ARAB ACADEMY FOR SCIENCE, TECHNOLOGY AND MARITIME TRANSPORT

College of International Transport and Logistics

INVESTIGATING THE STORAGE PRACTICES OF PHARMACIES IN ALEXANDRIA: PROPOSED SOLUTIONS FOR THE PHARMACEUTICAL SUPPLY CHAINS.

By

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DECLARATION

We hereby certify that the material in this research project report that is not our ownwork has been identified, and that the contents of this research project report reflectour own personal views, and are not necessarily endorsed by the Academy.

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Abstract

Project title: Investigating the storage practices of pharmacies in Alexandria: Proposed solutions for the pharmaceutical supply chains.

Degree: B. Sc

Proper storage of pharmaceutical products are very important, the expiry date of pharmaceutical products is the main issue but not the only one, because improper storage of pharmaceutical products may damage the product and become ineffective for the human use.

It is very easy to read the expiry date on the package of a drug, but it is very difficult to know whether the drug is damaged or not because improper storage, because some drugs require temperature control like vaccines and cold chains they must be stored according to the manufacturer instructions and between the required temperatures.

If the drug is exposed to direct sunlight it will be damaged and the chemical materials become ineffective.

The World Health Organization publishes the Good Storage Practice (GSP) for pharmaceuticals, this module is important for all parties involved in the storage, transportation and distribution of pharmaceuticals, and this module is closely linked to other existing guides like Good Manufacturing Practices (GMP).

This research addresses the importance of proper storage of drugs in the pharmaceuticals supply chain, from the upstream suppliers to the downstream customers, and in the pharmaceutical company, focusing on the storage practices in the manufacturing and pharmacies, and determining the challenges in managing the storage of drugs and the challenges faced by pharmaceutical companies and pharmacies.

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ABBREVIATIONS

BOM	Bill of Material
CSCMP	Council of Supply Chain Management Professionals
DAF	Deliver at Frontier
EEFO	Earliest expiry/ First Out
ETR	Effective Tax Rate
FDA	Food and Drug Association
FIFO	First In/First Out
GDP	Good distribution practices
GDTP	Good Trade and Distribution Practices
GMP	Good Manufacturing Practices
GSP	Good Storage Practices
JIT	Just in Time
MOH	Ministry of Health
SC	Supply Chain
SCM	Supply Chain Management
SIOP	Sales, Inventory and Operation Planning
WHO	World Health Organization

CHAPTER ONE

INTRODUCTION

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INTRODUCTION

1.1. Introduction

Humans everywhere and everyday are attached to common products affecting their health; these are pharmaceutical products. People are unaware of how these products are reserved and kept healthy and properly used for patients. Pharmaceutical products are counted as the most sensitive products, they require specific temperature storage, and they can be damaged and became useless not only to the expiration date but to wrong handling and storage.

Distribution channels and pharmacies should differentiate between the handling and storage of these products than any other materials, as a result of wrong storage, quality is heavily affected.

The storage should be considered during transportation, warehousing, and in stores as well, also containers should be reliable to carry these products during transportation in order to make sure the product will reach its destination safely.

Pharmaceutical manufacturers are bound to strict regulatory guidelines that define how they produce, package and supply medicinal products for human use. This often means moving temperature-sensitive and perishable items in a timely and controlled environment. With that in mind, high-risk pharmaceutical products that require a temperature between 35 and 46 degrees must be protected from freezing and sub-zero temperatures, even for brief periods of time. While in transit, such sensitive "cold-chain" materials, which may include vaccines, insulins and blood products, need at least a thermometer placed within the load that measures maximum and

minimum temperatures. They also may require a precise electronic control to maintain the appropriate climate.

Timeliness is also critical. That's because clinical test substances or sensitive medicines
may lose some active ingredients if they're not delivered on time, meaning transport measures must be carefully planned and executed in a just-in-time (JIT) technique. In addition, a JIT distribution model helps increase the efficiency of supply chains by reducing stock levels by storing inventory at a customer's warehouse or near-site facility. Maintaining proper storage conditions for pharmaceutical products and paramedical is vital to ensure their quality, safety and efficacy.

Successful storekeeping is the ability to maintain the received drugs in the same quantity and quality until they are issued and to minimize stock holding costs while maintaining acceptable service level.

Drug products are to be tested in the same container-closure system in which the drug is marketed and, if full shelf life data are not available, accelerated studies combined with stability information of the components, including finished drug product and container-closure system, may be used to support tentative expiration dates.
Before shipping, the manufacturer must store the product under appropriate temperature, humidity, and light conditions.

1.2. Research Problem

This research investigates whether the Pharmaceutical companies and the pharmacies in Egypt in general, and in Alexandria in particular, are applying the regulations of Ministry of Health according to World Health Organization Guidelines issued for Good Storage Practices of pharmaceutical products.

Also, this research aims to provide a clear overview for the pharmaceutical supply chain, the relation of the focal firm (Production Company) with the upstream suppliers and the downstream customers, and investigating the level of coordination and cooperation between various internal department in the pharmaceutical company.

1.3. Research Objectives

- To examine the practices of supply chain management in the pharmaceuticals industry.
- To emphasize the importance of storage in the pharmaceuticals supply chain.
- To examine previous research on storage of pharmaceuticals in Egypt.
- To investigate the storage instructions of pharmaceutical companies.
- To investigate the actual practices of storage in pharmacies.
- To determine the gaps of storage practices between the manufacturers' instructions and pharmacies.
- To propose solutions for the potential drawbacks found in the storage practices within the pharmaceuticals supply chain.

1.4. Research Method

The literature review in this research covers the Good Practices in pharmaceutical supply chain, and covers the minimum requirements of storage for pharmaceutical companies starting materials and finished products as well as storage practices in pharmacies that are published by Ministry of Health (MOH) in Egypt according to World Health Organization (WHO) guidelines of good storage practices (GSP) guidelines.

The research method used in this research is qualitative analysis by conducting semi-structured interviews with pharmaceutical company managers from various departments and interviews with different categories of pharmacies in Alexandria in

order to investigate the storage practices in pharmacies in order to define the gaps between the pharmaceutical companies' storage instructions and the actual storage in pharmacies.

This research resulted in five chapters divided as follows:

Chapter 1 (Introduction): this chapter covers the importance of storage of pharmaceutical products into safe area to ensure that the quality is not affected and provide a brief explanation of the main elements.

Chapter 2 (Literature Review): this chapter cover the importance of supply chain in pharmaceutical companies, and cover the good practices provided by ministry of health to pharmaceutical companies and pharmacies.

Chapter 3 (Research Methodology): this chapter explain in brief the types of researches, and the data collection tools used , the advantages and disadvantages of questionnaire, as well as the criteria used in sampling the populations.

Chapter 4 (The Case Study): this chapter contains interview with Pharco Pharmaceutical Company, and nine pharmacies interview classified into three classes.

Chapter 5 (Conclusion and Recommendations): this chapter provides the conclusion of the literature review and the interviews with Pharco and pharmacies, and we provide our recommendations depending on the findings of interviews.

CHAPTER TWO

LITERATURE REVIEW

CHAPTER TWO
LITERATURE REVIEW

2.1 Introduction

This chapter will discuss the main concepts of supply chain and cover the importance of supply chain in doing business, focusing on the supply chain of pharmaceutical products and the main challenges of managing the complex supply chain of pharmaceutical products and how to maintain a good supply chain model.

The second part will focus on the storage practices in each chain within the pharmaceutical supply chain, also the good storage practices of pharmaceutical products in manufacturing facilities by focusing on the standards provided by World Health Organization (WHO) for storage requirements needed in manufacturing facilities for medicinal products, then to discuss the good trade and distribution practices of starting materials and final products, and finalizing this chapter by providing the good storage practices in medical stores and hospitals. The standards provided concerning the good storage practices in this chapter are provided by Ministry of Health (MOH) in Egypt under the provision of World Health Organization (WHO).

2.2 The Concepts of Supply Chain and Supply Chain Management

Council of Supply Chain Management Professionals (CSCMP) defined supply chain as:

starting with unprocessed raw materials and ending with the final customer using the finished goods, the supply chain links many companies together and the logistical process stretching from acquisition of raw materials to delivery of finished products to the end(CSCMP, 2010).

Also, Council of Supply Chain Management Professionals defined Supply Chain Managementas:

Supply Chain Management encompasses the planning and management of all activities involved in sourcing and procurement, conversion, and all logistics management activities. Importantly, it also includes coordination and collaboration with channel partners, which can be suppliers, intermediaries, third-party service providers, and customer's .and also supply chain management integrates companies. An integrating function with primary responsibility for linking includes all of the logistics management activities noted above, as well as manufacturing (CSCMP,2010).

2.3. Importance of Supply Chain Management in Business

Supply chain management is important now for companies in order to organize the information and material flow as illustrated in Figure 2.1

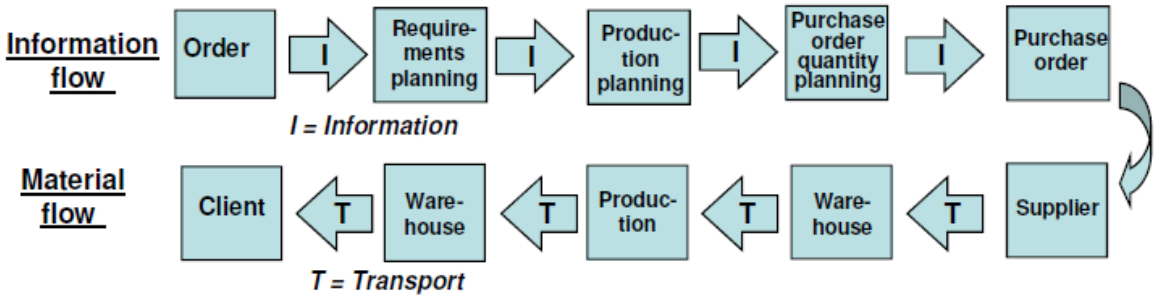

Figure 2.1 Information and Material Flow

(Source: Sovereign, 2008)

Supply chain management activities involved in the production of goods and services, from suppliers to manufacturers to wholesalers to retailers to final consumers. Managing production and logistics helps for delivering goods to

consumers while the supply chain philosophy ensures that customers receive the right products at the right time at an acceptable price and at the desired location. Supply chain management becomes more complex the larger the company and its range of products, and the more international the locations of its suppliers, customers, and distribution facilities (Sovereign,2008).

2.3.1. Competitive Edge through Core Competencies

Business now do not need only to compete at a lower cost but also needs to make their own core competencies to distinguish their selves from their competitors in order to do so they need to know how they can use their resources . SCM allows companies to rethink and restructure so they can focus on their core competencies and outsource processes that are not within the core competencies of the company, by focusing companies can also develop specialization of core area (Razamith Sovereign,2008).

2.3.2. Value Advantage

With mass customization, customers are given the value advantage through flexible manufacturing and customized adaptation. Improving product life cycle can be through SCM. Value advantage changed the concept ‘one-size-fits-all (Sovereign, 2008).

2.4. Pharmaceutical Supply Chain

Pharmaceutical manufacturers are bound to strict regulatory guidelines that define how they produce, package and supply medicinal products for human use. This often means moving temperature-sensitive and perishable items in a timely and controlled environment. High-risk pharmaceutical products that require a temperature between 35 and 46 degrees must be protected from freezing and sub-zero temperatures, even for brief periods of time.

While in transit, such sensitive “cold-chain” materials, which may include vaccines, insulins and blood products, need at least a thermometer placed within the load that

measures maximum and minimum temperatures. They also may require a precise electronic control to maintain the appropriate climate.

Timeliness is also critical, because clinical test substances or sensitive medicines may lose some active ingredients if they're not delivered on time, meaning transport measures must be carefully planned and executed.

Inventory in a business is a list of goods or products that is held in stock. Every business owner knows it is important to keep a proper inventory for several reasons. It is vital in bookkeeping because without it, businesses would not have a proper count of its assets and properties. In addition to bookkeeping, inventory should be kept to meet the uncertainty of business and for time reasons. It takes a lot of time to keep inventory, but failure to do so could result in major financial disasters. Depending on the size of business, there are people whose sole job is to keep track of inventory. In a small business, this would not have to be their only task (Josh,2009).

Having no inventory or having wrong inventory can lead to many problems. Because inventory is reflected in the company's books, a business owner may make decisions based on the inventory numbers he sees in the books. If the number is wrong, he just made a wrong decision that could be costly. In order to prevent this from happening, there are ways to keep proper inventory that any business can use.

Following these tips may even lead to a more efficient system:

- Keep every document your company receives to know the company spending and earning.
- Proper inventory records can help in decreasing the company costs.
- Hiring an specialized inventory management individual to maintain proper inventory (Josh, 2009)

2.4.1. Main Challenges of Managing the Supply Chain in Pharmaceutical Products

Pharmaceutical, biotech, medical and healthcare products a more unified industry as mergers and acquisitions connect between organizations. This translates into expanded supply chain challenges and increased pressure to become experts in multi-channel and multi-national strategy.

Tompkins (2011) points out top ten priorities for pharmaceutical and related industries as:

- Uncertainty: The Great Recession over understanding of the "New Norm" in this industry is still unclear. Uncertainty is certain and organizations must implement agile processes that allow them to move forward regardless of the business climate. Uncertainty by making it an ally in achieving profitable growth.
- Inventory/SIOP: companies have reduced inventory not by improving their Process-People-Technology. In 2011, Sales, Inventory & Operations Planning (SIOP) must be brought to a whole new level to both enhance inventory turns while improving customer service.
- Tax Effective Supply Chains: Effective Tax Rate (ETR) is just as important as inventory, transportation and operations costs in the supply chain. The ETR depends on the country how it applies it. Create tax effective supply chains that benefit your entire network.
- Security and Brand Protection: A huge priority is protecting products throughout their lifecycle from tampering, theft, and counterfeiting. Worldwide supply chain profile to protect your organization's brand while improving financial performance.
- Patent Expiration and Generics: Global pharmaceutical companies will be impacted by the loss of patents on blockbuster products during 2011-2013. Whether you implement generic strategies within your organization or choose to diversify by acquiring generic companies, these come with supply chain issues often not associated with brand products.

- Regulatory: The use of country-specific partners will become more critical in 2011 for avoiding unnecessary and costly market related mistakes.
- Service Supply Chain: Having solid service supply chain processes in place now will help avoid costly corrective actions later.
- Mergers and Acquisitions: While emerging markets are heavily weighted towards China and India, many acquisitions will occur not only to buy geographical coverage, but also to buy distribution channels.
- Market Channel Expansion: The blending of multiple product markets – all with different packaging, shipping, security, and tracking requirements – will greatly challenge supply integration in the coming year.
- Lean/Efficiency: Focus on lean initiatives that take waste out of supply chain processes by reducing costly process steps that do not add value to the product for healthcare provider customers and consumers

  Global borders will continue to melt away in pharmaceutical, biotech and medical product organizations (Tompkins Associates, 2011).

2.4.2. Challenges to Maintain a Resilient Pharmaceutical Supply Chain

First, the emerging trends in pharmaceutical supply chains are giving rise to a host of new issues, challenges, and research topics that impact the management of emergencies and disruptions (U. Juettner, H. Peck and M.,2003).

- Risk measurement and evaluation: candidate facility locations before companies make major decisions concerning sourcing, subcontracting, inventory management or facility location.
- Sourcing mitigation: dual sourcing, supply options is increasingly favored over inventory mitigation as supplier become less frequent but longer .There is a need for studies that evaluate and compare these two mitigation strategies.
- Supplier quality assurance: pharmaceuticals can be compromised in complex supply chains with a variety of storage facilities and long lead-times. Quality assurance is

particularly important when managing high-consequence events with severe health implications.

- Location analysis of distribution centers: Consequently, joint optimization of locations and sizing of distribution centers has rarely been undertaken by collaborating teams of distributors and manufacturers aiming to minimize the negative impact of disruptions.
- Backup facility capacity planning: In addition to safety stocks, the availability of a level of standby capacity would further increase supply chain reliability. This presents a new optimization problem that must trade off supply risks and additional costs subject to various constraints.
- Economic impact of port disruptions: The bulk of imported pharmaceuticals as well as raw material and intermediate compounds arrive in the U.S. via maritime ports. Storage requirements of many pharmaceuticals can affect their medicinal efficacy.
- Continuous quality management in charge with Chemical compounds for pharmaceutical products is provided by suppliers. Small pharmaceutical companies often partner with contract manufacturers to produce their pharmaceutical products, and many parties contribute to product safety.
- Disruptions at contract manufacturers is the general approach to enhancing the reliability of the manufacturing in a supply chain is to construct a portfolio of manufacturing sources, including contract manufacturing and in-house manufacturing.

Second, Response and Recovery from Pharmaceutical/Healthcare Supply Chain Emergencies and Disruptions, following is a list of issues pertaining to response and recovery actions in the wake of an emergency or significant disruption of a pharmaceutical/healthcare supply chain:

- Dynamic demand estimation and forecasting is the course of an infection process as a swine flu will strongly influence decision making. In such cases, accurate forecasts of the demand (for vaccines and drugs) to treat severely ill patients are essential to

controlling the outbreak. Epidemiological studies are needed to model the spread of infection in time and space (using population density data across geographical regions) in order to forecast demand for Pharmaceuticals.

- Dynamic allocation of resource is the outbreak of pandemic would dramatically increase demand in pharmaceutical is it better to proportionally allocate resources to different areas (might be politically correct) or maybe it is better to make sure we control the possible spread of virus from the largest infected areas
- Inventory positioning for short shelf-life products of safety stocks can protect a supply chain against potential disruptions, and improve customer service levels. Pharmaceuticals have a limited shelf life, with many drugs having a short expiration date. These fact severe constraints on safety stock management, thereby increasing management complexity.
- Information sharing and collaboration is information sharing and collaboration among all supply chain such as suppliers, contract manufacturers and pharmaceutical companies, are critical to managing recovery processes from supply chain disruptions. Information sharing and collaboration should be studied
- Developing business models for minimizing counterfeiting in recent years, pharmaceutical supply chains have been attacked by increasingly sophisticated criminals who divert, counterfeit and adulterate patient medications. Pharmaceutical industry is under severe pressure to further enhance supply chain security (DHS workshop, 2009)

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- Keep every document your company receives to know the company spending and earning.
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2.5. Good Practices in Pharmaceuticals Supply Chain

Today's pharmaceutical manufacturers have realized the importance of efficient temperature controlled supply chain.

2.5.1. Introduction

It is necessary to ensure compliance to temperature limits in the storage of pharmaceutical products that are introduced in the guidelines of regulatory authorities.

Auditing of storage facilities is important in the industry to ensure compliance with standards when product is shipped in bulk from pharmaceutical manufacturing sites to the distribution centers and warehouses along to the wholesaler, retailer (pharmacies and hospitals) to the end user (patient).

The major challenge is to control temperature and to ensure compliance throughout the supply chain, because the supply chain is becoming increasingly complex, involving a great number of storage and transit locations (airports and docks) (Revell and Mitchell,2006).

2.5.2. Potential Compromises in the Supply Chain

The supply chain complexity is compounded by the requirements of pharmaceuticals manufacturers that aim to maximize the cost efficiencies in their logistics operations and make savings by improving the efficiency of the entire supply chain, therefore companies must take a holistic approach to their supply chain to achieve optimum results on both local and global market to support end to end pharmaceuticals supply chain (from manufacturers to the end customer).

2.5.3. Supply Chain Requirements for Temperature-Controlled Products

Temperature-controlled logistics is the seamless movement from manufacturer to customer (patient) of medicinal products that require temperature and/or environment controls, in order to maintain product safety and efficacy (Revell and Mitchell,2006). The function of logistics tasks are illustrated in figure 2.2

Figure 2.2 The Function of Logistics Tasks

(Source: Revell and Mitchell, 2006)

2.5.4. Transport Solutions

The temperature sensitive pharmaceuticals are categorized into two types of transportation, primary and secondary transport. First, the primary movement represent the highest risk to manufacturers because they are often across regions and the shipments are large in size and have a high value therefore it is important to ensure the validity of temperature control.The primary transport of cold chain requires the provision of packaging protection because the shipment may be exposed to temperature extremes. In order to achieve cost and waste reduction these added protection is can be recycled in order to respond to the environmental legislation. (Revell and Mitchell,2006).

Second type is the secondary transport shipments are typically in transit for up to 72 hours serving the operations of just-in-time, twice daily basis, with the final destination direct into the pharmacy. The monitoring process during secondary transportation is required to ensure the efficacy of shipments and serve the auditing process to provide a clear picture to which the products have been exposed during the transport operation. Secondary transport types are during transport to pre-wholesaler and wholesaler, picked loads awaiting dispatch, loading or transit during secondary delivery and transfer and storage at hospital, pharmacy, local practice and storage.

Validated temperature controlled vehicles are very expensive investment for transportation service providers but when pharmaceutical manufacturers take into consideration savings in expensive thermal packaging thus can be a very cost effective solution. It is important that the pharmaceuticals products are not transported with other consignments in the vehicle. It is also important to monitor and record the temperature in-transit to provide the ability to manage returns back into stock, rather than incurring expensive product write-offs (Revell and Mitchell,2006).

2.5.5. Storage Solutions

The good storage practices are very important in pharmaceuticals, thus the storage of pharmaceuticals should be temperature mapped and controlled to avoid extremes of temperature. That is why certified standards are published to regulate storage in manufacturing and distribution processes. Warehouses must comply with Good Distribution Practice (GDP) and Good Manufacturing Practice (GMP) guidelines but also with the manufacturer's own quality standards. (Revell and Mitchell,2006).

2.5.6. Integrating Solutions

The challenge in pharmaceuticals supply chain is to provide temperature-controlled and ensuring that the basic requirements are done to be sure that the products are stored and distributed to the end user efficiently and within the strict temperature range.

The most important standards are Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), and Good Storage Practice (GSP) published by World Health Organization(WHO) Also the pharmaceuticals companies have their own internal quality standards.

Logistics supplier's main objective is to raise their standards to the level of leading pharmaceutical companies. These companies are consolidating supply chain operations and looking to providers who can leverage project management and supply chain visibility to ensure end to end temperature control across local, regional and global scale

Finally, all partners in the supply chain must coordinate the complexities across the whole supply chain, ensuring validation to the required standards and a clear audit to ensure temperature controlled of products to the end user (Revell and Mitchell,2006).

2.6. Good Manufacturing Practice (GMP)

The Good manufacturing practices is governed by Ministry of Health (MOH) by the General Inspection Department under the provision of Central Administration For Pharmaceutical Affaires in Egypt, and this practices are published by the World Health Organization (WHO), those regulations and practices are standardized in most of countries, but it depends on matching the legislation with the good practices.

The GMP is an integrated management control system that includes the methods and the facilities used for manufacturing, packaging, storage, and installation of devices to assure that such devices will be safe for human use.

The FDA (Food and Drug Association) and other governmental bodies obliged pharmaceutical manufacturers to prove the product efficiency and safety through data, preclinical and clinical and that products are manufactured consistently with good manufacturing practice guide that prescribe to drug manufacturers how to manufacture.

The GMP is not concerned with distribution and supply chain issues like transportation and storage, but the GMP will lead to GDP (Good Distribution Practice) which is concerned with good storage and transportation practices.

2.6.1. Storage Areas

Storage areas should be sufficient to allow the storage of various categories of materials and products beginning from the starting materials and intermediate bulk to the finished products, products in quarantine, released, rejected returned or recalled. To protect materials and products from the weather, the storage area should contain receiving and dispatch bays, also receptions areas should be designed and equipped to allow containers of incoming materials to be cleaned before storage if necessary.

The quarantine area should be separated from storage areas; these areas should be marked and restricted access for any persons but only authorized personnel. The sampling area of starting materials should be normally separated from other areas, but if sampling is performed in the storage area, they should be conducted in a way to avoid contamination or cross contamination.

The rejected, recalled or returned materials or products should be stored in segregated areas. In order to minimize the risk of fire or explosion highly active and radioactive materials, narcotics, other dangerous drugs and substances should be stored in safe and secure areas.

Printed packaging materials are critical to the medicinal products and special attention should be paid to the safe and secure of these materials.

2.7. Good Trade and Distribution Practice for Pharmaceutical Products

Good Trade and Distribution Practice (GTDP) are an extension of good manufacturing practices, this is a reference used for all distribution companies and wholesalers working in pharmaceutical starting materials and final products distribution, the used version here is WHO technical report series, no. 917, 2003 annex two.

The good distribution practice serves all persons and companies involved in handling pharmaceuticals starting materials including the materials removed during the process of pharmaceutical product manufacture.

Also the good trade practice is concerned with all parties involved in trade and distribution such as brokers, suppliers, distributors, traders, transport companies, forwarding agents and processors. This is applicable to every step in the distribution and supply chain of pharmaceuticals.

2.7.1. Warehousing and Storage

The application of Good Storage Practice in all situation and areas where materials are stored, thus there are procedures describing the activities related to the receipt, storage and distribution of materials.

In order to allow orderly storage of different categories of materials, this reflects the need for sufficient capacity in storage areas.

The storage conditions required such as particular requirements for temperature and humidity should be provided and monitored, and the need for special attention should be given when using and cleaning or maintaining the equipments for bulk handling and storage such as tanks.

The need for proper and safe storage of waste materials awaiting disposal, also toxic substances and flammable materials should be stored in separate, closed containers specially designed for them.

The strategy of distribution is earliest expiry/first out (EEFO) when materials due to expire first are sold or distributed first, but when no expiry dates are specified for the materials the first in, first out (FIFO) principle is applied.

The storage area should be clean and free from accumulated waste, that is why a written program indicating the cleaning methods and pest control should be used.

2.7.2. Repacking and Relabeling

The labeling of the container should be clear and fixed in good manner within the company's agreed format; each container should at least contain the following information shown in figure 2.3

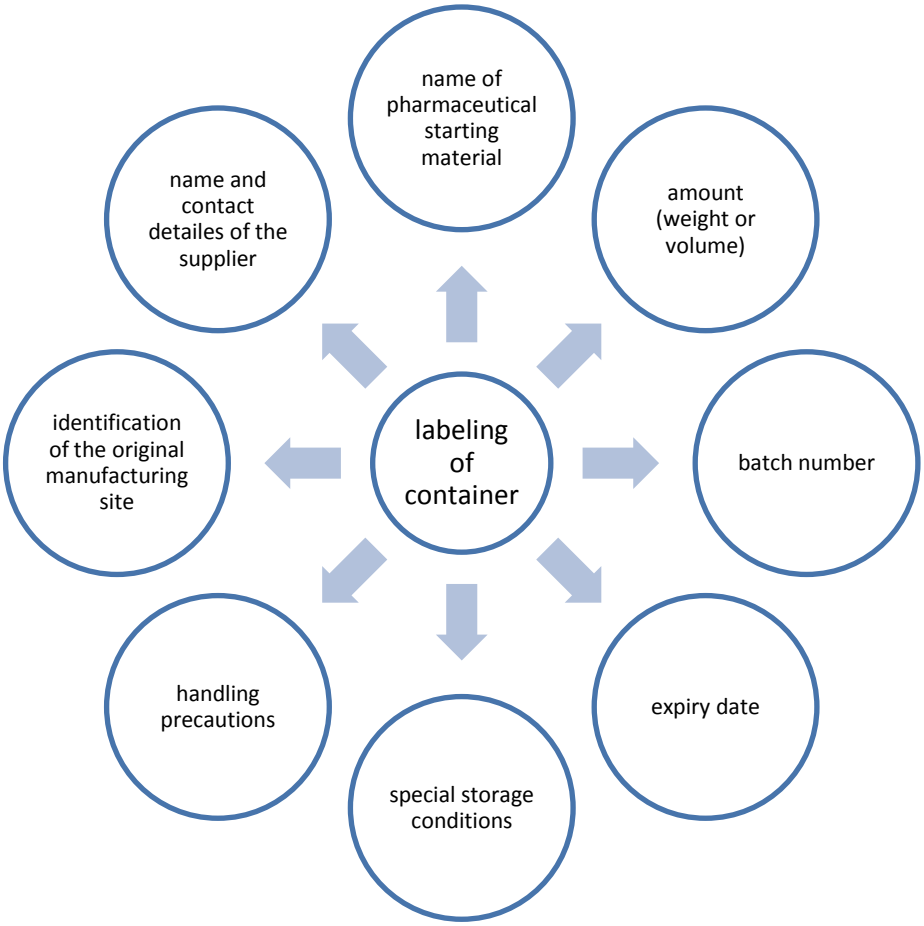

Figure 2.3 Labeling of Container

(Source: WHO technical report series no.917,2003)

Some parts require special attention; first, to prevent contamination, cross-contamination and mix ups as usual in all good practices guides. Second, labels of stocks should be secured and line clearance checks, on-line inspections, and if there is excess of batch-printed labels they must be destroyed. It is forbidden to mix different batches of the same solid materials that are why it is important to maintain batch integrity.

When repackaging of materials the new pack should be similar to the primary one or better to ensure the quality and durability of the container and the supplier should approve for the packaging material used for the repackaging.

To re-use the containers it is not accepted unless they have been cleaned according to a valid procedure, the same for recycled containers they should not be used unless there is evidence that the quality of the material packed will not be affected.

It is not accepted to repack materials unless the efficient environmental control exists; the reason is to ensure that there is no any possibility of contamination or mix ups. Also the quality of air should be suitable with efficient filtration for the activities performed.

Finally, the repacked and relabeled should ensure that the stability of materials and the characteristics are not affected with the repackaging or relabeling, and stability studies should be conducted to justify the expiry or retest dates assigned if the starting material is repackaged in new container different that the used by the original manufacturer.

2.7.3. Complaints

Complaints about defective materials must be reviewed according to written procedures that describe the action to be taken, and this includes the criteria on which a decision to recall a product should be based.

When taking a complaint that is related to material defect, this complaint should be recorded and investigated in order to know the reasons for the complaint, for example if the complaint related to the repackaging procedure or the original manufacturing process, etc.
If the defect is discovered and known the source of it, the other batches should be checked, and if necessary the appropriate follow-up action should be taken including a recall to investigate and evaluate the complaint.

The final step is to inform the manufacturer and customers if action is needed following possible faulty manufacturing, packaging, or any other quality problems with the pharmaceutical starting material.

2.7.4. Recalls

After the complaints are done, there should be an effective recall system from the market and the original manufacturer should be informed in the event of a recall, the recall should be done according to well established written procedures related to recall activity and should be regularly checked and updated.

The storage of recalled materials should be secured and in a segregated area to avoid any potential use or mixing with other materials.
If the recalled materials may cause serious or potential life threat, all customers and competent authorities in all countries to which a given material may have been distributed should be informed of any intention to recall the material.
The records of recalls should contain sufficient information on materials supplied to customers including exported materials and should be readily available to the designated persons responsible for recalls and the effectiveness of the arrangements for recalls should be evaluated on regular basis.

2.7.5. Returned Goods

When returning goods to supplier they should be appropriately identified and handled in accordance with the procedures, those procedures stating that the materials should be kept in quarantine area and its assessment and disposition by the designated person only, and when the problem is related to the quality of materials they should not be considered suitable for reuse or reissue.

2.7.6. Handling of Non-Conforming Materials

The most important issue when handling non conforming materials is that to be sure that those materials will not be reintroduced again into the market, and all the records covering all activities such as destruction, disposal and reclassification should be maintained.

Also other batches should be investigated to know if any other batches are also affected, then the corrective measures should be taken when necessary, and when disposing materials including downgrading to other suitable purpose should be documented.

Finally, non conforming materials should never be stored with other materials that comply with specifications.

2.7.7. Dispatch and Transport

The transport process should not affect the materials; they must be transported in a manner that ensures the maintenance of temperature, protection from the environment and other controlled conditions.

When some materials require special transport or storage conditions those requirements are stated on the label, this label should include the name and address of the manufacturer, quality of contents, special transport conditions and any special legal requirements should also be included on the label.

The transporter of the materials should be aware of the appropriate storage and transport conditions to avoid any problem related to temperature control that may

cause serious problem to the materials transported, also proper cleaning and prevention of cross-contamination when liquid tanks and bulk or packed materials are transported.

2.7.8. Contract Activities

This part is related to contract agreements between parties involved in trade and distribution of pharmaceutical products or materials.

The agreement should be in written contract when the activities performed are referenced in the GMP and GDTP guidelines, and the contract acceptor should evaluate the proposed contract before entering into an agreement, because the contract acceptor will be obliged to comply with the requirements in these guidelines.

The contract should also define the detail of responsibilities, and which party is responsible for which quality measures (World Health Organization,2003).

2.8. Good Storage Practices in Medical Stores and Hospitals

The good storage practices (GSP) is a guideline issued in 2004 by Central Administration of Pharmaceutical Affairs in Egypt, Ministry of Health (MOH) and Population, Faculty of Pharmacy, Cairo University and this guideline is prepared according to WHO regulations that govern the storage of pharmaceutical products in most of countries.

2.8.1. Storage Facilities

The facilities areas utilized for storage purposes should comply with the minimum standards and requirements, they should be located, serviced and maintained to protect the stored materials from any potential harmful influences such as variations in humidity, dust and odor, and entry of animals and insects.

The basic requirements facilities must be provided for

- The safe and orderly receipt or dispatch of all materials, products and components.

- The safe sampling and cleaning of any incoming materials to prevent contaminating the areas of other materials.
- Sufficient separation and segregation of pharmaceuticals, food products, chemicals, and cleaning materials to eliminate the risk of unacceptable cross contamination.
- The safe storage of hazardous materials
- The storage of temperature sensitive materials as appropriate in deep freezers, cold rooms or air conditioned areas,
- The storage of cleaning equipment and materials.
- Secure storage of any controlled drugs such as drug of addictions and narcotics.
- The separation or segregation of reception and dispatch facilities
- The safe storage of materials requiring dry or humidity controlled conditions.
- Racking and shelving must conform the Good Manufacturing practices

2.8.2. Security and Safety in Storage

Security arrangements with respect of poisons and drugs should at least meet the standards in the relevant legislation. Stock control procedures should be sufficiently tight to ensure the significant loss by theft can be detected; also the arrival and departure of visitors to the warehouse must be controlled.

It is important to secure the handling, transportation, usage and disposal of highly flammable liquids, toxic and corrosive materials according to the appropriate guide to be safe working.

Safety controls for flammable storage areas include:

- Electricity conductive floor.
- Raised door sill.
- Explosion-proof light fixtures.
- Blow-out wall.
- Forced draft vapor take-off (at floor level and near the ceiling)
- Rate of temperature-rise fire alarm
- Fire alarm monitored at fire station

- Switches for lights and vapor take-off fans located outside the room.
- Supply of safety cans for dispensing fluids
- Alcohol storage located in this area meets treasury regulations
- Heavy safe for storage of nitro compounds and other explosives

Finally, the operations relating to the manufacture, processing, and packing of penicillin shall be performed in facilities separate from those used for other drug products for human use.

2.8.3. Storage Procedures and Instructions

The storage of materials must be under conditions in order to minimize deterioration, contamination or damage, they must be stored under conditions compatible with their recommended storage requirements of temperature or humidity and when necessary to comply with segregation conditions.

2.8.3.1. General Principles

The appropriate temperatures for pharmaceutical products are:

- Store in refrigerator, those materials should be stored at temperature between 2˚C and 15˚C.
- Store in freezer, they should be stored at temperature not higher than -10˚C.
- In absence of storage requirements pharmaceutical products and raw materials should be stored at an average over any month of below 25 ˚C with the maximum usually below 30 ˚C and above 4˚C , and should be protected from direct sunlight
- Temperature or humidity controlled environments must be equipped with suitable indicators devices which must be checked at appropriate intervals and the results recorded, and the temperature in uncontrolled storage areas for products or raw materials should also be monitored.
- Temperature should be monitored at different levels in the warehouse and if necessary storage of sensitive materials should be restricted to locations in the warehouse where they will be protected from extreme conditions.

- There must be an appropriate formal stock control system which record the receipt, location and issue of materials and facilities proper stock rotation, the stock control procedure ensure that the materials with the shortest life are used first as the concept of First in First out (FIFO).
- Materials and products should be inspected to ensure that containers are properly closed, labeled, and that there is no evidence of serious damage or deterioration in the containers or their contents and that the stock rotation system is functioning correctly.

2.8.3.2. Storage of Approved Products

When storing the products they should be accurately documented with respect to product name, batch number, expiry date and quantity, also comprehensive records should be maintained of the receipt and issue of all products.

The products should be protected from excessive climatic conditions during storage and transit such as heat, frost, moisture and direct sunlight. Also they should be distributed if they are approaching the end of their life, a written policy laying down the remaining shelf-life must be written and after this date products must not be distributed other than under exceptional circumstances.

Picking stock should be stored to facilitate stock security, rotation, order assembly and dispatch, the picking and assembly areas should be organized to minimize the distance traveled by operators. Handling of goods should be kept to a minimum on grounds of high efficiency and safety, in large facilities the provision of mechanized order assembly system should be considered, also there should be a laid down procedure for the checking of assembled orders.

2.8.3.3. Storage at Clinical Facilities

The basic characteristics of goods storage space at clinical facilities are the same as for warehouses. Storerooms require ready access, good circulation, dryness and security; because in clinics smaller quantities of drugs are stored this will permit use of shelving. Products are arranged in convenient manner and in the order they appear

on requisitions and large labels placed on the shelves with each product in order to facilitate recognition.

The storekeeper and assistant storekeeper are the two only persons that are allowed to access the storeroom, and the door should be only the top half of the door opens while the bottom remains closed to keeps out unauthorized persons and at the same time to permit easy communication. But at lower level facilities, clinical personnel frequently perform all supply management activities and the result is that the quality of supply handling and storage conditions deteriorates as one move to the periphery of the delivery system.

The training programs for clinical personnel who will handle supplies should include specific courses of instruction in the following subjects:

- Setting up a storeroom and good storage practices.
- Use of stock control forms including requisitions, stock records and prescriptions.
- Cold chain procedures, including the use and preventive maintenance of refrigerators

2.8.3.4. *Special Storage Conditions*

Some categories of supplies require special storage conditions. These include vaccines, narcotics, and combustibles. Vaccines require both refrigerators and freezers. And narcotics and other controlled substances should be kept in secure locking rooms with only one entrance and the keys should be kept in a safe and secure place, only the warehouse director and one other person should have access to them.

Combustibles such as alcohol and fuels must be stored in special rooms and it is preferred to be separate out building since it guarantees that fire will not spread throughout the warehouse, if a special building is not available the room used to store combustibles supplies must be fireproof and well-ventilated.

2.8.4. Stock Arrangement Rotation and Control

When receiving products comprehensive records should be maintained showing all receipts and issues of materials according to batch number, and a periodic stock

reconciliations should be performed comparing the actual and recorded stocks, in any event this should be performed when each batch is totally used up. All significant stock discrepancies should be investigated as a check against mix ups and wrong issues, when expiry dated materials are stored the use of (first in first out) issues are concerned.

When partly used containers of materials the containers should be securely re-closed to prevent spoilage and contamination during subsequent storage, and damaged containers should not be issued but should be brought to the attention of the organization responsible for quality control.

2.8.4.1. Arrangement of Stocks

When arranging stocks in warehouse and storerooms, drugs are arranged according to a specified organizational principle (pharmacological class, clinical indication, alphabetic order, and level-of-use) within the warehouse itself as well as in clinical facilities, the reason for using the pharmacological classification is that it provides a frame of reference within which workers can easily recognize individual products. Level of use can be combined with this approach by using preprinted requisition tickets for each type of facility. With this system drug are arranged in the warehouse by their classes in the same orders as they appear on the requisition ticket.

Workers move along the rows of pallets packing only the type and quantity of drugs shown on the ticket, a final check before sealing the boxes assures that auxiliaries have not requested unauthorized drugs such as morphine for backaches.

2.8.4.2. Control of outdated stocks

All stocks should be checked regularly for obsolescent and degraded materials; materials with an expired shelf life should be destroyed unless an extension shelf life is granted following the satisfactory results or re-analysis. Finally, all due precautions should be observed to preclude issue of outdated materials.

2.8.5. Materials and Drugs Requiring Special Storage Conditions

Some materials in pharmaceutical products require special storage conditions such as medical gases, aerosols, creams, ophthalmic solutions and drops, capsules, suppositories, emulsions and suspensions, vaccines and radiopharmaceuticals.

- Medical gases: Gas cylinders should be stored under cover, and not subjected to extremes of temperature. Areas where they are stored should be clean, dry, well ventilated and free of combustible materials. They should also be stored vertically and secured to prevent falling and Flammable gases should be segregated from oxygen and other oxidizing gases.
- Aerosols: They should be stored in a clean separate area away from heat and sunlight, because the container contents are under pressure. Filled containers must be checked for weight loss over the expiration dating period, and for contents under pressure the label should carry out do not expose to hear or store at temperature above 49˚C and to keep out of children reach.
- Creams: they can be destroyed under extreme temperature fluctuations therefore; they should be stored at temperature above 10˚C and not exceeding 30˚C. If the cream is opened they should not be kept more than 14 days to avoid microbial contamination.
- Solutions and drops: they should be stored according to the conditions specified on the label and after opening they should not be used for more than one month at home and not more than 15 days in hospitals.
- Capsules: extremes of humidity and temperature should be avoided, because high humidity produces more lasting effect on the capsule shell. Since moisture is absorbed, the capsule become softer, and if temperature is increased the capsule shells may melt and fuse together. High temperature above 40 ˚C in a dry place may cause cracking of the capsule shell therefore; capsules should be stored in an air conditioned area in which the humidity does not exceed 21 ˚C to 24˚C.
- Vaccines: Tetanus should not be stored in a freezer; they should be stored at a cold place. But some other vaccines should be stored in freezers; it depends on the type of vaccines.

- Radiopharmaceuticals: storage of radiopharmaceuticals must take into consideration the chemical state of the radioactive drug, the quantity and type of radiation involved. And any special storage and stability requirements. For example, gaseous or volatile radiopharmaceutical should be kept in specially vented areas whereas certain other radioactive drugs require refrigeration. Storage conditions are normally specified in product package inserts. In addition, appropriate shielding must be used for storage areas to minimize personnel exposure.

2.9. Chapter Summary

This chapter covered the main concepts of supply chain and discussed the importance of supply chain, focusing on the supply chain of pharmaceutical products and the main challenges of managing the complex supply chain of pharmaceutical products and how to maintain a good supply chain model.

The second part covered the storage practices in each chain within the pharmaceutical supply chain, also the good storage practices of pharmaceutical products in manufacturing facilities by focusing on the standards provided by World Health Organization (WHO) for storage requirements needed in manufacturing facilities for medicinal products, then the good trade and distribution practices of starting materials and final products, and closing this chapter by providing the good storage practices in medical stores and hospitals.

CHAPTER THREE

RESEARCH METHODOLOGY

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RESEARCH METHODOLOGY

3.1 Introduction

This chapter will cover the type research rationale and the research design, also this chapter differentiate between qualitative and quantitative data collection tools, and cover the advantage and disadvantages of each.

This chapter also points out the types of interviews used to collect data from respondents, and provides a brief explanation for each type, as well as the advantages and disadvantages of interviews.

The questions of interview used with pharmacies are included in the chapter with the aim of each question, and the purpose and types of sampling, and finally the research sample.

3.2 Research Rationale

The research aim is to investigate the storage practices implementation in pharmacies in order to define the gaps between the pharmaceutical companies' storage instructions and the actual storage in pharmacies, this aim will be achieved through the following set of objectives:

1- Highlighting the Importance of storage functions of pharmaceutical products in the supply chain.
2- Examine previous research on storage of pharmaceuticals in Egypt.
3- To investigate the storage instructions of pharmaceutical company.
4- To investigate actual practices of pharmacies.
5- Determine the gap between manufacturing and pharmacies, and proposing solutions.

3.3 Research Design

This is an exploratory research using qualitative analysis method (interviews) composed of a set of questions for the pharmaceutical companies to investigate the storage practices in the company itself and whether they apply the Good Storage Practices guideline, and the relation between the pharmaceutical company and the upstream suppliers and downstream customers.

Also, the interviews of pharmacies will be composed of a set of questions for sample of pharmacies in Alexandria to investigate whether they apply the Good Storage Practices in managing drugs inside the pharmacy, and to investigate whether ministry of health conduct periodical inspections for the storage areas inside the pharmacies or not, as well as the relation between pharmacies, distributors and manufacturers.

3.4 Exploratory Research

Exploratory research or qualitative research is a type of scientific research which consists of an investigation that:

- Seeks answers to a question
- Systematically uses a predefined set of procedures to answer the question
- Collects evidence
- Produces findings that were not determined in advance
- Produces findings that are applicable beyond the immediate boundaries of the study

Qualitative research shares these characteristics. Additionally, it seeks to understand a given research problem or topic from the perspectives of the local population it involves. Qualitative research is especially effective in obtaining culturally specific information about the values, opinions, behaviors, and social contexts of particular populations (HR, 1995).

3.5 The Difference Between Qualitative and Quantitative Methods

Qualitative research explores attitudes, behavior and experiences through interviews or focus groups; it aims to get in depth opinion from participants that are important. These methods fewer people take part in the research but the contact with them tends to last longer Table 2.1 compares between qualitative and quantitative research approaches (Lander, 2008).

	Qualitative	Quantitative
General framework	Seek to confirm hypotheses about phenomena instruments. Use highly structured methods such as questionnaires, surveys, and structured observation	Seek to explore phenomena instruments use more flexible. Use semi-structured methods such as in-depth interviews, focus groups, and participant observation
Analytical objectives	To quantify variation .To predict causal relationships. To describe characteristics of a population	To describe variation .To describe and explain relationships .To describe individual experiences. To describe group norms.
Question format	Closed-ended	Open-ended
Data format	Numerical (obtained by assigning numerical values to responses)	Textual (obtained from audiotapes, videotapes, and field notes)
Flexibility in study design	Study design is stable from beginning to end. Participant responses do not influence or determine how and which questions researchers ask next Study design.	Some aspects of the study are flexible, participant responses affect how and which questions researchers ask next study design. Data collection and research questions are adjusted according to what is learned.

Table 3.1 Comparing Qualitative and Quantitative approaches

(Source: Lander, 2008)

Qualitative research is concerned with finding the answer to questions which begin with why? How? In what way? And when conducting qualitative research, the researcher collects data consisting mostly of words, pictures, and observations of events by using narrative data to gain insights into phenomena of interest, these can be categorized in some way and possibly quantified. Data analysis includes the coding of the data and production of verbal sentences, the analysis of such data can be very time consuming. The steps of qualitative research are represented in Figure 3.1.

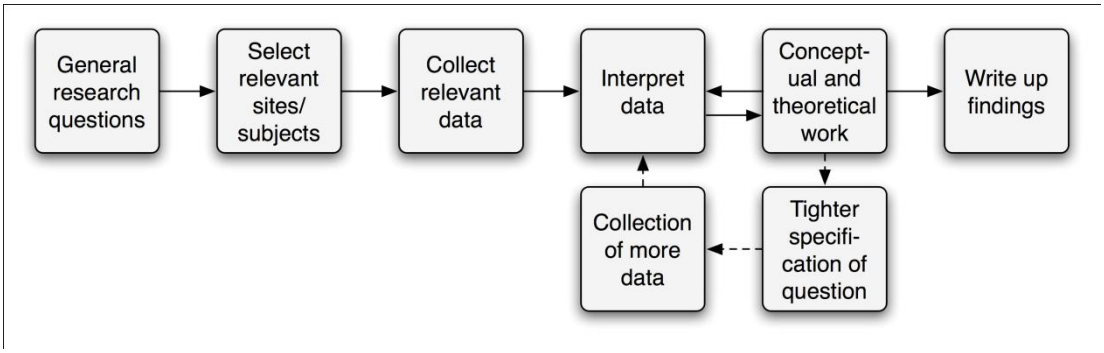

Figure 3.1 Qualitative Research Steps

(Source: Lander, 2008)

Quantitative research generates statistics through the use of large scale survey research using methods such as questionnaires, or structured interviews, those questions are direct and most of them are yes or no questions. The quantitative research collects numerical data in order to explain, predict and control phenomena of interest, and the data analysis is mainly statistical, it is categorized with descriptive research, correlation and experimental research.

The result of research is a number or a series of numbers presented in tables, graphs or other forms of statistics. Quantitative research is concerned with question about

how much? How many? How often? To what extent? (Lander, 2008). Figure 3.2 shows the steps of quantitative research.

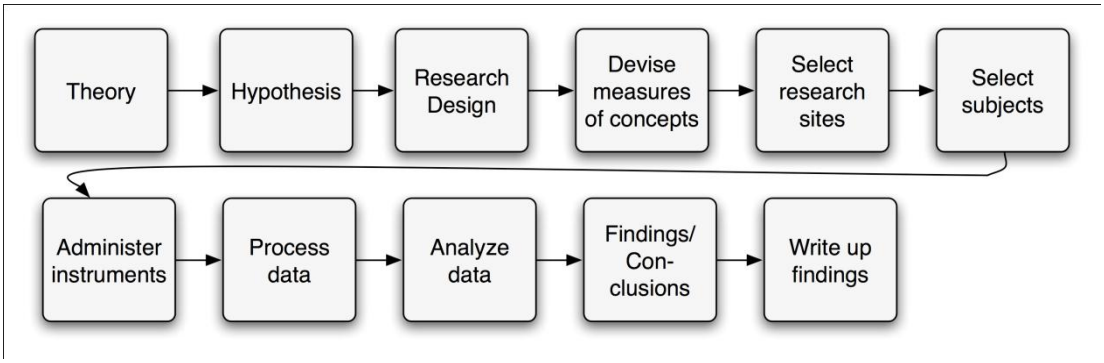

Figure 3.2 Steps of Quantitative Research

(Source: Lander, 2008)

3.6 Advantages and Disadvantages of Qualitative and Quantitative Research

The advantages of qualitative research is that qualitative research involves studying phenomena in their natural habitat, rather than in a laboratory setting like quantitative research, therefore the results are more true to life and general to similar situation. Unlike quantitative research that focuses on isolating, reducing and controlling the variables involved.

Also quantitative research provide rich information , and it may be impossible or unethical to study a particular subject using quantitative research methods, that is why the nature of qualitative research is an advantage in that it allows the study of such phenomena in those cases (Scruggs,2011).

The disadvantages of qualitative research is that the results are dependent upon the researcher interpretations and descriptions, also when surveys are used the data

collected can be inaccurate because respondents are often untruthful, finally the replication of results is much more difficult in qualitative research and in some cases even impossible (Scruggs, 2011).

Second type is the quantitative research, the advantage of this type is that the number of variables is significantly less than in qualitative research, because the variables are controlled and studied and the results are easier to be analyzed. Also, the use of random assignment when placing participants into different treatment groups greatly contributes to the objectivity of the results. Another advantage is that quantitative research often allows researchers to identify a cause and effect relationship, and the data measurements provide meaningful information also the numbers used in quantitative research allow one to make evaluations about the subjects of study.

The disadvantages of implementing quantitative research methods is that the results found in quantitative research are not necessarily applicable to similar situation found in the real world, as research is conducted for a particular setting; therefore, generalization is low in quantitative research. Also the characteristics are a problem because participants in a quantitative research study will act differently because they are studying in an unfamiliar environment. Another problem is that results focus on identifying trends and norms and individual differences are not appreciated (Scruggs, 2011).

To investigate practices of storage and to know whether those practices are applied or not, qualitative methods will be used in this research to gather natural information from the respondent. The best data collection tool is interviews with pharmaceuticals companies and pharmacies in Alexandria. Interviews will consist of constructed questions related to the Good Storage Practices provided by ministry of health according to WHO organization, the investigation will determine the gaps between practices between the manufacturer’s and WHO instructions and to gather information about the relation and integration between the pharmacies and companies.

3.7 Interviews

Interviews are particularly useful for getting the story behind a participant's experiences. The interviewer can pursue in-depth information around the topic. Interviews may be useful as follow-up to certain respondents to questionnaires, e.g., to further investigate their responses (McNamara, 1999).

3.7.1. Types of Interviews

- Informal, conversational interview, no predetermined questions are asked, in order to remain as open and adaptable as possible to the interviewee's nature and priorities; during the interview the interviewer "goes with the flow".
- General interview guide approach, the guide approach is intended to ensure that the same general areas of information are collected from each interviewee; this provides more focus than the conversational approach, but still allows a degree of freedom and adaptability in getting the information from the interviewee (Arthur and Nazroo, 2003).
- Standardized, open-ended interview, the same open-ended questions are asked to all interviewees; this approach facilitates faster interviews that can be more easily analyzed and compared (Arthur and Nazroo, 2003)
- Closed, fixed-response interview -where all interviewees are asked the same questions and asked to choose answers from among the same set of alternatives. This format is useful for those not practiced in interviewing (Arthur and Nazroo, 2003).
- Structured interviewing involves asking each interviewee the same set of standardized questions. The questions and the responses given tend to fit into predetermined categories, confirming or disconfirming the hypothesis the interviewer is pursuing. In studies where interviewers need to make comparisons between responses from different interviewees, they will require their interviews to be more structured, so that the same issues are covered by each respondent (Arthur and Nazroo, 2003).
- Semi-structured interviewing is more flexible than standardized methods such as the structured interview or survey. Although the interviewer in this technique will have

some established general topics for investigation, this method allows for the exploration of emergent themes and ideas rather than relying only on concepts and questions defined in advance of the interview. The interviewer would usually use a standardized interview schedule with set questions which will be asked of all respondents. The questions tend to be asked in a similar order and format to make a form of comparison between answers possible. However, there is also scope for pursuing and probing for novel, relevant information, through additional questions often noted as prompts on the schedule. The interviewer frequently has to formulate questions in order to follow up leads that emerge during the interview. The advantages and disadvantages of interviews are shown in table 3.2 (Arthur and Nazroo, 2003).

Advantages	**Disadvantages**
1. Very good technique for getting the information about the complex, emotionally laden subjects. 2. Can be easily adapted to the ability of the person being interviewed. 3. Yields a good percentage of returns. 4. Yields perfect sample of the general population. 5. Data collected by this method is likely to be more correct compared to the other methods that are used for the data collection.	1. Time consuming process. 2. Involves high cost. 3. Requires highly skilled interviewer. 4. Requires more energy. 5. May sometimes involve systematic errors. 6. More confusing and a very complicated method.

Table 3.2 Advantages and Disadvantages of Interviews

(Source: MBA, 2011)

The type of interview that will be used in this research is semi structured interview, the interview will consist of a set of questions asked for the pharmaceutical company and the pharmacies sample. The information in the company interview will be collected through tape recording and then gathered and analyzed. The semi structured interview will be applied to the pharmacies since there will be a set of eleven questions asked to all the pharmacies. The questions will be in the same form and sequence in order to compare the answers of the pharmacies and investigate the main difference between their storage practices. The aim of each question asked to the pharmacies and the company will be shown in table 3.3.

ew Question	Aim
any problems in storing drugs?	To know the common problem in storing drugs in pharmacies.
e main challenges in managing the storage of	To know the difficulties in storing drugs.
y the manufacturer's instructions in storage?	To know the level of application of manufacturer instructions.
health performs inspection for storage	To discover if ministry of health perform periodical inspection and i inspected or not
percentage of returns from patients? What are sons for returns?	To know the main reasons for returns, as well as the average percentage of
ave place for special storage (cold or ?	To know if pharmacies at all levels are aware of the temperature controlled
eck receipt for quantity, quality, damaged ype, storage, conditions and expiry dates?	To know if they make auditing on the main characteristics of the drugs inspection.
nplement proper care and control over bstances?	To ensure that they exercise safety standards toward hazardous drugs and t
age areas situated so that the products are m potentially harmful influence?	To check if pharmacies are designing the storage area according to prote the quality of drugs.
e characteristics of the storage area you have harmacy (Design, organization, sorting,	To know if the pharmacies have similar trend in designing, and sorting as pharmacy storage area.
parate area for storage in pharmacy?	To check if they are storing the drugs into separate area and if this area is c

Table 3.3 Pharmacies Interview Questions and Aim of Question

Therefore, investigating the storage instruction of pharmaceutical companies will be through conducting semi-structured interview, therefore managers are allowed to answer the questions and add their own comments and explanations; also semi-structured interview will be conducted to the sample of pharmacies to investigate the difference between good storage practices in pharmacies and what they actually exercise toward storage of drugs.

3.8 Purpose of Sampling

Sampling is the act, process, or technique of selecting a suitable sample, or a representative part of a population for the purpose of determining parameters or characteristics of the whole population. For good sample the sample must be valid, validity of a sample depends on two considerations: accuracy and precision.

The purpose of sampling is to draw conclusions about populations from samples, by using inferential statistics which enables to determine a population`s characteristics by directly observing only a portion (or sample) of the population. In this research a sample is obtained rather than a complete enumeration (a census) of the population for many reasons. Obviously, it is cheaper to observe a part rather than the whole.

3.9 Types of Sampling

- Simple Random Sampling, a simple random sample (SRS) of size *n* is produced by a scheme which ensures that each subgroup of the population of size *n* has an equal probability of being chosen as the sample.
- Stratified Random Sampling, Stratified Random Sampling divide the population into "strata". There can be any number of these. Then choose a simple random sample from each stratum. Combine those into the overall sample. That is a stratified random sample

- Multi-Stage Sampling, is used when the population is too large and scattered for it to be practical to make a list of the entire population from which to draw a SRS.

3.10 Research Sample

The sample used in this research is Multi-Stage Sampling because the number of pharmacies in Alexandria is very large, the sample is 9 pharmacies to be interviewed, each category consist of 3 pharmacies, and those pharmacies were chosen according to three categories, A, B, C. Category (A) is large chain pharmacies, Category (B) is medium size pharmacies and may have more than one branch but operating on a medium scale, and Category (C) consists of small pharmacies in relatively poor facilities and design, operating in a very limited scale.

3.11 Chapter Summary

This chapter covered the criteria used to conduct a research, differentiate between qualitative and quantitative research types, and provides the types of interview as well as the advantages and disadvantages of interview.

The second part covered the purpose of sampling and the main types used in sampling, the final part is the explanation of the research sample used in this project.

CHAPTER FOUR

THE CASE STUDY

CHAPTER FOUR

THE CASE STUDY

4.1. Introduction

This chapter contains interviews to examine the application of Good Storage Practices in pharmaceuticals supply chain, by conducting interviews with managers from Pharco Corporation as a one of the largest manufacturers of pharmaceutical products in Egypt.

This chapter contains interviews with the exports manager to know the problems related to storage in exporting pharmaceuticals products into the global markets, also interview with the planning manager to have a general overview of how the company work and its internal functions, how they coordinate the internal activities within the company various departments, as well as the relation of the company with upstream suppliers and downstream customers within the value chain, also the level of integration with suppliers to source raw materials needed for production, and the requirements for good manufacturing, and the relation with distributors.

The last interview in Pharco Corporation with the storage manager to discover the problems related to the storage of raw materials and finished products, the criteria and the challenges in managing warehousing activities.

The second part of this chapter contains interview with 9 pharmacies from Alexandria, they are categorized into 3 classes, class A are large pharmacies chains, EL-Ezaby Pharmacy, Khalil Pharmacy, and EL-Tayebi pharmacy, class B consists of medium pharmacies, and class C consist of small pharmacies operating in a small scale.

The aim of classing pharmacies into 3 categories to know how pharmacies in different categories operate, how they manage the storage, and to know if ministry of health make periodical inspections for all categories, and what are the challenges in

managing the storage of pharmaceuticals finished products, as well as the percentage of returns from customers and the reasons related to returns.

4.2. Overview Pharco Corporation

Founded by Dr. Hassan Abbas Helmy1984, Today, Pharco Corporation employs 5500 employees and boasts over 1 billion LE in sales while ranking number one in both units and value among all pharmaceutical companies in Egypt. It is a group of healthcare companies that developed productive alliances and partnerships that advance the capacity to develop innovative medicines at affordable price. Pharco Corporation works towards one goal, and that is to provide highly effective products to patients that need them at an affordable price.

In 1987, The official launch of Pharco Pharmaceuticals based in Amriya, Alexandria Egypt. The company knew no boundaries where they introduced for the first time in Egypt, locally manufactured soft gelatin capsules (by leasing four encapsulation machines from RP Scherer) and manufacturing antibiotics under licensed from Mead Johnson(now known as Bristol-Myers Squibb), in addition to other traditional pharmaceutical forms; Tablets, Syrups, Hard Gelatin capsule, Ampoules, Sachets, Creams, Ointments, Suppositories, Drops and Powders.

In 1993, Market share and demand for soft gelatin capsules increased immensely and so Dr. Hassan partnered with RP Scherer, forming RP Scherer Egypt thus doubling the production capacity of soft gelatin capsules by operating eight machines instead of four.

The high potential of the Romanian market and the mutual trust between both parties led to the creation of Pharco Impex which is the import / export branch of Pharco Pharmaceuticals in Romania. Pharco Impex distributes and promotes more than 50 pharmaceutical products in the Romanian market to date.

In 1996, Dr. Hassan Abass Helmy bought out both the partners and the Banks shares, to completely own Pharco Pharmaceuticals.

In 1999, Pharco Corporatition constructed a dedicated facility to manufacture sterile and non-sterile Beta-Lactams to avoid cross contamination in compliance with cGMP regulations.

In 2002, Pharco made acquisition of three major local companies, Amriya Pharmaceutical Industries, European Egyptian Pharmaceutical Industries (certified by the European Union authorities part of the PICS scheme), and Technopharma Egypt (a local soft gelatin capsule manufacturer).

In 2004, Pharco Pharmaceuticals formed an alliance with one of the major Egyptian Pharmaceutical companies; Egyptian International Pharmaceutical Industries Company (EIPICO) and Batterjee Group, Kingdom of Saudi Arabia (KSA) to establish Baterjee Pharmaceuticals in Jeddah KSA which offers a wide range of pharmaceutical products.

In 2008, establishment of Pharco B International starting with a dedicated facility for the manufacturing of sterile and non-sterile Cephalosporin antibiotics certified by the European Union authorities (part of the Pharmaceutical Inspection Cooperation Scheme(PICS).

In 2010, According to extensive feasibility studies, Pharco constructed a new sterile building to produce water for injection in plastic ampoules and other sterile products in Pharco B International. At the same time, due to the high consumption of empty hard gelatin capsules, a hard gelatin capsules line was added to Technopharma Egypt

4.3. Pharco Interview

The interview was conducted with three managers, first Youssef Salah export manager, then Wael Oreby planning manager and finally, Maher Abd El-Mawla El-Sayed Warehousing manager.

4.3.1. Export Department

Interviewee: Youssef Salah Position: Export manager

1- How many countries do your company export to?
most of them Arabian countries for example Yemen, Saudi Arabia, Lebanon, Qatar, Emirates and from European market they are dealing with Romania only.

2- Which mode of transport is used the most in exporting?
Air transport is the most, because in transporting pharmaceuticals finished products we need to minimize the trip time in order to be sure that the shipment is transported and stored in a good conditions and that the quality of the packages are the same during the trip as well as the quality of product itself.

3- What is the percentage of exports from the total?
It is approximately 30%.

4- Is there any percentage of returns because of bad storage or any problem related to shipments?

Yes, it is approximately 1%, and this occurs because of packaging sometimes not according to specifications, and problems related to the exporting country ministry of health.

5- What is the most common incoterms used for exporting?
Deliver at frontier (DAF)

6- Does your company have any authority in setting the final price of the exported drugs in the global market?
No, we do not have the authority to restrict or make a limitation for the price of our products in other countries.

7- What if there are any recalls from exported products? Who is responsible for that?
If the quantity is low, the importing country executes the shipment and the importing country bear the cost for execution, and if the shipment is large they return it to Pharco and we execute it in the factory.

4.3.2. Planning Department

Interviewee: Wael El-Oreby Position: Planning Manager

1- What are the products that your company offers to the market?
The company produces all the forms of pharmaceuticals products, ampoules, tablets, syrup, and suppository.

2- Which market are you serving? Local or global or both markets?
We are serving both markets, local and global markets, but we are serving local market more than the global market.

3- How many suppliers does the company deal with? Local or global?
The database of suppliers in the company consists of around 800 suppliers, but the dependency of the company is not the same for the 800 suppliers. They are composed of local and global suppliers, the dependency on global suppliers are much more than local suppliers.

4- How many distributors does the company deal with to distribute the drugs?
All the distribution of drugs is outsourced to 4 or 5 companies to distribute our drugs.

5- How many pharmacies in Egypt are used to sell the drugs produced by your company?

We are dealing with all Egyptian pharmacies, I can not give accurate number because the number of pharmacies in Egypt is increasing every day. But they are around 40,000 pharmacies in Egypt, also we are dealing with distributors therefore we do not know the number of pharmacies exactly.

6- Do you have any authority in selecting the pharmacies through which your drugs will be sold?

Yes, through our distributors and the selection criteria depends on the payment methods, and the credibility between the distributors and pharmacies, for example the distributors give us feedback about the pharmacies that they stopped dealing with.

7- Which stage of the company's supply chain adds value the most to the whole supply chain?

The suppliers add the most value to the entire supply chain that is why we should deal with various suppliers for sourcing materials required for production

8- What are the obstacles that the company faces in managing its supply chain?

The major problems in managing the supply chain is the delay from suppliers for shipping the raw materials required, also problems related to laboratory in doing inspection for samples this cause delay to accepting or rejecting shipments, the obstacles from distributors is that we must make surveys to the covered area by the distributors to be sure that the distributor distribute the drugs according to the company's plan.

9- Can we have an overview of the supply chain and planning in Pharco?

The major problem in Pharco Managerial decision making about planning is that we are working on forecasting the future demand, and that the actual planning is much easier than working on forecasting future demand, therefore we are forecasting based on the previous 5 years.

After that, the marketing manager who makes the sales plan discusses the sales plan with the planning manager.

10- Why are you forecasting an increase in some types of products? Or why do you think the sales of a given products will decrease in the future?

planning requires to know what are the roles and responsibilities of other departments inside the pharmaceutical company, I was working first in Information Technology in Pharco, therefore I have noticed the inputs of information from various department for example inputs from sales department, purchasing department, production department, I have noticed the relation between sales plan and the quantity of purchased items for manufacturing and the outputs of production department that is what i am now a planning manager, because the planning manager must construct a relation between various departments and use the data from various departments to have indications about the relation between the actual and the future plan, and if the future plan is realistic or not.

When I receive the sales plan I transform it to production plan, the production plan must be more than the sales plan to cover any increase in demand. So the difference in sales and production plan is the safety stocks, for example if the demand from wholesaler is 100,000 units from specific product therefore I must produce 120,000 to cover the demand and have a 20,000 units safety stocks to cover any potential increase.

By collecting the production plan of all product categories, and collect the various components needed to be purchased to serve the production, I must prepare the Bill of Material (BOM), consists of all the components that will be used for production, for example the master formula of a product consist of 20 raw materials, divided into active ingredients, inactive ingredients those are the inputs for production.

Therefore here the company produces over 300 finished products; we have common raw materials used in more than one product for example the packaging like Poly Vinyl Chloride Sheet known as PVC.

11- Do you place the raw materials order once for the total yearly production?

No, because the warehouse cannot handle around 800 raw material, and the warehouse of Pharco is constructed 25 years ago, and the upgrade of warehouses is not periodically in the company, therefore the challenge here to adjust the shipments with the warehouse optimal capacity.

Therefore the BOM is divided into various planning orders based on the Economic Order Quantity, after that the planning order is transformed into purchasing order.

For example if I need 300 tons from a specific raw materials, therefore I will send the planning order to the purchasing department, they divide the planning order into various purchasing orders consisting of partial shipments depending on the price of raw materials and the fluctuation of price, if the price is low now so the purchasing department make annual contract with specific supplier on the agreed upon price, the supplier must be legal and have all the licenses from WHO for approved supplier and that he is applying GMP in producing the raw materials of pharmaceuticals, therefore the challenge here is to know the perfect time for purchasing raw materials and components from suppliers to reduce costs, inventory, and time.

To make the purchase order into process, first ordering the quotations and prices from suppliers to begin negotiation, and make a purchasing committee representing the various departments in Pharco to discuss the problems related to raw materials and if any previous experience with supplier is not good and did not match the production in efficient way.

It is better to work directly with suppliers rather than working with subagents to avoid the increase in the price of the materials due to the subagent profit margin.

The criteria of dealing with global or local suppliers is based on the quantities required for production, therefore if the raw material quantity required is too small, it is better to work with local supplier because it is not efficient to have small orders

from global suppliers because of the freight charge is high, but if the quantity is large it is better to order from global suppliers, because of better quality and lower prices than local suppliers.

This case always happens when purchasing the PVC required in packaging the products, if I ordered the PVC from global suppliers, I must get them printed, doing this with 300 product category is very costly and difficult, therefore it's better to work with local supplier in purchasing PVC on the basis of make to order rather than having extra stocks in warehouses.

12- What are the criteria in selecting the modes of transport in global sourcing?

When the quantity ordered is small it is better to transport the shipment by air, and when the quantity is large it is better to transport the shipment by sea transport to reduce the transportation cost and achieve economies of scale.

But sometimes large quantities are transported by air transport when the materials are sensitive to be transported by sea; therefore transporting sensitive materials by sea incur higher risk of damage.

Another case if sourcing materials from Japan sometimes it is more costly to transport the shipment by sea than using air, because the land transportation in Japan to reach the sea ports is high.

After the raw material shipment is delivered at destination in Egypt, the clearance of pharmaceutical raw materials requires the documents related to GMP from suppliers and to take random samples from the shipments to ensure that those materials are according to the required specifications and shipped into good condition.

If the materials are lost during transportation it is not the greatest risk, but the greatest risk if the materials after it arrives to the company and after inspection we

find that the materials are not conforming, therefore in quotations we must have alternative suppliers to reduce the risk of non conformity.

Pharco is working with agents that manage the suppliers, because if not the company will coordinate with more than 800 suppliers, so it's better to work through agents for suppliers, for example working with 10 agents and each agent work with 60 suppliers, therefore it is better to coordinate with 10 agents rather than coordinate with 600 suppliers directly.

13- What is the main criterion in selecting suppliers? Price or quality?

quality is number one, then the cost and freight and all other functions is following, because the ministry of health make inspection on raw materials, so the ministry of health requires that the supplier is following the good manufacturing practices GMP, and after production ministry of health takes samples of finished products, therefore we must comply with quality standards.

14- Do you have any problems relating to the handling or shipping of raw materials and finished products?

Yes, but the problem is not big, because in the warehouses we handle a stock for 2 months production not more, the problem sometimes in storage was in the first years for the company before improving the warehouses and the factory facilities, also some problems resulted from the shipping company when handling the pallets sometimes they damage the products by the forklifts in loading or unloading the shipments, and if any damage happens, the shipment will be eliminated from production if it is raw materials , and from sales if it is finished goods.

15- Why Pharco products are not effective like other multinational medicines as Pfizer products for example?

Because Egyptian Ministry of Health fixes the price when preparing the plan to make a new formula for pharmaceutical products, the fixed price depends on the raw

materials, manufacturing, transportation costs, therefore the profit margin is defined by ministry of health and not by the producing company.

Also, the quality in Pharco Products are not bad and it is effective, and the quality is not related to the price of materials, but the issue is that some raw materials purity is less than other materials, both have the same effect but the absorption of the materials into human body differs from one person to another.

16- Which department is responsible about the storage of drugs?

The warehousing department is responsible for storage of raw materials and finished products.

17- What are the main responsibilities of this department?

To store the raw materials and finished products in a good storage practices, and to make the flow of finished goods between Pharco and distributors usually working in an efficient way, and to share the stocks between the distributors and the warehouse of the company to avoid the problem of over stocking in the company's warehouse facility.

18- What is the mean of communication that your company uses to provide the storage instructions of drugs for pharmacies?

Through the package of the drug, we write the storage conditions of this drug so the pharmacy will store the product according to Pharco's instructions that are written on the package.

19- Do companies have the authority to give any instructions to the pharmacies?

The company does not have any authority to enforce or give any instruction to the pharmacies, it is the responsibility of ministry of health, but we can stop dealing with the pharmacies that are not applying the instructions.

20- Do you monitor the implementation of the storage instructions you provide to pharmacies?

No, we are not monitoring the implementation it is not our task, this is the responsibility of the ministry of health, but we do not accept returned drugs from pharmacies that are damaged from bad storage practices. for example if a pharmacy in Aswan arranges the drug into shelves and the temperature in Aswan between 35˚ and 42˚, but we have written on the package that is should be stored between 20˚ and 25˚, therefore the pharmacy cannot return the drug because of damage, but we can stop dealing with this pharmacy until it makes improvements on the storage practices.

21- Do pharmacies apply the instructions given by the pharmaceutical company?

They are applying the instructions because they know they cannot return damaged drugs resulted from bad storage practices.

22- What types of danger could result from not implementing the correct storage instructions in pharmacies?

The bad impact on customer is that the customer will not find the drug effective, and this will have a bad impact on our company, but there is no any danger that will cause poisoning from consuming a drug damaged from storage.

23- From your point of view, do you think that generally pharmacies in Egypt have problems in following the instructions provided by pharmaceutical companies to store drugs?

Yes, they have problems but we are aiming that ministry of health help us more by making more periodical inspection on pharmacies, and they must help us more by enforcing pharmacies to apply the instructions.

24- From your point of view, what are the challenges that pharmacies might face in implementing the storage instructions by pharmaceutical companies?

The challenges is that some pharmacies they do not want to operate air condition in storage area of the pharmacy, therefore in hot weather some products are damaged from hot temperature, but the main challenge we face with pharmacies is that sometimes pharmacies make payments problems with distributors.

25- From your point of view, what are your recommendations to enforce pharmacies to implement the storage instructions provided by pharmaceutical companies?

I recommend that ministry of health be more strict which pharmacies that they do not apply the storage instructions, make a periodical inspection and they must apply penalties on pharmacies that they do not apply the good storage practices, our task is to provide our feedback to ministry of health about the pharmacies that do not store drugs according to our instructions.

26- What are the rewards granted to pharmacies if they apply the instructions? And what are the penalties for not applying the instructions?

We can help pharmacies by provide them with refrigerators, air conditions, and temperature calibration, to help them to store the drugs into acceptable temperatures.

27- What is the percent of returned drugs that the company receives monthly from pharmacies?

The percentage of returned drugs that the company receives monthly is around 0.5%

28- What is the process that pharmaceutical companies follow in the case of recall?

We make recalls by the batch number, we make advertising in newspapers, and we provide the distributors with the batch number needed to collect the drugs wanted from the market.

29- How do companies react with the returned drugs?

We only accept returned drugs before the expiry date with 3 month, if the pharmacy wants to return drug they must return the drug before the acceptance period be passed, and we redistribute them again to other pharmacies that have demand on this product, in case of damage from storage we are not responsible and we do not return any drugs damaged for any reasons, this is not our responsibility.

30- What are the most common reasons for returning drugs to the pharmaceutical company?

We do not accept returns other than products that will be expired in 3 months, if less than 3 months we do not accept to return them, and we return money back to pharmacies without any reduction from the payment.

4.3.3. Warehousing Department

Interviewee: Maher Abd El-Mawla Position: Storage manager

1- Can we have general overview for the storage in the company?

We have in the warehouse around 7000 different raw materials, they are composed of chemicals that enter into production, primary packages like PVC, bottles or ampoules that are directly in touch with the product, and secondary packages like cartons used to package the final product.

We are importing from global suppliers around 99.9% of chemicals raw materials, also we are importing a large quantity of primary packages, and for making easy access to the materials in the warehouse we have made a unique code for each material that exist on the computerized system to make easy retrieval of the materials

in the warehouse, we are coding chemicals raw materials, packages, and for finished products.

2- Is the storage area of Pharco complying with the Good storage practices provided by the ministry of health and WHO?

I should provide space for the raw materials for storage; all the chemical materials must be stored into room temperature, the room temperature in storage guide between 25˚ and 30˚.

3- Can you tell us any cases that happened because of bad storage inside the warehouses that make product damaged or raw materials?

We do not have any previous case for bad storage inside the warehouses, because we are using parameters and we store the products into the required temperature, so it is not allowed to have any percentage of bad storage practices.

4- I know that some materials require refrigeration and cold storage area, does the company store these materials according to the required temperature provided in the GSP?

Most of the products that the company produces are stored at the normal storage temperature named room temperature from 25˚ to 30˚, but we have a small percentage of materials required cool storage area ranging from 15˚ to 25˚, and we provide the required place for those materials.

5- What are the challenges that the company faces and the obstacles by complying with ministry of health instructions for storage?

Ministry of health updates the guidelines for storage periodically, they are always making updates, that is why we should comply with the ministry of health instructions and otherwise we cannot produce and we will be illegal therefore, the challenge is to comply with the guidelines of ministry of health.

6- Are the workers in storage area having periodical training, and they are wearing the safety clothes in the warehouses?

We have two types of products, open products and closed products, the warehouse in this company is closed that means that they are packaged, but in the laboratories workers are dealing with open products, they should wear safety clothes.

7- What is the difference between Pharco old factory and the new Pharco B in storage?

The difference is that Pharco B produce antibiotics, those products require that the storage area to be totally separated from other areas, because antibiotics raw materials such as types of materials could make serious damage to human health and sometimes death, therefore they require to be stored into separated area.

8- Are you sure that the company did not face any problems or risk in storage during the last 20 years?

I want to mention that to have a problem therefore we must have a bad storage practices, the problem occurs when handling a lot of materials that are now required in the current production plan, but we have a good production plan, that is why we do not have risk in storage.

9- My previous question is not related to managerial decisions effect on the storage, I am asking about the problems that could occur because of lack of experience of workers or something related to techniques not managerial issue?

Workers in our company must take storage courses to increase the worker experience, therefore they are aware of good storage practices well, and they know how to store those materials, and I want to mention again that the pharmaceutical production is very special type of production that we do not accept any percentage of faults or risks because it is related to human life.

4.4. Pharmacies Interviews

this part consists of interviews with 9 pharmacies, they are classified into 3 categories, each category consists of 3 pharmacies, the A class category are large chain pharmacies operating on a large scale and holding large amount of drugs into pharmacies, the B class category are medium size pharmacies they are operating on a medium scale and holding average inventory, the C class category are small pharmacies operating on small scale and holding small amount of inventory on shelves and lockers inside the pharmacy.

4.4.1. Class A Interviews

This class consists of 3 major chains in Alexandria.

4.4.1.1. El-Ezaby Pharmacy, Saint Stefano Branch

1- Do you have separate area for storage in pharmacy?

Yes we have separate area for storage area the upper floor and we have a warehouse for all branches.

2- Are the storage areas situated so that the products are protected from potentially harmful influence?

Yes, the pharmacy has air condition in the whole place to maintain the right temperature needed.

3- Do you apply proper care and control over hazardous substances? They are separated from others?

Yes,the substances are situated away from all the other products.

4- Do you check receipt for quantity, quality, damaged containers, type, storage, conditions and expiry dates?

There is common software between all ten branches to give notifications with the needed quantity and if any other branches have this product, it will be sent to the branch that needs it.

5- Do you have a place for special storage (cold or refrigerated)?
There is more than one fridge just in case a problem happened to any of the fridges.

6- What is the percentage of returns from patients? What are the main reasons for returns?
2 %, the main reason is that sometimes the doctor changes the medicine. They have one month return policy.

7- Does the Ministry of Health perform inspection for storage instructions?
Yes, they perform inspections for health but they are not making periodical inspection on a fixed basis.

8- Do you apply the manufacturer’s instructions in storage?
No we do not apply the manufacturer's instructions in storage.

9- What are the main challenges in managing the storage of drugs?
To have the space and all the equipment needed to have safety storage.

10- What are the characteristics of the storage area you have in the pharmacy (Design, organization, sorting, cleanliness)?
The organization of the medicines is alphabetically, and the sorting according to the products categories and the design is racks for the tablets.

11- Do you have any problems in storing drugs?
The only problem is that there is only one fridge.

4.4.1.2. Khalil Pharmacy, Saint Stefano Branch

1- Do you have separate area for storage in pharmacy?
   Yes we have storage room for storing the medicines.

2- Are the storage areas situated so that the products are protected from potentially harmful influence?
   Yes, the pharmacy is equipped with air condition.

3- Do you apply proper care and control over hazardous substances? They are separated from others?
   Yes, by separating the ingredients of the medicines in a separate area.

4- Do you check receipt for quantity, quality, damaged containers, type, storage, conditions and expiry dates?
   Yes, there is a common system between all branches that gives notifications to collect medicines before one month of the expiry date. Sometimes when medicines are received there were damaged medicines due to the conditions during the transportation.

5- Do you have a place for special storage (cold or refrigerated)?
   Yes we have only one refrigerator; when there is any problem in the fridge, the medicines are sent directly to the nearest branch.

6- What is the percentage of returns from patients? What are the main reasons for returns?
   5 %, some patients return the medicines because the doctor has changed the dose or the medicine itself; another reason is that medicine will expire soon.

The pharmacy has a policy of returning any drug within fourteen days and refrigerated products can not be refunded.

7- Does the Ministry of Health perform inspection for storage instructions?
Yes performs inspections for health yearly and inspector is sent from the production company every seven months.

8- Do you apply the manufacturer’s instructions in storage?
No we do not apply the manufacturer's instructions in storage.

9- What are the main challenges in managing the storage of drugs?
We just have one fridge, when there is a problem in the fridge the medicines are exposed to high risk.

10- What are the characteristics of the storage area you have in the pharmacy (Design, organization, sorting, cleanliness)?
The space of the pharmacy is wide enough for the medicines to be organized in a good manner; the medicines are organized according to the type of the medicines.

11- Do you have any problems in storing drugs?
The only problem is storing the refrigerated products since there is only one fridge located in the pharmacy.

4.4.1.3. El-Tayebi Pharmacy, El-Ekbal Branch

1- Do you have separate area for storage in pharmacy?
Yes, there is a separate area for storage in the upper floor.

2- Are the storage areas situated so that the products are protected from potentially harmful influence?

Yes, the products are protected from potentially harmful influence with the suitable storage area needed for every drug, there are some products that need to be stored in the refrigerator but the rest in normal temperature.

3- Do you apply proper care and control over hazardous substances? They are separated from others?

Yes, we apply proper care and control over hazardous substances, and they are separated from each other to avoid damage.

4- Do you check receipt for quantity, quality, damaged containers, type, storage, conditions and expiry dates?

Yes, there is software for checking the receipts pharma fly software.

5- Do you have a place for special storage (cold or refrigerated)?

Yes, there is a place for special storage such as eye drops we store them in refrigerators.

6- What is the percentage of returns from patients? What are the main reasons for returns?

The percentage of returns from patients is nearly 2% and the main reason for returns is the expiry date.

7- Does the Ministry of Health perform inspection for storage instructions?

Yes, they perform inspections periodically; those inspections are general inspections and storage area inspections.

8- What are the main challenges in managing the storage of drugs?

The space is the main challenge in managing the storage of drugs.

9- What are the characteristics of the storage area you have in the pharmacy (Design, organization, sorting, cleanliness) ?

The design depends on the place of the pharmacy, products are organized alphabetically with stickers also we are sorting drugs into 3 categories: tablets, syrups, suppositories, and we are cleaning the dust from shelves on a daily basis.

10- Do you have any problems in storing drugs?

No, We do not have any problem in sorting the drugs

11- What are the potential storage problems that pharmacies in general face?

The potential storage problem that pharmacies in general face is when the ice melts on the medicine.

4.4.2. Class B Interviews

This class consists of 3 medium size pharmacies, they were chosen randomly from different districts in the city of Alexandria.

4.4.2.1. Alex Pharmacy, El-Saraya Branch

1- Do you have separate area for storage in pharmacy?

There is a separate area for storage in an apartment located above the pharmacy.

2- Are the storage areas situated so that the products are protected from potentially harmful influence?

Yes, we have air conditions everywhere and also the windows dimensions are according to ministry of health instructions.

3- Do you apply proper care and control over hazardous substances? They are separated from others?

Yes we apply proper care for hazardous and also they are separated in the lab in drawers.

4- Do you check receipt for quantity, quality, damaged containers, type, storage, conditions and expiry dates?

Yes, we check in the moment we receive the order and open it and if there is any problem we fix it immediately for example if there is any damage in the container they return it.

5- Do you have a place for special storage (cold or refrigerated)?

Yes, we have more than one refrigerator for Example because insulin are very sensitive to high temperature.

6- What is the percentage of returns from patients? What are the main reasons for returns?

The percentage is 1% from patients, the main reason is that the patient when they take the medicine that the date is near to the expiry date or the pack of the medicine have damages.

7- Does the Ministry of Health perform inspection for storage instructions?

Yes, they perform inspections for storage instructions, and they conduct yearly inspections.

8- Do you apply the manufacturer's instructions in storage?

Yes, we apply the manufacturer's instructions in storage.

9- What are the main challenges in managing the storage of drugs?

The main challenge is the storage of temperature controlled drug that requires refrigeration especially in summer because of high temperature, if the refrigerator stops working therefore the drug will be damaged.

10- What are the characteristics of the storage area you have in the pharmacy (Design, organization, sorting, cleanliness) ?

We organize the medicine in drawers according to alphabetic orders, and our layout of pharmacy is according to ministry of health recommendations.

11- Do you have any problems in storing drugs?

Yes, the risk if the refrigerator stop working, and another risk if the drugs are exposed to direct light, the chemical materials in some drugs may become ineffective.

12- What are the potential storage problems that pharmacies in general face?

The potential storage problems is that our pharmacy storage area is not very large to handle all types of products, and this is a general problem in most of pharmacies, therefore we need to improve the storage area in order to handle the potential growth of drugs over the coming years.

4.4.2.2. Peter Pharmacy, Sirya Street

1- Do you have separate area for storage in pharmacy?

No, we do not have separate area for storage in pharmacy.

2- Are the storage areas situated so that the products are protected from potentially harmful influence?

No, the layout of pharmacy is not good, therefore the air circulation in the pharmacy do not serve us to store products into good manner.

3- Do you apply proper care and control over hazardous substances? They are separated from others?

Yes, we are applying the minimum requirements; we are separating them from other substances.

4- Do you check receipt for quantity, quality, damaged containers, type, storage, conditions and expiry dates?

Not usually, we check only for quantity in receipt.

5- Do you have a place for special storage (cold or refrigerated)?

Yes, we have one refrigerator in the pharmacy to store refrigerated products.

6- What is the percentage of returns from patients? What are the main reasons for returns?

1% returns from patients, we have 24 hours return policy, and the common reason for returns is that the package is damaged.

7- Does the Ministry of Health perform inspection for storage instructions?

Yes, they perform general inspection and storage inspections.

8- Do you apply the manufacturer's instructions in storage?

No, we do not apply the manufacturer instruction, we only apply ministry of health instructions.

9- What are the main challenges in managing the storage of drugs?

The main challenge that we do not have separate storage area, we store the products into shelves and racks only.

10- What are the characteristics of the storage area you have in the pharmacy (Design, organization, sorting, cleanliness) ?

We do not organize the drugs according to system, we store them according to our practice, they are not organized alphabetically, we clean the pharmacy every month, and we are sorting tablets and capsules together, and syrups, creams together.

11- Do you have any problems in storing drugs?

No, we do not have problems in storing drugs, we are using our resources to store them and we try to avoid any damage to drugs.

12- What are the potential storage problems that pharmacies in general face?

The most common problem is that the storage area in most of pharmacies are smaller than the inventories they should carry, this problem cause that we do not carry all types of products, or to carry many products into small area, also the amount of recalls is increasing, and most of them are important drugs that are highly demanded products for the patients.

4.4.2.3. Sirya pharmacy, Sirya street

1- Do you have separate area for storage in pharmacy?

Yes, we have separate storage area in the upper floor.

2- Are the storage areas situated so that the products are protected from potentially harmful influence?

Yes, we have air condition in the pharmacy to protect the drugs from high temperature in summer.

3- Do you apply proper care and control over hazardous substances? They are separated from others?

Yes, we separate hazardous substances in the laboratory , they are stored into isolated place.

4- Do you check receipt for quantity, quality, damaged containers, type, storage, conditions and expiry dates?
Not usually, but sometimes we check for quantity and expiry dates.

5- Do you have a place for special storage (cold or refrigerated)?
Yes, we have refrigerator for eye drops and insulin.

6- What is the percentage of returns from patients? What are the main reasons for returns?
We do not accept returns from patients for any reasons.

7- Does the Ministry of Health perform inspection for storage instructions?
Yes, they perform inspection, but they are not monitoring whether the pharmacy if they are operating at the same level or not, and they are not performing fixed periodical inspections.

8- Do you apply the manufacturer's instructions in storage?
No, we do not apply the manufacturer instructions, we are applying the common practice in storing the products in room temperature or refrigerated.

9- What are the main challenges in managing the storage of drugs?
The main challenge is that there is no specialized employee into drug storage, we are storing them according to the common practice used in most of pharmacies.

10- What are the characteristics of the storage area you have in the pharmacy(Design, organization, sorting, cleanliness) ?

We organize the product according to our practice; we do not store them alphabetically, and sometimes the owner is unsatisfied with the cleanliness of the storage area.

11- Do you have any problems in storing drugs?

The problem is that we do not store all types of drugs because of limited number of racks, and the storage area in the pharmacy is not organized well.

4.4.3. Class C interviews

Class C consists of 3 pharmacies, those pharmacies are operating in a lower scale, they have poor layout and design and relatively poor storage area than class B.

4.4.3.1 Doctor Ahmed Sabry Pharmacy, Bakous

1- Do you have separate area for storage in pharmacy?

Yes, we are storing them on shelves and lockers

2- Do you apply the manufacturer's instructions in storage?

No, we do not apply with the manufacturer instruction, we place the drugs into shelves but they are not exposed to direct sunlight, the manufacturers do not care how we store the drugs.

3- Do you apply proper care and control over hazardous substances? They are separated from others?

Yes, we place the drugs into the lockers, so they are away from any harmful influence.

4- Do you check receipt for quantity, quality, damaged containers, type, storage, conditions and expiry dates?

Yes, we check for quantity and expiry date only, and we check also for visual damage to the secondary package, but we cannot know the quality by visual inspections.

5- You have place for special storage (cold or refrigerated)?

Yes, we have a refrigerator, but we do not check for the temperature periodically, it is all the same inside the refrigerator there is no damage because of different temperature inside the refrigerator.

6- What is the percentage of returns from patients? What are the main reasons for returns?

The percentage vary from month to another, we do not calculate accurate percentage, the main reasons for returns from customers that after purchasing the product they found that they do not need it, and my pharmacy stopped dealing with some distributors because the main reasons of returns to those distributors is the damages caused by high temperatures and humidity.

7- Does the Ministry of Health perform inspection for storage instructions?

Yes, they inspect pharmacies, but in my pharmacy they only make inspections in the first two months from the start of operation then they came after 3 years, it depends on the credibility of pharmacies.

8- What are the main challenges in managing the storage of drugs?

We have no challenges; we store the products only into shelves, lockers, and refrigerators, the potential challenge could occur when the refrigerator stops working at night when we are closed.

9- What are the characteristics of the storage area you have in the pharmacy (Design, organization, sorting, cleanliness)?
We do not have separate storage area, we organize the products according to the type of drug and expiry date on shelves, every 2 days we clean the shelves.

10- Do you have any problems in storing drugs?
No, we do not have any problem in storing drugs; we do not have a lot of stocks in the pharmacy.

11- What are the potential storage problems that pharmacies in general face?
The potential problems is that distributors and warehouses of pharmaceuticals sometimes they deliver products damaged from high temperature and humidity, we need more inspections from ministry of health on warehouses

4.4.3.2. El-Shabrawishi Pharmacy (medical insurance), Sidi Beshr

1- Do you have separate area for storage in pharmacy?
Yes, we have shelves, lockers, quarantine area, and refrigerator.

2- Do you apply the manufacturer's instructions in storage?
Yes, we apply with the manufacturer instructions that are printed on the packages.

3- Are the storage areas situated so that the products are protected from potentially harmful influence?

Yes, we store the products into lockers, those lockers are closed with key and we do not expose drugs into direct heat or sunlight.

4- Do you apply proper care and control over hazardous substances? They are separated from others?

Yes, we separate the hazardous substances in closed lockers, and they are separated from other drugs, the pharmacist only has the authority to deal with hazardous substances.

5- Do you check receipt for quantity, quality, damaged containers, type, storage, conditions and expiry dates?

Yes, usually when we receive shipments we check for quantity to be exact to the order, and that the expiry date are enough, and if any damaged package we return it to the distributors, we apply the storage according to the type of drugs, but it is very difficult to check the quality of drugs by visual inspections.

6- Do you have a place for special storage (cold or refrigerated)?

Yes, we have refrigerator, and we usually check that the temperature inside the refrigerator between 2˚ and 8˚.

7- What is the percentage of returns from patients? What are the main reasons for returns?

The percentage is about 2% monthly, the main reasons is price related, they find another substitute with lower price, the percentage of returns to distributors because of expiry date, some distributors accept to return before 3 months, and the others before one month, but we do not have high percentage of returns because we order small quantities from each product.

8- Does the Ministry of Health perform inspection for storage instructions?
Yes, they perform inspections every 2 months, they perform full inspection on pharmacy as well as storage areas.

9- What are the main challenges in managing the storage of drugs?
The challenge is that the pharmacist must be aware of product types and how they are storage in a good manner, for example some products do not accept to be exposed to sunlight.

10- What are the characteristics of the storage area you have in the pharmacy (Design, organization, sorting, cleanliness)?
We organize and design the shelves according to First In, First out (FIFO), we clean the shelves periodically, also sorting is according to computer system.

11- Do you have any problems in storing drugs?
No, we do not have any problems in storing drugs, because we store them according to the manufacturer instructions, therefore they are protected.

12- What are the potential storage problems that pharmacies in general face?
The potential storage problems is that the number of drugs is increasing and we have to handle all types of drugs, while the storage area is limited, so we must have a solution for this problem in the future.

4.4.3.2 Doctor Moustafa Hussien Pharmacy, Miami

1- Do you have separate area for storage in pharmacy?
Yes, we store the products into racks and we have room for storage.

2- Do you apply the manufacturer's instructions in storage?

All the manufacturer instructions are the same, the drugs are stored into room temperature, and they must not be exposed to direct sunlight.

3- Are the storage areas situated so that the products are protected from potentially harmful influence?

Yes, the storage room is not accessible to anyone; also we store the products away from any other materials.

4- Do you apply proper care and control over hazardous substances? They are separated from others?

Yes, we have special racks for hazardous substances, they are not totally separated but we write on the rack that this is a hazardous substances.

5- Do you check receipt for quantity, quality, damaged containers, type, storage, conditions and expiry dates?

It is normal to check the quantity and if any damage in the order, also we check the expiry dates of the entire order, but we cannot check for quality but we are dealing with approved distributors and we avoid dealing with unknown distributors or agents.

6- Do you have a place for special storage (cold or refrigerated)?

Yes, we have a refrigerator in the pharmacy used for storage of some eye drops, and vaccines.

7- What is the percentage of returns from patients? What are the main reasons for returns?

The percentage of returns is not high because we do not accept returns from patients for any reasons other than the product is damaged or expired, and we do not have expired products into the pharmacy, but sometimes only the

internal package of the product have minor damage therefore we accept returns in this case.

8- Does the Ministry of Health perform inspection for storage instructions?

Yes, I think every 4 months they make a visual inspection, but they do not perform full inspection unless there is a big problem in the pharmacy or if they have complaints from customers.

9- What are the main challenges in managing the storage of drugs?

The challenge is to manage the multiple types of drugs and to make them easy accessible on racks and shelves.

10- What are the characteristics of the storage area you have in the pharmacy (Design, organization, sorting, cleanliness)?

We store the products into shelves and racks according to the expiry date, the first in first out, and every month we make audit on the stocks, we also clean the racks and the storage room.

11- Do you have any problems in storing drugs?

We do not have problems in storing the drugs, but we have problems with distributors, we cannot reach them for returning drugs if we want to return them before the expiration, and the main aim of distributors is to sell only the maximum quantity and they usually want cash payments.

12- What are the potential storage problems that pharmacies in general face?

The distributors problems are increasing and they do not get feedback from pharmacies, they only want to sell products, and the solution is that Ministry of health performs detailed instructions that define the relation between

distributors and pharmacies, because distributors are more powerful than pharmacies.

4.5 Chapter Summary

After conducting interview with Pharco Corporation and the pharmacies sample, the finding is that not all pharmacies are applying the manufacturer instructions, and they are not complying with all the regulations of Ministry of Health, also large chains category (A) are not the ideal example of good pharmacies, they have shortage on the application of the instructions.

Most of pharmacies are not satisfied by dealing with distributors and they prefer to deal with the manufacturer directly.

Another finding is that Pharmaceutical Companies do not have the authority to enforce pharmacies to apply the regulations and this is a weakness point.

CHAPTER FIVE

CONCLUSIONS AND RECOMMENDATIONS

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CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter provides the conclusions of the analysis of the interview with Pharco Corporation managers, and the pharmacies interviewed in Chapter four.

After concluding this chapter the proposed recommendations are included by comparing the answers of different interviewee and define the gaps between the pharmaceutical company and the pharmacies, and the role of ministry of health as they are the source of regulations according to the WHO.

5.2 Conclusions

The conclusions of the study could be summed up in the following points:

- Temperature-sensitive and perishable items must be transported and stored in a controlled environment.
- The expiry date is useless if the drug is stored into bad conditions and if exposed to direct light.
- Medicines may lose some active ingredients if they are not delivered by refrigerated and well ventilated trucks.
- Pharmaceutical Companies must have a supply chain department to manage the internal and external relationship with partners and manage cross functional activities of the company.
- The WHO is the responsible organization to publish guidelines for good practices of pharmaceuticals supply chain, including Good Manufacturing practices (GMP), Good Distribution practices (GDP), and good storage practices (GSP).

- WHO guide to good storage practices is issued to all parties involved in the storage, transportation and distribution of pharmaceuticals, this guide is closely linked to other guides like (GMP).
- Storage conditions must be observed during transportation taking into consideration the requirements for personnel experience, the suitability of premises and equipments, delivery of products, return of drugs and self inspections.
- Egyptian Ministry of Health (MOH) enforces manufacturers of drugs, as well as pharmacies to comply with the regulations but they are not following them usually or in a fixed basis.
- Ministry of Health performs periodical inspection into manufacturing facilities as well as the storage area inside the company.
- Good storage practices should be followed by distributors, not only by pharmaceutical companies and pharmacies but also distributors must comply with it, because distributors are not complying with good storage practices and they ignore the application of GSP guidelines as required.
- There is a lack of coordination between various departments in the pharmaceutical companies.
- Exporting activities in Egyptian pharmaceutical companies are not well planned, and most of problems are related to inappropriate packaging of drugs and this is the main reason for returns.
- Companies rely on local and international suppliers for sourcing starting materials needed for drug production.
- Most of active ingredients are sourced from international suppliers, and the secondary materials like packaging are sourced from local suppliers due to lower cost of materials and to avoid high transportation costs.
- There is a risk in companies of receiving non conforming starting materials for production.

- Pharmaceutical companies do not have the power to enforce pharmacies to comply with their own storage requirements printed on the package of drugs.
- The storage area for finished products into the manufacturing facilities are not well planned, there is no pest control, the handling equipments are relatively old, and the required area for storage did not serve the quantity produced, also the workers in the warehouses did not wear safety clothes.
- The storage manager mentioned that they do not have any problem in storage of pharmaceuticals and they do not have any potential problem in the future, because they are managing the company well, this is considered as a weakness because they must take into consideration the potential problems that could occur in the future.
- There is a common problem into pharmacies that the storage area is not sufficient for handling all current types of product and this represents a risk for the pharmacies in the future, because they will not have the ability to carry inventories from all types of drugs from different manufacturers.
- Not all pharmacies have a separated quarantine area for expired products and for recalls or returns; also not all pharmacies have air conditions especially small pharmacies in class C.
- The percentage of customer returns vary from pharmacy to another, and some pharmacies do not accept returns and have a strict policy with customers.
- Pharmacies see that manufacturers are not aware of the problems related to pharmacies and they are focusing on increasing sales only.
- Pharmacies see that most of storage problems resulting from inappropriate storage activities in warehouses of distributors, the packages are damaged during handling and put away of pallets.
- Ministry of Health does not perform periodical inspections to all pharmacies.

5.3 Recommendations

1. Pharmaceutical companies must improve the storage area and update the facilities because they are applying only the basic requirements assigned to them.
2. Manufacturing companies must have the authority to enforce pharmacies to apply the storage instructions provided to them, also they must have the authority to apply penalties for any pharmacy that do not apply the instructions.
3. Egyptian pharmaceutical companies must be aware of the importance of supply chain department, because the manager of this department is responsible for the coordination of activities with upstream suppliers to the downstream customers (distributors and pharmacies) involved in delivering the drug to the patient.
4. All the parties involved in the pharmaceutical industry (supplier, manufacturers, and distributors) must have similar goal, this goal must be to deliver the drug to the patient in a high quality and at affordable price, because independent goals will not deliver the product as required.
5. Ministry of health must provide more strict regulations for pharmacies; those regulations must be applied to all pharmacies regardless the location of pharmacy.
6. Ministry of health must ensure that the pharmacy is storing the drug at the required temperature, it is not sufficient to ensure only that pharmacies have refrigerators.
7. A periodical check must be conducted to the transportation vehicles of temperature controlled drugs, to ensure that those vehicles are complying with the standards, as well as the warehouse of distributors must be inspected by manufacturers before dealing with any distributors, and this is a good method to enforce distributors to comply with the regulations.

8. Manufacturers must have feedback from customers about the pharmacies and conduct interviews with patients about the major problems they found in dealing with pharmacies.
9. Manufacturers must provide the necessary feedback to ministry of health about pharmacies that are not complying with the regulations and the GSP.
10. Each pharmacy must have an employee specialized in storage of pharmaceutical products, this employee must have experience about the storage conditions of the drugs, and to conduct inspections in receipt of shipments from distributors and check for quality, quantity, expiry dates, and any damage in the packaging.

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