



# **Philippine Health Care System**



### *Learning Objectives:*

At the end of the session, the learner should be able to:

1. Identify the major functions of the national health department;
2. Describe the Philippine health care system;
3. Recognize the conceptual framework of the Universal Health Care (UHC) or *Kalusugan Pangkalahatan* (KP); and
4. Describe the role of medicines in the provision of health care.

### *Introduction*

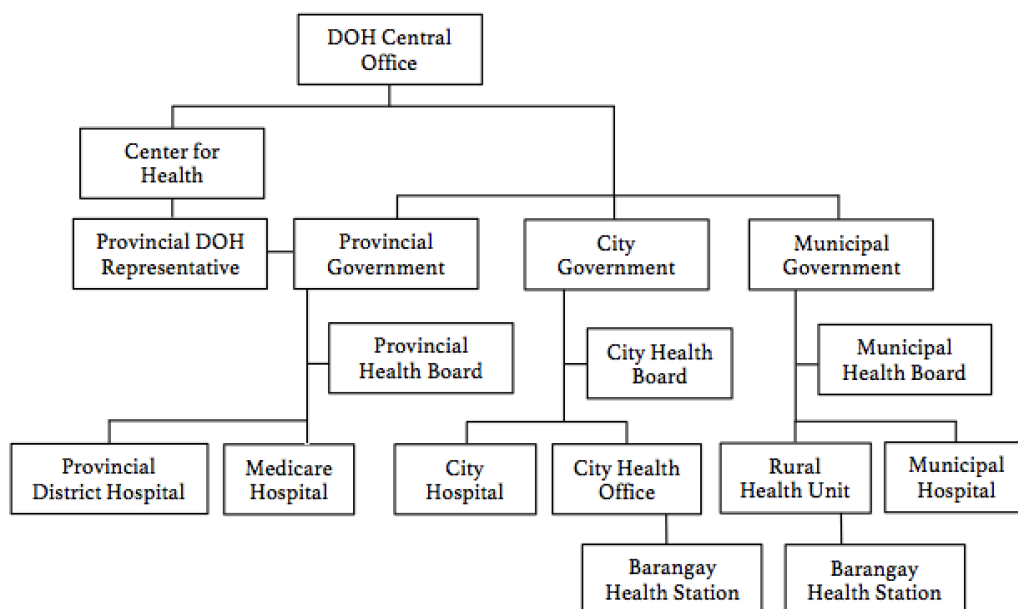
The Philippines recognizes health as a basic human right. It protects and promotes the right to health of the people and instills health consciousness among them. The Department of Health (DOH), which is the national health department, is the overall technical authority on health in the country. Its mission is to “guarantee equitable, sustainable and quality health for all Filipinos, especially the poor, and to lead the quest for excellence in health.” The DOH has three major roles in the health sector: (1) leadership in health; (2) enabler and capacity builder; and (3) administrator of specific services.





### *Organizational Structure*

The Philippines has a devolved health care delivery system since 1991 as a result of the implementation of the Local Government Code of 1991. As a decentralized system, the DOH serves as the governing agency and is mandated to provide national policy direction and develop national plans, technical standards and guidelines on health. The local government units (LGUs) are granted autonomy and responsibility for their own health services, but are to receive guidance from the DOH through the Centers for Health Development (CHDs), which are located in major cities in the provinces. Figure 1.1 shows the organizational structure of the Philippine health system.



**Figure 1.1. The organizational structure of the government health care system**

Source: Department of Health Organizational Structure, 2014



### *National Health Situation Statistics*

The Philippines, with a total population of 96,707,000 as of 2012 suffers a “triple burden of disease”. It has high incidences of all key communicable diseases, increasing level of non-communicable diseases and high prevalence of risk factors and the third highest disaster prone country in the world. Table 1.1 shows the top ten leading causes of morbidity and mortality in the country. The Philippines also has the fastest growing HIV epidemic in the world as evidenced by the 587% increase in people reported as living with HIV in the last 5 years.

**Table 1.1. Top ten leading causes of mortality and morbidity**

Leading Causes of Mortality	Leading Causes of Morbidity
1. Diseases of the Heart	1. Acute Respiratory Infection
2. Diseases of the Vascular System	2. Acute Lower Respiratory Tract Infection and Pneumonia
3. Malignant Neoplasms	3. Bronchitis/ Bronchiolitis
4. Pneumonia	4. Hypertension
5. Accidents	5. Acute Watery Diarrhea
6. Tuberculosis, all forms	6. Influenza
7. Chronic lower respiratory diseases	7. Urinary Tract Infection
8. Diabetes Mellitus	8. TB Respiratory
9. Nephritis, nephrotic syndrome and nephrosis	9. Injuries
10. Certain conditions originating in the perinatal period	10. Disease of the Heart

Source: Department of Health Statistics (as of 2010), 2014



### *Health Financing*

Health financing system in the country is complex because of the different layers of financial sources, regulatory bodies and health service providers. There are four main sources of financing: (1) national and local governments, (2) insurance (government and private), (3) user fees/ out of pocket, and (4) donors. Of these four, the major source of financing is out of pocket as it accounts for about 53% of the of the total health expenditure. The country's social health insurance, the National Health Insurance Program (NHIP), which is the largest insurance program in terms of coverage and benefit payments, accounts for a small share of total health spending (9%).

### *Health Care Delivery*

Health care services are provided by the public and private sectors. In the public sector, health service delivery is devolved to the LGUs as a result of the implementation of the Local Government Code in 1991. Provincial governments are mandated to provide secondary hospital care, while the city and municipal governments are in charge of providing primary care, including maternal and child care, and nutrition services. Attached to the municipal government are the rural health units (RHUs). Under each RHU are the Barangay Health Stations (BHS), which provide basic health services at the community level. The DOH retained the management of tertiary level facilities such as the regional hospitals, medical centers, specialty hospitals and metropolitan Manila district hospitals.



The private sector comprises 50% of the health system. This includes providing health services in clinics and hospitals, health insurance, manufacture of drugs, medicines, vaccines, medical supplies, equipment and other health and nutrition products, research and development, human resource development and other health-related services. These providers however, are concentrated in the cities.

The Philippines has a huge human reservoir for health. However, they are unevenly distributed in the country. Most are concentrated in urban areas such as Metro Manila and regional cities. The largest category of health workers is the nurses and midwives. In contrast, there is underproduction in other categories such as doctors, dentists and occupational therapists compared to the needs of the population.

### *Health Care Reforms*

Several health care reforms have been implemented by the DOH in the country over the years in order to address concerns on accessibility, inequities and efficiencies of the health system and achieve its mission. The major areas of reform are health service delivery, health regulation and health financing. Among these reforms are the primary health care (PHC) approach which was adopted in 1979 in line with the Alma Ata Declaration; integration of public health and hospital services in 1983 as per Executive Order (EO) 851;



reorganization of the DOH in 1987 in accordance with EO 119; the promulgation of the Philippine National Drug Policy (PNDP) in 1987 which had the Generics Act of 1988 and the Philippine National Drug Formulary (PNDF) as its components; the Local Government Code of 1991; the enactment of the National Health Insurance Act or the Republic Act (RA) 7875 in 1995 which created the NHIP; the Health Sector Reform Agenda (HSRA) in 1999 and the FOURmula ONE (F1) for Health in 2005.

However, despite the substantial gains and improvements in the health sector, the poor Filipino families have yet to access critical health care services. Inadequate health budgets resulted to deterioration and poor quality of many government facilities. Weaknesses in management and compensation of human resources for health have not been adequately addressed and inadequacies in health information systems remain. Moreover, the country is lagging behind in reducing maternal and infant mortality. In order to address the challenges and weaknesses of the current health care system, the Aquino government launched the Aquino Health Agenda (AHA) to improve, streamline and scale up reform interventions already started in the previous administrations. This agenda is implemented as the Universal Health Care (UHC) or the *Kalusugan Pangkalahatan* (KP) in 2010.



### *The Universal Health Care*

The UHC is an approach that seeks to improve, streamline, and scale up the reform strategies in HSRA and F1 in order to address inequities in health outcomes by ensuring that all Filipinos, especially those belonging to the lowest two income quintiles, have equitable access to quality health care.

The three strategic thrusts of UHC are: financial risk protection through expansion in NHIP enrollment and benefit delivery, improved access to quality hospitals and health care facilities and the attainment of health-related millennium development goals (MDGs).

The six strategic instruments to achieve the AHA strategic thrusts are:

1. *Health Financing* – to increase resources for health that will be effectively allocated and utilized to improve the financial protection of the poor and the vulnerable sectors;
2. *Service Delivery* – to transform the health service delivery structure to address variations in health service utilization and health outcomes across socio-economic variables;
3. *Policy, Standards and Regulations* – to ensure equitable access to health services, essential medicines and technologies of assured quality, availability and safety;



4. *Governance for Health* – to establish the mechanisms for efficiency, transparency and accountability and prevent opportunities for fraud;
5. *Human Resources for Health* – to ensure that all Filipinos have access to professional health care providers capable of meeting their health needs at the appropriate level of care; and
6. *Health Information* – to establish a modern information system that shall:
  - a. Provide evidence for policy and program development, and
  - b. Support for immediate and efficient provision of health care and management of province-wide health systems

The implementation of the UHC will be facilitated by the DOH that shall engage local health systems (provinces and their component LGUs, cities, private and public health care providers, local partners, and families) through the formation of regional clusters based on their catchment areas.



### *Review Questions*

Answer the following questions:

1. What are the major functions of the DOH?
2. What are the six (6) strategic instruments to achieve UHC or KP?
3. Which government arm serves as the link between national and local governments?
4. Draw the organizational structure of the public health care system.
5. Give the four (4) sources of health financing.



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# **Principles of Drug Management**



### *Learning Objectives:*

At the end of the session, the learner should be able to:

1. Discuss the importance of managing medicines;
2. Describe the various aspects of the pharmaceutical supply chain and management cycle; and
3. Identify gaps and weaknesses in the different aspects of the drug management cycle.

### *Introduction*

Medicines, in general, are used for the diagnosis, prevention, mitigation or treatment of a disease and are an integral part of a nation's health care delivery system. They account for a significant percentage of the entire expenditure for health. In contrast with other modes of therapeutic interventions, medicines rank high among the expenses paid for by health institutions. The expenditure on medicines is also shouldered by the government, third party payers, and out-of-pocket by patients themselves.

### *The Philippine Pharmaceutical Supply Chain*

The provision of medicines, on a national level, differs from country to country. The *pharmaceutical supply chain* generally describes the process from sourcing raw materials and drug products to medicine use by individual patients. It involves several stakeholders – suppliers of raw materials, exporters of finished drug products, importers of both raw materials and finished



products, manufacturers (local, multinational), distributors (importers, traders including repackaging companies, wholesalers), funders (government, private institutions, third party payers – government health insurance, health maintenance organizations), pharmacies and other drug outlets, and lastly, the patients and consumers. An illustration of the typical pharmaceutical supply chain in the Philippines is provided in Figure 2.1.

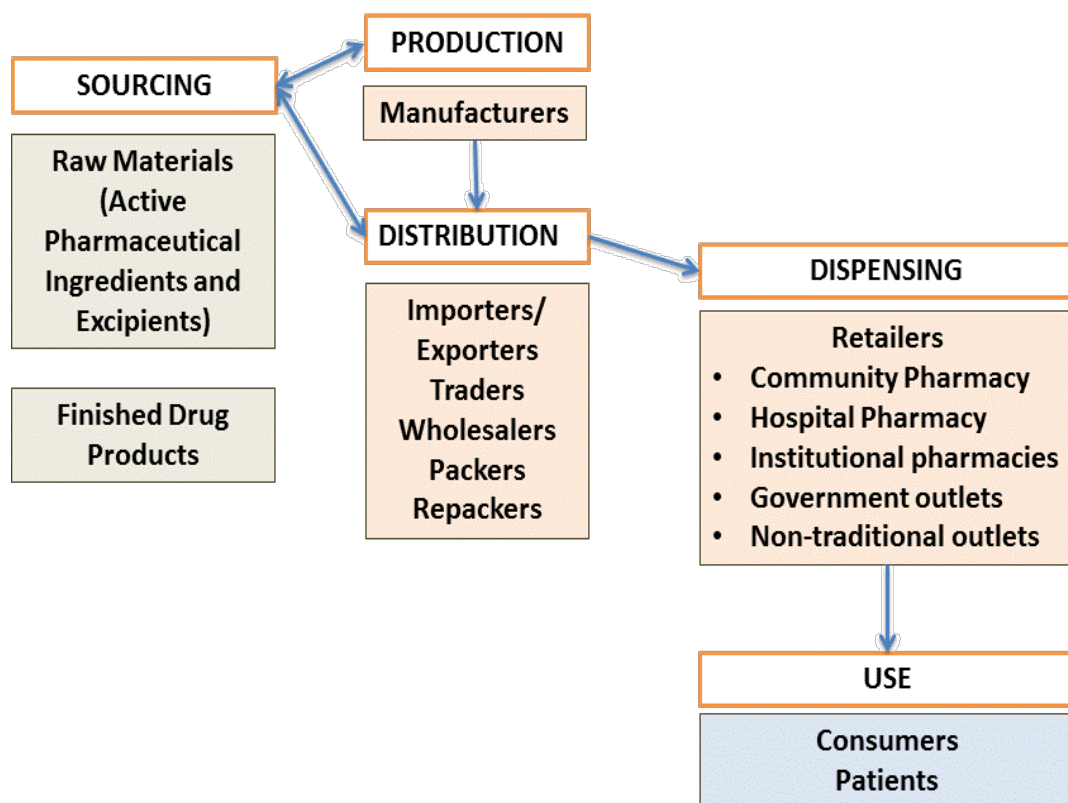


Figure 2.1. The Philippine pharmaceutical supply chain



The sourcing of raw materials may be in the form of importation or local production, based on the country's capability and resources. Raw materials in the form of active pharmaceutical ingredients (APIs) and excipients are needed for local production of finished products. Drug manufacturers and traders may also act as importers of finished products for domestic distribution.

The distribution chain is a massive network of importers, traders, repackaging companies, and wholesalers which serves as suppliers of medicines to the retailers. Most of the wholesalers are located in the National Capital Region. Others are found in major cities, such as Cebu City and Davao City.

Retailers for drug products can be classified as:

- Community pharmacies (large- and medium-chain, single proprietors, generic drug pharmacies)
- Hospital pharmacies (public – regional, provincial, district, private)
- Government health facilities (rural health units, barangay health stations)
- Other institutional pharmacies (government offices, private companies)
- Retail Outlets for Non-Prescription Drugs (RONPD)



Currently, the largest community pharmacy chain provides more than 60% of the country's medicine supply with the remaining shared by regional chain pharmacies and other outlets. The enactment of RA 9502 (Universally Accessible Cheaper and Quality Medicines Act) in 2008 expanded the retail drug industry with the establishment of pharmacies solely for generic products as well as non-traditional outlets for over-the-counter (OTC, non-prescription) medicines. Public and private hospital pharmacies make available the medicines needed in the hospital setting. The government provides medicines through rural health centers, primary care units, secondary hospitals and tertiary hospitals. Private hospitals are also classified under three categories, Levels 1-3, based on the range of services that they are allowed to provide.

An emerging outlet for pharmaceutical products, which before was either unregistered or registered as community pharmacy with the Philippine Food and Drug Administration (FDA), is the institutional pharmacy. This is a pharmacy within a company which provides medical benefits to its employees and their dependents. Medicines prescribed by company doctors are provided free or subsidized, based on company policy. RONPDs include the community drug outlet or Botika ng Barangay (BnB) and its variants. Some of these outlets are owned by cooperatives, barangay councils, or similar local groups. Currently, there is a moratorium in granting special permits to operate BnBs. Other RONPDs are the local and convenience stores.



While many of retailers purchase their products through large distributors, there are distributors who directly import finished products from countries like India, China, Pakistan, and Bangladesh. The government agency, Philippine International Trading Corporation (PITC), led the parallel importation of medicines in early 2000s to supply medicines for the pharmaceutical access program of the government – BnB and Botika ng Bayan. Many generic and innovator products are sourced from India, Pakistan, China and some local manufacturers. Lately, PITC has also sourced products from multinational and local companies as this has become more cost-effective over the years.

### *Regulation of the Medicine Supply*

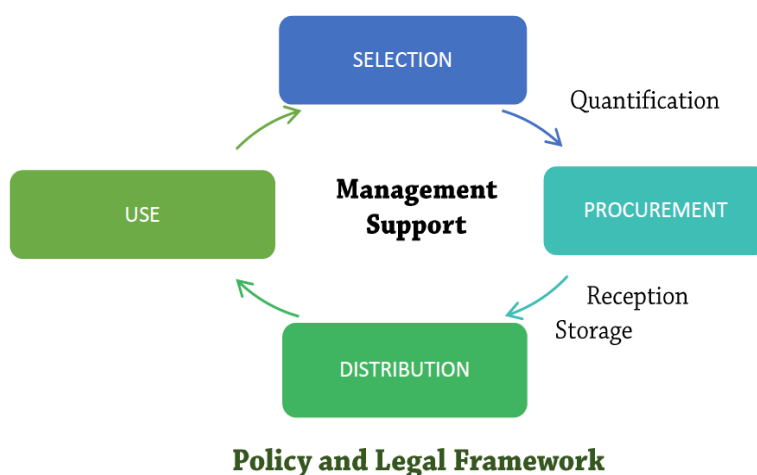
The regulation of medicine supply in the country falls under the jurisdiction of the DOH, in particular, the FDA. Based on its mandate, this agency is responsible for the quality and safety of drug products in the Philippine market. The FDA regulates drug establishments, retail outlets, and drug products. Drug establishments and retailers are issued the appropriate License to Operate (LTO) upon compliance with FDA requirements and similarly, drug products are registered and provided certificate of product registration (CPRs) after complying with specific requirements.



In addition to FDA's requirements, each establishment must comply with business requirements imposed by the Department of Trade and Industry (DTI) and the local government where an establishment is located. The list of FDA requirements and application documents are found at their website, <http://www.fda.gov.ph>.

### *Drug Management Cycle*

Drug management cycle, medicine management cycle, and pharmaceutical management system, are terms interchangeably used to describe the process or cycle by which the provision of medicines is managed by the government as a provider of medicines to its population or to a lesser degree, an institution providing medicines to its patients, such as a hospital. The drug management cycle is composed of four main phases or components, namely, selection, procurement, distribution, and use of medicines (Figure 2.2).



**Figure 2.2. The drug management cycle**

Source: Managing Access to Medicines and Health Technologies, 2012



The Philippine government is responsible for providing the policy and legal framework necessary to ensure the systematic supply of medicines in the country. Part of that mandate is to enact a national medicines policy. In the last 25 years, several laws were legislated as part of the Philippine National Drug Policy (PNDP). The PNDP is the government's initiative in 1988 to address the problem of inadequate provision of good quality essential medicines to the people. It stands on five pillars which are expected to improve the availability and affordability of safe, effective, and good quality drugs for all sectors of the country, especially the majority of the Filipinos who are able to afford them. The five pillars were:

- People empowerment
- Quality of drug
- Rational use of drugs
- Self-reliance
- Tailored procurement

The Generics Act of 1988 (RA 6675) is a law which promotes, requires and ensures the production of an adequate supply, distribution, use and acceptance of drugs and medicines identified by their generic names.



In 2001, as part of the mission to increase access to essential medicines, the Pharma-50 Unit of the DOH was established. It managed the creation of the village drug outlets called BnBs all over the country. Parallel importation was also started by the government to ensure availability of medicines at the BnB level. In 2008, RA 9502, was enacted allowing the government to regulate drug prices and use TRIPS flexibilities for medicines under patent to address public health concerns. From the ad-hoc Pharma-50 Unit, the DOH National Center for Pharmaceutical Access and Management (NCPAM) was established on January 8, 2010 to operationalize, strategize and implement the national medicines policy and the provisions of RA 9502.

Under NCPAM, the PQIRST pillars of the PNDP were expanded in the acronym, SARAHS which covers the following aspects:

- Safety, efficacy and quality
- Availability and affordability
- Rational use of medicines
- Accountability, transparency and good governance
- Health systems support





**POINTS FOR EMPHASIS**

- The pharmaceutical supply chain in any country is a network of various stakeholders with roles in sourcing raw materials and finished products, production, distribution, dispensing, and use.
- The main regulatory body which controls the availability, quality and safety of drugs in the country is the DOH – FDA.
- The drug management cycle is composed of four (4) major components or phases which include selection, procurement, distribution and use.



**Review Questions**

Match the stakeholders (A) with their expected functions in the pharmaceutical supply chain (B) by drawing a line to connect them.

A	B
1. Consumers and patients	A. Sourcing of active ingredients and excipients from other countries
2. Traders	B. Dispenser of non-prescription drugs
3. Importers	C. Production of medicines
4. Retail outlets for OTC products	D. Sells drug ingredients to other countries
5. Manufacturers	E. Users of medicines
	F. Distribution of medicines



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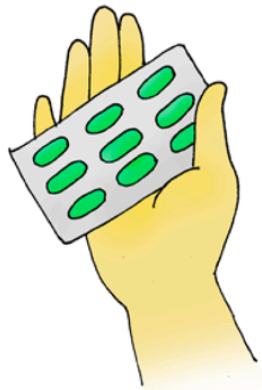


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# Selection of Medicines





### *Learning objectives:*

At the end of the session, the learner should be able to:

1. Describe the selection process of medicines at the national and local government levels;
2. Identify gaps and weaknesses in the selection of medicines in the health care system; and
3. Propose ways on how to address gaps and weaknesses in the selection of medicines.

### *Introduction*

The selection of medicines to address the health needs of a country's population must be based on a sound national medicines policy that includes the Essential Medicines List (EML). WHO defines essential medicines as those medicines which satisfy the priority health care needs of the population and should be available at all times. The *essential medicines* concept (then known as the *essential drugs* concept) was defined in 1975, and followed up in 1977, with the first WHO Model List of Essential Medicines. The Model List has formed a key component of the information required by countries, in relation to their medicine procurement and supply programmes. The WHO Model List of Essential Medicines is a useful reference, derived from the consensus of recognized international experts and updated every two to four years. The medicines that appear on this list are recognized as safe, efficacious and cost effective.



Careful selection of medicines to be included in a national EML should be based on quality, safety, affordability and efficacy criteria. The use of EML will ensure higher quality of care, better management of medicines, more cost-effective use of available health resources, and better inventory management. With the country's limited financial resources and the rising costs of medicines, judicious selection of medicines should be carried out appropriately and efficiently.

### *The Philippine National Formulary*

The Philippines is one country with a national medicines policy (PNDP) that includes the use of an EML, the Philippine National Formulary (PNF) formerly known as the Philippine National Drug Formulary (PNDF).

The PNF is a major strategy in the promotion of rational use of medicines, by assuring the availability and accessibility of essential medicines of proven efficacy, safety and quality at affordable cost in the country.





By virtue of EO No. 49 s. 1993 and the RA 7875, it was officially adopted as the basis for procurement of drug products within the entire DOH and the basis for drug reimbursement of PhilHealth for its confined beneficiaries in hospitals. The selection of medicines for the PNF considers, among others, the following important points:

- Relevance to disease which is indicated in the treatment of prevalent diseases;
- Efficacy and safety based on pharmacologic studies;
- Quality control standards;
- Cost of treatment regimen;
- Appropriateness to the capability of health workers at the different levels of health care;
- Local health problems; and
- Most favorable benefit/risk ratio.

At the national level, the Formulary Executive Committee (FEC) under the NCPAM is responsible for the PNF revision and updating. The FEC is a multidisciplinary committee composed of medical specialists, epidemiologists, pharmacologists, and pharmacists. It reviews all applications submitted for inclusion in or deletion from the PNF, and makes appropriate recommendations to the Secretary of Health who will make the final approval or disapproval. The approved medicines in the latest formulary in its downloadable form is made available to the public through the DOH website.



The use of the PNF is mandatory among government hospitals and health facilities in the procurement of medicines under RA 9184. It is expected to improve supply of medicines, promote rational prescribing and lower the cost of treatment. The group responsible for the development of the hospital formulary at the hospital level is the Drug and Therapeutics Committee (DTC) or the Pharmacy and Therapeutics Committee (PTC).

### *The Drug and Therapeutics Committee*

Selection of medicines for procurement in private hospitals is assumed by their respective DTCs, composed of representatives from the medical staff, pharmacy, nursing and hospital administration. The number of drugs, extent of function of the committee and process of selection vary from hospital to hospital. The list of selected medicines is embodied in the hospital formulary which serves as guide for rational prescribing, procurement, and use. The common principle for drug selection is Safety, Affordability, Necessity, and Efficacy (SANE). With the shift towards evidence-based practice, some hospitals include evidence-based drug evaluation as a function of the DTC. In addition to the PNF, government hospital and local health facilities also develop their own hospital formularies to focus on medicines that are needed locally based on epidemiologic data.



WHO provides a comprehensive guide in the setting up of the DTCs in hospitals and other health care facilities, with the goals and objectives provided in Box 3.1.

**Box 3.1. Goals and Objectives of DTC**

- Develop and implement an efficient and cost-effective formulary system which includes consistent standard treatment protocols, a formulary list and formulary manual
- Ensure that only efficacious, safe, cost-effective and good quality medicines are used
- Ensure the best possible drug safety through monitoring, evaluating and thereby preventing, as far as possible, adverse drug reactions (ADRs) and medication errors
- Develop and implement interventions to improve medicine use by prescribers, dispensers and patients

Source: Drug and Therapeutics Committee – A Practical Guide, 2013

The DTC also performs the following functions:

- Serves as advisory staff to medicine, administration, and pharmacy
- Develops drug policies on:
  - Criteria for inclusion of medicines on the hospital formulary
  - Periodic use of medicines not on the formulary list
  - Drugs that are under investigation for safety or efficacy
  - Generic substitution and therapeutic interchange
  - Drug representatives and promotional literature



- Evaluates and selects medicines for the formulary list
- Develops standard treatment guidelines
- Assesses medicine use to identify problems
- Conducts effective interventions to improve medicine use
- Manages adverse drug reactions
- Manages medication errors
- Disseminates information as part of transparency

The DTC plays a very important role in the drug management cycle by providing support and coordination with those involved in the procurement and distribution of medicines in the hospital. This role will ensure safe and rational use of medicines in coordination with the clinical staff, pharmacy and hospital administrators. The absence of an active DTC is an identified contributory factor in the problems enumerated in Box 3.2.

**Box 3.2. Problems associated with the absence of a functional DTC**

- Irrational prescribing
- Problematic procurement
- Unpredictable stocking
- Entry of ineffective medicines including counterfeits
- Waste of the hospital's resources due to overstocking of some drugs

Source: Drug and Therapeutics Committee – A Practical Guide, 2013



**POINTS FOR EMPHASIS**

- In selecting medicines for procurement, the roles and functions of the FEC at the national level and the DTC at the hospitals and health facilities are essential.
- The formulary system serves to guide the selection, procurement and use of medicines in all levels of the health care system.
- Standard treatment guidelines should rationalize the prescribing and use of medicines in any health facility.
- The absence of a functioning DTC in a hospital has a negative impact on prescribing, procurement, and the assurance of effective medicines.
- Rational selection of medicines is necessary for rational procurement and use to take place.



### *Review Questions*

Answer the following questions:

1. What are the advantages of using an EML or a formulary?
2. Which group is responsible for the revision of the Philippine National Formulary?
3. Give three (3) goals or objectives of the DTC.
4. Give three (3) problems resulting from inactive DTC.
5. What is the composition of the Drug and Therapeutics Committee?



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# **Procurement of Medicines**



### *Learning Objectives:*

At the end of the session, the learner should be able to:

1. Describe the procurement processes of the government health care system; and
2. Identify possible actions to address identified gaps and weaknesses in the procurement of medicines.

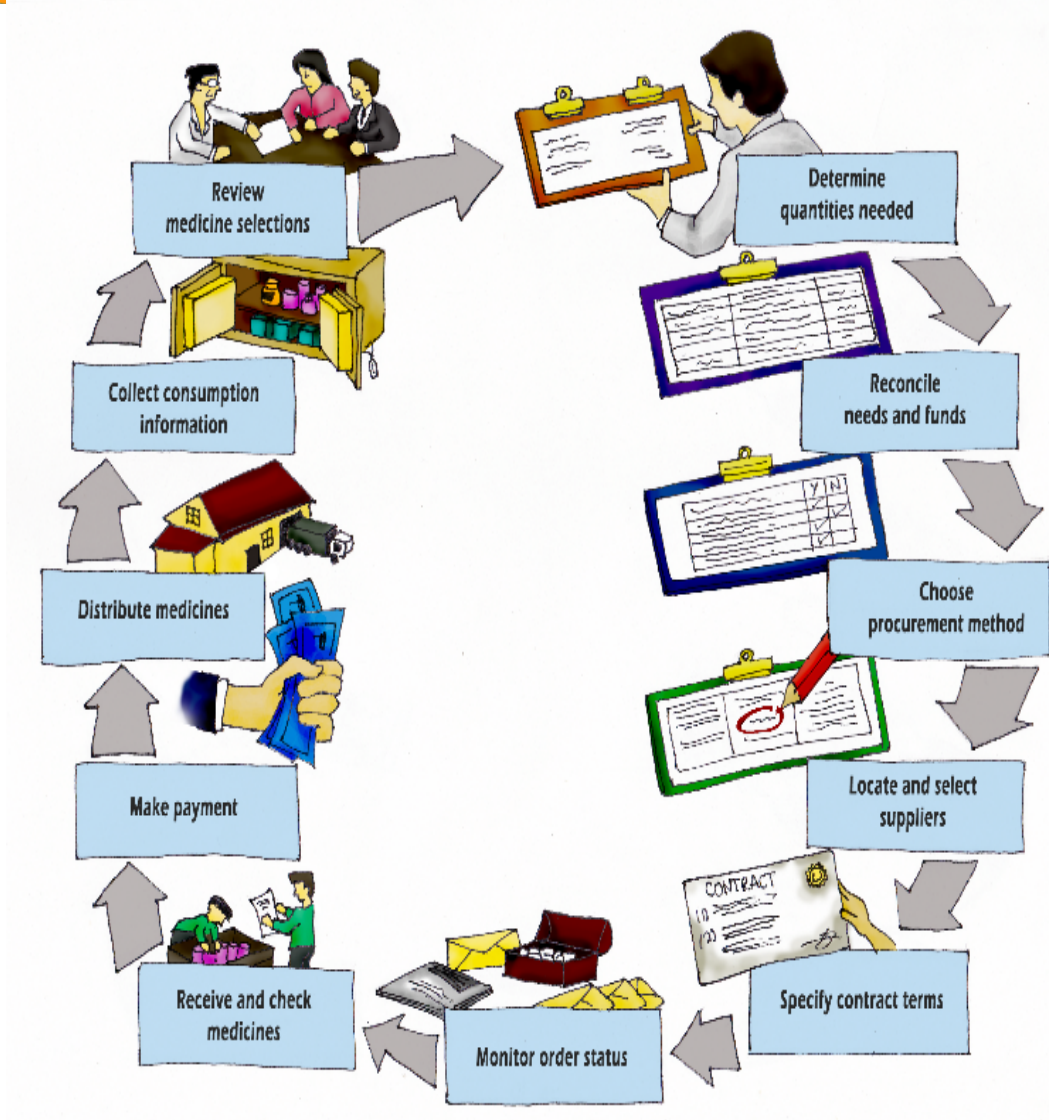
### *Introduction*

The United States Pharmacopeia (USP), as part of its drug quality and information program, stated that, “An effective and efficient procurement system is designed to obtain the correct medicines and products of good quality, at the right time, in the required quantities, and at favorable costs.” To achieve these, a procurement unit should work closely with other personnel in the drug management cycle – supplier, distributor and customer. The four components required of a procurement system include:

- Financial resources,
- Human resources,
- Operational resources, and
- System resources

Figure 4.1 shows the procurement process.





**Figure 4.1. Medicine procurement process**

Source: Managing Access to Medicines and Health Technologies, 2012

### **Good Procurement Practices**

The *Good Procurement Practices* presented in Table 4.1 for pharmaceuticals summarizes the key principles for appropriate drug procurement by various sectors – individual procurement agencies to pooled procurement system serving multiple health systems.



Table 4.1. Good procurement practices

<p><b><i>Reliable payment and good financial management</i></b></p> <ul style="list-style-type: none"> <li>• Develop mechanisms for prompt reliable payment</li> <li>• Establish financial mechanisms with separate pharmaceutical accounts (revolving drug fund)</li> </ul>	<p><b><i>Order quantities based on reliable estimate of actual needs</i></b></p> <ul style="list-style-type: none"> <li>• Develop reliable consumption records and morbidity data</li> <li>• Adjust systematically for past surpluses, shortages, stockouts</li> <li>• Adjust for expected program growth and changing disease patterns</li> </ul>
<p><b><i>Procurement by generic name</i></b></p> <ul style="list-style-type: none"> <li>• Use generic names for fair competition</li> <li>• Specify quality standards, not specific brands, for medicines with bioavailability problems</li> </ul>	<p><b><i>Transparency and written procedures</i></b></p> <ul style="list-style-type: none"> <li>• Develop and follow written procedures for all procurement actions</li> <li>• Make information on the tender process and results public to the maximum extent possible</li> </ul>
<p><b><i>Procurement limited to essential medicines list or formulary list</i></b></p> <ul style="list-style-type: none"> <li>• Select safe, effective and cost-effective medicines</li> </ul>	<p><b><i>Separation of key functions</i></b></p> <ul style="list-style-type: none"> <li>• Separate key functions that require different expertise</li> </ul>

Source: Managing Access to Medicines and Health Technologies, 2012



Table 4.1. Good procurement practices (cont.)

<ul style="list-style-type: none"> <li>• Use formal approval procedures for procurement of nonlisted medicines</li> </ul>	<ul style="list-style-type: none"> <li>• Functions that involve different committees, units or individuals may include selection, quantification, approval of suppliers, and awards of contracts</li> </ul>
<p><b><i>Procurement in large volume</i></b></p> <ul style="list-style-type: none"> <li>• Content purchases on a limited list to increase quantities, reduce price</li> <li>• Specify divided deliveries</li> </ul>	<p><b><i>Product quality assurance program</i></b></p> <ul style="list-style-type: none"> <li>• Establish and maintain a formal system for product quality assurance</li> <li>• Include quality assurance product certification, inspection of shipment, targeted laboratory testing, and reporting of suspected products</li> </ul>
<p><b><i>Formal supplier qualification and monitoring</i></b></p> <ul style="list-style-type: none"> <li>• Use formal supplier qualification, based on pharmaceutical quality, service reliability and financial viability</li> </ul>	<p><b><i>Annual financial audit with published results</i></b></p> <ul style="list-style-type: none"> <li>• Conduct an annual financial audit to assess compliance with procurement procedures, promptness of payment, and related factors</li> </ul>

Source: Managing Access to Medicines and Health Technologies, 2012



Table 4.1. Good procurement practices (cont.)

<ul style="list-style-type: none"> <li>• Approve suppliers before tendering (prequalification) or after (postqualification)</li> <li>• Use a formal monitoring system to ensure continued supplier qualification</li> </ul>	<ul style="list-style-type: none"> <li>• Present results to the appropriate public supervising body</li> </ul>
<p><b><i>Competitive procurement</i></b></p> <ul style="list-style-type: none"> <li>• Use competitive bidding on all purchases but very small or emergency purchases to obtain the best prices</li> <li>• Allow only prequalified suppliers to compete in restrictive bidding</li> <li>• Evaluate suppliers after submission of bids in open tender</li> </ul>	<p><b><i>Regular reporting on procurement performance</i></b></p> <ul style="list-style-type: none"> <li>• Report key performance indicators against targets at least annually</li> <li>• Use key indicators such as ratio of prices to world market prices, supplier lead times, percentages of purchases made through competitive tendering, and planned versus actual purchases</li> </ul>
<p><b><i>Monopsony commitment</i></b></p> <ul style="list-style-type: none"> <li>• Procure all contracted pharmaceuticals from winning supplier</li> <li>• Do not enter into separate deals with non-contracted suppliers</li> </ul>	

Source: Managing Access to Medicines and Health Technologies, 2012



### *The Government Procurement Process*

The procurement of medicines in many countries is carried out by the government and private entities using a variety of methods. Given the volume and cost of medicines, the process tends to be chaotic and corrupted unless a proper system is in place. In the Philippines, procurement of medicines is governed by the Government Procurement Reform Act (RA 9184, s. 2002). This law provides the different procurement methods that the government may use in the purchase of goods and services, which will allow transparency, competition among suppliers and cost-effectiveness.

For procurement of medicines, the method used is competitive bidding. In bidding, the Bids and Awards Committee (BAC) prepares the documents for bidding and make them available to interested prospective bidders. The steps in the bidding process are provided in RA 9184, namely:

- Pre-procurement Conference
- Advertising and Invitation to Bid
- Pre-bid Conference
- Receipt and Opening of Bids
- Bid Evaluation
- Post-qualification
- Awarding of the contract



While the procurement law of the Philippines defines the process for procurement of goods and services as well as consultancies, the quality of drugs, as a component of the bidding process is mainly based on the supplier's License to Operate (LTO) and Certificate of Product Registration (CPR) from the FDA. The certificate of cGMP compliance is another proof of the quality of the products manufactured.

The procurement process for medicines in private hospitals differs from institution to institution. The utilization of a hospital formulary, adherence to standard treatment guidelines, and having an active DTC do help in rationalizing procurement and in selecting worthy suppliers of medicines.

### *Procurement Methods*

The primary method of procurement in a government facility as stipulated in RA 9184, is Competitive or Public Bidding. This procurement method is open to any interested and qualified party. Other methods of procurement may be employed whenever justified by the conditions stipulated in the policy and as recommended by the Bids and Awards Committee (BAC). These alternative methods include:

- Limited Source Bidding
- Direct Contracting
- Repeat Order
- Shopping
- Negotiated Procurement



USP however suggests that the preferred method for procuring medicines is Limited Source Bidding. Limited source bidding involves a pre-qualification process where a supplier's technical capacity, financial capability and reputation are evaluated before the invitation to bid is released. Only pre-qualified suppliers receive the invitation.

### *Receipt of Medicines*

Upon delivery of suppliers to the health facility, the medicines are inspected and checked against the specifications listed in the Purchase Order. The following must be checked:

- Actual quantity versus quantity indicated on the requisition/delivery form;
- Unopened and in good condition original container (e.g., boxes, tins, bottles);
- Labels, expiry dates, dosage forms, dosage strengths indicated on the products versus specifications;
- Physical condition such as appearance, color, volume, etc.; and
- Clarity for liquid products.

If there are discrepancies in the deliveries and specifications, these should be properly documented and deliveries should not be accepted.





### *Supplier Performance*

Monitoring of supplier performance and product quality is an important step to make sure that the medicines procured produce their expected effects in patients. This step requires coordination of procurement group with the health care team. The latter, through the DTC, should provide a regular report of medicines with problematic outcomes at the clinical setting. The report will serve as guide to the procurement group to limit repeat purchases to those medicines which have good clinical outcomes. It should be submitted to the regulatory agency as part of its pharmacovigilance program. On the other hand, the procurement should also have a system for tracking a supplier's performance on the basis of the following data:

- Lead time;
- Compliance with pricing terms;
- Partial shipments;
- Compliance with remaining shelf life requirements;
- Compliance with packaging and labeling instructions;
- Compliance with technical specifications;
- Compliance with contract terms; and
- Summary of outcomes of performed inspections.



**POINTS FOR EMPHASIS**

- The procurement of medicines is governed by the Procurement Act, RA 9184 at all levels of the public health care system.
- There are different methods of procurement based on the nature and volume of medicines to be purchased.
- There are important steps to follow in the procurement process to which every procurement officer should adhere to.



*Review Questions*

Answer the following questions:

1. Which law governs the procurement of government including medicines?
2. Give the seven (7) steps in the government's public bidding process.
3. What are the four (4) components of the procurement system?
4. What is the monopsony commitment mentioned in Good Procurement Practices?
5. What is the USP-recommended method of procurement for medicines?



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# Storage and Distribution of Medicines





***Learning Objectives:***

At the end of the session, the learner should be able to:

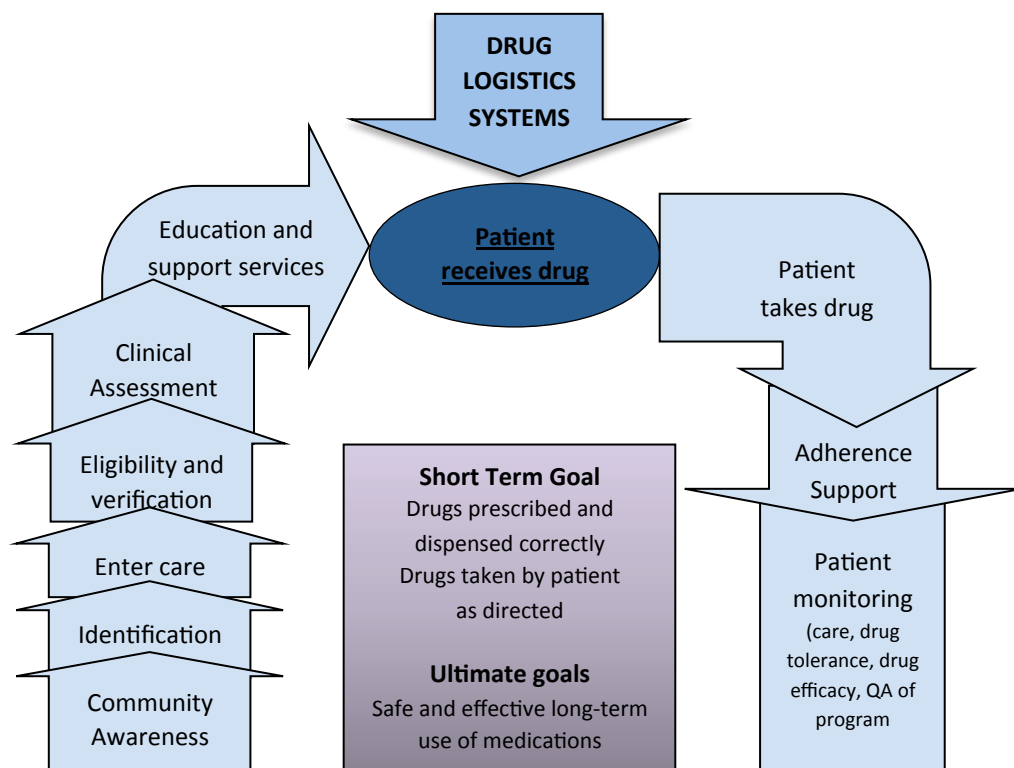
1. Discuss the good distribution and storage practices for medicines;
2. Identify management control measures and guidelines to address gaps and weakness in the distribution of medicines; and
3. Propose ways of monitoring the status of medicines distribution and storage at all levels of the public health care system.

***Introduction***

The objective of the supply chain management is to ensure that right quantities of the right medicines reach the target population in a timely and appropriate manner (Figure 5.1). In addition to that, an effective distribution system should also be able to achieve the following:

- Constant supply
- Maintenance of quality of medicines
- Minimal loss or pilferage
- Accurate and timely inventory and transaction information
- Proper storage
- Efficient transport and delivery
- Adequate geographic coverage





**Figure 5.1. The goal of supply chain management of medicines**

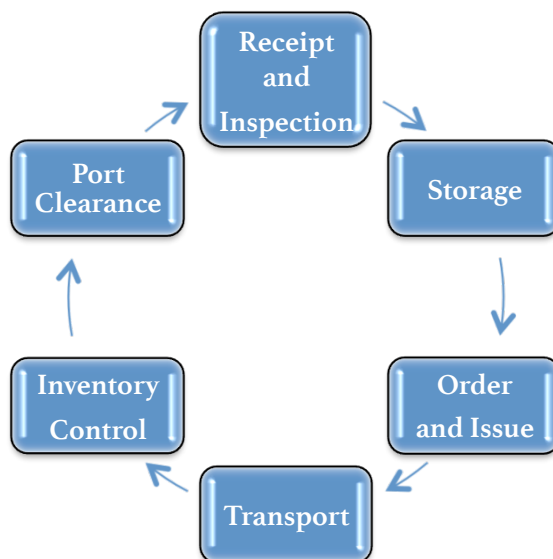
Source: World Bank Training Program: Managing Procurement and Logistics of HIV/AIDS Drugs and Related Supplies, 2005

### *The Distribution System*

For a distribution system to work, specific elements and their respective procedures, as provided in Figure 5.2, have to be present.

Medicines have to undergo inspection upon receipt at the port of entry and stored properly in the warehouse based on good storage practice. When orders are made for specific drug products by the hospitals and other health facilities, they are prepared, packed and transported to the procuring entity. Upon receipt by the latter, the products become part of the inventory.





**Figure 5.2. Essential elements of the distribution system**

Source: The Drug Management Cycle – Distribution, 1999

There are minimum standards to be followed in this distribution system. The USP Convention in 2007 provided a list of the important aspects to be considered in the storage and distribution practices as provided in the table below (Table 5.1).





**Table 5.1. Minimum quality assurance for distribution and storage practices**

<b>Receive Incoming Goods</b>	<ol style="list-style-type: none"> <li>1. Follow Standard Operating Procedure (SOP) for receiving goods, including checking for completeness, accuracy, and validity of documents.</li> <li>2. Quarantine.</li> <li>3. Perform visual/physical inspection for name of drug, strength, dosage form, quantity, labeling and packaging.</li> <li>4. Take suspected or random samples to laboratory for testing.</li> </ol>
<b>Storage</b>	<ol style="list-style-type: none"> <li>1. Follow SOP for good storage practice.</li> <li>2. Check temperature, humidity and light.</li> <li>3. Place each drug in its designated space.</li> <li>4. Update stock card or product register.</li> </ol>
<b>Dispatch / Delivery</b>	<ol style="list-style-type: none"> <li>1. Follow SOP for dispatching goods, including checking for completeness, accuracy, and validity of documents.</li> <li>2. Perform visual inspections for name of drug, strength, dosage form, quantity, labeling and packaging.</li> </ol>
<b>Transportation</b>	<ol style="list-style-type: none"> <li>1. Follow SOP for dispatching goods, including checking for completeness, accuracy, and validity of documents.</li> <li>2. Pay attention to the mode of transport, transport conditions (e.g., temperature, humidity), and transport duration.</li> <li>3. Pay attention to products requiring low temperature.</li> </ol>

Source: Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide, 2007



### *Good Distribution Practices*

Box 5.1 summarizes key points of good distribution practices.

#### **Box 5.1. Key points of distribution practices**

- Clear products rapidly through customs to avoid storage deterioration and fees.
- Inspect medicines for quality and quantity before distribution.
- Maintain proper storage conditions (temperature, humidity, etc.) during transport.
- Verify and document delivery orders.
- Check the integrity of packaging when medicines arrive.
- Clearly label containers.
- Maintain delivery records.
- Provide easy access to delivery records.

Source: Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide, 2007

### *Measures to Take for Rapid Customs Clearance*

The time spent in the port of entry usually determines the timeliness of delivery to areas where medicines are needed, especially during disasters. It is important to ensure that proper documentation and requirements be complied with to clear products out of customs for immediate release of goods.



Below are some tips on how the process of customs clearance could be expedited:

- Designate an experienced staff person in port clearance to be responsible for custom clearance activities and processes;
- Establish a written protocol for customs clearance and make sure it is followed;
- Communicate frequently with the supplier/consigner to provide all necessary documents as required by the national and local regulations on custom clearance (e.g., packing lists, airway bills, and pro-forma invoices) as soon as they are available;
- Communicate frequently with the supplier/consigner and the port authorities (customs) enquiring about the status of the shipment, (e.g., expected arrival dates and time, mode of transport, etc.);
- Collect and prepare all required documents with necessary signatures and stamps before physically going to the port;
- Coordinate with all relevant authorities and with the customs officer, making an appointment in advance, if applicable, to inspect the shipment; and
- Make every effort to ensure that the customs clearance takes less than two (2) weeks.



### *Receipt of Incoming Materials and Pharmaceutical Products*

Upon receipt of pharmaceutical products, the following must be performed/ checked:

- Goods should match the appropriate purchase order and each container should be labeled with batch number, type of material or pharmaceutical product, and quantity.
- Container uniformity should be checked and subdivided according to the supplier's batch number, should the delivery comprise more than one batch.
- Each container should be inspected for contamination, tampering, and damage. Suspect containers should be quarantined for further investigation. The quarantine should remain in effect — in a separate area — until an authorized release or rejection is obtained.

### *Transport*

The mode and duration of transportation, as well as the destination, must be taken into account to ensure the integrity of the medicines in transit. The two primary factors to consider are temperature and humidity, which need to be continually monitored and recorded. Extra attention should be paid to transporting products requiring low-temperature storage, taking environmental and seasonal changes into consideration.



Small-volume deliveries that require a short transit time (less than three hours) can be adequately protected by insulated packaging, without cooling elements. Larger deliveries requiring longer transit time should be transported in proper cooling environments. When using dry ice (solid carbon dioxide), measures must be taken to make sure the ice does not directly contact the products, as extremely cold temperature might affect the integrity of the product. Cold chain management is essential for biologicals and other high temperature-sensitive products. The duration of transport should determine the quantity of ice gels or other coolants to maintain the required low temperature throughout the period of transport.

### *Good Storage Practices*

Good storage practices do not only involve the provision of adequate space for storing drug products. Part of it is the establishment of clear SOPs which the personnel could easily follow in receiving, labelling, inventory and security. Box 5.2 summarizes key points of good storage practices.





**Box 5.2. Key points of good storage practices**

- Limit access to storage areas to authorized personnel.
- Ensure proper storage conditions (temperature, humidity, and lighting).
- Organize and clearly label storage areas.
- Label clearly an expiry date on all containers.
- Arrange products following First Expiry/First Out (FEFO) and First In/First Out (FIFO) principles.
- Perform regular inventories of pharmaceutical materials and products.
- Maintain records of all materials in storage and update regularly.

Source: Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide, 2007





### *Safety and Security*

- Only authorized personnel with proper identification should have access to locked storage areas.
- Each storage site should have an adequate number of qualified and certified personnel to perform quality assurance functions.
- Security protocols for entering storage areas should involve at least two levels of clearance to minimize the likelihood of unauthorized entrance (e.g., multiple locks controlled by multiple staff members).
- Storage areas need to have clearly marked fire exits, and all personnel should be familiar with those locations.
- Smoke detectors should be checked monthly.
- Fire extinguishers and fire alarms should be visible and accessible.
- A personnel should be trained and assigned to administer first aid.





### *Storage Areas*

- When selecting a storage location, the amount of space required, transport accessibility and convenience, and security need to be factored in.
- Storage areas should have adequate lighting, and protection from adverse weather conditions.
- Pharmaceutical products should be stored off the floor and suitably spaced to permit cleaning and inspection.
- The floor and surfaces of storage areas should be covered by tiles or other materials that can be easily cleaned.
- Storage areas should have an adequate number of shelves, clearly labeled, and there must be easy access to products stored on top shelves.
- Storage areas must be well organized and easily accessible, with separate areas for storing different categories of materials and products — packaging materials; raw, intermediate, and finished products; products in quarantine; and released, rejected, returned, or recalled products.
- A sanitation program should be in place to maintain cleanliness of the storage area.





### *Storage Conditions*

The storage conditions and their corresponding temperature requirements are provided in the following table, Table 5.2.

**Table 5.2. Storage conditions and temperature requirements**

Storage Label	Recommended Storage Condition
Store between 15°C and 25°C	Store at normal room temperature
Store between 2°C and 8°C	Refrigerate; do not freeze
Store between 8°C and 15°C	Store in a cool place
Store below 8°C	Refrigerate
Store between -5°C and -20°C	Freeze
Store below -20°C	Deep freeze
Protect from moisture	No more than 60% relative humidity in normal storage condition; to be provided to the patient in a moisture-resistant container
Protect from light	To be stored and provided to the patient in a light- resistant container

Source: Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide, 2007



Storage conditions should be monitored for temperature, if possible, daily, and readings must be recorded. Equipment used for monitoring storage conditions—thermometer and hygrometer—should be calibrated at defined intervals, according to SOP. All necessary precautions should be taken to make sure that the quality and stability of drug products are maintained. This is especially important for products requiring storage at low temperature. Use of commercially available refrigerators designed for medicine products is recommended instead. Temperature can be monitored with a thermometer that has an accuracy rate of  $\pm 0.5^{\circ}\text{C}$ .

In most cases, drug products should be stored under normal storage conditions: dry, well-ventilated premises at temperatures of  $15^{\circ}\text{C}$  to  $25^{\circ}\text{C}$ . If humidity can be controlled, products may be stored up to  $30^{\circ}\text{C}$ . Extraneous odors, other indications of contamination, and intense light must be noted and excluded.

### *Documentation of Records*

Written records of all storage area activities, including the handling of expired materials or products, should be well maintained and easily accessible. These should describe the storage procedures and the distribution history of pharmaceutical products, in case a product must be recalled.



Permanent written or electronic information should exist for each stored material or product. The information should clearly indicate recommended storage conditions, any necessary precautions, and retest dates.

Delivery records, including a description of the products, their quality as described on the label, quantity, name of supplier, supplier batch number, date of receipt, assigned batch number, and expiry date should be kept. These records should be retained for at least the shelf life of the product.

Comprehensive records should be maintained showing all receipts and issues of pharmaceutical products according to a specified system (i.e., by batch number).

Material safety data sheets (MSDS) are information about the product and its safe handling. They can be obtained from most pharmaceutical manufacturers and should be displayed and made clearly visible in storage areas.





### *Labelling and Containers*

Proper containers should be used to store all pharmaceutical products to avoid contamination. All finished medicine products should bear labels that include their dosage form and strength.

All containers should be clearly labelled with at least:

- Name of the material;
- Batch number;
- Arrival or receipt date;
- Expiry or retest date; and
- Specified storage conditions

### *Inventory*

An inventory software program is the most efficient method for controlling inventory management; however, a monthly inventory check can be performed by hand using a simple checklist to compare actual product to product records.





### *Stock Rotation and Control*

Materials and pharmaceutical products should be handled and stored to prevent contamination, mix-ups, and cross-contamination. Stock should be appropriately rotated. The First Expiry/First Out (FEFO) and First In/First Out (FIFO) principles should be followed.

### *Expired, Rejected, and Recalled Drugs*

- All stocks should be checked regularly for expired materials and pharmaceutical products.
- Expired or rejected products should be identified and controlled under a quarantine system.
- Broken or damaged items should be separated and withdrawn immediately from usable stock.
- All returned goods should be destroyed or placed in quarantine, only to be returned to storage after a satisfactory quality re-evaluation.
- Any reissued stock should be identified and recorded in stock records.
- Records of all returned and recalled goods should be maintained.





**POINTS FOR EMPHASIS**

- Good storage and distribution practices should be observed for pharmaceutical products to ensure maintenance of quality and safety.
- Personnel in charge of medicines at all levels of health care should have the proper training in handling specific storage requirements.
- Documentation is important in every aspect of the distribution system for medicines.
- Standard operating procedures should be developed for the various tasks associated with product storage and distribution.



### *Review Questions*

Answer the following questions:

1. What is the primary objective of the drug supply chain management?
2. Give the seven (7) key points of good storage practices.
3. What is FEFO?
4. What is the temperature range required by the storage condition, *freeze*?
5. What five (5) items of information should a label for a pharmaceutical product have?



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# Use of Medicines





***Learning Objectives:***

At the end of the session, the learner should be able to:

1. Describe rational use of medicines;
2. Identify measures to address gaps and weaknesses in the use of medicines; and
3. Discuss ways to promote rational use of medicines at various levels of the health care system.

***Introduction***

Rational use of medicines requires that “patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community”. Since its launch in 1985, the rational use of medicines has become a goal for every country to achieve given the numerous problems and adverse consequences of irrational use.





### *Irrational Use of Medicines*

- Worldwide, it is estimated that half of all medicines are inappropriately prescribed, dispensed or sold, and that half of all patients fail to take their medicine properly.
- An estimated two-thirds of global antibiotic sales occur without any prescription, and studies in Indonesia, Pakistan and India show that over 70% of patients were prescribed antibiotics. The great majority – up to 90% – of injections are estimated to be unnecessary.
- The inappropriate use of medicines is not only widespread, it is costly and extremely harmful both to the individual and the population as a whole.
- Adverse drug events rank among the top 10 causes of death in the USA and are estimated to cost that country between US\$ 30 and US\$ 130 billion each year.
- Growing resistance to antimicrobial medicines is a particularly serious challenge in countries at all economic levels, and results largely from inappropriate prescribing and use. For the treatment of malaria, chloroquine resistance is now established in 81 of the 92 countries in which the disease is endemic.



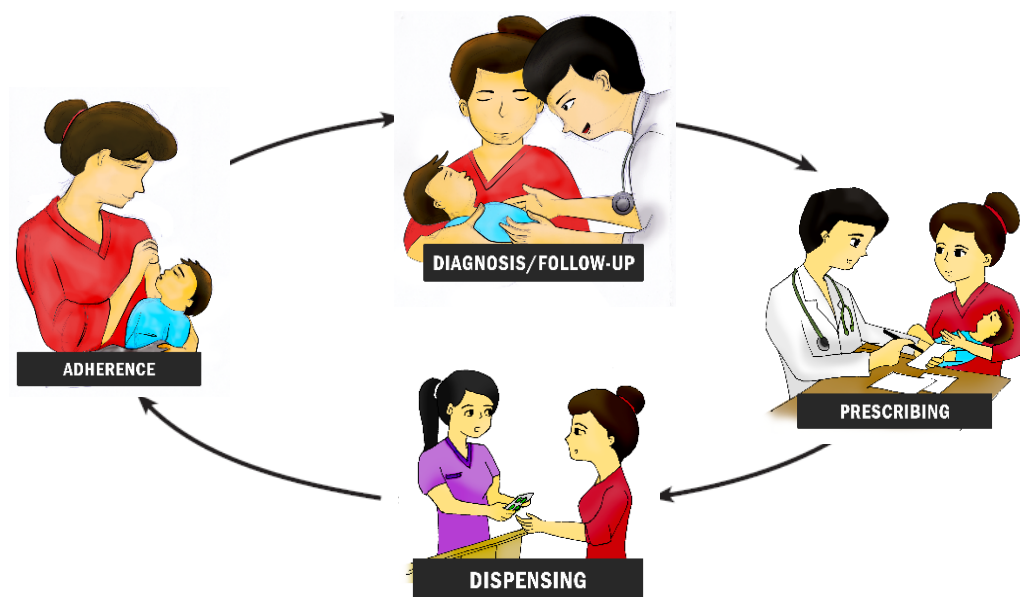
Examples of irrational use of medicines are:

- Too many medicines are prescribed per patient (polypharmacy);
- Injections are used where oral formulations would be more appropriate;
- Antimicrobial medicines are prescribed in inadequate doses or duration;
- Antibiotics are prescribed for non-bacterial infections;
- Prescriptions do not follow clinical guidelines; and
- Patients self-medicate inappropriately or do not adhere to prescribed treatment.

### *Monitoring for Rational Use of Medicines*

The responsibility of rational use is not dependent on the patient alone but includes all health professionals who are part of the drug use process as shown in Figure 6.1. Effective regulation, clear clinical guidance, supportive incentive structures, training, education and management, are key components of an effective policy in this process.





**Figure 6.1. Medicine use process**

Source: Managing Access to Medicines and Health Technologies, 2012

Physicians are responsible for the diagnosis of a patient's condition and subsequent selection of mode of treatment. In most cases, medicines are prescribed. It is expected that prescribers base their choice of drugs on clinical evidence of efficacy and on current standard treatment guidelines. Clinical evidence has been used in the development of the WHO Essential Medicines List, EMLs and formularies of different countries. The use of formulary medicines is a wise measure to ensure rational use while the use of standard treatment guidelines is necessary for the appropriate use of medicines in patients. To address the issue of cost, the availability of generic medicines whose quality has been assured by the regulatory agency like the FDA provides cheaper alternatives.



To determine rational use of medicines in primary health care facilities, there are various indicators developed by WHO/INRUD as reflected in the box.

**Box 6.1. WHO/ INRUD indicators of drug use**

***Prescribing Indicators***

- Average number of medicines prescribed per patient encounter
- Percentage of medicines prescribed by generic name
- Percentage of encounters with an antibiotic prescribed
- Percentage of encounters with an injection prescribed
- Percentage of medicines prescribed from an EML or formulary

***Patient Care Indicators***

- Average consultation time
- Average dispensing time
- Percentage of medicines actually dispensed
- Percentage of medicines adequately labeled
- Percentage of patients with knowledge of correct dose

***Facility Indicators***

- Availability of essential medicines list or formulary to practitioners
- Availability of clinical guidelines
- Percentage of key medicines available

***Complementary Drug Use Indicators***

- Average medicine cost per encounter
- Percentage of prescriptions in accordance with clinical guidelines

Source: Promoting rational use of medicines, 2002



These indicators made clear that dispensing of medicines would also have a bearing on rational use. The indicator on medicines actually dispensed is a measure of the availability and actual quantity of medicines which reached the patients. The indicator which provides data on knowledge of correct dose by patients would show whether health professionals like doctors, pharmacists, and nurses have given advice on proper use of medicines. The instructions on dose, frequency, duration of treatment and indication provided by health professionals may influence adherence to medication regimen, and when followed, actually prevent irrational use of medicines by patients.

Drug utilization data, whether at the health facility or at the national level are valuable since they can:

- Monitor trends in medicines consumption;
- Provide a benchmark for comparison with similar countries or regions;
- Carry out an audit of medicines use against practice guidelines;
- Increase awareness among stakeholders, including governments; and
- Assess the accessibility, quality and cost-effectiveness of care.



A secondary evaluation of indicator by age, category and diagnosis can be very useful in targeting interventions for managing the rational use of medicines. The following indicators may be used:

- Drug use by level of care, and by geographic/district/province level;
- Drug use by age group, diagnosis and drug prescribing; and
- Antimicrobial resistance.

At the national level, it is important to utilize the drug use indicators provided in order to determine what interventions must be implemented to address irrational use of medicines by the health care professionals, health care facilities and the population of the country as a whole. Policies crafted at the national level would be helpful in promoting rational use of medicines in both public and private health care facilities.



### *Strategies to Promote Rational Use*

WHO recommended several interventions to support rational use of medicines at the different levels of the health system. Box 6.2 summarizes these interventions.

#### **Box 6.2. WHO-recommended interventions to support rational use of medicines**

- A mandated multi-disciplinary national body to coordinate medicine use policies
- Clinical guidelines
- Essential medicines list based on treatment choice
- DTC in districts and hospitals
- Problem-based learning in pharmacotherapy in undergraduate curricula
- Continuing in-service medical education as a licensure requirement
- Supervision, audit and feedback
- Independent information on medicines
- Public education about medicines
- Avoidance of perverse financial incentives
- Appropriate and enforced regulation
- Sufficient government expenditure to ensure availability of medicines and staff

Source: Promoting rational use of medicines, 2002



**POINTS FOR EMPHASIS**

- Rational use of medicines is multidisciplinary and will entail responsibility by the regulatory authority, pharmaceutical industry, prescriber, dispenser, other health professionals and the patients.
- Monitoring use of medicines is fundamental to the successful implementation of national medicines policy.
- There are various recommended interventions that can support government's effort to promote rational use of medicines.



### *Review Questions*

Answer the following questions:

1. What is rational use of medicines?
2. What are the five (5) steps in the medication use process?
3. Enumerate the five (5) patient care indicators recommended by WHO/INRUD.
4. What interventions recommended by WHO apply to education of physicians and other health professionals?
5. List five (5) regulatory measures to support rational use.



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## Use of Medicines

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# Pharmaceutical Donations



*Learning Objectives:*

At the end of the session, the learner should be able to:

1. Explain the importance of guidelines on the acceptance of foreign and local donations especially during emergency and disaster situations;
2. Discuss the national policy governing foreign and local donations
3. Identify criteria for accepting donations;
4. Identify current weakness of the existing policy/process in accepting donations at the national level; and
5. Formulate policy recommendations related to pharmaceutical donations.

*Introduction*

The Philippines has consistently suffered from health problems and disruption of health services arising from various forms of disasters. In times of disasters, large quantities of pharmaceuticals from local and international sources are donated thereby partially addressing the medical needs of its recipients. Often however, these donations also cause problems of inadequate storage spaces and disposal. Some pharmaceuticals may arrive past or near expiry, in extremely large or unwanted quantities, labeled in a foreign language or simply unwanted or not needed in a particular area. These problems necessitate clear policies to guide both donors and recipients and hence maximize the potential benefit of drug donations.



### *WHO Guidelines for Accepting Donations*

The WHO had set general guidelines for accepting donations which receiving countries could adopt. The guidelines are as follows:

- Define and prioritize medicine needs.
- Appoint a medicines donation coordinator.
- Describe and develop official documentation required for medicine donations.
- Describe the registration requirements.
- Describe procedures for unacceptable products.

In principle, donated medicines should conform to the same rules and regulations that apply to all medicines entering a country, and there should be no difference whether medicines have been received as donations, purchased on the local market, or procured internationally.

Special consideration should be given to the fact that donated medicines also represent a financial value. The value of a donation should always be represented realistically and correctly. In the case of regular donor aid, the value of a donation might be deducted from the total convened amount of aid, or interest might have to be paid in cases where aid is given as a loan.



### *The Philippine System for Donations during Emergencies and Disasters*

In the Philippines, AO 2007-0017, known as Guidelines on the Acceptance and Processing of Foreign and Local Donations during Emergency and Disaster Situations, provides a rational and systematic procedure for the acceptance, processing and distribution of foreign and local donations that are exclusively for unforeseen, impending, occurring and experienced emergency and disaster situations. It specifies the criteria for accepting donations as well as responsibilities of the different government institutions within the DOH.

AO 2007-0017 states that donations related to health and medicine fall under the jurisdiction of the DOH. The DOH accepts, distributes and monitors movement of the donated items. The criteria for drugs and medicines are as follows:

- Shelf life of at least 12 months from the time of arrival to the Philippines;
- Labeling with English translation understood by health professionals;
- Packaging that complies to international shipping regulations;
- Weight per carton should not exceed 50 kg;
- Exclusive packaging with regard other supplies;
- Documentary proof of compliance to applicable quality standards; and
- Documentary proof that items are obtained from reliable sources.



This policy also states that acceptance of donations shall be based on the expressed need of the beneficiaries and relevant to the diseases pattern and health concerns that are prevailing in the affected area. The DOH Package List for Emergencies and Disasters shall be the basis for determining the acceptability of items for emergencies and disaster situations.

Figure 7.1 shows the channel of distribution of foreign and local donations during disaster. The main office of the DOH in charge of accepting foreign donations is the Bureau of International Health Cooperation (BIHC). All drug donations have to be approved and coordinated with NCPAM based on existing government guidelines on drug donations. Once approved, the foreign donor prepares the medicines for shipment to the Philippines.

Upon arrival at the port of entry, the FDA (as a one-stop shop) performs inspection of the medicines prior to release from the Bureau of Customs (BOC). Once the shipment is cleared, then the medicines are transported either to the Materials and Management Department (MMD) warehouse or direct to regional warehouses under the care of the CHD. The donations are first divided and distributed based on allocation to the affected areas. However, as the effects of the disaster subside, specific needs on the health facilities should supersede the quantities under allocation.



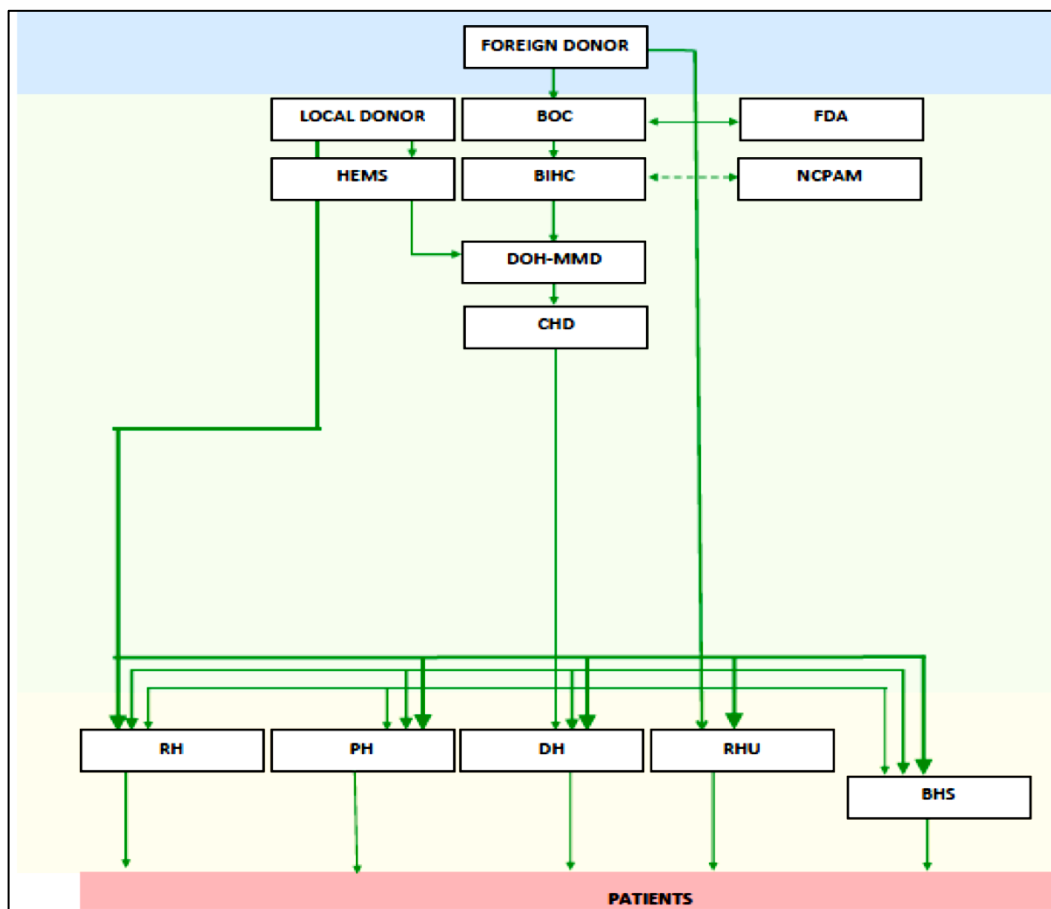


Figure 7.1. The system for accepting donations at the national level

Donations are also accepted at the local government level, in all hospitals and other health facilities. Guidelines on accepting donations should be developed to standardize the donation process.



During emergencies and disasters, other than what AO 2007-0017 requires, the following documents will be required by the embassy of the country of the donor in requesting duty-free certification from the Philippine government for incoming donations from overseas:

- Deed of donation duly authenticated by the Philippines Embassy or Consulate;
- Itemized list of donation (also referred to as packing list or inventory of donated items);
- Proforma invoice or commercial invoice;
- Shipping documents (bill of lading or airway bill);
- Distribution plan for medicines;
- Letter to the DOH-BHIC requesting endorsement to FDA for the issuance of clearance. The letter request should be submitted with the complete list of drugs and quantity to be donated, with the following information:
  - Generic name/brand name
  - Formulation (in English)
  - Dosage forms/strengths
  - Batch/lot number and expiration date (shelf life of at least one year upon arrival in the Philippines)
  - Name and address of manufacturer
- FDA Certificate of Product Registration (CPR)



### *Considerations in Accepting Donations during Disasters and Emergencies*

The process indicated in the national guidelines (AO 2007-0017) should be followed at all levels of the health care system.

Special provisions may be made to the national guidelines to receive and manage medicine donations during disasters and emergencies in view of the extent and nature of the disaster as well as the identified needs of the affected population. The change must be properly communicated to parties involved in the donated medicines supply chain to make timely adjustments in the process of distribution.

#### **POINTS FOR EMPHASIS**

- National guidelines should be followed during disasters and emergencies.
- Information on how medicines are distributed and used by target population must be properly communicated to the donors by the national government.
- Existing guidelines in handling pharmaceutical donations must be reviewed in line with the recently identified gaps and weaknesses in the handling of donations at all health care levels.



### *Review Questions*

Answer the following questions:

1. What are the national criteria for accepting donations?
2. List down five (5) wrong practices regarding acceptance of donations.
3. Propose an SOP for accepting foreign donations which applies to your health care facility.
4. What DOH office is in charge of processing donations from foreign countries?
5. What is the specific administrative order which provides the guidelines for the acceptance and processing of foreign and local donations?



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## Pharmaceutical Donations

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# **Disposal of Pharmaceuticals**



### *Learning Objectives*

At the end of the session, the learner should be able to:

1. Discuss the importance of safe disposal for unwanted pharmaceuticals;
2. Explain the importance of sorting pharmaceuticals into categories that require different disposal methods;
3. Differentiate the various methods for disposing unwanted pharmaceuticals; and
4. Identify the appropriate disposal method for a sorting category.

### *Introduction*

Health care facilities generate all sorts of hazardous waste, from sharps to materials contaminated with biological fluids to expired or damaged drugs. Improper drug disposal can result in contaminated water supplies, resale of poor-quality drugs, and polluted air from improper incineration.

Often, health care facilities can return products to the supplier from where they were obtained. However, when that option is not available, a disposal plan should be in place and should be regularly monitored. Disposal of small amounts of drug waste is easy and relatively cheap; large amounts require the use of special treatment facilities. Before a disposal technique is instituted, any government laws and regulations relevant to health care waste management and environmental protection should be reviewed.



### *Importance of Safe Disposal*

Safe disposal of unwanted pharmaceuticals is a necessary task because of the possible threat to public health and to the environment if improperly disposed of. The WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies list these threats as:

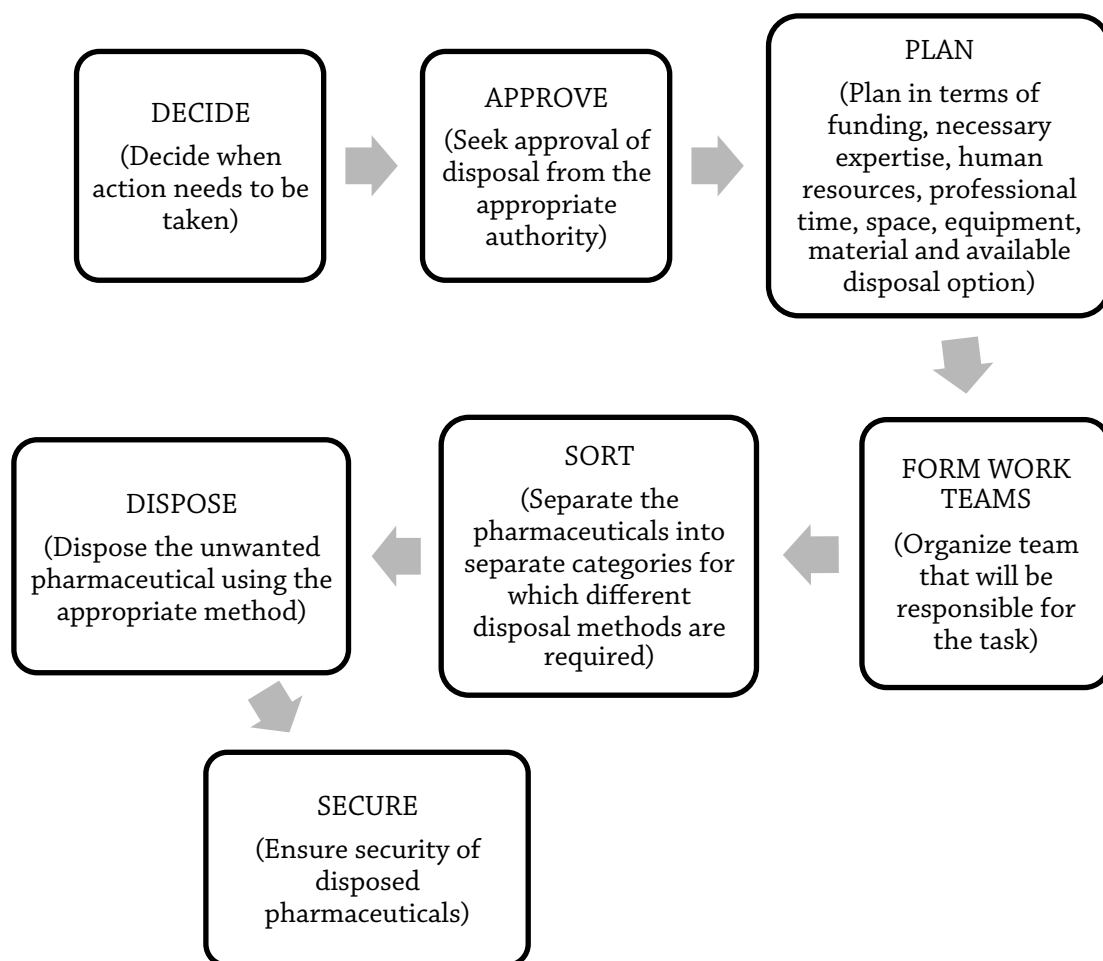
- Contamination of water supplies and damage to aquatic life;
- Reduction or destruction of bacteria necessary for treatment of sewage when non-biodegradable antibiotics, antineoplastics and disinfectants when thrown into the sewage;
- Release of toxic pollutants into the air when burning pharmaceuticals at low temperatures or in open containers; and
- Diversion for resale of expired drugs to the general public due to inefficient and insecure sorting and disposal.

### *Steps in Disposal*

Disposal of unwanted pharmaceuticals may require a series of steps to be taken. Figure 8.1 outlines these steps.







**Figure 8.1. Steps in disposal**

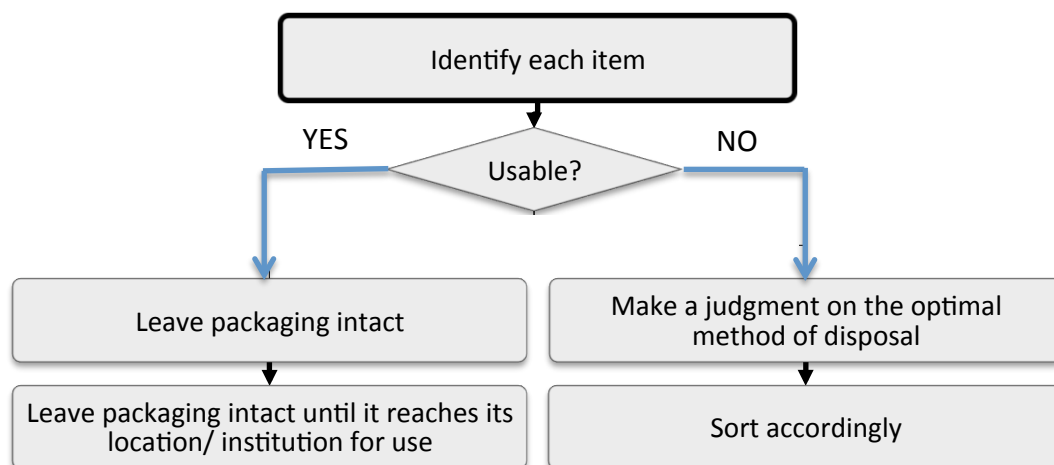
Source: WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies, 1999

Work teams should consist of supervising pharmacists and general medical workers, who are preferably pharmaceutical technicians or experienced pharmaceutical warehouse personnel. Health and safety of work teams must likewise be ensured by wearing appropriate protective equipment including overalls, boots, gloves, masks and caps when appropriate.



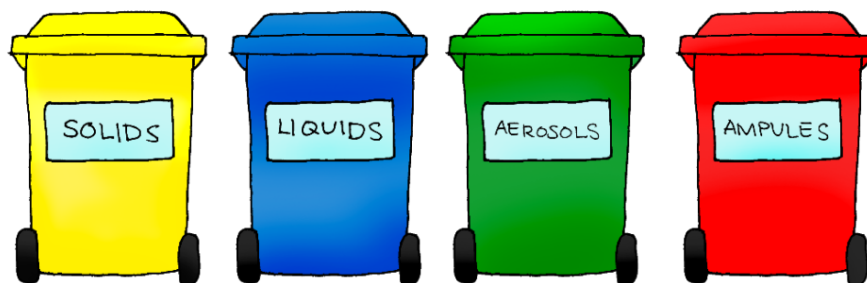
### Sorting

Sorting is to separate pharmaceuticals into categories that require disposal methods. The dosage form of the medicine is a primary consideration in determining the appropriate safe disposal method. Segregated temporary storage areas must be provided for each sorted category. Below is a diagram showing the sorting process (Figure 8.2).



**Figure 8.2. The sorting process**

Source: WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies, 1999





Sorting must be conducted in a well-ventilated, covered area. The staff performing the sorting process must be supplied with protective gear, have undergone proper training on the sorting criteria and health and safety risks associated with handling the materials and should work under the direct supervision of a pharmacist. Once sorting is completed, the pharmaceuticals must be carefully packed into steel drums or into sturdy containers, labeled properly and stored in a dry, secure and preferably separate room (from other pharmaceuticals) until disposal is carried out.

### *Methods of Disposal*

There are several methods that can be employed to dispose unwanted pharmaceuticals. These methods have advantages and disadvantages and may be appropriate for specific types of pharmaceuticals only. Table 8.1 summarizes these disposal methods.

The Philippine Clean Air Act (RA 8749) of 1999 sets the standards for environmental protection while pursuing national development. This law specifically bans the method of incineration for the disposal of waste, including medical and pharmaceutical wastes. This is in view of the amount of chemical pollutants that may be released into the atmosphere that could adversely affect humans, animals and vegetation. Because of this restriction of the law, the use of incineration, while accepted globally as a method of waste disposal, may not be considered as an acceptable method for disposing medicines in the Philippines.



Table 8.1. Methods of disposal of unwanted pharmaceuticals

Disposal Methods	Types of Pharmaceuticals	Comments
Return to donor or manufacturer, transfrontier transfer for disposal	All bulk waste pharmaceuticals, particularly antineoplastics	Usually not practical - transfrontier procedures may be time consuming
High temperature incineration with temperatures greatly in excess of 1200°C	Solids, semisolids, powders, antineoplastics, controlled substances	Expensive; effectively disintegrates all organic waste
Medium temperature incineration with two-chamber incinerator with minimum temperature of 850°C; Cement kiln incineration	In the absence of high temperature incinerators, solids, semi-solids, powders; Controlled substances	Requires dilution of pharmaceutical waste with large quantities of municipal waste prior to incineration; not designed to incinerate halogenated compounds safely

Source: WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies, 1999



Table 8.1. Methods of disposal...(cont.)

Disposal Methods	Types of Pharmaceuticals	Comments
Immobilization		
Waste encapsulation	Solids, semi-solids, powders, liquids, antineoplastics, controlled substances	Involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum
Inertization	Solids, semi-solids, powders, antineoplastics, controlled substances	A variant of encapsulation which involves removal of packaging materials from the pharmaceuticals prior to the procedure; relatively inexpensive
Sewer	Diluted liquids, syrups, intravenous fluids, small quantities of diluted disinfectants (supervised)	Antineoplastics, and undiluted disinfectants and antiseptics not Recommended  May require assistance of hydrogeologist or sanitary engineer

Source: WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies, 1999



Table 8.1. Methods of disposal...(cont.)

Disposal Methods	Types of Pharmaceuticals	Comments
<b>Landfill</b>		
Highly engineered sanitary landfill	Limited quantities of untreated solids, semi-solids and powders; Disposal of waste pharmaceuticals after immobilization preferable; PVC plastics	Offers a relatively safe disposal route
Engineered landfill	Waste solids, semi-solids and powders, preferably after immobilization; PVC plastics	With features to protect loss of chemicals into the aquifer
Open uncontrolled non-engineered dump	As last resort untreated solids, semisolids, powders - must be covered immediately with municipal waste; Immobilization of solids, semi-solids, powders is preferable	Not for untreated controlled substance; Can lead to pollution if not sufficiently isolated from the aquifer

Source: WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies, 1999



Table 8.1. Methods of disposal...(cont.)

Disposal Methods	Types of Pharmaceuticals	Comments
Fast-flowing watercourse	Diluted liquids, syrups, intravenous fluids; small quantities of diluted disinfectants (supervised)	Antineoplastics, and undiluted disinfectants and antiseptics not Recommended  May require assistance of hydrogeologist or sanitary engineer
Burning in open containers	As last resort, packaging, paper, cardboard	Not acceptable for PVC plastics or pharmaceuticals; may release toxic pollutants into the air; only for very small quantities of waste pharmaceuticals
Chemical decomposition	Not recommended unless special chemical expertise and materials available	Not practical for quantities over 50 kg; tedious and time-consuming

Source: WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies, 1999



### *Review Questions*

Answer the following questions:

1. What are the negative effects of improper disposal to the environment?
2. Outline the steps in the safe disposal of pharmaceutical products.
3. Provide one (1) appropriate disposal method for the following types of pharmaceuticals:

Type of pharmaceutical product	Disposal method
a. Antineoplastics	
b. Syrups	
c. Untreated solids, semi-solids and powders	

4. What is the government agency responsible for the implementation of the Clean Air Act?
5. Which method of disposal is not allowed under the Clean Air Act?



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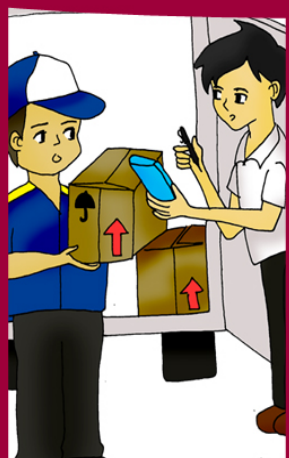




# Training Manual on Pharmaceutical Supply Chain Management

## PARTICIPANT'S MANUAL

**for Department of Health (DOH) National Agencies  
and Centers for Health and Development (CHDs)**





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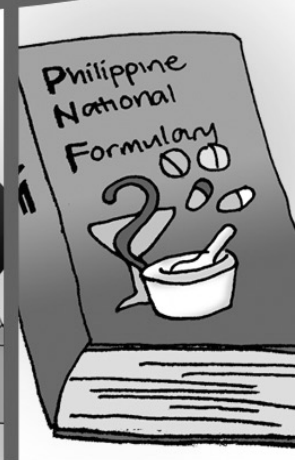
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# Glossary of Abbreviations



Abbreviation	Terms
AHA	Aquino Health Agenda
API	Active Pharmaceutical Ingredient
BAC	Bids and Awards Committee
BHS	Barangay Health Station
BnB	Botika ng Barangay
BOC	Bureau of Customs
CPR	Certificate of Product Registration
DH	District Hospital
DOH	Department of Health
DTC	Drug and Therapeutics Committee
DTI	Department of Trade and Industry
EML	Essential Medicines List
FDA	Food and Drug Administration
FEC	Formulary Executive Committee
FEFO	First to Expire, First Out
FIFO	First In, First Out
HEMS	Health Emergency Management Staff
HSRA	Health Sector Reform Agenda
INRUD	International Network for the Rational Use of Drugs
KP	Kalusugang Pangkalahatan
LGU	Local Government Unit
LTO	License to Operate





# Glossary of Abbreviations

Abbreviation	Terms
MDG	Millenium Development Goals
MMD	Materials Management Division
MRA	Medicines Regulatory Authority
MSDS	Material Safety Data Sheets
NHIP	National Health Insurance Program
NRA	National Reform Agenda
OTC	Over the Counter
PH	Provincial Hospital
PHC	Primary Health Care
PITC	Philippine International Trading Corporation
PMP	Philippine Medicines Policy
PNDP	Philippine National Drug Policy
PNF	Philippine National Formulary
PNFS	Philippine National Formulary System
PTC	Pharmacy and Therapeutics Committee
RH	Relative Humidity
RHU	Rural Health Unit
RONPD	Retail Outlet for Non-prescription Drugs
RUM	Rational Use of Medicines
SOP	Standard Operating Procedure
UHC	Universal Health Care
USP	United States Pharmacopeia
WHO	World Health Organization