection shall be closed after review and acceptance of CAPA, where applicable.

CHAPTER THREE

Responsibilities:

Party	Responsibilities
Drug Safety Center	Establish regulatory requirements, conduct inspections, review CAPA, monitor compliance, investigate quality issues, coordinate recall actions and take regulatory measures where required.
Senior Management of Regulated Entity	Ensure that the quality system is implemented, resourced, maintained and periodically reviewed.
Responsible Person / Quality Manager	Oversee compliance with GSP and GDP, approve procedures, manage deviations, CAPA, complaints, returns, recalls and quality risk management.
Warehouse Manager	Ensure proper receiving, storage, stock control, dispatch, segregation, cleanliness and security of medical products.
Pharmacist / Licensed Professional	Ensure compliance with legal and professional requirements related to handling, storage and distribution of medical products.
Logistics / Transport Provider	Maintain required transport conditions, ensure vehicle suitability, protect products from damage or theft and report deviations.
Personnel Handling Medical Products	Follow approved procedures, maintain hygiene, complete records accurately, report deviations and protect product integrity.
Supplier / Distributor	Supply authorized medical products, maintain traceability, provide required documentation and cooperate in complaints, returns, recalls and investigations.
Contract Acceptor	Perform outsourced activities according to written agreement, GSP, GDP and regulatory requirements.

CHAPTER FOUR

Document History and Version Control

Version	Description	Review Date
1	Initial release	Aug 2026
2		

References:

- World Health Organization. WHO Technical Report Series No. 1025, Annex 7: Good Storage and Distribution Practices for Medical Products, 2020.
- World Health Organization. WHO Good Manufacturing Practices for Pharmaceutical Products: Main Principles.
- World Health Organization. WHO Good Distribution Practices for Pharmaceutical Products.
- World Health Organization. Guide to Good Storage Practices for Pharmaceuticals.
- World Health Organization. Guidance on Good Data and Record Management Practices.
- World Health Organization. Guidelines on Quality Risk Management.
- Applicable national laws, regulations, ministerial decisions, circulars and Drug Safety Center requirements.

Annex

Appendix 1: Recommended Storage Conditions

Label Description	Recommended Limits
Store at controlled room temperature	15°C to 25°C
Store in a cold or cool place	8°C to 15°C
Store in a refrigerator	5°C ± 3°C
Store in a freezer	-20°C ± 5°C
Store in deep freezer	-70°C ± 10°C
Store in a dry place	Not more than 60% relative humidity
Protect from moisture	Not more than 60% relative humidity
Store under ambient conditions	15°C to 30°C, well-ventilated premises, not more than 60% relative humidity, protected from contamination and intense light
Protect from light	Maintain in the original manufacturer's light-resistant container
Chilled	5°C ± 3°C