

Principles of Drug Management



Learning Objectives

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

- Discuss the importance of managing drugs
- Identify main elements of the drug management cycle

Medicine is an important health resource. It does not only save lives and improve health. It also promotes trust and participation in health services. Medicine supply management therefore is critical in any health facility.

NOTE:

For the purpose of this manual, the terms “drugs” and “medicines” are used interchangeably.

MANAGEMENT OF DRUGS

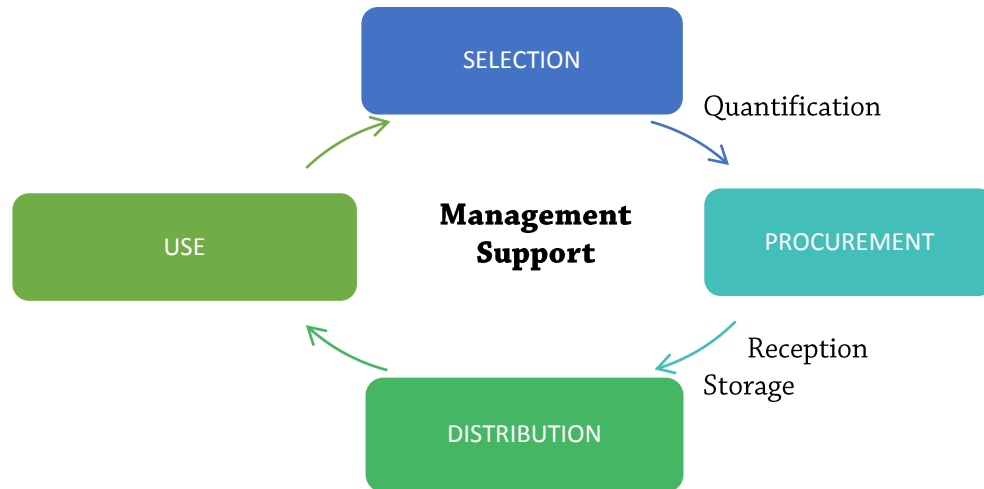
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A well-functioning and efficient supply chain management system must be in place to ensure that medicines are accessible when and where it is needed, in sufficient quantities at reasonable prices and with acceptable quality. Poor medicine management may lead to:

- Stock outs and treatment interruptions;
- Overstock and economical losses due to expiry of products; and
- Negative impact on the quality of health care



There are four principal phases in medicine management, which are interlinked and reinforced by appropriate management support systems. The following figure illustrates the drug management cycle.



Policy and Legal Framework

Figure 1.1. Drug management cycle

Source: Managing Access to Medicines and Health Technologies, 2012

DRUG MANAGEMENT CYCLE

1

Medicines are selected based on pre-determined criteria. After determination of the quantities required, the selected medicines go through a procurement process. Medicines are then delivered to the procuring entity and distributed to the different health facilities. Finally the use of medicines requires prescribing, packaging, dispensing and counseling. These tasks require qualified health personnel with adequate knowledge, appropriate



skills and right attitude. Management support tools are important for the acquisition of relevant skills in drug management within a given legal and policy framework.

In each phase of the drug management cycle, the quality of the product must be ensured through proper storage, transport, distribution, dispensing and use by the people responsible in each phase such as distributors, procurement agencies, dispensers and users.



DRUG MANAGEMENT CYCLE

1

Quality is built into a medicine during its design, development and manufacture. This is the primary responsibility of the manufacturers by following Good Manufacturing Practices (GMP). Quality of medicines must be maintained when it leaves the manufacturer's premises.



REVIEW QUESTIONS

Answer the following, for numbers 2 to 4, write T if the statement is true and F if it is false:

1. Give the (4) phases of the drug management cycle.
2. Quality of medicine is the sole responsibility of the manufacturer.
3. Poor management of medicines leads to poor quality of health care.
4. Poor management of medicines entails additional costs to the health system.
5. Medicines promote trust and participation in health services.

CANN, JM. 2014. *Drug Management Cycle: Overview and Introductory Concepts*. [Powerpoint slides]. Presented at a lecture at Smallville 21 Hotel, Iloilo City.

MANAGEMENT SCIENCES FOR HEALTH, INC. 2012. *Managing Access to Medicines and Health Technologies*. [online]. [Accessed 10 November 2014]. Available from World Wide Web: <<http://www.msh.org/sites/msh.org/files/mds3-jan2014.pdf>>

UNITED STATES PHARMACOPEIAL CONVENTION. 2007. *Ensuring Quality of Medicines in Limited-Resource Countries*. [online]. [Accessed 10 November 2014]. Available from World Wide Web:
<http://www.usp.org/sites/default/files/usp_pdf/EN/dqi/ensuringQualityOperationalGuide.pdf>

WORLD HEALTH ORGANIZATION. 2004. *Training Manual for Drug Management at the Health Center Level*. [online]. [Accessed 10 November 2014]. Available from World Wide Web: <<http://apps.who.int/medicinedocs/en/d/Js7919e/>>

Selection of Medicines



Learning Objectives

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

- Explain the medicine selection process
- Discuss the criteria used in medicine selection

Medicines comprise as much as 40% of the health care budget in the developing countries like the Philippines, yet a significant proportion of the population still lack access. With limited financial resources and rising costs of medicines, its selection must be managed appropriately and efficiently. The World Health Organization (WHO) suggests the use of an essential medicines list to manage the selection of medicines.

Essential medicines are those that satisfy the needs of the majority of the population and therefore should be available at all times. The selection and use of a limited number of essential medicines lead to an improved supply of medicines, more rational prescribing and lower costs.



In the Philippines, the essential medicines list is incorporated in the Philippine National Formulary (PNF) [formerly known as Philippine National Drug Formulary or PNDF] Manual. The Department of Health, through the Formulary Executive Council (FEC) determines the types of medicines and dosage forms to be included in the formulary. This formulary lists the medicines that are considered as most essential for the diseases and conditions encountered in the country. It also describes the appropriate use of these essential medicines. It is periodically reviewed to ensure that it will incorporate significant and new therapeutic advances and information. The criteria for inclusion of medicines into the formulary include the following:

- Relevance to disease
- Efficacy and safety
- Quality
- Cost
- Appropriateness to the capability of health workers at different levels of health care
- Local health problems
- Benefit/risk ratio

The PNF serves as basis for selection of medicines in a government health facility including local health facilities such as the City Health Office (CHO), Municipal Health Office (MHO) and Rural Health Unit (RHU). The Executive Order (EO) No. 49 (21 January 1993) and the Guidelines for the Procurement of Drugs and Medicines, Medical Equipment and Other Health Related Goods explicitly state the mandatory use of the PNF in the requisition of medicines in all government health facilities.

Hence all medicines selected must only be those that are found in the PNF. Meanwhile, the Administrative Order (AO) No. 163 s. 2002 sets the necessary requirements if non-formulary medicines are warranted.



The international non-proprietary names (INN) or the generic names of medicines are used in the PNF and should likewise be used by the local health facilities in selecting medicines. This is also in compliance with the Republic Act (RA) 6675 or the Generic Drugs Act. The generic name is the medicine's official name, regardless of what company or organization manufacturers or markets it. A proprietary, commercial, trade or brand name is chosen by the manufacturer to facilitate recognition and association of the product with a particular firm for marketing purposes. For many medicines, there are several branded products that share the same generic name.

The use of generic names in medicine selection and eventually procurement and prescribing offers the following advantages:

- Generic names are more informative and facilitate purchase of products from multiple suppliers;
- There is easy recognition of the type of medicine;
- Generic prescribing facilitates product substitution whenever appropriate; and
- The confusion associated with the use of brand names can be avoided.

Table 2.1. Examples of generic medicines and some of their brand names

Generic Names	Brand Names
Diphenhydramine	Benadryl©
Salbutamol	Ventolin©, Asmalin©
Amoxicillin	Himox©, Moxillin©, Amoxil©
Ciprofloxacin	Cipro©, Ciprobay©
Cotrimoxazole	Bactrim©
Amlodipine	Amvasc©, Norvasc©, Vasalat©

For numbers 1 to 4, write T if the statement is true and F if it is false; for number 5, choose the letter of the correct answer.

1. The use of PNF as basis for the selection of medicines in public health facilities is voluntary.
2. Cost should be the primary criterion considered in the inclusion of medicines in any health facility.
3. The use of generic names facilitates purchase from multiple sources thus leading to a more competitive price.
4. The public health facilities may request medicine outside the PNF.
5. The following are criteria for inclusion of a drug/medicine into the PNF except:
 - a. Local health problems
 - b. Quality
 - c. Appropriateness to the capability of health workers at different levels of health care
 - d. None of the above

GOVERNMENT PROCUREMENT POLICY BOARD. n.d. *Manual of Procedure for the Procurement of Goods*. [online]. [Accessed 11 November 2014]. Available from World Wide Web: <<http://www.gppb.gov.ph/downloadables/forms/GPM%20-%20Vol.2.pdf>>

NATIONAL FORMULARY COMMITTEE. 2008. *The Philippine National Drug Formulary*. 7th ed. [online]. [Accessed 11 November 2014]. Available from World Wide Web: <http://www.philhealth.gov.ph/partners/providers/pdf/PNDFvol1ed7_2008.pdf>

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Procurement of Medicines



RHU
BHS

Learning Objectives

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

- Discuss the medicine procurement process
- Calculate order quantities and request indicator for procurement
- Identify components of a medicine requisition form and delivery form
- Describe procedure of receipt of medicines at the local health facility and detection of discrepancies in supplies/ orders

After selecting medicines appropriate for the local public health facilities, the procurement process commences. RA 9184, otherwise known as the “Government Procurement Reform Act” defines procurement as the acquisition of goods, consulting services and the contracting for infrastructure projects by the procuring entity. This policy governs the procurement process in all government entities in the country.

A procurement system must be effective and efficient in order to ensure that the correct medicines of good quality are obtained at the right time, in the required quantities and at favorable costs. The procurement process consists of a series of steps (Figure 3.1).

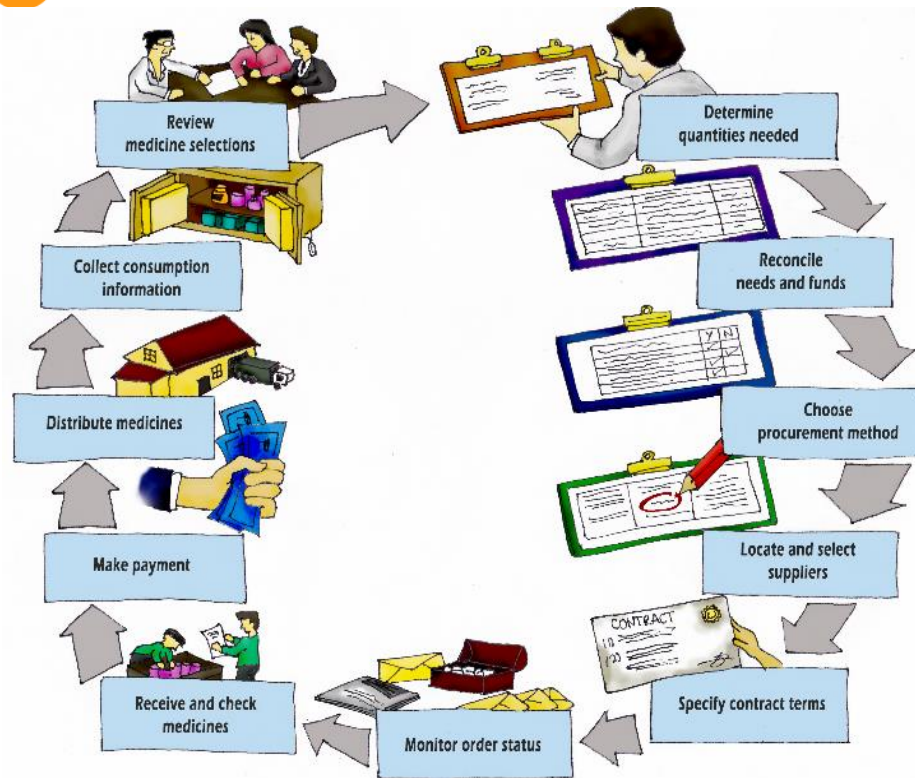


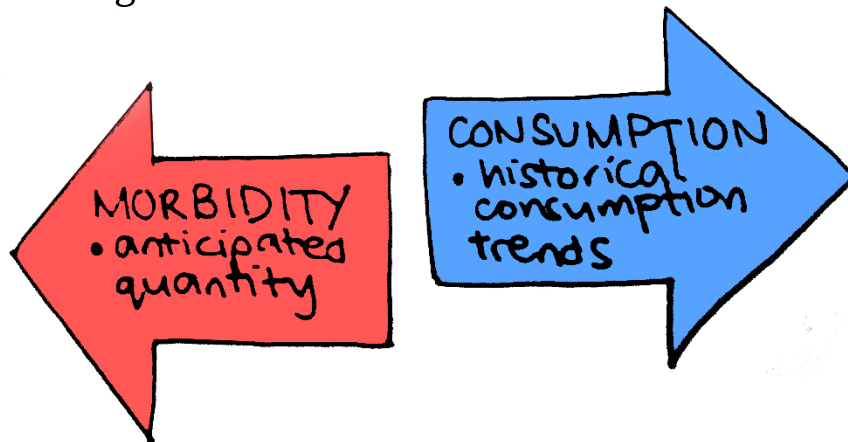
Figure 3.1. Medicine procurement process

Source: Managing Access to Medicines and Health Technologies, 2012

Quantification is the process of determining the estimated quantity of a needed product for a specific period of time based on a set of assumptions. It likewise includes the estimation of the financial means required for purchasing the item. The objectives of quantification are:

- Determine rational quantities of products to be procured;
- Avoid stockout and ensure continuous availability;
- Avoid overstock and wastage due to expiry;
- Make the best use of resources and budgets;
- Provide data on specific product's use; and
- Calculate emergency needs for disaster relief and/ or epidemics.

The two most common methods for quantifying product requirements are the morbidity and consumption methods. Morbidity method forecasts the anticipated quantity of medicines needed to treat an expected number of cases for specific diseases based on incidence data. Consumption, on the other hand, is based on past consumptions of every item. It involves analysis of historical consumption trends and assumptions about factors that may influence the demand in the future. Boxes 3.1 and 3.2 outline the steps in quantification of requirements using the two methods.



Box 3.1. Quantification of drug requirements using morbidity method**Morbidity Method**

1. Specify list of problems encountered in the locality. Consider only those that are according to diagnostic capacity.
2. Establish list of medicines to be quantified. List down essential medicines that cover the major health problems.
3. Establish standard or average treatments. Using standard treatment guidelines, compute for the standard or average treatment regimens for each health problem. (Q_E)

$$Q_E = D_{CU} \times N_D \times L_D$$

4. Collect morbidity data for each health problem. Estimate the expected number of treatment episodes for each health problem from step 1. (C_E)

$$C_E = C + (C \times A_U)$$

Box 3.1. Quantification of drug requirements using morbidity method (cont.)

5. Calculate the number of treatment episodes for each health problem. (E_T)

$$E_T = C_E \times F$$

6. Calculate the quantity of medicines needed for each health problem. (Q_T)

$$Q_T = E_T \times Q_E \times P_T$$

D_{CU} = Basic units per dose; N_D = Number of Doses per day; L_D = length of treatment in days; C = Past total number of contacts; A_U = Utilization adjustment; C_E = Expected total number of contacts; F = Frequency of health problem (per thousand); E_T = Expected treatment episodes; Q_T = Total quantity required; P_T = Percentage of cases expected to be treated

Box 3.1. Quantification of drug requirements using morbidity method (cont.)

Example:

	age group	episode/ 1000	past year estimated # of episodes	projected # of episodes	# of regimen	%cases treated w/ regimen	drug product	basic unit	basic unit/ dose	dose/ day	# of days	basic units/ episode	Q _T
gastritis, heartburn	<5	11	34,537	36,955	1	100%	antacid susp	mL	5	4	5	100	3,695,459
	>5	77	240,502	257,337	1	70%	antacid susp	mL	10	4	5	200	36,027,200
					2	30%	cimetidine 300mg tablet	tablet	1	4	5	20	1,544,023

Box 3.2. Quantification of drug requirements using consumption method

Consumption Method

1. Prepare list of medicines to be quantified.
2. Determine data on the following:
 - Past consumption for each of the medicines in the list (at least 3 months)
 - Number of days of stockout
 - Losses
 - Inventory
3. Calculate average monthly consumption as:
 - Average monthly consumption, $AMC = \text{consumption} / \text{number of months of consumption}$
4. Calculate the quantity of each medicine required in the next procurement period.
 - Quantity to order, $Q_O = \text{number of months to cover} \times AMC - \text{remaining stock}$

Box 3.2. Quantification of drug requirements using consumption method (cont.)*Example Consumption Method*

Data of monthly consumption of paracetamol 500-mg tablets over a six-month period.

April 2014	2,000 tablets
May 2014	3,100 tablets
June 2014	2,300 tablets
July 2014	2,100 tablets
August 2014	3,100 tablets
September 2014	3,200 tablets
Total	15,800 tablets

Average monthly consumption of tablet:

$$\frac{15,800}{6} = 2633.3 \text{ tablets}$$

If number of months to cover is also 6 months and remaining inventory is 4,000 tablets

$$Q_0 = (2,633.3 \times 6) - 4,000 \\ = 11,799.8 \text{ tablets}$$

After quantification of need, this is usually reconciled with available funds and quantities are adjusted accordingly.

REQUEST INDICATOR

3

The request indicator (RI) is the level of drugs in stock. It indicates when new orders should be made. It is the quantity that is calculated to last between the period of placing the order and the delivery of the new consignment.

The RI is marked with pencil in the space “RI” on the top right-hand corner of the stock card. It should be updated at least twice a year because consumption may vary due to seasonal changes or epidemics.

This will ensure that no stockout occurs before the next consignment is expected. The stock should not be allowed to fall below this level before a new order is placed. Each stock card must have an RI that is updated from time to time as consumption varies.

The stock should never reach “0 level” before a request is made, as there will be a stockout for some time. It is easy to calculate the RI once the monthly consumption is obtained.

If the delivery time is three months and the monthly total consumption is 2633.3, RI is:

$$2633.3 \text{ tablets} \times 3 \text{ months} = 7,900 \text{ tablets}$$

Since the unit of issue is tins of 1,000 tablets, the above figure must be brought to the nearest tin, which is:

$$\begin{array}{r} 7,900 \\ \hline 1000 \end{array} = 7.90 \text{ or } 8 \text{ tins}$$

This means that when the stock of paracetamol is reduced to 8 tins, a new request must be made.

PROCUREMENT METHODS

3

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

- Limited Source Bidding or Selective Bidding;
- Direct Contracting;
- Repeat Order;
- Shopping; and
- 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.

RECEIPT OF MEDICINES

3

Upon delivery of supplies to the local health facility, these should be inspected and checked against the specifications listed in the Purchase Order:

- Quantity actually corresponds to the quantity indicated on the requisition/ delivery form;
- Original boxes, tins or bottles are unopened and in good condition;
- Labels, expiry dates, dosage form, strength indicated are consistent with the specifications; and
- Physical conditions such as appearance, color, volume, clarity, etc. are within specifications.

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



In order to enhance safety and ensure quality of products, performance of suppliers must be monitored. A reporting system must be in place and shared to the BAC for use in evaluating suppliers in the future. Data regarding supplier performance that may be tracked include:

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

REVIEW QUESTIONS

3

For numbers 1 to 4, write T if the statement is true and F if it is false; for number 5, choose the letter of the correct answer.

1. Procurement in a government health facility such as the RHU is governed by RA 6675.
2. An efficient procurement system avoids stock outs and ensures continuous availability of medicines.
3. Monitoring supplier performance should be an integral part of the procurement process.
4. Limited Bidding is WHO's recommended procurement method because of the pre-qualification process for suppliers.

5. The following factors are considered in quantifying medicine requirements using consumption method except:
- a. Lead time
 - b. Stockouts
 - c. Prevalence data
 - d. Procurement period

GOVERNMENT PROCUREMENT POLICY BOARD. 2002. *Republic Act 9184: Government Procurement Reform Act*. [online]. [Accessed 11 November 2014]. Available from World Wide Web: <http://www.gppb.gov.ph/laws/laws/RA_9184.pdf>

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Storage and Distribution of Medicines



**RHU
BHS**

Learning Objectives

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

- Explain importance of good storage practices and distribution practices
- Describe good storage and distribution practices
- Identify common problems encountered in storage and distribution of medicines

The next phase of the drug management cycle is distribution. The primary distribution management goal is to maintain a steady supply of pharmaceuticals and supplies to facilities where they are needed, while ensuring that resources are being used in the most effective way.

An effective distribution system should be able to achieve the following:

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

Activities pertaining to distribution include storage, inventory control, delivery, and the return of overstocked and nearly expired medicines.

Good medicine quality depends in large part on proper storage and distribution practices. Clear policies must be in place and good practices must be observed in order to protect the quality and stability of the product throughout the distribution chain.

Distribution schemes can be defined by which levels of the system order medicines and which, if any, passively receive medicines distributed from higher levels. The two basic alternatives are:

1. Pull system, is when each level in the system determines what types and quantities of medicines are needed and places orders with the supply source. This is also sometimes referred to as an independent demand or requisition system.
2. Push system, is when supply sources at some level in the system determine what types and quantities of medicines will be delivered to lower levels. This is also known as an allocation system.

The push system is usually used when sufficient data is not available to conduct quantification. This is also useful after disasters. Pull system is more reliable and is the recommended system of distribution.

Box 4.1. Good distribution practices

Key points of good distribution practices

- Inspect medicines for quality and quantity before distribution.
- Maintain proper storage conditions during transport.
- Verify and document delivery orders.
- Check the integrity of packaging when medicines arrive.
- Clearly label containers.
- Maintain delivery records.
- Provide easy access to delivery records.

Source: Ensuring Quality in Resource-Limited Countries, 2007



4

STORAGE OF MEDICINES

Proper storage conditions are critical to maintain the quality of medicines. Good storage practices should be implemented in order to:

- Ensure stability of the products;
- Avoid contamination and deterioration of the products;
- Avoid deterioration of the packaging/ labeling;
- Prevent or reduce pilferage, thefts and losses; and
- Prevent infestation of pests or vermin.



Good storage practices involve maintaining adequate facilities and developing procedures for receiving, labeling, inventory and security of products. Box 4.2 summarizes key points of good storage practices as recommended by WHO.

Box 4.2. Good storage practices

Key points of good storage practices

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

Source: Ensuring Quality in Resource-Limited Countries, 2007

An adequate storage facility should have an identified area, sufficient space, adequate lighting, clean conditions, temperature and humidity controls, cold chain facility (if needed), shelves and pallets. The shelves maybe used for retail items while bulk supplies may be placed on pallets. The floor and surfaces of storage areas should be covered by materials that can be easily cleaned.

Ideally, products should be arranged by pharmaceutical form then by alphabetical order of generic names then by expiry dates.

Follow any specific indication on packaging (i.e. arrows up). Products should be stored off the floor and adequately spaced to permit cleaning and inspection. It should also be ensured that there is space between boxes of medicines and the wall to prevent absorption of humidity.



STORAGE OF MEDICINES

4

Cleanliness must be maintained in the storage area. Some considerations for cleaning the area include:



- Cleaning on a weekly basis or more often based on the facility's activities;
- Use of dust mop instead of brooms for sweeping since the latter tends to create airborne dust;
- Mopping with soapy water or disinfectant after dusting; and
- Preventing direct contact between cleaning solution and storage containers.

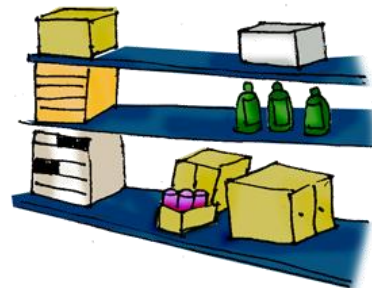
Orderly Arrangement

- Provide sufficient shelving
- Arrange by pharmaceutical dosage form then by alphabetical order of generic names then by expiry dates
- Guard against spoilage: lightweight items higher up; heavy fluids, fragile items lower
- Arrange neatly and label shelf for each item



No shelves?

Then improvise: Support planks with bricks or crates; using strong cartons and other empty containers

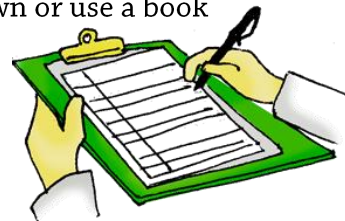
**Accountability**

- Restrict access and check stock frequently
- Maintain a stock card for each item if possible
- Keep stock card next to item
- Fasten stock card to shelf



No stock cards?

Then improvise: make your own or use a book



STORAGE OF MEDICINES

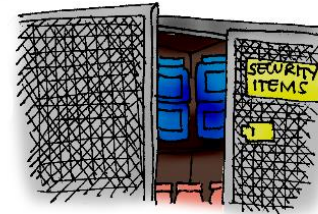
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Security

- Secure the storeroom
- Double doors/double locks on entrance
- Burglar bars on windows
- Use extra precaution for attractive items



No lockable cupboards?
Then improvise: secure using wire mesh, latch and padlock

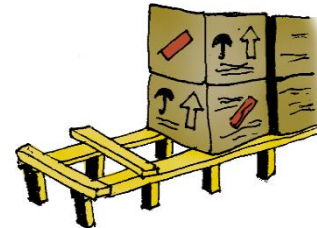


Bulk Storage

- Store bulk off the floor
- Allow air circulation
- Limit the height of stacks to prevent crushing

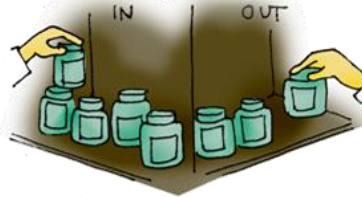


No pallets?
Then improvise: construct a wood frame



Stock Rotation

- When receiving, place containers according to expiry date
 - Later expiry at back
 - Earlier expiry at front
- When issuing
 - Take the container with the earliest expiry date



What about without expiry date?

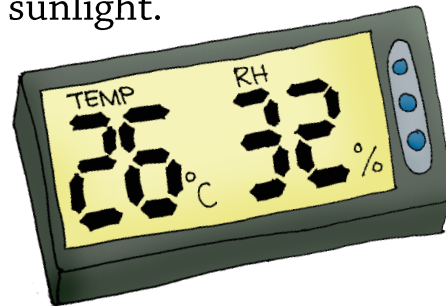
Use FIFO



Figure 4.1. Tips for managing stock in the store room

Source: Managing Access to Medicines and Health Technologies, 2012

Temperature and humidity conditions in the storage area must be monitored daily and records should be kept. A thermometer is used for measuring temperature while a hygrometer is used for measuring relative humidity (RH). These equipment used for monitoring storage conditions should be calibrated at defined intervals, according to standard operating procedures set by the local health facility. In most cases, medicines must be kept in dry, well-ventilated premises at temperatures of 15°C to 25°C. If humidity can be controlled, products maybe stored up to 30°C. Humidity in the storage area must not be more than 65% RH. Products must be protected from direct sunlight.



For products with temperature storage requirements like vaccine, a commercially available refrigerator especially designed for medicines is recommended. These refrigerators possess precise electronic control necessary to maintain a temperature range of between 2°C and 8°C and are usually equipped with a thermometer to facilitate ease in monitoring the temperature. These refrigerators should not be placed in the same area where other medicines are stored.

Two general storage rules to follow are:

- Products sensitive to temperatures above 8°C should not be stored near the door.
- Products susceptible to temperatures below 2°C should not be placed in the airflow of the refrigeration unit.

Inventory should be inspected monthly for instability problems such as change in appearance, consistency and color for most dosage forms; crystallization in liquids; and sedimentation for suspensions.

Record-keeping is part of good storage practice. A list of stock items in the store room must be maintained and regularly updated by performing regular inventories of the products. An inventory software program is considered as the most efficient method for controlling inventory management. However in the absence of a computer other systems maybe employed such as use of stock cards.

Periodic stock reconciliation should be performed by comparing the actual and recorded stocks. Stock discrepancies must be investigated as a check against inadvertent mix-ups and/or correct issue.

Damaged containers should not be issued unless the quality of the product has been shown to be unaffected. All damaged containers must be replaced by new containers.

All stocks should be checked regularly for expired products. Expired products should be identified and disposed of following the protocol set.

For recalled items, these should be handled by approved procedures according to national or local regulations. These should be stored separately from other materials and products while awaiting destruction or return to the supplier.



Dispatch and delivery of medicines to the BHS are scheduled once these are available at the local health facility (RHU/ CHO). The midwife, who primarily manages the BHS, receives the requested or allocated medicines at the RHU/ CHO. Dispatch records should include the date of dispatch; the name of midwife; BHS served; and product description which includes name, dosage form and strength, batch number, quantity and expiry date. The midwife should verify and check the products against the dispatch records. He/she should also keep a list of medicines received.

Medicines should be transported in a way that maintains their quality and meets their storage requirements. The outside container should offer adequate protection from all external influences and should be indelibly and clearly labeled.

DISPATCH AND DELIVERY

Expired medicines in the BHS should be returned to the RHU/ CHO for proper disposal. This should be accompanied by proper documentation.



REVIEW QUESTIONS

4

For each of the following statements, write T if the statement is true and F if it is false:

1. Access to storage room for medicines must be secured with locks and limited to authorized personnel.
2. Storage rooms must be equipped with a temperature monitoring device.
3. Medicines that are found to display instability problems should not be dispensed to patients.
4. All medicines must be placed in an insulated container equipped with ice packs when transported from one facility to another.
5. First Expiry First Out is a good practice to observe in storing medicines.

CANN, JM. 2014. *Drug Management Cycle: Overview and Introductory Concepts*. [Powerpoint slides]. Presented at a lecture at Smallville 21 Hotel, Iloilo City.

DELIVER. 2003. *Guidelines for the Storage of Essential Medicines and Other Health Commodities* [online]. [Accessed 10 November 2014]. Available from:
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FOOD AND DRUG ADMINISTRATION. 1988. RA 6675. [online]. [Accessed 10 November 2014]. Available from:
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WORLD HEALTH ORGANIZATION. 2003. *Good Storage Practices for Pharmaceutical Products*. [online]. [Accessed 10 November 2014]. Available from World Wide Web:
<http://apps.who.int/prequal/info_general/documents/TRS908/WHO_TRS_908-Annex9.pdf>

REFERENCES

WORLD HEALTH ORGANIZATION. 2004. *Training Manual for Drug Management at the Health Center Level*. [online]. [Accessed 10 November 2014]. Available from: <<http://apps.who.int/medicinedocs/en/d/Js7919e/>>

WORLD HEALTH ORGANIZATION. 2010. *Good Distribution Practices for Pharmaceutical Products*. [online]. [Accessed 10 November 2014]. Available from: <http://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf>



Use of Medicines

RHU
BHS

Learning Objectives

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

- Define rational use of medicines
- Explain the medication use process
- Identify parts of the prescription
- Explain processes involved in preparing, proper labeling, and dispensing the required medication
- Explain process of recording consumption of medicines

The goal of a pharmaceutical supply chain management is to deliver the correct medicine to the patient who needs that medicine. The steps of appropriate selection, procurement and distribution are necessary precursors to the rational use of medicines which is the last phase of the drug management cycle. Rational use of medicines

requires rational prescribing practices, good dispensing procedures and patient adherence. Irrational medicine use includes overuse, underuse, and inappropriate use, caused by such factors as lack of adequate regulatory systems; shortages of essential medicines and availability of nonessential medicines; lack of sound, objective medicine information; and the considerable influence of medicine promotion on both prescribers and patients.

Rational use of medicines requires that the patient is prescribed with the appropriate medicine after proper diagnosis. It also requires that the patient receives the medicine according to the following:

- Appropriate dose;
- Appropriate dosage form;
- Appropriate route of administration;
- Appropriate frequency of administration;
- Appropriate duration of treatment;
- Appropriate information to the patient; and
- Adequate follow up.

The medicine use process is outlined in Figure 5.1.

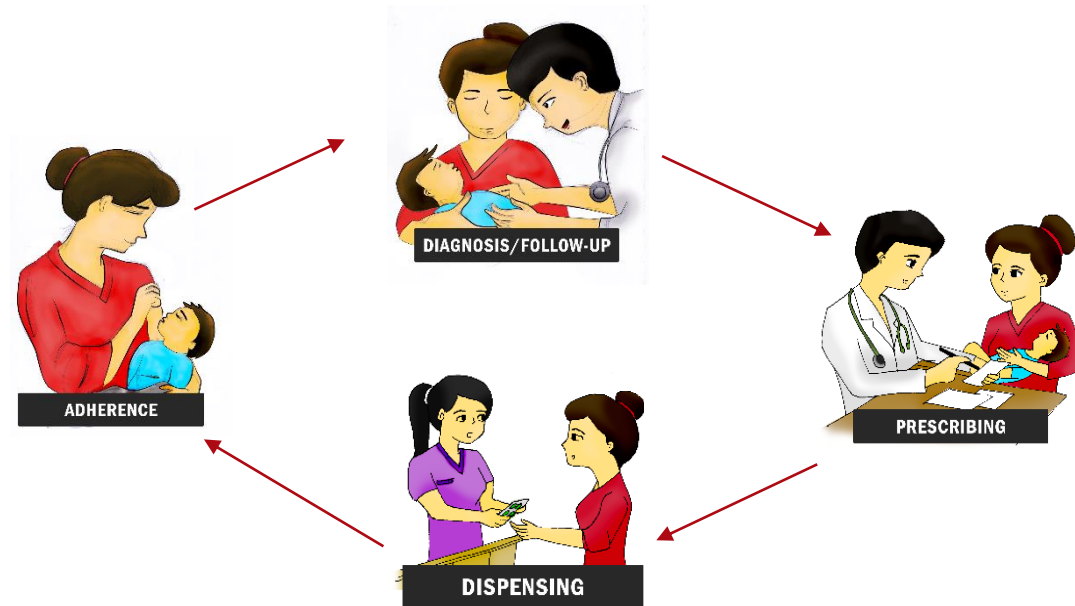


Figure 5.1. The medicine use process

Source: Managing Access to Medicines and Health Technologies, 2012

A prescription is written after diagnosis or a health problem has been identified by a doctor. It is a set of instructions written by a doctor to the dispenser for supply of medicines. Doctors should prescribe according to the PNF and the latest standard treatment guidelines. A prescription should have the following:

- Name of patient and age;
- Date;
- Generic name and dosage form;
- Dose;
- Frequency of administration;
- Duration of treatment; and
- Prescriber's signature and name.



Figure 5.2 shows an example of the parts of a prescription.

RATIONAL PRESCRIBING

5

Use of Medicines

Prescriber Information	<p>→ Juan Dela Cruz, MD Tower A Bldg., Boni Ave, Mandaluyong City Tel No. : 531-4534</p> <p>Clinic Schedule: Monday: 1:00PM – 5:00PM Friday: 9:00AM – 12:00PM Tue – Thur: 10:00AM – 3:00PM Saturday: 12:00PM – 3:00PM</p>	
Patient Information	<p>Name: <u>Sarah Gonzales</u></p> <p>Address: <u>Boni Avenue, Mandaluyong City</u></p> <p>Age: <u>8</u> Sex: <u>F</u> Date: <u>6/21/2012</u></p>	Date Prescription is Written
Superscription (Rx in Latin is Recipe meaning 'take thou')	<p>→ R_x</p>	Inscription (Medication Prescription)
Subscription (Instructions to Pharmacist)	<p>→ Amoxicillin 250mg/5ml Susp.</p> <p># 2 lots</p> <p>→ Reconstitute with water to make 60 mL suspension</p> <p>Sig. Take 1 tablespoon TID for 777 days</p>	<p>→ 6/21/2012</p> <p>→ Amoxicillin 250mg/5ml Susp.</p> <p>→ # 2 lots</p> <p>→ Reconstitute with water to make 60 mL suspension</p> <p>→ Sig. Take 1 tablespoon TID for 777 days</p>
	<p>Physician's Sig. <u>J. Dela Cruz</u></p> <p>Lic. No. <u>12345</u></p> <p>PTR No. <u>1234567</u></p> <p>S2 No. _____</p>	

Figure 5.2 Parts of a prescription

Just as there is proper area for storing medicines, there should also be a proper area for dispensing work. This is referred to as the dispensary. A dispensary is an area suitably designed for the preparation and distribution of medicines to the patients. The following practices are encouraged in the dispensary:

- Retain a daily drug use record;
- Provide a table for dispensing drugs;
- To facilitate work, do not overcrowd the dispensing table;
- Arrange documents in an orderly manner on the table, away from the dispensing area;
- Clean after each use tablet counters and place within easy reach on the table;
- Avoid dispensing wrong drugs by arranging drugs on the table in alphabetical order so that the drug being dispensed is not confused with another; and
- Always close drug containers from which drugs are not being dispensed to prevent spillage or dispensing the wrong drug.

DISPENSING AT THE LOCAL HEALTH FACILITIES

5

Use of Medicines

The dispenser has to issue the correct medicine in the dosage form and dose prescribed and in quantity corresponding to the duration stated on the prescription. Ideally, he/she should be able to detect an error done at the time of prescription or a misunderstanding from the patient about his illness and his treatment. The dispenser should also be rigorous in recording all medicine movements. This will ensure that accurate consumption records are documented, which can be used as basis for quantification.



DISPENSING AT THE LOCAL HEALTH FACILITIES

The dispensing process is as follows:

1. Check for the following:
 - Name and signature of the prescriber and the stamp (or other identifiers) of the local public health facility (CHO/RHU);
 - Date, name and age of patient;
 - Endorsement of the prescriber of the center if prescription did not come from the local public health facility; and
 - In case of doubt or error, report to the prescriber.
2. Prepare prescribed medicines.
 - Check name of prescribed drug against that of the container.
 - Check expiration date on the container.
 - Prepare the correct quantities.
 - Repack if needed.
 - Prepare labels.
 - Double check.

DISPENSING AT THE LOCAL HEALTH FACILITIES

5

Use of Medicines

3. Record the dispensed quantities.
4. Provide information to the patient which should include the following:
 - When to take medicine;
 - How to take medicine;
 - How long will the medicine be taken;
 - How to store the medicine;
 - Not to share the medicine with other persons; and
 - Keep medicines out of reach of the children.
5. Issue medicine to the patient.

At the BHS, only the midwife may dispense medicines. Since most of these medicines are over-the-counter (OTC), a prescription is not necessary. The midwife makes an initial assessment of the patient's condition and recommends the OTC preparation for minor ailments.

If however the symptoms presented by the patient were not relieved by the OTC preparation or if the midwife believes that the patient requires a physician's attention, the patient is referred to the RHU/ CHO for proper diagnosis. Ideally, the dispensing process in the BHS is similar to what is done at the RHU/ CHO.



LABELING OF DISPENSED MEDICINES

5

Medicines should be placed in a suitable and appropriately labeled container to ensure correct use and maintain potency and quality during the period of use. This is also in compliance to RA 6675. The label should contain the following:

- Name of patient;
- Name of local public health facility;
- Generic name of medicine;
- Strength;
- Quantity;
- Clear instructions for use in familiar language;
- Date of dispensing;
- Expiration date; and
- Cautionary label (e.g Keep out of reach of children).



LABELING OF DISPENSED MEDICINES



Figure 5.3. Examples of label materials for repackaging

ADVERSE DRUG REACTIONS

5

Adverse Drug Reaction (ADR) is a harmful response in the patient caused by the drug itself given in the recommended manner (dose, frequency, route, administration technique). Examples include allergic reactions, effects from withdrawal, or reactions caused by interactions with other drugs.

Serious ADR

WHO defines a serious ADR as any reaction that is fatal, life-threatening, or permanently or significantly disabling; requires or prolongs hospitalization; or relates to misuse or dependence.

ADR Monitoring

The Pharmacovigilance Unit of the FDA is responsible for ADR monitoring and reporting. To facilitate information gathering, the FDA provides case report forms to health providers on ADRs. All healthcare providers, including doctors, pharmacists, nurses, dentists, and others, should report ADRs as part of their professional responsibility. The completed case report form is then sent to the regional or national ADR center or to the manufacturer of the product. For the BHS, it should be sent to the RHU/ CHO. The form contains the following:

- Patient's particulars;
- Details of the ADR;
- Management of ADR; and
- Reporter's particulars.

Figure 5.4 shows an example of an ADR monitoring form.

ADVERSE DRUG REACTIONS

5

Use of Medicines

SUSPECTED ADVERSE REACTIONS FORM v 5 (4/2012)
"Saving Lives Through Vigilant Reporting"
THIS FORM MUST BE COMPLETED.

For FDA use only. All reports are confidential.
 AER No. 2012-0001
 Date received: _____

PATIENT'S PARTICULARS

*Patient's Name or Initials: _____ *Sex: ☐ Male ☐ Female Weight: _____ Kg Height (cm): _____
 Address or Contact Number: _____ *Age: _____ Date of Birth (mm/dd/yy): _____
 Medical History/Admitting Diagnosis: _____ Ethnic group: ☐ Filipino ☐ Chinese ☐ Caucasian
 Any Known Allergy: ☐ No ☐ Yes, Specify: _____ Pregnancy Status: ☐ No
 Hospital/facility: If admitted: _____ Yes (1st, 2nd, 3rd trimester)

***DETAILS OF THE ADVERSE REACTION**

Date of onset: _____ : _____ am, _____ pm Do you consider the reaction to be serious? ☐ Yes, if yes indicate why: ☐ No
 Describe the reaction, including pertinent laboratory data: _____
☐ Patient died due to reaction
☐ Involved or prolonged in-patient hospitalization
☐ Life threatening
☐ Involved persistent or significant disability
☐ Congenital anomaly in the newborn
☐ Other outcome, please give details: _____
 Can this be due to Medication Error? ☐ No
☐ Yes, if yes, which type:
 _____ Prescribing
 _____ Transcription
 _____ Dispensing
 _____ Administration

Can the adverse reaction be due to:
 1. Product quality defect: ☐ No ☐ Yes, Specify, enclose: color change; caking; powdering; counterfeit; odor change; defective container; contaminants; separation of components; undissolved suspension/powder
 2. Therapeutic failure: ☐ No ☐ Yes, Specify, enclose: antimicrobial resistance; drug interaction; poor compliance; counterfeit; expired; improper storage; under-dosing; inappropriate medication; inappropriate route of administration; excipient/preservatives

Suspected drug product(s) Indicate brand name	Daily Dose	Route	Date started	Date stopped	Reason (s) for using the product (Indication)	Manufacturer and Batch/Lot #

List all other drugs taken at the same time and/or 3 months before. If none, check box. ☐ No Other drug's taken

Brand name of the drug	Daily Dose	Route	Date started	Date stopped	Reason's for using the drug	Manufacturer and Batch & Lot #s.

***MANAGEMENT OF ADVERSE REACTION**

Was treatment given? ☐ No ☐ Yes (if yes, please specify): _____
 Outcome: ☐ Recovered (Date of recovery): _____ ☐ Unrecovered ☐ Other diseases: _____ liver _____ renal _____ HPN
☐ Fatal (Date of death): _____ ☐ Unknown ☐ Diabetes _____ CVS _____ Endocrine _____ Cancer
 Sequela/e: (any permanent complications or injuries as a result of the ADR) Re-challenge? ☐ Yes Result: _____
☐ Yes (Please specify) _____ ☐ No ☐ Unknown ☐ No

***REPORTER'S PARTICULARS**

*Printed Name of Reporter: _____ *Contact no.: _____
 Signature of reporter: _____ Email address: _____
 Date reported (mm/dd/yy): _____ *Profession: MD RPH RN Patient Dentist other
 *Facility: Clinic Hospital Other

FDA National Pharmacovigilance Center
"Saving Lives Through Vigilant Reporting"
 Send completed forms to: ADR Unit, FDA, Cebu Drive, Filinvest Corporate, Alabang, Muntinlup City 1781.
 Or fax to: (02) 8070751 or 807-85-11, c/o The ADR Unit. Send sample, if any, of suspect drug for analysis.

Figure 5.4. Example of an ADR monitoring form

Downloadable from: https://www.mims.com/resources/portal/Philippines/document/ADR_Form.pdf

For each of the following statements, write T if the statement is true and F if it is false:

1. Rational use of medicines includes rational prescribing, good dispensing procedures and patient adherence.
2. All health care providers are encouraged to report ADRs as part of their professional responsibility.
3. Bottles and plastics are recommended for repacking tablets and capsules.
4. Written information is provided to the patient to replace actual provision of information by the dispenser.
5. An ADR is a life-threatening, disabling response caused by medicines.

MANAGEMENT SCIENCES FOR HEALTH, INC. 2012. *Managing Access to Medicines and Health Technologies*. [online]. [Accessed 10 November 2014]. Available from World Wide Web: <<http://www.msh.org/sites/msh.org/files/mds3-jan2014.pdf>>

WORLD HEALTH ORGANIZATION. 2004. *Training Manual for Drug Management at the Health Center Level*. [online]. [Accessed 10 November 2014]. Available from: <<http://apps.who.int/medicinedocs/en/d/Js7919e/>>

Pharmaceutical Donations



RHU
BHS

Learning Objectives

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

- Explain the need for guidelines on the acceptance of foreign and local donations especially during emergency and disaster situations
- Discuss the national policy governing foreign and local donations
- Identify criteria for accepting donations
- Identify problems encountered on pharmaceutical donations at the local public health facility

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.

PHARMACEUTICAL DONATIONS

6

Often however, these donations also cause problems. Among these are:

- Not relevant for the emergency situation;
- Unfamiliarity of the health workers with donated pharmaceutical;
- Not registered for use in the country;
- Unsorted;
- Labeled with brand names or other language not readily understood;
- Quality not compliant with standards of donor country;
- Distribution plan ignores normal administrative procedures;
- High declared value reflective of market value in donor country rather than world market price; and
- Donated in wrong quantities.

PHARMACEUTICAL DONATIONS

There are several underlying causes for these problems. First is the belief that any type of pharmaceutical is better than nothing at all or similarly that expired pharmaceuticals are good enough for people in need. Second, donations are made prior to clearance by the recipient. Lastly, donations are tax-deductible at full market price. This is why so many donations arrive close or past their expiry dates and why such products are typically not high-use, high-volume items.



ACCEPTING DONATIONS

6

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

WHO identified four core principles for a useful pharmaceutical donation:

- A donation benefits the recipient to the maximum extent possible;
- Donation should be given with full respect for the wishes and authority of the recipient;

ACCEPTING DONATIONS

- Items that are not acceptable in the donor country for quality-related reasons are also not acceptable as donations; and
- Effective communication between donor and recipient is necessary before any donation.

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

ACCEPTING DONATIONS

6

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 that can be accepted are as follows:

- Shelf life of at least 12 months from the time of arrival to the Philippines;
- Labeling with English translation understood by health professionals;
- Packaging that complies to international shipping regulations (must have a detailed packing list that specifies quantity);
- Weight per carton should not exceed 50 kg;
- Exclusive packaging with regard to other supplies;

ACCEPTING DONATIONS

- Documentary proof of compliance to applicable quality standards; and
- Documentary proof that items are obtained from reliable sources.

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



ACCEPTING DONATIONS

6

At the LGU level, the primary health care facilities in the locality, may accept donations but are likewise expected to follow the existing criteria set forth by the DOH. The policy however does not define administrative procedures for receipt of donations at their level. The absence of clear administrative procedures may result to problems discussed earlier.

The WHO Guidelines on Drug Donations listed important issues that should be addressed and defined:

- Decide who is responsible for defining the needs, and who will prioritize them.
- Decide who coordinates all drug donations.
- Which documents are needed when a donation is planned; who should receive them?

- Which procedure is used when donations do not follow the guidelines?
- What are the criteria for accepting/rejecting a donation, and who makes the final decision?
- Decide who coordinates reception, storage and distribution of the donated drugs.
- How are donations valued and entered into the budget/expenditure records?
- How will inappropriate donations be disposed of?

ACCEPTING DONATIONS

6

It is important that the local health facilities create specific and clear guidelines regarding acceptance of donations taking into consideration the current policy of the DOH. Equally important is compliance to these guidelines. During emergency situations, the systems for reception, storage and distribution of medicines are very often disrupted and overloaded hence non-compliance to set criteria regarding acceptance of donations may result to accumulated medicines. These in turn could lead to additional concerns on storage and disposal.

REVIEW QUESTIONS

Answer the following. For numbers 2 to 4, write T if the statement is true and F if it is false.

1. Give 2 implications of inappropriate donations.
2. Medicine donations with short expiration dates may be accepted as long as it can be utilized prior to expiration.
3. Donations must be accepted only if there is an expressed need for the said medicine/ supply.
4. RHUs should never accept donations but rather course it to the PHO or CHD.
5. Medicine donations will always be beneficial to the recipient.

REFERENCES

DEPARTMENT OF HEALTH. 2012. *Policy and Guidelines on Logistics Management in Emergencies and Disasters*. [online]. [Accessed 12 November 2014]. Available from: <http://hems.doh.gov.ph/uploads/policy_attachments/a0705d4d53d9111af10e97158b78daf4aa337fa3.pdf>

WORLD HEALTH ORGANIZATION. 1999. *Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies*. [online]. [Accessed 12 November 2014]. Available from: <http://www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf>

Disposal of Pharmaceuticals



Learning Objectives:

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

- Discuss the importance of safe disposal for unwanted pharmaceuticals
- Explain the importance of sorting pharmaceuticals into categories that require different disposal methods
- Differentiate the various methods for disposing unwanted pharmaceuticals
- Identify the appropriate disposal method for a sorting category

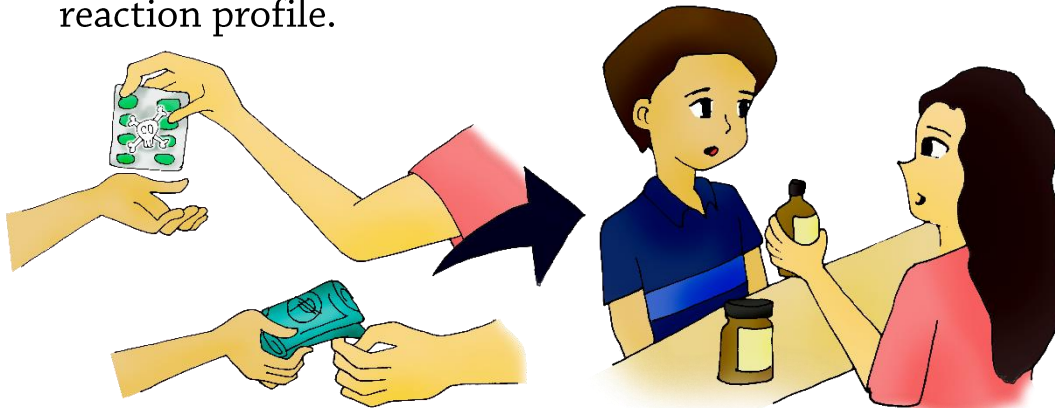
Overstocking of medicines in any health facility may result to their expiration hence the need for its disposal. In times of disasters, calamities and other emergencies, large quantities of pharmaceuticals are often donated as part of assistance.

While many of these save lives by addressing the medical needs of the affected areas, a significant number of these pharmaceuticals can exacerbate disposal concerns. Some pharmaceuticals may arrive past or near expiry, in extremely large or unwanted quantities, labeled in a foreign language or simply unwanted or not needed in 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 local health facility especially that it also entails additional resources.

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

1. Contamination of water supplies or local sources used by nearby communities or wildlife;
2. Reduction or destruction of bacteria necessary for treatment of sewage when non-biodegradable antibiotics, anti-neoplastics and disinfectants are thrown into the sewage. Antineoplastics flushed into watercourses may damage aquatic life or contaminate drinking water.

3. Release of toxic pollutants into the air when burning pharmaceuticals at low temperatures or in open containers; and
4. 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

Disposal of unwanted pharmaceuticals may require a series of steps to be taken. Figure 7.2 outlines these steps.

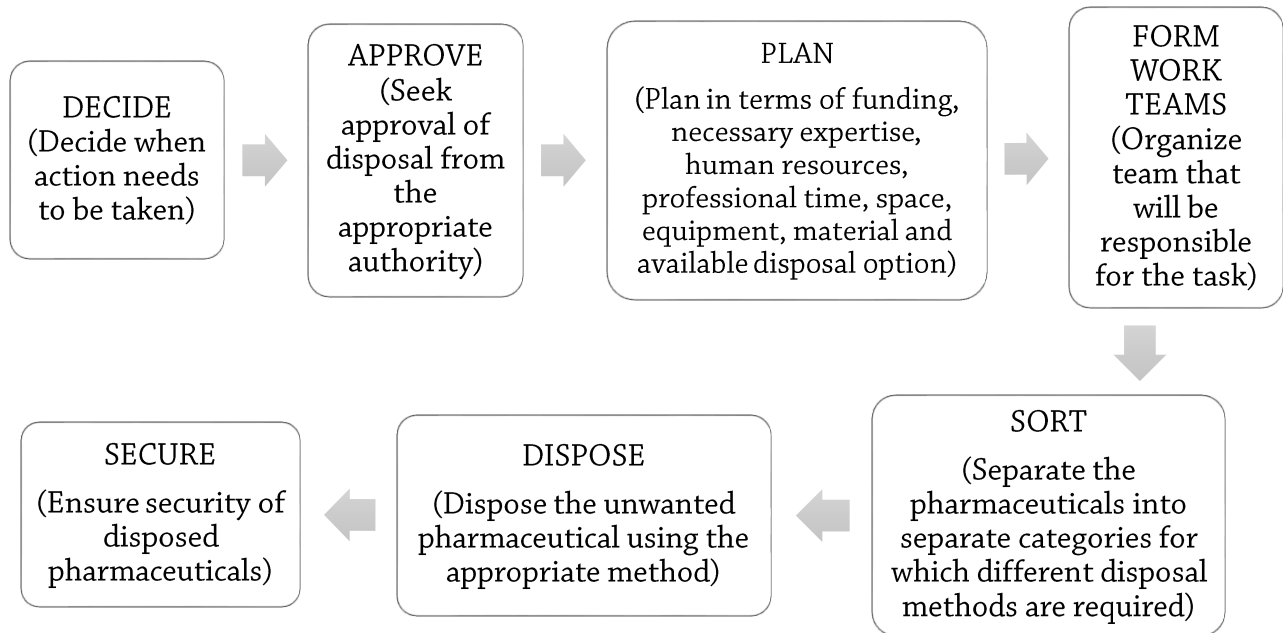


Figure 7.2. Steps in the proper disposal of unwanted pharmaceuticals

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

STEPS IN DISPOSAL

7

NOTE: 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 is to separate pharmaceuticals into categories that require disposal methods. The dosage form of the drug is a primary consideration in determining the appropriate safe disposal method. Segregated temporary storage areas must be provided for each sorted category.

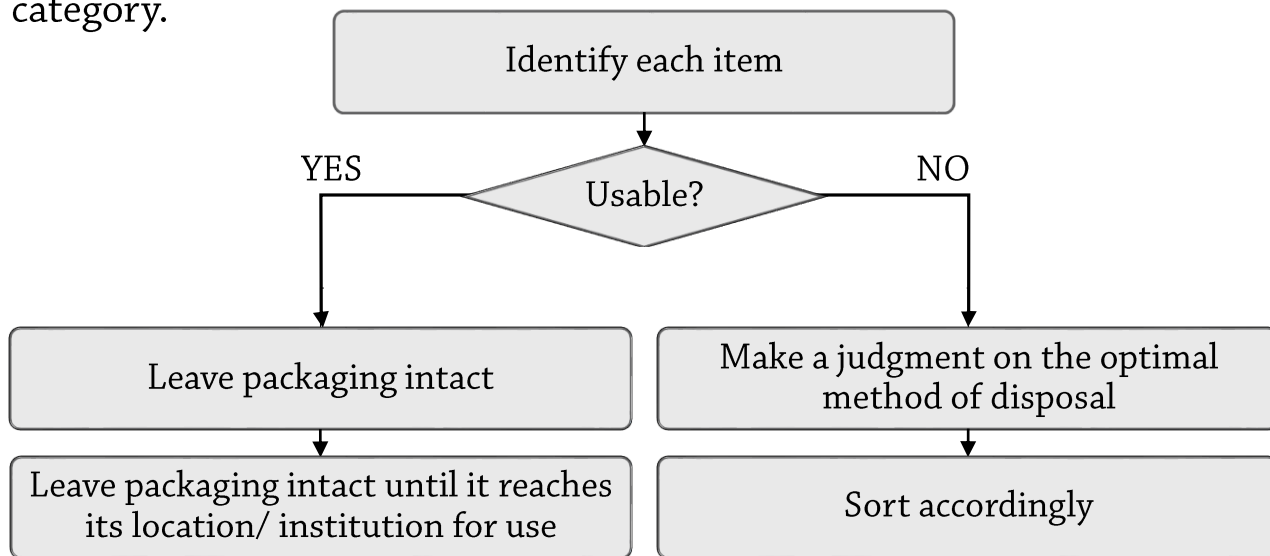


Figure 7.1. The sorting process

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

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



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.); and
- Aerosol containers (including propellant-driven sprays and inhalers)

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. The choice of disposal method must also take into consideration existing government laws and regulations on health care waste management and environment protection. The following table (Table 7.1) summarizes these disposal methods.

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

Table 7.1. Methods of disposal of unwanted pharmaceuticals

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

METHODS OF DISPOSAL

7

Table 7.1. Methods of disposal...(cont.)

Disposal Methods	Types of Pharmaceuticals	Comments
Immobilization		
<i>a. Waste encapsulation</i>	Solids, semi-solids, powders, liquids, antineoplastics, controlled substances	Involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum
Landfill		
<i>a. Highly engineered sanitary landfill</i>	Limited quantities of untreated solids, semi-solids and powders; Disposal of waste pharmaceuticals after immobilization preferable.; PVC plastics	Offers a relatively safe disposal route
<i>b. Engineered landfill</i>	Waste solids, semi-solids and powders, preferably after immobilization. PVC plastics	With features to protect loss of chemicals into the aquifer

Table 7.1. Methods of disposal...(cont.)

Disposal Methods	Types of Pharmaceuticals	Comments
<i>c. Open uncontrolled non-engineered dump</i>	As last resort untreated solids, semisolids, powders - must be covered immediately with municipal waste. Immobilization of solids, semi-solids, powders is preferable	Not for untreated controlled substance; Can lead to pollution if not sufficiently isolated from the aquifer
Sewer	Diluted liquids, syrups, intravenous fluids, small quantities of diluted disinfectants (supervised)	Antineoplastics, and undiluted disinfectants and antiseptics not recommended May require assistance of hydrogeologist or sanitary engineer

METHODS OF DISPOSAL

7

Table 7.1. Methods of disposal...(cont.)

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

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

DISPOSAL METHODS FOR SORTING CATEGORIES

The recommended disposal methods for various sorting categories are summarized in Table 7.2

Table 7.2. Disposal method per pharmaceutical category

Category	Disposal Methods	Comments
Solids	Landfill	No more than 1% of the daily municipal waste should be disposed of daily in an untreated form (non-immobilized) to a landfill
Semi-solids	Waste encapsulation	
Powders	Waste inertization	
Liquids	Sewer	Antineoplastics not to sewer

DISPOSAL METHODS FOR SORTING CATEGORIES

7

Table 7.2. Disposal method per pharmaceutical category (cont.)

Category	Disposal Methods	Comments
Anti-infective drugs	Waste encapsulation	Liquid antibiotics may be diluted with water, left to stand for several weeks and discharged to a sewer
	Waste inertization	
Antineoplastics	Return to donor/ manufacturer	Not to landfill unless encapsulated
	Waste encapsulation	Not to sewer
	Waste inertization	No medium temperature incineration

DISPOSAL METHODS FOR SORTING CATEGORIES

Table 7.2. Disposal method per pharmaceutical category (cont.)

Category	Disposal Methods	Comments
Controlled drugs	Waste encapsulation	Not to landfill unless encapsulated; destroyed under supervision of a pharmacist or the police depending on the regulations
	Waste inertization	
Aerosol containers	Landfill (Only if it does not contain poisonous substances)	Not to be burnt; may explode
	Waste encapsulation	

DISPOSAL METHODS FOR SORTING CATEGORIES

7

Table 7.2. Disposal method per pharmaceutical category (cont.)

Category	Disposal Methods	Comments
Disinfectants	Use To sewer or fast-flowing watercourse: small quantities of diluted disinfectants (max. 50 liters per day under supervision)	No undiluted disinfectants to sewers or water courses; Maximum 50 litres per day diluted to sewer or fast-flowing watercourse; No disinfectants at all to slow moving or stagnant watercourses
PVC plastic, glass	Landfill	Not for burning in open containers.
Paper, cardboard	Recycle, burn, landfill	

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

For each of the following statements, write T if the statement is true and F if it is false:

1. Improper disposal of expired pharmaceuticals may pose a threat to public health and the environment.
2. All liquid pharmaceutical preparations maybe disposed into the sewer but require dilution prior to disposal.
3. The dosage form of the drug is a primary consideration in determining the appropriate disposal method.
4. Disposal of unwanted medicines is the sole responsibility of the pharmacist- or personnel-in-charge of managing medicines in the local public health facility.
5. Returning to donor or manufacturer is the easiest and most practical way of disposing unwanted medicines.

WORLD HEALTH ORGANIZATION. 1999. *Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies*. [online]. [Accessed 12 November 2014]. Available from: <http://www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf>

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Training Manual on Pharmaceutical Supply Chain Management

PARTICIPANT'S MANUAL
for Local Government Facilities
(City Health Offices, Municipal Health Offices,
Rural Health Units, and Barangay Health Stations)



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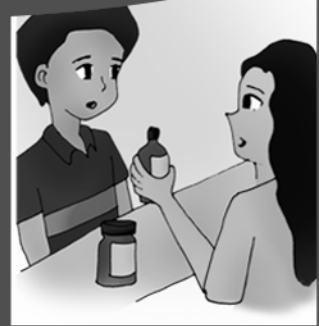




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Glossary of Abbreviations

ADE	Adverse Drug Event	FDA	Food and Drug Administration
ADORS	Adverse Drug Online Reporting System	FEC	Formulary Executive Council
ADR	Adverse Drug Reaction	FEFO	First Expiry, First Out
AO	Administrative Order	FIFO	First In, First Out
BAC	Bids and Awards Committee	GMP	Good Manufacturing Practice
BHS	Barangay Health Stations	INN	International Nonproprietary Name
CHO	City Health Office	LGU	Local Government Unit
DOH	Department of Health	MHO	Municipal Health Office
EO	Executive Order	FEC	Formulary Executive Council

Glossary of Abbreviations

NCCMERP	National Coordinating Council for Medication Error Reporting and Prevention	PVC	Polyvinyl Chloride
NCPAM	National Center for Pharmaceutical Access and Management	RA	Republic Act
OTC	Over-the-Counter	RH	Relative Humidity
SALADs	Sound-alike look-alike drugs	RHU	Rural Health Unit
PNDF	Philippine National Drug Formulary	RI	Request Indicator
PNF	Philippine National Formulary	USP	United States Pharmacopeia
PTC	Pharmacy and Therapeutics Committee	WHO	World Health Organization