



# **Philippine Health Care System**

# **The Philippine Health Care System**

Slide 1.1

## Session Objectives

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)
4. Describe the role of medicines in the provision of health care

Slide 1.2

Present the learning objectives for the session.

## DOH - Philippines

“To guarantee equitable, sustainable and quality health for all Filipinos, especially the poor, and to lead the quest for excellence in health.”

Leadership in  
Health

Enabler & Capacity  
Builder

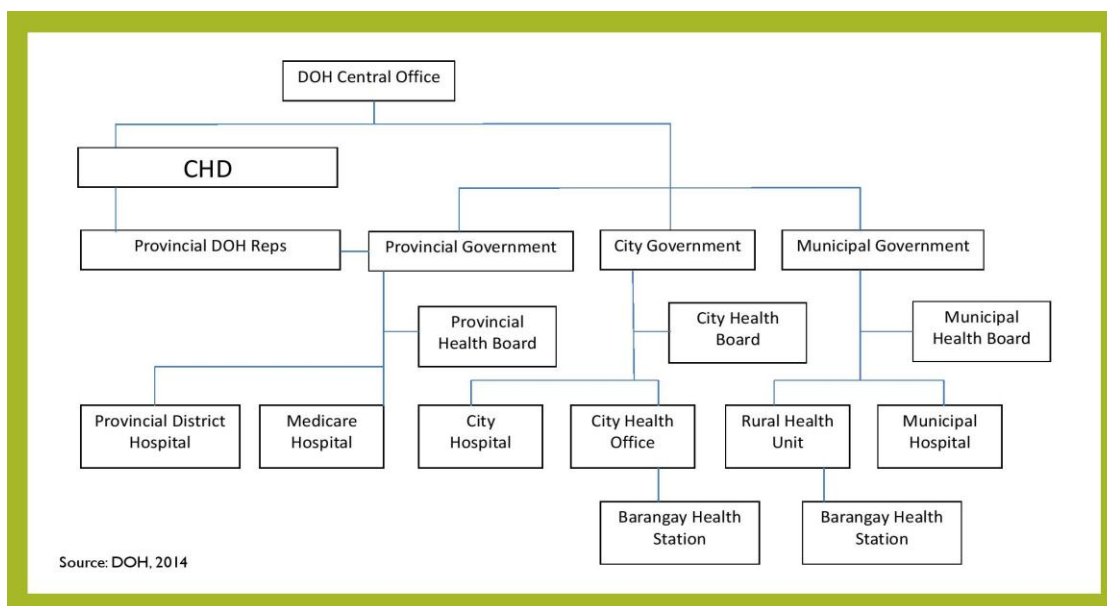
Administrator of  
Services

Slide 1.3

### *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.





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### ***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.

MORTALITY	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

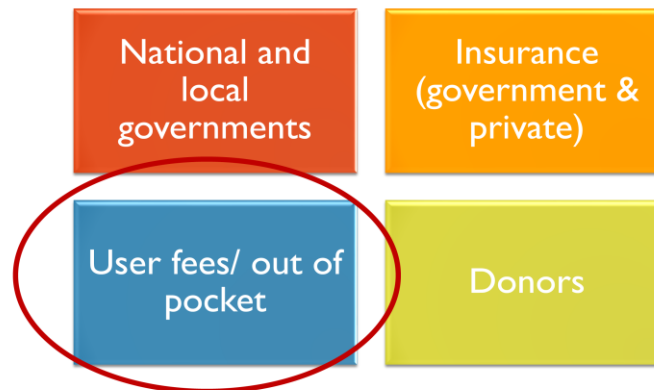
Source: DOH Statistics, 2010

### Slide 1.5

#### ***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. This table 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.

## Health Financing



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### ***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



### Public

- LGUs (primary and secondary care)
- DOH (regional hospitals, medical centers, specialty)

### Private

- 50% of the health system
- Clinics, hospitals, health insurance, drug manufacture, medical supplies, etc.

### Slide 1.7

### *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.

## Health Care Delivery

- Human resources for health
  - ✓ Mostly in urban areas
  - ✓ Largest category is the nurses and midwives
  - ✓ Underproduction of doctors, dentists and occupational therapists

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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

Year	Reform
1979	Primary health care (PHC) approach
1983	EO 851
1987	Reorganization of DOH; PNDP
1988	Generics Act
1991	Local Government Code
1995	National Health Insurance Program
1999	Health Sector Reform Agenda
2005	FOURmula ONE for Health

### Slide 1.9

### *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 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.

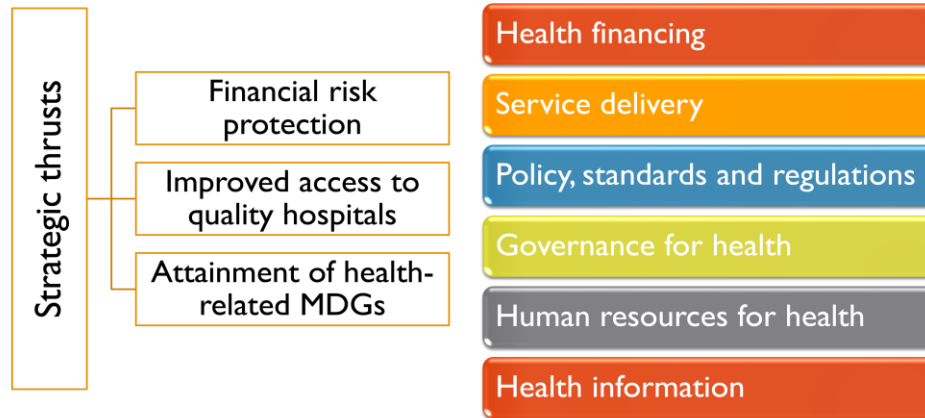
## Aquino Health Agenda (AHA)

- Seeks to improve, streamline, and scale up the reform already started in the previous administrations
- UHC or the *Kalusugan Pangkalahatan* (KP)

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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.

## Universal Health Care



### Slide 1.11

#### ***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).



## Slide 1.11

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

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?

### Slide 1.12

After the lecture, ask the participants to answer the Review Questions found in their manuals. After 15 minutes, discuss the answers.

### **Answers**

1. Major functions of the DOH - (1) leadership in health; (2) enabler and capacity builder; and (3) administrator of specific services
2. Six strategic instruments of UHC or KP – (1) health financing; (2) service delivery; (3) policy, standards, and regulations; (4) governance for health; (5) human resources for health; and (6) health information
3. Link between national and local governments – Centers for Health Development (CHDs)

## Review Questions

4. Draw the organizational structure of the public health care system.
5. Give the four (4) sources of health financing.

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## Answers

4. Draw the organizational structure of the public health care system – see Figure 1.
5. Four (4) sources of health financing - National and local governments, insurance (private and government), out of pocket by patients, donors

## Group Activity

- I. Make groups of 5 participants each.
  - Study the various health care reforms provided in your readings.
  - Choose 1 health care reform to focus on.
  - Using the chosen health care reform, formulate strategies how medicine access could be improved.
  - Prepare a 10-minute presentation in class.

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**Materials Needed:** Manila paper, markers

### Instructions to Facilitator:

Ask the participants to group themselves into 5. Ask them to assign a facilitator and a reporter. Distribute 1 Manila paper and permanent marker per group. After 30-45 minutes, ask the groups to report their outputs. The trainer may opt to select which group/s will report.

## Group Activity

2. Group discussion on communication
  - Discuss how could you improve communication on medicines use from local health facilities up to DOH National Office.
  - Choose a spokesperson to share the results of your discussion to the rest of the class.

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# **Principles of Drug Management**

## Principles of Drug Management

### Slide 2.1

#### ***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. Because of the implications of medicine on health and health expenditure, there is a need to properly manage them.

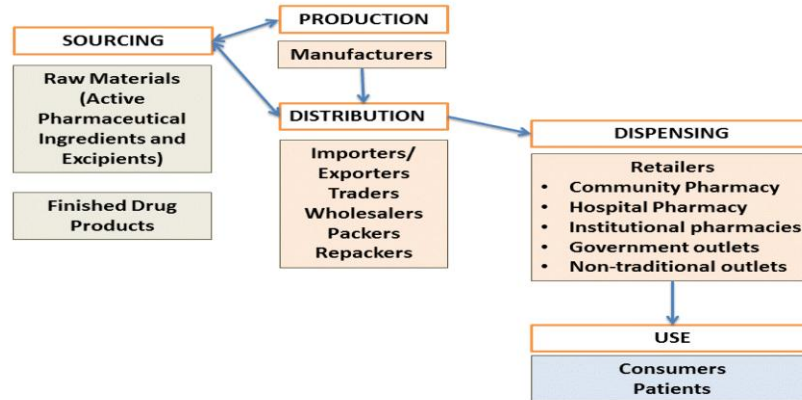


## Session Objectives

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

Slide 2.2

Present the learning objectives for the session.



## The Philippine Pharmaceutical Supply Chain

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.

## Slide 2.3

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

- Community pharmacies
- Hospital
- Government health facilities
- Other institutional pharmacies
- Retail outlets for non-prescription drugs

### Slide 2.4

These are the different retailers for drug products.

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 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.

## Slide 2.4

An emerging outlet for pharmaceutical products, which before was either unregistered or registered as community pharmacy with the 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 Medicine Supply

- Jurisdiction of DOH – FDA
  - ✓ Responsible for the quality and safety of drug products in the Philippine market → CPR
  - ✓ Regulates drug establishments, retail outlets, and drug products → LTO

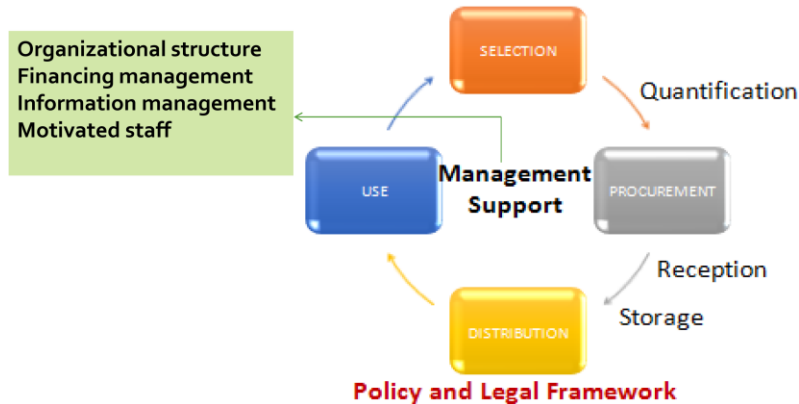
Slide 2.5

### *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 lists of FDA requirements and application documents are found at their website, <http://www.fda.gov.ph>.

## Drug Management Cycle



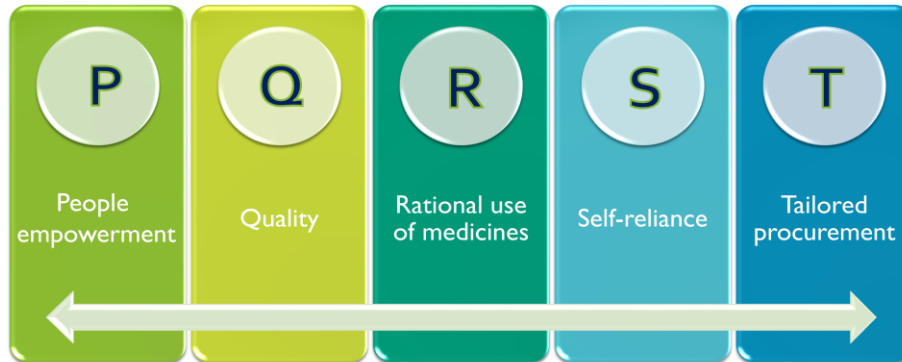
Slide 2.6

### *The 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.

In the Philippines, the 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 PND.

## Philippine National Drug Policy



### Slide 2.7

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 medicines for all sectors of the country, especially the majority of the Filipinos who are able to afford them.



## Slide 2.7

The five pillars were:

- People empowerment – patients are offered information regarding the purchase of affordable medicines so they can make an informed decision;
- Quality – assurance of the safety, efficacy and usefulness of pharmaceutical products through quality control which will involve the regulation of the importation, manufacture, marketing, and consumer utilization of all drugs and their intermediates;
- Rational use of drugs – promotion of the rational use of medicines by both health professionals and the general public;
- Self-reliance – development of self-reliance in the local pharmaceutical industry in which basic and intermediate ingredients for drugs and medicines are locally produced to reduce the country's dependence on imported drugs; and
- Tailored procurement – tailored procurement of drugs by government to address access and affordability.

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

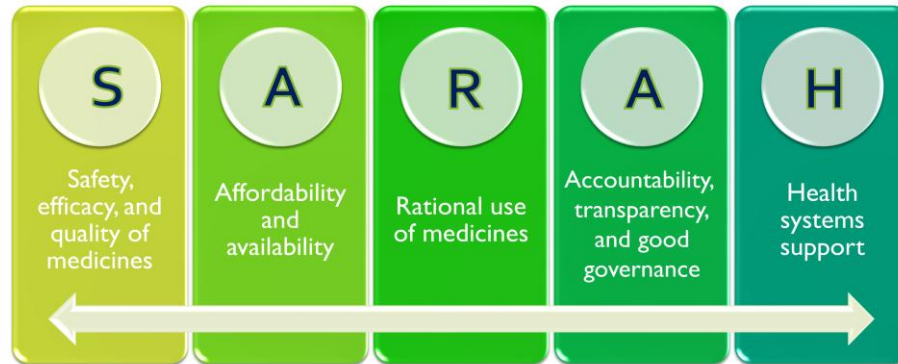
## Other Initiatives to Improve Accessibility

- Establishment of Pharma-50 Unit of the DOH
  - ✓ Botika ng Barangay (BnB)
- Parallel importation
- Enactment of RA 9502 – allowed for regulation of medicine prices
- Creation of NCPAM

### Slide 2.8

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 (Universally Accessible Cheaper and Quality Medicines Act), 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.

## Philippine Medicines Policy



Slide 2.9

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

- **S**afety, efficacy and quality – includes all policies and strategies employed by the state and the tools for all stakeholders to constantly assure the safety, efficacy and quality of essential medicines along the supply chain and at all levels of care;
- **A**ffordability and availability – pertains to the full range of mechanisms that government shall employ in a collaborative endeavor with all partners and sectors to ensure that Filipinos have adequate and timely access to medicines at all points of health service delivery;

### Slide 2.9

- **Rational use of medicines** – promotion of the rational and cost effective use of medicines to achieve the best treatment outcomes for patients while generating efficiency and cost-savings in the healthcare system;
- **Accountability, transparency and good governance** – anchored on the fact that strategies to improve access to medicines can only happen within a framework that institutionalizes accountability, transparency and good governance in regulatory and management systems along the medicines supply chain; and
- **Health systems support** – supports other pillars of the Philippine Medicines Policy. The government should take the lead that enabling human, technical, technological and financial resources and instruments are made available to expand medicines access across all levels of the health care system.

## 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

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After the lecture, ask the participants to answer the Review Questions found in their manuals. After 5 minutes, discuss the answers.

### Answers

1. E
2. F

## Review Questions

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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### *Answers*

- 3. A
- 4. B
- 5. C

## Group Activity

- I. Form five groups of participants to represent each letter forming the **S A R A H** Framework.
  - Describe the specific meaning of the letter assigned to them
  - Identify policy recommendation/s or action/s that would be necessary to ensure implementation of the specific aspect of the framework

Slide 2.12

**Materials Needed:** Manila paper, markers

### Instructions to Facilitators:

Ask the participants to group themselves into 5. Ask them to assign a facilitator and a reporter. Distribute 1 Manila paper and permanent marker per group. After 30-45 minutes, ask the groups to report their outputs. Give each group 5-7 minutes to present their outputs.

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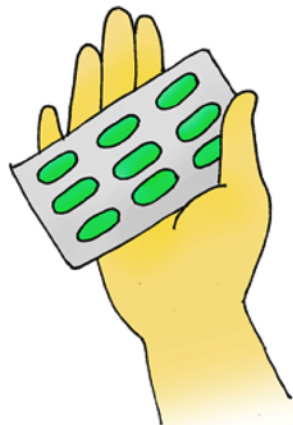
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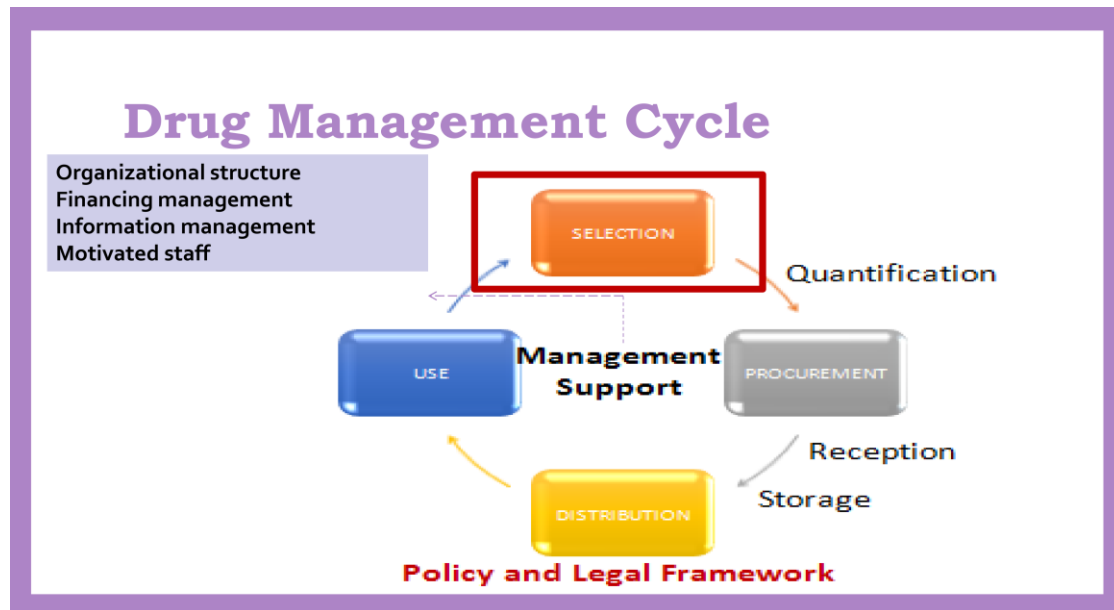
# Selection of Medicines



## Selection of Medicines



Slide 3.1



Slide 3.2

Introduce the drug management cycle once again. Mention that for this session, the focus will be on medicine selection.

### Session Objectives

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
3. Propose ways on how to address gaps and weaknesses in the selection of medicines

#### Slide 3.3

Present the learning objectives for the session.

## Essential Medicines

- Those medicines which satisfy the priority health care needs of the population and should be available at all times
- **WHO Model List of Essential medicines** – derived from the consensus of recognized international experts and updated every two to four years

Slide 3.4

### Introduction

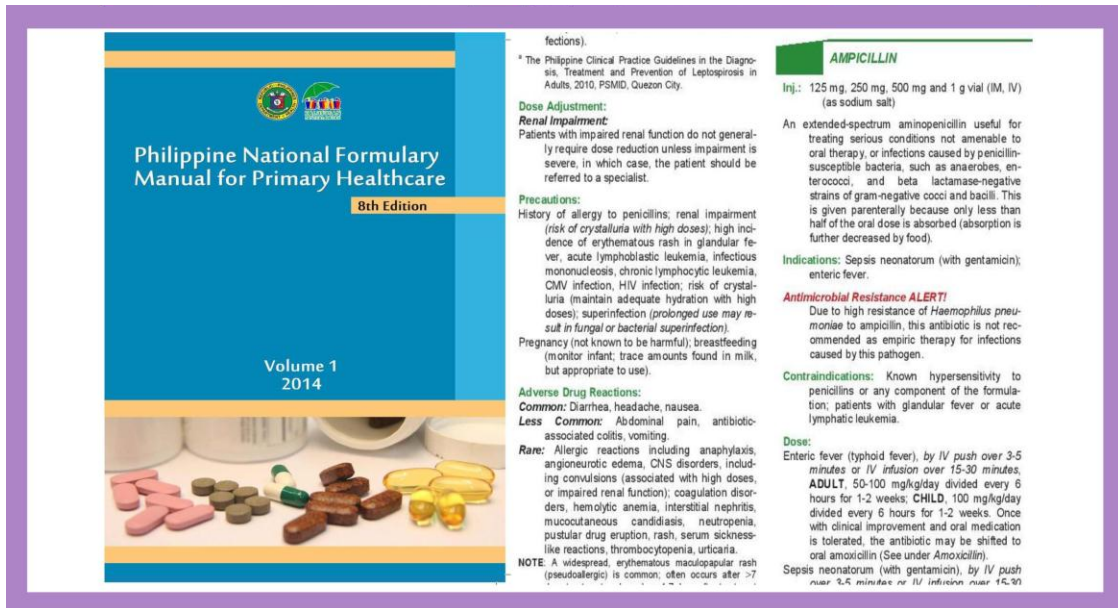
The selection of medicines to address the health needs of a country's population must be based on a sound national medicines policy that includes the Essential Medicines List (EML). WHO defines essential medicines as those medicines which satisfy the priority health care needs of the population and should 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.

### Essential Medicines List



#### Slide 3.5

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.



Slide 3.6

## The Philippine National Formulary

The PNF is an important component of the National Drug Policy. It is a major strategy in the promotion of rational drug use, by assuring the availability and accessibility of essential drugs of proven efficacy, safety and quality at affordable cost in the country. By virtue of Executive Order No. 49 s.1993 and 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.

## Criteria for Inclusion to PNF



### Slide 3.7

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.



## PNF

- Formulary Executive Committee (FEC) – responsible for revision and updating
- Mandatory use among government hospitals and health facilities in the procurement of medicines under RA 9184

Slide 3.8

At the national level, the Formulary Executive Committee (FEC) under the NCPAM is responsible for the PNF revision and updating. It is a multidisciplinary committee composed of medical specialists, epidemiologists, pharmacologists, and pharmacists. The approved drugs in the latest formulary in its downloadable form is made available to the public through the DOH website.

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. The group responsible for the development of the hospital formulary at the hospital level is the Drug and Therapeutics Committee (DTC) or also known as Pharmacy and Therapeutics Committee (PTC).

## Drug and Therapeutics Committee (DTC)

- Pharmacy and Therapeutics Committee (PTC)
- Selection of medicines
- Composed of representatives from the medical staff, pharmacy, nursing, and hospital administration
- Safety, Affordability, Necessity, and Efficacy (SANE)
- Evidence-based

### Slide 3.9

### *The Drug and Therapeutics Committee*

Selection of medicines for procurement in 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.

## Goals of DTC

- Develop and implement an efficient and cost-effective formulary system
- Ensure that only efficacious, safe, cost-effective and good quality medicines are used
- Ensure the best possible drug safety
- Develop and implement interventions to improve medicine use

Slide 3.10

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

- 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; and
- Develop and implement interventions to improve medicine use by prescribers, dispensers and patients.

### Problems with Absence of 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

#### Slide 3.11

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 that are enumerated in this slide.

## Review 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?

Slide 3.12

Ask the participants to answer the Review Questions found in their manuals. After 10 minutes, discuss answers.

## Answers

1. Higher quality of care, better management of medicines, more cost-effective use of available health resources, and better inventory management
2. The Formulary Executive Committee
3. Develop and implement an efficient and cost-effective formulary system; Ensure that only efficacious, safe, cost-effective and good quality medicines are used; Ensure the best possible drug safety through monitoring, evaluating; or Develop and implement interventions to improve medicine use by prescribers, dispensers and patients
4. Irrational prescribing; problematic procurement; unpredictable stocking; entry of ineffective medicines; and waste of hospital resources
5. Composed of representatives from the medical staff, pharmacy, nursing and hospital administration

## Group Activity

- I. It came to your knowledge that some government health facilities still do not use the PNF in the selection of medicines for procurements while some do not have a working Drug and Therapeutics Committee.
  - What policy recommendation or action would be necessary so that the different hospitals and health facilities will use the PNF in the selection of medicines for procurement? Please provide specific recommendation or action.

Slide 3.13

**Materials Needed:** Manila paper, markers

### Instructions to Facilitators:

Ask the participants to group themselves into 5. Ask them to assign a facilitator and a reporter. Distribute 1 Manila paper and permanent marker per group. After 30-45 minutes, ask the groups to report their outputs. Give each group 5-7 minutes to present their outputs.

## Group Activity

- What actions should be taken so that every hospital (at different levels of care) will have a working Drug and Therapeutics Committee?

Slide 3.14

### ***References***

HALLOWAY, K. and T. GREEN. 2003. Drug and Therapeutics Committee – A Practical Guide. France: World Health Organization.

NATIONAL FORMULARY COMMITTEE. 2008. Philippine National Drug Formulary, 7th Edition. Manila: National Drug Policy – National Pharmaceutical Unit.

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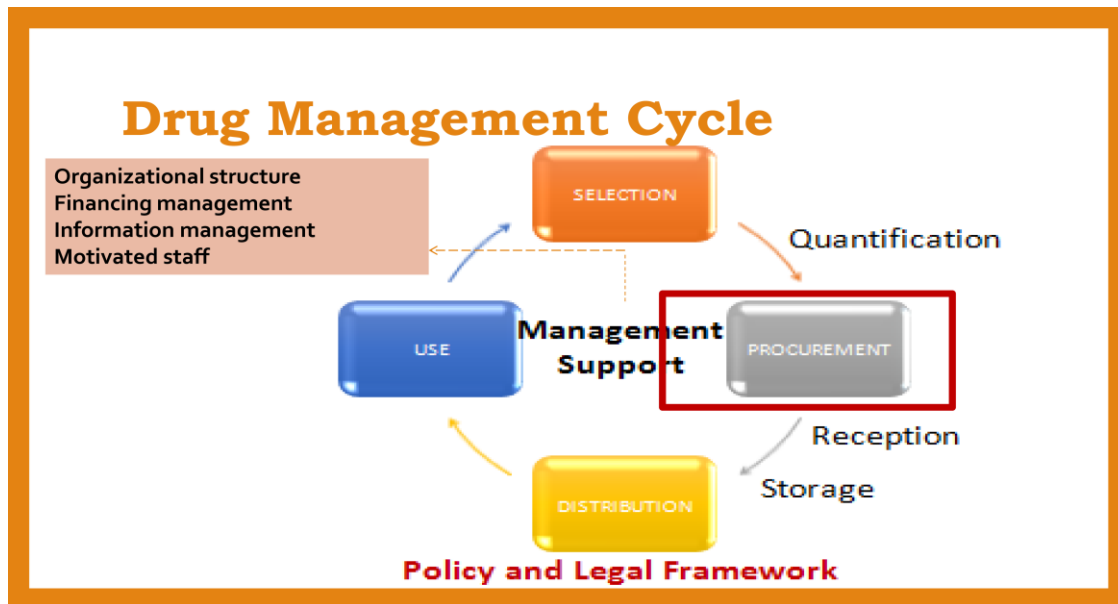


# **Procurement of Medicines**

## Procurement of Medicines



Slide 4.1



Slide 4.2

Introduce the drug management cycle once again. Mention that for this session, the focus will be on procurement of medicines.

### Session Objectives

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

#### Slide 4.3

Present the learning objectives for the session.

“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.”

Slide 4.4

### ***Introduction***

The United States Pharmacopeia (2007), 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.

## Components of a Procurement System

Financial resources

Human resources

Operational resources

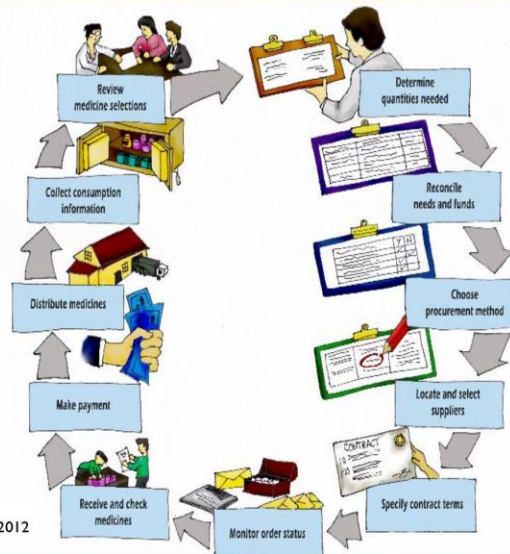
System resources

### Slide 4.5

The four components required of a procurement system include:

- **Financial resources.** An adequate budget available to hire and retain competent staff and provide necessary operational resources;
- **Human resources.** Experienced staff, including management, who are qualified and trained in procurement procedures, logistics, international trade, and finance, and who have no conflicts of interest;
- **Operational resources.** Adequate office space and proper equipment to maintain operations and current information about suppliers and products; and
- **System resources.** A written procurement policy that identifies a transparent selection process and evaluation procedures, documentation requirements, and government procurement regulations.

## Procurement Process



Slide 4.6

This figure shows the procurement process.

## Good Procurement Practices

- Key principles for appropriate drug procurement by various sectors – individual procurement agencies to pooled procurement system serving multiple health systems

### Slide 4.7

A table on good procurement practices is provided in the Participant's Manual.



### **The Government Procurement Process**

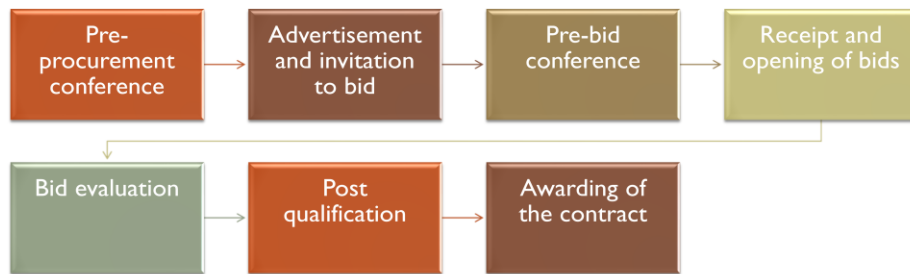
- RA 9184 provides the different procurement methods that the government may be used in the purchase of goods and services, which will allow transparency, competition among suppliers, and cost-effectiveness
- Competitive bidding

Slide 4.8

### ***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). 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.

## Steps in Bidding Process



### Slide 4.9

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:

1. **Pre-procurement Conference** – This meeting, attended by the BAC Committee, officials who prepared the bidding documents, consultants and end-users, will assess the readiness of the procurement in terms of confirming the certification of the availability of funds as well as reviewing all relevant documents in relation to their adherence to the law.
2. **Advertising and Invitation to Bid** – Every Invitation to Bid has to be advertised by the Procuring Entity to ensure the widest possible dissemination in newspapers of general circulation, in government e-procurement system website and website of the Procuring Entity.
3. **Pre-bid Conference** – This is a meeting of prospective bidders with the end-user and BAC members during the BAC meeting for clarification purposes.

## Slide 4.9

4. **Receipt and Opening of Bids** – This consists of dropping of bid at designated date, place and time. The bid consists of two components, technical and financial, each of which is contained in separate sealed envelopes.
5. **Bid Evaluation** – Only bids that are determined to contain all the bid requirements of the technical component shall be considered for opening and evaluation of their financial component. The bids that passed the preliminary examination shall be ranked from lowest to highest in terms of their corresponding calculated prices. The bid with the lowest calculated price shall be referred to as the “Lowest Calculated Bid”.
6. **Post-qualification** – This is the stage where the bidder with the Lowest Calculated Bid, in the case of Goods and Infrastructure Projects, or the Highest Rated Bid, in the case of Consulting Services, undergoes verification and validation whether he has passed all the requirements and conditions as specified in the Bidding Documents.
7. **Awarding of the Contract** – Within a period not exceeding fifteen (15) calendar days from the determination and declaration by the BAC of the Lowest Calculated Responsive Bid or Highest Rated Responsive Bid, and the recommendation of the award, the Head of the Procuring Entity or his duly authorized representative shall approve or disapprove the said recommendation. In case of approval, the Head of the Procuring Entity or his duly authorized representative shall immediately issue the *Notice of Award* to the bidder with the Lowest Calculated Responsive Bid or Highest Rated Responsive Bid.

## For Medicines



### Slide 4.10

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 LTO and CPR from the Food and Drug Administration. The certificate of Current Good Manufacturing Practice (cGMP) compliance is another proof of the quality of the products manufactured by a manufacturing firm.

The procurement process for medicines in private hospitals differs from hospital to hospital. 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

Limited Source Bidding

Direct Contracting

Repeat Order

Shopping

Negotiated Procurement

Slide 4.11

### ***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 BAC. These alternative methods include:

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

The United States Pharmacopeia (USP) however suggests that the preferred method for procuring medicines is Limited Source Bidding. Limited bidding involves a prequalification 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 a request for bids.

#### Slide 4.12

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

- Actual quantity versus quantity indicated on the requisition/delivery form
- Unopened and in good condition original container
- Labels, expiry dates, dosage forms, dosage strengths indicated on the products versus specifications
- Physical condition such as appearance, color, and volume
- Clarity for liquid products

Slide 4.13

### ***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

Lead time	Compliance with pricing terms	Partial shipments	Compliance with remaining shelf life requirements
Compliance with packaging and labelling instructions	Compliance with technical specifications	Compliance with contract terms	Summary of outcomes

Slide 4.14

### **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 labelling instructions;
- Compliance with technical specifications;
- Compliance with contract terms; and
- Summary of outcomes of performed inspections (USP 2010).



## Review Questions

1. What 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?

Slide 4.15

After the lecture ask the participants to answer the Review Questions found in their manuals. After 10-15 minutes, discuss the answers.

## Answers

1. Republic Act 9184 or the Government Procurement Reform Act of 2002
2. Pre-procurement conference, advertising and invitation to bid, pre-bid conference, receipt and opening of bids, bid evaluation, post-qualification, and awarding of contract
3. Financial resources, human resources, operational resources, and system resources
4. It is the commitment to procure all contracted pharmaceuticals from winning supplier and not to enter into separate deals with non-contracted suppliers
5. Limited Source Bidding

## Group Activity

- I. First part of the activity:
  - Arrange chronologically the steps of the procurement process

Slide 4.16

**Materials Needed:** Manila paper, markers

### Instructions to Facilitators:

Ask the participants to group themselves into 5. Ask them to assign a facilitator and a reporter. Distribute 1 Manila paper and permanent marker per group. After 30-45 minutes, ask the groups to report their outputs. Give each group 5-7 minutes to present their outputs.

## Group Activity

2. Answer the following:

- How can the quality of medicines be assured at the procurement process from the national down to the local government?
- What measures could be done to ensure the integrity and ethical performance of suppliers? Please provide specific recommendation or action.

Slide 4.17

### ***References***

MANAGEMENT SCIENCES FOR HEALTH. 2012. Managing Access to Medicines and Health Technologies. Arlington: Management Sciences for Health, Inc.

Republic Act No. 9184. 2002. Government Procurement Reform Act.

THE UNITED STATES PHARMACOPEIAL CONVENTION. 2007. Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide. Rockville, Maryland: United States Pharmacopeia.



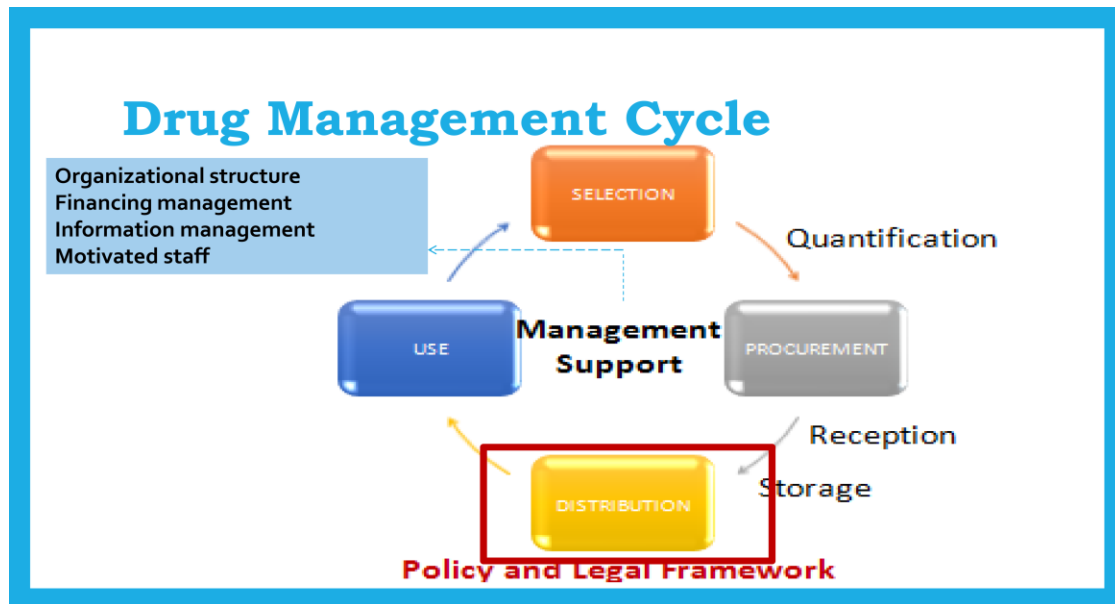
# **Storage and Distribution of Medicines**



## Storage and Distribution of Medicines



Slide 5.1



Slide 5.2

Introduce the drug management cycle once again. Mention that for this session, the focus will be on storage and distribution of medicines.

### Session Objectives

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
3. Propose ways of monitoring the status of medicines distribution and storage at all levels of the public health care system

Slide 5.3

Present the learning objectives for the session.



## Distribution

Ensure that right quantities of the right medicines reach the target population in a timely and appropriate manner.

Constant supply

Maintenance of quality of medicines

Minimal loss or pilferage

Accurate and timely inventory

Proper storage

Efficient transport & delivery

Adequate geographic storage

Slide 5.4

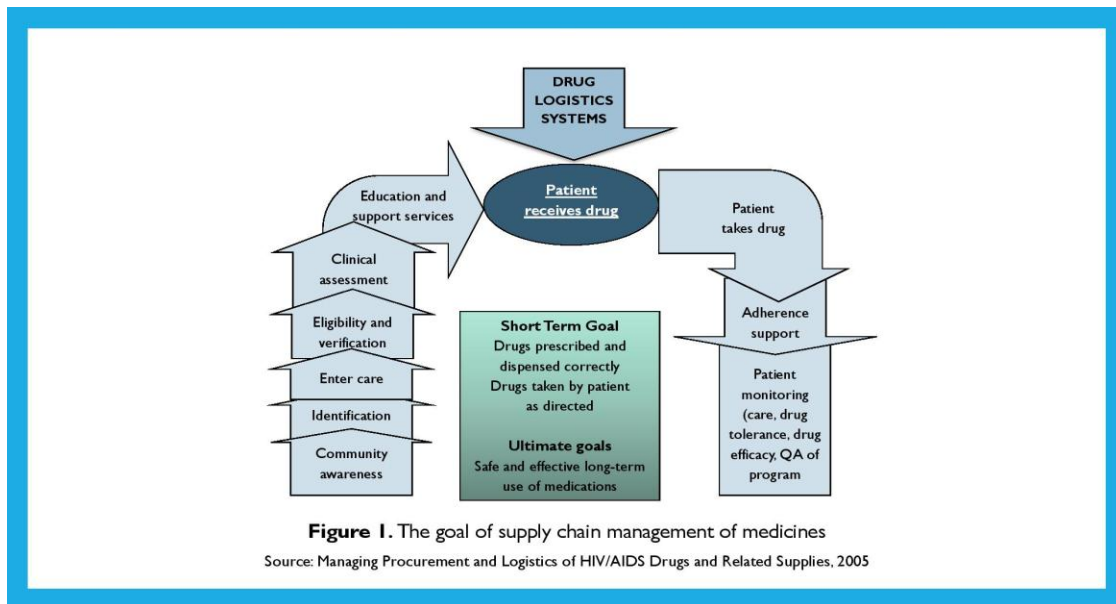
### Introduction

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. In addition to that, an effective distribution system should also be able to achieve the following:

- **Constant supply.** Since medicines are needed by patients for acute and chronic ailments, they have to be constantly provided and made available in various health care settings. Disruption in supply, such as in disasters and unforeseen events, may affect goals of treatment, aggravate disease states, and endanger lives.
- **Maintenance of quality of medicines.** A good distribution system should also ensure the quality of medicines from the point of manufacture to their use. Factors which will affect quality of medicines such as temperature and humidity must be controlled and specific storage conditions must be maintained for certain products.

## Slide 5.4

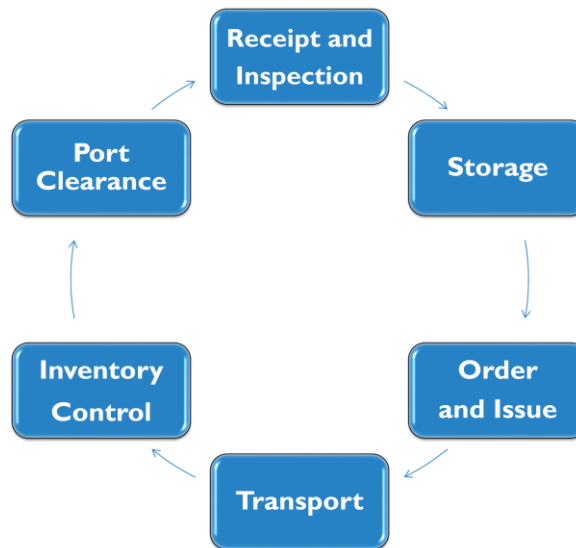
- **Minimal loss or pilferage.** Pilferage or loss of medicines due to theft must be prevented where medicines are stored. Any loss will redound to reduction in the institution's capability to meet the needs of the patients and will also limit the capacity to buy other needed medicines. Control measures must be in place in order to keep track of the stocks in storerooms and warehouses at all levels of health care.
- **Accurate and timely inventory and transaction information.** Accurate and timely inventory and transaction information are necessary to provide current inventory status and monitor items which have reached minimum re-order level. The movement of products will be easily monitored when data about drug products' receipt and delivery are properly recorded.
- **Proper storage.** Medicines have their specific storage requirements which should be maintained throughout their shelf life and during transport. *Shelf life* of a drug product refers to the time that the average characteristics (e.g. potency) remains within an approved specification after manufacture. Products like vaccines and other biologicals require cold chain management and deviation from required temperature may result to loss of potency. In general, medicines should be stored with temperature, humidity and light requirements complied with.
- **Efficient transport and delivery.** Medicines are transported in boxes and other forms of packaging which are expected to preserve their physical and chemical integrity throughout the duration of transport. The mode of transport and the prevailing conditions of the chosen vehicle could affect the quality of the products it carries. The storage requirement of the medicines prior to actual transport should be determined ahead of time so that preparation could be made to satisfy the requirement.
- **Adequate geographic coverage.** Since medicines are needed at all levels of the health care system, the supplier or the distributor should be able to meet the demand of large segment of the population and is able to deliver to a wider geographical area. The use of courier companies in addition to company-provided transport has already been accepted as an alternative mode of transport to reach more health care facilities and hospitals in the different regions of the country.



Slide 5.5

This figure likewise illustrates the objective of a supply chain management system.

### The Distribution System



Slide 5.6

#### ***The Distribution System***

For a distribution system to work, specific elements and their respective procedures, as provided in the figure, 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. There are minimum standards to be followed in this distribution system.

Receive Incoming Goods	Storage	Dispatch/ Delivery	Transportation
<ol style="list-style-type: none"> <li>1. Follow 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, labelling and packaging.</li> <li>4. Take suspected or random samples to lab for testing.</li> </ol>	<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>	<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, labelling and packaging.</li> </ol>	<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>

Slide 5.7

The USP Convention in 2007 provided a list of the important aspects to be considered in the storage and distribution 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 standard operating procedures (SOPs) which the personnel could easily follow in receiving, labelling, inventory and security. A copy of good storage practices is provided in the Participant's Manual.

## Good Distribution Practices

Clear products rapidly through customs

Inspect medicines for quality and quantity before distribution

Maintain proper storage conditions

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

Slide 5.8

### ***Good Distribution Practices***

This summarizes key points of good distribution practices:

- Clear products rapidly through customs to avoid storage condition 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.

### **Tips to Expedite Customs Clearance**

- Designate an experienced staff person in port clearance to be responsible for custom activities
- Establish a written protocol for customs clearance
- Communicate frequently with the supplier/consigner to provide all necessary documents
- Communicate frequently with the supplier/consigner and the port authorities (customs) enquiring about the status of the shipment,

Slide 5.9

### ***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 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 as soon as they are available. These include, but are not limited to, packing lists, airway bills, and pro-forma invoices.
- 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.

## Tips to Expedite Customs Clearance

- Collect and prepare all required documents with necessary signatures and stamps
- Coordinate with all relevant authorities and with the customs officer
- Make every effort to ensure that the customs clearance takes less than two (2) weeks

### Slide 5.10

- 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.
- Make every effort to ensure that the customs clearance takes less than two (2) weeks.



## Receipt of Incoming Materials and Pharmaceutical Products

Goods should match the appropriate purchase order

Container uniformity should be checked

Each container should be inspected for contamination

Slide 5.11

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

During receipt of incoming materials and pharmaceutical products the following should be performed/ checked:

- Goods should match the appropriate purchase order and each container should be labelled 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

- Mode, duration of transportation, destination must be taken into account to ensure the integrity of the medicines in transit
- Temperature and humidity
- Different transport requirements for small volume deliveries, large volume deliveries, biologicals, and other high temperature sensitive products

Slide 5.12

### *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 CO<sub>2</sub>), 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

Limit access to storage areas to authorized personnel.

Ensure proper storage conditions

Organize and clearly label storage areas.

Label clearly an expiry date on all containers.

Arrange products following FEFO and FIFO principles

Perform regular inventories

Maintain records of all materials

Slide 5.13

### ***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.

The key points of good storage practices are:

- 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.

## Safety and Security

- Limited access
- Security protocols
- Fire exits
- Smoke detectors
- Fire extinguishers and fire alarms
- Personnel trained to administer first aid

Slide 5.14

### ***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

- Space, transport accessibility and convenience, and security
- Adequate lighting, and protection from adverse weather conditions
- Store off the floor and suitably spaced to permit cleaning and inspection
- Floor and surfaces of storage areas should be covered by tiles or other materials that can be easily cleaned

Slide 5.15

### **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

- Adequate number of shelves, clearly labelled, 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

### Slide 5.16

Storage areas should have an adequate number of shelves, clearly labelled, 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.

## Storage Conditions

- Monitor for temperature, if possible, daily, and readings must be recorded
  - ✓ Thermometer
  - ✓ Hygrometer

Source: USP 2007

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 conditions; 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: Adapted from World Health Organization, 1996a, and United States Pharmacopeia, 2006. *Good Storage and Shipping Practices*, USP 29, The National Formulary 24 (USP–NF). Rockville, Md., The United States Pharmacopeia.

Slide 5.17

### Storage Conditions

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, medicines should be stored under normal storage conditions: dry, well-ventilated premises at temperatures of 15°C to 25°C. If humidity can be controlled, products may be stored up to 30°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
- Permanent written or electronic information should exist
- Delivery records
- Comprehensive records should be maintained
- Material safety data sheets (MSDS)

Slide 5.18

### ***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), which can be obtained from most medicine manufacturers, 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 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.

Slide 5.19

### ***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
- Monthly inventory check can be performed by hand using a simple checklist

Slide 5.20

### *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
  - ✓ FEFO & FIFO

Slide 5.21

### ***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 Drug 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
- Any reissued stock should be identified and recorded in stock records

Slide 5.22

### ***Expired, Rejected and Recalled Drug Products***

Stocks should be regularly checked for expired, rejected, and recalled 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.

## Review 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?

Slide 5.23

After the lecture, ask the participants to answer Review Questions found in their manuals. After 10-15 minutes, discuss the answers.

## Answers

1. To ensure that right quantities of the right medicines reach the target population in a timely and appropriate manner
2. 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, and Maintain records of all materials in storage and update regularly
3. First to Expire, First Out

## Review Questions

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?

Slide 5.24

### Answers

4. -5°C and -20°C
5. Name of the material; Batch number; Arrival or receipt date; Expiry or retest date; and Specified storage conditions

## Group Activity

1. What support can the national government provide to ensure the proper warehousing of medicines under government health care system? Please provide specific recommendation or action.

Slide 5.25

**Materials Needed:** Manila paper, markers

### Instructions to Facilitators:

Ask the participants to group themselves into 5. Ask them to assign a facilitator and a reporter. Distribute 1 Manila paper and permanent marker per group. After 30-45 minutes, ask the groups to report their outputs. Give each group 5-7 minutes to present their outputs.

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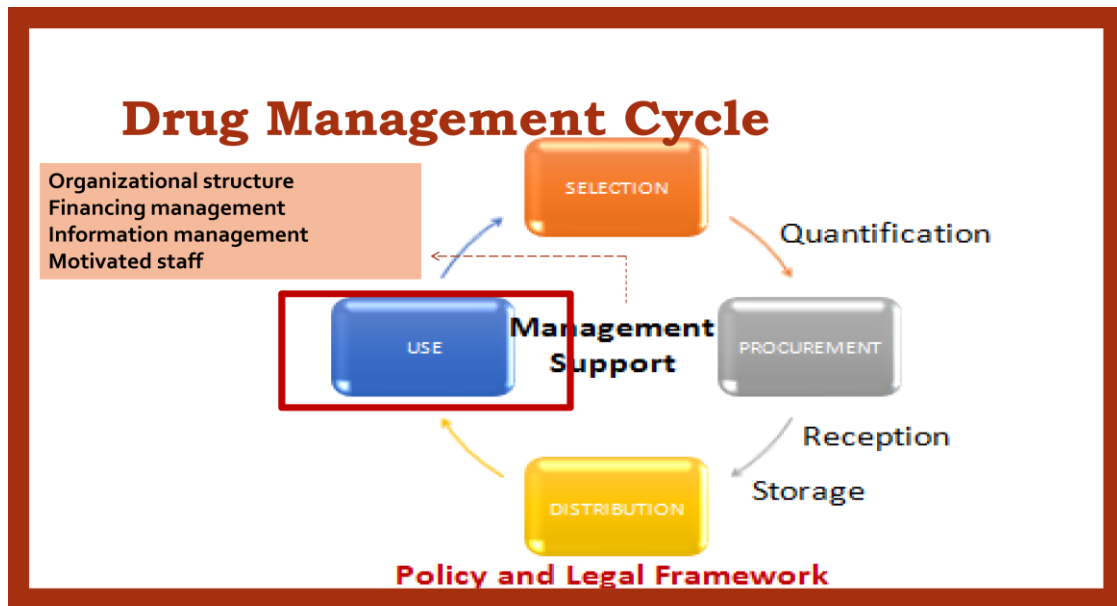


# Use of Medicines



## Use of Medicines

Slide 6.1



Slide 6.2

Present the drug management cycle once again but emphasize that this session will be on use of medicines.

## Session Objectives

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

### Slide 6.3

Present the learning objectives for the session.

## Rational Use of Medicines

- 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



Slide 6.4

### ***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” (WHO 2002). 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**

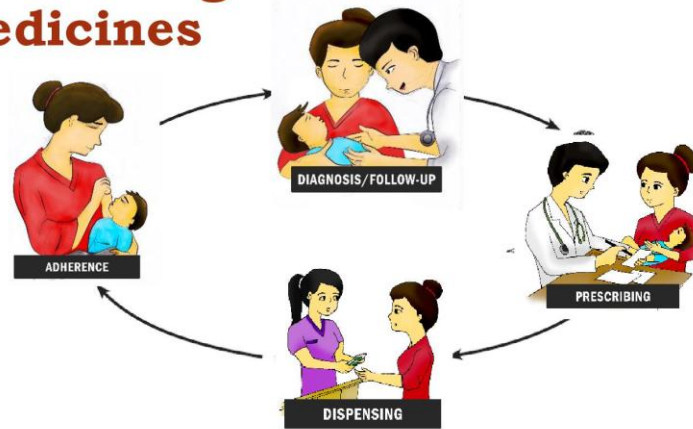
- Polypharmacy
- Injections are used where oral formulations would be more appropriate
- Antimicrobial medicines are prescribed in inadequate doses or duration or antibiotics prescribed for non-bacterial infections
- Prescriptions do not follow clinical guidelines
- Patients self-medicate

### Slide 6.5

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 or antibiotics prescribed for non-bacterial infections, thereby contributing to the growing problem of antimicrobial resistance
- Prescriptions do not follow clinical guidelines
- Patients self-medicate inappropriately or do not adhere to prescribed treatment.

## Monitoring Rational Use of Medicines



Source: Managing Access to Medicines and Health Technologies, 2012

Slide 6.6

### ***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.

## Slide 6.6

The medication use process. This enumerates the functions of each health care professional involved in the medication use process:

**Prescribing - Doctor**

- Evaluate patients
- Establish need for medicine
- Select right medicine
- Determine drug interactions and allergies
- Prescribe medicine

**Transcribing/ documenting - Nurse**

- Transcribe prescription order
- Transmit to pharmacy

**Dispensing - Pharmacist**

- Review prescription order
- Verify transcription
- Contact prescriber for discrepancies
- Prepare medicine
- Distribute medicine
- Give advice on use of medicine

**Administering – Nurses**

- Review prescription order
- Check medicine delivered
- Review warnings, interactions, and allergies
- Evaluate patient
- Administer medicine

**Monitoring – Health Care Team**

- Assess patient's response to medicines
- Document results and report



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 have been assured by the regulatory agency like the Food and Drug Administration provide cheaper alternatives.

## WHO Indicators for Drug Use

Source: WHO, 2002

### 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 labelled
- 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.

### Slide 6.7

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

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.

## WHO Indicators for Drug Use

- 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
- Assess the accessibility, quality and cost-effectiveness of care

Slide 6.8

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.

## Other Indicators

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

### Slide 6.9

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.

## **Strategies to Promote Rational Use**

Slide 6.10

## WHO-Recommended Interventions

A mandated multi-disciplinary national body to coordinate medicine use policies

Clinical guidelines

Essential medicines list

Drug and therapeutics committees

Problem-based learning in pharmacotherapy

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

### Slide 6.11

### ***Strategies to promote Rational Use***

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

- A mandated multi-disciplinary national body to coordinate medicine use policies
- Clinical guidelines
- Essential medicines list based on treatment choice
- Drug and therapeutics committees 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

## **Multidisciplinary National Body**

- Develop, implement and evaluate interventions to promote rational use of medicines
- Coordinate policy and strategies at national level, in both the public and private sectors

Slide 6.12

### ***Multidisciplinary National Body***

Many societal and health system factors, as well as professionals and many others, contribute to how medicines are used. Therefore, a multidisciplinary approach is needed to develop, implement and evaluate interventions to promote more rational use of medicines. A national regulatory authority is the agency that develops and implements most of the legislation and regulation on pharmaceuticals. Ensuring rational use will require many additional activities which will need coordination with many stakeholders. Thus a national body is needed to coordinate policy and strategies at national level, in both the public and private sectors.

## Multidisciplinary National Body



### Slide 6.13

The form this body takes may vary with the countries, but in all cases it should involve government (Ministry of Health), the health professions, academia, regulatory authorities, pharmaceutical industry, consumer groups and non-governmental organizations involved in health care.



## Multidisciplinary National Body

- PNDP
  - ✓ National Drug Committee to ensure pillars of PNDP were implemented
  - ✓ National Formulary Committee
- Philippine National Formulary System
  - ✓ Formulary Executive Committee

Slide 6.14

The Philippines enacted the PNDP in 1988. A National Drug Committee was formed to ensure that the pillars of the policy will be implemented. The Committee was later reconstituted to serve as the National Formulary Committee with the basic responsibility of revising the PNDP. The revision process was multisectoral and consultative, involving representatives from government health facilities, private hospitals, academe, and non-government organizations. In 2012, the Philippine National Formulary System (PNFS) was created with the FEC taking on the function of the NFC. The PNFS, through the FEC, Evidence Review Groups and a pool of Specialty Experts, is expected to develop a new format for the PNF and promote its use at the different levels of health care. The PNF is used as the basis for medicine procurement in all government health facilities and also as a guide in rational prescribing.

## Clinical Guidelines

- Standard treatment guidelines, prescribing policies
- Consist of systematically developed statements to help prescribers make decisions about appropriate treatments
- Evidence based clinical guidelines are critical to promoting rational use of medicines

Slide 6.15

### ***Clinical Guidelines***

Clinical guidelines (standard treatment guidelines, prescribing policies) consist of systematically developed statements to help prescribers make decisions about appropriate treatments for specific clinical conditions. Evidence based clinical guidelines are critical to promoting rational use of medicines.

## Clinical Guidelines

- Provide a benchmark of satisfactory diagnosis and treatment
- Proven way to promote more rational use of medicines
- Introduced with an official launch, training and wide dissemination
- Reinforced by prescription audit and feedback

Slide 6.16

Clinical guidelines provide a benchmark of satisfactory diagnosis and treatment against which comparison of actual treatments can be made, proven way to promote more rational use of medicines provided they are developed in a participatory way involving end-users and easy to read. Clinical guidelines must be introduced with an official launch, training and wide dissemination and reinforced by prescription audit and feedback.

Guidelines should be developed for each level of care (ranging from paramedical staff in primary health care clinics to specialist doctors in tertiary referral hospitals), based on prevalent clinical conditions and the skills of available prescribers. Evidence-based treatment recommendations and regular updating help to ensure credibility and acceptance of the guidelines by practitioners. Sufficient resources are needed to reimburse all those who contribute to the guidelines, and to cover the costs of printing, dissemination and training.

In the Philippines, clinical guidelines are used by the FEC in the deliberation involving medicines for inclusion into the PNF. The pool of Specialty Experts assists the committee by providing the current clinical guidelines being followed in their specific specializations. The utilization of clinical guidelines at the level of the hospitals depends on the presence of a functioning DTC.

## Essential Medicines List (EML)

- Makes medicine management easier
  - ✓ Procurement, storage, and distribution are easier with fewer items, and prescribing and dispensing are easier for professionals
- Based on national clinical guidelines
- RA 9184 specifies use of PNF in procurement

Slide 6.17

### ***Essential Medicines List***

The EML makes medicine management easier in all respects: procurement, storage, and distribution are easier with fewer items, and prescribing and dispensing are easier for professionals if they have to know about fewer items. A national EML should be based upon national clinical guidelines. Medicine selection should be done by a central committee with an agreed membership and using explicit, previously agreed criteria, based on efficacy, safety, quality, cost (which will vary locally) and cost-effectiveness. EMLs should be regularly updated and their introduction accompanied by an official launch, training and dissemination. Public sector procurement and distribution of medicines should be limited primarily to those medicines on the EML, and it must be ensured that only those health workers approved to use certain medicines are actually supplied with them.

The procurement law in the Philippines specifies the use of the PNF as the basis for the procurement of medicines using the budget allotted through General Appropriations. While many hospitals adhere to this practice, there are still those institutions which purchase medicines beyond the PNF which patients may pay out-of-pocket.

## **DTC/ PTC in Districts and Hospitals**

- Ensures the safe and effective use of medicines in the facility or area under its jurisdiction.
- Members should represent all the major specialties and the administration
- Clear objectives, a firm mandate, support by the senior hospital management, transparency, wide representation, technical competence, multidisciplinary approach, sufficient resources

Slide 6.18

### ***Drug and Therapeutics Committee in Districts and Hospitals***

A DTC ensures the safe and effective use of medicines in the facility or area under its jurisdiction. Such committees are well-established in developed countries as a successful way of promoting more rational, cost-effective use of medicines in hospitals. Governments may encourage hospitals to have DTCs by making it an accreditation requirement to various professional societies. DTC members should represent all the major specialties and the administration; they should also be independent and declare any conflict of interest. A senior doctor would usually be the chairperson and the chief pharmacist, the secretary.

Factors critical to success include: clear objectives; a firm mandate; support by the senior hospital management; transparency; wide representation; technical competence; a multidisciplinary approach; and sufficient resources to implement the DTC's decisions.

In the Philippines, DTCs of public hospitals fulfill their function by limiting medicines in the hospital formulary to those in the PNF. This is observed in hospitals with fully functional DTC. The scope of functions, though, varies from hospital to hospital. What is clear is that hospitals with active DTCs have better control of drug use in their institution and have better procurement practices.

## Problem-based Learning in Pharmacotherapy

- Quality of basic training in pharmacotherapy can significantly influence future prescribing
- Rational pharmacotherapy training must be linked to clinical guidelines and essential medicines lists
- Training is more successful if it is problem-based, concentrates on common clinical conditions, takes into account students' knowledge, attitudes and skills, and is targeted to the students' future prescribing requirements

Slide 6.19

### ***Problem-based Learning in Pharmacotherapy***

The quality of basic training in pharmacotherapy for undergraduate medical and allied medical students can significantly influence future prescribing. Rational pharmacotherapy training, linked to clinical guidelines and essential medicines lists, can help to establish good prescribing habits. Training is more successful if it is problem-based, concentrates on common clinical conditions, takes into account students' knowledge, attitudes and skills, and is targeted to the students' future prescribing requirements. The WHO Guide to Good Prescribing describes the problem based approach, which has been adopted in a number of medical schools.

Several medical schools in the Philippines had adopted the problem-based approach to medical education which takes into consideration analysis of patient cases and their individualized therapy. It is expected that medical students will prescribe more appropriate medicines after they have carefully assessed and analyzed patient, drug, and disease information.

With the adoption of problem-based approach to medical education, schools in the Philippines also adopted various learner-centered learning methods. These include small group discussion, case studies, patient case oral reporting with peer feedback, among others.

## Supervision, Audit, and Feedback

- Essential to ensure good quality of care.
- Supervision that is **supportive, educational** and **face-to-face**, will be more effective and better accepted by prescribers than simple inspection and punishment
- Effective forms of supervision:
  - ✓ Prescription audit and feedback
  - ✓ Peer review
  - ✓ Group processes

Slide 6.20

### ***Supervision, Audit and Feedback***

Supervision is essential to ensure good quality of care. Supervision that is supportive, educational and face-to-face, will be more effective and better accepted by prescribers than simple inspection and punishment. Effective forms of supervision include prescription audit and feedback, peer review and group processes. Prescription audit and feedback consists of analyzing prescription appropriateness and then giving feedback. Prescribers may be told how their prescribing compares with accepted guidelines or with that of their peers. Involving peers in audit and feedback (peer review) is particularly effective.

## Public Education about Medicines

- Education about medicines to consumers to ensure that expected clinical outcomes are achieved
- Ensure that OTC medicines are sold with adequate labelling and instructions
- Monitor and regulate advertising
- Run targeted public education campaigns

Slide 6.21

### ***Public Education about Medicines***

Without sufficient knowledge about the risks and benefits of using medicines, and when and how to use them, people may not get the expected clinical outcomes. In some cases, they may suffer from adverse effects. This is true for prescribed medicines, as well as over-the-counter medicines. The government has a responsibility to ensure both the quality of medicines and the quality of the information about medicines available to consumers. This will require:

- Ensuring that over-the-counter medicines are sold with adequate labelling and instructions that are accurate, legible, and easily understood by laypersons. The information should include the medicine name, indications, contra indications, dosages, drug interactions, and warnings concerning unsafe use or storage.
- Monitoring and regulating advertising, which may adversely influence consumers as well as prescribers, and which may occur through television, radio, newspapers and the internet.
- Running targeted public education campaigns, which take into account cultural beliefs and the influence of social factors. Education about the use of medicines may be introduced into the health education component of school curricula or into adult education programs, such as literacy courses.



## Regulatory Measures

Registration of medicines

Limiting prescription of medicines by level of prescriber

Setting educational standards for health professionals

Licensing of health professionals

Licensing of medicine outlets

Monitoring and regulating medicine promotion

Slide 6.22

### ***Regulatory Measures to Support Rational Use***

Some regulatory measures to promote rational use include:

- Registration of medicines to ensure that only safe efficacious medicines of good quality are available in the market and that unsafe non-efficacious medicines are banned;
- Limiting prescription of medicines by level of prescriber; this includes limiting certain medicines to being available only with a prescription and not available over-the-counter;
- Setting educational standards for health professionals and developing and enforcing codes of conduct; this requires the cooperation of the professional societies and universities;
- Licensing of health professionals – doctors, nurses, pharmacies – to ensure that all practitioners have the necessary competence with regard to diagnosis, prescribing and dispensing;
- Licensing of medicine outlets – retail shops, wholesalers – to ensure that all supply outlets maintain the necessary stocking and dispensing standards;
- Monitoring and regulating medicine promotion to ensure that it is ethical and unbiased. All promotional claims should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. WHO's ethical guidelines (1988) may be used as a basis for developing control measures.

## Slide 6.22

Based on current practices in the Philippines, the pharmaceutical industry has to comply with the labelling requirements of the FDA and include all the necessary prescribing information on the immediate label of the medicine container and package insert. In doing so, the prescriber has sufficient information about the appropriate use of the medicine. However, unethical practices still prevail among some practitioners as they are still influenced by heavy advertising and unfair marketing schemes. The impending issuance of the DOH's support for the Mexico Principles in Business Ethics is seen as a deterrent to improper practices in the pharmaceutical industry.

## Pharmacovigilance

- The detection, assessment and prevention of adverse drug reactions
- Requires the rapid transmission of drug information detected by monitoring systems
- One of the components of patient safety that should be implemented in every health facility

Slide 6.23

### **Pharmacovigilance**

The detection, assessment and prevention of adverse drug reactions, known as *pharmacovigilance*, is also becoming increasingly important. Pharmacovigilance requires the rapid transmission of drug information detected by monitoring systems used both nationally and internationally. The information it provides is very useful for prescribing and for patient counselling and efforts are needed to improve the dissemination of this information at all levels. A policy on pharmacovigilance including the implementation of a workable reporting system must be created from the national level down to the primary care level.

Pharmacovigilance is one of the components of patient safety that should be implemented in every health facility. While a number of tertiary hospitals have patient safety programs, there has been poor reporting of adverse drug effects and other drug-related events among Philippine hospitals and smaller health facilities. Currently, Philippine FDA is reviewing its pharmacovigilance guidelines to ensure better feedback mechanism from health facilities.

### **Sufficient Government Expenditure to Ensure Availability of Medicines and Staff**

- Lack of essential medicines leads to the use of nonessential medicines, and lack of appropriately trained personnel leads to irrational prescribing by untrained personnel
- Poor clinical outcome, needless suffering and economic waste are sufficient reasons for large government investment
- Funds are necessary to ensure that all public health facilities have sufficient, appropriately trained health professionals and enough essential medicines at affordable

Slide 6.24

### ***Sufficient Government Expenditure to ensure Availability of Medicines and Staff***

Lack of essential medicines leads to the use of nonessential medicines, and lack of appropriately trained personnel leads to irrational prescribing by untrained personnel. Furthermore, without sufficient competent personnel and finances, it is impossible to carry out any of the core components of a national program to promote rational use of medicines. Poor clinical outcome, needless suffering and economic waste are sufficient reasons for large government investment.

Governments are responsible for investing the necessary funds to ensure that all public health facilities have sufficient, appropriately trained health professionals and enough essential medicines at affordable prices for all the population, with specific provisions for the poor and disadvantaged. Achieving these will require limiting government procurement and supply to essential medicines only, and investing in adequate training, supervision and health staff salaries.

## Review 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.

Slide 6.25

After the lecture, ask the participants to answer Review Questions found in their manuals. After 10-15 minutes, discuss the answers.

## Answers

1. Rational use of medicines means, “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”.
2. Prescribing, transcribing, dispensing, administering, monitoring
3. Average consultation time, Average dispensing time, Percentage of medicines actually dispensed, Percentage of medicines adequately labelled, Percentage of patients with knowledge of correct dose
4. Problem-based learning, continuing in-service medical education, supervision, audit, and feedback
5. Registration of medicines to ensure that only safe efficacious medicines of good quality are available in the market; Limiting prescription of medicines by level of prescriber; Setting educational standards for health professionals and developing and enforcing codes of conduct; Licensing of health professionals; Licensing of medicine outlets; and Monitoring and regulating medicine promotion

## Group Activity

- I. For the following irrational use of medicines, recommend two solutions to address them:

Factors hindering monitoring of irrational use	Recommendations
Lack of public awareness of the scale of the problem and its economic and health costs	
Decision-makers' lack of knowledge of the most cost-effective ways to tackle irrational use	
Lack of financial and human resources	
High cost of medicines	

Slide 6.26

**Materials Needed:** Manila paper, markers

### Instructions to Facilitators:

Ask the participants to group themselves into 5. Ask them to assign a facilitator and a reporter. Distribute 1 Manila paper and permanent marker per group. After 30-45 minutes, ask the groups to report their outputs. Give each group 5-7 minutes to present their outputs.

## Group Activity

2. What programs should be developed at the national level to encourage rational use of medicines? Please provide specific recommendation or action.

Slide 6.27

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# **Pharmaceutical Donations**



## Pharmaceutical Donations

Slide 7.1

### Session Objectives:

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
5. Formulate policy recommendations related to pharmaceutical donations

Slide 7.2

Present the learning objectives for the session.

## Introduction

- Large quantities of donated pharmaceuticals
  - ▶ Pharmaceuticals may arrive past or near expiry
  - ▶ In extremely large or unwanted quantities
  - ▶ Labelled in a foreign language
  - ▶ Unwanted or not needed in the particular area



### Slide 7.3

#### **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, labelled in a foreign language or simply unwanted or not needed in the particular area. These problems necessitate clear policies to guide both donors and recipients and hence maximize the potential benefit of pharmaceutical donations.



Slide 7.4

Inappropriate pharmaceutical donations create logistical problems because donated products must be sorted, stored and distributed, sometimes using precious resources and transport volume in disaster area or war zones. They may also pose an environmental threat if they have to be destroyed. Often the total transport costs are higher than the value of pharmaceuticals. Stockpiling of unused pharmaceuticals can encourage pilfering and black market sales.

Even donations that are appropriate in every way can cause problems when they far surpass the quantities that are needed.

## The Philippine Experience



### Slide 7.5

The same problems were experienced especially during the typhoon Yolanda.

## Need for Guidelines

Donor and recipient do not communicate on equal terms

Donors mean well but do not realize the difficulties at the receiving end

Pharmaceutical needs vary by county and by situation

Medicines are different from donated items

Slide 7.6

### **Need for Guidelines**

These problems necessitate the need for clear policies to guide both donors and recipients and hence maximize the potential benefit of drug donations.

Guidelines are needed because:

- Donor and recipient do not communicate on equal terms. The recipients therefore need assistance in specifying how they want to be helped.
- Donors mean well but do not realize the difficulties at the receiving end, and therefore need guidance.
- Pharmaceutical needs vary by country and by situation. Donations should be based on analysis of actual needs and selection and distribution must fit within pharmaceutical policies and administrative systems. Inappropriate donations frustrate the implementation of national policies and programs to promote rational drug use.
- Medicines are different from other donated items. Medicines can be harmful. They require labels and written information. They need special storage conditions and adequately trained personnel to be used effectively. They may expire and need to be destroyed in a particular way.

## WHO Core Principles

Maximum benefit to  
the recipient

Respect for wishes  
and authority of the  
recipient

No double  
standards in quality

Effective  
communication  
between donor and  
recipient

Slide 7.7

### *WHO Core Principles for Accepting Donations*

WHO identified four core principles for a useful pharmaceutical donation:

1. A donation benefits the recipient to the maximum extent possible.
2. Donation should be given with full respect for the wishes and authority of the recipient.
3. Items that are not acceptable in the donor country for quality-related reasons are also not acceptable as donations.
4. Effective communication between donor and recipient is necessary before any donation.



## WHO Guidelines for Accepting Donations

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.

Slide 7.8

### **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.** Specify medicine needs according to the needs of the country rather than based on quantities and medicine formulations proposed by donors.
- **Appoint a medicines donation coordinator.** Appoint one officer, preferably a staff member of the medicines regulatory authority (MRA), who has explicit and final responsibility for all donation matters.
- **Describe and develop official documentation required for medicine donations.** Develop text for national guidelines for medicine donations and ensure that the guidelines are adopted by the relevant authorities. Disseminate guidelines among all concerned departments, including the Ministry of Finance, customs, port and airport authorities, government clearing agents, etc. Donated medicines should be exempted from port-of-entry excise tax and other duties.

## Slide 7.8

- **Describe the registration requirements.** Describe whether donated medicines should be registered with the MRA, exempt from registration, or follow a fast-track registration process.
- **Describe procedures for unacceptable products.** Describe what procedures to follow when donations do not meet the national guidelines. These procedures should be defined in unambiguous standard operating procedures, which should follow those the MRA requires for good quality medicines arriving in the country.

## AO 2007-0017

- ▶ 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

Slide 7.9

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

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.

## Criteria for Accepting Donations

Shelf life of at least 12 months from the time of arrival to the Philippines

Labelling with English translation or in a language understood by health professionals

Packaging that complies to international shipping regulations accompanied by a detailed packing list

### Slide 7.10

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;
- Labelling with English translation or in a language understood by health professionals;
- Packaging that complies to international shipping regulations accompanied by a detailed packing list;
- 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.

## Criteria for Accepting Donations

Weight per carton should not exceed 50 kg

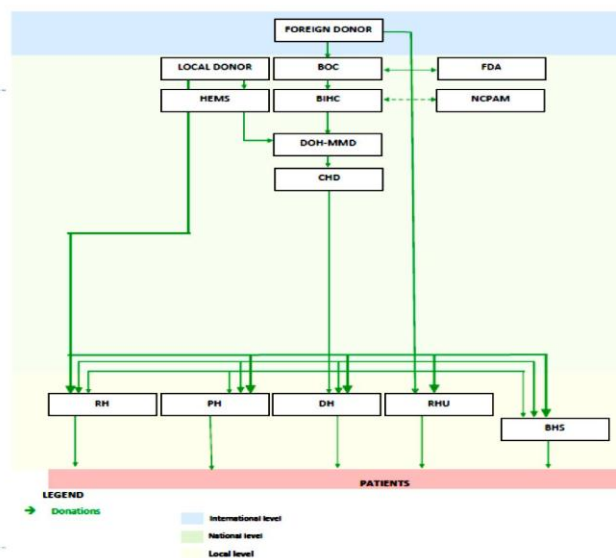
Exclusive packaging with regard other supplies

Documentary proof of compliance to applicable quality standards

Documentary proof that items are obtained from reliable sources

Slide 7.11

## The Philippine System for Donations during Disasters and Emergencies



Slide 7.12

The preceding illustration 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 the 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 Regional CHD. The donations are at 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

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)

## Slide 7.12

***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.



## Review Question

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.

Slide 7.13

After the lecture, ask the participants to answer Review Questions found in their manuals. After 10-15 minutes, discuss the answers.

### Answers

1. Shelf life of at least 12 months from the time of arrival to the Philippines;  
Labelling 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.
2. Check of acceptability of answers.
3. Check for adequateness of SOP.

### Review Question

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?

Slide 7.14

### Answers

4. Bureau of International Health Cooperation (BHIC)
5. A.O. 2007-0017

## Group Activity

1. What policy recommendation or action would be necessary so that the criteria for accepting donations are complied with from national down to local health care facilities? Please provide specific recommendation or action.

Slide 7.15

**Materials Needed:** Manila paper, markers

### Instructions to Facilitators:

Ask the participants to group themselves into 5. Ask them to assign a facilitator and a reporter. Distribute 1 Manila paper and permanent marker per group. After 30-45 minutes, ask the groups to report their outputs. Give each group 5-7 minutes to present their outputs.

### *References*

Administrative Order 2007-0017. 2007. Guidelines on the Acceptance and Processing of Foreign and Local Donations During Emergency and Disaster Situations.

THE UNITED STATES PHARMACOPEIAL CONVENTION. 2007. Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide. Rockville, Maryland: United States Pharmacopeia.

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# **Disposal of Pharmaceuticals**

## Disposal of Pharmaceuticals



### Slide 8.1

Before the training, read the **WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals**. A photocopy of the Guideline is provided in a separate booklet.

### ***Introduction***

In times of disasters, calamities and other emergencies, large quantities of pharmaceuticals are often donated as part of assistance. And while many of these save lives by addressing the medical needs of the affected areas, a significant number of these pharmaceuticals may also cause problems. Some pharmaceuticals may arrive past or near expiry, in extremely large or unwanted quantities, labelled in a foreign language or simply unwanted or not needed in the particular area. These problems result to additional concerns of inadequate storage rooms and disposal. Safe disposal of these expired or unwanted pharmaceuticals is often a major problem for the RHU especially that it also entails additional resources.

## Session Objectives

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
4. Identify the appropriate disposal method for a sorting category

Slide 8.2

Present the learning objectives for the session.

## Importance of Safe Disposal

Contamination of water supplies

Reduction or destruction of bacteria necessary for treatment of sewage

Release of toxic pollutants into the air

Diversion for resale of expired drugs to the general public

Slide 8.3

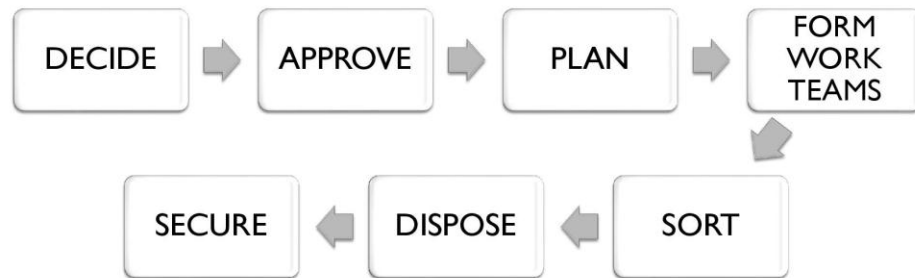
### ***Importance of Safe Disposal***

Safe disposal of unwanted pharmaceuticals is a necessary task because of the possible threat to public health and/ or 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 or local sources used by nearby communities or wildlife.
- Reduction or destruction of bacteria necessary for treatment of sewage when non-biodegradable antibiotics, antineoplastics and disinfectants when thrown into the sewage. Antineoplastics flushed into watercourses may damage aquatic life or contaminate drinking water.
- Release of toxic pollutants into the air when burning pharmaceuticals at low temperatures or in open containers.
- Diversion for resale of expired drugs to the general public due to inefficient and insecure sorting and disposal. Most pharmaceuticals past their expiry date become less efficacious and some may develop a different adverse drug reaction profile.



## Steps in Disposal



Slide 8.4

### ***Steps in Disposal***

Disposal of unwanted pharmaceuticals may require a series of steps to be taken. These steps are outlined in this slide.

## Slide 8.4

Disposal of unwanted pharmaceuticals may require a series of steps to be taken:

1. DECIDE (Decide when action needs to be taken)
2. APPROVE (Seek approval of disposal from the appropriate authority)
3. PLAN (Plan in terms of funding, necessary expertise, human resources, professional time, space, equipment, material and available disposal option)
4. FORM WORK TEAMS (Organize team that will be responsible for the task)
5. SORT (Separate the pharmaceuticals into separate categories for which different disposal methods are required)
6. DISPOSE (Dispose the unwanted pharmaceutical using the appropriate method)
7. SECURE (Ensure security of disposed pharmaceuticals)

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

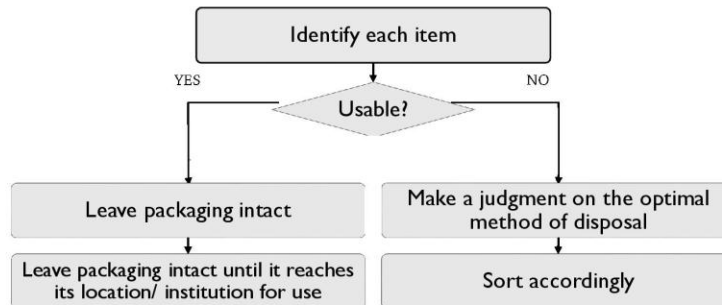
- Separate pharmaceuticals into categories that require disposal methods
- Dosage form is the primary criterion for disposal

Slide 8.5

### ***Sorting***

Sorting is to separate pharmaceuticals into categories that require disposal methods. The dosage form of the drug/ medicine is a primary criterion in determining the appropriate safe disposal method. 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.

## The Sorting Process



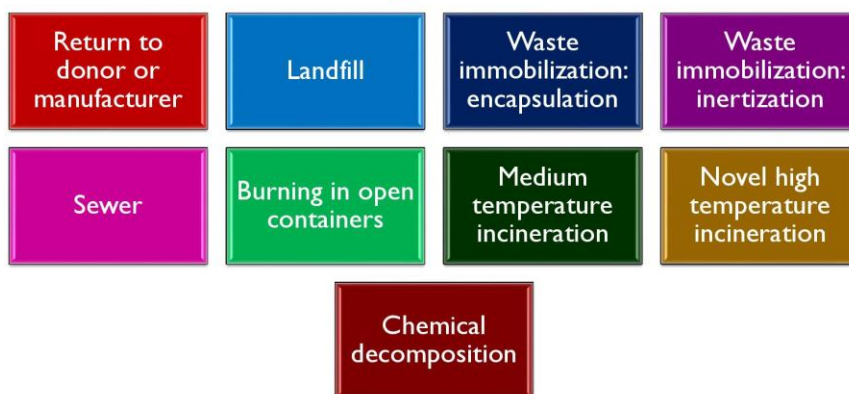
### Slide 8.6

Separated temporary storage areas must be provided for each sorted category. The sorting process includes:

- Identify each item;
- Make a decision on whether it is usable;
- If usable, leave packaging intact;
- Leave packaging intact until it reaches its location/ institution for use;
- If not usable, make a judgment on the optimal method of disposal; and
- Sort accordingly.

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, labelled properly and stored in a dry, secure and preferably separate room (from other pharmaceuticals) until disposal is carried out.

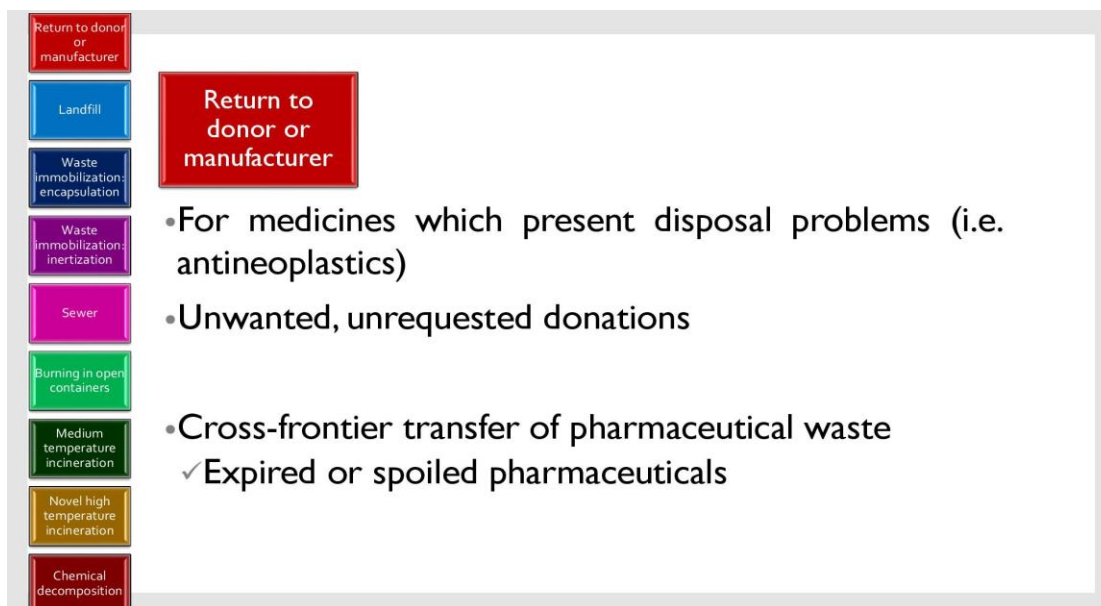
## Methods of Disposal



Slide 8.7

### ***Methods of Disposal***

There are several methods that can be employed to dispose unwanted pharmaceuticals. These methods have its advantages and disadvantages and may be appropriate for specific types of pharmaceuticals only. A summary of the advantages and disadvantages of the different disposal methods is provided in the Participant's Manual.



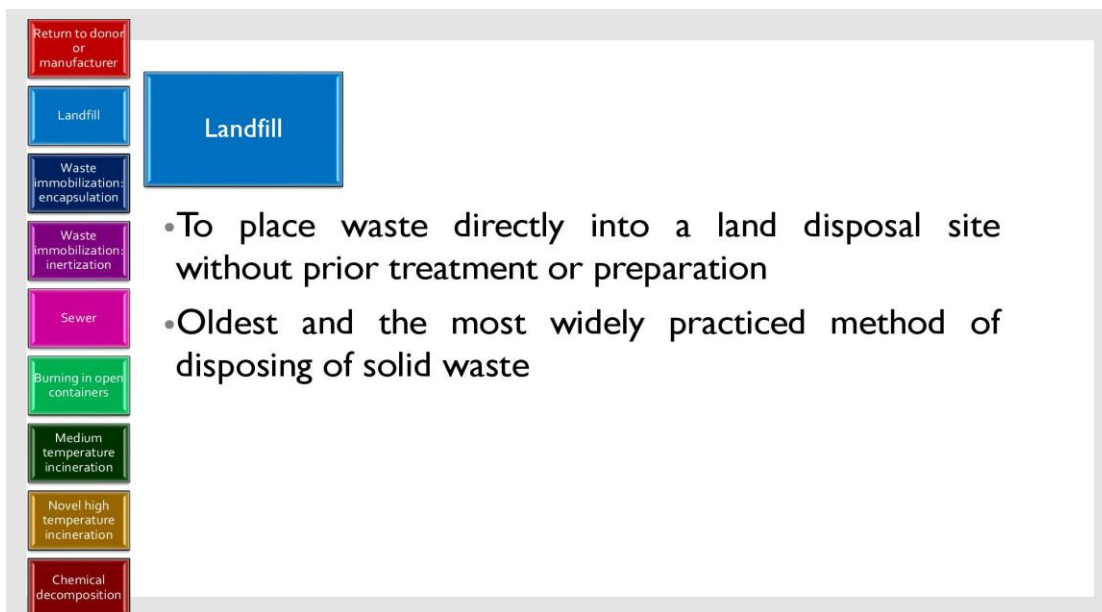
Slide 8.8

### ***Return to Donor or Manufacturer***

Wherever practical the possibility of returning unusable drugs for safe disposal by the manufacturer should be explored; particularly drugs which present disposal problems, such as antineoplastics. For unwanted, unrequested donations, especially those that arrive past or unreasonably near their expiry date it may be possible to return them to the donor for disposal.

Cross-frontier transfer of pharmaceutical waste:

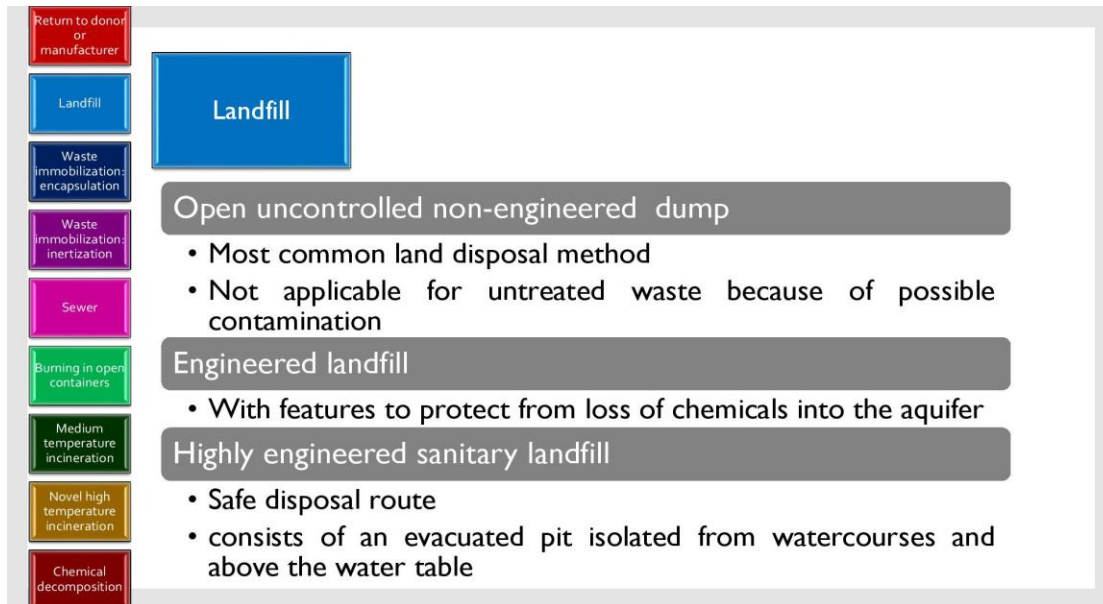
- There are currently no international conventions regulating transfer of pharmaceutical products across frontiers. However, expired or spoiled pharmaceuticals are considered as hazardous waste and as such, if transferred across frontiers, become regulated and subject to the Basel Convention on the Transfrontier Shipment of Hazardous Wastes. This involves prescribed procedures to obtain permission to cross international borders along the transit route prior to actual transport. These procedures can take several months to complete.



Slide 8.9

***Landfill***

To landfill means to place waste directly into a land disposal site without prior treatment or preparation. It is the oldest and the most widely practiced method of disposing of solid waste.

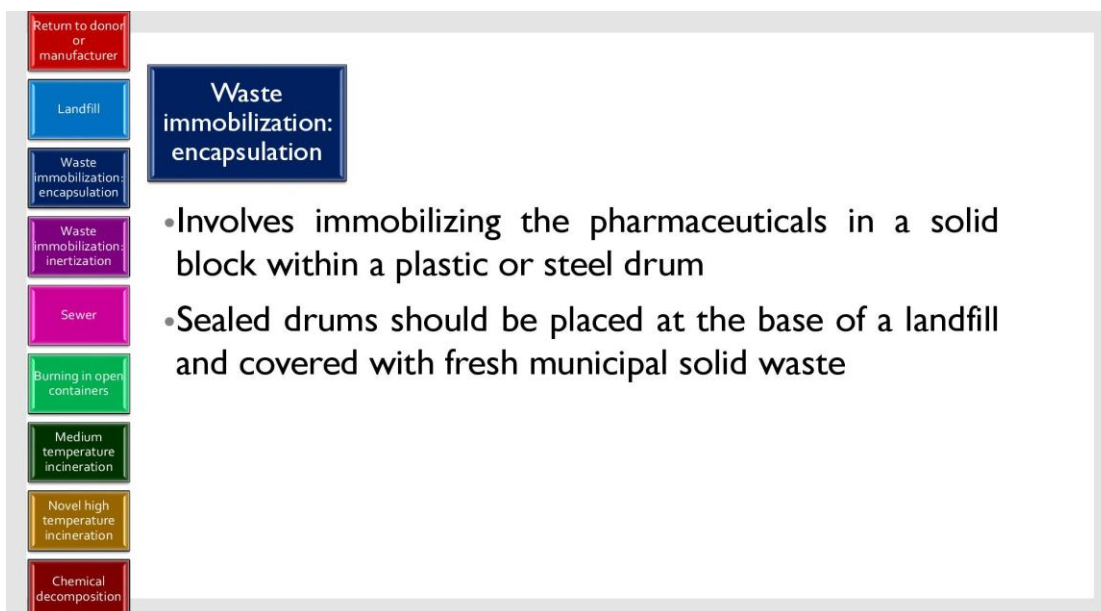


Slide 8.10

There are three types of landfill:

- Open controlled non-engineered type – This is the most common land disposal method in developing countries. Discarding of untreated waste pharmaceuticals into such a site is not recommended because of possible contamination
- Engineered landfill – This type of landfill has some features to protect from loss of chemicals into the aquifer.
- Highly engineered sanitary landfill – This landfill offers a relatively safe disposal route for municipal solid wastes, including pharmaceuticals because it is able to protect the aquifer.

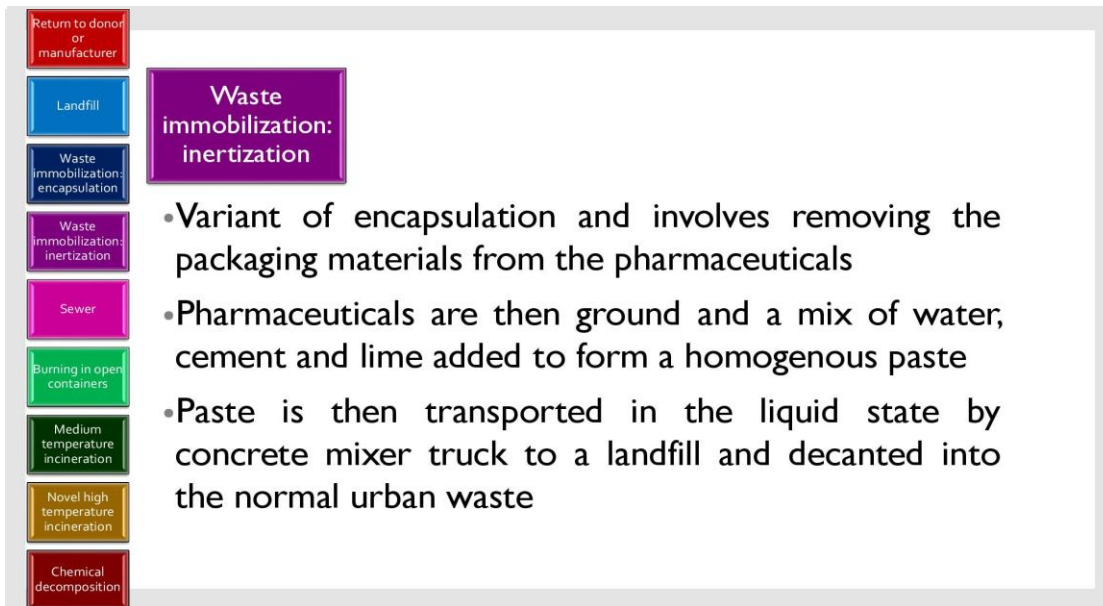




Slide 8.11

***Waste Immobilization: Encapsulation***

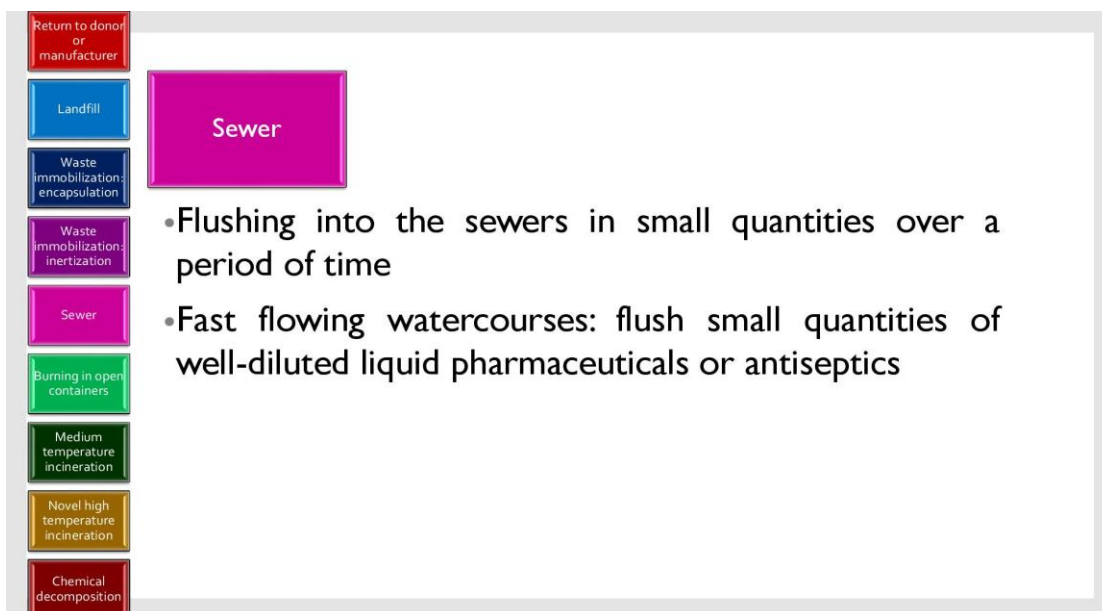
Encapsulation involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum. Drums should be cleaned prior to use and should not have contained explosive or hazardous materials previously.



Slide 8.12

### ***Waste Immobilization: Inertization***

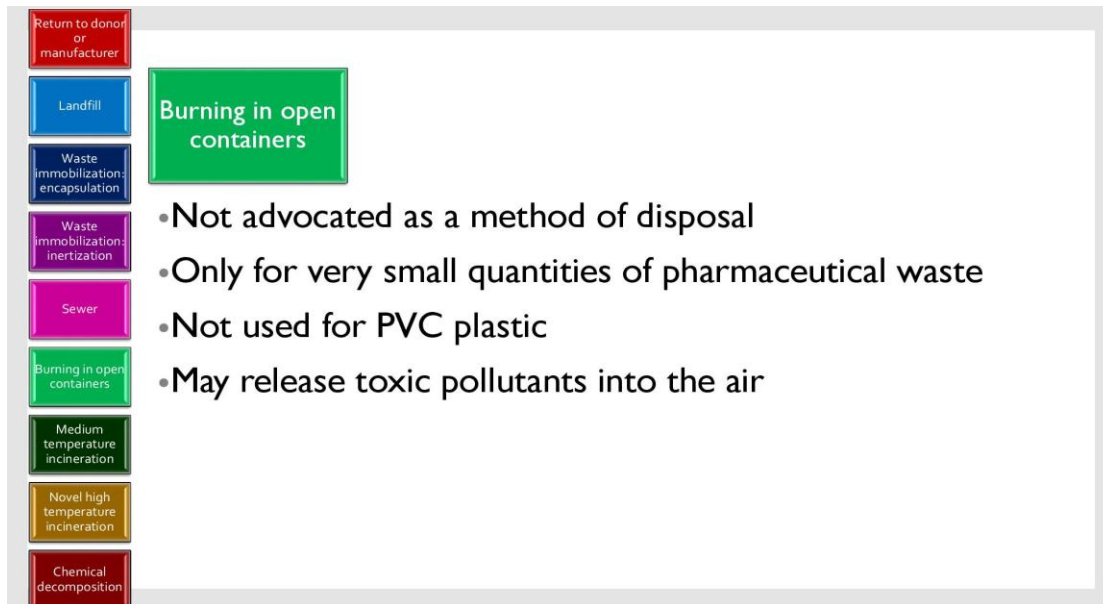
Inertization is a variant of encapsulation and involves removing the packaging materials, paper, cardboard and plastic from the pharmaceuticals. This process is relatively inexpensive and may be carried out using unsophisticated equipment.



Slide 8.13

### **Sewer**

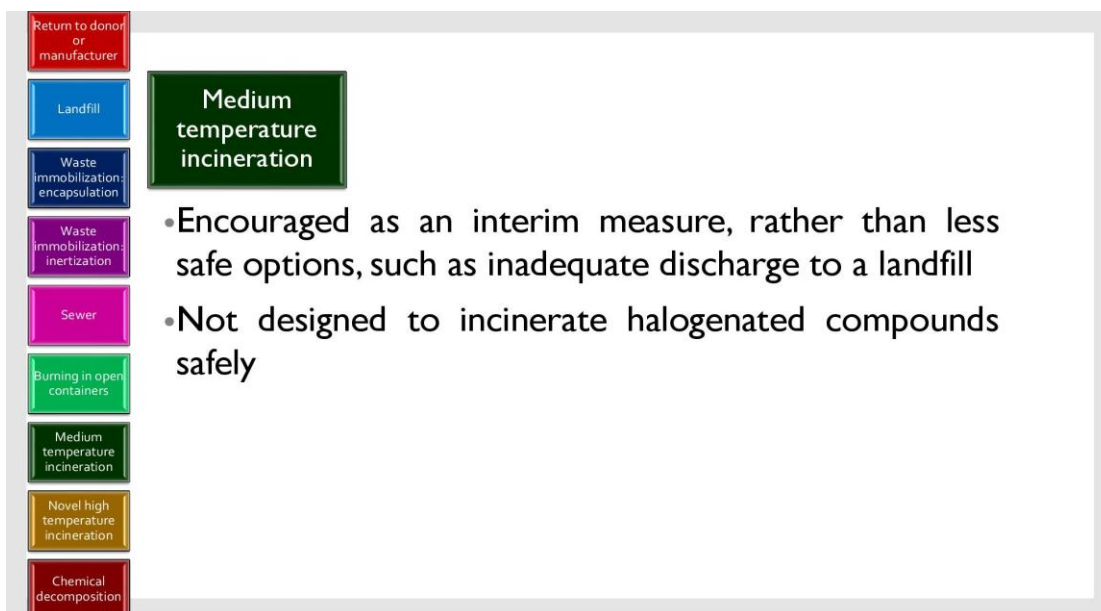
Some liquid pharmaceuticals such as syrups and intravenous fluids can be diluted with water and flushed into the sewers in small quantities over a period of time without serious public health or environmental effect. Fast flowing watercourses may also be used to flush small quantities of well-diluted liquid pharmaceuticals or antiseptics.



Slide 8.14

### ***Burning in Open Containers***

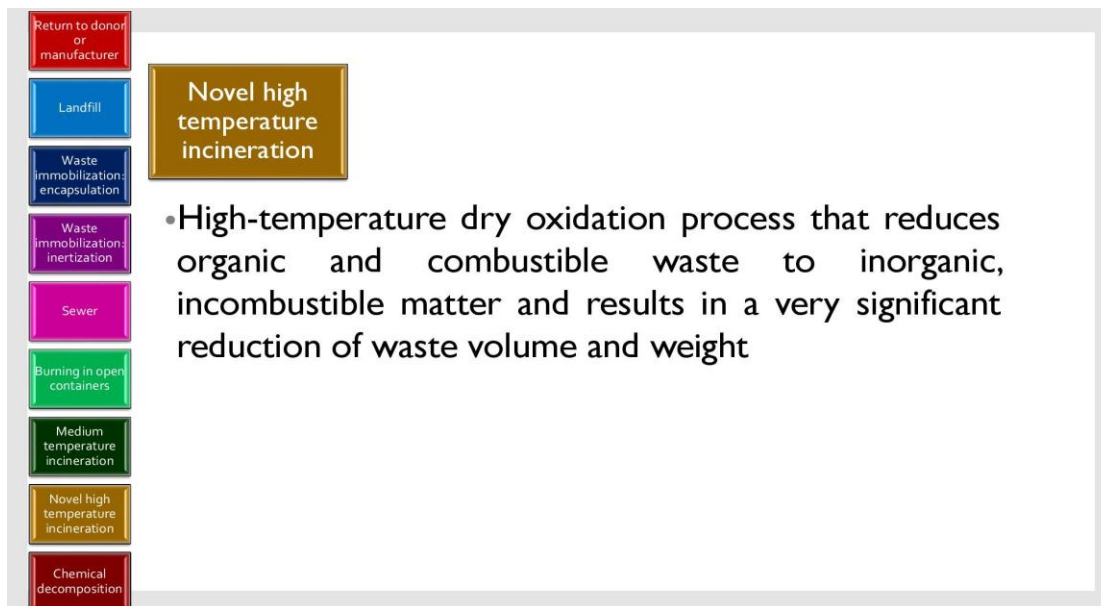
Burning in open containers is not advocated as a disposal method because toxic pollutants may be released into the air. If this method will be used, it is strongly recommended that only very small quantities of waste pharmaceuticals be disposed in this manner. Paper and cardboard packaging, if they are not to be recycled, may be burnt. Polyvinyl Chloride (PVC) plastic however must not be burnt.



Slide 8.15

### ***Medium Temperature Incineration***

Medium temperature incinerators encouraged as an interim measure, rather than the less safe options such as inadequate discharge to landfill. These incinerators are not designed to incinerate halogenated compounds safely. If medium temperature incinerators will be used, it is recommended that the pharmaceutical waste is diluted with large quantities of municipal waste (1:1000).

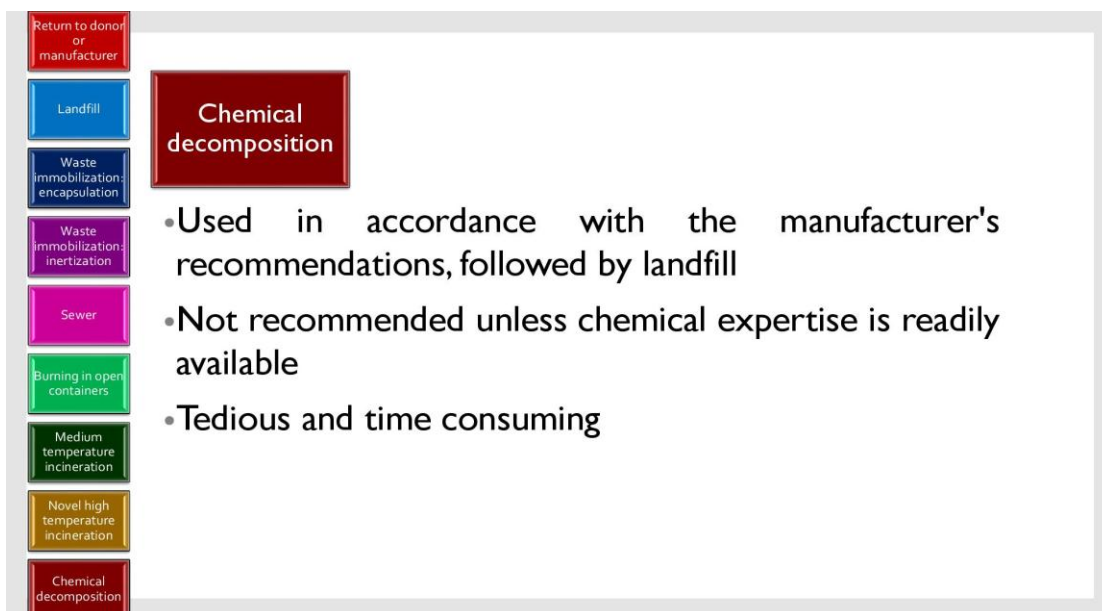


Slide 8.16

### ***Novel High-temperature Incineration***

Incineration is a high-temperature dry oxidation process that reduces organic and combustible waste to inorganic, incombustible matter and results in a very significant reduction of waste volume and weight.

It should be noted however that the Philippine Clean Air Act (RA 8749) of 1999 which sets the standards for environmental protection while pursuing national development 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.



Slide 8.17

### ***Chemical Disposition***

The option of chemical decomposition can be used in accordance with the manufacturer's recommendations followed by landfill. This method is tedious and time consuming and is not recommended unless chemical expertise is readily available.

## Pharmaceutical Categories

Solids, semi-solids and powders (tablets, capsules, granules, powders for injection, mixtures, creams, lotions, suppositories etc.)

Liquids (solutions, suspensions, syrups etc.)

Aerosol containers (including propellant-driven sprays and inhalers)

Slide 8.18

### ***Recommended Disposal Methods***

In sorting, the top priority is to separate out the pharmaceuticals that are categorized as controlled substances, antineoplastics and any other non-pharmaceutical products that may have been mixed among the pharmaceuticals. These should be stored in separate, secure areas prior to safe disposal. The remaining unwanted pharmaceuticals should be sorted into different categories by dosage form:

- Solids, semi-solids and powders (tablets, capsules, granules, powders for injection, mixtures, creams, lotions, suppositories etc.)
- Liquids (solutions, suspensions, syrups etc.)
- Aerosol containers (including propellant-driven sprays and inhalers)





## Solids, Semi-solids and Powders

- Anti-infective drugs, controlled drugs & antineoplastics
  - ✓ Return to manufacturer
  - ✓ Encapsulation or inertization before discharge to landfill
- Other drugs
  - ✓ Not more than 1% → landfill

Slide 8.19

### ***Solids, Semi-solids and Powders***

For solids, semi-solids and powders the following are the recommended disposal methods:

Anti-infective drugs, controlled drugs & antineoplastic

- Return to manufacturer
- Encapsulation or inertization

Other drugs

- If the quantities of solid and semi-solid pharmaceuticals is not more than 1% of the total daily waste, landfill may be used



## Liquids

- Pharmaceuticals with no or low toxicity
  - ✓ Sewer
  - ✓ Dilute with large volume of water then poured into large watercourses
  - ✓ Cement encapsulation procedure
  - ✓ Never in slow moving or stagnant surface waters



Slide 8.20

### **Liquids**

For liquid preparations the following are the recommended disposal methods:

Pharmaceuticals with no or low toxicity

- Sewer

Other liquid pharmaceuticals (except controlled drugs, antineoplastics or anti-infectives)

- Sewer
- Dilute with large volumes of water then poured into large watercourses
- Cement encapsulation procedure
- Never in slow moving or stagnant surface waters



## Ampoules

- Crushed on a hard impermeable surface
- Not burnt or incinerated as they will explode, possibly causing injury to operators and damage to the furnace or incinerator
- Volatile liquids in small quantities can be allowed to evaporate in the open air

Slide 8.21

### **Ampoules**

Ampoules of antineoplastics or anti-infective drugs must not be crushed and the liquid discharged to sewers. They should be treated using the encapsulation or inertization disposal methods described above.



## Anti-infective Drugs

- Drugs should not be discarded in an untreated form
- Encapsulated or inertized
- May be diluted in water, left for two weeks and disposed to the sewer

Slide 8.22

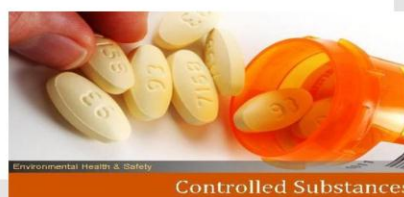
### ***Anti-infectives***

Anti-infective medicines should not be discarded in an untreated form. They may be encapsulated or inertized or they may be diluted in water, left for two weeks and disposed to the sewer.



## Controlled Substances

- Destroyed under supervision of a pharmacist or the police depending on national regulations
- Rendered unusable, by encapsulation, or inertization, and then dispersed among the municipal solid waste in a landfill
- Incineration



Environmental Health & Safety  
Controlled Substances

Slide 8.23

### **Controlled Substances**

Controlled substances must be destroyed under the supervision of a pharmacist or the police depending on national regulations. Such substances must not be allowed into the public domain as they may be abused. These should either be rendered unusable by encapsulation or inertization and then dispersed among the municipal solid waste in a landfill or incinerated.



## Antineoplastics

- Returned to the supplier for disposal
- Waste encapsulation
- Do not use:
  - ✓ Low and medium temperature incineration
  - ✓ Disposal to sewers and water courses
  - ✓ Directly to landfill

Slide 8.24

### ***Antineoplastics***

Antineoplastic medicines have the ability to kill or stop growth of living cells. These are used in the chemotherapy of cancer which is usually performed in specialized treatment centers. Antineoplastics should never be discharged into the environment because of serious environmental threats.

Antineoplastics should be segregated from other pharmaceuticals and kept separately in clearly marked containers with rigid walls. Ideally, these should be safely packaged and returned to the supplier for disposal. Another option is waste encapsulation.



## Disinfectants

- Store and gradually use
- Large quantities of disinfectants must not be flushed into the sewer
- To sewer or fast-flowing watercourse: small quantities of diluted disinfectants (max. 50 L/day under supervision)



Slide 8.25

### ***Disinfectants***

In general disinfectants do not have an expiry date. As such these can be stored and gradually used over time. Large quantities of disinfectants must not be flushed into the sewer, as they may kill the bacteria in a sewage works and so stop the biological treatment of the sewage. Similarly large quantities should not be put into watercourses since the disinfectants will damage aquatic life. Small quantities of diluted disinfectant may be disposed of by discharge to a sewer providing the operation is supervised by a pharmacist and the quantities are strictly controlled to set limits.





## Aerosol Containers

- Do not burn or incinerate
- Disposed of in a landfill, dispersed among municipal solid wastes

Slide 8.26

### **Aerosols**

Disposable aerosol canisters and inhalers should not be burnt or incinerated, as high temperatures may cause them to explode, possibly causing injury to operators and/or damage to the furnace or incinerator. Provided they do not contain poisonous substances they should be disposed of in a landfill, dispersed among municipal solid wastes.



## Review Questions

1. What are the negative effects of improper disposal to the environment?
2. Outline the steps in the safe disposal of pharmaceutical products.

Slide 8.27

After the lecture, ask the participants to answer the Review Questions found in their manuals. After 10-15 minutes, discuss the answers.

### Answers

1. Contamination of water supplies and damage to aquatic life;  
Reduction or destruction of bacteria necessary for treatment of sewage;  
Release of toxic pollutants into the air; and  
Diversion for resale of expired drugs to the general public
2. Steps in Disposal: decide, approve, plan, form work teams, sort, dispose, secure

## Review Questions

Type of medicines	Disposal Method
Antineoplastics	
Syrups	
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?

Slide 8.28

### Answers

3. Antineoplastics: Return to donor/ manufacturer  
Syrup: Sewer/ fast-flowing watercourse  
Untreated solids, semi-solids, and powders: Landfill
4. Department of Environment and Natural Resources
5. Incineration (all forms)

## Group Activity

1. Divide the participants into groups. Ask them to assign a facilitator and reporter.
2. Ask the groups to discuss answers and present their outputs, after 30-45 minutes, to the following questions:
  - What policies should be in place regarding disposal of medicines?
  - What monitoring mechanism should be developed to ensure compliance with proper disposal of medicines? Please provide specific recommendation or action.

Slide 8.29

**Materials Needed:** Manila paper, markers

### Instructions to Facilitators:

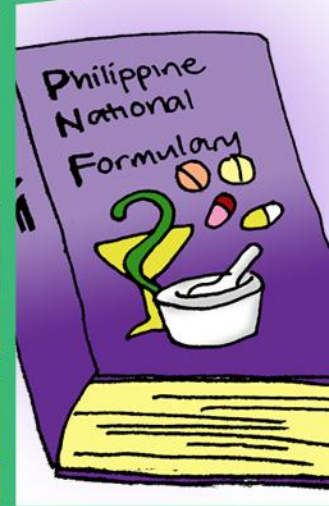
Ask the participants to group themselves into 5. Ask them to assign a facilitator and a reporter. Distribute 1 Manila paper and permanent marker per group. After 30-45 minutes, ask the groups to report their outputs. Give each group 5-7 minutes to present their outputs.

## References

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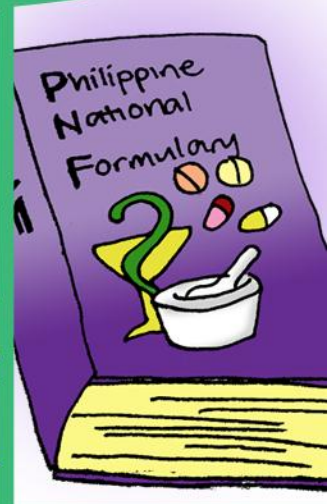




# Training Manual on Pharmaceutical Supply Chain Management

TRAINER'S MANUAL

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



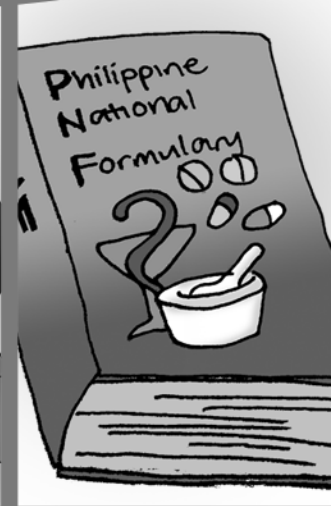
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# How to Use this Manual

This “Training Manual on Pharmaceutical Supply Chain Management for Department of Health (DOH) National Agencies and Centers for Health and Development (CHDs)” is meant to guide facilitators in the conduct of the training. The PowerPoint presentations for each of the steps in the drug or medicine management cycle are found in this Manual. More importantly it includes explanation for each slide to guide lecturers/ facilitators in the discussion. Important readings referred to in this Manual are found in a separate booklet (Appendix). At the end of each step of the cycle, review questions and answer to these questions are found. The Training Manual is color coded. Different colors are used for each step and topic in the drug management cycle – Yellow Green (Philippine Health Care System), Green (Principles of Drug Management), Violet (Selection of Medicines), Orange (Procurement of Medicines), Blue (Storage and Distribution of Medicines), Red (Use of Medicines), Yellow (Pharmaceutical Donations), and Gray (Disposal of Pharmaceuticals).

The instructional design for the entire training is found at the end of the manual.

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# Glossary of Abbreviations

<b>AHA</b>	Aquino Health Agenda
<b>API</b>	Active Pharmaceutical Ingredient
<b>BAC</b>	Bids and Awards Committee
<b>BHS</b>	Barangay Health Station
<b>BnB</b>	Botika ng Barangay
<b>BOC</b>	Bureau of Customs
<b>CPR</b>	Certificate of Product Registration
<b>DH</b>	District Hospital
<b>DOH</b>	Department of Health
<b>DTC</b>	Drug and Therapeutics Committee
<b>DTI</b>	Department of Trade and Industry
<b>EML</b>	Essential Medicines List
<b>FDA</b>	Food and Drug Administration
<b>FEC</b>	Formulary Executive Committee
<b>FEFO</b>	First to Expire, First Out
<b>FIFO</b>	First In, First Out

# Glossary of Abbreviations



<b>HEMS</b>	Health Emergency Management Staff
<b>HSRA</b>	Health Sector Reform Agenda
<b>INRUD</b>	International Network for the Rational Use of Drugs
<b>KP</b>	Kalusugang Pangkalahatan
<b>LGU</b>	Local Government Unit
<b>LTO</b>	License to Operate
<b>MDG</b>	Millenium Development Goals
<b>MMD</b>	Materials Management Division
<b>MRA</b>	Medicines Regulatory Authority
<b>MSDS</b>	Material Safety Data Sheets
<b>NHIP</b>	National Health Insurance Program
<b>NRA</b>	National Reform Agenda
<b>OTC</b>	Over the Counter
<b>PH</b>	Provincial Hospital
<b>PHC</b>	Primary Health Care



# Glossary of Abbreviations

<b>PITC</b>	Philippine International Trading Corporation
<b>PMP</b>	Philippine Medicines Policy
<b>PNDP</b>	Philippine National Drug Policy
<b>PNF</b>	Philippine National Formulary
<b>PNFS</b>	Philippine National Formulary System
<b>PTC</b>	Pharmacy and Therapeutics Committee
<b>RA</b>	Republic Act
<b>RH</b>	Relative Humidity
<b>RHU</b>	Rural Health Unit
<b>RONPD</b>	Retail Outlet for Non-prescription Drugs
<b>RUM</b>	Rational Use of Medicines
<b>SOP</b>	Standard Operating Procedure
<b>UHC</b>	Universal Health Care
<b>USP</b>	United States Pharmacopeia
<b>WHO</b>	World Health Organization