

# **GOOD WAREHOUSING & DISTRIBUTION PRACTICES**

## **❖ GOOD WAREHOUSING**

Good warehousing practices (GWP) means storing supplies so that products are always available, accessible, and in good condition. Bad warehousing lead to damages resulting in losses. Pharmaceutical warehousing, therefore, is much more than the simple storage of products. It is an operation that preserves the integrity of drugs. According to cGMP Drugs must be stored to prevent contamination, and be positioned to allow for inspection and cleaning of the area. Each lot of drug products must be identified with a distinctive (and traceable) code, and the lot's status must be identified (approved, quarantined, rejected). Written procedures must describe the distribution process for each drug. This includes procedures for recalls. Written procedures must describe the appropriate storage conditions for each drug. Different drugs can have vastly different requirements in terms of temperature, humidity, and lighting. The warehousing official ensures that the storage of each drug is in line with its specific requirements defined by the manufacturer. This can involve temperature-controlled warehousing and/or climate-controlled warehousing space<sup>20</sup>, both of which require state-of-the-art control and monitoring equipment to keep the space with in specific environmental parameters.



**GOOD WAREHOUSING**



**BAD WAREHOUSING**

## **IMPORTANCE OF GOOD WAREHOUSING PRACTICES**

- To optimize the resources available for a large scale storage in a specified manner.
- As an integral part of the supply chain.
- Making the best use of the real time data for effective supply chain and optimization of the stock put away and Bin utilization.
- To save time and effort in identifying and locating goods.
- To maintain a safe, clean and segregated environment.
- To control the movement and storage of material within the stores.
- To help in easy stock take and stock verification & reconciliation and help in stock corrections if necessary.
- Regulatory requirement for pharmaceuticals.
- To develop a zone concept for product wise segregation.
- To streamline the process of receipt, storage and distribution.

## **GOOD WAREHOUSING PRACTICES**

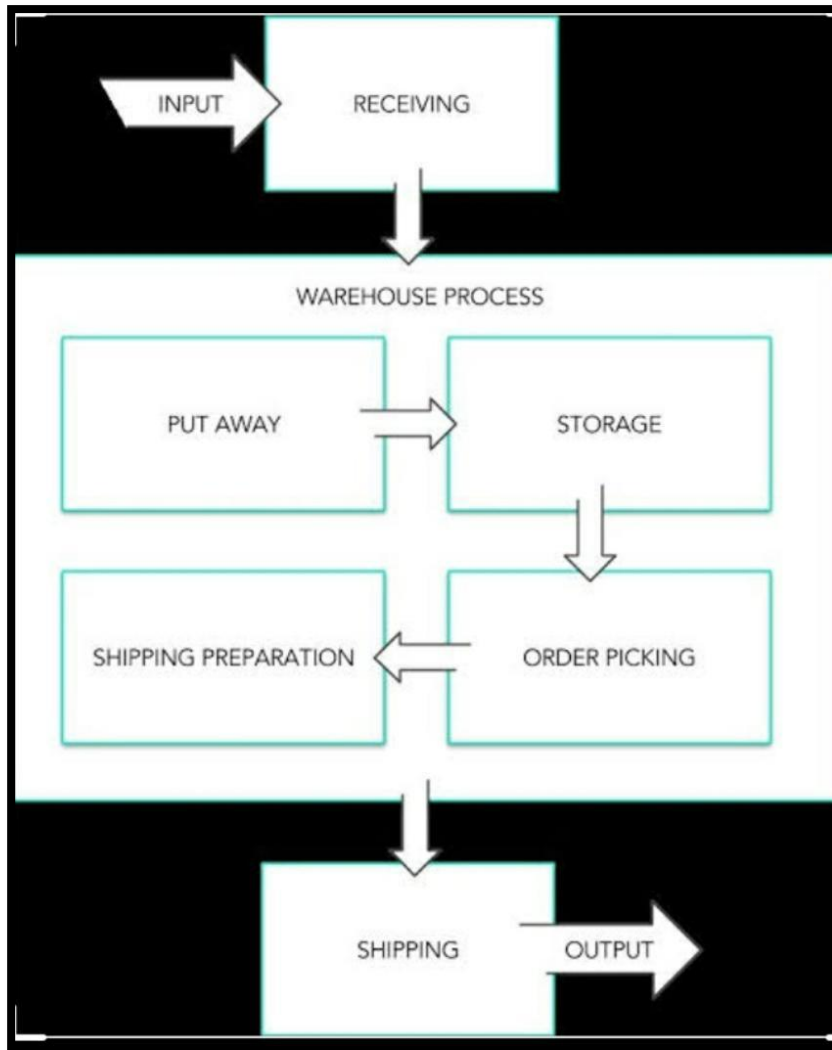
Warehousing and storage is an act of storage and assorting the finished goods so as to create maximum time utilization at the minimum cost. The key activities concerned with warehousing are:

- Receiving
- Identifying
- Holding
- Assembling and processing of the orders to meet the demand.

## **FUNCTIONS OF WAREHOUSING**

- 1. Receiving and Recording of goods:** While receiving the goods it is the responsibility of the warehouse department to check and verify the goods that are coming into the warehouse by weighing the shipper coming in and counting the same. The correctness and quantity of the goods coming in should be verified at the time of receipt and recorded in a document. It should be mutually agreed and signed between the person transferring the goods and the person receiving the goods.
- 2. Storage:** Major function of storage is to ensure that the product is protected and stored in a manner to ensure that the goods are easy to identify and as per the category. It is advisable to have zoning concept where the products can be stored as per the zone.
- 3. Order Picking:** After the receipt of the order the line manager shall ensure that he has picked the same order as indicated in the picking list and the same batch number should appear in all the documents i.e., the invoice, the picking list and the delivery note.
- 4. Distribution:** The line manager hand over the goods to the packers who verify the goods against the delivery note and do the necessary marking on the shippers as per the customer. It is the responsibility of the loading supervisor to check the vehicle and confirm that it is matching as per the requirements and is clean and tidy for loading pharmaceutical goods.
  - The incoming material in the warehouse to be immediately sent to quarantine.
  - The quarantine goods to be sampled by the Quality Department and sent for analysis. (In case of manufacturing unit the samples may be taken online before the batch is transferred to Quarantine).
  - After getting release from the Quality Department the goods need to be transferred to the Approved area.
  - In case if the goods are rejected they are supposed to be transferred to the Rejected area the keys of the rejected area shall remain with the Quality Department.
  - There should also be provision for customer returned goods and market returned Goods which should go through the Quality Department for further segregation into either approved or rejected.
  - Provision for goods to be stored under controlled temperature is a must.

- This area should be mapped for temperature distribution.
- Another important area is for the controlled substances which can be misused and are required to be stored under BOND by the law.



### **ELEMENTS OF GOOD WAREHOUSING PRACTICES**

**Costs involved in warehouse:** As a practice it is good to follow first expiry first out (FEFO) for the finished goods, which helps to maintain the inventory with the maximum shelf life FIFO is also equally valid as FEFO. The imported goods need to be scrutinized and checked for expiry dates at the time of receipt.

**Stock Verification:** Orderly, timely and frequent stock verification is the key to correct stocks and the same affect the business positively. The warehouse must on a routine basis share the data on the non moving, dead stock and the near expiry products so that the management can take a decision on the fate of the drugs. The data collected from the stock review should also be shared with the supply chain and planning Department regular basis so as to facilitate in an effective planning process.

**Safety:** Safety is of foremost important in a warehouse considering the various types of activities and equipment like the forklift, Trolley, pallets drums shippers etc. Some are kept at a height which if not stored properly can be precarious and lead to fatal accidents. OHSASZ 21guidelines need to be followed religiously and all the employees should wear protective garments commonly called PPE 22, to protect them from any accidental harm. Helmets, Safety shoes, garments, masks are necessary. Abrupt and rapid movements are uncalled for and cause more damage than benefits. So the warehouse employees need to be disciplined and cautious in their approach. Any and every accident should be reported immediately. The fire end emergency exit plans shall be well laid out and fire drills to be performed to validate the exit plan. The



entire warehouse has to be subjected for pest control activities and the rodent baits should be checked at regular intervals. The baits and chemicals should be kept away from the pharmaceutical preparations and at any given point should not come in contact with the workmen of the products kept in the area.

**Premises, Health & Hygiene:** The area should be kept clean and away from objectionable odors, smoke dust and other contaminants. The warehouse should be well ventilated. It should protect the goods from adverse weather conditions. Opening leading to entry of rodents, pests, birds and vermin should be closed. Floors should be non slip evenly graded to prevent stagnation and can be drained to trapped outlets protected by a grill. The floor should be constructed using material that is impervious, non-toxic, non adsorbent and crack resistant. Walls should be made of smooth, durable, impervious, non adsorbent and crack resistant material that can be cleaned easily. All ceiling are to be constructed and finished so as to prevent condensation, leakage and formation of molds and should be easily and regularly cleaned. Door should be easily cleanable surfaces. Adequate lighting and lux 24 levels. Toilets must not open directly into any place where the products are stored. The recommended storage conditions for the cold storage is 2-8° C. which should be mapped and the temperature sensor to be placed at the hot spot identified manual temperature recording. Cold storage should not be overloaded should have racks inside for proper storage. It should be in sanitary condition at all times. The cleaning equipment should be placed in a well designated area with proper labelling. Eating, drinking, smoking, chewing gum or tobacco, littering and undesirable behavior at the designated areas in the premises is prohibited. Any person who has open wounds and lesions, boils sores or infectious disease must be sent on leave till they achieve complete recovery Attested by a medical supervisor.

**Good documentation:** Last but not the least is the documentation for the activities done. It is a common saying in GMP that “if it is not documented it never happened”. SOP, records & Bin card need to be checked, updated and religiously followed. Maintain the invoices, delivery notes and other documents

## **❖ WHO GOOD DISTRIBUTION PRACTICES FOR PHARMACEUTICAL PRODUCTS**

Distribution is an important activity in the integrated supply-chain management of pharmaceutical products. Various people and entities are generally responsible for the handling, storage and distribution of such products. The objective of these guidelines is to assist in ensuring the quality and identity of pharmaceutical products during all aspects of distribution process. These aspects include, but are not limited to, procurement, purchasing, storage, distribution, transportation, repackaging, relabeling, documentation and record keeping practices. The storage sale and distribution of pharmaceutical products are often carried out by various companies, institutions and individuals. This document sets out important and appropriate step to assist in fulfilling the responsibilities involved in the different aspects of the distribution process within the supply chain and to avoid the introduction of counterfeits into the marketplace via the distribution chain.

The relevant section should be considered by various participants as applicable to the particular role that they playing the distribution of pharmaceutical products. The nature of risk involved is likely to be similar to that for risks encountered in the manufacturing environment e.g. mix-ups, adulteration, contamination and cross-contamination. When the distribution chain is interrupted by manufacturing steps such as repackaging and relabeling, the principles of good manufacturing practices (GMP) should be applied to these processes. Weak points in the distribution processes of pharmaceutical products provide an avenue for counterfeit as well as illegally imported, stolen and substandard medicines to enter the supply chain. This is a concern in both developed and developing countries. The methods by which such products enter the supply chain have become increasing complex and have resulted in the development of thriving secondary and grey markets throughout the world.

The involvement of unauthorised entities in the distribution and sale of pharmaceutical products is a particular concern. Only a joint approach including all parties involved in the supply chain can be successful in the fight against counterfeit pharmaceutical products and, therefore all parties active in the market should

take an active part in collaborative activities. Different models for the distribution of pharmaceutical products are used in different countries and sometimes within the same country, for example TRS957, .indd 236 21.04.10 11:04 237 in the public and the private sector. These guidelines are intended to be applicable to all persons and outlets involved in any aspect of the distribution of pharmaceutical products from the premises of the manufacturer of the product to the person dispensing or providing pharmaceutical products directly to a patient or his or her agent. Every activity in the distribution of pharmaceutical products should be carried out according to the principles of GMP, Good Storage Practice (GSP), Good Distribution Practice (GDP), as applicable. These guidelines do not deal with all aspects of the standards for the storage of the pharmaceuticals which are covered in the WHO guide to good storage practices for pharmaceuticals, the main principles established in this document may also be used where applicable for medical devices.

### **DEFINITION:**

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

### **GENERAL PRINCIPLES:**

The principles of GDP are applicable both to pharmaceutical products moving forward in the distribution chain from the manufacturer to the entity responsible for dispensing or providing pharmaceutical products to the patient and to products which are moving backwards in the chain, for example, as a result of the return or recall thereof. There should be collaboration between all parties including governments, customs agencies, law enforcement agencies, regulatory authorities, manufacturers, distributors and entities responsible for the supply of pharmaceutical products to patients to ensure the quality and safety of pharmaceutical products and prevent the exposure of patients to counterfeit pharmaceutical products.

### **ORGANIZATION AND MANAGEMENT:**

There should be an adequate organisational structure for each entity defined with the aid of an organizational chart. The responsibility, authority and interrelationships of all personnel should be clearly indicated. At every level of the supply chain, employees should be fully informed and trained in their duties and responsibilities. A designated person should be appointed within the organization, who has defined authority and responsibility for ensuring that a quality system is implemented and maintained. The responsibilities placed on any one individual should not be so extensive as to present a risk.

### **PERSONNEL:**

All personnel involved in distribution activities should be trained and qualified in the requirements of GDP, as applicable. Training should be based on written standard operating procedures (SOPs). There should be an adequate number of competent personnel involved in the stages of the distribution of pharmaceutical products in order to ensure that the quality of the product is maintained. Personnel involved in the distribution of the pharmaceutical products should wear garments suitable for the activities that they perform. Procedures and conditions of employment for employees, including contract and temporary staff, and other personnel having access to pharmaceutical products must be designed and administered to assist in minimizing the possibility of such products coming into the possession of unauthorized persons or entities. Codes of practice and punitive procedures should be in place to prevent and address situations

### **QUALITY SYSTEM:**

Within an organisation, quality assurance serves as a management tool. There should be a documented quality policy describing the overall intentions and requirements of the distributor regarding quality, as formally expressed and authorized by management. Where electronic commerce is used i.e. electronic means are used for any of the distribution steps, defined procedures and adequate systems should be in place

to ensure traceability and confidence in the quality of the pharmaceutical products concerned. Electronic transactions, relating to the distribution of the pharmaceutical products, should be performed only by authorized persons or entities. Inspections, auditing and certification of compliance with a quality system by external bodies is recommended. Such certification should not, however, be seen as a substitute for compliance with these GDP guidelines and the applicable principle of GMP relating to pharmaceutical products, distributors should from time to time conduct risk assessments to assess potential risks to the quality and integrity of pharmaceutical products.

### **PREMISES, WAREHOUSING AND STORAGE:**

Precautions must be taken to prevent unauthorized persons from entering storage areas. Employees should comply with the company policies to maintain a safe, secure and efficient working environment. Storage areas should be of sufficient capacities to allow the orderly storage of the various categories of pharmaceutical products namely commercial and non-commercial products, products in quarantine, and released, rejected returned or recalled products as well as those suspected to be counterfeits. Storage areas should be clean and free of accumulated waste and vermin. If sampling is performed in the storage area, it should be conducted in such a way as to prevent contamination or cross contamination. Adequate cleaning procedures should be in place for the sampling areas. Radioactive materials, narcotics or other hazardous, sensitive and/or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fire or explosion should be stored in dedicated areas that are subject to appropriate additional safety and security measures. A system should be in place to ensure that the pharmaceutical products due to expire first are sold and/or distributed first. Exceptions may be permitted as appropriate provided that adequate control is in place to prevent the distribution of expired products.

Storage conditions for pharmaceutical products should be in compliance with the recommendation for the manufacturer. Equipment used for monitoring of storage conditions should also be calibrated at defined intervals. Stock discrepancies should be investigated in accordance with a specified procedure to check that there have been no inadvertent mix-ups, incorrect issues and receipts, thefts and/or misappropriations of pharmaceutical products. Documentations relating to the investigation should be kept for a predetermined period.

### **VEHICLES & EQUIPMENTS:**

These are used to distribute, store or handle pharmaceutical products should be suitable for their purpose and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity and to prevent contamination of any kind. Where feasible considerations should be given to adding technology such as Global Positioning System (GPS), electronic tracking devices and engine kill buttons to vehicles, which would enhance the security of products while in the vehicle. Where special storage conditions (e.g. Temperature/ Relative humidity), different from or limiting the expected environmental conditions are required during transportation, these should be provided, checked, monitored and recorded. All monitoring records should be kept for the shelf life of the product distributed plus one year or as required by national legislation.

### **SHIPMENT CONTAINERS & ITS LABELING:**

It should bear labels providing sufficient information on handling and storage conditions and precautions to ensure that the products are properly handled and secure at all times. It should enable identification of the containers contents and source. Normally, internationally or nationally accepted abbreviations, names or codes should be used in the labelling. Special care should be taken when using dry ice in shipment containers. It must be ensured that the pharmaceutical product does not come into contact with the dry ice as it may have an adverse effect.

## **DISPATCH & RECEIPT:**

Prior to the dispatch of the products, the supplier should ensure that the person or entity is aware of the products to be distributed and complies with the appropriate storage and transport conditions. Record for the dispatch of products should be prepared and should include at least the following information:

- Date of dispatch
- Complete business name and address, type of entity responsible for transportation, telephone number and names of contact persons
- Complete business names, address and status of the address
- Description of the products including name, dosage form and strength
- Quantity of the products: number of containers and quantity per container
- Applicable transport and storage conditions
- Unique number to allow identification of the delivery order and assigned batch number and expiry date

Care should be taken to ensure that the volume of the products ordered doesn't exceed the capacity of storage facilities.

## **TRANSPORTATION & THE PRODUCTS IN TRANSIT:**

Products and shipment containers should be secured to prevent or provide evidence of unauthorised access. Vehicles and operations should be provided with additional security to prevent theft and other misappropriation of products during transportation. Products should be stored and transported in accordance with procedures such that

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

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

## **DOCUMENTATION :**

- Written instructions and records which document all activities relating to the distribution of pharmaceutical products, including all applicable receipts and issues (invoices) should be available.
- Records should be kept for seven years, unless otherwise specified in national or regional regulations,.
- Distributors should keep records of all pharmaceutical products received. Records should contain at least the following instructions:- date, name of the pharmaceutical product, quantity received or supplied and the name and address of the supplier.

The nature, content and retention of documentation relating to the distribution of pharmaceutical products and any investigation conducted and action taken, should comply with national legislative requirements. Where such requirements are not in place, the documents should be retained for at least 1 year after the expiry date of the product concerned. Procedures should be in place for temperature mapping, security services to prevent theft or tampering with goods at storage facilities, destructions of unsaleable or unusable stocks and on retention of the records.

## **REPACKING AND RELABELLING :**

- Repacking and relabeling of the pharmaceutical products should be limited, as these practices may represent a risk to the safety and security of the supply chain.
- Where they do occur, they should only be performed by entities appropriately authorized to do so and in compliance with the applicable national, regional and international guidelines, I.e accordance with the GMP principles,.
- In the event of Repacking by companies other than the original manufacturer, these operations should result in at least equivalent means of identifications and authentication of the products. Procedures should be in place for the secure disposal of original packaging.

## **COMPLAINTS:**

- There should be a written procedure in place for handling of complaints.
- A distinction should be made between complaints of the product or its packaging and those relating to distribution.
- In the case of complaint about the quality of the product or its packaging, the original manufacturer and or marketing authorization holder should be informed as soon as possible.
- Where necessary, appropriate follow up action should be taken after investigation and evaluation of complaint. There should be a system in place to ensure that the complaint, the response received from the original product manufacturer, or the results of investigation of complaint, are shared with all the relevant parties.

## **RECALLS:-**

There should be a system, which includes a written procedure, to effectively and promptly recall

- There should be a system, which includes a written procedure, to effectively and promptly recall pharmaceutical products known or suspected to be a defective or counterfeit, with a designated persons responsible for recalls.
- The system should comply with the guidance issued by the national or regional authority.
- This procedure should be checked regularly and updated as necessary.
- The original manufacturer and or marketing authorization holder should be informed in the event of a recall.
- Where a recall is instituted by an entity other than the original manufacturer and or marketing authorization holder, consultation with the original manufacturer or marketing authorization holder should, where possible, take place before the recall is instituted.
- Recalled pharmaceutical products should be segregated during transit and clearly labelled as recalled products.
- Where segregation in transit is not possible, such goods must be securely packaged, clearly labelled, and be accompanied by appropriate documentation.

## **RETURNED PRODCUTS:-**

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

**Counterfeit pharmaceutical products** – Provisions should be made for appropriate and safe transport of returned products in accordance with the relevant storage and other requirements. Rejected pharmaceutical products and those returned to a distributor should be appropriately identified and handles in accordance



with a procedure which involves at least the physical segregation of such pharmaceutical products in quarantine in a dedicated area or other equivalent (e. g electronic) segregation.

### **COUNTERFEIT PHARMACEUTICAL PRODUCT:-**

Counterfeit pharmaceutical products found in the distribution chain should be kept apart pharmaceutical products to avoid any confusion. They should be clearly labelled as not for sale and national regulatory authorities and the holder of the marketing authorization for the original product should be informed immediately. Upon confirmation of the product being counterfeit a formal decision should be taken on its disposal, ensuring that it does not re-enter the market, and the decision recorded.

### **IMPORTATION :-**

The number of ports of entry in a country for the handling of imports of pharmaceutical products should be limited by appropriate legislations. Such ports could be designated by the state. The chosen port(s) of entry should be those most appropriately located and best equipped to handle imports of pharmaceutical products. At the port of entry, consignments pharmaceutical products should be stored under suitable conditions for as short a time as possible. All reasonable steps should be taken by importers to ensure that products are not mishandled or exposed to adverse storage conditions at wharves or airports.

### **CONTRACT ACTIVITIES:-**

Any activity relating to the distribution of a pharmaceutical product which is delegated to another person or entity should be performed by parties appropriately authorized for that function and in accordance with the terms of a written contract. The contract should define the responsibilities of each party including observance of the principles of GDP and relevant warranty clauses. It should also include responsibilities of the contractor for measures to avoid the entry of counterfeit medicines into the distribution chain, such as by suitable training programmes. Contract accepters should be audited periodically.

### **SELF-INSPECTION:-**

The quality system should include self-inspections. These should be conducted to monitor implementation and compliance with the principles of GDP and, if necessary, to trigger corrective and preventive measures. Self-inspections should be conducted in an independent and detailed way by a designated, competent person. The results of all self inspections should be recorded. Reports should contain all observations made during the inspection is and, where applicable, proposals for corrective measures. There should be an effective follow-up programme. Management should evaluate the inspection report of any corrective actions taken.

## **❖ MATERIAL MANAGEMENT**

Material management is an important management tool which will be very useful in getting the right quality & right quantity of supplies at right time, having good inventory control adopting sound methods of condemnation & disposal will improve the efficiency of the organization & also make the working atmosphere healthy any type of organization whether it is Private, government Small organization, Big organization and Household.

- It is concerned with planning, organizing and controlling the flow of materials from their initial purchase through internal operations to the service point through distribution.
- Material management is a scientific technique, concerned with Planning, Organizing & Control of flow of materials, from their initial purchase to destination.

### **OBJECTIVES OF MATERIAL MANAGEMENT:**

- To gain economy in purchasing

- To satisfy the demand during period of replenishment
- To carry reserve stock to avoid stock out
- To stabilize fluctuations in consumption.
  - To provide reasonable level of client services

### **FOUR BASIC NEEDS OF MATERIAL MANAGEMENT:-**

1. To have adequate materials on hand when needed
2. To pay the lowest possible prices, consistent with quality and value requirement for purchase materials.
3. To minimize the inventory investment
4. To operate efficiently

### **BASIC PRINCIPLES OF MATERIAL MANAGEMENT:-**

1. Effective management & supervision  
It depends on managerial functions of
  - Planning
  - Organizing
  - Staffing
  - Directing
  - Controlling
  - Reporting
  - Budgeting
2. Sound purchasing methods.
3. Skilful and hard poised negotiations.
4. Effective purchase system.
5. Should be simple.
6. Must not increase other costs.
7. Simple inventory control Programme.

### **ELEMENTS OF MATERIAL MANAGEMENT**

1. Demand estimation
2. Identify the needed items
3. Calculate from the trends in consumption during 2 years
4. Review with resource constraints

### **FUNCTIONAL AREAS OF MATERIAL MANAGEMENT**

1. Purchasing
2. Central service supply
3. Central store
4. The print shops
5. The pharmacy
6. Dietary and linen services

### **PROCUREMENT**

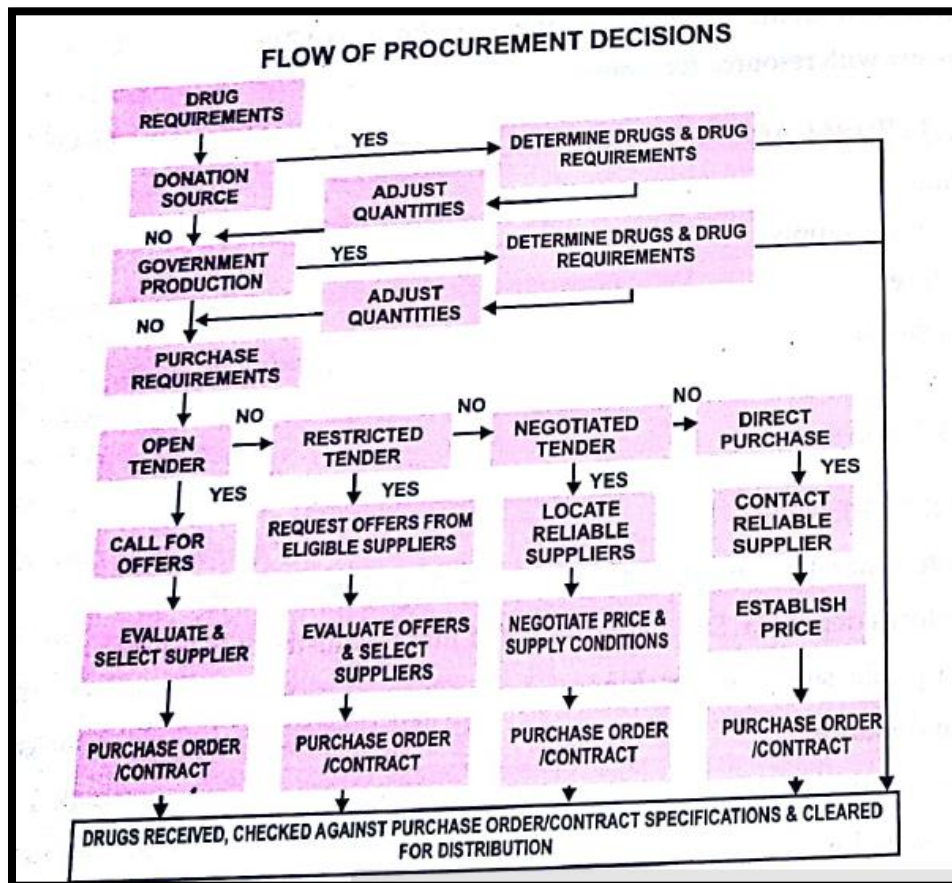
1. Directorate general of supply and disposal (DGS AND D,GOvt of india)
2. Medical stores depot (M.S.D Government of india.Ministry of H FW)
3. Private or public sector undertakings
4. Receiving donations

## PROCUREMENT CYCLE

- Review selection
- Determine needed quantities
- Reconcile needs and funds
- Choose procurement method
- Select suppliers
- Specify contract terms
- Monitor Order status
- Receipt and inspection

## OBJECTIVES OF PROCUREMENT SYSTEM

- Acquire needed supplies as inexpensively as possible
- Obtain quality supplies
- Assure prompt and dependable delivery.
- Distribute the procurement workload to avoid period of idleness and overwork.
- Optimise inventory management through scientific procurement procedures



## OPEN TENDER

- Public bidding, resulting in low prices
- Published in news papers
- Term 4 weeks
- Quotations must be sent in the specific forms that are sold, before the time and date mentioned in the tender form.
- In technical items, two packets or 2 bins system is followed. Offers are given in two separate packets

- Technical bid
- Financial bid

### **POINTS TO REMEMBER WHILE PURCHASING**

- Proper specification
- Invite quotations from reputed firms
- Comparison of offers based on basic price, freight and insurance, taxes and levies.
- Quantity and payment discount
- Payment terms
- Delivery period, guarantee
- Vendor reputation
- Short listing for better negotiation terms
- Seek order acknowledgement

### **STORAGE:**

- Store must be of adequate space
- Materials must be stored in an appropriate place
- Group wise and alphabetical arrangement
- Identification and retrieval
- First-in, first-out principle to be followed
- Monitor expiry date
- Follow two bin or double shelf system, to avoid
- Stock outs
- Reserve bin should contain stock that will cover
- Lead time and a small safety stocks

**ISSUE AND USE:** Can be centralised and decentralised.

### **INVENTORY CONTROL**

It means stocking adequate number and kind of stores, so that the materials are available whenever required and wherever required. Scientific inventory control results in optimal balance.

Functions of inventory control:

- To provide maximum supply service, consistent with maximum efficiency & optimum investment.
- To provide cushion between forecasted & actual demand for a material.

### **Economic order of quantity**

$EOQ = \text{Average Monthly Consumption} \times \text{Lead Time (in months)} + \text{Buffer Stock} - \text{Stock on hand}$

- Re-order level: stock level at which fresh order is placed.
- Average consumption per day  $\times$  lead time + buffer stock.
- Lead time: Duration time between placing an order & receipt of material.
- Ideal – 2 to 6 weeks.

#### **ABC ANALYSIS**

(ABC = Always Better Control)

- This is based on cost criteria.
- It helps to exercise selective control when confronted with large number of items it rationalizes the number of orders, number of items & reduces the inventory.
- About 10% of materials consume 70% of resources.
- About 20% of materials consume 20% of resources.



- About 70% of materials consume 10% of resources.

**'A' ITEMS** small in number, but consume large amount of resources

Must have:

- Tight control
- Rigid estimate of requirements
- Strict & closer watch
- Low safety stocks
- Managed by top management

**'B' ITEM:** Intermediate

Must have:

- Moderate control
- Purchase based on rigid requirements
- Reasonably strict watch & control
- Moderate safety stocks
- Managed by middle level management.

**'C' ITEMS:** Larger in number, but consume lesser amount of resources

Must have:

- Ordinary control measures
- Purchase based on usage estimates.
- High safety stocks

ABC analysis does not stress on items those are less costly but may be vital.

**VED Analysis:**

Based on critical value & shortage cost of an item. It is a subjective analysis.

Items are classified into:

**Vital:** shortage cannot be tolerated

**Essential:** shortage can be tolerated for a short time.

**Desirable:** shortage will not adversely affect but may be using more resources. These must be strictly scrutinized

**Procurement of equipment:**

Points to be noted before purchase of an equipment:

- Latest technology
- Availability of maintenance & repair facility, with minimum down time
- Post warranty repair at reasonable cost
- Upgradeability
- Reputed manufacturer
- Availability of consumables
- Low operating costs
- Installation
- Proper installation as per guidelines

## **Preventive maintenance**

- Purchase with warranty spares.
- Safeguard the electronic equipments with: ( as per guidelines)
  - Voltage stabilizer, UPS
  - Automatic switch over generator
- Requirement of electricity, water, space, atmospheric conditions, etc. Must be taken into consideration
- Well equipped maintenance cell must be available
- Monitoring annual maintenance contracts. [AMC]
- Maintenance cell
- Communications between maintenance cell & suppliers of the equipment
- Follow-up of maintenance and repair services
- Repair of equipment
- Outside agencies
- In-house facility

## **Condemnation <sup>27</sup> and disposal**

**Criteria for condemnation:** The equipment has become: Non-functional and beyond economical repair

- Non-functional & obsolete
- Functional but obsolete
- Functional but hazardous
- Functional, but no longer required

### **Procedure for condemnation:**

- Verify records.
- History sheet of equipment
- Log book of maintenance & repairs
- Performance record of equipment
- Put up in proper form & to the proper authority

## **Disposal**

- Circulate to other units, where it is needed
- Return to the vendor, if willing to accept
- Sell to agencies, scrap dealers, etc
- Auction
- Local destruction

## **REFERENCE:**

Pee Vee book of Pharmaceutical Quality Assurance by Dr. Swarnali Das Paul, Mrs. Gunjan Jeswani, Page no: 255 – 275