REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

GUIDELINES ON GOOD STORAGE & DISTRIBUTION PRACTICES OF PHARMACEUTICAL PRODUCTS IN LEBANON

TOWARDS A CONTINUOUS IMPROVEMENT CYCLE


01 Organization & Management


02 Personnel


03 Quality System


04 Premises, Warehousing & Storage


05 Vehicles & Equipement


06 Shipment Containers & Container Labeling


07 Dispatch & receipt


08 Documentation


09 Repackaging & Relabeling


10 Complaints


11 Recalls


12 Returned Products


13 Counterfeits Pharmaceutical Products


14 Importation


15 Contract activities


16 Internal Quality Audit


17 Self inspection


18 Measurement, Analysis & Improvement


19 Going green

Edition - 5 2024

Edited by: Dr. Rita Karam & Mrs. Christelle Fransawi

Table of Contents

01 Introduction

Distribution is an important activity in the integrated supply chain management of pharmaceutical products that involves various members responsible for the handling, storage and distribution of such products.

The objective of these guidelines is to ensure the quality and identity of pharmaceutical products during the whole distribution process. Furthermore, it sets out appropriate steps to assist in fulfilling the responsibilities involved in the different aspects of the distribution process within the supply chain and to avoid the introduction of counterfeits products into the marketplace via the distribution chain.

These guidelines are issued, according to the guidelines and instructions of the World Health Organization, by the Lebanese Ministry of Public Health, which stresses the importance of adhering to it by all parties involved in any aspect of the distribution of pharmaceutical products, as relevant to the particular role that they play, from the premises of the manufacturer of the product to the person dispensing or providing pharmaceutical products directly to a patient or his agent.

Amendments from last revision

Year	Page- Section	Revision	Description of Main Changes
2023	Page 15 – Chapter 4	5	Inclusion of temperature mapping
	Page 22 – Chapter 8		Further requirements related to records of stock levels and stock discrepancies management
	Page 27 – Chapter 12		Further requirements related to data security
			Further requirements related to returned products

02 Glossary

The definitions provided below apply to the words and sentences used on these guidelines:

Agent

The party involved in providing, either directly or indirectly, any service related to clearing and forwarding operations, in any form, to any other party. [1]

Agreement

Arrangement undertaken by and legally binding on parties. [1]

Auditing

An independent and objective activity designed to add value and improve an organization's operations by helping the organization to accomplish its objectives by using a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control and governance processes. [1]

Batch

A defined quantity of pharmaceutical products processed in a single process or series of processes so that it is expected to be homogeneous. [1]

Batch number

A distinctive combination of numbers and/or letters used to uniquely identify a batch, for example, on the labels, its batch records and corresponding certificates of analysis. [1]

Corrective and Preventative Actions (CAPA)

A system for implementing corrective and preventive actions resulting from an investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings and trends from process performance and product quality monitoring.[7]

Consignment (delivery)

The quantity of pharmaceutical(s) made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.

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. [1]

Counterfeit pharmaceutical product

A pharmaceutical product deliberately and fraudulently mislabeled, with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit pharmaceutical products may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with an incorrect quantity of active ingredient or with fake packaging. [1]

Contract

Business agreement for the supply of goods or performance of work at a specified price. [1]

Distribution

The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of pharmaceutical products, with the exception of the dispensing or providing pharmaceutical products directly to a patient or his or her agent. [1]

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. It is established for each batch by adding the shelf-life to the date of manufacture. [1]

First expiry/First out (FEFO)

A distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used. [1]

Good Distribution Practices (GDP)

That part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products. [1]

Good Storage Practices (GSP)

That part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the storage thereof. [1]

Labeling

Process of identifying a pharmaceutical product including the following information, as appropriate: name of the product; active ingredient(s), type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; names and addresses of the manufacturer and/or the supplier. [1]

Pharmaceutical product

Any product intended for human use, or veterinary product intended for administration to foodproducing animals, presented in its finished dosage form, which is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals and vaccines. It does not, however, include medical devices. [1]

Product recall

A process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, importer, wholesaler, distributor or a responsible agency. [1]

Quality assurance

A wide-ranging concept covering, all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. [1]

Quality control

All measures taken including the setting of specifications, sampling, testing and analytical clearance, to ensure that sampling materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.

Quality system

An appropriate infrastructure encompassing the organizational structure, procedures, processes and resources and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality. [1]

Quarantine

The status of pharmaceutical products isolated physically or by other effective means, while a decision is awaited on their release, rejection or reprocessing. [1]

Shelf-life

The period of time during which a pharmaceutical product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product.

Standard operating procedure (SOP)

An authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection). [1]

Storage

The storing of pharmaceutical products and material up to the point of use from end user. [1]

Vehicles

Trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey pharmaceutical products. [1]

Storage conditions

Some pharmaceutical products require specific conditions to be stored within, and needs special instructions for storage handling and methods:

- Not to exceed 30 °C: means to store within the range from 2+ to 30+ °C.
- Not to exceed 25 °C: means to store within the range from 2+ to 25+ °C.

- Not to exceed 15 °C: means to store within the range from 2+ to 15+ °C.
- Not to exceed 8 °C: means to store within the range from 2+ to 8+ °C.
- The product shall be protected from humidity: means to protect it from conditions where humidity exceeds %60, and shall be kept in a humidity resistant container.
- Keep away from light: means that shall be stored in places not exposed to light. It shall be kept in light proof containers. [1]

Quality

The degree to which a set of inherent characteristics fulfills requirements. [4]

Continuous improvement

The recurring activity to increase the ability to fulfill requirements. [4]

Corrective actions

Action to eliminate the cause of a detected nonconformity or other undesirable situation. [4]

Preventive actions

Action to eliminate the cause of a potential nonconformity or other undesirable potential situation. [4]

Plan Do Check Act

The methodology known as "Plan-Do-Check-Act" can be applied to all organization's operations. It can be briefly described as follows:

-Plan: establish the objectives of the system and the resources needed to deliver results in accordance with customers' requirements and the warehouse's policies and identify and address risks and opportunities.

-Do: implement what was planned.

-Check: monitor and measure operations and the resulting products and services against policies, objectives, planned activities and requirements and report the results.

-Act: take actions to continually improve process performance, as necessary. [4]

1.Organization and management

1.1 There shall be an adequate organizational structure for each entity, defined with the aid of an organizational chart that clearly identifies responsibilities, authorities and interrelationships of all personnel. [1]

1.2 Duties and responsibilities shall be clearly defined through documented job descriptions and understood by the concerned individuals, who shall be trained on their respective duties and responsibilities and who shall be aware of the relevance and importance of their activities and how they contribute to the achievement of the warehouse quality objectives and policy. [4] [1]

1.3 A designated competent person shall be appointed within the warehouse, who has defined authority and responsibility for ensuring that a quality system is implemented and maintained. He shall be accountable on reporting to top management on the performance of the quality management system and any need for improvement and ensuring the promotion of awareness of customer requirements throughout the warehouse. [4] [1]

1.4 There shall 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. [1]

1.5 The organization shall determine, provide and maintain the infrastructure necessary for its operations and needed to achieve conformity to product and service requirements. Infrastructure can include:

-Buildings and associated utilities

-Equipment, including hardware and software

-Transportation resources

-Information and communication technology [4]

1.6 The organization shall determine, provide and maintain the environment necessary for its operations and needed to achieve conformity of products and services. A suitable environment can be a combination of human and physical factors, such as:

-Social (e.g. non-discriminatory, calm)

-Psychological (e.g. stress-reducing, burnout prevention)

-Physical (e.g. temperature, humidity, light, hygiene, noise) [4]

2.Personnel

2.1 The warehouse shall determine the necessary competence of personnel involved in distribution activities, doing work that affects the performance and effectiveness of the quality management system. [4] [1]

2.2 All personnel involved in the distribution activities shall be competent on the basis of appropriate education, training, skills and experience in the requirements of good distribution and storage practices, as applicable. The warehouse shall provide necessary training to achieve needed competency. [4] [1]

2.3 The warehouse shall assess personnel performance in line with their job descriptions and shall take appropriate measures, detecting and providing necessary training needs to achieve needed competency. [4] [1]

2.4 There shall be an adequate number of competent personnel involved in all stages of the distribution of pharmaceutical products in order to ensure that the quality of the product is maintained. [4] [1]

2.5 Personnel training shall be based on written standard operating procedures (SOPs). They shall receive initial and continuing training relevant to their tasks, in accordance with a written training program and they shall be assessed as applicable to evaluate the effectiveness of the actions taken. Appropriate records shall be maintained, including details of subjects covered and participants trained. [4] [1]

2.6 Delivered trainings shall cover the topic of good storage and distribution practices, product security, as well as aspects of product identification, the detection of counterfeits and the avoidance of counterfeits entering the supply chain. Trainings shall also cover how to deal with hazardous pharmaceutical products (such as highly active materials, radioactive materials, narcotics, and other hazardous, environmentally sensitive and/or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fire or explosion). [4] [1]

2.7 Personnel involved in the distribution of pharmaceutical products shall wear garments suitable for the activities that they perform. Personnel dealing with hazardous pharmaceutical products, including products containing materials that are highly active, toxic, and infectious or sensitizing, shall be provided with protective garments as necessary. [4] [1]

2.8 Appropriate procedures relating to personnel hygiene and safety, relevant to the activities to be carried out, shall be established and observed. Such procedures shall cover health and safety, hygiene and clothing of personnel. [1]

2.9 Codes of practice and punitive procedures shall be in place to prevent and address situations where persons involved in the distribution of pharmaceutical products are suspected of, or found to be implicated in, any activities relating to the misappropriation, tampering, diversion or counterfeiting of any product. [1]

3.Quality system

3.1 There shall be a documented quality policy describing the overall intentions and requirements of the warehouse regarding quality, and including a commitment to comply with those requirements and continually improve the effectiveness of the quality system, as formally expressed and authorized by management. This policy shall be communicated and understood by all personnel. [4] [1]

3.2 The warehouse shall conduct a risk assessment to assess potential risks to the quality and integrity of pharmaceutical products. The quality system shall be developed and implemented to address any potential risks identified. The quality system shall be reviewed and revised periodically to address new risks identified during the risk assessment. [1]

3.3 Risk Management System strategies should ensure that each organization's best interests are served by adhering to proper practices, controls, and procedures, including but not limited to the following: the nature of the drug products; distribution requirements on the readable container labeling; exposure to adverse environmental conditions; number of stages/receipts in the supply chain; manufacturer's written instructions; contractors; and drugs at risk from freezing (vaccines, insulin, and biological products) or elevated temperatures (fatty-based suppositories, vaccines, insulin, and biological products).[8]

3.4 Top management shall review the organization's quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review shall take into consideration: a.The status of actions from previous management review meetings;

b.Changes in external and internal issues that are relevant to the quality management system;

c.Information on the performance and effectiveness of the quality management system including including trends in:

-Customer satisfaction and feedback from relevant interested parties

-Non conformities and corrective actions

-Warehouse performance and conformity of products and services -Audit results

-The performance of external providers d.The adequacy of resources;

e.The effectiveness of actions taken to address risks and opportunities;

f.Opportunities for improvement. [4]

3.5 Records from management review shall be retained. The outputs of the management review shall include decisions and actions related to opportunities for improvement, any need for changes to the quality management system and resource needs. [4]

3.6 Inspection, auditing and certification of compliance with a quality system (such as the applicable International Standardization Organization (ISO) series, or national or international guidelines) by external bodies are recommended. Such certification shall not, however, be seen as a substitute for compliance with these guidelines and the applicable principles of good manufacturing practices relating to pharmaceutical products. [1]

Traceability of pharmaceutical products

3.7 The warehouse shall foster a safe, transparent and secure distribution system which includes product traceability throughout the supply chain. There shall be procedures in place to ensure traceability of products received and distributed in order to facilitate product recall. [1]

3.8 The warehouse shall identify all parties involved in the supply chain, depending on the product's type and national policies and legislations. [1]

3.9 Measures shall 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. [1]

4.Premises, warehousing and storage

4.1 Storage areas shall be of sufficient capacity to allow the orderly storage of the various categories of pharmaceutical products. [1]

4.2 Storage areas shall be designed or adapted to ensure appropriate and good storage conditions.
In particular, they shall be clean and dry and maintained within acceptable temperature limits. Pharmaceutical products shall be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets shall be kept in a good state of cleanliness and repair. [1]

4.3 The following factors, which may contribute to temperature variability, should be considered during the process of temperature mapping storage locations: (1) size of the space; (2) location of HVAC equipment, space heaters, and air conditioners; (3) sun-facing walls; (4) low ceilings or roofs; (5) geographic location of the area being mapped; (6) airflow inside the storage location; (7) temperature variability outside the storage location; (8) workflow variation and movement of equipment (weekday vs. weekend); (9) loading or storage patterns of product; and (10) equipment capabilities (e.g., defrost mode, cycle mode).[8]

4.4 Storage areas shall be provided with adequate lighting to enable all operations to be carried out accurately and safely. [1]

4.5 The warehouse shall ensure that premises and storage areas undergo regularly a pest control program or must ensure that pest control activities are subcontracted to a specialized entity followed up regularly. [1]

4.6 Spillages shall be cleaned up as soon as possible to prevent possible contamination and hazards. Written procedures shall be in place for the handling of such occurrences. Special precautions shall be taken for cytotoxic products. [1]

4.7 Precautions must be taken to prevent unauthorized persons from entering storage areas and precautions. [1]

4.8 The warehouse shall establish a procedure to identify the potential for emergency situations (such as firefighting, flooding and other emergencies) and to respond to such emergency situations. This procedure shall be tested and reviewed periodically where practical. [5]

4.9 Receiving and dispatch bays shall protect pharmaceutical products from the weather. Receiving areas shall be designed and equipped to allow incoming containers of pharmaceutical products to be cleaned, if necessary, before storage. [1]

4.10 Physical or other equivalent validated segregation shall be provided for the storage of commercial and non-commercial, rejected, expired, recalled or returned products and suspected counterfeits. The products and the areas concerned shall be appropriately identified during their temporary storage until a decision as to their future has been made. [1]

4.11 Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and access restricted to authorized personnel. Any system replacing physical quarantine shall provide equivalent security. For example, computerized systems can be used, provided that they are validated to demonstrate security of access. [1]

4.12 narcotics shall be stored in designated areas according to the Act No. 98/673.

4.13 A system shall be in place to ensure that the pharmaceutical products due to expire first are sold and/ or distributed first (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. [1]

Storage conditions / stock control and rotation

4.14 Storage conditions for pharmaceutical products shall be in compliance with the recommendations of the manufacturer. [1]

4.15 Records of temperature and humidity monitoring data shall be available for review. There shall be defined intervals for checking temperature. [1]

4.16 The equipment used for monitoring shall be checked at suitable predetermined intervals and the results of such checks shall be recorded and retained. All monitoring records shall be kept for at least the shelf-life of the stored pharmaceutical product plus one year. Temperature mapping shall show uniformity of the temperature across the storage facility. [1]

4.17 Records of stock levels for all medical products in store should be maintained, in either paper or electronic format. These records should be updated after each operation (e.g., entries, issues, losses, adjustments). These records should be kept for a predetermined period of time. Periodic stock reconciliation should be performed at defined intervals, by comparing the actual and recorded stock.[7]

4.18 The root cause for stock discrepancies should be identified and appropriate CAPAs taken to prevent recurrence.[7]

5.Vehicles and equipment

5.1 Pharmaceutical products shall be 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. [1]

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

5.3 Vehicles and equipment used to distribute, store or handle pharmaceutical products shall be of sufficient capacity to allow orderly storage of the various categories of pharmaceutical products and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity, and to prevent contamination. [1]

5.4 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. [1]

5.5 Vehicles and equipment shall be kept free from rodents, vermin, birds and other pests. There shall be written programs and records for such pest control. The cleaning and fumigation agents used shall not have any adverse effect on product quality. [1]

5.6 Where special storage conditions (e.g. temperature and/or relative humidity), different from, or limiting, the expected environmental conditions, are required during transportation, these shall be provided, checked, monitored and recorded. All monitoring records shall be kept for a minimum of the shelf-life of the product distributed plus one year, or as required by national legislation. [1]

5.7 Equipment used for monitoring conditions, e.g. temperature and humidity, within vehicles and containers shall be calibrated at regular intervals. [1]

5.8 Defective vehicles and equipment shall not be used and shall either be labeled as such or removed from service until maintained. [1]

5.9 Drivers responsible for the transportation of pharmaceutical products shall be informed about all relevant conditions for storage and transportation. These requirements shall be adhered to throughout transportation and at any intermediate storage stages. [1]

5.10 Products containing narcotics and other dependence-producing substances, hazardous substances, such as toxic, radioactive material, and other dangerous pharmaceutical products shall be transported in safe and secure containers and vehicles and be stored in safe and secure areas. [1]

5.11 Physical or other equivalent segregation shall be provided for the distribution of rejected, expired, recalled or returned pharmaceutical products and suspected counterfeits. The products shall be appropriately identified, securely packaged, clearly labeled and be accompanied by appropriate supporting documentation. [1]

5.12 Measures shall 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. [1]

5.13 Where feasible, consideration shall be given to adding technology, such as global positioning system (GPS) electronic tracking devices and others, which would enhance the security of pharmaceutical products while in the vehicle. [1]

5.14 Where third-party carriers are assigned to conduct local distribution of pharmaceutical products, the warehouse shall develop written agreements with carriers to ensure that appropriate measures are taken to safeguard pharmaceutical products, including maintaining appropriate documentation and records. [1]

6.Shipment containers and container labeling

6.1 The warehouse shall ensure that imported pharmaceutical products are 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. Shipment containers shall also be secured to prevent or provide evidence of unauthorized access [1]

6.2 The warehouse shall ensure that shipment containers have labels providing sufficient information on handling and storage conditions and precautions to ensure that the products are properly handled and secured at all times. The shipment container shall enable identification of the container's contents and source. [1]

6.3 The need for any special transport and/or storage conditions shall be stated on the shipment container label and on the shipped products. 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, shall also be included on the container label. [1]

6.4 Written procedures shall be available for the handling of damaged and/or broken shipment containers. Particular attention shall be paid to those containing potentially toxic and hazardous products. All related events or problems that occur shall be recorded and reported to the relevant department, entity or authority, and investigated [1]

6.5 Incoming shipments shall be examined to verify the integrity of the container, ensure that the packaging features are intact, and labelling appears intact. When required, samples shall be taken only by appropriated trained and qualified personnel, in accordance with written sampling instructions.
Containers from which samples have been taken should be labelled accordingly.[2]

7. Dispatch and receipt

7.1 Pharmaceutical products shall only be sold and/or distributed to persons or entities that are authorized to acquire such products in accordance with the applicable national, regional and international legislation. Written proof of such authority must be obtained prior to the distribution of products to such persons or entities. [1]

7.2 The dispatch and transportation of pharmaceutical products shall be undertaken only after the receipt of a valid delivery order. [1]

7.3 Written procedures for the dispatch and release of pharmaceutical products shall be established. Such procedures shall 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. [1]

7.4 Records for the dispatch of pharmaceutical products shall be prepared and shall include at least the following information: date of dispatch; complete business name and address of the entity responsible for the transportation, complete business name and status of the addressee (e.g. retail pharmacy, hospital or community clinic); a description of the products including, e.g. name, dosage form and strength (if applicable); quantity of the products; applicable transport and storage conditions; a unique number to allow identification of the delivery order; assigned batch number and expiry date to facilitate trac eability. [1]

7.5 Records of dispatch shall contain enough information to enable traceability of the pharmaceutical product, the assigned batch number and expiry date of pharmaceutical products. Such records shall facilitate the recall of a batch of a product when necessary. [1]

7.6 Delivery schedules shall be established and routes planned, taking local needs and conditions into account. Such schedules and plans shall be realistic and systematic. Security risks shall also be taken into account when planning the schedules and routes of the delivery. [1]

7.7 Vehicles shall be loaded carefully and systematically, where applicable on a first-out/last-in basis, to save time when unloading, prevent physical damage and reduce security risks. Extra care shall be taken during loading and unloading of cartons to avoid damage. [1]

7.8 Pharmaceutical products shall 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. [1]

8. Documentation

8.1 The warehouse shall establish appropriate documented procedures and instructions related to all storage and distribution of pharmaceutical products activities. [1]

8.2 The title, nature and purpose of each document shall be clearly stated and shall comply with national legislative requirements. The contents of documents shall be clear and unambiguous. Documents shall be laid out in an orderly fashion and be easy to check. [1]

8.3 All documents shall be completed, approved, signed (as required) and dated by an appropriate authorized person(s) and shall not be changed without the necessary authorization. [1]

8.4 Procedures shall be established and maintained for the editing, review, approval, use of and control of changes to all documents relating to the distribution and storage activities. Procedures must be in place for both internally generated documents and those from external sources. [1]

8.5 The warehouse shall keep records of all pharmaceutical products received. Records shall contain at least the following information: date, name of the pharmaceutical product, quantity received or supplied and name and address of the supplier. [1]

8.6 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. [1]

8.7 Permanent records, written or electronic, shall exist for each stored product indicating recommended storage conditions, any precautions to be observed and retest dates. Pharmacopoeial requirements and current national regulations concerning labels and containers shall be respected at all times. [1]

8.8 he warehouse shall ensure appropriate backup systems for electronic documents and records. The server room shall also be appropriated maintained to prevent any data loss. [1]

8.9 Data shall be secured by physical or electronic means and protected against accidental or unauthorized modifications. Stored data shall be checked periodically for accessibility. Data shall be protected by backing up at regular intervals. The backed-up data shall be retained for the period of at least five years at a separate and secure location.[3]

9.Repackaging and relabeling

9.1 Repackaging and relabeling of pharmaceutical products shall not be allowed, as these practices may represent a risk to the safety and security of the supply chain.

9.2 Printing and/or adding extra stickers shall not be allowed unless authorized by the concerned entity. In that event, appropriate procedures shall be developed in order to define responsibilities and implement appropriate control measures.

9.3 The re-printing is forbidden in the law No. 1994/367 related to pharmacy profession.

10.Complaints

10.1 There shall be a written procedure in place for the handling of complaints. A distinction shall 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 shall be informed as soon as possible. [1]

10.2 All complaints and other information concerning potentially defective and potentially counterfeit pharmaceutical products shall be reviewed carefully according to written procedures describing the action to be taken, including the need to consider a recall where appropriate. Consideration shall be given to whether other batches of the product shall also be checked. [1]

10.3 Appropriate follow-up action shall be taken after investigation and evaluation of the complaint. There shall be a system in place to ensure that the complaint, the response received from the original product manufacturer, or the results of the investigation of the complaint, are shared with all the relevant parties. [1]

11.Recalls

11.1 There shall 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 shall be checked regularly and updated as necessary. [1]

11.2 The original manufacturer and/or marketing authorization holder shall be informed in the event of a recall. Where a recall is instituted by an entity other than the original manufacturer and/or marketing authorization holder, consultation with the original manufacturer and/or marketing authorization holder shall, where possible, take place before the recall is instituted. Information on a recall shall be shared with the appropriate national regulatory authority. 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 shall be informed. [1]

11.3 The effectiveness of the arrangements for recalls shall be evaluated at regular intervals. [1]

11.4 Recalled pharmaceutical products shall be segregated and clearly labeled as recalled products. All recalled pharmaceutical products shall be stored in a secure, segregated area pending appropriate action. [1]

11.5 The particular storage conditions applicable to a pharmaceutical product which is subject to recall shall be maintained during storage until such time as a decision has been made regarding the fate of the product in question. [1]

11.6 All customers and competent authorities of all countries to which a given pharmaceutical product may have been distributed shall be informed promptly of any intention to recall the product. [1]

11.7 All records shall be readily available to the designated person(s) responsible for recalls. These records shall contain sufficient information on pharmaceutical products supplied to customers (including exported products). [1]

11.8 The progress of a recall process shall be recorded and a final report issued, which includes reconciliation between delivered and recovered quantities of products. [1]

11.9 Pharmaceutical products intended for destructions shall be appropriately identified, held separately and handled in accordance written procedure. It shall be in accordance with Lebanese or international requirements for handling, transport and disposal of such products. Records of all destroyed pharmaceutical products shall be maintained for a defined period of time.[3]

12. Returned products

12.1 A distributor shall 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 shall be accountable for administering their returns process and ensuring that the aspects of this operation are secured and do not permit the entry of counterfeit products and that provision are made for the appropriate and safe transport of returned and rejected pharmaceutical products prior to their disposal. [1]

12.2 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, shall all be taken into account in this assessment. Where any doubt arises over the quality of a pharmaceutical product, it shall not be considered suitable for reissue or reuse. [1]

12.3 The warehouse shall maintain any particular storage conditions applicable to a pharmaceutical product which is rejected or returned until decision has been made regarding its fate. [1]

12.4 The warehouse shall establish appropriate procedures for the management of rejected pharmaceutical products and those returned to a distributor in a way to ensure they are appropriately identified, segregated and handled. [1]

12.5 Pharmaceutical products that shall be disposed shall be manipulated in accordance with international, national and local requirements regarding disposal of such products, and with due consideration to protection of the environment. [1]

12.6 Where applicable, records of all returned, rejected and/or destroyed pharmaceutical products shall be kept for a predetermined period. [1]

12.7 Where applicable, the procedure related to products returned shall be in compliance with the protocol issued between the Syndicate of Pharmacists and the Syndicate of pharmaceutical importers and owners of warehouses in Lebanon in 2006/09/01.

12.8 For pharmaceutical products requiring specific temperature storage conditions such as low temperature, returns to saleable stock shall only be made if there is documented evidence that the product has been stored under the authorized storage conditions throughout the entire time.

In case of any deviation, a risk assessment shall be performed, on which basis the integrity of the product can be demonstrated. The evidence shall cover: delivery to customer, examination of the product, opening of the transport packaging, return of the product to the packaging, collection and return to the distributor, return to the distributor site refrigerator. Products returned to saleable stock shall be placed such that the FEFO system operates effectively. Stolen products recovered cannot be returned to saleable stock and sold to customer.[3]

13. Counterfeit pharmaceutical products

13.1 The quality system shall include provisions to ensure that the holder of the marketing authorization, entity identified on the label (if different from the manufacturer), the appropriate national and/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 shall be kept apart from other pharmaceutical products to avoid any confusion, stored in a secure, segregated area and clearly identified to prevent further distribution or sale. [1]

13.2 Where applicable, the warehouse using holograms to identify and prevent the proliferation of counterfeit pharmaceutical products as well as tracing the product all the way to the end user, shall take appropriate measures to avoid the misuse of holograms and tampering actions.

13.3 The sale and distribution of a suspected counterfeit pharmaceutical product shall be suspended and the national regulatory authority notified without delay. [1]

13.4 Upon confirmation of the product being counterfeit a formal decision shall be taken on its disposal, ensuring that it does not re-enter the market, and the decision recorded. [1]

14. Importation

14.1 At the port of entry, the warehouse shall take appropriate measures to ensure that consignments of pharmaceutical products shall be stored under suitable conditions for as short a time as possible. [1]

14.2 All reasonable steps shall be taken by importers to ensure that products are not mishandled or exposed to adverse storage conditions at wharves or airports or land fronts. Where necessary, personnel with pharmaceutical training shall be involved with the customs procedures or shall be readily contactable.[1]

15. Outsourced activities

15.1 Any activity relating to the distribution and storage of pharmaceutical products which is delegated to another person or entity shall be performed by parties appropriately authorized for that function and in accordance with the terms of a written contract. [1]

15.2 The written contract shall define the responsibilities of each party including observance of the principles of good distribution and storage practices. It shall also include responsibilities of the contractor to provide adequate training for involved personnel to avoid the entry of counterfeit pharmaceutical products into the distribution chain.[1] It shall define the conditions of subcontracting subject to the written approval of the contract giver.[7]

15.3 All contract accepters shall comply with the requirements of these guidelines and shall be audited periodically. Proof of audits shall be maintained. [1]

16. Internal quality audit

16.1 The warehouse shall conduct internal audits at planned intervals to determine whether the quality system conforms to planned arrangements, to the requirements of the GSDP guidelines and to the quality management system requirements established by the warehouse. Internal audits allow also ensuring the quality system is effectively implemented and maintained. [4]

16.2 Internal audits shall be planned taking into consideration the status and importance of the operations and areas to be inspected, as well as the results of previous audits. [4]

16.3 The internal audit criteria, scope, frequency and methods shall be determined. [4]

16.4 The selection of internal auditors and conduct of internal audits shall ensure objectivity and impartiality of the audit process. [4]

16.5 A documented procedure shall be established to define the responsibilities and requirements for planning and conducting internal audits, establishing records and reporting results. [4]

16.6 The results of all internal audits shall be recorded. Reports shall contain all observations made during the audit and, where applicable, proposals for corrective measures. There shall be an effective follow-up program. Management shall evaluate the internal audit report and the records of any corrective actions taken. [4]

17. Self-inspection

17.1 The warehouse shall conduct a self-assessment of its operations in order to monitor implementation and compliance with the principles of the good storage and distribution practices of pharmaceutical products and if necessary to trigger corrective and preventive measures according to Resolution ,2/962
1] .2014]

17.2 Self-assessments shall be conducted in an independent and detailed way by a designated competent person. [1]

17.3 The results of the self-assessment shall be recorded on the latest version of the self-assessment sheets available on the Lebanese Ministry of Public Health website (www.moph.gov.lb). Sheets shall include all observations and relevant evidences detected during the assessment and where applicable, proposals for corrective measures shall be submitted. An effective follow up program shall be in place. [1]

18. Measurement, analysis and improvement

18.1 The warehouse shall determine:

-What needs to be monitored and measured;

-The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

-When the monitoring and measuring shall be performed;

-When the results from monitoring and measurement shall be analyzed and evaluated.

The warehouse shall evaluate the performance and the effectiveness of the quality management system and shall retain appropriate documented information as evidence of the results. [4]

18.2 The warehouse shall apply suitable methods for monitoring and where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the operations to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate. [4]

19. Going Green

19.1 The warehouse shall adopt a systematic approach to environmental management by implementing environmental practices such as adopting the 3Rs practice, for Re-use, Reduce and Recycle. The warehouse shall also keep up with environmental news and green trends to identify areas of improvement. [6]

19.2 The warehouse shall ensure that persons doing work under the warehouse's control are aware of its environmental approaches in order to ensure the proper implementation of environmental practices and promote a cultural shift. [6]

19.3 The warehouse shall go digital where possible and save paper. [6]

19.4 The warehouse shall institute an energy saving, waste management and recycling program and shall promote awareness among its employees to ensure proper implementation. [6]

03 References

1. WHO good distribution practices for pharmaceutical products (WHO technical report series, No. ,957 2010)

2. WHO guide to good storage practices for pharmaceuticals (WHO technical report series, No. 2003 ,908)

3. Commission guidelines on good distribution practices of medicinal products for human use, European commission, 2013

4. ISO 9001:2015, quality management systems requirements

5. ISO 45001:2018, occupational health and safety management systems requirements

6. ISO 14001:2015, environmental management systems requirements

7. WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-fourth report (WHO Technical Report Series, No. 2020 ,1025)

REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

GUIDELINES ON GOOD STORAGE & DISTRIBUTION PRACTICES OF PHARMACEUTICAL PRODUCTS IN LEBANON

Edition 5 - 2024

Edited by: Dr. Rita Karam & Mrs. Christelle Fransawi