Guideline of Good Storage and Distribution Practices (GSDP)

Version 1.0

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Guideline of Good Storage and Distribution Practices (GSDP)

Version 1.0

Drug Sector

Saudi Food & Drug Authority

Kingdom of Saudi Arabia

Please visit SFDA’s website at
for the latest update

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### Vision

To be the leading regional Drug Regulatory Authority for pharmaceuticals and cosmetic products, with professional excellence and services that contribute to the protection and advancement of public health in the Kingdom of Saudi Arabia.

### الرؤية

أن يكون قطاع البواء رائداً إقليمياً في الرقابة على الأدوية ومستحضرات التجميل، ويقدم خدماته بمهنية تميز تسهم في حماية وتعزيز الصحة في المملكة العربية السعودية.

### Mission

Protecting public health by ensuring safety, quality, efficacy and accessibility of human, veterinary drugs and biological products, and safety of cosmetics, through administration of a national regulatory system which is consistent with international best practice. Through our mission, we also provide accurate and scientific-based information to the public and healthcare professionals.

### الرسالة

حماية الصحة العامة من خلال ضمان أمان وجودة وفعالية وتوفر الأدوية البشرية والبيطرية والمنتجات الحيوية وسلامة مواد التجميل عبر تطبيق نظام وطني للرقابة متوافق مع أفضل الممارسات الدولية وتقديم المعلومات الدوائية المبنية على أسس علمية للعامة والمهنيين الصحيين.
**Document Control**

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1- Introduction:

The stage of storing Pharmaceutical Preparation and its distribution is one of the most important stages since its production and until reaching the patient. This stage is related to many parties starting with pharmaceutical plants, through the warehouses and pharmacies, and finally at the hands of the patient in his home.

The good storage and distribution based upon scientific grounds, keeps the safety of drugs from any external influences, and ensures the stability of these pharmaceuticals and their effectiveness over time. So the health authorities around the world are keen to develop legislations and regulations to control dealing with the Pharmaceutical Preparations, including the emphasis on good storage and distribution practices.

This Guideline aims to direct staff working in distribution and good storage of appropriate steps to assist in fulfilling the responsibilities related to the various aspects of distribution, storage, transportation and avoid the introduction of fake or counterfeit products to the market through the distribution chain. To maintain the quality and safety of Pharmaceutical Preparations, all parties involved in any stage of the distribution, storage and transport of these products, should comply with the applicable legislations and regulations adopted by Saudi Food & Drug Authority.

This Guideline ensures that all activities in the distribution, storage and transport of pharmaceuticals should be commensurate with the principles and rules of Good Manufacturing Practices (GMP), Good Storing Practice and Good Distribution Practices (GSP) (GDP).

2- Guideline scope:

This Guideline covers the rules of the distribution and storage of all Pharmaceutical Preparations, whether for human or veterinary use. Also, it covers the rules of the distribution and storage of active pharmaceutical products and excipients.
3- Definitions:

The below-mentioned definitions provide the words and phrases used in this Guideline, and in spite of the effort to use standard definitions as much as possible, but they may have different meanings in other contexts or documents.

**Authority:**
Saudi Food & Drug Authority

**Personnel:**
They are staff working in warehouses, have the knowledge of supervisory and regulatory aspects, have the required knowledge and experience of laws and regulations and also have professional and technical qualifications that enable them to do their functional tasks.

**Pharmaceutical products (drugs):**
Any product intended for human use, or veterinary product intended for administration to food-producing animals, presented in its finished dosage form and includes products for which a prescription is required, products which may be sold to patients without a prescription.

**Contamination**
The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material, intermediate or pharmaceutical product during handling, production, sampling, packaging or repackaging, storage or transportation.

**Batch number:**
A distinctive combination of numbers and/or letters which uniquely identifies a batch, for example, on the labels, its batch records and corresponding certificates of analysis.
Expiry date
The date given on the individual container (usually on the label) of a pharmaceutical product up to and including the date on which the product is expected to remain within specifications, if stored correctly.

Product label:
It is a label put on the preparation and / or containers including the product data (trade name, scientific name, additional materials, concentration, batch number, production date, and expiry date, coding VBN number.

Container:
It is a box intended to ship and store Pharmaceutical Preparations during transportation from one location to another, provided with special fittings for these purposes that may be suitable for repeated use.

Contracts:
Business agreement for the supply of goods or performance of work at a specified price.

Storage:
The storing of pharmaceutical products, according to appropriate specifications up to the point of use, and to maintain the stability of the product and ensure its effectiveness.

Distribution:
The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of pharmaceutical products.

Importer:
The person who imports, distributes, or stores pharmaceutical preparations according to this code.
Segregated area:
A particular area for a specific use and is different from the surrounding areas and may be either separated by a barrier or not.

Isolated area:
It is part of the isolation. It has an entrance and / or an outlet, closed by barriers from all sides.

Temperature mapping:
It is the study of the temperature distribution for a specific area with three dimensions (length, width, height), to record and set the regions of the highest and lowest temperature in the selected area.

Quality system
An appropriate system, encompassing the organizational structure, procedures, processes and resources to ensure adequate confidence that a product (or services) will satisfy given requirements for quality.

Standard operating procedures (SOP)
They are certified and written procedures to describe the processes or steps that must be implemented to perform specific activities.

Product Recall
A process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution and storage chain because of defects in the product, complaints of serious adverse reactions to the product and/or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, importer, wholesaler, distributor or Saudi Food & Drug Authority.
Counterfeit pharmaceutical product
A pharmaceutical product which is deliberately and fraudulently mislabeled with respect to identity or source. Counterfeiting can apply to both branded and generic products, and counterfeit pharmaceutical products may include products with the correct active ingredients, with the wrong ingredients, without active ingredients, with an incorrect quantity of active ingredient or with fake packaging.

4- General principles
4.1 All parties involved in the distribution of pharmaceutical products have a responsibility to ensure that the quality of pharmaceutical products and the integrity of the distribution chain is maintained throughout the distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient or his or her agent.

4.2 The principles of GSDP are applicable both to pharmaceutical products moving forward in the distribution chain from the manufacturer to the entity responsible for dispensing or providing pharmaceutical products to the patient and to products which are moving backwards in the chain, for example, as a result of the return or recall thereof.

4.3 The principles of GSDP should also be adhered to in the case of pharmaceutical products which are donated.

4.4 All entities involved in the distribution process should apply due diligence with adherence to the principles of GSDP, for example, in procedures relating to traceability and in recognition of security risks.

5- Regulation of the distribution of pharmaceutical products
5.1 All persons or entities involved in the distribution of pharmaceutical products should adhere to this code to regulate the activities of persons or entities involved in the storing, distribution, selling, and transport pharmaceutical products.
5.2 Importers or entities involved in the storing, distribution and selling should be authorized to do so by Saudi Food & Drug Authority and should be held accountable for the activities they perform.

5.3 Only entities holding an authorization are entitled to import, store, distribute, and sell pharmaceutical products.

5.4 Holders of an authorization to store, distribute, and sell pharmaceutical products should obtain their supplies of pharmaceutical products only from entities which are in possession of the applicable authorization to sell or supply such products.

5.5 Importers or their agents should supply and sell pharmaceutical products from and to entities which are in possession of the applicable authorization to deal in pharmaceutical products.

5.6 Some duties and responsibilities may be delegated or contracted by the importers or their agents or distributors to suitably designated persons or entities. Duties and responsibilities should be specified in a written agreement that adheres to the code. There should be a periodic audit of such activities by the importers or their agents or distributors to ensure that duties and responsibilities adhere to the code.

5.7 If the importer, the distributor or his or her agent subcontracts some duties and responsibilities to another entity, the person or entity to which the activity is subcontracted must be appropriately authorized to perform the subcontracted activity and should uphold the same standards.

5.8 Entities of storing and distributing pharmaceutical products should adhere to the working hours stated by the authority.

5.9 in the event of the intention of closing the facility, the authority should be notified as follows:

If the period of closure isn't more than 30 days, they should nominate the person responsible for providing storage conditions of pharmaceuticals during the period of closure.

If the period of closure is more than 30 days, pharmaceuticals should be transferred to an authorized entity as per a certified contract stating the period (no more than 6 months). Providing appropriate storage and transport is a must. If there are any narcotic drugs and psychotropic substances, they should be disposed as follows:
- Transport of the custody to another entity, according to official stipulations.
- Returning the custody to the Warehouse of the agent or local factory after obtaining the approval to do so.
- Re-export the imported custody after obtaining approval from the relevant health authorities in the country of origin.
- Direct selling the custody to a public or private therapeutic institution, or a pharmacist as per the Authority's requirements.
- Lending the custody to a public or private therapeutic institution, or a pharmacist as per the Authority's formal procedures.

6- Organization and management

6.1 There should be an adequate organizational structure for the entity clearly defining the responsibility, authority and interrelationships of all personnel.

6.2 Duties and responsibilities should be clearly defined and understood by the individuals concerned and recorded as written job descriptions. At every level of the supply chain, employees should be fully informed and trained in their duties and responsibilities.

6.3 A designated qualified person should be appointed within the organization, for ensuring that a quality system is implemented and maintained.

6.4 Managerial and technical personnel must have the authority and resources needed to carry out their duties and responsibilities to set up and maintain a quality system. (see section 8).

6.5 The responsibilities placed on any one individual should not be so extensive as to present any risk to product quality.

6.6 There should be arrangements in place to ensure that management and personnel are not subject to commercial, political, financial and other pressures or conflict of interest that may have an adverse effect on the quality of service provided or on the integrity of pharmaceutical products.

6.7 Safety procedures relating to the safety of personnel and property, environmental protection, should be in place.
7- Personnel

7.1 All personnel involved in distribution, storage and sale activities should be trained and qualified in the requirements of GDP and GSP, as applicable. Training should be based on written standard operating procedures (SOPs). Personnel should receive initial and continuing training relevant to their tasks, and be assessed as applicable, in accordance with a written training program. In addition, training of the personnel should include aspects of product identification, the detection of counterfeits and the avoidance of counterfeits entering the supply chain. A record of all training, which includes details of subjects covered and participants trained, should be kept.

7.2 Key personnel involved in the storage and distribution of pharmaceutical products should have the ability and experience appropriate to their responsibility for ensuring that pharmaceutical products are distributed properly.

7.3 There should be an adequate number of competent personnel involved in all stages of the distribution, storage and selling of pharmaceutical products in order to ensure that the quality of the product is maintained.

7.4 National regulations relating to the qualifications and experience of personnel should be adhered to.

7.5 Personnel dealing with hazardous pharmaceutical products (such as highly active materials, radioactive materials, narcotics, and other hazardous, and/or dangerous pharmaceutical products, as well as products presenting special risks fire should be given specific training.

7.6 Personnel involved in the distribution, storage and selling of pharmaceutical products should wear garments suitable for the activities that they perform. Personnel dealing with hazardous pharmaceutical products, including products containing materials that are highly active and toxic should be provided with protective garments as necessary.

7.7 Appropriate procedures relating to personnel hygiene, relevant to the activities to be carried out, should be established and observed. Such procedures should cover health, hygiene and clothing of personnel.

7.8 Procedures and conditions of employment for employees, including contract and temporary staff, and other personnel having access to pharmaceutical products must
be designed and administered to assist in minimizing the possibility of such products coming into the possession of unauthorized persons or entities.

7.9 Codes of practice and punitive procedures should be in place to prevent and address situations where persons are suspected of, or found to be implicated in, any activities relating to the misappropriation, tampering, diversion or counterfeiting of any product.

7.10 Those who are responsible for the storage and distribution of pharmaceutical products (such as warehouse manager) should be present during the entire working hours specified in the license.

8- Quality system

8.1 There should be a documented quality policy describing the overall intentions and requirements of the distributor regarding quality.

8.2 The quality system should include an appropriate organizational structure, procedure, processes and resources and systematic actions necessary to ensure adequate confidence that a product or service and its documentation will satisfy given requirements for quality.

8.3 The quality system should include provisions to ensure that the holder of the marketing authorization, entity identified on the label (if different from the manufacturer), the appropriate national or international regulatory bodies, as well as other relevant competent authorities, would be informed immediately in a case of confirmed or suspected counterfeiting of a pharmaceutical product. Such products should be stored in a secure, segregated area and clearly identified to prevent further distribution or sale.

8.4 Defined and approved administrative and technical procedures for purchasing processes should be in place to ensure that appropriate pharmaceutical products are sourced only from approved suppliers and distributed by approved entities. The approval should come from the competent authority.

8.5 It is recommended that the entity acquire certification of compliance with a quality system (such as the applicable International Standardization Organization (ISO) series, or national or international guidelines) by external bodies. Such certification
should not, however, be seen as a substitute for compliance with these GDSP guidelines and the applicable principles of GMP relating to pharmaceutical products.

8.6 If measures to ensure the integrity of the pharmaceutical products in transit are in place, they should be managed properly. Written procedures should be in place for use in situations where pharmaceutical products are suspected of being or are found to be counterfeit.

8.7 Entities involved in storing and/or distributing and selling pharmaceutical products should from time to time conduct risk assessments to assess potential risks to the quality and integrity of pharmaceutical products. The quality system should be reviewed and revised periodically to address new risks identified during a risk assessment.

**Traceability of pharmaceutical products**

8.8 Regulations should foster a safe, transparent and secure distribution system which includes product traceability throughout the supply and distribution chain. This is a shared responsibility among the parties involved. There should be procedures in place to ensure document traceability of products received and distributed, to facilitate product recall.

8.9 All parties involved in the supply chain should be identifiable, depending on the type of product and on national policies and legislation.

8.10 Measures should be in place to ensure that pharmaceutical products have documentation that can be used to permit traceability of the products throughout distribution channels from the manufacturer/importer to the entity responsible for selling or supplying the product to the patient or his or her agent. Records including expiry dates and batch numbers may be part of a secure distribution documentation enabling traceability.

8.11 Ideally there should be a procedure in place for the identification of counterfeit products. Provision should be made for a visual or analytical identification of potential counterfeit products. The procedure to be followed when a suspected product is identified should include notification of the agent or the reference printed on the label (if different from the manufacturer), Saudi Food & Drug Authority and also governmental concerned bodies.
8.12 A suitable and, to the extent possible, internationally compatible product coding, identification system should be in place and developed in collaboration with the various parties involved in the supply, distribution and storage chain.

9- Premises and storage

9.1 Good storage practices (GSP) are applicable in all storage and distribution stages.

**Premises:**

9-2 The warehouse should be in the area dedicated by the competent authority for the establishment of warehouses with the exception of cities and governorates that don't have areas for warehouses dedicated by the competent authorities.

9-3 The premises should be well-insulated, thermally and hydraulically, well-ventilated and supplied with water and electricity, with a height not less than three (3) meters and equipped with sealed doors.

9-4 The warehouse floors should be easily cleaned, and in the case of water discharge openings, they should be sealed from the outside and distributed in places not accessible by cranes on their move inside the warehouse.

9-5 There should be no source of fire and smoke with guiding signs to prevent smoking.

9-6 The warehouse should have one entrance or more dedicated to the receipt and delivery of pharmaceutical products. The entrance/s should be away from the storage area with easily and clearly identified emergency exits.

9-7 Where there are Pharmaceutical Products need to be kept in refrigerators or freezers (according to the manufacturer's recommendation), there should be a reserve generator that works automatically in the event of power outage. For more detail please refer to: (Guidance for the Storage and Transport of Time and Temperature Sensitive Pharmaceutical Products) in the codes and guidelines in the website of the Food and Drug Authority.

9-8 The sign leading to the warehouse should in a clear place, in Arabic, with dimensions not less than 3.00 m x 1.5m and contain the name of the warehouse, the warehouse activity, working hours, telephone number and fax.
The authority should be notified before doing repair, modification or expansion of the storage areas, with business and clarify the proposed duration to finish them and precautionary measures to ensure that pharmaceutical products would not be affected.

Storage areas

9.10 Precautions must be taken to prevent unauthorized persons from entering storage areas. Employees should comply with the company policies to maintain a safe, secure and efficient working environment.

9.11 The storage space should not be less than 60 square meters, and that the minimum distance between the ceiling and the maximum height for storage should not be less than one meter.

9.12 The warehouse should be divided into:

- Receiving and dispatch bays should protect pharmaceutical products from the weather during receiving and delivery. Receiving areas should be designed and equipped to allow incoming containers of pharmaceutical products to be cleaned, if necessary, before storage.
- The storage area should have shelves and specified area for storing.
- A closed and segregated quarantine area for expired products.
- A specific and segregated area for the recalled products.
- A specific and isolated area for storing non-commercial products.

9.13 In case there is an authorization for more than one activity, each one should be stored orderly and separately.

9.14 Storage areas should be designed or adapted to ensure appropriate and good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Pharmaceutical products should be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets should be kept in a good state of cleanliness and repair.

9.15 The person in charge of storing Pharmaceutical products should ensure that Storage areas are cleaned regularly. There should also be a written program for insect and pest control or contracting a company to do so periodically.
9.16 Areas dedicated for decayed, expired, recalled and non-commercial products should be known and accessible for only authorized personnel.

9.17 Any electronic qualified and validated system replacing physical quarantine and segregations precautions should provide equivalent security and validity.

9.18 There should be electronic devices to measure temperature and humidity in storage, refrigerators and freezer areas and are periodically calibrated to ensure that the temperature and humidity are within acceptable limits. The temperature and humidity monitors are distributed in different places and heights according to Temperature Mapping approved for the warehouse. It is recommended that temperature monitors be located in areas that are most likely to show fluctuations. These monitors should record readings for a period of not less than one year.

9.19 Alarms should be provided in the refrigerator and freezer used to store pharmaceutical products. The alarms operate at high or low temperature and are calibrated periodically.

9.20 Damaged or expired pharmaceuticals should not be retained for more than one year from the date of noticing damage or expiry date, to be destroyed by a specialized company to dispose medical waste.

9.21 The recalled Pharmaceutical products should be stored in a dedicated area and have their own records, until a decision as to their future has been made by Food & Drug Authority and should be within acceptable temperature and humidity limits.

9.22 The non-commercial Pharmaceutical products should be stored in a dedicated area and have their own records, should be within acceptable temperature and humidity limits.

9.23 Radioactive materials and other hazardous, sensitive and/ or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fire or explosion (e.g. combustible or flammable liquids and solids and pressurized gases) should be stored in a dedicated area(s) that is subject to appropriate additional safety and security measures.

9.24 Pharmaceutical products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.
9.25 A system should be in place to ensure that the Pharmaceutical products due to expire first are sold and/or distributed first expiry/first out (FEFO)). Exceptions may be permitted as appropriate, provided that adequate controls are in place to prevent the distribution of expired products.

9.26 Written procedures should be provided for dealing with damaged or broken products to be transported directly into a dedicated segregated area.

9.27 Storage areas should be provided with adequate lighting to enable all operations to be carried out accurately and safely.

9.28 In the case of storing narcotic drugs and psychotropic substances, as well as the requirements of the GSDP (good distribution and storage practices, the following conditions must be met:

Be kept in accordance with the specifications and conditions of storage established by the manufacturer.

Be stored in a safe or an isolated storage area within the facility licensed to deal in narcotic drugs and psychotropic substances.

C) This safe (or storage area) is dedicated to storing narcotic substances, psychotropic substances and only has its own records.

D) This safe (or storage area) should be tightly sealed, and nobody is allowed to remove, break, or move it and should be provided with a separate security alarm system for protection.

E) The storage area should be made of concrete with a separate air-conditioning units storage area (Split)

**Storage conditions and stock control:**

9.29 Storage conditions for pharmaceutical products should be in compliance with the recommendations of the manufacturer.

9.30 All equipment and possibilities should be present in the facility (suitable temperature and humidity) to allow storage of all pharmaceuticals in suitable conditions should also be kept. The readings of temperature and humidity, especially sensitive products to some of the conditions of storage.
9.31 Records of temperature monitoring data should be available at the warehouse for review. There should be defined intervals for checking temperature. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained. All monitoring records should be kept for at least the shelf-life of the stored pharmaceutical product plus one year.

9.32 Periodic stock reconciliation should be performed by comparing the actual and recorded stocks.

9.33 Stock discrepancies should be investigated in accordance with a specified procedure to check that there have been no inadvertent mix-ups, incorrect issues and receipts, thefts and/or misappropriations of pharmaceutical products. Documentation relating to the investigation should be kept for at least the shelf-life of the stored pharmaceutical product plus one year.

10- Vehicles and equipment

10.1 Vehicles and equipment used to distribute, store or handle pharmaceutical products should be suitable for their purpose and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity, and to prevent contamination of any kind.

10.2 The design and use of vehicles and equipment must aim to minimize the risk of errors and permit effective cleaning and/or maintenance to avoid contamination, build-up of dust or dirt and/or any adverse effect on the quality of the pharmaceutical products being distributed.

10.3 Where feasible, consideration should be given to adding technology, such as global positioning system (GPS) electronic tracking devices and engine-kill buttons to vehicles, which would enhance the security of pharmaceutical products while in the vehicle.

10.4 Dedicated vehicles and equipment should be used, where possible, when handling pharmaceutical products. In the case of contracting with specialized transport companies, the firm and equipment should be compatible with the requirements of this Guideline.
10.5 Where non-dedicated vehicles and equipment are used, procedures should be in place to ensure that the quality of the pharmaceutical product will not be compromised. Appropriate cleaning should be performed, checked and recorded.

10.6 Procedures should be in place to ensure that the integrity of the products is not compromised during transportation.

10.7 Where third-party carriers are used, distributors should develop written agreements with carriers to ensure that appropriate measures are taken to safeguard pharmaceutical products, including maintaining appropriate documentation and records. Such agreements should be in line with the requirements of this Code.

10.8 Defective vehicles and equipment should not be used and should either be labeled as such or removed from service.

10.9 There should be procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.

10.10 Vehicles, containers and equipment should be kept clean and dry and free from accumulated waste.

10.11 Vehicles, containers and equipment should be kept free from rodents, vermin, birds and other pests. There should be written programs and records for such pest control. The cleaning and fumigation agents used should not have any adverse effect on product quality.

10.12 Equipment chosen and used for the cleaning of vehicles should not constitute a source of contamination. Agents used for the cleaning of vehicles should be approved by management.

10.13 Special attention should be paid to the design, use, cleaning and maintenance of all equipment used for the handling of pharmaceutical products which are not in a protective shipping carton or case.

10.14 Where special storage conditions (e.g. temperature and/or relative humidity), different from the expected environmental conditions required during transportation, these 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, or as required by national legislation. Records of
monitoring data should be made available for inspection by the Food and Drug Authority.

10.15 Equipment used for monitoring conditions, e.g. temperature and humidity, within vehicles and containers should be calibrated at regular intervals.

10.16 Vehicles and containers should be of sufficient capacity to allow orderly storage of the various categories of pharmaceutical products during transportation.

10.17 Where possible, mechanisms should be available to allow for the segregation during transit of rejected, recalled and returned pharmaceutical products as well as those suspected of being counterfeits. Such goods should be securely packaged, clearly labeled, and be accompanied by appropriate supporting documentation.

10.18 Measures should be in place to prevent unauthorized persons from entering and/or tampering with vehicles and/or equipment, as well as to prevent the theft or misappropriation thereof.

11- Shipment containers and container labelling

11.1 Pharmaceutical products should be stored and distributed in shipment containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination or different temperatures than recommended.

11.2 Shipping containers should bear labels providing sufficient information on handling and storage conditions and precautions to ensure that the products are properly handled and secure at all times. The shipment container should enable identification of the container’s contents and source.

11.3 The need for any special transport and/or storage conditions should be stated on the shipment container label. If a pharmaceutical product is intended for transfer to areas outside the control of the manufacturer’s products management system, the name and address of the manufacturer, special transport conditions and any special legal requirements, including safety symbols, should also be included on the container label.
11.4 Normally, internationally and/or nationally accepted abbreviations, names or codes should be used in the labeling of shipment containers.

11.5 Special care should be taken when using dry ice in shipment containers. In addition to safety issues it must be ensured that the pharmaceutical product does not come into contact with the dry ice, as it may have an adverse effect on the quality of the product.

11.6 Written procedures should be available for the handling of damaged and/or broken shipment containers. Particular attention should be paid to those containing potentially toxic and hazardous products.

12. Dispatch and receipt

12.1 Pharmaceutical products should only be sold and/or distributed to persons or entities that are authorized to acquire such products. Written proof of such authority must be obtained prior to the distribution of products to such persons or entities.

12.2 Prior to the dispatch of the pharmaceutical products, the supplier should ensure that the person or entity, e.g. the contract acceptor for transportation of the pharmaceutical products, is aware of the pharmaceutical products to be distributed and complies with the appropriate storage and transport conditions.

12.3 The dispatch and transportation of pharmaceutical products should be undertaken only after the receipt of a valid delivery order or material replenishment plan, which should be documented.

12.4 Written procedures for the dispatch of pharmaceutical products should be established. Such procedures should take into account the nature of the product as well as any special precautions to be observed. Pharmaceutical products under quarantine will require release for dispatch by the person responsible for quality (see 6.3).

12.5 Records for the dispatch of pharmaceutical products should be prepared and should include at least the following information: — date of dispatch, complete business name and address, quantity of the dispatched and remaining products, name of the carrier (in case of a third party), scientific name, product concentration,
pharmaceutical form, manufacture and expiry dates, batch number, signature of receivers or dispatchers.

12.6 Records of dispatch should contain enough information to enable traceability of the pharmaceutical product. Such records should facilitate the recall process, as well as the investigation of counterfeit or potentially counterfeit pharmaceutical products.

12.7 Methods of transportation, including vehicles to be used, should be selected with care, and local conditions should be considered, including the climate and any seasonal variations experienced. Delivery of products requiring controlled temperatures should be in accordance with the applicable storage and transport conditions.

12.8 Delivery schedules should be established and routes planned, taking local needs and conditions into account. Such schedules and plans should be realistic and systematic. Security risks should also be taken into account when planning the schedules and routes of the delivery.

12.9 Care should be taken to ensure that the volume of pharmaceutical products ordered does not exceed the capacity of storage facilities at the destination.

12.10 Vehicles and containers should be loaded carefully and systematically, to prevent physical damage and reduce security risks. Extra care should be taken during loading and unloading of cartons to avoid damage.

12.11 Pharmaceutical products should not be supplied or received after their expiry date, or so close to the expiry date that this date is likely to be reached before the products are used by the consumer.

12.12 Incoming shipments should be examined to verify the integrity of the container/closure system, ensure that tamper-evident packaging features are intact, and that labelling appears intact.

13. Transportation and products in transit

13.1 Products and shipment containers should be secured to prevent or provide evidence of unauthorized access. Vehicles and operators should be provided with additional security, as appropriate, to prevent theft and other misappropriation of products during transportation.
13.2 Product shipments should be secured and include the appropriate documentation to facilitate identification and verification of compliance with regulatory requirements. Policies and procedures should be followed by all persons involved in the transportation, to secure pharmaceutical products.

13.3 The people responsible for the transportation of pharmaceutical products should be informed about all relevant conditions for storage and transportation. These requirements should be adhered to throughout transportation and at any intermediate storage stages.

13.4 Pharmaceutical products should be stored and transported in accordance with procedures such that:

- The identity of the product is not lost.
- The product does not contaminate and is not contaminated by other products.
- Adequate precautions are taken against spillage, breakage, misappropriation and theft.
- Appropriate environmental conditions are maintained, e.g. using cold chain for thermolabile products.

13.5 The required storage conditions for pharmaceutical products should be maintained within acceptable limits during transportation. If a deviation has been noticed during transportation by the person or entity responsible for transportation, this should be reported to the distributor and recipient. In cases where the recipient notices the deviation, it should be reported to the distributor. Where necessary, the manufacturer of the pharmaceutical product should be contacted for information about appropriate steps to be taken.

13.6 Where special conditions are required during transportation that are different from or limit the given environmental conditions (e.g. temperature and humidity) these should be provided by the manufacturer on the labels, monitored and recorded.

13.7 Written procedures should be in place for investigating and dealing with any failure to comply with storage requirements, e.g. temperature deviations.

13.8 Transportation and storage of pharmaceutical products containing hazardous substances, such as toxic, radioactive material, and other dangerous pharmaceutical products presenting special risks of abuse, fire or explosion should be stored in
safe, dedicated and secure areas, and transported in safe, suitably designed, secured containers and vehicles.

13.9 Products containing narcotics and other psychotropic substances, according to the Authority requirements, should be transported in safe and secure containers and vehicles and be stored in safe and secure areas.

13.10 Spillages should be cleaned up as soon as possible to prevent possible contamination, cross-contamination and hazards. Written procedures should be in place for the handling of such occurrences.

13.11 Physical or other equivalent (e.g. electronic) segregation should be provided for the storage and distribution during transit of rejected, expired, recalled or returned pharmaceutical products and suspected counterfeits. The products should be appropriately identified, securely packaged, clearly labeled and be accompanied by appropriate supporting documentation.

13.12 The interiors of vehicles and containers should remain clean and dry while pharmaceutical products are in transit.

13.13 Packaging materials and shipment containers should be of suitable way that prevents damage to the products during transport. Closure should also be tight using seals system.

13.14 Drivers of vehicles should identify themselves and present appropriate documentation to demonstrate that they are authorized to transport the load.

13.15 Damage to containers and any other event or problem that occurs during transit must be recorded and reported to the relevant department, entity or authority, and investigated.

13.16 Pharmaceutical products in transit must be accompanied by the appropriate documentation.

13.17 Electronic devices Should be provided according to the requirements of the Authority so as to measure the temperature and humidity in the storage vehicles or containers during transport. These devices should be effective from the time of the transport until the arrival of the cargo, calibrated periodically where the temperature and humidity measuring devices are distributed in places and heights according to approved Temperature Mapping.
13-18 The records of temperature and humidity of pharmaceuticals that have been transferred should be kept for a minimum of the shelf-life of the product distributed plus one year.

14- Documentation

14.1 The original permissions and other relevant records should be kept in the entity responsible for storing and distributing Pharmaceutical products.

14.2 The certified seal of the entity responsible for storing and distributing Pharmaceutical products should be provided.

14.3 The standard operating procedures (SOP) for the storage and distribution of pharmaceutical products and the records of the entity (including bills) should be present in the warehouse.

14.4 Agents and distributors should be retained receiving and dispensing documents containing the required data in the warehouse. (See Article 12-5)

14.5 Procedures should be established and maintained for the preparation, review, approval, use of and control of changes to all documents relating to the distribution process. Procedures must be in place for both internally generated documents and those from external sources.

14.6 Documents, and in particular instructions and procedures relating to any activity that could have an impact on the quality of pharmaceutical products, should be designed, completed, reviewed and distributed with care, so that they are comprehensive, appropriate and clear to the persons concerned.

14.7 The title, nature and purpose of each document should be clearly stated. The contents of documents should be clear and unambiguous. Documents should be laid out in an orderly fashion and be easy to check.

14.8 All documents should be completed, approved, signed (as required) and dated by an appropriate authorized person(s) and should not be changed without the necessary authorization.

14.9 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.
14-10 The distributor must establish and maintain procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation.

14-11 All records must be readily retrievable, and be stored and retained using facilities that are safeguarded against unauthorized modification, damage, deterioration and/or loss of documentation.

14-12 Documents should be reviewed regularly and kept up to date. When a document has been revised, a system should exist to prevent inadvertent use of the superseded version.

14-13 Mechanisms should exist to allow for transfer of information, including quality or regulatory information, between a manufacturer and a customer, as well as the transfer of information to the relevant regulatory authority as required.

14-14 Records relating to storage of pharmaceutical products should be kept and be readily available upon request in accordance with the WHO guidelines on good storage practice for pharmaceuticals (1).

14-15 Procedures should be in place for security services to prevent theft or tampering with goods at the storage facilities, destruction of unsalable or unusable stocks and on retention of the records.

14.16 Where the records are generated and kept in electronic form, backups should be maintained to prevent any accidental data loss.

14.17 Special records should be kept for the following pharmaceutical products:

A- The recalled products for a minimum of the shelf-life of the product distributed plus one year.

B- The expired products for a minimum of the shelf-life of the product distributed plus one year.

C- The broken products for a year since the products have been broken.

D- Non-commercial products since distributed.
15- Repackaging and printing:

15.1 Distributed pharmaceutical products shouldn't be repacked as these practices may endanger the safety and security of pharmaceutical products.

15.2 All pharmaceutical products shouldn't have a printed or additional label without the approval of the Authority.

16- Complaints

16.1 There should be a written procedure in place for the handling of complaints. A distinction should be made between complaints about a product or its packaging and those relating to distribution. In the case of a complaint about the quality of a product or its packaging, the original manufacturer and/or marketing authorization holder should be informed as soon as possible.

16.2 All complaints and other information concerning potentially defective and potentially counterfeit pharmaceutical products should be reviewed carefully according to written procedures describing the action to be taken, including the need to consider a recall where appropriate.

16.3 Any complaint concerning a material defect should be recorded and thoroughly investigated to identify the origin or reason for the complaint.

16.4 If a defect relating to a pharmaceutical product is discovered or suspected, consideration should be given to whether other batches of the product should also be checked.

16.5 There should be a follow-up after an investigation and evaluation of the complaint. It should provide a system to ensure that the results of the investigation will be shared with the relevant parties.

16.6 The problems related to the quality of the product or suspected counterfeiting should be documented and Presented to the authority and competent authorities if discovered.
17-Recalls:

17.1 There should be a system, which includes a written procedure, to effectively and promptly recall pharmaceutical products known or suspected to be defective or counterfeit, with a designated person(s) responsible for recalls. This procedure should be checked regularly and updated as necessary.

17.2 The original manufacturer and/or marketing authorization holder should be informed in the event of a recall. If a recall of the original product is necessary because of a counterfeited product which is not easily distinguishable from the original product, the manufacturer of the original product and the relevant health authority should be informed.

17.3 The effectiveness of the arrangements for recalls should be evaluated at regular intervals. All recalled pharmaceutical products should be stored in a secure, segregated area pending appropriate action.

17.4 Recalled pharmaceutical products should be segregated during transit and clearly labeled as recalled products. Where segregation in transit is not possible, such goods must be securely packaged, clearly labeled, and be accompanied by appropriate documentation.

17.5 The particular storage conditions applicable to a pharmaceutical product which is subject to recall should be maintained during storage and transit until such time as a decision has been made regarding the fate of the product in question.

17.6 All customers and competent authorities of all countries to which a given pharmaceutical product may have been distributed should be informed.

17.7 All records should be readily available to the designated person(s) responsible for recalls. These records should contain sufficient information on pharmaceutical products supplied to customers (including exported products).

17.8 The progress of a recall process should be recorded and a final report issued, which includes reconciliation between delivered and recovered quantities of products.

17.9 When necessary emergency recall procedures should be implemented.
18-Returned products:

18.1 A distributor/agent should receive pharmaceutical product returns or exchanges pursuant to the terms and conditions of the agreement between the distributor and the recipient. Both distributors and recipients should be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of counterfeit products.

18.2 The necessary assessment and decision regarding the disposition of such products must be made by a suitably authorized person. The nature of the product returned to the distributor, any special storage conditions required, its condition and history and the time elapsed since it was issued, should all be taken into account in this assessment.

18.3 Provision should be made for the appropriate and safe transport of returned products in accordance with the relevant storage and other requirements.

18.4 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.

18.5 Provision should be made for the appropriate and safe transport of rejected pharmaceutical products prior to their disposal.

18.6 Destruction of returned or rejected pharmaceutical products should be done after the approval of the Authority. This can be done by contracting a specialized company for medicine waste disposal.

18.7 Records of all returned, rejected and destroyed pharmaceutical should be kept for one year such time as a decision has been made.

19- Counterfeit pharmaceutical products

19.1 Counterfeit pharmaceutical products found in the distribution chain should be kept apart from other pharmaceutical products. They should be clearly labeled as not for sale and the agent and the authority should be informed immediately.
19.2 The sale and distribution of a suspected counterfeit pharmaceutical product should be suspended and the national regulatory authority notified without delay.

19.3 Upon confirmation of the product being counterfeit a formal decision should be taken on its disposal, ensuring that it does not re-enter the market, and the decision recorded.

20-Contract activities

20.1 Any activity relating to the distribution of a pharmaceutical product which is delegated to another person or entity should be performed by parties appropriately authorized for that function and in accordance with the terms of a written contract.

20.2 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.

20.3 All contract accepters should comply with the requirements in this code.

20.4 Subcontracting may be permissible, under certain conditions and subject to the written approval of the contract giver; however, the subcontractors should be authorized for the function entrusted to it.

20.5 Contract accepters should be audited periodically.

21-Self-inspection

21.1 The quality system should include self-inspections. These should be conducted to monitor implementation and compliance with the principles of GSDP.

21.2 Self-inspections should be conducted in an independent and detailed report by a designated, competent person.

21.3 The self-inspections reports should contain all observations made during the inspection and, where applicable, proposals for corrective measures.

21.4 There should be an effective follow-up program. Management should evaluate the inspection report and the records of any corrective actions taken to address such observations.