

# PRACTICAL GUIDE FOR THE MANAGEMENT OF PHARMACEUTICALS AND HEALTH-RELATED COMMODITIES

Standard Operating Procedures and Tools for Health Facility Staff and Warehouse Personnel

Department of Health May 2015



SIAPS Systems for Improved Access to Pharmaceuticals and Services Systems for Improved Access to Pharmaceuticals and Services Management Sciences for Health Room 4011, Lung Center of the Philippines, Quezon Ave., Quezon City Philippines Tel no. (632) 921-6486 / (632) 921-6292 This guide is made possible by the generous support of the American people through the US Agency for International Development (USAID), under the terms of cooperative agreement numberAID-OAA-A-11-00021 The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

#### ABOUT DOH AND NTP

The Department of Health (DOH) of the Philippines has overall technical authority for health as the national health policy maker and regulatory institution. Its mandate is to develop national plans, technical standards, and guidelines on health with the goal of universal health care by: 1) financial risk protection through expansion of enrollment and benefit delivery of the National Health Insurance Program; 2) improved access to quality hospital and health care facilities; and 3) attainment of health-related Millennium Development Goals. The National Tuberculosis Control Program (NTP) is a priority public health program. Under the leadership of the Disease Prevention and Control Bureau, the NTP has been implemented nationwide since 1978. The main strategy of the NTP since 1997 is the World Health Organization-recommended DOTS.

### **ABOUT SIAPS**

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and quality pharmaceutical services.

# **RECOMMENDED CITATION**

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# **KEY WORDS**

TB, drugs and commodities, NTP, supply chain, supply management, warehouse management, logistics

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# ACRONYMS

ADR     adverse drug reaction       APP     annual procurement plan       CHD     Center for Health Development	
CHD Center for Health Development	
CHO City Health Office	
COBAC Central Office Bids and Awards Committee	
DOH Department of Health	
Disease Prevention and Control Bureau	
FDA Food and Drug Administration	
FEFO first expiry, first out	
FIFO first in, first out	
FQ fluoroquinolones	
GMP Good Manufacturing Practices	
AEB Invitation to Apply for Eligibility and to Bid	
D identification	
DO Infectious Disease Office	
IRP invoice receipt for property	
IRR implementing rules and regulations	
LCRB lowest calculated and responsive bid	
LGU Local Government Unit	
LMD Logistics Management Division	
MDR-TB multidrug-resistant TB	
MMD Material Management Division	
MOP Manual of Procedure	
MSH Management Sciences for Health	
NCDPC National Center for Disease Prevention and Control	
NGO nongovernmental organization	
NSAID nonsteroidal anti-inflammatory drug	
NTRL National TB Reference Laboratory	
PhilPACT Philippine Plan of Action to Control TB	
PHO Provincial Health Office	
PMDT Programmatic Management of Drug-resistant TB	
PNDF Philippine National Drug Formulary	
PPMP Project Procurement Management Plan	
RHU Rural Health Unit	
RIS requisition and issue slip	
RITM Research Institute for Tropical Medicine	
SLD second-line anti-TB drug	
SOP standard operating procedure	
Satellite Treatment Center	
STG standard treatment guidelines	
TC Treatment Centers	
TB tuberculosis	
TWG technical working group	
USAID US Agency for International Development	
WHO World Health Organization	

# FOREWORD



Republic of the Philippines Department of Health OFFICE OF THE SECRETARY



Tuberculosis (TB) is the sixth leading cause of mortality in the Philippines, impacting at least 2.5 million Filipinos and their families in 2009. The Department of Health is deeply committed to achieving the 2016 Philippine Plan of Action to Control TB (PhilPACT) targets on treatment success rates for TB and multidrugresistant TB (MDR-TB) cases. However, there needs to be a comprehensive and collaborative effort to improve pharmaceutical management at the service delivery level.

This *Practical Guide for the Management of Pharmaceuticals and Health-Related Commodities*, as jointly prepared by the Department of Health and the USAID-funded Systems for Improved Access to Pharmaceutical Services (SIAPS) program, provides an action-oriented reference tool for the selection, procurement, distribution, and use of TB supplies. It is targeted for use by all health care workers and professionals in the local health units and storage facilities. The document includes a catalog of TB medicines and supplies as well as standard operating procedures (SOP) for the management of the TB supply chain.

The Department of Health believes that the use and adoption of this manual's guidelines and procedures are necessary to strengthen the management of the supply chain system. Along with regular mentoring, monitoring, and supervision of local supply chain workers, this publication will contribute to ensuring the quality, safety, and uninterrupted supply of TB medicines and other commodities.

Janette P. Loreto-Garin, MD, MBA-H Secretary of Health

#### **RATIONALE AND PURPOSE**

The results of the 2013 National Tuberculosis Control Program (NTP) Joint Program Review and other monitoring findings show that there are gaps in the knowledge, attitude, and practices of health workers to ensure the safety and uninterrupted supply of TB medicines and other required commodities for the program. Most health facilities and warehouse staff do not maintain inventory records, know how to calculate their facility's needs, submit medicine requirement reports, and safeguard the quality of medicines and commodities.

The primary goal of this document is to provide a basic action-oriented reference tool for supply chain management and standard operating procedures (SOP) for use by the health units and storage facilities. This practical guide aims to be a supplemental source of recommended practices for health workers handling and managing medicines and health commodities in the field in specific areas of the supply management framework. In addition, this material is intended to aid in addressing various pharmaceutical management issues, including stock-outs, overstocking, and damage as well as to contribute to the attainment of the PhilPACT indicator that there should be no stock-outs of medicines and other needed commodities in health facilities.

# TARGET AUDIENCE

The target audience for this document are personnel who are directly involved in the management of medicines and commodities. This includes staff from the health-facility level and warehouses involved in the distribution, storage, and use of TB medicines and commodities. Managers at the national, regional, and provincial/city level who are monitoring and supervising supply chain management may also learn and benefit from this Practical Guide.

# **DESCRIPTION OF THE PRACTICAL GUIDE**

This document is divided into sections highlighting the components of the supply chain management cycle. Each section is divided into three parts, as described below:

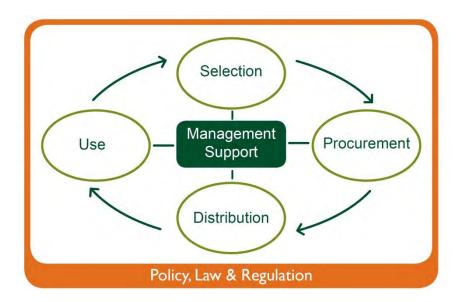
	<b>Overview</b> gives a brief description of the particular section and its various topics.
	Key Activities details the major activities that are done under the specific section. It also refers the reader to the corresponding procedure number.
PROCEDURES	<b>Procedure</b> describes the step-by-step process of how to do the set of activities listed in the summary of key activities part.

# SUMMARY OF PROCEDURES

1	SELECTION
2	PROCUREMENT
3	DISTRIBUTION
Procedure 1	Receipt and Inspection
	Inventory Control
Procedure 3	
Procedure 4	Requisition
Procedure 5	Allocation
Procedure 6	Delivery/Issuance
Procedure 7	Disposal of Expired and Damaged Commodities
4	RATIONAL USE
Procedure 8	Drug Education
Procedure 8 Procedure 9	
Procedure 8 Procedure 9 Procedure 1	Drug Education Dispensing Medicines
Procedure 8 Procedure 9 Procedure 1 Procedure 1	Drug Education Dispensing Medicines O Management of Adverse Drug Reactions (ADRs) I Reporting of ADRs
Procedure 8 Procedure 9 Procedure 1	Drug Education Dispensing Medicines <b>0</b> Management of Adverse Drug Reactions (ADRs)
Procedure 8 Procedure 9 Procedure 1 Procedure 1	Drug Education Dispensing Medicines O Management of Adverse Drug Reactions (ADRs) I Reporting of ADRs MANAGEMENT SUPPORT
Procedure 8 Procedure 9 Procedure 1 Procedure 1 5 Section 1 Rec	Drug Education Dispensing Medicines O Management of Adverse Drug Reactions (ADRs) 1 Reporting of ADRs
Procedure 8 Procedure 9 Procedure 1 Procedure 1 5 Section 1 Rec Section 2 Rec	Drug Education Dispensing Medicines O Management of Adverse Drug Reactions (ADRs) I Reporting of ADRs MANAGEMENT SUPPORT cording and Reporting at the Health Facilities
Procedure 8 Procedure 9 Procedure 1 Procedure 1 5 Section 1 Rea Section 2 Rea Section 3 Rea	Drug Education Dispensing Medicines O Management of Adverse Drug Reactions (ADRs) 1 Reporting of ADRs MANAGEMENT SUPPORT cording and Reporting at the Health Facilities cording and Reporting at the Warehouse

# INTRODUCTION

Management of medicines and health-related commodities follows the supply chain management cycle depicted in Figure 1 below. It consists of four components: SELECTION, PROCUREMENT, DISTRIBUTION, and USE, supported by management systems and guided by a POLICY AND LEGAL FRAMEWORK.



Source: Center for Pharmaceutical Management. 2011. Center for Pharmaceutical Management: Technical Frameworks, Approaches, and Results. Arlington, Virginia: Management Sciences for Health.

# Figure 1. Supply chain management cycle

**Selection** involves the identification of medicines and commodities that are required and essential, and that are made available for the health program. It is important to ensure that the medicines and health commodities managed are based on approved standard treatment guidelines (STG) and the essential medicines list (EML) of the Department of Health (DOH).

**Procurement** includes the quantification and determination of the procurement method designed to acquire quality and affordable medicines and health commodities. In the Philippines, this is governed by the Republic Act (RA) 9184 of 2003 and its implementing rules and regulations (IRR). **Distribution** is the movement of medicines and commodities, including their storage, from the central store to the point of care. The term, **rational use**, refers to the appropriate, safe, and effective use of medicines and other supplies.

**Management support** provides the right structure and systems to establish a functioning and effective health program, which includes a quality assurance system, human resources, funding, information management, training, monitoring and evaluation, etc. The **policy and legal framework** establishes the goal and the main strategies for attaining a high-functioning health program as well as the structures to coordinate activities.

# ROLES OF STAKEHOLDERS

SUPPLY CHAIN MANAGEMENT is a process that requires teamwork among several stakeholders. Each stakeholder plays a vital role in ensuring that all components of the cycle are functioning and directly contributing to the attainment of the program's goal. The involvement of each stakeholder is unique and inter-related; this is why identifying and establishing the roles and responsibilities is very important. Several development partners are engaged in the DOH's tuberculosis control program. The following table describes the role of government agencies as stakeholders in the implementation of supply chain management within the NTP.

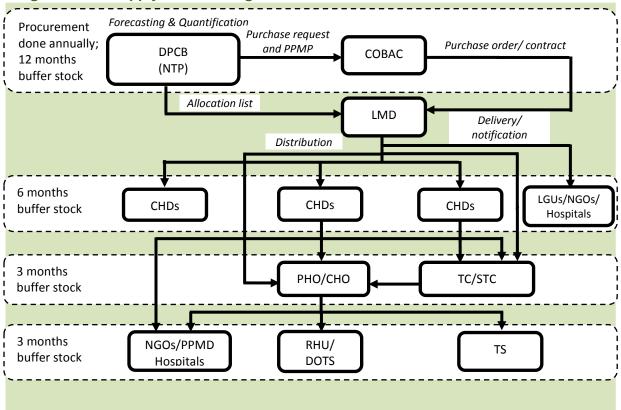
GOVERNMENT AGENCIES	FUNCTIONS
Disease Prevention and Control Bureau/National TB Control Program (DPCB/NTP)	<ul> <li>Formerly the National Center for Disease Prevention and Control (NCDPC)</li> <li>Supervises the overall implementation of the TB program in the country.</li> <li>Serves as the key decision maker in terms of policies and strategies to be undertaken.</li> <li>Identifies treatment regimens to be used by the program.</li> <li>Quantifies the medicines and other supplies required by the program.</li> <li>Allocates medicines and other supplies to regions and provinces.</li> </ul>
Research Institute for Tropical Medicine/National TB Reference Laboratory (RITM/NTRL)	<ul> <li>Coordinates with the NTP on the management of the laboratory network, including the management of laboratory supplies and equipment.</li> </ul>
Central Office Bids and Awards Committee (COBAC)	• Manages the procurement process for the DOH's Central Office in accordance with Republic Act 9184 of 2003.
Logistics Management Division (LMD)	<ul> <li>Formerly the Material Management Division (MMD).</li> <li>Manages the storage and distribution of medicines and health commodities for the various programs of the DOH, including the NTP.</li> <li>Manages the central warehouse of the DOH.</li> </ul>
Center for Health Development (CHD)	<ul> <li>Oversees the implementation of the NTP at the regional level and coordinates with the DOH's Central Office and Local Government Units.</li> <li>Manages the regional warehouse and distributes TB medicines and supplies to provinces/cities.</li> </ul>
Local Government Unit (LGU)	<ul> <li>Implements the NTP and other health services at the local government.</li> </ul>
Provincial/City Health Office (PHO/CHO)	<ul> <li>Oversees the implementation of DOTS at the provincial/city level.</li> <li>Stores TB medicines and supplies and distributes them to the health facilities.</li> </ul>
Rural Health Unit (RHU)/DOTS facilities	<ul> <li>Provides direct TB services to patients.</li> <li>Ensures the appropriate management and uninterrupted supply of TB medicines and commodities at the facility level.</li> </ul>

Diagram 1 presents the TB supply chain management process, from forecasting and quantification to distribution.

The Disease Prevention and Control Bureau (DPCB), formerly the NCDPC, through the NTP, prepares the forecast for TB medicines and other commodities, and submits a purchase request (PR) and Project Procurement Management Plan (PPMP) based on the quantification of the country's annual requirements. The PR and PPMP are sent to the Central Office Bids and Awards Committee (COBAC) for processing of the procurement.

Suppliers deliver the procured TB medicines and supplies to the Logistics Management Division (LMD), which acts as the central warehouse of the DOH. TB medicines are distributed from the central warehouse through a network of facilities, where medicines are stored and distributed until they reach the patients. The Center for Health Development (CHD) maintains six months of buffer stock; the Provincial Health Office (PHO) or City Health Offices (CHO) maintain three months of buffer stock; and the Rural Health Units (RHU) and DOTS facilities maintain three months of supply, plus buffer stock of TB medicines and health commodities.

# Diagram 1: TB Supply chain management



Selection		Distribution		Management support	
	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	
	Procurement		Rational Use		
		OVERVIEW			

The well-managed selection of medicines means that the TB program chooses medicines based on epidemiological profile, recent drug resistance data, and STGs or the NTP's Manual of Procedure (MOP). A good selection process also ensures that medicines to be used are cost effective, quality assured, and are able to pass the requirements set by the Food and Drug Administration (FDA).

The FDA, as per Administrative Order no. 67 series of 1989, requires that all selected medicines and medical supplies in the public sector are registered.

According to Executive Order no. 49, s 1993, only medicines listed in the latest Philippine National Drug Formulary (PNDF) are allowed to be procured and used by all government entities.

The rationale for selecting a limited number of essential medicines is that it may lead to better supply, more rational use, and lower costs. Essential medicines are those that are deemed to satisfy the health care needs of the majority of the population and that should be available in the appropriate dosage forms and strengths at all times. Because selection of medicines has a considerable impact on quality of care and cost of treatment, it is one of the most cost-effective areas for intervention.

*Source:* Management Sciences for Health. *MDS-3: Managing Access to Medicines and Health Technologies.* Arlington, VA: Management Sciences for Health; 2012.



Medicines and medical equipment used by DOH programs should be registered with the FDA. Product registration is a process whereby the FDA reviews and evaluates products to determine their quality, safety, and efficacy prior to public use.

Selection		Distribution		Management support	
	•	$\bigcirc$	$\bigcirc$	$\bigcirc$	
	Procurement		Rational Use		

#### OVERVIEW

An efficient procurement mechanism should have a good quantification system, which is the calculation of specific medicine needs. The procurement process requires skills in tendering and contracting to manage local procurement as well as international procurement, if needed. There should also be a prequalification process, including the Good Manufacturing Practices (GMP) certification requirement for choosing suppliers, to ensure that procured medicines and commodities are of good quality. A procedure for monitoring prices and supplier performance should also be in place.

Coordination with other partners, i.e., the Central Office of the DOH and LGUs, should be maintained to ensure that there is harmonization in procurement.

Procurement by the government is under the jurisdiction of RA 9184, which ensures transparency and standardization of the process.

Under the current policy, TB medicines are procured annually by the DOH Central Office. Quantification is done by the NTP, as described below.



# SUMMARY OF KEY ACTIVITIES FOR PROCUREMENT

#### Quantification

The NTP Program Manager prepares the quantification based on case and inventory reports submitted by NTP coordinators at health facilities.

The DPCB submits the PPMP and procurement request to COBAC for procurement.

#### Procurement

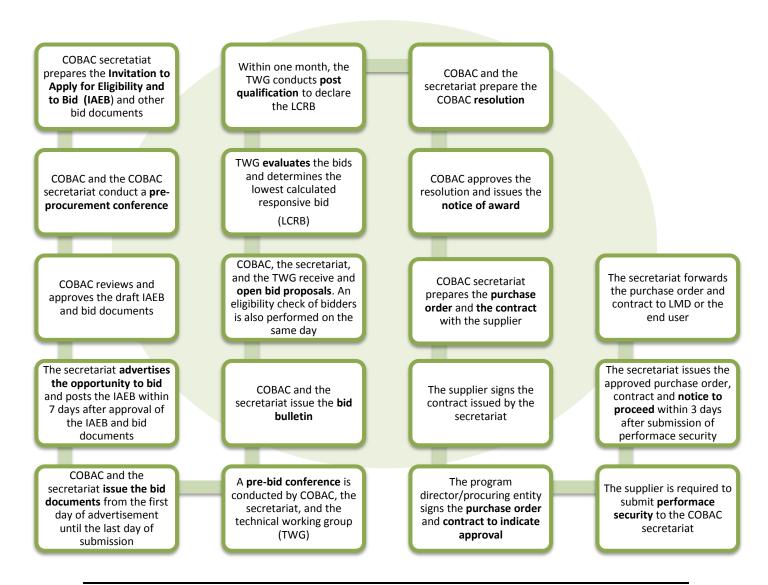
The procurement of medicines and supplies follows provisions of RA 9184 and its implementing rules and regulations (IRR).

Public bidding is the general mode of procurement. However, for highly exceptional cases, there are alternative methods of procurement, such as selective bidding, single source procurement, etc.



Accurate and timely submission of reports from the health facilities is very important for the DOH Central Office to prepare an accurate forecast and quantification.

# Diagram 2: Competitive bidding/public bidding process



Source: PSM MOP 2011



When procuring medicines for public health programs, you should consider the following:

- Provisions stated in RA 9184.
- Use competitive or public bidding as the general mode of procurement.
- *Medicines should be in accordance with international guidelines and are indicated in the national standard guidelines.*
- Medicines should be duly registered by the FDA.
- Medicines should be included in the PNDF.

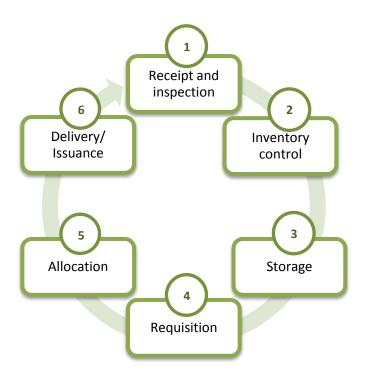
Selection		Distribution		Management support	
		•	$\bigcirc$	$\bigcirc$	
	Procurement		Rational Use		
		OVERVIEW			

To have a good distribution structure, there should be:

- A transportation system that is cost effective and timely.
- Appropriate delivery methods and management in the health care setting.
- Skilled and trained health facility staff and warehouse personnel for maintaining inventory, and storage and distribution practices.

Medicines and supplies require proper handling at all levels of the health care system because they are expensive and very valuable to the health program and to patients. To do this effectively requires a lot of effort and commitment on the part of the warehouse and health facility staff. Diagram 3 below depicts the processes involved in the distribution cycle for TB medicines and health commodities.

# **Diagram 3: Distribution cycle**



The distribution cycle for TB medicines for both health facilities and warehouses follows the same path, for the most part, which involves receipt and inspection, inventory control, and storage. However, only health facilities request medicines and only warehouses deliver or issue medicines to health facilities based on the allocation list.



# SUMMARY OF KEY ACTIVITIES FOR DISTRIBUTION

Procedure 1
Receipt and Inspection
Procedure 2
Inventory Control
Procedure 3
•Storage
Procedure 4
•Requisition
Procedure 5
•Allocation
Procedure 6
•Delivery/Issuance
Procedure 7
• Disposal of Expired and Damaged Commodities

Proce 1	dure Objective: To define the standard procedure for ensuring that all commodities are received and inspected properly upon delivery. Time/Frequency: Every delivery Responsibility: Warehouse personnel/RHU nurse/point person for medicines
STEP	PROCEDURE
••••	Receive the commodities from delivery staff:
1.1	<ul> <li>a. Ensure that the delivered stocks are placed separately while undergoing inspection to avoid mix up with other stock.</li> <li>b. Review the delivery receipt documents to determine whether they are consistent with the purchase request or requisition form: <ul> <li>At the warehouse, check the bill of lading, purchase order, and invoice receipt for property (IRP).</li> <li>At the facility, check the requisition and issue slip (RIS).</li> </ul> </li> <li>c. Count the delivered commodities and check for accuracy: <ul> <li>Name of the item, strength, and dosage form.</li> <li>Quantity in the specific unit of measure (in tablets, boxes, or cartons, etc.).</li> <li>Expiry date and batch number.</li> </ul> </li> </ul>
	The <b>delivery receipt</b> is a document that is typically signed by the receiver of a shipment to indicate that it
	has, in fact, received the item being shipped and has taken possession of it. Examples include: IRP, RIS.
1.2	<ul> <li>Check the condition of commodities:</li> <li>a. Commodities needing refrigeration: Ensure cold chain during transport. These items should be checked first for immediate storage.</li> <li>b. Signs of damage by checking the condition of the cartons and packaging.</li> <li>c. Quality of items delivered. (Refer to Annex 2.A1.)</li> <li>It is very important to meticulously check the boxes and containers for signs of damage!</li> <li>Some cartons may contain several types of medicine and/or medicines that will expire. Check them properly and account separately to ensure observance of first expiry, first out (FEFO).</li> </ul>
1.3	<ul> <li>Document any discrepancy or damage:</li> <li>a. Record discrepancies clearly the delivery receipt.</li> <li>b. Take pictures of damaged goods for documentation.</li> <li>c. Report and notify supervisor or coordinator of discrepancies or damage immediately and seek advice.</li> <li>d. Plan necessary actions.</li> </ul>
	Request for inspection of goods (for warehouses receiving commodities directly from market suppliers).
1.4.	<ul> <li>a. Submit a request for an inspection of the goods to the inspection committee (Annex 2F).</li> <li>b. If the goods pass inspection, request an Inspection and Acceptance Report (Annex 2G).</li> <li>c. If the goods DO NOT pass inspection, inform the DOH Central Office and seek advice.</li> <li>d. Give a copy of the inspection report to the Program Manager.</li> </ul>
	Sign the delivery receipt as a proof of acceptance.
1.5.	<ul> <li>a. Ensure that delivery staff also affixes their signature to the form.</li> <li>b. Keep and file the forms properly.</li> <li>c. Report or notify the supervisor or coordinator regarding the delivery.</li> </ul>





#### Inventory Control

Objective: To define the standard procedure for ensuring that proper inventory management is followed. Time/Frequency: Every medicine movement Responsibility: Warehouse personnel/RHU nurse/point persons

#### STEP PROCEDURE

Fill out a stock card for every commodity:

- a. Use separate stock cards for different dosages, strengths, unit sizes, or expiration dates.
- b. Update the stock card when receiving commodities:
  - b.1. Fill in date received
  - b.2. Enter quantity received
  - b.3. Update stock balance
  - b.4 Indicate the source of the commodity
- c. Update the stock card when issuing or dispensing commodities:
  - c.1 Fill in the date issued
  - c.2.Enter quantity issued
  - c.3. Update stock balance
  - c.4 Indicate the recipient of the commodity

Stock cards are the inventory management tools used for monitoring the movement of commodities, expiration, and quantity.

Ensure that recorded quantities tally with the actual stock on hand:

- a. Count actual stocks on hand regularly (i.e., quarterly) and compare with the stock card.
- b. Record and investigate discrepancies in quantities.
- c. File stock cards for future reference.

Counting stocks regularly ensures that the stock balance on the stock cards is consistent with the physical count. This is done by the warehouse personnel and RHU nurse.

Update the electronic inventory systems, such as the National Online Stock Inventory Reporting
System (NOSIRS). Ensure that the data entered in NOSIRS is consistent with the actual stocks on hand.

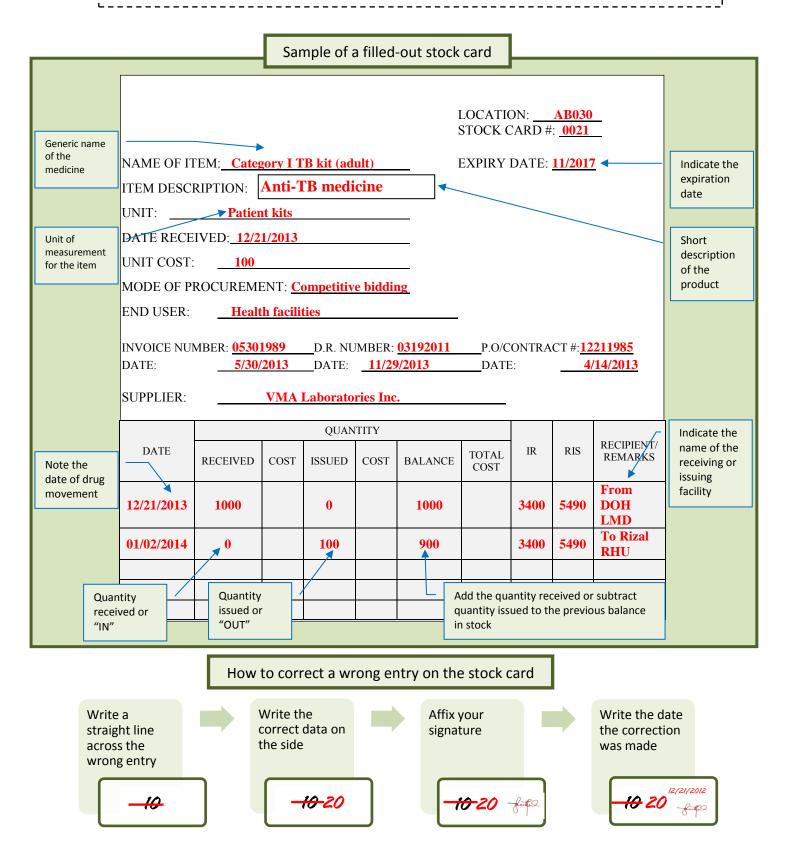


Pencil should not be used to fill out a stock card and liquid eraser should not be used for corrections.

2.1

2.2

STOCK CARD Time/Frequency: Every delivery and maintained during the storage period. Responsibility: Warehouse personnel/RHU nurse/point person





3

#### **PROCEDURES: DISTRIBUTION**

#### Procedure Storage Objectiv

Objective: To define the standard procedure for ensuring that all commodities are stored and well maintained. Time/Frequency: Every delivery Responsibility: Warehouse personnel/RHU nurse/point person

STEP	PROCEDURE		
3.1	Prepare the storage area. (Refer to Annex 2.A2 for proper storage practices.)		
3.2	Assign an appropriate area for the storage of received commodities.		
	<ul> <li>Assign fast moving items to the most accessible area.</li> </ul>		
2.2	If applicable, fill in a locator card for each commodity.		
3.3	Locator cards are used by storage facilities to record and document the designated storage areas for each commodity.		
3.4	<ul> <li>Transfer commodities to assigned storage area and organize stocks:</li> <li>a. Ensure that commodities are handled properly during transfer.</li> <li>b. Arrange similar items together by type or by classification; (separate medicines from other supplies or chemicals).</li> <li>c. Arrange stocks with expiration dates according to FEFO, and other commodities without expiration dates according to FIFO.</li> </ul>		
	<ul><li>FEFO (first expiry, first out): products with the earliest expiry date are the first issued.</li><li>FIFO (first in, first out): the first products received are the first issued.</li><li>FEFO and FIFO are both used in storage facilities, FEFO for commodities with expiration dates, and FIFO for commodities without expiration dates or with the same expiration.</li></ul>		
	Monitor temperature regularly in the refrigerator and storage room:		
3.5	a. Ensure appropriate temperature conditions, as per recommendations of the manufacturers. (See Table 1 .		
	b. b. File all temperature monitoring forms or logbook. (See Annex 3A.)		

Schedule regular cleaning and maintenance of the storage area.

3.6 Ideally, the temperature should be monitored three times a day: morning, noon, and afternoon.

Make sure that expiration dates of commodities are visible for easy observance of FEFO.:

#### Table 1: Standard temperature range

Description	Temperature range
Protect from excess heat	25-30° Celsius
Room temperature	15-25° Celsius
Keep cool	8-15° Celsius
Refrigerated	2-8° Celsius
Frozen	<0° Celsius



# Procedure A A Objective: To define the standard procedure for reporting and requisition of medicines and supplies. Time/Frequency: Quarterly Responsibility: Coordinator/RHU nurse/point person STEP PROCEDURE

SIEP	PROCEDURE
4.1	Identify the facility's needs based on the previous quarterly report.
4.2	Update stock inventory by conducting a physical count and updating the stock cards.
4.3	Fill in the "Quarterly report on drugs and supply inventory and requirement" (next page). Consider the quarterly need, buffer and stock on hand when preparing the report.
4.4	Submit the quarterly report to the coordinator. See Table 2 for the recommended schedule on the submission of the requisition. File a copy for documentation.

Procedure 5

#### Allocation

Objective: To define the standard procedure for allocating medicines and supplies.
Time/Frequency: Quarterly
Responsibility: Coordinator/supply officer/warehouse personnel

#### STEP PROCEDURE Provincial/city coordinators review and validate the "Quarterly report on drugs and supply inventory and 5.1 requirement" of the RHUs and DOTS facilities. Provincial/ city coordinators provide feedback to RHUs and DOTS facilities on any adjustments and 5.2 clarifications. Based on validated and consolidated quarterly reports, prepare an allocation list for distribution to all 5.3 RHUs and DOTS facilities and submit it to the provincial/city supply officer. 5.4 Submit the validated and consolidated quarterly reports to the regional office. Regional coordinators review and consolidate provincial and city quarterly reports and submit them to 5.5 the Central Office. Central Office Coordinator prepares an allocation list of medicines and supplies for the regional 5.6 warehouses and submits it to the central warehouse supply officer.

5.7 Warehouse supply officer confirms the receipt of the allocation list and prepares for delivery/issuance.

# Table 2: Requisition schedule

Quarter	Month of Requisition (first week of)
1	January
2	April
3	July
4	October



#### DRUG INVENTORY AND REQUIREMENT REPORT

\_\_\_\_\_

Time/Frequency of submission: Quarterly

Responsibility: RHU nurse/point person

Sample Drug Inventory and Requirement Report Report 4. Quarterly report on drug and supply inventory and requirement (Data Source- Stock Inventory Records and Program Reports) CHD: <u>Region X</u> Province/City: <u>Y Province</u> Report for <u>2nd</u> Quarter of <u>2014</u> Municipality: Maharlika Municipality Date reported: April 7, 2014 Prepared by: Anya Eliza Cristobal DOTS Facility: Maharlika Health Center Total population of catchment area: <u>10,000</u> Designation: <u>HC Nurse</u> \_\_\_\_\_ A. Quarterly Drug Inventory and Requirements Expected cases based Category 2 TB Category 1 TB Category 2 TB Category 1 TB on past Treatment Regimen Kits (Adult) Kits (Adult) Kits (Children) Kits (Children) quarter's > 33 New cases 2 accomplish-Retreatment cases 3 0 ment Total stocks required in a quarter (A) 2 0 33 3 Stock + buffer (B) =Ax2 66 4 0 6 Stock on Stock on hand (C) 0 2 0 8 hand based =B-C Total kits to request 58 6 2 0 on stock card or For DOTS Facilities: actual To get the total request, Did your facility experience stock-outs of Cat 1 anytime during this quarter? physical subtract the stock on count hand from the required Yes stock with buffer. No Tick "Yes" if Example, 66 – 8 = 58 your facility For province, city and regional level: had stock outs of Cat 1 No. of DOTS Facilities with stock-outs of Cat 1 in this guarter and "No" if Total no. of DOTS facilities none



A good requisition system for commodities depends primarily on reliable consumption data and accurate physical inventory reports.



# Procedure 6

#### **Delivery/Issuance**

Objective: To define the standard procedure for ensuring that all commodities are handled well during delivery. Time/Frequency: Quarterly Responsibility: Supply officer/warehouse personnel

#### STEP PROCEDURE

Check if stocks are available and sufficient based on the allocation received from the coordinator:

- a. If commodities are not available or are insufficient, inform the coordinator.
- b. If the goods are for cross-docking, inform the coordinator and recipient.
- 6.1

6.5

"Cross-docking" is a delivery method used wherein stocks are shipped directly to subsidiary levels of the supply chain, thus limiting storage and handling. For example, when medicines are distributed from the LMD central warehouse directly to the PHO. This should be done in coordination with the CHD.

Prepare the following documents:

- a. Invoice receipt for property
  - b. Requisition and issue slip

6.3 Pick medicines and commodities from the storage area, and prepare them for packaging and labeling according to the allocation list.

6.4 Update inventory records: stock cards and/or electronic system, such as NOSIRS.

Determine if the goods are to be picked up by recipients or delivered:

- a. If the goods are to be picked up, inform the recipients of the following:
  - Schedule when goods are available for pickup
  - Description and quantity of items
- b. If the goods are to be delivered, arrange for vehicle and driver. Inform the recipient of the delivery schedule and time/date of arrival.
- 6.6 When handing over the medicines and supplies, secure the signature of the recipient on the RIS and IRP.

6.7 File the RIS and IRP.



NOSIRS captures inventories of all commodities purchased/received and distributed by the Logistics Management Division (LMD) of the DOH to the different CHDs, retained hospitals, and other health facilities, and purchased and dispensed/distributed by the CHDs and different health facilities (other than the LMD).

*Source*: <u>http://www.ncpam.doh.gov.ph/index.php/26-presentation/70-nosirs-presentation</u>



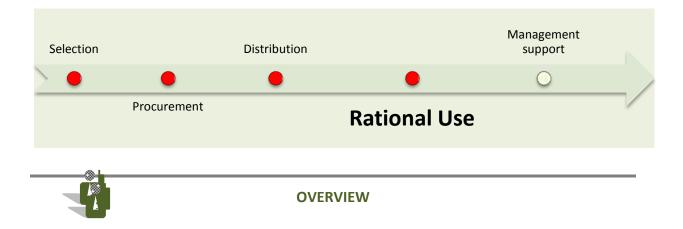
Pro	<ul> <li>Disposal of Expired and Damaged Commodities</li> <li>Objective: To define the standard procedure for ensuring that all expired and damaged commodities are handled and disposed of properly.</li> <li>Time/Frequency: When necessary</li> <li>Responsibility: Warehouse personnel/RHU nurse/point person</li> </ul>		
STEP	PROCEDURE		
7.1	Carefully identify the expired medicines and damaged commodities.		
	(Use the indicators of poor quality and damaged supplies in Annex 2.A1 as a reference.)		
7.2	Separate the storage of expired or damaged medicines from the good stock and label the containers properly.		
7.3	Reflect the quantities expired or damaged on their corresponding stock cards.		
7.4	Coordinate with the sanitary engineer or sanitary officer of the health facility or PHO/CHO for their proper disposal.		
7.5	Complete a report on the expired or damaged medicines and submit to the supervisor and sanitary officer. File a copy for the facility's documentation.		
7.6	Get samples and take pictures of the damaged or expired commodities for documentation.		
7.7	Take direction from the sanitary officer regarding the disposal method to be implemented. Refer to Annex 2.A3 (Guide for Disposal Method of Pharmaceuticals) and the DOH Health Care Waste Management Manual as references.		
7.8	Participate in, take pictures of, and document the disposal process.		
7.9	File all documentation.		



Facilities should regularly monitor expiry dates, and expired medicines should be immediately removed from stock.



It is important to properly label expired or damaged medicines and take pictures for documentation.



Use of medicines and health commodities is maximized in any health care setting if there is a correct diagnosis, rational prescribing, proper dispensing, and patient counseling. It is important that information is available for health care providers to ensure that the right treatment and strategies are being implemented. Monitoring, documenting medicine use, and seeking feedback from patients are also important to evaluate the effectiveness of treatment.

Continuous training and staff development should also be given to health care personnel to improve the quality of treatment services given to every patient. Management, recording, and reporting of ADRs are also important for observing pharmacovigilance. Ancillary medicines are provided to aid in addressing ADRs. Patient kits with fixed- dose combination (FDC) tablets improve the compliance of patients. The DOTS strategy of the NTP requires patients to be under direct observation when taking their medicines. Below are the list of anti-TB medicines (Table 3) and the common ADRs and their management (Table 4). For the complete list of TB medicines and supplies, see Annex 1: Catalog of TB Commodities.

	First-line	
Cat I Adult kit	Intensive Phase: FDC HRZE: Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), Ethambutol (E)	75 mg, 150 mg, 400 mg, 275 mg
	<u>Continuation Phase:</u> FDC HR: Isoniazid (H), Rifampicin (R)	75 mg, 150 mg
Cat II Adult kit	Intensive phase: FDC HRZE Streptomycin (S) <u>Continuation phase:</u> FDC HRE	75 mg, 150 mg, 400 mg, 275 mg 1 gram 75 mg, 150 mg, 275 mg
TB in Children kit	Bottles of H suspension R suspension Z suspension	200 mg/5 ml 200 mg/5 ml 250 mg/5 ml
TB in children IPT kit II	H suspension	200 mg/5 ml, 100 mg/5 ml
Single formulation	H suspension	300 mg
	Z tablet	500 mg
	E tablet	400 mg
	Second-line	
Injectables	Kanamycin (Km) Capreomycin (Cm)	1 g 1 g
Fluoroquinolones (FQs)	Levofloxacin (Lfx)	250 mg, 500 mg
	Moxifloxacin (Mfx)	400 mg
Bacteriostatic oral second-line drugs	Prothionamide (Pto)	250 mg
(SLD)	Cycloserine (Cs)	250 mg
	Para-amino salicylic acid/sodium (PAS)	4 g
Reinforcers	Clofazimine (Cfz)	100 mg
	Amoxicillin-Clavulanic acid (Amx-Clv)	1 g
	Clarithromycin (Clr)	500 mg

#### Table 3. List of anti-TB medicines

Table 4. Common adverse drug reactions and	their management
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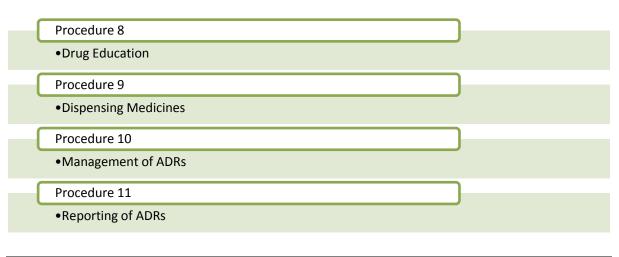
Table 4. Common advers	RESPONSIBLE	MANAGEMENT
	AGENT	
Gastro-intestinal intolerance	H, R	1. Give medication at bedtime or small meals.
Mild skin reaction	Any kind of medicines	1. Give antihistamines.
Orange/red-colored urine	R	1. Reassure the patient.
Pain at the injection site	S, Km and Cm	1. Apply warm compress. Rotate sites of injection.
Burning sensation in the feet due to peripheral neuropathy	н	1. Give Pyridoxine 100-200 mg daily for treatment. 10 mg daily for prevention.
Arthralgia due to hyperuricemia	Z, fluoroquinolones (FQ)	<ol> <li>Give aspirin or nonsteroidal anti-inflammatory drug (NSAID).</li> <li>If symptoms persist, consider gout and request a blood chemistry (uric acid determination and manage accordingly).</li> <li>Advise patient to avoid high-uric diet.</li> </ol>
Flu-like symptoms (fever, muscle pain, inflammation of the respiratory tract)	R	1. Give antipyretics.
Severe skin rash due to hypersensitivity	Any kind of medicines (especially S)	1. Discontinue anti-TB medicines and refer to DOTS physician.
Jaundice due to hepatitis	Any kind of medicines (especially H, R, Z)	<ol> <li>Discontinue anti-TB medicines and refer to DOTS physician.</li> <li>If symptoms subside, resume treatment and monitor clinically.</li> </ol>
Impairment of visual acuity and color vision due to optic neuritis	E	1. Discontinue E; refer to an ophthalmologist.
Hearing impairment, ringing in the ear, and dizziness due to damage of the eight cranial nerves	S, Km and Cm	1. Discontinue and refer to DOTS physician.
Oliguria or albuminuria due to renal disorder	R, S	1. Discontinue anti-TB medicines and refer to DOTS physician.
Psychosis and convulsion	H, Cs	1. Discontinue anti-TB medicines and refer to DOTS physician.
Thrombocytopenia, anemia, shock	R	1. Discontinue anti-TB medicines and refer to DOTS physician.
Seizures	Cs, FQs	<ol> <li>Rule out any other likely causes.</li> <li>Treat any suspected causes.</li> <li>Initiate anticonvulsant treatment phenytoin; valproic acid; carbamazepine; phenobarbital.</li> <li>Increase pyridoxine to 100 mg daily.</li> <li>Lower dose or discontinue suspect medicine.</li> </ol>
Peripheral neuropathy	Cs, S, Km, Cm, Pto, FQs	<ol> <li>Increase pyridoxine to 200 mg/day.</li> <li>Begin exercise regimen; focus on affected regions.</li> <li>Initiate therapy with tricyclic antidepressant medicines.</li> <li>Lower dose or discontinue suspected medicine.</li> <li>Initiate therapy with gabapentin.</li> </ol>
Hypothyroidism	PAS, Pto	1. Initiate thyroxine.
Hearing loss	S, Km, Cm	<ol> <li>Conduct audiometry and compare with baseline.</li> <li>Consider reducing frequency of the medicine.</li> <li>Lower the dose or discontinue suspected medicine if this will not compromise the regimen.</li> </ol>
Depression	Cs, FQs, Cm, Pto	<ol> <li>Rule out side effects of concomitant medications (e.g., amoxicillin-clavulanate, penicillin, benzodiazepines).</li> <li>Refer to psychologist or psychiatrist for assessment.</li> <li>Initiate group or individual psychological therapy.</li> <li>Initiate anti-depressant medicines ( e.g., amitriptyline, nortiptyline, fluoxetine, sertraline), but use with caution when there is a history of convulsions.</li> <li>Increase pyridoxine to 200 mg daily.</li> </ol>

ADR	RESPONSIBLE	MANAGEMENT
	AGENT	
		6. Lower dose or discontinue suspect medicine if this will not
		compromise the regimen.
		1. Assess for rehydration and rehydrate if indicated.
Nausea and vomiting	Z, E, Pto, PAS, Cm	2. Initiate anti-emetics 30 minutes prior to administering anti-TB
	, ,, -, -	medicines.
		3. Lower dose or discontinue suspect medicine.
		1. Administer medicine with small amount of food.
		2. Caffeine and cigarettes should be avoided.
		3. Consider use of:
		<ul> <li>Antacids (e.g., calcium carbonate, aluminum hydroxide, magnacium budrovida)</li> </ul>
Gastritis	Z, E, PAS, Pto	magnesium hydroxide)
		<ul> <li>H2-Blockers (e.g., cimetidine, ranitidine), proton pump inhibitors (e.g omeprazole)</li> </ul>
		<ol> <li>Withhold suspect medicine(s) for short periods of time (e.g., 1-7</li> </ol>
		days).
		5. Lower dose or discontinue suspect medicine.
		Discontinue causative medicine.
		<ol> <li>Consider dosing 3 times per week and monitor creatinine</li> </ol>
Renal failure and	S, Km, Cm	clearance.
nephrotoxicity		3. Adjust dose of all the medicines according to creatinine
		clearance.
		4. Consider use of capreomycin if patient is on aminoglycoside.
		1. Replenish potassium.
		2. Treat associated vomiting or diarrhea.
Electrolyte disturbances		3. Check magnesium levels if potassium levels do not improve.
(hypokalemia,	Cm, Km, S	4. Discontinue arrythmogenic medicines (e.g., digoxin,
hypomagnesemia)		amitriptyline, cisapride, and haloperidol) if patient is taking
		them.
		5. Discontinue aminoglycosides if condition is severe.

Sources: Department of Health, Republic of the Philippines. NTP Manual of Procedures. Manila: Department of Health; 2014; World Health Organization. Guidelines for the Programmatic Management of Drug-resistant Tuberculosis. Geneva: WHO; 2008.



# SUMMARY OF KEY ACTIVITIES

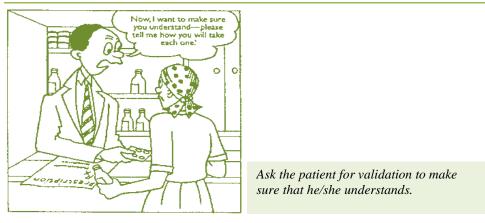




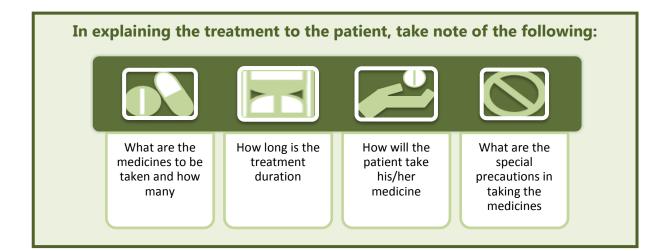
# **PROCEDURES: RATIONAL USE**

Proc	A Drug Education Objective: To define the standard procedure for ensuring that patients and family members receive proper education on their medicines. Time/Frequency: During initiation of treatment Responsibility: Health facility staff/treatment partner
STEP	PROCEDURE
8.1	Upon finalization of diagnosis and prescription, gather the patient together with family member(s) or companion.
8.2	Explain the treatment to be started, for how long, what medicines, need for supervised treatment, etc.
8.3	Explain the possible side effects of each medicine.
8.4	Encourage the patient to voice any complaints of ADRs.
8.5	Ask for any questions or clarifications.

8.6 Validate by asking the patient about his/her treatment.



Source: Management Sciences for Health/Euro Health Group. *Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals.* West Hartford, CT: Kumarian Press; 1997.



	PROCEDURES: RATIONAL USE			
Procedure 9 9 Dispensing Medicines Objective: To define the standard procedure for ensuring that medicines and other commodities are being handled properly during dispensing. Time/Frequency: Every day Responsibility: Health facility staff/treatment partner				
STEP	PROCEDURE			
9.1	Start treatment based on the doctor's prescription indicated in the patient's chart.			
9.2	Check the label for the correct medication. Assign one kit per patient, except for MDR-TB, where second-line anti-TB medicines are not arranged in kits. Write the patient identification (ID) number and other relevant information on the kit.			
9.3	Count correct quantity of medicines to be dispensed. Review and ensure correct dosing based on the patient's weight. If necessary, add more tablets to the kit from surplus of other patients or from a new unused kit.			
9.4	<ul> <li>Keep medicines and other commodities clean, safe, and organized:</li> <li>a. Keep medicines properly labeled and covered to avoid contact with direct sunlight and dust.</li> <li>b. Maintain medicines requiring cold chain in the refrigerator or in a cooler with frozen ice packs.</li> <li>c. Do not remove tablets from blisters until they are to be taken.</li> </ul>			
9.5	Check for the quality of the medicines. Do not give medicines that are dirty, discolored, cracked, broken, or have an odd smell.			
9.6	<ul> <li>In preparing and administering injections, take note of the following:</li> <li>a. Always use a new syringe and needle for each patient.</li> <li>b. Ensure aseptic technique in preparation and administration.</li> <li>c. Rotate injection site.</li> <li>d. Discard used syringe and needles in a safe container.</li> </ul>			
9.7	Explain the proper way of taking medicines to the patient. Encourage the patient's adherence to treatment and provide counseling.			
9.8	Observe the patient while taking all the medicines.			
9.9	Update the patient's treatment card and ID card after the patient's intake.			





# **PROCEDURES: RATIONAL USE**

Proce	dure Objective: To define the standard procedure for ensuring that ADRs experienced by patients are properly managed and documented. Time/Frequency: Every day Responsibility: Health facility staff/treatment partner
STEP	PROCEDURE
10.1	Get details about patient's adverse reaction.
10.2	Record and document details in a logbook or the patient progress report form.
10.3	Classify the side effect according to severity.
10.4	Refer the patient to the physician for consultation.
10.5	Carry out the physician's orders and provide clarification to the patient.
10.6	Document the intervention and the ancillary medicine dispensing done.
10.7	Follow up with the patient during the next visit if adverse reactions have resolved. If ADRs have not resolved, refer to the coordinator or nearest hospital for management.



Interview the patient regarding his/her condition during DOTS and take note of his/her important feedback or response.

*Source:* Rational Pharmaceutical Management Plus. *Managing TB Medicines at the Primary Level.* Arlington, VA: Management Sciences for Health; 2007.



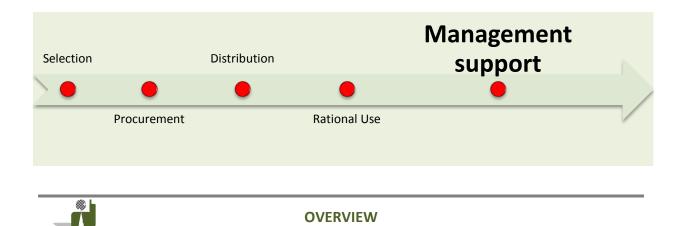
# **PROCEDURES: RATIONAL USE**

# Procedure 1 Objective: To define the standard procedure for ensuring that ADRs experienced by patients are properly reported. Time/Frequency: Monthly Responsibility: Health facility staff STEP PROCEDURE

- **11.1** Health facility prepares a hard copy or electronic copy of the FDA ADR report (see Annex 3B).
- **11.2** Health facility submits consolidated ADR reports monthly/quarterly to the provincial/city coordinators. The provincial/city coordinators submit them to regional coordinators, who submit them to the DOH Central Office.
- **11.3** The Central Office coordinates the submission of ADR reports to the FDA.
- **11.4** The Central Office completes all the necessary information required for FDA analysis.



As defined by the World Health Organization (WHO), pharmacovigilance is the science of and activities relating to the detection, assessment, understanding, and prevention of adverse events or any other possible medicine-related problems.



One of the main things to consider in management support, especially for medicines and health commodities, is the establishment of a good mechanism for reporting and information management to ensure that there is no stock-out or overstock. Regular reporting is done on a monthly or quarterly basis.

There are two information systems currently in place: a paper-based one and an electronic-based system.

The electronic-based system plays a big role in terms of ease of use and in speeding up processes for inventory management, requisition, distribution, and monitoring.

While the electronic system is continuously undergoing development, the paper-based system should remain a reliable source of information.

Monitoring and evaluation is another key component of management support. A good monitoring system keeps track of accomplishments and identifies areas for improvement. Monitoring visits can also be a form of support for health facility staff or warehouse personnel in terms of strengthening their performance.

As seen in figure 2, information management is a very essential process. Raw data are analyzed and interpreted as the basis for key program decisions, treatment strategies, and quantification. Therefore, reliable information taken from the consolidated reports of health facilities and warehouses means sound program decisions, good quantification, and better performance.

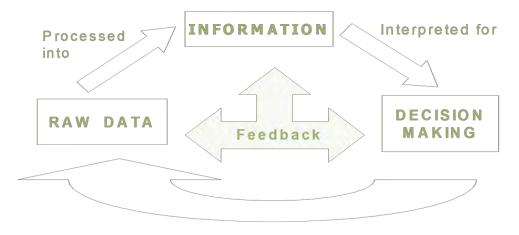


Figure 2: Information for decision making

*Source:* Rational Pharmaceutical Management Plus. *Managing Pharmaceuticals and Commodities for Tuberculosis: A Guide for National Tuberculosis Programs.* Arlington, VA: Management Sciences for Health; 2008.



# SUMMARY OF KEY ACTIVITIES/SECTIONS

#### Section 1

• Recording and Reporting at Health Facilities

#### Section 2

•Recording and Reporting at the Warehouse

Section 3

•Recording and Reporting at the Coordinator's Office

Procedure 12

• Monitoring Drugs and Supplies Management



### SECTION: INFORMATION MANAGEMENT



# **Recording and Reporting at Health Facilities**

Objective: To define records and reports maintained by health facilities. Responsibility: RHU nurse/point person

Below are the records and reports that need to be maintained at the health facility:

	References, records, and reports related to	
Number	pharmaceutical management	Remarks
1.1	NTP Manual of Procedure	Reference
1.2	Programmatic Management of Drug- Resistant TB (PMDT) training modules	Reference
1.3	Stock cards	(storage) Updated every medicine movement
1.4	Temperature monitoring form	(storage) Updated every day
1.5	Quarterly report on drug and supply	(requisition) submitted to coordinator quarterly,
	inventory and requirement	for filing
1.6	Request and issue slip (RIS)	(receipt) for filing
1.7	Adverse drug reaction logbook	(rational use) submitted to coordinator, for filing
1.8	Disposal of expired and damaged medicines	(when there are expired and damaged medicines
	and supplies document(s)	and supplies), for filing



Section 2

<u>Recording and Reporting at the Warehouse</u> Objective: To define records and reports maintained by warehouses.

Responsibility: Warehouse supply officer

Below are the records and reports that need to be maintained at the warehouse:

Number	References, records, and reports	Remarks
2.1	Warehouse operations manual	Reference
2.2	Delivery documents from suppliers	(receipt) for filing
2.3	Bill of lading	(receipt) for filing
2.4	Purchase order	(receipt) for filing
2.5	Request for inspection and acceptance	(receipt) for filing
2.6	Inspection and acceptance report	(receipt) for filing
2.7	Stock cards/locator cards	(storage) updated every medicine movement
2.8	Temperature monitoring form	(storage) updated every day
2.9	Inventory report	(inventory) monthly, submitted to coordinator,
		for filing
2.10	Allocation list	(delivery) from coordinators, for filing
2.11	Request and issue slip (RIS)	(delivery) for filing
2.12	Invoice Receipt for Property (IRP)	(delivery) for filing
2.13	Disposal of expired and damaged medicines and supplies document(s)	(when there are expired and damaged medicines and supplies), for filing

# Section 3

Recording and Reporting at the Coordinator's Office

Objective: To define records and reports maintained by the coordinator's office. Responsibility: TB coordinator at provincial, city, and regional levels

Below are the records and reports that need to be maintained at the coordinator's office:

Number	References, records, and reports	Remarks
3.1	NTP Manual of Procedure	Reference
3.2	PMDT training modules	Reference
3.3	Consolidated quarterly report on drug and supply inventory and requirement	(requisition) submitted quarterly, for filing
3.4	Inventory reports	(inventory) from warehouse supply officer, for filing
3.5	Allocation list	(delivery) submitted to warehouse supply officer, for filing
3.6	Consolidated ADR reports	(rational use) submitted to CHD/Central Office, for filing
3.7	Disposal of expired and damaged medicines and supplies document(s)	(when there are expired and damaged medicines and supplies), for filing
3.8	Monitoring reports	Every monitoring, for filing



### **PROCEDURES: MANAGEMENT SUPPORT**

# Procedure

12

Monitoring Drugs and Supplies Management

Objective: To define the standard procedure for monitoring of medicines and supplies management.

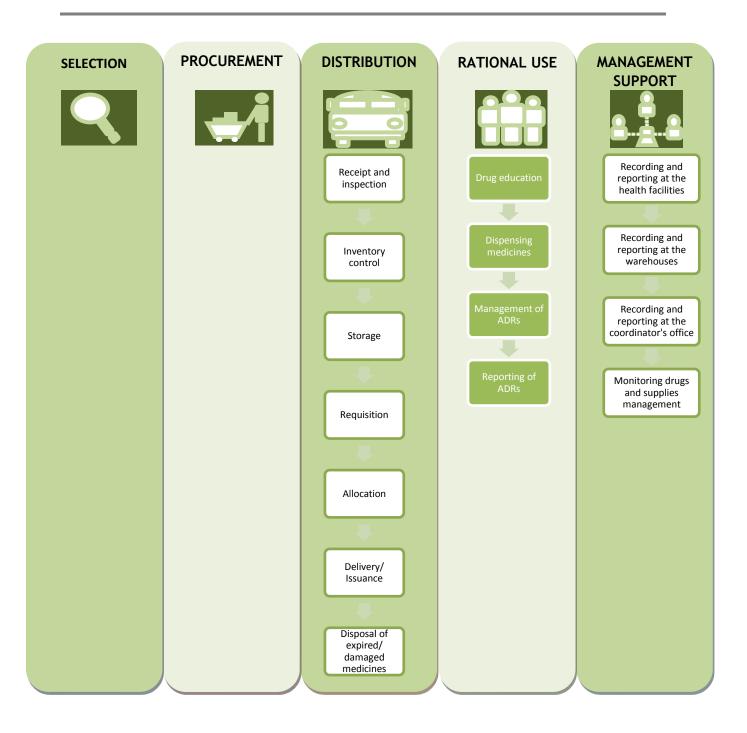
Responsibility: TB coordinator at provincial, city and regional levels, and health facility staff

### STEP PROCEDURE

- **12.1** Plan prior to monitoring visit. Arrange communications and logistical requirements.
- **12.2** Introduce the objective of the monitoring.
- 12.3 Employ the following techniques in data collection: Personnel interviews Document reviews Physical inventory checks Patient chart reviews
- **12.4** Complete data collection/monitoring tool (see Annex 4A).
- **12.5** Interpret results and preliminary findings.
- **12.6** Provide feedback and recommendations to the facility.
- **12.7** Prepare written report and disseminate to the facility.



Health-facility staff and warehouse personnel can do self-monitoring so that they will know where to re-educate themselves or pay special attention during that aspect of their work.



## SUMMARY OF ALL KEY ACTIVITIES

### PRACTICAL APPROACHES FOR PROBABLE SITUATIONS

### I. STORAGE AND DISTRIBUTION A. TYPHOON/FLOOD

In case of typhoon or flood, the following steps should be taken:

$\checkmark$	Be alert
	Monitor surroundings
	Monitor updates through radio, television, etc.
	Follow emergency plan
$\checkmark$	Assemble disaster supplies
	Battery-powered radio
	Medication and first aid supplies
	Flashlight and extra batteries
$\checkmark$	Secure all utilities and ensure that power is switched off. Avoid touching if you are wet.
$\checkmark$	Protect commodities
	Place items in dry and elevated areas. Make use of racks and pallets.
	Waterproof commodities by placing them in plastic containers or sealing them in plastic bags.
	Waterproof the storage area by sealing building openings, such as doors or windows.
	Conduct inspection for probable leaks and other damages.
Ø	Inform the supervisor or coordinator of any assistance needed.
$\checkmark$	Prepare to evacuate, if necessary
	Identify safe areas
	Turn off main breaker or switch of the circuit breaker
	Ensure that the doors and windows are locked before leaving
	Walk carefully and do not run to the nearest exit
	Follow instructions from authorities
$\checkmark$	Wait for further instructions before returning to the facility.

### B. BLACKOUT

In case of blackout, the following steps should be taken:

Be alert
Monitor surroundings
Monitor updates through radio, television, etc.
Follow emergency plan
Assemble disaster supplies
Battery-powered radio
Medication and first aid supplies
Flashlight and extra batteries
Turn off all switches in the building, including that of equipment and any appliances. Leave one
light switch on so that you will know when the power returns.
Use flashlight for emergency lighting. Use of candles may pose a risk of fire.
Do not open refrigerators or coolers to preserve medicines and commodities inside.
Protect commodities
Place items in dry and elevated areas. Make use of racks and pallets.
Inform the facility administrator of any assistance needed.
Open windows or doors to increase ventilation and lighting.
Prepare to evacuate, if necessary
Turn off main breaker or switch of the circuit breaker.
Ensure that the doors and windows are locked before leaving
Do not use elevators
Walk carefully and do not run to the nearest exit
Follow instructions from authorities
Wait for further instructions before returning to the facility.

### PRACTICAL APPROACHES FOR PROBABLE SITUATIONS

#### C. FIRE SAFETY MEASURES

For fire safety and prevention, the following steps should be taken:

$\checkmark$	Review and keep emergency plans updated.	
$\checkmark$	Participate in fire drills being conducted at the facility.	
$\checkmark$	Ensure that the fire alarm system, fire extinguishers, and other fire control equipment are working.	
$\checkmark$	Store combustible items away from heat-generating devices.	
V	Keep the storage area clean and free from piles of trash, which can be a fire hazard.	
V	Keep corridors and stairways clear of any obstruction.	
V	Keep all exit signs visible and maintain emergency lighting in good working condition.	
	Keep emergency exit doors closed but not locked to prevent the further spread of fire.	



Make sure that storage for combustible items is properly labeled and fire extinguishers are available nearby.

### D. TRANSFER OF COMMODITIES TO OTHER FACILITIES

In case of the need to transfer stocks from one facility to another (e.g., because of a stock-out or overstock at another facility or product recall), the following steps should be taken:

Ø	Coordinate with the other facility and with the coordinator regarding the transfer of the commodities.
$\checkmark$	Arrange the transfer (pick-up/delivery, schedule and personnel).
V	Prepare the commodities to be transferred and complete the RIS.
	Take note of the:
	<ul> <li>recipient facility</li> </ul>
	<ul> <li>date of transport</li> </ul>
	<ul> <li>quantity of commodities to be transferred</li> </ul>
	<ul> <li>lot number and expiration date</li> </ul>
$\checkmark$	Pack the items
	Provide appropriate packaging and proper cushioning to protect the commodities from shock
	and friability during transport (i.e., use foam, bubble wrap, etc.).
	Seal and label the items properly.
$\checkmark$	Ensure temperature stability for medicines needing refrigeration.
	Make use of Styrofoam boxes and frozen ice packs.
	Ensure that there are enough frozen ice packs to generate the temperature requirement of
	the commodities during transport.
	Ask the receiving facility to validate the temperature upon receipt
$\overline{\mathbf{A}}$	Have the transport personnel check and sign the receipt form.
$\mathbf{\nabla}$	File the receipt form accordingly.
V	Inform the recipient facility once the commodities are ready for pick up and ask for confirmation of
	delivery.

### PRACTICAL APPROACHES FOR PROBABLE SITUATIONS

### II. RATIONAL USE

### A. PRODUCT RECALL

In case of product recall, the following steps should be taken:

	Secure a copy of the letter issued by the NTP and/or FDA regarding the recall.	
V	Check if there is any of the recalled lot in the facility's stock.	
Ø	Secure and separate the recalled lot from the good stocks.	
Ø	Label the container properly to note that the stock is "recalled."	
Ø	Send back the recalled stock to your supervisor or coordinator, or as instructed.	
$\checkmark$	Prepare the commodities for transfer and refer to the Transfer of Commodities to Other Facilities	
	checklist.	

### **B. DONATIONS**

In case of donations, the following steps should be taken:

V	Make a list of priority medicines and supplies that are needed and indicate the required quantity.	
V	Check national policies on importation of goods.	
V	Confirm the donor's capacity to fulfill the request.	
V	Provide potential donors the complete information regarding the needed items and their intended	
	use.	
V	Do the following before agreeing to accept a donation:	
	Check if the supplies being offered conform to national policy or the WHO Guidelines for	
	Drug Donations.	
	Confirm who will be responsible for covering the costs of transportation, freight,	
	insurance, import duties, and customs clearance.	
	Check if the goods will have adequate expiry dates.	
M	Check expiry dates and labeling upon receipt of the donation.	
M	Confirm receipt of donated goods with the donor and provide information regarding the condition	
	and appropriateness of the goods.	
$\checkmark$	File all records of donations received, including those you have not requested, and inform donors	
	of unsolicited donations.	
V	Refuse inappropriate donations and provide an explanation of the reasons for refusal.	

### C. EXCESS QUANTITY OF STOCKS DELIVERED

In case the delivered commodities are found to be excessive based on a review of actual needs, the following steps should be taken:

$\checkmark$	Validate and review the previous request/need compared to the delivered items.	
$\checkmark$	If the quantity delivered exceeds the quantity requested and needed, receive the items and	
	indicate in the RIS the excess quantity.	
V	If the excess quantity cannot be consumed before expiration, inform your coordinator and seek	
	advice for redistribution.	
V	Identify the specific quantities in excess and secure the quantities needed for the facility.	
V	Refer to the Transfer of Commodities to Other Facilities checklist.	

### **REFERENCES / ADDITIONAL READING**

1	Management Sciences for Health. <i>MDS-3: Managing Access to Medicines and Health</i> <i>Technologies</i> . Arlington, VA: Management Sciences for Health; 2012.
2	Rational Pharmaceutical Management Plus. <i>Managing Pharmaceuticals and Commodities for Tuberculosis: A Guide for National Tuberculosis Programs</i> . Arlington, VA: Management Sciences for Health; 2008.
3	Rational Pharmaceutical Management Plus. <i>Managing TB Medicines at the Primary Level</i> . Arlington, VA: Management Sciences for Health; 2007.
4	World Health Organization. <i>Guide to Good Storage Practices for Pharmaceuticals,</i> Annex 9 (WHO Technical Report Series, No. 908). Geneva: World Health Organization; 2003.
5	World Health Organization. <i>Good Distribution Practices for Pharmaceuticals</i> , Annex 5 (WHO Technical Report Series, No. 957). Geneva: World Health Organization; 2010.
6	WHO. <i>Guidelines for Safe Disposal of Unwanted Pharmaceuticals In and After Emergencies</i> . Geneva: World Health Organization; 1999.
7	WHO. Guidelines for Drug Donations. Geneva: World Health Organization; 1999.
8	Department of Health, Republic of the Philippines. <i>NTP Manual of Procedures, fifth edition</i> . Manila: Department of Health; 2014.
9	Department of Health, Republic of the Philippines. <i>Best Practices in Warehouse Management</i> . Manila: Department of Health;2010.
10	Department of Health, Republic of the Philippines. <i>Health Care Waste Management Manual 3rd edition</i> . Manila: Department of Health; 2011.
11	Department of Health. NTP Pharmaceutical and Supply Management MOP. 2011.
12	USAID   DELIVER PROJECT, Task Order 4. <i>Guidelines for Warehousing Health Commodities</i> , second edition. Arlington, VA: USAID   DELIVER PROJECT, Task Order 4; 2014.
13	John Snow Incorporated/DELIVER. <i>Guidelines for the Storage of Essential Medicines and Other Health Commodities</i> . Washington, D.C.: John Snow Incorporated/DELIVER, for the U.S. Agency for International Development; 2003.
14	Tropical Disease Foundation and Department of Health, Philippines. <i>Management of Drug-Resistant TB Training for Health Facility Staff in the Philippines. Module F: Manage Drugs and Supplies for MDR-TB</i> . Manila: Tropical Disease Foundation (TDF) and Department of Health, Philippines (DOH); 2008.

### **ANNEX 1: CATALOG OF TB COMMODITIES**

#### A. MEDICINES

No.	FIRST-LINE DRUGS	DOSAGE FORM
1	Adult patient kits CAT I	Fixed-dose combination kits
2	Adult patient kits CAT II	Fixed-dose combination kits
3	TB drugs for children kit I	Oral suspension
4	TB drugs for children IPT kit	Oral suspension
5	Isoniazid 300 mg	Tablet
6	Rifampicin 300 mg	Tablet
7	Pyrazinamide 500 mg	Tablet
8	Ethambutol 400 mg	Tablet
9	Streptomycin 1 g	Vial

No.	SECOND-LINE DRUGS	DOSAGE FORM
1	Capreomycin 1 g	Vial
2	Clofazimine 100 mg	Capsule
3	Clarithromycin 500 mg	Tablet
4	Co-Amoxiclav 1 g	Tablet
5	Cycloserine 250 mg	Capsule
6	Kanamycin 1 g	Vial
7	Levofloxacin 250 mg and 500 mg	Tablet
8	Moxifloxacin 400 mg	Tablet
9	Para-Amino Salicylic acid 4 g	Granule sachet
10	Para-Aminosalicylate Sodium 4 g	Powder sachet
11	Prothionamide 250 mg	Tablet

#### **B. LABORATORY SUPPLIES**

No.	NAME OF ITEM
1	HIV testing kit
2	Reagent for automate growth detection
3	Potassium dihydrogen orthophosphate 500 g
4	Magnesium citrate dibasic
5	Sodium glutamate 500 g
6	Glycerol 2.5 ml
7	Malachite green 100 g
8	Sodium hydroxide pellets 500 g
9	LJ base medium
10	Kanamycin 5 g for DST
11	Ofloxacin 5 g for DST
12	Levofloxacin 5 g for DST
13	Isoniazid 5 g for DST
14	Rifampicin 1 g for DST
15	Streptomycin 5 g for DST
16	Ethambutol 5 g for DST
17	Reagent refill for qualitative fit test kit

#### C. OTHER

- a. Ancillary medicines
- b. Medical equipment
- c. Medical supplies
- d. Forms

### ANNEX 2: DISTRIBUTION (FORMS, RECORDS, AND REPORTS)

#### A1. INDICATORS OF POOR QUALITY OR DAMAGED SUPPLIES

**Objective:** Serve as a guide for the assessment of the quality of commodities. **Time/Frequency:** Every shipment arrival **Responsibility:** Warehouse personnel/RHU nurse/point person

#### INDICATORS OF POOR QUALITY OR DAMAGED SUPPLIES

PACKAGING, LOOK FOR:		
•	Broken or ripped packaging (vials, bottles, boxes, etc.)	
	LOOK FOR:	
•	Missing, incomplete, or unreadable labels	
	DS, LOOK FOR:	
•	Discoloration	
•	Cloudiness	
•	Sediment	
•	Broken seal on bottle	
•	Cracks in ampoule, bottle, or vial	
•	Dampness or moisture in packaging	
•		
	Torn or ripped packaging K PRODUCTS, LOOK FOR:	
•	Dryness Brittleness	
•		
	Cracks ICATED LATEX PRODUCTS, LOOK FOR:	
	Sticky packaging	
•	Discolored product or lubricant	
•	Stained packaging	
•	Leakage of the lubricant (moist or damp packaging)	
	LOOK FOR:	
•	Perforations in the packaging	
	IICAL REAGENTS, LOOK FOR:	
•	Discoloration	
IF TABL	ETS, LOOK FOR:	
•	Discoloration	
•	Crumbled pills	
•	Missing pills (from blister pack)	
•	Stickiness (especially coated tablets)	
•	Unusual smell	
IF CAPSULES, LOOK FOR:		
•	Discoloration	
•	Stickiness	
•	Crushed capsules	
IF INJEC	TABLES, LOOK FOR:	
•	Liquid not returning to suspension after shaking	
IF STERI	LE PRODUCTS (including intrauterine devices), LOOK FOR:	
•	Torn or ripped packaging	
•	Missing parts	
•	Broken or bent parts	

• Moisture inside the packaging

### • Stained packaging

# IF TUBES, LOOK FOR:

- Stickiness
- Leaking contents
- Perforations or holes in the tube

Adapted from John Snow, Inc./DELIVER in collaboration with the World Health Organization. *Guidelines for the Storage of Essential Medicine and Other Health Commodities*. Arlington, VA.: John Snow, Inc./DELIVER, for the U.S. Agency for International Development; 2003.



If the commodities received are of poor quality or damaged, follow the procedure for disposal of expired or damaged commodities.

#### A2. GUIDE FOR PROPER STORAGE PRACTICES

**Objective:** To guide the proper storage practices in facilities. **Time/Frequency:** Every shipment arrival **Responsibility:** Warehouse personnel/RHU nurse/point person

### A. PREPARATION OF STORAGE AREA

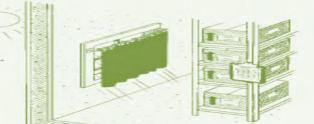
- a. Ensure that there is enough space to store commodities.
  - Report to provincial/ city coordinators if there is insufficient storage space and propose the expansion of the storage area.
- b. Ensure that there is sufficient space in the aisles for passage.
- c. Ensure that the storage room is a secured area.
- d. Ensure that the temperature and humidity of the storage room is controlled and monitored using the temperature and humidity monitoring form (see Annex 3A).
- e. There should be good ventilation (open windows for air circulation).



*Electric fans can be used to facilitate air circulation.* 

Source: John Snow, Inc./DELIVER in collaboration with the World Health Organization. *Guidelines for the Storage of Essential Medicines and Other Health Commodities*. Arlington, VA.: John Snow, Inc../DELIVER, for the U.S. Agency for International Development; 2003.

- f. Ensure that the physical structure of the storage room is well maintained.
- g. Ensure that there are no leaks. The roof should have gutters.
- h. Storage equipment should be available (racks, shelves, pallets, etc.).
- i. Ensure that lighting is controlled. (Avoid direct sunlight.)



Curtains or blinds can be used to protect medicines and commodities from sunlight.

*Source:* John Snow, Inc./DELIVER in collaboration with the World Health Organization. *Guidelines for the Storage of Essential Medicines and Other Health Commodities*. Arlington, VA.: John Snow, Inc../DELIVER, for the U.S. Agency for International Development; 2003.

- j. Ensure that the storage area is pest free. (Use screens to keep insects out.)
- k. Ensure that the storage area is clean.
  - Free of dust
    - Floors are clean and mopped
    - Walls are clean
  - Stocks are properly stacked and stored on shelves or racks
  - Fire extinguishers should be available and functioning

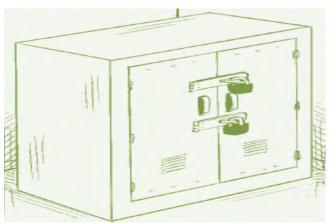


Maintaining a clean storage area prevents pests.

Source: John Snow, Inc./DELIVER in collaboration with the World Health Organization. *Guidelines for the Storage of Essential Medicines and Other Health Commodities*. Arlington, VA.: John Snow, Inc./DELIVER, for the U.S. Agency for International Development; 2003.

#### B. ORGANIZATION OF STOCKS IN STORAGE

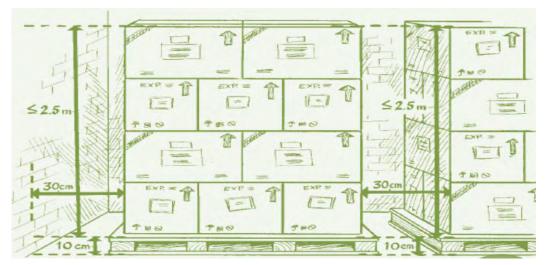
- a. Arrange similar items together.
  - Separate medicines from other supplies or chemicals.
- b. Arrange items according to classification (TB, malaria, etc.).
- c. Put label in front of every item on the shelves.
- d. Store controlled substances in a separate and secured area.



Access to the storage of controlled substances should be limited.

Source: John Snow, Inc./DELIVER in collaboration with the World Health Organization. *Guidelines for the Storage of Essential Medicines and Other Health Commodities*. Arlington, VA.: John Snow, Inc./DELIVER, for the U.S. Agency for International Development; 2003.

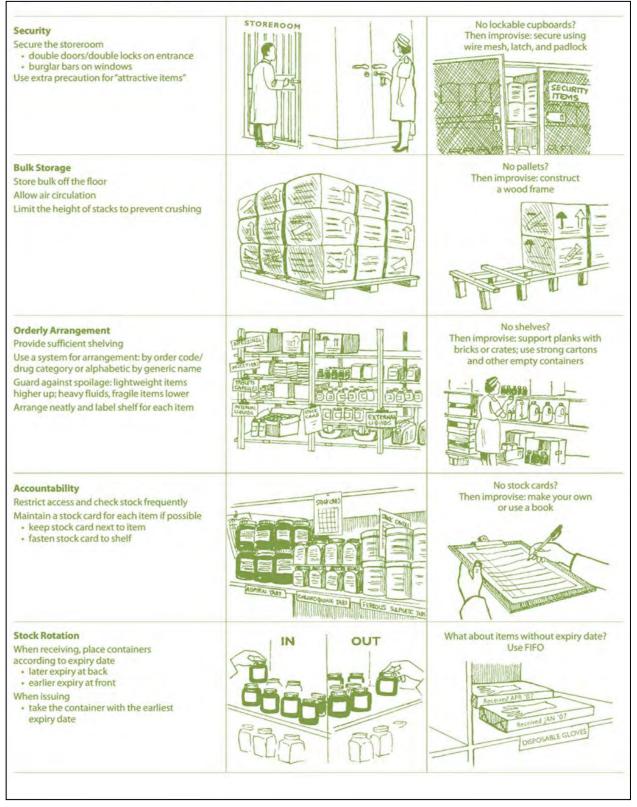
- e. Store dry medicines on shelves on top of liquids.
- f. Prioritize items that are not heat sensitive or not used regularly on the top shelves, if shelves are near the ceiling.
- g. Do not store items directly on the floor; use pallets to avoid water to perforate the boxes in case of flood or spillage. When stacking boxes using pallets:
  - Should be at least 10 cm (4 inches) off the floor
  - Should be at least 30 cm (1 foot) away from the walls and other boxes
  - Should be no more than 2.5 m (8 feet) high



Source: John Snow, Inc./DELIVER in collaboration with the World Health Organization. *Guidelines for the Storage of Essential Medicines and Other Health Commodities*. Arlington, VA.: John Snow, Inc./DELIVER, for the U.S. Agency for International Development; 2003.

- h. Do not store items directly against walls to avoid water leaks or excessive heat that may generate from the walls.
- i. Store all medicines according to first expiry, first out (FEFO).
- j. Store all medical supplies and other commodities without expiry dates according to first in, first out (FIFO).
- k. Separate storage of expired and damaged items.

#### C. TIPS FOR MANAGING STOCKS IN THE STOREROOM



Source: Management Sciences for Health. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health; 2012.

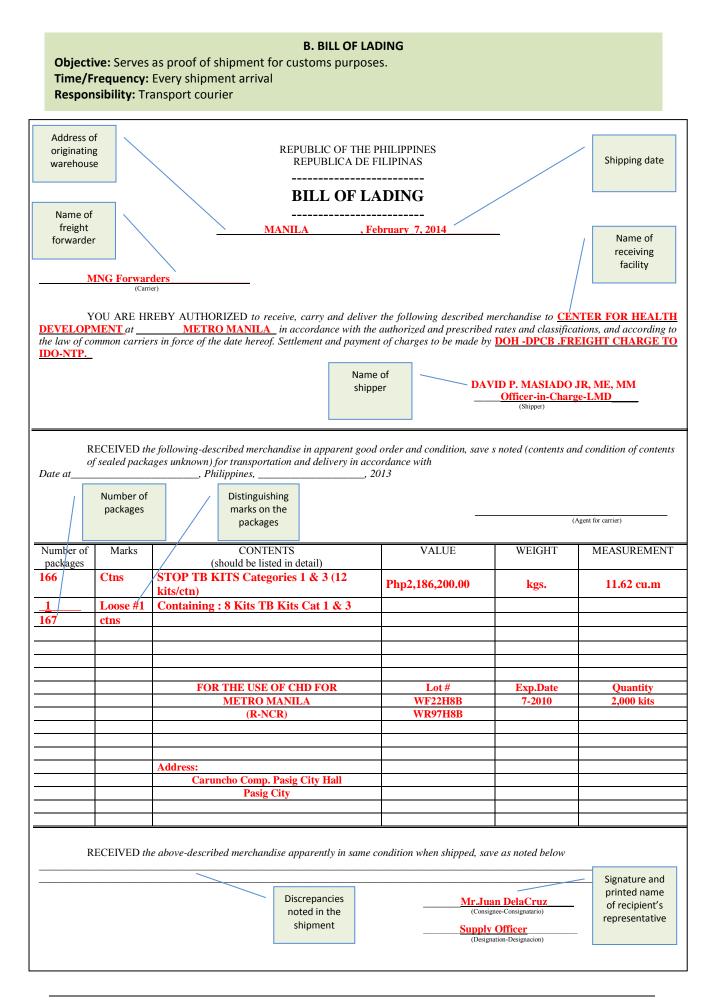
#### A3. GUIDE FOR DISPOSAL OF PHARMACEUTICALS

**Objective:** Guide the proper disposal of pharmaceuticals. **Time/Frequency:** Every time there are damaged/expired pharmaceuticals for disposal. **Responsibility:** Warehouse personnel/RHU nurse/point person

Disposal methods	Types of pharmaceuticals	Comments
Return to donor or manufacturer,	All bulk waste pharmaceuticals,	Usually not practical –
international transfer for disposal.	particularly antineoplastics.	international procedures may be
		time consuming.
High temperature incineration	Solids, semisolids, powders,	Expensive, particularly for
with temperatures greatly in	antineoplastics, controlled	purpose-built incinerators. Use of
excess of 1200°C.	substances.	existing industrial plants may be
		more practical.
Medium temperature incineration	In the absence of high	Antineoplastics are best
with two–chamber incinerator	temperature incinerators, solids,	incinerated at high temperature.
with minimum temperature of	semi-solids, powders. Controlled	
850°C. Cement kiln incineration.	substances.	
Immobilization, waste	Solids, semi-solids, powders,	
encapsulation	liquids, antineoplastics, controlled	
	substances.	
Inertization	Solids, semi-solids, powders,	
	antineoplastics, controlled	
	substances.	
Landfill, highly engineered sanitary	Limited quantities of untreated	
landfill	solids, semi-solids and powders.	
	Disposal of waste pharmaceuticals	
	after immobilization preferable.	
	PVC plastics.	
Engineered landfill	Waste solids, semi-solids and	
	powders, preferably after	
	immobilization. PVC plastics.	
Open uncontrolled non-	As a last resort. Untreated solids,	Not for untreated controlled
engineered, dump	semisolids, powders – <b>must</b> be	substances.
	covered immediately with	
	municipal waste. Immobilization	
	of solids, semi-solids, and powders	
	is preferable.	
Sewer	Diluted liquids, syrups, intravenous	Antineoplastics, and undiluted
	fluids, small quantities of diluted	disinfectants and antiseptics are
	disinfectants (supervised).	not recommended.
Fast-flowing watercourse	Diluted liquids, syrups, intravenous	Antineoplastics, and undiluted
	fluids; small quantities of diluted	disinfectants and antiseptics are
	disinfectants (supervised).	not recommended.
Burning in open containers	As a last resort; packaging, paper,	Not acceptable for PVC plastics or
	cardboard.	pharmaceuticals.
Chemical decomposit	Not recommended unless special	Not practical for quantities over 50
	chemical expertise and materials	kg.
	are available.	

Source: WHO. Guidelines for Safe Disposal of Unwanted Pharmaceuticals In and After Emergencies. Geneva: World Health Organization; 1999.

Available at: http://apps.who.int/medicinedocs/en/d/Jwhozip51e/.



			C. INVOICE RI		ROPERTY				
	-		s proof of purchase and deliver very shipment	y of goods.					
			ply officer or representative						
_									_
	GENERAL FORM Revised March, 193								
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			ER of property from <u>LMD</u>		to <mark>C</mark>	ID METRO N	ANILA (R-1	NCR)	
	authorized b	у							
	Quantity	Unit	NAME AND DESCRIPTION	Date of purchase	LOT No.	Expiry date	Unit Value	Total Value	
	2,000	kis	STOP TB KITS Categories 1 & 3	purchase	WF2100	Jul-11	Php1.00	Php2,000.00	•
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						(quanti	-		
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### D. NOTICE OF DELIVERY

**Objective:** Serves as a formal document to notify the resident DOH auditor of a specific delivery or shipment. **Time/Frequency:** Every shipment **Responsibility:** Supply officer or representative

PROCUREMENT AND LOGISTICS SERVICE MATERIAL AND MANAGEMENT DIVISION	Date form was
POP II WAREHOUSE	completed
August 31, 2	<u>013</u>
Date	
	Notice of
NOTICE OF DELIVERY	delivery number
No. <u>00212121</u>	number
THE RESIDENT AUDITOR	
DEPARTMENT OF HEALTH	
SAN LAZARO COMPOUND	Purchase
MANILA forwarder	order (PO) number
	number
SIR / MADAM:	Date of PO
This is to inform your office of the delivery at CHD Metro Manila (R-NCR)	
Warehouse made by <u>MNG Forwarders</u> Under P.O No./Contract/APR No. <u>212121</u> date under Invoice / D.R. No. <u>55341</u> dated <u>August 21, 2013</u> in the amount of <u>21,934.00</u>	ed August 10, 2013
	<i>c</i> , , , , , , , , , , , , , , , , , , ,
Invoice number Date of Invoice Amount	of invoice number
In compliance to Sec 465 (C) of GAAM Vol. 1, "All items inspected shall inva	riably be accepted
first by the requisitioning of property officer" and COA Circular No. 95-006 Sec. 6.06 da	
"Officials responsible foraccepting deliveries, within twenty four hours from such	
notify the Auditor".	-
Very truly yours	
JUAN DELA CRUZ	
Supply Officer	
Signature of	
authorized	
personnel	

#### E. PURCHASE ORDER

**Objective:** Serves as a document to prove the purchase of goods from a specific supplier. **Time/Frequency:** Every purchase and delivery **Responsibility:** Supplier

**Note:** This form arrives at the warehouse already filled in. The following merely describes the information that goes into each data field.

Name of receiving warehouse Supplier: _V		ratories	PUF	CHASE OR	DER P.O No.:_ <u>212</u>	2121			Number of days wherein the delivery of items should be made
Address: <u>Ma</u>					Date: <u>Augu</u>		)13	/ .[	Number of
	3-003-000				Mode of Proc			/ /	days whereii
Gentlemen:	Ì						/		the paymen
Please fur	nish this of	fice the following	articles su	biect to the teri	ns and condition	on contaiı	ned herein:		to the supplier
		warehouse_			Delivery		10 days		should be
Date of delive		ust 31 , 2013_		-	Payment		10 days	7	made
Item No.	Unit	Quantity		Descri	ption		Unit Cost	Amoun	t
0213	pc	200		Isoniazid 3	00mg tab		200.00	40,000.0	0
(Total Amount	In Words)			Forty thou	sand Pesos			40,000.0	0
everyday of de		to make full deliv imposed.	ery within	the time specifie Signature and printed name o supplier or representative	f		tenth (1/10) of o	Si	gnature of Bids and Awards Committee representative
	<u>A</u>	Juan Dela Cr (Signature over printed	name)				Pedro De G (Authorized O	uzman fficial)	Allocation of
	e.	Date		Signature of Chief		DBS No.:	1724		nount allocated
Funds availabl					L ALO		1434 /		

#### F. REQUEST FOR INSPECTION AND ACCEPTANCE

**Objective:** Serves as a document for inspection to ensure that all goods are authorized to be accepted. **Time/Frequency:** Every delivery **Responsibility:** Supply officer

Date of request DEPARTMENT OF HEALTH March 2, 2014 Date REQUEST FOR INSPECTION AND ACCEPTANCE No. 9002 Sir/Madam: Pursuant to the provision of Administrative Order No. 14-B s, 1997 dated August 1, 1997, particularly II, 11, III, 1.16 and III.4.12, we hereby request for a duly authorized representative from your office to inspect the goods reflected under the following attached proofs of delivery: D.R. No 2/31/2014 55341 dated Invoice dated 2/21/2014 63412 P.O. No. dated 212121 2/10/2014 Further, attached are copies of acceptance report to COA which are due for submission to the same through this office within three (3) working days from the receipt of this notice, should treceipt of this notice, should tyour office. In case the items may not be acceptable to your office, please notify us within forty eight (48) hours. Date of inspection March 14, 2014 The inspection date is scheduled on Thank you. Signature of Very truly yours, requesting 1 1 1 1 officer

> VIRGILIO D. OLEDAN JR. Supply Officer II

Noted by:

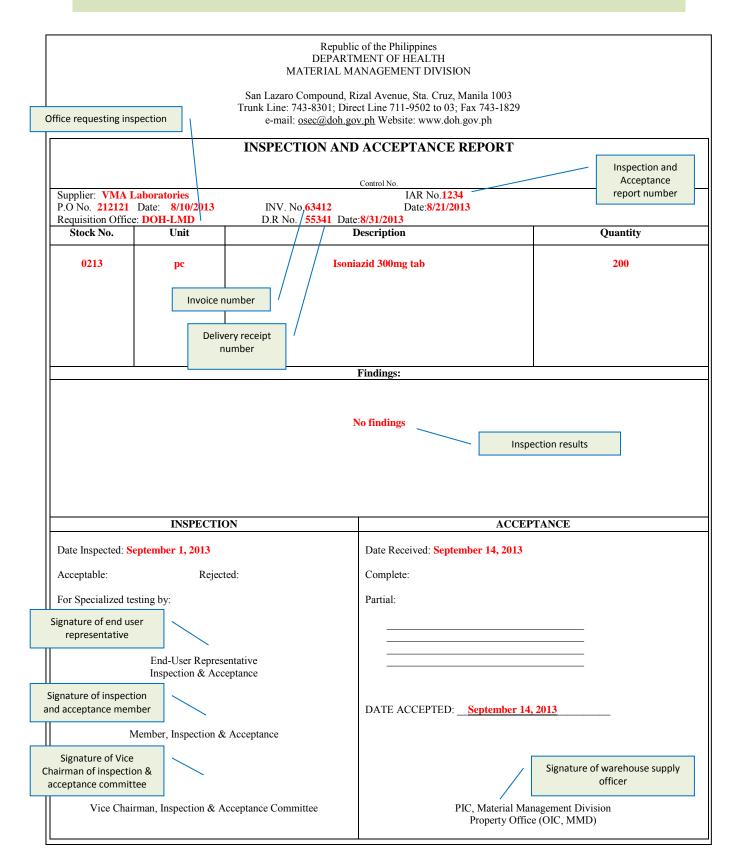
DAVID P. MASIADO JR., ME, MM OIC, Material Management Division

#### G. INSPECTION AND ACCEPTANCE REPORT

**Objective:** Serves as a document stating the findings of the inspection and the report, if goods are accepted or rejected.

Time/Frequency: Every delivery

Responsibility: Inspection and Acceptance Committee



### H. LOCATOR CARD

**Objective:** To aid warehouse personnel in locating specific goods inside the warehouse. **Time/Frequency:** Every delivery and maintained during the period of storage **Responsibility:** Warehouse personnel

	MATERIAL MANAGEMENT DOH WAREHOUS SAN LAZARO COMPOUND, RIZAL A' STA. CRUZ, MANILA, PHILIPPIN TEL NO, 711-68-31	<b>E</b> venue	
	LOCATOR (		Designated rack or area of storage of items
	RACK A		
Locator code	<b>Description/Items</b> As of <u>September 1, 2013</u>	Quantity	Unit
123	Isoniazid 300 mg tab	200	Tablets
Loca code o	· · · · ·		Unit of counting of item

#### I. REQUISITION AND ISSUE SLIP (RIS)

**Objective:** Serves to document the requisition and issuance of goods being given to divisions and offices. **Time/Frequency:** Every delivery

Responsibility: Warehouse personnel

the ocks Division: P. Office: L.M		REQ Code for the issuance of stocks	DEPARTM	ENT OF HEALT (Agency)	SUE SLIP TH RIS No. 456 SAI No. 789	Office responsible the issuan Date 8/1/2013 Date 8/2/2013		
		Re	quisition		Issu	uance		
fice Stock No.	Unit		Description	Quantity	Quantity	Remarks		
f the DOH vision suing the ocks	tablet	Isoniazid 300 SOURCE: P.O No. 211 INV. No. 634 D.R. No. 553	2121 dated 8/10/2 112 dated 8/21/2	013	100 Quantity requested	Quantity issued		
Purpose:	Purpose: FOR THE USE OF CHD MM							
F		_	Requested by:	Approved by:		Received by		
			Juan Dela Cruz	DAVID P. MASIADO, JI		Juan Dela Cru		
Signature Printed nar			Juan Dela Cruz					
Signature			Supply Officer	MM OIC, Logistics Manage Division	ment	Warehouseman		

### ANNEX 3: RATIONAL USE (FORMS, RECORDS, AND REPORTS)

#### A. TEMPERATURE MONITORING LOG

**Objective:** Serves to monitor temperature and humidity condition in the commodity storage area. **Time/Frequency:** Every day **Responsibility:** Point person

			TEMPE	RATURE MONIT	ORING LOG	perso	designated point on to monitor the
Name o	f facility: _	Maharlik	ka D <mark>OTS C</mark> e	nter	,		torage room temperature
Person i	responsible	e: _ <b>Za M</b>	unez		/		
For the	month of:	Septe	<u>mber 2013</u>				
Day		AM			NN		PM
	Temp	Si	gnature	Temp	Signature	Temp	Signature
1	24°C	Z	AM	25°C	ZAM	23°C	ZAM
2	24°C	Z	AM	25°C	ZAM	23°C	ZAM
3	24°C	Z	AM	25°C	ZAM	24°C	ZAM
4	24°C	Z		25°C	ZAM	24°C	ZAM
5		The		The initial of	The		The
6		temperatur	e	the designated	temperature in		temperature in
7		in Celsius upon openii	ησ	point person who logged the	Celsius at noontime		Celsius upon closing of the
8		of the	6	temperature	noontime		treatment
9		treatment					facility
10		facility					
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#### **B. FDA ADR FORM**

**Objective:** To monitor and document ADRs of medicines being utilized in the country. Time/Frequency: All the time Responsibility: Point person/physician

USPECTED ADVERSE REACTION Saving Lives Through Vigilant Re FIELDS MUST BE COMPLETED.		4)		AER	FDA use only All repo No. 2012-0001 received:	
ATIENT'S PARTICULARS						
"Patient's Name or Initials		*Sex:	O Male	C Female	Weight Kg I	Height (cm)
Address or Contact Number:					A CONTRACTOR OF	
Medical History/Admitting Diagno						
					and the second	
Any Known Allergy: 🗆 No 🛛	and the second			Pregr	and the second se	
Hospital/facility, if admitted:					Yes (	1", 2"d, 3" trimester
DETAILS OF THE ADVERSE READ	TION					
Date of onset:;;	am,pm Do	you conside	r the reaction t	o be serious?	Yes, if yes indicate w	rhy: 🗖 No
Describe the reaction, including pertin	ent laboratory data:				Patient died due to reactiv Involved or prolonged in- Ufe threatening Congenital anomaly in the Other outcome, please gi Can this be due to Medi Yes, If yes, whichPrescribingTranscriptoTranscripto	natient hospitalization nificant disability e newborn ve details: cation Error? N h type:
					Dspensing Administrati	
container: contaminants; sep 2. Therapeutic failure:N	oYes, Specify,	encircle: an	timicrobial resis	tance, drug int		a contract the second
	oYes, Specify,	encircle: an edication; ina;	timicrobial resis	tance, drug int	eraction, poor compliance, c	and the second second
<ol> <li>Therapeutic failure:Noi improper storage; under-dos Suspected drug product(s)</li> </ol>	oYes, Specify, ing.inappropriate me	encircle: an edication; ina;	timicrobial resis ppropriate route Date	tance, drug int of administrati Data	eraction, poor compliance, c on; excipients/preservatives Reason (s) for using the product	Manufactureran
<ol> <li>Therapeutic failure:Noi improper storage; under-dos Suspented drug product(s)</li> </ol>	oYes, Specify, ing.inappropriate me	encircle: an edication; ina;	timicrobial resis ppropriate route Date	tance, drug int of administrati Data	eraction, poor compliance, c on; excipients/preservatives Reason (s) for using the product	Manufactureran
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2. Therapeutic failure:Ni improper storage; under-dos Suspected drug product(s) idicate brand mame  at all other drug/s taken at the set rand name of the drug  MANAGEMENT OF ADVERSEREA As treatment given?No utcome: Recovered (Date of recovery): Recovered (Date of recovery): Fatal (Date of death): equela/e: (any permanent complie [Yes (Please specify)].	oYas, Specify, ing. inappropriate m Daily Doss me time and/ or 3 m Daily Doss Daily Doss ACTION Yes (if yes cations or injuries a	encircle: an addration; ins; Route nonths befor Route Route	Imicrobial resis propriate route Date started I I I I I I I I I I I I I	tance, drug int of administration Date stopped Date stopped	eraction, poor compliance, c on; excipients/preservatives Parasion (s) for using the product (Indication) No Other drug/s to Reason/s for using the drug tes:liverrensi etesCVSEndoc ge?Yes Result	Manufacturer an Batch/Lot # aken Manufacturer an Batch & Lot No.
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National Pharmacovigilance Center

National Pharmacovignance Center "Saving Lives Through Vigilant Reporting" Send completed form tet ADR Unit, FDA, Civie Drive, Filinwes Estate, Alabang, Muntinlapa , (78). Or fax to: (02) 807-85-11, elo The ADR Unit. Send sample, If any, of suspect drug for analysis, Website: www.fda.gov.ph



#### ANNEX 4: MANAGEMENT SUPPORT (FORMS, RECORDS, AND REPORTS)

#### A. DRUGS AND SUPPLIES MANAGEMENT MONITORING FORM

**Objective:** Serves as a sample tool for monitoring. **Time/Frequency:** Every monitoring scheduled **Responsibility:** Coordinator/point person

# DRUGS AND SUPPLIES MANAGEMENT MONITORING FORM

Visit Date					]
FACILITY NAME:			Tick "wes" or "po"		
Supply Officer/ Person-in-charge	1		Tick "yes" or "no" according to results of interview or		
Other staff in the Facility			observation or desk review.		
Conducted by					
I. INVENTORY	YES	NO	REMA	ARKS	
a. Was there any accountability/stock card available?					
b. Was drug inventory documentation complete and updated?			`	Indicate notes on findings and othe	
c. Does the stock card correspond to actual count of drugs? (do actual inventory count)				remarks	-
d. Is there an electronic system for drug management?					
<ul><li>e. Were drug management documentations filed?</li><li>Receipt invoice</li></ul>					
Stock cards					
Utilization or delivery records					
Quarterly drug requisition forms					
II. EXPIRATION	YES	NO			1
a. Was FEFO followed?					
b. Is there a system for monitoring expiration?				, [	Indicat
c. Are there expired medicines?				xp Qty ate	expired
d. Are there medicines/supplies expiring in the next 6 months?			-	ate Qty	Indicat near expiry medici

III. STORAGE AREA	YES	NO		
a. Was the storage area in good condition?			/	Describe storage
<ul><li>Exposure to direct sunlight</li><li>Leaking roof or flooding</li></ul>				room
<ul> <li>Unsecure location (no locks, multiple</li> </ul>				
unguarded entry, broken windows or				
doors)				
<ul> <li>Pests noted (rats, mice, cockroaches)</li> </ul>			/	Based on number
•				of cases in past
b. Is there adequate storage space to				quarter, is the
accommodate full stock level?				space adequate for
c. Was there sufficient storage equipment/				1 quarter's supply and 1 quarter
fixtures available?				buffer?
• Pallets or shelves				
Room thermometer				
d. Is temperature monitoring being done and				
updated?				
Room temp during visit:				
e. Was the temperature of the storage area				
acceptable?				
Room temperature:15°C-25°C				
Keep refrigerated: 2°C-8°C				
f. Was the security/fire alarm system available and functioning?				
			/	Physically check
				available stocks for
IV. STOCK MANAGEMENT	YES	NO		damage. (Ask if
a. Were stocks checked properly upon receipt?				damaged before or after delivery).
Check the receipt invoice				alter delivery).
b. Are stocks checked properly before			/	Check for a written
delivery/use?				policy/documentation
Check for delivery or utilization records				
c. Is there a system of drug and supplies				
disposal?				
			,	Ask them to
	VEC	NO	/	demonstrate if they
V. REQUISITION	YES	NO	/	say YES. If NO, ask
a. Does the staff know how to compute for				how they compute
drug requests based on previous			/	for medicine
consumption and current stocks?				requests.
b. Does the facility request for medicines on a				How often do the
regular basis?			/	request? as neede
			/	Any reason why?
c. Were drug management reports submitted				
on time? (i.e., quarterly report on drug				If not being
inventory and request)			,	submitted,
			/	why?
d. Are drugs regularly delivered by the next				t, explain current
higher level (e.g., PHO) to the facility?				ice of medicine
		1	proc	
			distr	bution from PHO to

e. f.	Is the quantity of drugs received the same as what was requested? Is there a system of monitoring to track requests and deliveries?				Check for a written policy/ documentation.
	·				
VI.	USE	YES	NO	/	Are kits
a.	Is the entire kit (Cat 1 or 2) allocated to only 1 patient?			/	broken?
b.	Are the NTP treatment cards/ID cards updated in terms of daily intake?			/	Check NTP cards if updated
c.	Are the allocated kits stored in a secure and safe location?				record of intake.
d.	Is there a record of occurrence of adverse drug reactions?				
e.	Are adverse drug reactions reported to higher levels?			/	Check reports on ADR, if present
GE	NERAL COMMENTS AND RECOMMENDATIONS	5:		/	Indicate general comments and possible steps for improvement