Regulatory Guide for Good Storage and Distribution Practices (GSDP)

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Introduction

Mission: To protect public health by ensuring the safety, quality, efficacy, and availability of human and veterinary medicines, biological products, medical devices, pharmaceutical raw materials, and the safety of cosmetics through the implementation of a regulatory system compatible with international best practices, and by providing scientifically grounded pharmaceutical information to the public and healthcare professionals.

Distribution is one of the most critical activities in the integrated supply chain management of pharmaceutical products and medical devices. However, it is also one of the most vulnerable due to the involvement of numerous individuals and entities handling these products during storage, transport, or distribution. Consequently, it is necessary to establish requirements and foundations for good practice. The objective is to secure and guarantee the quality of pharmaceutical products and medical devices across all aspects of the storage and distribution process to ensure that safe and effective medicine reaches every patient.

Since storage and distribution involve a sequence of successive steps that cumulatively affect the quality and safety of pharmaceutical products and medical devices, appropriate measures must be defined to monitor the distribution process from the moment the pharmaceutical product or medical device leaves the factory until it reaches the patient, maintaining its quality and safety, and preventing the entry of counterfeit products into the market through the distribution chain. Various participants in the departments related to storage and distribution must be aware that the nature of the risks involved in this process is similar to those encountered in a manufacturing environment.

Falsified pharmaceutical products and medical devices pose a genuine threat to public health and safety. Therefore, it is imperative to protect the pharmaceutical supply chain from the penetration of such products. Since vulnerabilities in distribution operations serve as a conduit for the spread of counterfeit, adulterated, and illegally imported medicines into the supply chain, every active party in the distribution chain must comply with the applicable decisions and regulations in accordance with the principles of Good Manufacturing Practice (GMP), Good Storage Practice (GSP), and Good Distribution Practice (GDP) to preserve product quality.

2. Abbreviations

- **GMP:** Good Manufacturing Practice
- **GSP:** Good Storage Practice
- **GSDP:** Good Storage and Distribution Practices
- **FEFO:** First Expired, First Out
- **SOP:** Standard Operating Procedure
- **CAPA:** Corrective and Preventive Actions.

3. Scope of Application

This regulatory guide encompasses the rules of good storage and distribution practices for pharmaceutical and biological products, medical devices, cosmetics, medicinal plant extracts, disinfectants, insecticides, and raw materials used in the manufacturing of any of the aforementioned products. These fall under the jurisdiction of the Egyptian Drug Authority in accordance with its establishment law, its executive regulations, and the decisions and regulatory guides issued in this regard, pursuant to the laws in force, active decrees, and the Good Storage and Distribution guide issued by the World Health Organization and its updates.

Upon fulfilment of the requirements and compliance with the criteria stipulated in this regulatory guide, the Egyptian Drug Authority shall grant the pharmaceutical facility (store/warehouse) a certificate stating that the store or warehouse complies with the standards and requirements of Good Storage and Distribution Practices (GSDP) set forth herein. The facility shall remain subject to inspection according to a risk-assessment-based inspection plan conducted by the Authority's inspectors to ensure continuous compliance with the standards.

4. Definitions

- **Pharmaceutical Products:** Any product or preparation containing a substance or a combination of substances used for treatment, prevention, or diagnosis in humans or animals, or described as having another medical effect, or aimed at restoring, correcting, or modifying physiological functions through a pharmacological, immunological, or metabolic effect on public health, according to applicable references and standards, as well as any products or substances that may be introduced according to scientific developments and/or international standards and references.
- **Medical Device:** Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent, software, material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
    - Diagnosis, prevention, monitoring, treatment, or alleviation of disease.
    - Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury.
    - Investigation, replacement, modification, or support of the anatomy or of a physiological process.
    - Supporting or sustaining life.
    - Control of conception.
    - Disinfection of medical devices.
    - Providing information by means of in vitro examination of specimens derived from the human body.
    - Provided that its primary intended action is not achieved by pharmacological, immunological, or metabolic means in or on the human body, but which may be

assisted in its intended function by such means.

- **Biological Products:** Products containing one or more active substances produced or extracted from a biological source, including but not limited to: human vaccines, sera, blood and plasma products and derivatives, as well as products manufactured using biotechnology and similar technologies, and any products or substances that may be introduced according to scientific developments and/or international standards and references.
- **Plasma Derivatives:** Biological products derived from human blood plasma components, including, for example, albumin, clotting factors, and other plasma derivatives.
- **Raw Materials:** Active or inactive substances used in the manufacturing of pharmaceutical products and medical devices subject to the provisions of this law, excluding materials used in packaging.
- **Cosmetics:** Products intended to be placed in contact with the external parts of the human body, teeth, or the mucous membranes of the oral cavity, for the purpose of cleaning, perfuming, protecting, keeping them in good condition, or changing and improving their appearance, or any other products that exist or are introduced and classified as cosmetics according to international references.
- **Medicinal Plant Extracts:** Plants containing one or more medicinal substances capable of treating a specific disease or reducing its incidence or containing the primary raw materials used in preparing medicinal substances.
- **Disinfectants:** Products or formulations containing substances with antiseptic properties and having no therapeutic purposes, taking into account the classifications contained in international references.
- **Insecticides:** Substances or products intended to control insects that pose a threat to public health, either by killing them, inhibiting their growth, or repelling them.
- **Circulation of Pharmaceutical Products and Medical Devices:** Any process or processes involving the production, distribution, possession, offering, exposing for sale, storage, use, preservation, packaging, transport, delivery, import, or export of pharmaceutical products and medical devices subject to the provisions of this law.
- **Product Sampling:** The process by which a product is removed from the supply chain, during which the consumer or user is advised to take appropriate action.

5.Guidelines of the World Health Organization Adopted as Egyptian Rules

1. Premises

1.1 General Requirements:

1. Premises should be located in a suitable site and designed appropriately for storage

operations to ensure process quality and ease of traceability, such as receiving, storing, picking, packaging, and dispatching products subject to this guide, and they should be periodically maintained and documented.

2. Appropriate controls and separation should be provided for products requiring special handling or storage conditions, such as, but not limited to, sera and vaccines.
3. Receiving and dispatch areas should be separate to avoid mix-ups wherever possible, and activities related to receiving and dispatch should be conducted in accordance with authorized procedures.
4. Premises must be kept clean, floors must be easy to clean, and cleaning equipment and agents must not become potential sources of contamination.
5. Premises must be protected against the entry of birds, rodents, insects, and other animals, and a rodent and pest control program must be in place.
6. Toilets and washing area must be separated from areas where these products are handled.
7. Eating, drinking, and smoking must be prohibited in all areas where products subject to this guide are stored or handled.
8. The building must be well-insulated thermally and hydraulically, well-ventilated, and provided with a permanent, stable, and independent source of electricity, as well as a separate water supply and independent drainage if a restroom is present.
9. The Authority must be notified prior to conducting any renovation, modification, or expansion works in the storage areas, detailing the proposed works, the estimated duration for completion, and the precautionary measures taken to ensure that the products are not affected. No renovation, modification, or expansion works may commence until approval is obtained from the competent department of the Egyptian Drug Authority.
10. Storage premises should be divided into:
    - a- A receiving and delivery area separate from the storage area in a manner that prevents external elements from entering the storage area during receipt and delivery. It should be equipped to receive and clean containers of products subject to this guide (if necessary) before storage.
    - b- A storage area equipped with shelves and designated storage spaces.
    - c- A Separate & segregated quarantine area for damaged or expired products.
    - d- A Separate area for returned products.
    - e- A Separate & segregated area for recalled products.
    - f- A dedicated area for storing products requiring low temperatures; if cold rooms are present, they must be calibrated and temperature-mapped.
    - g- A separate area for storing certain pharmaceutical raw materials that require separate storage from other raw materials, such as antibiotics.

1.2 Special Requirements for the Receiving and Delivery Area:

1. Every incoming delivery must be verified by matching it with the relevant documentation to ensure that the correct product is delivered from the correct supplier. This includes, but is not limited to, the purchase order, product name, batch number, production date,

expiration date, quantity, and ensuring the integrity and cleanliness of containers before storage.
2. Receiving and delivery areas should be of sufficient capacity for their designated purpose.
3. The recipient must review the transport temperature data upon receipt or download the data from temperature monitoring devices accompanying the pharmaceutical or biological product during shipment, if present, to ensure that the specific storage conditions for each product, as written on the packaging, have been maintained.
4. Necessary measures must be taken to ensure that rejected, recalled, or falsified products do not enter the storage area, ensuring their separation and secure storage in their designated areas while awaiting destruction or return to the supplier through a clear mechanism.

1.3 Special Requirements for the Storage Area:

1. Necessary precautions must be taken to prevent unauthorized persons from entering storage areas, and authorized personnel must adhere to facility policies to maintain a sound, safe, and effective working environment.
2. Adequate lighting must be provided in storage areas to perform all tasks accurately and safely.
3. Calibrated electronic devices must be provided to measure temperature and humidity in storage areas, refrigerators, and freezers. Alarms must be provided in refrigerators and freezers used for storing medical products, these alarms shall operate when the temperature rises or falls beyond the permitted limit by emitting an audible or visual alarm or sending a text message to the designated person.
4. Storage areas must be of sufficient capacity to allow for the orderly storage of various categories of medical products.
5. Storage areas must be maintained within the accepted and specified temperature limits. If special storage conditions (such as temperature and relative humidity) are required on labels, they must be provided, monitored, and recorded.
6. Medical materials and products must be stored off the floor, away from walls and ceilings, protected from direct sunlight, and distributed at appropriate distances to allow for ventilation, cleaning, and inspection. Suitable pallets must be used and maintained in a good state of cleanliness and repair.
7. There must be a written sanitation program detailing the frequency of cleaning and the methods used to clean the premises and storage areas.
8. Appropriate procedures must be in place to clean up any spillage to ensure the complete removal of any risk of contamination.

1.4 Good Storage Practices:

1. Temperature and relative humidity mapping studies (Temperature Mapping) must be conducted, and calibrated temperature and humidity measuring devices must be distributed at different locations and heights according to the approved temperature map (Temperature Mapping), which identifies areas most likely to experience temperature fluctuations. Devices in these areas must record readings for a period of no less than one year in records to be presented to the Authority upon request. In the event of serious temperature or humidity issues being detected, the Authority must be notified, any updates shall be presented to EDA, and any circulation activities must be suspended in the affected area until evaluation by the Egyptian Drug Authority.
2. All devices used to measure temperature and humidity in storage areas, refrigerators, and freezers must be periodically calibrated, with proof of calibration available.
3. Products must be stored in areas off the floor, away from walls and ceilings, and the distance between the ceiling and the maximum storage height must not be less than 60 cm. They must be protected from direct sunlight and adequately spaced to allow for ventilation, cleaning, and inspection. Suitable pallets must be used and maintained in a good state of cleanliness and repair.
4. Products must be stored under conditions that ensure the maintenance of their quality, thereby guaranteeing appropriate stock rotation based on the First Expired, First Out (FEFO) principle.
5. Broken, damaged, or expired items must be withdrawn from usable stock and separated according to approved written procedures for handling damaged or expired products. They must be transferred directly to their designated isolated areas, accessible only to authorized persons, and damaged or broken quantities must be recorded in logs. An application for destruction must be submitted to the Egyptian Drug Authority. Damaged or expired medical products shall not be retained for a period exceeding one year from the date the damage was noted or the expiration date.
6. There must be a written fire control procedure, including fire prevention, fire detection, the presence of detection and firefighting equipment, and training of personnel

2. Quality Management

There should be a comprehensively designed, documented, and properly implemented quality system that incorporates principles of GSP, GDP and quality risk management and management review.
The quality system should ensure the following:

- Adoption and application of the GSDP system to ensure that the quality of medical products is maintained throughout their shelf-life in the supply chain.
- Medical products are purchased, stored, distributed, and delivered appropriately in accordance with laws and ministerial decrees to recipients authorized to handle medical products.

- All operations must have their own clear and defined Standard Operating Procedures (SOPs), which ensure that the product or service provided and all related documentation meet the approved quality requirements.
- Responsibilities are clearly defined in job descriptions.
- All risks are identified and necessary and effective controls are implemented to avoid them.
- Necessary measures are in place to ensure the management of outsourced activities.
- There is a procedure for internal inspection and quality audit.
- A quality risk management system is in place.
- Systems for managing complaints and recalls exist.
- Systems for managing changes, deviations, and Corrective and Preventive Actions (CAPAs) are established.

2.3 The facility is advised to obtain quality-related certificates from international organizations, such as ISO certification, but these certificates are not considered a substitute for working with the Good Storage Distribution Practices (GSDP) principles.

2.4 Potential risks to the quality and safety of pharmaceutical products should be assessed, and the quality system should be periodically developed and updated to confront new risks that may arise through the risk tracking process.

3. Quality Risk Management

1. There should be a system for assessing, controlling, communicating, and reviewing identified risks across all stages of the supply chain.
2. Risk assessment should be based on scientific knowledge and experience and ultimately link to ensuring the efficacy and safety of the product.
3. Appropriate controls must be developed and implemented to confront all risks, and the effectiveness of the implemented controls should be evaluated at periodic intervals.

4. Management Review

1. There should be a system for periodic management review, and the review must involve senior management.
2. Review of the quality system and its effectiveness using quality metrics and key performance indicators (KPIs) through an approved review system.
3. Identification of opportunities for continuous improvement.
4. Follow-up on recommendations issued from previous management review meetings.
5. Minutes and relevant documentation from management review meetings must be available.

5. Qualification and Validation

Qualification and validation of equipment, instruments, processes, and procedures shall be carried out by following the organized procedures and protocols detailed by the store or warehouse for that purpose, using documented risk assessment principles (Risk Assessment), and recording results in approved reports. Investigations must be conducted in the event of any deviation.

6. Personnel

1. There should be a sufficient number of personnel possessing the appropriate educational qualifications, experience, and training in relation to the activities performed, and the specific authority and responsibility assigned to them to ensure the implementation and maintenance of the quality management system.
2. Personnel should receive initial and continuous training in accordance with a training program. The training must cover GSDP requirements, with records maintained for all trainings, attendance, and evaluations.
3. Personnel handling hazardous products, as well as products involving special risks of misuse or reuse, should be given special training.

7. Equipment

1. Equipment, including computer systems, must be suitable for their intended use. All equipment must be appropriately designed, located, installed, qualified, and maintained, and computer systems must be capable of achieving the desired outputs and results.
2. When using any electronic means for any of the steps, specific procedures and appropriate systems must be established to ensure traceability and confidence in the supply chain and the products concerned. These steps should only be carried out by authorized persons, in accordance with specified and authorized rules, and only after the approval of the Authority.

8. Documentation

1. Documentation includes all procedures, records, and data, whether paper or electronic. Documents must be appropriately designed, completed, reviewed, authorized, used, distributed, and retained as required, and documentation must be readily available.
2. The facility responsible for the distribution and storage of products subject to this guide must provide its own stamp(s), and it shall not be used until an official notification containing a copy of the stamp is submitted to the Authority.
3. Written procedures must be followed for the preparation, review, approval, use, and control of all documents related to the policies and activities of the storage and distribution process for products subject to this guide.

4. Documents must be placed in an organized manner that is easy to complete, review, and verify. The title, scope, objective, and purpose of each document must be clear. All documents must be completed, signed, and dated as required by the authorized person(s) and must not be altered without necessary authorization.
5. Documents must be prepared and maintained in accordance with the regulatory laws and ministerial decrees and the principles of Good Documentation Practices.
6. Records must be accurate, legible, and traceable. Electronic data must be backed up according to written procedures, and records of backups and data restoration must be maintained.
7. Procedures for identifying, collecting, indexing, retrieving, storing, maintaining, disposing of, and accessing all applicable documents must be followed.
8. All records must be stored and retained using facilities that prevent unauthorized access, modification, damage, and/or loss of documents throughout the entire record lifecycle, and records must be easily retrievable.
9. Comprehensive records must be maintained for all purchase invoices, sales invoices, and transfers.
10. Special records must be provided for medical products that require special storage and transport needs and warnings.
11. A mechanism must be provided allowing the exchange of quality information and regulatory procedures between the manufacturer and the customer, such as the agent or authorized distributor, and also provided to the Authority upon request.

9. Complaints

1. There must be Standard Operating Procedures (SOPs) for handling complaints. A distinction must be made between complaints related to the quality of the product or its packaging and those related to distribution. In the case of a complaint related to the quality of the product or its packaging, the manufacturer, agent, or authorized distributor must be notified within a specific time mentioned in the SOP for complaints.
2. All complaints must be recorded and appropriately investigated. The root cause and risk assessment must be determined, and appropriate Corrective and Preventive Actions (CAPAs) taken in accordance with the complaint work instructions.
3. If the complaint is related to distribution, the extent of its impact on other batches of the same product or other products must be studied, and appropriate CAPAs taken.
4. Information must be shared with the Authority immediately upon receipt of the complaint, and information must be shared with the manufacturer or importer of the product subject to the complaint without delay.
5. All complaints regarding defective or falsified products must be handled thoroughly according to written and approved procedures detailing how to deal with them.
6. Follow-up must be conducted after the investigation and evaluation of the complaint.

Issues related to product quality or suspected falsification must be documented and escalated to the Authority, and investigation results shared with the relevant parties of the submitted complaint.

10. Returned Goods

1. There must be approved Standard Operating Procedures (SOPs) for handling returned products subject to this guide. This must be established in the contracts concluded between the product owner and the distributor, stating that medical products must be recalled or replaced by the product owner if necessary.
2. All parties, including the agent, distributor, or pharmaceutical facility, are responsible for ensuring the safety of the return process and defining procedures for accepting returns in a manner that does not allow falsified or counterfeit products to enter the supply chain.
3. All returned products subject to this guide must be placed in quarantine upon receipt, and the status of the goods must be clear, taking precautions to prevent access to them or their distribution until a decision is made regarding their disposition.
4. Special storage conditions applicable to these products must be maintained until disposal. Regarding products that require specific storage conditions such as temperature and humidity, they shall not be redistributed unless their previous storage conditions during handling within the distribution chain have been verified.
5. When handling returned goods, at least the following considerations must be taken into account:
    - A risk-assessment-based process must be followed when deciding the fate of returned goods, which includes, but is not limited to: the nature of the product or medical device, the time interval since distribution, the mode of transport, its condition during return, any special storage conditions it requires, its condition upon return, the expiration date of the returned products, or the time elapsed since its release.
    - Returned goods must be inspected and evaluated by qualified and experienced persons.
    - When any doubt arises about the quality of the medical product, it should not be considered suitable for release or reuse.
6. Returned pharmaceutical products, medical devices, and raw materials must be destroyed unless it is confirmed, following evaluation, that their quality is satisfactory.
7. Records of all returned, rejected, and damaged medical products must be retained for a specified period according to the control of records for each process, and any action taken must be appropriately recorded.

11. Recalls

1. A clear and effective mechanism must be established including written and approved Standard Operating Procedures (SOPs) for recalling the products subjected to this guide for which a Detention and Seizure Order or recommendations have been issued by the Egyptian Drug Authority to perform a recall, or instructions from the product owner company. These procedures must comply with the "Guide on Recall and Rapid Alert System for Medicinal Products" issued by the Egyptian Drug Authority, detailing the persons designated for the recall task, as well as the timeline of the mechanism and its target, considering the supplied quantity, distribution locations, nature of products, time interval since distribution, and the time elapsed since its release.
2. It is required to include a clause in any concluded contracts detailing the recall mechanism and the extent of each party's commitment and responsibility to execute the recall. Procedures must be periodically updated and reviewed as necessary.
3. Regulations must be reinforced with secure and transparent systems to track medical products at all stages of the supply and distribution chain, and there must be written procedures to ensure the tracking process of incoming and distributed products to facilitate the products recall process.
4. Recalled products must be kept in a secure, locked, and isolated area awaiting appropriate action by the company owning the product under the supervision and approval of the Egyptian Drug Authority.
5. Recalled products must be isolated during transport and clearly labelled, accompanied by the necessary documentation indicating that they are recalled products.
6. All records, including distribution records, must be accessible to the persons responsible for recall operations as well as the Egyptian Drug Authority's inspectors.
7. The statement of recalled quantities must be updated daily, provided to the Authority, and a final report containing the reconciliation between delivered and recalled quantities of pharmaceutical products and medical devices must be issued and submitted to the Authority.
8. Provide work procedures for emergency recall when necessary.

12. Stock Control and Rotation

1. Records of stock levels for all products subject to this guide must be maintained for an appropriate period, either in paper or electronic form. These records must be updated after each operation (e.g., entries, issues, losses, adjustments).
2. Periodic stock reconciliation must be conducted at specified time intervals by comparing actual and recorded stock.
3. The root cause of stock discrepancies must be determined, and appropriate CAPAs taken to prevent recurrence.
4. All stock must be checked at regular intervals to identify items approaching their expiration date or retest date through an approved written Standard Operating Procedure.

Appropriate actions, such as removing these items from usable stock, must be taken.

13. Activities and Operations

13.1 All activities and operations must be conducted in accordance with GDP-GSP principles and all associated updates, and implemented according to written and approved procedures that comply with the recommendations contained in this guide.

13.2 Receipt:

1. The products covered by this guideline shall be procured only from suppliers licensed by the Egyptian Drug Authority to distribute such products
2. Receipt must be conducted according to an approved model prepared for that purpose, including all points to be reviewed during receipt, such as, but not limited to: incoming shipping conditions, product name, expiration dates, batch numbers, quantity of each batch, visual inspection of packaging, and other relevant aspects such as the availability of a certificate of analysis when applicable.
3. Packages that do not meet the acceptance criteria at the time of receipt must be identified, kept separate, and investigated; this includes products suspected of adulteration.
4. Products must not be received after their expiration date.

13.3 Storage:

1. Appropriate controls must be implemented to prevent contamination and/or mix-ups during storage.
2. Controls and procedures must be established to prevent spillage, breakage, handling thereof, misappropriation, and theft.
3. Products requiring specific storage conditions must be processed without delay and stored according to their requirements.
4. Each product must be stored according to the requirements stated on its packaging, and goods must be protected from direct sun exposure during storage, transport, and distribution.
5. Storage must be conducted under appropriate lighting conditions to prevent any errors or mix-ups between products.
6. A secure, designated area accessible only to authorized persons must be provided for non-compliant and/or expired products, accompanied by an approved and updated statement containing the product names, quantities, batch numbers, date of entry, and their specific status.

13.4 Distribution:

1. The distribution process must be conducted according to approved and detailed procedures at the store.
2. Pharmaceutical products, medical devices, and pharmaceutical raw materials must be sold and/or distributed to persons or entities licensed to obtain these products in accordance with the regulatory laws and ministerial decrees and the licenses issued to them.
3. The activity license issued by the Egyptian Drug Authority to the entity requesting the products shall be an essential requirement for the coding process.
4. A file must be created for each customer containing the store license and a copy of their approved stamps, and the documentation must be available.
5. Dispatch and transport must only take place after receiving a documented order, detailing all means through which the request can be made and how it is documented, and establishing necessary precautions to prevent any transgressions or the creation of false orders.
6. Sales invoices must not violate regulatory laws and decrees, and must include information such as, but not limited to:
    - Date.
    - Full name and address of the pharmaceutical facility (without abbreviations).
    - Description of the products, including, for example, the name, dosage form, strength (if applicable), and quantity.
    - A unique number to allow identification of the delivery order.
    - Batch number and expiration date (to facilitate tracking).
    - A box indicating the person responsible for receipt, as well as a space for the stamp, which must be matched with the approved stamp; delivery must be rejected in case of non-matching.
7. Pharmaceutical products, medical devices, and pharmaceutical raw materials must not be supplied after their expiration date.

13.5 Transport:

1. Means of transport must be suitable for their purpose, such as using the cold chain for degradable and temperature-sensitive products, with sufficient space appropriately equipped to protect products subject to this guide and protect them from direct sun exposure.
2. Transport of products subjected to this guide must be conducted according to the conditions stated on the labels and specified by the manufacturer.
3. Means of transport must be loaded carefully and systematically on a Last-In/First-Out (LIFO) basis to save time during unloading, prevent physical damage, and minimize security risks. Extreme care must be taken during loading and unloading of cartons to

avoid damage.

4. Means of transport and equipment dedicated to products subject to this guide must be used. In the event of using vehicles and equipment not dedicated for this purpose, necessary measures and steps must be taken to achieve the required transport and storage conditions, providing evidence thereof to ensure the quality and safety of the products.
5. Defective means of transport and equipment must not be used and must be labelled as such or removed from service. In the case of contracting with specialized transport companies, the company and its equipment must comply with the requirements of this guide, and a contract or agreement must be written stating that necessary precautions and procedures shall be taken to ensure the protection and preservation of medical products, including the retention of records and documentation.
6. There must be applied and approved procedures for the operation and maintenance of all vehicles and equipment according to a verified stated schedule.
7. Equipment and materials used to clean means of transport must not become a source of contamination or have a negative impact on products quality.
8. Appropriate environmental conditions must be maintained, monitored, and recorded, with all monitoring records retained for a specified period, and monitoring data records made available for inspection.
9. Instruments used to monitor conditions, for example, temperature and humidity inside means of transport, must be calibrated at regular intervals.
10. Transport of products containing hazardous substances must be in secure, appropriately designed, and secured means of transport.
11. Spillages must be cleaned up as quickly as possible to prevent potential contamination, cross-contamination, and hazards. Written procedures must be in place to handle such events.
12. Damage to containers and any other event or problem occurring during transport must be recorded.
13. Written procedures must be established to investigate and handle any deviation in compliance with storage requirements, for example, temperature deviations during transport, by the person or entity responsible for transport. Accordingly, the supplier, distributor, and recipient must be notified in cases where the recipient notices the deviation, and the notification must include the duration of the deviation and the highest and lowest temperatures recorded.
14. Products in transit must be accompanied by appropriate documentation.
15. Drivers of transport vehicles must be identified and provide appropriate documentation proving they are authorized to transport pharmaceutical products and medical devices.

14. Outsourced Activities

The store and warehouse must have a system that ensures the quality of activities performed

through external contracted parties and record those activities in compliance with good storage and distribution requirements.

15. Internal Audit

1. The quality system of the storage site or warehouse must include internal audit operations, verifying that work instructions are implemented, effective, and comply with the principles and foundations of Good Storage and Distribution Practices (GSDP).
2. Internal audits must be conducted periodically according to an annual schedule.
3. The team conducting the inspection must be free from bias, and members must possess appropriate knowledge and experience.
4. The results of all internal audits must be recorded, and reports must contain all observations detected during the inspection and be presented to the relevant personnel and management.
5. Necessary Corrective and Preventive Actions (CAPAs) must be taken, and their implementation reviewed and effectiveness monitored within a specified timeframe.

16. Substandard and Falsified Products

1. The quality system must include procedures to assist in identifying and handling medical products, whether by visual inspection or by referencing the manufacturing or importing company and dealing with products suspected of being substandard or falsified.
2. Falsified medical products detected within the distribution or storage chain must be stored in a secure area separate from the rest of the products and clearly labelled "Not for Sale," with the sale or distribution of medical products suspected of being falsified suspended.
3. The Authority must be notified directly without delay, providing all documents indicating the product, such as purchase invoices, storage conditions, and any documents requested by the Authority that can be used to track it throughout the distribution stages.
4. An official declaration must be submitted in the presence of falsified medical products, with a pledge that they shall not return to the market.

17. Cold Chain for Sera and Vaccines

17.1 Appropriate conditions must be provided for biological products during storage, maintaining the conditions as written on the packaging (or as described by the product owner company) during storage.

Description on Packaging	Recommended Limits for Storage Conditions
Store at room temperature	Not exceeding 30°C

Description on Packaging	Recommended Limits for Storage Conditions
Store in a cool place	From 8°C to 15°C
Store in a refrigerator	5°C ± 3°C (2°C to 8°C)
Store in a freezer	-20°C ± 5°C
Store in a deep freezer	-70°C ± 10°C
Store in a dry place	Relative humidity not exceeding 65%
Protect from moisture	Relative humidity not exceeding 65%
Store in ambient conditions	Well-ventilated place - temperatures ranging between 15°C to 30°C - relative humidity not exceeding 65%
Keep away from light	To be kept stored in the specific container provided by the manufacturer to protect from light and preserve the product.

17.2 Regarding verification of the proper cold chain for sera and vaccines, reference shall be made to the latest editions of the World Health Organization guidelines and relevant international references.

6. Inspection of Storage and Distribution Facilities/ Institutions

1. Egyptian Drug Authority inspectors shall inspect storage and distribution institutions/facilities based on a periodic risk-based inspection plan, which is grounded on several elements, including but not limited to: the importance of the products under storage and distribution, the size of the store, the volume of transactions, and the extent of the store's compliance with good storage and distribution practices according to previous reports.
2. Inspections may be either periodic or non-periodic to verify a complaint, track a recall process, investigate quality defects, address previous non-compliance with good storage requirements, or investigate suspected falsified products.
3. Storage and distribution institutions/facilities must be inspected by Egyptian Drug Authority inspectors based on a periodic risk-based inspection plan that considers several elements, such as the importance of the medicines and products stored and distributed, the size of the store and its transaction volume, as well as the extent of the store's compliance with good storage and distribution specifications in previous reports.
4. The inspection committee evaluates the store's status regarding its compliance with good

storage and distribution requirements, prepares a report, and submits it to the entity subject to inspection within a specified period from the final day of the inspection, provided that observations are classified based on risk assessment.

5. The Authority's inspectors have the right to draw random samples of pharmaceutical products, medical devices, and raw materials for analysis in the Egyptian Drug Authority laboratories to ensure compliance with specifications in the event of violations necessitating such action.
6. Inspections must cover premises, equipment, personnel, the quality system, and other relevant aspects as specified in this guide.
7. Corrective and Preventive Actions (CAPA) for the listed observations must be submitted for review by inspectors within the specified period in the inspection report.
8. Egyptian Drug Authority inspectors review the corrective plan and the evidence attached to it regarding the actions proposed by the facility and those responsible for implementation, evaluating its validity to eliminate the observations recorded during the inspection. In the event that the corrective plan is rejected, the facility's officials shall be contacted to submit another corrective plan.
9. Egyptian Drug Authority inspectors follow up on the corrective plan (Follow-up), review the Corrective and Preventive Actions (CAPA) submitted by the store, and monitor their implementation.
10. In the event of detecting violations that may affect the quality and safety of products subject to this guide, which could affect the health of the Egyptian patient, immediate action must be taken, and the matter raised to the Head of the Central Administration of Inspection on Pharmaceutical Institutions, taking the appropriate measure until the necessary corrective actions are fulfilled.
11. A facility/institution is considered non-compliant in the following cases:
    1. Detection of a critical observation (violations resulting in harm to the user).
    2. Detection of more than five major violations (a severe deviation from good storage requirements or violations leading to the circulation of products non-compliant with registration requirements or non-compliant with circulation permit requirements).
    3. Refusal to submit the corrective plan for previously recorded deficiencies after submitting two unacceptable corrective plans. Legal and regulatory measures shall be taken against the non-compliant facility/institution.

Procedures for Applying for GSDP Certification to Comply with Good Distribution and Storage Practices

7.Procedures for Applying for GSDP Certification to Comply with Good Distribution and Storage Practices

First: Definition of GSDP Certificate

It is a document granted by the Egyptian Drug Authority to licensed stores or warehouses after they fulfil the standards and requirements contained in the regulatory guide.

Second: Validity Period of the Certificate

The Egyptian Drug Authority grants a certificate of compliance of stores or warehouses with Good Storage and Distribution Practices (GSDP). It remains valid until the date of the next periodic inspection, provided that the stores and warehouses do not violate good storage and distribution practices.

Third: How to Apply for the Certificate from the Egyptian Drug Authority

1. The owner of the store or warehouse, or their authorized representative, shall submit an official request to the Egyptian Drug Authority, represented by the Central Administration of Inspection on Pharmaceutical Institutions, to obtain the GSDP compliance certificate.
2. The competent entity within the Central Administration of Inspection on Pharmaceutical Institutions evaluates the periodic inspection report/corrective plan of the store or warehouse and determines the extent of its compliance with what is stated in the regulatory guide. Based on this evaluation, the following occurs:
    - **a- In case of compliance of the store or warehouse with the requirements:** The certificate is granted within 10 working days from the date of submitting the request.
    - **b- In the presence of observations requiring first the submission and evaluation of a CAPA plan:** The store is given a grace period of one month from receiving the final inspection report to submit a CAPA plan, which is evaluated by the Egyptian Drug Authority inspectors.

Fourth: Cases in Which the GSDP Certificate is Suspended:

1. In the event that the store is considered non-compliant according to item 6.11, the Head of the Central Administration of Inspection on Pharmaceutical Institutions has the right to suspend the Good Storage and Distribution Practices certificate granted to any of the stores or warehouses, based on a technical memorandum submitted to him/her by the General Manager of the General Administration of Factories Inspection, in cases of:

    (a) Recording a critical observation(s) (violations resulting in harm to the user).

    (b) Recording more than five major observations (a severe deviation from good storage requirements or violations leading to the circulation of products non-compliant with registration requirements or non-compliant with circulation permit requirements).

    (c) Refusal to submit the CAPA plan for previously recorded deficiencies or submitting 2 unacceptable CAPA plan. The Head of the aforementioned Central

Administration may, as an alternative to cancelling the certificate, evaluate the situation of the store or warehouse subject to the violations, and develop the necessary and appropriate recommendations to correct the status of the store or warehouse and correct the recorded violations, provided that the store or warehouse commits to implementing them within a specified period.

(d) The issuance of an administrative closure decision for the store.

2. The certificate is suspended in case of the closure of the store or warehouse, its relocation, demolition, or change of activity, as it is a certificate linked to the store or warehouse that was subjected to evaluation.

8. References

1. Pharmacy Profession Practice Law No. 127 of 1955.
2. Egyptian Drug Authority Establishment Law No. 151 of 2019.
3. Prime Minister Decree No. 777 of 2020.
4. Head of the Authority Decree No. 121 of 2022 regarding the adoption of the World Health Organization guidelines for good storage and distribution practices.
5. Ministerial Decree No. 25 of 2009 regarding the requirements for licensing pharmaceutical stores.
6. Ministerial Decree No. 499 of 2012 regarding the determination of profit margins.
7. Ministerial Decree No. 725 of 2024 regarding store licensing procedures and necessary requirements.
8. WHO TRS 1025 Annex 7 for good storage and distribution practices.
9. Manual for benchmarking of national regulatory system of medical products and formulation of institutional development plans. (Version 1, February 2021 WHO document).
10. ISO 22716:2007 guidelines for production, control, storage & shipment of cosmetic products.
11. Ministerial Decree No. 725 of 2024 outlines the procedures and requirements for licensing pharmaceutical warehouses in Egypt

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