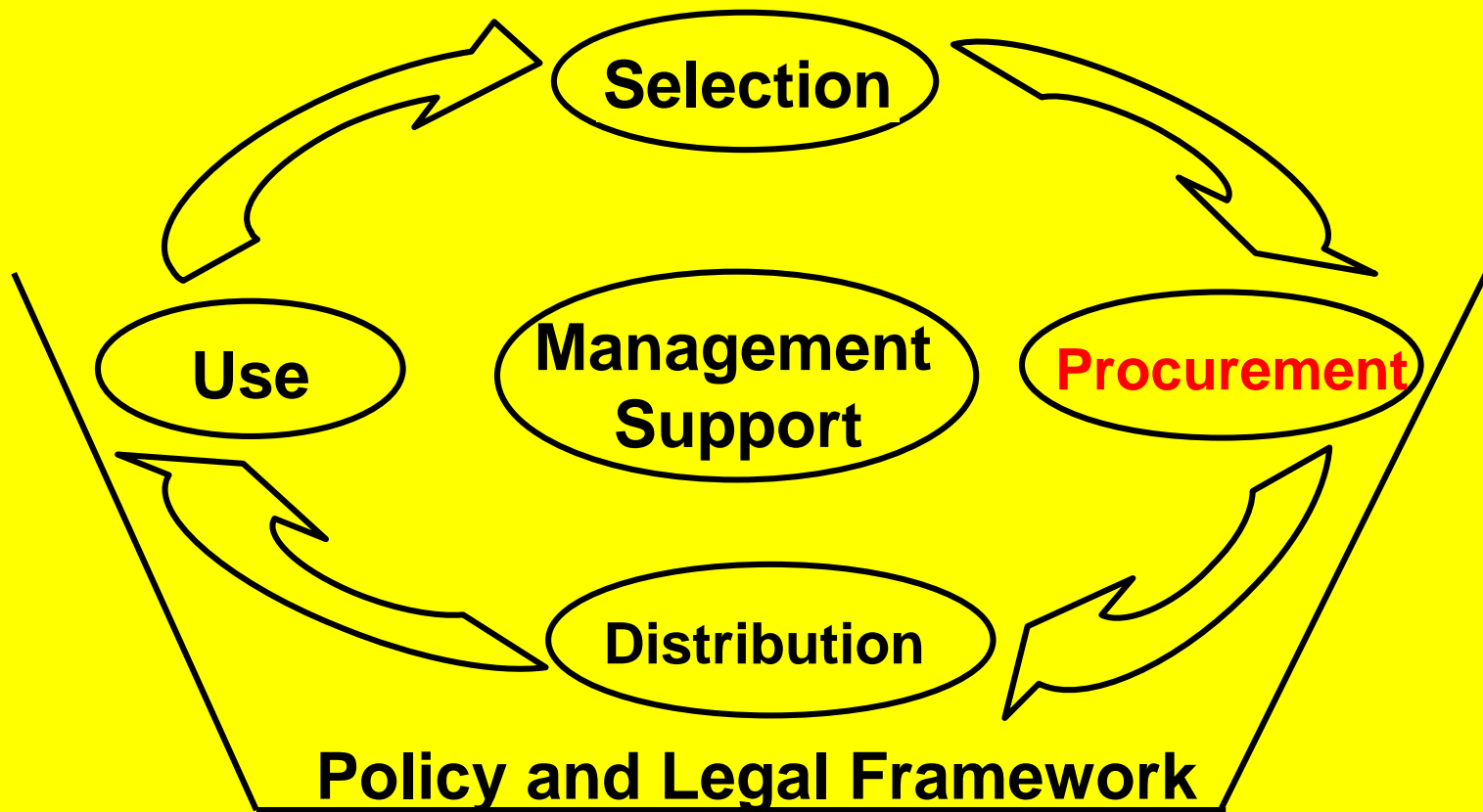




Drug Procurement

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Drug Supply Management Cycle



Definitions

- **Safety stock:** this is the buffer stock kept in reserve to prevent stock outs.
 - It is used on average during the average lead-time.
- ***Lead-time:*** is the time period between the date the drug requisition is initiated and the date the drugs purchased/procured are received and available for issue.
- **Procurement period:** the period of time between an order to a supplier and the next scheduled order.

Definitions.....

- **Hidden costs:** costs in addition to the contract price that are not paid to the supplier but are real costs to the supply system.
- include costs associated with
 - poor quality, late deliveries, defaults on deliveries, short packing and other factors.
- ***Drug procurement*** is the process of acquiring drugs through *purchase*, *manufacture* and *donation*.
 - The major determinant of drug availability and total health costs.

Objective of drug procurement

- ❖ The main objective is to satisfy the need of health institutions and/or patients.
- ❖ The purchase shall comply with the **5R'S**
 - Right Quality
 - Right Quantity
 - Right price
 - Right time
 - Right source

Objective of drug procurement

An effective procurement process should:

- ☞ Procure the **right drugs** in the **right quantities**;
- ☞ Obtain the **lowest possible purchase price**;
- ☞ Ensure that all drugs procured meet recognized **standards of quality**;
- ☞ Arrange **timely delivery** to avoid shortages and overstocks;
- ☞ Ensure **supplier reliability** with respect to **service** and **quality**;
- ☞ Set the purchasing schedule, formulas for order quantities and safety stock levels to achieve the lowest total cost at each level of the system;

Major activities in procurement(cycle)

1. *Identify what to procure/* Review the selected drugs

- Select more of the essential drugs.

2. *Determine how much to procure*

3. *Reconcile needs and fund/budget*

- If the estimated quantity of drugs needed exceeds the available drug budget/fund, reduce the type and quantity of drugs systematically (VEN system).
- ☞ Omit the less essential items and give emphasis to live-saving and then to essential items.

Major activities in procurement.....

4. Choose procurement method

- Virtually all pharmaceutical **procurement methods** fall into one of the following four categories;
 - i. Open tender
 - ii. Restricted tender (closed bid or selective tender, short listed Bidders)
 - iii. Competitive negotiation (negotiated procurement or local or inter shopping)
 - iv. Direct procurement

Major activities in procurement.....

i) Open tender

- In open tendering any manufacturers or manufacturer's representatives(both local and global) are invited.
- All are subject to the terms and conditions specified in the tender invitation document.

ii) Restricted tender

- This is also termed **closed bid** or **selective tender**
- Interested suppliers must be approved in advance through a formal prequalification process that considers adherence to Good Manufacturing Practice (GMP), past supply performance, financial viability and related factors.

Major activities in procurement.....

iii) Competitive negotiation

- The buyer approaches a limited number of selected suppliers (at least three) for price negotiation.
- This method is also known as *proforma procurement* and *negotiated procurement*.
- Buyers may also bargain with these suppliers to achieve specific price or service arrangements

iv) Direct procurement

- This is the simplest but usually the most expensive method.
- It involves direct purchase of a product from a single supplier, either at quoted price or at negotiated price.
- In single-source drugs the buyer has two choices – direct procurement or selection of an alternative drug.

Contract Terms in Drug Procurement

- i. Trade terms
- ii. Purchase quantities
- iii. Exchange rates and price comparisons
- iv. Payment currency
- v. Validity of contract prices
- vi. Payment terms
- vii. Quality standards

Contract Terms in Drug Procurement.....

- viii. Labeling and nomenclature
- ix. Packaging
- x. Shelf life and expiry date
- xi. Bid bonds and performance bonds
- xii. Shipment date
- xiii. Patent provision
- xiv. Penalties for default

Major activities in procurement.....

5. Determine when to buy

- In order to execute drug procurement, prepare procurement time-table which indicates the date on which **each activity has to be performed**.
- In procurement planning, consider **lead time** and **demand fluctuations** which have impact on determining the time of purchase.
 - If the lead-time is long, make your drug requisition as early as possible to avoid unnecessary delay.
 - Failure to consider lead-time in drug procurement results in unexpected shortage of drugs.

Major activities in procurement.....

6. Locate and select suppliers

- All suppliers should be pre- or post qualified through a process that considers product quality, service reliability and delivery time, and financial viability.
- The process of evaluating new suppliers can include:
 - Formal registration
 - Reference checks with past clients and international agencies
 - Test purchases in small quantities
 - Informal local information gathering.

Major activities in procurement.....

7. Prepare purchase order/requisition

Purchase order is the drug requisition to be sent to the immediate supplier and should be prepared in triplicate.

The form is to be filled in triplicate

- Original--→sent to the supplier
- 2nd copy--→sent to the archive of the institution
- 3rd copy--→remains in the pharmacy section

Drug Requisition Form

Name & type of Health Institution _____

Region _____ Zone _____ Woreda _____ Town _____ Telephone _____ P.O.Box _____

Annual Drug Budget in Birr _____ balance at the time of request in birr _____

Co de No	Descript ion (Name, Strengt h, and Dosag e form)	Unit	monthly consum ption	Quantity in stock	Quantity requested	Quantity supplied*	unit cost*	total cost*
Total estimated cost of the requested items in birr _____								

Requested by _____ approved by _____

Signature _____ Signature _____

Date _____ Date _____

***for supplier use only**

Major activities in procurement.....

8. Monitor order status

- Send your drug request based on the standard drug requisition or purchase order.
- The progress of the order must be closely monitored.

Major activities in procurement.....

9. Receive & check drugs

Check the drugs to be received for:

- The type & quantities received against the drug requisition & invoice
- The quality, packaging, shelf- life & labeling of the products in order to verify whether they meet the required standards
- Report any discrepancy in quantity, quality to the supplier (filled in three copies of which the original copy is sent to the supplier) 2nd copy to the archive & the 3rd copy remains in the pharmacy section)

undertaking physical inspection when receiving drugs , model discrepancy reporting form

Name of Health Institution _____

Region _____ Zone _____ Woreda _____ Town _____ Telephone _____ P.O.Box _____

Supplier _____

s e r N o	Descript ion (Name , Strengt h, and Dosag e form)	Unit	Batch No	Expiry date	manu factur er	Country	unit cost	Quantity			Reaso n for differe nce
								On invoice	Actually receive	Affected *	

Reported by _____ received by _____

Signature _____ Signature _____

Date _____ Date _____

Action taken and by whom _____

Name _____ sig _____ date _____

***Quality affected->drugs damaged, missed, expired, mislabelled, etc**

Major activities in procurement.....

10. Make payment

11. Distribute drugs

12. Up -date the balance of drug budget

- Once the purchased drugs & inventory control format are received, subtract the cost of them from previous balance in order to know the current stage of the drug budget.
- Summarize & report the value of drugs purchased monthly, quarterly & annually to the concerned body.

Organization and management.....

Drug procurement systems

1. Central Medical Stores system
2. Autonomous Supply Agency system
3. Direct delivery system
4. Prime vendor system
5. Fully private supply system

Organization and management.....

1. Central Medical Stores system(CMS)

- Drugs are procured and distributed by a centralized government unit.
- Selection, procurement, and distribution are all handled by the government.

Organization and management.....

2. Autonomous Supply Agency system

- Bulk procurement, storage and distribution managed by an autonomous or semi-autonomous supply agency, and directly managed by the government.

3. Direct delivery system

- A Decentralized approach, government procurement office tenders to establish prices and suppliers for each essential drug, but the suppliers deliver the drugs directly to individual regional stores, district stores or major health facilities.

Organization and management.....

4. Prime vendor system

- Drug Procurement office established contracts with drug suppliers and separate contract negotiated with a single prime vendor, which warehouses and distributes drugs to districts and facilities

5. Fully private supply

- Public-sector patients obtain pharmaceutical services from private pharmacies.
- Government may or may not reimbursement the cost of these services , less any co-payments.

Organization and management.....

○ Sources of fund for pharmaceutical procurement

- Government financing
- User fees
- Health insurance
- Donor financing

Principles of Good Pharmaceutical Procurement Practices

- Procurement by generic name (INN)
- procurement limited to Essential Drug List or formulary list
 - Use formal approval procedure for procurement of non-listed drugs
- Procurement in bulk
- Formal supplier qualification and monitoring
- Competitive procurement
- Sole-source commitment
 - All contracted drugs are procured from winning supplier(s)
- Order quantities based on reliable estimate of actual need
- Reliable payment and good financial management

Principles of Good Pharmaceutical Procurement Practices.....

- Transparency and written procedures
- Separation of key functions – selection, quantification, preparation of product specifications, approval of suppliers, adjudication & award of contracts.
- Product quality assurance program
 - Company registration
 - product registrations
 - inspection of shipments
 - targeted laboratory testing
 - reporting of suspected products
- Annual audit with published results.
- Regular reporting on procurement performance.

Factors influence drug prices & total costs.....

1. Unit prices/acquisition cost

- There are many considerations involved by drug pricing by manufacturers and distributor, and many factors that cause price to vary from country to country.
- A fundamental principle is that **increasing competition among supplier decrease drug prices.**

Factors influence drug prices & total costs.....

- Several factors influence competition and pricing in pharmaceutical market.
- One main issue is how many different drug products are on the market.
 - This can be influenced by government policies on registration, licensing for manufacturing and distribution, authority to prescribe and dispense, generic substitution and price control.

Factors influence drug prices & total costs.....

2. Purchasing models and **the total variable cost** of purchasing.

- **Drug acquisition prices** are only one part of the total cost of drug purchasing, the other important costs are:
 - cost associated with **holding inventory**,
 - **the cost of operating the purchasing system** and
 - the extra costs occurred when stock outs occur (**shortage costs**).

Factors influence drug prices & total costs.....

- The total purchasing cost can be minimized by choosing the optimal purchasing model as defined by:
- The interval between orders- options include:
 - ➡ Annual, (one order per year)
 - ➡ Scheduled (periodic orders e.g. every four months (quarterly)).
 - ➡ Perpetual (orders are placed whenever stock falls to specified level).

Factors influence drug prices & total costs.....

3. Visible and hidden costs

the total **variable** cost has four components:

- Drug acquisition/purchase cost,
- Inventory holding costs
- Purchasing operation/ordering costs and
- Shortage costs.

Factors influence drug prices & total costs.....

- Some of these costs are easily visible to managers
 - The total expenditure on drug acquisition, or the salaries of procurement staff.
- However the costs also associated with **shortage** and **poor supplier performance** are not so obvious.
- Hidden costs associated with poor performance by the supplier (or the procurement office) include:-

Factors influence drug prices & total costs.....

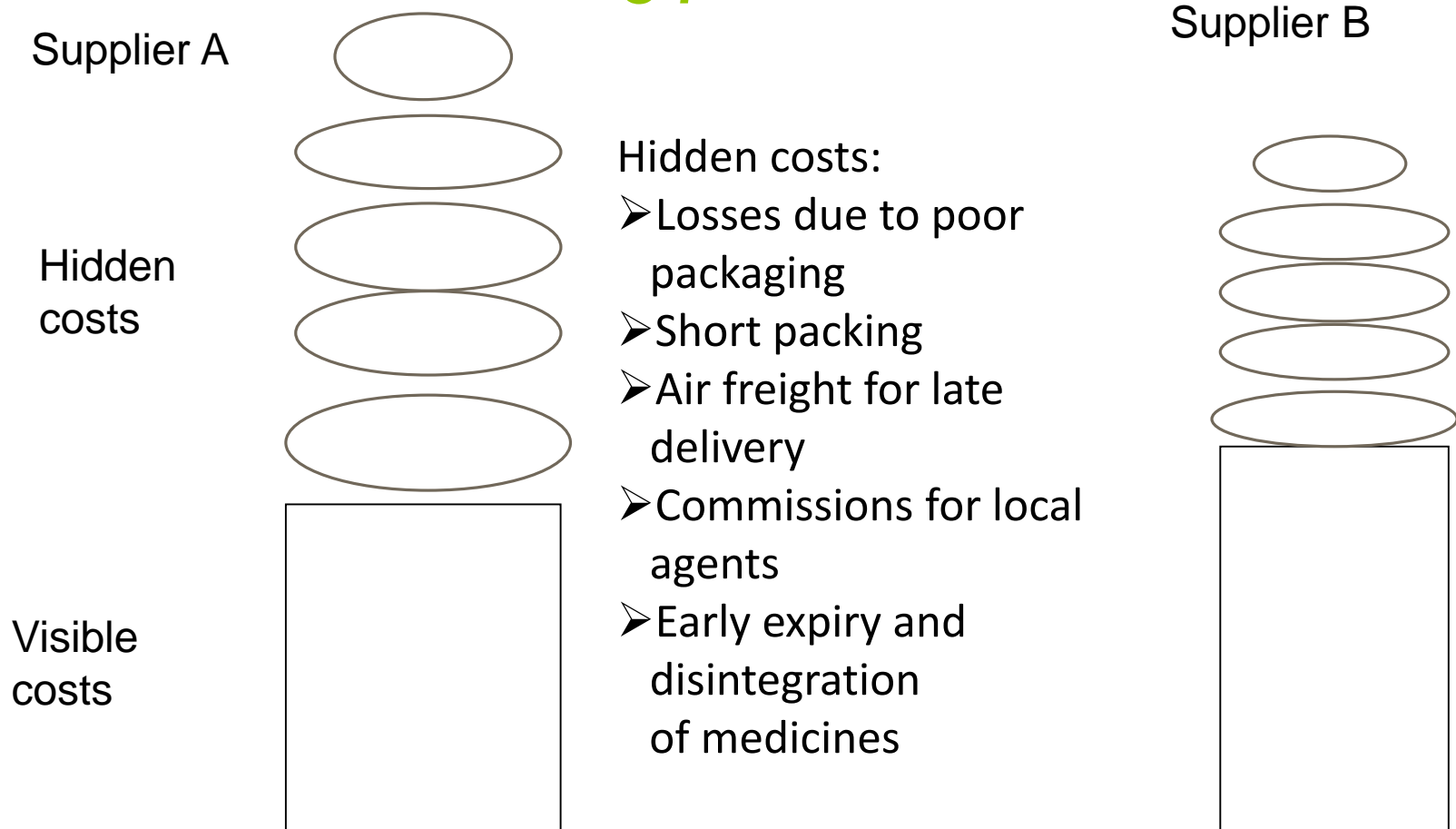
- ☞ Increased acquisition cost due to **emergency procurement** such as when vital drug ordered too late or the supplier fail to deliver on time.
- ☞ Replacement cost when good are **lost** or must be discarded b/c of poor packaging, improper shipping conditions, rapid spoilage or short shelf life.
- ☞ Replacement costs for **short shipments, incorrect concentrations of liquid preparations, wrong dosage forms**, and so on.

Factors influence drug prices & total costs.....

- ☞ **Storage, port charges & administrative expense** due to inefficient clearing procedures, or lack of funds or proper documentation.
- ☞ Health and economic cost of stock out resulting from **delay or default** on delivery.
- ❖ A system to investigate and monitor supplier performance is essential to minimize the impact of hidden costs.

Total cost = visible cost + Hidden cost

Factors influence drug prices & total costs.....



Supplier A lower price but high additional expenses \Rightarrow poor performance-rise total prices, the total cost above that quoted by supplier B.

Drug donations

- Donations of medicines are an essential element in alleviating people's suffering, and international humanitarian relief efforts benefit from regular donations by private individuals, groups and organizations.
- Most pharmaceutical donations are given with the best of intentions
- Often, donated pharmaceuticals are not relevant to the needs of the recipient, or they arrive unsorted or close to expiry.
- ✎ Many pharmaceutical donations counteract government policies or violate national regulations of the recipient country and can be expensive for the country to store or destroy.

Problems with drug donations

- Donated drugs are often not relevant for the emergency situation, for the disease pattern, or for the level of care that is available
- Health workers are not always familiar with the donated drugs
- The drugs are often not registered for use in recipient country and may not comply with local treatment guidelines
- The drugs that arrive are frequently unsorted, difficult to identify, unknown in the recipient country, labeled with brand names, or labeled in a language that is not locally understood.

Problems with drug donations....

- The quality of the drugs does not always comply with standards in the donor country.
- The donor agency sometimes ignores local administrative procedures for receiving and distributing medical supplies. The distribution plan of the donor agencies may conflict with the wishes of national authorities.

(World Health Organization (1999), Guidelines for Drug Donations, Second edition, Geneva, Switzerland).

Examples of inappropriate donations:

Eritrea, 1993. During the war for independence, despite careful wording of appeals, much time and energy had to be spent sorting pharmaceutical consignments.

- Examples of inappropriate donations included:
 - Seven truckloads of expired aspirin tablets that took six months to burn,
 - A whole container of unsolicited cardiovascular related medicines with two months to expiry, and
 - 30,000 half-liter bottles of expired amino-acid infusion that could not be disposed of anywhere near a settlement because of the smell.

Examples of inappropriate donations....

- **Croatia, 1991.** Starting in 1991, war and political instability affected countries that were part of the former Yugoslavia, prompting large amounts of pharmaceutical donations from the international community.
- In Croatia, 2,700 tons of inappropriate donations of foreign origin classified as “pharmaceutical wastes” were stored in 250 warehouses.
- USD 4 million was budgeted to ensure its safe disposal.

Drug donations.....

Management of drug donation by the recipients

- Recipient government must play a role in managing donations.
- National guideline and administrative procedure need to be defined
- It is difficult to refuse a donation that is already under way, therefore, the recipient should clearly indicate to their donors what kind of assistance they are likely to need and how they would like to receive it.

Drug donations.....

○ Activities that should be done by recipients include:

- Define needs
- Prioritize among different requirements
- Decide what documentation is needed when a pharmaceutical donation is being proposed, and who should receive these papers
- Establish criteria for accepting or rejecting a donation
- Coordinate reception, storage, and distribution of donated drugs
- Agree on whether the donor or the recipient will pay for transportation, warehousing, port clearing, and similar costs before the donation shipment arrives.
- Dispose of worthless donations

Management of drug donation by the recipients.....

Activities that should be done by recipients include.....

- Agree on how charging for donated drugs in the context of a public user fee program
 - Deal with donated drugs not registered or included in the national essential drug list in the country
 - Supervise the distribution of donated medicines and supplies to prevent them from being diverted for export, for commercial sale, or to illicit channels
- Dispose of worthless donations.

Core principles for good drug donations

- The four core principles for a useful pharmaceutical donation are—
 - i. A donation benefits the recipient to the maximum extent possible.
 - ii. A donation should be given with full respect for the wishes and authority of the recipient.
 - iii. Items that are not acceptable in the donor country for quality-related reasons are also not acceptable as donations: there should be no double standards in quality.
 - iv. Effective communication between the donor and recipient is necessary before any donation.

Monitoring and **evaluation** of Drug procurement

○ Sample Indicators

- Degree of adherence to procurement time table
- Consideration of lead – time
- Use of informative drug requisition
- Availabilities of significant amount of defective drug products
- ❖ On the basis of the result of monitoring & evaluation, necessary adjustment should be made on time.

Thank You