الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Guideline of Good Storage and Distribution Practices (GSDP)

Version No 1.2

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Drug Sector
Saudi Food and Drug Authority

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www.sfda.gov.sa

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Saudi Food and Drug Authority
Vision and Mission

Vision

To be a globally leading authority based on scientific principles to enhance and safeguard public health.

Mission

To protect the community through effective legislation and regulatory system to ensure the safety of food, drugs, medical devices, cosmetics, pesticides, and feed products.

Documentation

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Introduction:

The storage and distribution phase of pharmaceuticals and cosmetics is an important stage that the product goes through from production to reaching the consumer, involving many entities starting from manufacturers, through warehouses and sales outlets, and ending with the consumer.

Good distribution and storage practices that are based on scientific principles. Will maintain the safety of pharmaceuticals and cosmetics, As well as ensure the stability of these products and their effectiveness over time.

Therefore, Global health authorities are keen to establish legislation and regulations for controlling the handling of pharmaceuticals and cosmetics, including emphasizing good practices in distribution and storage.

This guideline is intended to inform all those involved in the field of good distribution and storage with the appropriate steps to help fulfill responsibilities related to the various aspects of distribution, storage, and transportation operations, and to avoid the access of counterfeit products into the market through the distribution chain.

To maintain the quality and safety of pharmaceuticals and cosmetics, every party involved in any stage of the distribution, storage, and transportation of these pharmaceuticals and cosmetics must comply with the applicable legislation and regulations approved by the Saudi Food and Drug Authority.

This guideline emphasizes that every activity in the distribution, storage, and transportation of pharmaceuticals and cosmetics should be in line with the principles and foundations of Good Manufacturing Practice and the principles and foundations of Good Distribution and Storage Practice.

Guideline Scope:

This Guideline covers the principles of distributing, storing, and transporting for different kinds of pharmaceuticals, whether for they were for human or veterinary use. In addition, it covers the principles of distributing, storing, and transporting of active substances, excipients, and cosmetic products.

Definitions:

The following definitions specify the words and phrases used in this Guideline, which considered as standard definitions, although they may have different meanings in other contexts or documents.

- **The Authority:**

  The Saudi Food and Drug Authority.

- **Personnel:**

  They are staff working in the field of storage, distribution, and transportation who are familiar with the supervisory, regulatory aspects as well as having the knowledge and experience which are required by the Regulations and laws, while obtaining suitable professional and technical qualifications for the assigned tasks.

- **Pharmaceutical Product:**

  Any product manufactured pharmaceutically containing one or more substances used, whether externally or internally, in the treatment and diagnosis of human or animal diseases, and includes products that are dispensed by prescription or over-the-counter, as well as herbal and health products.

- **Cosmetic Product:**

  Any cosmetic product containing one or more substances intended for use on the external parts of the human body, including the skin, hair, nails, lips, or on the external parts of the genital organs, teeth, or the mucous membranes of the oral cavity; for cleansing, perfuming, protecting, maintaining them in good condition, changing their appearance and improving it, or changing and improving body odor.

- **Contamination:**

  The exposure of raw materials or the final product to undesirable substances, whether chemical, microbial, or any foreign materials or contaminants, during the stages of manufacturing, production, sampling, packaging, repackaging, storage, or transportation.

- **Batch Number:**

  A distinctive combination of numbers and/or letters found on the inner and outer packaging of a product, that indicates records of the manufacturing stages of the product.
- **Expiry Date:**

  The period indicating the stability of the product from the manufacturing date to the end of its effectiveness. It is printed on the inner and outer packaging of the product.
- **Product's label:**

  It is a label put on the product and/or containers containing product's specific data such as (trade name, scientific name, excipients, concentration, batch number, production date, expiry date, coding number)
- **Container:**

  A box designed for shipping and storing pharmaceutical products during transportation process, equipped with fittings for these purposes and may be suitable for repeated use.
- **Contract:**

  A written agreement between two or more parties to supply products/materials, or to perform a task at a specific price.
- **Storage:**

  The process of storing and preserving the product according to appropriate specifications until the date of use, in order to maintain the product's safety .
- **Distribution:**

  All operations related to the transportation, supply, import, or export of the product.
- **Importer:**

  The entity that imports and distributes or stores pharmaceutical products according to this Guideline.
- **Segregated Area:**

  A defined area, which is separated by a barrier for a specific use that differs from the surrounding areas.

- **Isolated Area:**
  A part of a partition with an entrance and/or exit, enclosed by barriers on all sides.
- **Temperature Mapping:**
  A study of temperature distribution for a specific period and area in three dimensions (length, width, height), aimed to record and determine the areas with the highest and lowest temperatures in the specified area.
- **Quality System:**
  A system consisting of a suitable infrastructure that includes the organizational structure, procedures, processes, and resources, to ensure the safety and security of products and services that meet all quality requirements.
- **Standard Operating Procedures (SOP):**
  Written and authorized procedures describing the processes or steps that must be followed to perform specific activities.
- **Recall:**
  The action or measure taken to withdraw pharmaceuticals and cosmetic products from the distribution and storage chain due to a manufacturing defect, serious adverse reaction, or concerns that the product may be counterfeit or non-compliant with regulations.
  Recall actions might be taken by the manufacturer, agent, distributor, or at upon the request of the SFDA.
- **Counterfeit Products:**
  Pharmaceuticals that have been tampered with through deception and intentionally changing information or the source on the label Counterfeiting may include counterfeiting the genuine or generic products, counterfeiting the active ingredients of the drug, counterfeiting the drug without the active ingredient beside changing the quantity of the active ingredient, or counterfeiting the external packaging.

General Rules:

1. All relevant parties should adhere to the provisions of the Guideline to ensure the safety and quality of the product, as well as the safety of the distribution chain at all stages, starting from the manufacturer and ending with the person responsible for delivery to the consumer or their agent, or vice versa in the case of a recall.
2. All relevant parties should comply with the Guideline in distribution operations, such as procedures related to tracking and awareness of security risks.

Regulation of Distribution, Storage, Sale, and Purchase of Products:

1. Importers or establishments involved in distribution and storage must be licensed by the authority to perform their work and be responsible for the activities they carry out.
2. Licensed establishments for third-party storage or storage for others must comply with **the draft terms and responsibilities between the lessor and the lessee.**
3. Pharmaceutical products must be registered, and cosmetic products must be listed at the authority during distribution, sale, and purchase operations, unless contradicted by what is stated in the executive regulations of the establishment and pharmaceutical products system.
4. Companies/institutions holding pharmaceutical product agencies should provide those products according to the executive regulations of the establishment and pharmaceutical products law.
5. To deal with those products, licensed establishments should supply and sell products to/from establishments licensed by the competent authority.
6. Approved administrative and technical procedures should be provided for purchasing and selling operations, ensuring that pharmaceutical, herbal, and cosmetic products are purchased, sold, or distributed from and to licensed entities. This includes verifying suppliers and customers as follows:
    - Sign-up an account for each establishment and keeping copies of their licenses and addresses.
    - The recipient's name
    - Address should match the address on the ground.

- Periodic verification of the validity of the licenses.

7. Establishments involved in the distribution, storage, and sale of pharmaceutical products should have an electronic system to manage and organize supply, distribution, and sales operations. This system should be integrated with the electronic tracking system approved by the SFDA. in addition, the system should also be used to report all operations conducted on the product package, such as receipt, import, distribution, transport, and disposal.

Personnel:

1. All personnel working in the field of distribution and storage of pharmaceutical products should be trained and qualified for the requirements of good distribution and storage practices. Such training must be continuous and assessed according to a written program, in addition to their documentation in the Standard Operating Procedures (SOPs). Moreover, all training records should include training topics and the names of trainees participating in the program.
2. The trainer responsible for the training process should be qualified to train personnel and possess appropriate experience. Some personnel handle hazardous materials and must receive appropriate training for this.
3. Decision-makers who are involved in the distribution and storage of pharmaceutical products should have the ability and appropriate experience regarding the responsibility to ensure that the steps of distributing and storing pharmaceutical products are carried out correctly.
4. The number of qualified personnel working in all stages of distribution, storage, and sale of pharmaceutical products should be sufficient to ensure the safety and quality of the product. It is important to avoid any impact on the quality of the products by minimizing the responsibilities assigned to the facility's personnel.
5. Personnel working in the distribution, storage, and sale of pharmaceutical products should wear a suitable uniform to perform their activities, especially those who are dealing with hazardous materials Moreover, a hygiene

procedures must be created to be followed by personnel. Those procedures shall be focus on health, cleanliness, and clothing for employees.

6. Employment procedures and conditions, such as contracts and temporary employees as well as those with access to pharmaceutical products, should be established and managed to prevent unauthorized access to pharmaceutical products by individuals or entities not authorized to do so.
7. Disciplinary procedures should be provided in the facility to address and prevent individuals suspected or involved in any activity related to counterfeiting, fraud, embezzlement, or manipulation of any product. Relevant authorities must be reported within a period not exceeding three days from the date of the incident.
8. Those responsible for the distribution and storage of pharmaceutical products, such as the warehouse manager, must be on duty (available) during all working hours if not, he shall appoint someone to carry out his responsibilities on behalf of him.
9. A qualified person must be appointed or assigned to ensure the implementation and maintenance of quality. Such person must possess the appropriate qualifications for the job. Their duties should include:
    - Ensuring the implementation and maintaining the quality system.
    - Handling recalls.
    - Dealing with complaints related to the quality of the products.
    - Personnel training.
    - Internal auditing.
    - Destroying of pharmaceutical products.
    - Approval of any agreement related for process that are related to pharmaceutical products.

Quality System

The company/organization must have an effective quality system that outlines responsibilities, processes, and risk assessment related to all operations conducted by the company/organization. All operations of the company/organization should be reviewed and audited periodically within the quality system. Additionally, all stages of product development and variations to the process should be recorded and justified.

The quality system is the responsibility of the senior management in the company/organization and requires their active leadership and involvement, along with the commitment of all personnel to adhere to it.

1. The quality system must be written and approved by the senior management of the facility, and should include:
    - Quality policies
    - The company's/organization's vision and mission
    - Determine of authorities for management and employees
    - An organizational structure that clearly defines tasks, responsibilities, and relationships among personnel. .
    - A clear job description outlining duties and responsibilities clearly agreed upon by both parties' employees should be empowered and trained in subjects related to their duties and responsibilities to perform their duties
    - Any commercial agreements that are made with companies to provide services that include processes or operations related to the company/organization (such as studying the heat map, receiving and delivering services, the transportation of pharmaceuticals, pest control, safe disposal of medical waste, etc)
    - All pharmaceuticals Standard Operating Procedures (SOPs) conducted by the company. Quality should be reviewed regularly and developed continuously.
2. The quality system should include specific procedures to ensure that the exclusive agent of the pharmaceutical product (if different from the manufacturer), local or international regulatory bodies, as well as other relevant authorities, are immediately notified if the pharmaceutical product is

found or suspected to be counterfeited or defective. These products should be stored in a safe, isolated, and clearly marked area to prevent further distribution or sale.

3. Arrangements should be made within the facility to ensure that management is not subjected to any pressures that may have a negative impact on the provided service or the safety of pharmaceutical products.
4. It is recommended for the facility to obtain quality-related certificates and recognitions from international organizations such as ISO, but these certificates are not considered a substitute for compliance with the principles of Good Distribution Practice (GDP) and Good Manufacturing Practice (GMP), which are related to pharmaceutical products.
5. Written procedures should be provided in case of suspicion or discovery of counterfeiting, fraud, or incidents of non-compliance with pharmaceutical products.
6. Facilities involved in the storage, distribution and sale of pharmaceutical products should periodically assess potential risks to the quality and safety of pharmaceutical products. In addition, the quality system should be developed and updated periodically to address new risks identified through the risk management process.

Premises and Storage:

1. Location of the warehouse must be located in a designated area which is allocated by the relevant authority's cities and provinces that have not been designated special areas are excluded from this condition.
2. The building should be well- isolated thermally and protected by waterproof materials, have a well-ventilation system, and be equipped with water and electricity services. The height should not be less than three (3) meters and should be equipped with tightly closed doors. Also, the maximum height for storage should not exceed one meter.
3. The warehouse floors should be easy to clean. If there are any water drainage holes, located in places that do not. It is important to tightly close them from the outside and place them in areas not accessible to equipment when moving within the warehouse.

4. Ensure that there are no sources of fire and that informative signs are provided to prevent smoking. .
5. The warehouse should have one or more entrances designated for receiving and delivering pharmaceutical products, with clearly marked emergency exits.
6. In the case of products requiring refrigeration, either in a refrigerator or in freezer according to the manufacturer's recommendation, a backup generator should be provided that operates automatically in case of power failure.
7. The warehouse identification panel should be clearly located outside the warehouse and written in Arabic language with an appropriate size (minimum of 11.5 meters), containing the name and activity of the warehouse, working hours, and phone number.
8. Necessary precautions should be taken to prevent unauthorized personnel from entering storage areas. Personnel should adhere to the facility's policies to maintain a safe, secure, and efficient work environment.
9. The storage space must have enough space to comply with the principles of Good Distribution Practice (GDP)
10. The warehouse should include the following areas:
    - A separated area in the storage for receiving and delivering, designed to prevent external factors from entering the storage area during receiving and delivery process. Furthermore, it should be equipped to receive pharmaceutical containers, and sterilize them if necessary, before storage.
    - Storage area (Storing items on the floor should be avoided)
    - Closed and separated area for damaged or expired products.
    - Area designated for recalled products.
    - Area designated for storing free samples (if applicable).
11. If the company is licensed for multiple activities, each activity should be separated from the others in its own section.
12. Pharmaceutical products should be stored in areas where they do not touch the ground and in a manner that allows cleaning and inspecting them. Pallets should be in good condition in terms of cleanliness and maintenance.

13. Provide a system for pest and rodent control or contract with a specialized company to carry out the task regularly. In addition, the quality manager should review the cleaning operations and pest control system data.
14. Areas designated for damaged, expired, recalled, or free sample products should be specified, and isolated. Written procedures should be provided for handling products, ensuring they are moved directly to their designated areas.
15. If an electronic system is available as an alternative to separate and isolate storage areas, it should be equivalent in terms of safety and effectiveness.
16. Other systems specified by the authority. These devices should be calibrated regularly, while temperature and humidity measuring devices should be distributed in different locations and heights according to the approved warehouse temperature mapping, which should be done periodically based on risk assessment, indicating the area's most likely to fluctuate in temperature These devices should be calibrated regularly. Temperature and humidity measuring devices should be distributed at different locations and heights according to the approved warehouse temperature mapping. This should be done periodically based on risk assessment, indicating the area that is most likely to fluctuate in temperature.
17. Install alarms in the refrigerator and freezer that are used to store pharmaceutical products and activate when there is a temperature increase or decrease. These alarms should be calibrated regularly.
18. Damaged or expired pharmaceutical products should not be kept for more than one year from the date of damage or expiration discovered. They should be disposed of by contracting periodically with a specialized company for medical waste disposal.
19. Recalled pharmaceutical products should be stored directly in the designated area with their own records until a decision is made by the authority. These products should be stored at the temperature and humidity levels which specified by the manufacturer.
20. Store free samples in the designated area within the temperature and humidity levels specified by the manufacturer's requirements for the product. In addition, they must have their own records.

21. Store radioactive materials or hazardous, sensitive, flammable, or explosive pharmaceutical products (solid, liquid, or compressed gas) in designated areas subjected to additional security and safety measures.
22. Handle the storage of pharmaceutical products in a way that prevents contamination, mixing, or cross-contamination.
23. Provide a system that ensures the sale and distribution of pharmaceutical products closest to their expiration (FEFO), with exceptions as necessary, and provide a system to prevent the sale and distribution of expired products.
24. Provide sufficient lighting in storage areas to perform all tasks accurately and safely.
25. The following conditions must be met with the requirements of good distribution and storage practices when storing controlled drugs and psychotropic substances :
    - Store the products according to the specifications and conditions of storage recommendations by the manufacturer.
    - A licensed responsible person must supervise controlled drugs and psychotropic substances.
    - The facility which is licensed to deal with controlled drugs and psychotropic substances must store (keep) such products in a safe or in an isolated area within the facility.
    - This safe or storage area must be (a) a designated area for storing controlled drugs and psychotropic substances only, with its own records.
    - It is important to ensure that this safe or storage space is secure and cannot be tampered with, broken, or moved, and that it has a separate security alarm system for protection.
    - The storage area should be constructed of concrete and equipped with separate air conditioning units (split units)
    - Provide electronic scales that can be linked to regulatory authority systems based on the results of the thermal mapping study.
    - Comply with the necessary controls and requirements for handling controlled drugs and psychotropic substances.
26. The facility should have all the equipment and capabilities to store all pharmaceuticals under suitable conditions.

27. Temperature and humidity readings should be available in the warehouse upon request and records should be kept during shelf life of the product plus one year.
28. To prevent unintended mixing, errors during receipt, theft, or misappropriation of pharmaceuticals, it is necessary to regularly verify actual inventory quantities and compare them with recorded quantities in relevant records. These reviews should be based on written procedures. These reviews should be based on written procedures.
29. If the importer, agent, or distributor has entered into contract with another facility to carry out certain tasks and responsibilities, the contracted facility must be licensed to perform the same activity, and the guidelines must be adhered to.
30. No additional labels should be printed or placed on pharmaceutical products without the approval of the regulatory authority.
31. The working hours of pharmaceutical distribution and storage facilities should comply with the requirements of the regulatory authority, and all responsible personnel should be present during these hours.
32. In case of intending to close the facility, the SFDA should be notified as follows:
    - If the closure period does not exceed 30 days, a responsible person should be designated to ensure that the pharmaceuticals are stored probably during the closure period.
    - If the closure period exceeds 30 days, the pharmaceuticals should be transferred to a licensed facility through a documented contract for a period not exceeding 6 months, with the condition that suitable storage and transportation conditions are provided for the pharmaceuticals. In the case of narcotics and psychotropic substances, the following actions should be taken:
    - Transfer the custody (pharmaceuticals) to another facility according to official requirements.
    - Return them to the agent's warehouse or the local manufacturer after obtaining approval.

- Re-export them to the importing entity after obtaining official approval from the relevant health authorities in the export country.
- Sell the pharmaceuticals directly to a governmental or private healthcare institution or pharmacy in accordance with the regulatory requirements.

33. It is a shared responsibility among the involved parties to enhance regulations with safe and transparent systems for tracking pharmaceuticals in all supply and distribution chain stages. There should be written procedures to ensure the traceability of incoming and distributed pharmaceuticals to facilitate product recalls.
34. Compliance with the regulatory authority's systems regarding the tracking of pharmaceuticals and registration in the RASD system, **adhering to the requirements and specifications of the authority is monitoring system.**
35. Notifying the regulatory authority before carrying out any renovation, alteration, or expansion of storage areas to ensure that pharmaceuticals are not affected.
36. It is important to notify the SFDA in cases of natural disasters or fires that may affect the safety and security of pharmaceuticals.
37. It is important not to repackage pharmaceuticals after they have been supplied, as these practices may pose a risk to the safety and security of pharmaceuticals.

Vehicle and Transport

1. The capacity of Vehicles, equipment, and containers used in for the distribution, storage, or handling of pharmaceuticals should be suitable for the organized storage of different categories of pharmaceuticals during transportation. They should be equipped in a way that prevents any conditions that may affect the quality and safety of these pharmaceuticals.
2. The design and use of vehicles and equipment should aim to reduce the risk of errors and be easy to clean and maintain to avoid any contamination, dust formation, or dirt accumulation that may affect the quality of pharmaceuticals during distribution.

3. Ensure that there is no direct contact between pharmaceuticals and dry ice during transportation, as this may negatively affect the quality and stability of the pharmaceuticals.
4. Use modern technology where possible, such as Global Positioning System (GPS) and engine shutdown devices, to enhance the safety of pharmaceuticals while they are in the vehicle.
5. Allocate vehicles and equipment that handle pharmaceuticals, and in the case of contracting with specialized transport companies, the company and its equipment should comply with the requirements of this code.
6. Take all precautions and provide necessary measures to ensure that the quality and safety of pharmaceuticals are not affected during transportation.
7. In the case of contracting with a third party for transportation, a contract or agreement should be written specifying the precautions and measures necessary to ensure the protection and preservation of pharmaceuticals, including the preservation of records and documents. The contract or agreement should be compatible with the requirements of this guideline.
8. Any personnel or entity responsible for the transportation process should be informed of about all conditions of pharmaceuticals regarding storage and transportation. Compliance with all distribution and storage requirements should be maintained during temporary storage stages in transportation process.
9. Pharmaceuticals should be transported and stored according to procedures that ensure:
    - No loss of pharmaceutical identity.
    - No contamination of the pharmaceutical or mixing of its compositions with another product.
    - Provision of necessary precautions to prevent spillage, breakage, theft, or misappropriation.
    - Provision of appropriate storage conditions such as the cold chain for heat-sensitive pharmaceuticals.
    - Provision of data proving that the facility has transported the pharmaceuticals according to the recommended conditions by the manufacturer.

10. Storage conditions should be maintained within acceptable limits during transportation. If the individuals or entities responsible for transportation notice any deviation or differences during transportation, the authority, agent, distributor, or recipient should be notified. If there is any deviation or difference observed by the recipient, it should be reported to the authority, agent, or distributor. To obtain the necessary information, it is important to communicate with the manufacturer.
11. Written procedures should be provided for investigating and dealing with non-compliance of required storage requirements, such as temperature deviations.
12. Narcotics and psychotropic should be transported according to the SFDA's requirements and in safe containers and transportation means as well as providing special storage conditions for each product.
13. Written procedures should be provided for cleaning spills as soon as possible to protect the pharmaceuticals from contamination and damage.
14. Electronic devices that can be linked to the authority's systems or other systems that specified by it should be provided to measure temperature and humidity in vehicles or storage containers during transportation. These devices should be activated from the time of transport until the arrival of the shipment, and they should be regularly calibrated. Temperature and humidity measuring devices should be distributed in different locations and heights according to the approved Temperature Mapping, and they should be linked to the receiving and issuing records for all shipments.
15. Temperature and humidity records for pharmaceuticals that have been transported or received should be retained for the shelf life of the product plus one year.
16. Vehicles and equipment that are not in service should not be used. They should either have a label indicating their unsuitability or be taken out of service.
17. Operating and maintenance procedures should be provided for vehicles and equipment used in the distribution process, including cleaning and safety precautions.
18. Vehicles, containers, and equipment should remain clean, dry, and free from accumulated waste.

19. Vehicles, containers, and equipment should be free from rodents, insects, birds, and other pests. Written procedures for pest control should be provided. In addition, cleaning and sanitizing materials should not affect the quality and safety of pharmaceuticals.
20. The equipment and tools used to clean vehicles should not cause contamination. The management must approve the cleaning materials used.
21. Attention should be paid to the design, how to use, cleanliness of the equipment used for handling pharmaceuticals, and ensure that they are not stored in shipping containers.
22. Where special storage conditions (e.g. temperature and/or relative humidity), different from the expected environmental conditions required during transportation, these contains should be provided, checked, monitored and recorded. All monitoring records should be kept for a minimum of the shelf life of the product distributed plus one year. Records of monitoring data should be made available for inspection by the SFDA. .
23. Procedures should be provided for separating rejected, recalled, or returned pharmaceuticals during the transportation process, as well as those suspected to be counterfeit. They should be securely stored, labeled clearly, and records and supporting documents should be provided.
24. Measures should be in place to prevent unauthorized persons from entering or tampering with vehicles or equipment to prevent theft or embezzlement.

Receiving and Disbursing

1. Pharmaceutical products should not be sold or distributed except to authorized individuals and entities licensed under the law, and a license should be obtained before distributing pharmaceutical products to requesting entities.
2. Before receiving or dispensing the pharmaceutical products, ensure that they have been transported and distributed according to the appropriate distribution and storage conditions. It is recommended to keep electronic temperature and humidity records for the duration of the product's shelf life plus one year.
3. Pharmaceutical products should not be transferred or dispensed except upon receipt of a documented delivery request or renewal of the previous request.

4. Provide written procedures for the dispensing and receiving of pharmaceutical products, taking into consideration the nature of the products and any special precautions to be followed. The person who is responsible for the quantities should dispense products under suspension for any reason.
5. The outgoing and incoming systems and records used in dispensing or receiving in the warehouse should contain the following information：
    - Date of dispensing or receiving
    - Name of the sending or receiving entity, quantities dispensed, received, and remaining quantity in the warehouse
    - Name of the carrier if a third party
    - Scientific and trade name
    - Concentration,
    - Pharmaceutical form
    - Date of manufacture and
    - Expiration date
    - Batch number
    - Signature of receipt or dispensing personnel.
6. Dispensing and receiving records should contain sufficient information to trace pharmaceutical products, facilitate recall, and investigate counterfeit or suspicious products.
7. Select transportation methods (in addition to vehicles) that are compatible with climate conditions, taking into account seasonal climate changes. Transporting pharmaceutical products that require controlled temperature should comply with requirements during storage and transportation.
8. Develop a timeline and route for transportation, adhering to the needs and conditions during transportation. Timelines and routes should be organized and realistic, taking into account security risks when planning.
9. Ensure that the receiving entities can accommodate the required quantities of pharmaceutical products.
10. Do not receive or dispense expired or close-to-expiry pharmaceutical products that are expected to expire before reaching the patient.
11. Inspect each shipment upon receipt and dispensing, ensuring the integrity of the external appearance, packaging, and labels.

Records and Auditing

1. The original permissions and other relevant records should be kept in the entity responsible for storing and distributing Pharmaceutical products.
2. Licenses should be clearly displayed inside the warehouse for easy access.
3. The certified seal of the entity responsible for storing and distributing Pharmaceutical products should be provided.
4. The standard operating procedures (SOP) for the storage and distribution of pharmaceutical products and the records of the entity (including bills) should be available in the warehouse.
5. Sponsors and distributors should keep records of receipt and dispensing in the warehouse containing the required data for the product's shelf life plus one year.
6. Establish written standard operating procedures related to the preparation, review, approval, and use of SOPs for the distribution, storage, and transportation of pharmaceutical products.
7. Documents, instructions, and procedures related to any activity affecting the quality of pharmaceutical products should be prepared, reviewed, and distributed accurately and carefully to be comprehensive, appropriate, and clear to the relevant personnel. When updating SOPs, ensure that the old version is not used.
8. SOPs should clearly state the title, objective, and nature of the work, and should be in an organized order that allows for verification and review.
9. SOPs should be approved and signed with the date by the authorized responsible person, and authorized personnel should only make adjustment.
10. The nature, content and retention of documentation relating to the distribution of pharmaceutical products and any investigations conducted and action taken, should comply with national legislative requirements.
11. The process of retrieving, storing, and preserving SOP documents should be done using means that protect them from unauthorized modification, damage, or loss.
12. Provide a mechanism that allows for the exchange of quality and regulatory information for the pharmaceutical product between the manufacturer and the

client, such as the agent or distributor, and provide it to the regulatory authority upon request.

13. In the case that the record keeping and SOP systems are electronic, backup copies should be kept to prevent unintentional data loss.
14. The facility should retain records for the following pharmaceutical products:
    - The recalled products for a minimum of the shelf life of the product distributed plus one year.
    - The expired products for a minimum of the shelf life of the product distributed plus one year.
    - Damaged products for one year from the date of destruction.
    - Free samples for one year from the distribution date.

Complaints

1. Provide written procedures for handling complaints. Differentiate between complaints related to the quality of the product or its packaging and those related to distribution. In the case of complaints related to the quality of the product or its packaging, the manufacturer and/or the authorized agent or distributor and SFDA should be notified as soon as possible.
2. Review all complaints related to defective or counterfeit products carefully according to written procedures on how to deal with them, which may require withdrawing the product from the market.
3. Any complaint concerning a material defect should be recorded and thoroughly investigated to identify the origin or reason for the complaint.
4. When there is suspicion or discovery of a defect in the pharmaceutical product, consideration should be given to whether other batches of the product should also be checked.
5. Follow-up after the investigation and evaluation of the complaint should be conducted, and a system should be provided to ensure that the investigation results are shared with relevant parties.
6. The problems related to the quality of the product or suspected counterfeiting should be documented and Presented to the regulatory authority and relevant authorities upon discovery.

Recalls

1. Establish a clear and effective mechanism that includes written procedures for recalling pharmaceutical products that proven or suspected to be defective or counterfeit based on the severity of the recall. The procedures should include regularly informing the regulatory authority of the recall reports. Moreover, there should be designated person(s) responsible for the recall task, and the procedures should be updated and reviewed regularly.
2. If the recall is initiated by a party other than the manufacturer or the sponsor, coordination with the manufacturer or agent should be done before starting the recall process.
3. Notify the SFDA of the recalled products if it is necessary to withdraw the original product due to the presence of a counterfeit product that cannot be distinguished from the original.
4. Isolate the recalled pharmaceutical products during storage and transportation, and maintain their special conditions during storage and transportation process until appropriate action is taken regarding them.
5. Notify all customers and competent authorities in all countries where the pharmaceutical products have been distributed in case of a recall.
6. All records related to recalls should be accessible to designated person(s) responsible for the recalls, and these records should contain sufficient information about the pharmaceutical products that have been sent to customers (in addition to the exported products)
7. Record the progress of the recall process and issue a final report including compensatory quantities for customers.
8. Destruction of returned or rejected pharmaceutical products should be done after the approval of the SFDA. This can be done by contracting a specialized company for medicine waste disposal.

Returned Products

1. All parties, whether agents, distributors, or clients, are responsible for ensuring the safety of the return process. Counterfeit products are not allowed to be returned. Returns or exchanges should be in accordance with a written contract and agreement between the parties.

2. A qualified Authorized person, considering the nature and requirements of the returned products, their condition, and the elapsed time, should do evaluation of returned pharmaceutical products. Review of temperature and humidity records for storage and transportation should be taken into account in the evaluation process.
3. Rejected or returned pharmaceutical products should be segregated to prevent distribution until a decision has been taken with regard to their disposition. The particular storage conditions applicable to a pharmaceutical product which is rejected or returned should be maintained during storage and transit until such time as a decision has been made regarding the product in question.
4. All records of returned, rejected, and destroyed pharmaceutical products should be kept for a period of one year from the date of the decision regarding them.

Counterfeit Products:

1. Counterfeit pharmaceutical products discovered during distribution, storage, or transportation chain should be kept in a separate area from the rest of the products and labeled as "Not for Sale". The regulatory authority and the sponsor for the products should be informed directly.
2. The sale or distribution of suspected counterfeit pharmaceutical products should be suspended, and the regulatory authority should be informed immediately.
3. A formal decision confirming that the pharmaceutical products are counterfeit should be made to ensure that they are not returned to the market, and the decision should be recorded.

Contracts:

1. Any activity related to the distribution, storage, or sale of pharmaceutical products should be carried out by authorized and licensed persons or entities and should be in accordance with a written contract.
2. The contract should define the responsibilities of each party including observance of the principles of GDSP. It should also include responsibilities of

ensuring to avoid the entry of counterfeit medicines into the distribution chain, such as by suitable training programs.

3. All contracting parties must comply with the requirements of this guideline.
4. If the importer, sponsor, or distributor contracts with another facility to carry out some tasks and responsibilities, these tasks and responsibilities should be included in a written contract that does not conflict with the regulations. There should be regular inspections by the importer, agent, or distributor of the contracted facility to ensure that the responsibilities or tasks are in line with the regulations.

Internal Auditing:

1. The quality system in the facility should include internal auditing processes. Internal audits should be conducted to monitor compliance with the principles and provisions of good distribution and storage practices (GSDP).
2. Internal audit procedures should be conducted independently, and the results should be recorded in a specific and detailed report.
3. Internal audit reports should include all observations during the audit process, as well as suggestions for corrective actions for these observations.
4. There should be effective evaluation and monitoring of internal audit processes by the facility management, clarifying the corrective actions taken regarding the observations found.

Cosmetics Warehouse[1]:

1. Appoint a full-time Saudi technical manager.
2. The building should be well insulated thermally and waterproof, with good ventilation. The storage space should be sufficient, with a minimum height of 3 meters and be equipped with tightly closed doors. The ceiling height should not be less than one meter above the maximum storage height. The lighting should be suitable for the nature of the work, and there should be no source of fire in the warehouse, with signage to prevent smoking.

[1] These requirements apply to warehouses licensed to engage in the activity of storing cosmetic products only.

3. The warehouse building should be constructed of reinforced concrete or iron (hangar)
4. Provide electronic devices in storage areas and provide records for calibrating these devices to ensure the accuracy of temperature and humidity levels by the competent authority, while maintaining records of temperature and humidity and calibration documents, with the devices being linkable to the Authority's systems.
5. Temperature and humidity measuring devices should be distributed in different locations and heights in the warehouse.
6. The warehouse should be divided into:
    - Receiving and delivery area.
    - Storage area with shelves.
    - Separate area for damaged or expired products.
    - Area for recalled products.
    - Area for free samples.
7. The warehouse is required to adhere to the regulations outlined in item 13 on recalls of cosmetic products. .
8. The floors should be Soft and easy to clean, and they should be cleaned regularly with the cleaning processes documented. Compliance with storage on shelves is also required.
9. It is imperative to adhere to the manufacturer's recommended temperature during the storage and transportation stages of cosmetic products, with a maximum temperature of 30 degrees Celsius, unless otherwise specified by the manufacturer, and to maintain accurate temperature records.
10. Selling and purchasing cosmetic products should be done with/from entities licensed to conduct such activities. Cosmetic products should be listed before trading, and it is prohibited to sell or purchase cosmetic products that are not listed with the Authority.
11. The warehouse must have a system for incoming and outgoing data, including: the brand name, quantity, invoice number and date, batch number, manufacturing and expiration dates, remaining quantity, supplier name, and consumer or beneficiary name. Records for each shipment must be kept for at least one year.

12. Providing a system for waste disposal and destruction, while keeping records of destruction for a period of not less than one year.
13. Providing a system for controlling insects and rodents, which is monitored and verified periodically.
14. An external sign must be placed in Arabic and the sign must contain the following information:
    - Repository name
    - Warehouse activity
    - work hours
    - phone number
15. Licenses must be in a clear place inside the warehouse for easy access.
16. The original copies of all documents related to the warehouse, including invoices, must be kept in inside it the warehouse.
17. The Authority must be notified via an official letter submitted to the Authority or one of its branches depending on the facility's location in the event of a desire to modify the storage area building or temporarily close the warehouse.