Supply Chain Management Guidelines for Neglected Tropical Diseases

REPUBLIC OF KENYA

Ministry of Health

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Kenya Neglected Tropical Diseases Supply Chain Management Guidelines.

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ACRONYMS AND ABBREVIATIONS

ACSM	Advocacy, Communications, and Social Mobilization
AIHD	African Institute for Health and Development
AWP	Annual Work Plan
CHP	Community Health Promoters
CDD	Community HPT Distributor
CHAI	Clinton Health Access Initiative
CIF	Cost, Insurance and Freight
CIP	Carriage and Insurance Paid
CMS	Central Medical Stores
COA	Certificate of Analysis
COC	Certificate of Conformity
COD	Certificate of Donation
COO	Certificate of Origin
DAT	Direct Agglutination Test
DHIS2	District Health Information Software 2
eLMIS	Electronic Logistics Information Management
EpiRF	Epidemiological Reporting Form
FEFO	First Expiry First Out
FIFO	First In First Out
FILO	First In Last Out
FTS	Filarial Test Strips
HQ	Headquarters
HPT	Health Products and Technologies
IEC	Information, Education and Communication
IDA	Ivermectin, Diethylcarbamazine, Albendazole
ITI	International Trachoma Initiative
IU	Implementation Unit
JAP	Joint Application Package
JRF	Joint Reporting Form
JRSM	Joint Request for Selected HPTs
KHIS	Kenya Health Information System
KEMSA	Kenya Medical Supplies Authority
KIPRE	Kenya Institute of Primate Research
KNBS	Kenya National Bureau of Statistics
K-SRIC	Kenya Snakebite Research and Intervention Centre
LF	Lymphatic Filariasis
LPO	Local Purchase Order
LQAS	Lot Quality Assurance Sampling
MEC	Mectizan Expert Committee
MDA	Mass HPT Administration

MDP	Mectizan Donation Programme
MOE	Ministry of Education
MOH	Ministry of Health
MOU	Memorandum of Understanding
MS	Microsoft
MSF	Médecins Sans Frontières
NEMA	National Environment Management Authority
NEMIS	National Education Management Information System
NTD	Neglected Tropical Disease
ONCHO	Onchocerciasis
PC-NTDs	Preventive Chemotherapy NTDs
PM	Paromomycin
PoD	Proof of Delivery
PO	Purchase Order
POS	Powder for Oral Suspension
PPB	Poison and Pharmacy Board
PS	Principal Secretary
RFQ	Request for Quotations
rK39	recombinant K39 protein (rapid test for VL)
RMS	Regional Medical Stores
RPRG	Regional Programme Review Group
SAFE	Survey, Antibiotics, Facial Cleanliness and Environmental Improvements
SBE	Snakebite Envenoming
SCH	Schistosomiasis
SCM	Supply Chain Manager
SCO	Supply Chain Officer
SKU	Stock Keeping Unit
SOP	Standard Operating Procedure
SSD	Sodium Stibogluconate
STH	Soil Transmitted Helminthiases
TAS	Transmission Assessment Surveys
TEC	Trachoma Expert Committee
TEMF	Trachoma Elimination Monitoring Form TEO Tetracycline Eye Ointment
VBNTDs	Vector Borne and Neglected Tropical Diseases
VBNTDU	Vector Borne and Neglected Tropical Diseases Unit
VL	Visceral Leishmaniasis
WHO	World Health Organization
WHO AFRO	WHO African Regional Office
WHO	World Health Organization
WHO AFRO	WHO African Regional Office

GLOSSARY OF KEY TERMS

Annual Workplan
Form that provides information on key preventive chemotherapy and collateral activities by health ministries for planning purposes (see Joint Application Package).

Batch Number, or Lot Number
Any distinctive combination of letters, numbers or symbols, or any combination of them, from which the complete history of production, processing, packaging, handling and distribution of a batch or lot of medical product or other material can be determined. This number is available on the packing list, invoice, and pallet.

Demurrage
Daily fees assessed on containers inside a port until the consignment is cleared through customs and received by the consignee.

Health Products
These include human and veterinary medicines, medical products, medicinal substances, vaccines, diagnostics, medical devices, blood products, traditional and alternative medicine, therapeutic feeds and nutritional formulations, cosmetics and related products (Health Act, 2017).

Health Technologies
This is the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve the quality of life (Health Act, 2017).

Incoterms
A set of widely used terms of sale, which define the responsibilities of sellers and buyers.

LMIS
Logistics Management Information System used to manage government supply chain systems in a country.

First Expiry, First Out
Method used to organize stock including HPTs by expiry date and issue stock with the earliest expiry date regardless of the date of receipt.

First In, First Out
Method used to ensure stock that enters medical stores first is also distributed first.

Joint Application Package
WHO-led system through which countries request medicines donated by pharmaceutical companies for treatment of neglected tropical diseases amenable to preventive chemotherapy.

Joint Reporting Form
Form to assist countries in reporting annual progress on integrated and coordinated distribution of medicines across diseases in the reporting year in a standardized format.

Joint Request for Selected Medicines
Form to assist countries in applying for albendazole, diethylcarbamazine citrate, mebendazole, ivermectin and praziquantel for use in the year after the year of application.

Mass Drug Administration (MDA)
Distribution of medicines to the entire population of a given administrative setting (for instance, national, county, sub county, ward, location, or village).

Neglected Tropical Diseases (NTDs)
A diverse set of 20 diseases and disease groups that disproportionately affect populations living in poverty, predominantly in tropical and subtropical areas. They impose a devastating human, social and economic burden on more than 1 billion people worldwide. They include Buruli ulcer; Chagas disease; dengue and chikungunya; dracunculiasis; echinococcosis; foodborne trematodiases; human African trypanosomiasis; leishmaniasis; leprosy; lymphatic filariasis; mycetoma, chromoblastomycosis and other deep mycoses; onchocerciasis; rabies; scabies and other ectoparasitoses; schistosomiasis; snakebite envenoming; soil-transmitted helminthiases; taeniasis and cysticercosis; trachoma; and yaws.

Physical Inventory
Process of counting stock and reconciling records of stock.

Preventive Chemotherapy
Large-scale use of medicines, either alone or in combination, in public health interventions.

Proof of Delivery
Document signed by the recipient to confirm that the shipment was delivered in good condition.

Reverse Logistics
Process of returning usable surplus supplies including HPTs and/or expired or damaged supplies from lower levels to the next level within the supply chain to facilitate redistribution to places where HPTs are needed or need to be disposed of if damaged and/or expired.

Stock Card
Card to specifically record receipts, issues and adjustments for HPTs stored in a particular location and generally to keep track of inventories of HPTs while in storage.

Tax Exemption
The reduction or removal of liability to make a compulsory payment that would otherwise be imposed by a tax collecting agency upon persons, property income or transactions.

Transmission Assessment Survey
Survey designed to measure whether evaluation units have lowered the prevalence of filarial infection to a level where recrudescence is unlikely to occur, even in the absence of mass drug administration interventions.

Waybill
Document prepared by the carrier of a shipment of goods that contains details of the shipment, route, and charges.

FORWARD

The Supply Chain Management Guidelines for Neglected Tropical Diseases provides step by step process to manage the flow of health products and technologies (HPTs) from the source to the end users. It encompasses all the processes involved in planning, forecasting and quantification, donation of HPTs, procurement, shipping, customs clearance, warehousing, distribution, retrieving and accounting for leftover stock, and waste disposal.

Kenya is implementing its third NTD Master Plan, 2023-2027, with the mission to accelerate the prevention, control, elimination, and eradication of targeted NTDs in Kenya by 2030. Kenya is preparing for certification of elimination (interruption of transmission) of Onchocerciasis and Human African Trypanosomiasis by 2025 and elimination of Lymphatic Filariasis, Trachoma, Rabies, Soil Transmitted Helminths and Schistosomiasis as public health problems by 2027. To achieve these ambitious goals, Kenya requires a robust supply chain management plan for managing health products and technologies for NTDs amenable to preventive chemotherapy and individual case management. These guidelines will assist the MOH, partners and counties to effectively control and manage supply chain operations for NTD HPTs. The guidelines are designed to optimize each step of the supply chain to reduce costs, improve efficiency, ensure acquisition of high-quality products, and enhance the performance of the NTD program.

The guidelines were developed through a consultative process involving all stakeholders including government ministries, departments and agencies; counties, development partners (multilateral and bilateral) and implementing partners.

It is my sincere hope that this Supply Chain Management Guidelines for Neglected Tropical Diseases will be a great resource to managers involved in the NTD supply chain. With these guidelines in place, I expect a more robust and well-coordinated supply chain management in the country.

Dr. Patrick Amoth, EBS
Ag. Director General of Health

PREFACE

The goal of the Supply Chain Management Guidelines for Neglected Tropical Diseases is to support Kenya's NTD elimination agenda as set out in the NTD Master Plan 2023 – 2027. Specifically, the guidelines focus on strengthening the supply chain system involving access to donated and/or procured HPTs for NTDs.

Supply Chain Management is managing the flow of goods and services to and from an organization. The guidelines describe the standard operating procedures (SOPs) for supplying HPTs for NTDs amenable to preventive chemotherapy and case management. NTD HPTs include medicines, laboratory supplies and test kits, data tools, and Information, Education, and Communication (IEC) materials.

The guidelines aim to empower responsible persons and key supply chain stakeholders involved in managing HPTs for NTDs. These include but are not limited to, the following: MOH, KEMSA, county governments, donors, implementing partners, pharmaceutical companies, health care providers, community health promoters (CHPs), civil society groups, academia, media, and private sector.

These guidelines empower supply chain stakeholders by summarizing multiple processes in one place. These separate processes include WHO SOPs for supply chain management of health products for neglected tropical diseases amenable to preventive chemotherapy, KEMSA SOPs, PPB guidelines for safe management of pharmaceutical waste, PPB guidelines for disposal of expired drugs, MOH handbook for quantification of HPTs, among others.

By releasing these guidelines, the MOH aims to create an effective supply chain that ensures timely access to and availability of quality-assured NTD medicines, products, and pharmaceutical supplies at all levels and avoids or minimizes stockouts, wastage, and drug losses. The guidelines shall assist in mainstreaming and institutionalizing efficient supply chain management for NTD HPTs in Kenya.

Dr. Grace Ikahu - Muchangi
Ag. Director, Directorate of Public Health

ACKNOWLEDGEMENT

Developing the Neglected Tropical Diseases (NTD) supply chain management plan was a widely consultative and collaborative engagement with many stakeholders. It began with identifying the stakeholders involved in NTDs, identifying gaps and challenges in the supply chain management of NTD Health Products and Technologies (HPTs), and then the actual development and validation of the supply chain management plan referencing the World Health Organization (WHO) NTD Supply Chain Standard Operating Procedures.

The Ministry of Health (MOH) wishes to acknowledge the leadership of the office of the Deputy Director General for Health, the Director of Public Health and Sanitation, the Director of the National Public Health Institute, and the Head of the Division of Disease Surveillance and Response. The MoH wishes to acknowledge the African Institute for Health Development (AIHD) through the ARISE II Project from the END Fund for the financial and technical support in developing this manual.

The MOH also wishes to acknowledge the commitment and contribution of the members of the Vector Borne and Neglected Tropical Diseases Unit (VBNTDU) as well as members from the Directorate of Health Products and Technologies (DHPTs), Kenya Snakebite Research and Intervention Centre (K-SRIC), Kenya Institute of Primate Research (KIPRE) and different divisions of the MOH. We wish to acknowledge the efforts, contribution and time put in by the staff of the AIHD, Clinton Health Access Initiative (CHAI), Merck, Amref Health Africa, JSI/InSupply Health, Kenya Medical Supplies Authority (KEMSA) and County representatives (Siaya, Migori, Tharaka Nithi, Kajiado, Taita Taveta, and Narok) for their leadership and contribution towards the success in the development of the NTD Supply Chain Guidelines.

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Finally, we also wish to express gratitude to everyone who has contributed in various ways to the development of this document.

Wyckliff Omondi
Head, Vector Borne and Neglected Tropical Diseases Unit

CHAPTER 1: INTRODUCTION

1.1 Background

Neglected tropical diseases (NTDs) are a diverse group of diseases that include bacterial, viral, parasitic, fungal, and non-communicable conditions.[1] NTDs cause human suffering and devastating social and economic burdens among the poor and marginalized people in our country. Despite the health and economic burden they cause on disadvantaged communities, there are tools and effective interventions for the control and elimination of NTDs. Kenya is on track to achieve certification of elimination (interruption of transmission) of Onchocerciasis and Human African Trypanosomiasis by 2025 and elimination of Lymphatic Filariasis, Trachoma, Rabies, Soil-Transmitted Helminths and Schistosomiasis as public health problems by 2027.[2] The Ministry of Health (MOH) is dedicated towards the prevention and control of diseases such as Snakebite Envenoming (SBE), Leishmaniasis, Dengue and Chikungunya, among others by 2030.

To support the NTD elimination agenda, Kenya requires a robust Supply Chain Management (SCM) system that will ensure rapid access to donated and/or procured health products and technologies (HPTs) for NTDs amenable to preventive chemotherapy and individual case management. Supply Chain Management is the process of managing the flow of goods and services to and from an organization. In the case of the elimination of NTDs in Kenya, Supply Chain Management Supply Chain Management refers to the following processes: planning, forecasting and quantification, donation of HPTs, procurement, shipping, customs clearance, warehousing, distribution, retrieving and accounting for leftover stock and waste disposal.

1.2 Purpose

This Supply Chain Management Guideline is designed to support Kenya's NTD Master Plan 2023 - 2027 in the elimination and control of Neglected Tropical Diseases (NTDs). It provides comprehensive policies, measures and standard operating procedures tailored for the effective management of health products and technologies (HPTs) critical to NTDs. These HPTs include medicines, laboratory supplies, test kits, data tools, and Information, Education, and Communication (IEC) materials. The guideline aims to ensure a robust and efficient Supply Chain Management (SCM) system encompassing forecasting and supply planning, donation, procurement, shipping, customs clearance, warehousing, distribution, retrieval, and waste disposal. By streamlining these processes, the guideline seeks to enhance rapid access to necessary interventions, thereby accelerating Kenya's progress towards the elimination and control of NTDs by the targeted milestones of 2025, 2027, and 2030.

1.3 Target Audience

The SCM Guideline is intended for use as a reference document by responsible persons and key supply chain stakeholders, including but not limited to the following: MOH, KEMSA, county governments, donors, implementing partners, pharmaceutical companies, health care providers, NTD clients, community health promoters (CHPs), civil society groups, academia, media, and the private sector.

[1] https://www.who.int/publications/i/item/who-wer9738-465-480
[2] Kenya National Master Plan for the Elimination of Neglected Tropical Diseases, 2023 - 2027

CHAPTER 2: FORECASTING AND SUPPLY PLANNING

Forecasting and Supply Planning involves estimating the quantities of Health Products and Technologies (HPTs) needed for service delivery, determining costs, and scheduling deliveries to ensure an uninterrupted supply and alignment with consumption trends for each population and activity.

Different disease areas use various processes to forecast their HPT needs. For instance, Forecasting and Supply Planning for Preventive Chemotherapy (PC) NTDs such as Lymphatic Filariasis (LF), Soil Transmitted Helminthiasis (STH), Schistosomiasis (SCH), and Onchocerciasis are managed by the country's NTD Program. This process includes determining the number of Implementation Units (IUs) requiring Mass Drug Administration (MDA) campaigns and considering factors such as losses due to breakages, expiration of leftover HPTs, adjustments, and the opening stock from previous MDA campaigns. The pack size of the HPTs is also taken into account.

The program submits the Joint Request for Selected Medicines (JRSM), which is part of the Joint Application Package (JAP) discussed in Chapter 3, to the WHO to request HPTs from pharmaceutical donors. The WHO coordinates access to donated HPTs between countries and manufacturing companies, especially for preventive chemotherapy activities.

For case management NTDs like snakebite envenoming (SBE) and rabies, specific HPTs are quantified by order management teams at the sub-national level based on average monthly consumption. Forecasting and Supply Planning for case management NTDs such as Leishmaniasis, Human African Trypanosomiasis (HAT), and Mycetoma are also handled by the NTD program through the WHO. This process involves determining the number of cases, average monthly consumption, and reporting rates while considering factors such as stock on hand, losses due to breakages, expiration of leftover HPTs, adjustments, and the opening stock from the previous ordering cycle.

The specific processes for Preventive Chemotherapy and case management NTDs are detailed in Chapter 3.

Critical steps in forecasting

2.1 Formation of the Quantification Team[3]

The quantification team, otherwise known as the NTD Commodity Security team, is a multidisciplinary team consisting of members with various sets of skills and expertise. The team will carry out an annual estimation of NTD commodity requirements and generate a supply plan at the national level. The Principal Secretary Ministry of Health appoints it and reports to the Commodity Security Technical Working Group (CS TWG) at the national level.

The NTD Commodity security team chaired by the NTD Program Pharmacist comprises of and is not limited to the following:

- Head, VB NTD Program
- NTD Program Pharmacist
- NTD Disease Focal Points Persons
- NTD Monitoring and Evaluation (M&E) Officer
- NTD Program Logistician
- NTD Program Laboratory Officer
- WHO NTD Focal point person
- Donor Representation
- Implementing Partners Representation
- Pharmacist from the Directorate of Health Products and Technologies
- KEMSA Representation
- PPB Representation
- KNBS Representation
- Representative of County Pharmacists

[3] Ministry of Health. Quantification Handbook for Health Products and Technologies. 2020. Nairobi, Kenya

The NTD Commodity security team should:

- Have clear terms of reference and a work/action plan.
- Meet quarterly at the county level and biannually (6 months) at the national level to review the quantification assumptions, forecasts, and supply plans.
- The HPT/product list should be informed by the country's needs and clinical guidelines and the period to be covered by the quantification.
- Have an action/work plan that details processes for successful quantification and specifically addresses the following key aspects: date(s) for quantification, workshop logistics, tasks to be done, timelines and deliverables, and task and role assignments.

2.2. Determine the Quantification Scope

The NTD Commodity security team should define and communicate to CS TWG at the national level the scope of the activity, which covers three key areas:

i. The objectives of quantification
ii. The product list - informed by the country's needs and clinical guidelines.
iii. The period to be covered by the quantification.

2.3. Develop NTD HPT Lists

The selection of HPTs to be quantified should be based on a standard (pre-selected) essential health product list, including the Kenya Essential Medicines List, the Kenya Essential Medical Supplies List, and the Kenya Essential Diagnostics List, WHO guidelines for Mass Drug Administration for Preventive Chemotherapy, and Clinical Management Guidelines for NTD conditions.

2.4. Define the Purpose of Forecasting and Supply Planning for NTDs.

It is crucial to identify the purpose of the exercise and how it will support the delivery of health services. The exercise:

- Provides data on requirements of health products and costs for the government's annual budget allocations
- Informs donors about funding requirements and advocates for resource mobilization for commodity procurement
- Estimates commodity needs and assesses the stock status of the in-country supply pipeline to identify and correct supply imbalances
- Supports an estimate of commodity procurement, storage, and distribution costs

2.5. Determine Quantification Method

The quantification team will determine the appropriate method for quantifying HPTs based on specific diseases. The preferred methods are consumption, morbidity, and demographic data.

2.6. Data Collection

Different types of data and information will be required at each step in the quantification process, i.e., service data, consumption data, demography, and endemicity. These can be obtained from KHIS, the Kenya National Bureau of Statistics, MOE-NEMIS, Integrated database, iiLMIS and Survey reports.

2.7. Forecasting

After obtaining the necessary data and logistics for the exercise, the team will proceed to estimate the quantities of products that will be required or used to meet the health needs of the targeted population during a specific future. In the event of inadequate standard data, assumptions on quantification as guided by the Quantification Handbook for Health Products and Technologies3 will apply.

2.7a. Forecasting Process for PC Medicines (Lymphatic Filariasis, Soil-Transmitted Helminths and Schistosomiasis)

The following data sets are required:

a) MDA treatment data from the previous year
a) Demographic data from census reports
b) Endemicity data from the current epidemiological survey report
c) Number of rounds of treatment required

d) Availability of funding and implementation support
e) Calendar of events
f) Treatment guidelines
g) Stocks on hand at all levels
h) Review previous year JAP[4] (see detailed description of JAP in Chapter 3) pre-approval feedback to determine causes for persistent approval delays (if any). Some of the mitigating measures to take include:

- Developing solutions to prevent repeat delays.
- Discussing and assigning responsibilities for gathering components for the JAP.
- Scheduling preparatory meetings, to serve as the deadline for gathering required documentation.

2.7b. Forecasting for Onchocerciasis HPTs

WHO recommends treating Onchocerciasis with ivermectin at least once yearly for 10 to 15 years. The ivermectin HPTs are quantified based on the following parameters:

a) The population targeted for treatment in each area where Onchocerca Volvulus prevalence is greater than 0.1%.
b) Multiply by the average dose i.e., 2.5 tablets per person required by the targeted population.

The Mectizan Expert Committee (MEC) makes the final approval on the number of IUs specifically for the treatment of Onchocerciasis. MEC members submit recommendations to the Mectizan Donation Programme (MDP). Since donation for Ivermectin-Diethylcarbamazine Citrate-Albendazole (IDA) is a special provision to facilitate access to Ivermectin, all applications (initial or reapplications) are discussed among MEC members before a decision is made.

2.7c. Forecasting for HPTs for Lymphatic Filariasis

The following data sets are required:

a) MDA treatment data from the previous year.
b) Demographic data from census reports
c) Endemicity data from the current epidemiological survey report
d) Number of rounds of treatment required
e) Availability of funding and implementation support
f) Calendar of events
g) Treatment guidelines
h) Stocks on hand at all levels

LF MDA HPTs are quantified using demographic data provided by KNBS, and projections are made based on the targeted population. Historical data from previous targeted populations for the same activity are also considered. The LF program also requests sub-counties (IUs) to provide projections for their commodity needs based on their current population.

2.7d. Forecasting for Trachoma HPTs

The following data sets are required for each IU:

a) Trachoma prevalence
b) Population estimate
c) Number of rounds of MDA already conducted
d) Coverage achieved for each round
e) Schedule for population-based prevalence surveys (baseline, impact, and surveillance)
f) Availability of financial and implementation support for MDA.

Before the WHO annual trachoma alliance meeting in April, VBNTDU will meet with members of the International Trachoma Initiative (ITI), Pfizer, WHO, implementing partners, and key stakeholders to review the annual MDA plan and produce a forecast of Azithromycin requirements. This meeting also provides an opportunity to assess partner support for surgery, antibiotics, facial cleanliness, and environmental improvement (SAFE) strategy implementation and to review baseline and impact prevalence surveys.

[4] WHO JAP Annual Report https://espen.afro.who.int/system/files/content/resources/ESPEN%20%202020%20Annual%20Report%20En.pdf

The quantification team uses the Azithromycin shipping calculation tool for country quantification, and the program uses the Azithromycin Estimator for national and county quantification. Both tools use total population data as the denominator to get the number of Azithromycin tablets and Powder for Oral Suspension (POS) used by the country, national, county, and sub-county.

An Allocation Schedule (refer to the Azithromycin Management Guide[5]) estimates the quantity of Azithromycin required to treat the country's target population by county. The program pharmacist must create an allocation schedule to determine the quantity of azithromycin that should be sent to county storage facilities based on the approved county allocations by the Trachoma Expert Committee (TEC). Azithromycin must only be allocated to counties approved by the TEC. Allocating HPTs to non-approved counties violates the MOU between the MOH and ITI and will jeopardize the country's potential to receive Azithromycin. Based on the target population in each county, the number of bottles of tablets and POS required are calculated using the following formula:

- It is estimated that 98% of the population is 6 months or older and thus eligible for Azithromycin MDA.
- It is generally estimated that 70% of the eligible population is 7 or older and will be treated with tablets.
- Similarly, 30% of the eligible population is estimated to be six months to 7 years of age and will be treated with POS.

Figure 1: Formula for Calculating Azithromycin Quantities for MDA

Gross tablets required (bottles) = (Total approved x 0.8 x number of tablets / treatment) / 500	**Gross POS required (bottles)** = (Total approved x 0.2 x quantity of POS / treatment) / 30
Tablets required (cartons) = (Gross tablets required (bottles) - on hand inventory (bottles)) / 24	**POS required (cartons)** = (Gross POS required (bottles) - on hand inventory (bottles)) / 48

The required number of cartons should always be rounded up to integer values

2.7e. Forecasting for Leishmaniasis HPTs

The Leishmaniasis focal point at the national level uses the WHO extranet DHIS2 platform[6] to summarize all reported cases in the country for the current year (Calendar year Jan-December). This data forecasts HPTs for the following year.

WHO provides an Excel quantification tool that auto-populates the country's requirements. The program manager inputs the number of cases reported from the previous year and calculates the HPT requirements for the following year, adding a 15% buffer6 to account for potential disease upsurges in the country.

In addition, the counties may request Leishmaniasis HPTs through the KEMSA eLMIS platform for direct purchases to address the gap between the donated and actual needs. The eLMIS system will assist them in forecasting and quantifying HPTs based on the cases reported on the DHIS2 tool and consumption data (for diagnostic kits and HPTs).

2.7f. Forecasting of Information Education Communication (IEC) Materials

Information Education Communication (IEC) materials are a key component for creating awareness of NTDs, as most communities know little about the diseases. IEC materials are critical during campaigns such as MDAs, where they are procured in large quantities and must be distributed at the community level. In addition to creating awareness, IEC materials enhance community participation and may catalyze sustainable change within communities.

[5] https://www.trachoma.org/sites/default/files/2020-12/ITI_ZMG_ENG_121120_Online.pdf
[6] https://extranet.who.int/dhis2/dhis-web-commons/security/login.action

Forecasting is based on the following factors:

a) Demographic data[7]
b) Disease-specific prevalence rates as per the granular mapping survey report[8].
c) Outcomes of recent impact surveys, e.g., Transmission Assessment Surveys (TAS) for Lymphatic filariasis
a) National MDA macro-planning meeting reports
b) Total number of Community Drug Distributors (CDDs) per county of intervention
c) The total number of CDD supervisors

2.8 Supply Planning

Supply planning is the final output of the quantification process. It determines the quantities required to fill the health product pipeline, their related costs, lead times, and shipment dates to ensure optimal procurement and delivery schedules. To align the quantification process to the national medium-term expenditure framework, supply plans developed in the quantification process will cover a defined period and are used to identify funding sources and to mobilize additional resources to meet funding gaps, if needed.

The basic steps in supply planning are;

a) Organizing and analyzing the data.
b) Building the supply planning assumptions.
c) Estimation of the total commodity requirements and costs.
d) Developing the supply plan.
e) Compare costs to available funding.

Reference Document

1. Managing Access to HPTs and Health Technologies: https://msh.org/resources/mds-3-managing-access-to-HPTs-and- health-technologies / Quantification Handbook.
2. Kenya Quantification Handbook for Health Products and Technologies October 2020

[7] 2019 Kenya Population and Housing Census Results https://www.knbs.or.ke/2019-kenya-population-and-housing-census-results/
[8] Granular mapping report 2023 https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0011043

CHAPTER 3: MANAGING DONATED HPTs AT FIRST MILE

WHO DONATED ITEMS FOR PREVENTIVE CHEMOTHERAPY NTDS

3.1 Joint Application Package (JAP) Submission Process

The WHO coordinates donations of HPTs between countries and pharmaceutical companies. Beneficiary countries consolidate and submit requests for donated Health Products and Technologies (HPTs) using an electronic tool known as the Joint Application Package (JAP) provided by WHO. Countries use this tool to manage donated HPTs for diseases amenable to preventive chemotherapy (PC). They use separate forms to request medicines for foodborne trematodiases, taeniasis, cysticercosis, trachoma, and yaws.

The Vector-Borne and Neglected Tropical Diseases Unit (VBNTDU) prepares and submits the JAP forms to WHO for planned MDAs or surveys. The JAP comprises a set of four "joint" forms used to apply for HPTs, report on their use, and prepare for their distribution. These forms include:

1. Joint Request for Selected HPTs (JRSM)
2. Joint Reporting Form (JRF)
3. Epidemiological Reporting Form (EpiRF)
4. Annual Work Plan (AWP)
5. Ivermectin (IVM) Application Process for Triple (IDA) Therapy (JRSM-IDA)

The diseases covered under JAP and their respective HPTs are as follows:

Table 1: NTDs and their Preventive Chemotherapy HPTs supported by WHO

Disease	HPT
Lymphatic Filariasis (LF)	Albendazole (400 mg tablets), Diethylcarbamazine (100 mg tablets) and Ivermectin (3 mg tablets), Filarial Test Strips
Onchocerciasis (ONCHO)	Ivermectin (3 mg tablets)
Schistosomiasis (SCH)	Praziquantel (600 mg tablets)
Soil transmitted Helminthiases (STH)	Albendazole (400 mg tablets)/ Mebendazole (500 mg tablets)

3.2 JAP Outputs and Reports

The Head of VBNTDU receives the latest version of the joint forms as the country representative and is responsible for their submission to the WHO Country Office[9]. In the absence of the Head, the Program Managers for each targeted disease will complete the forms in consultation with the program pharmacist.

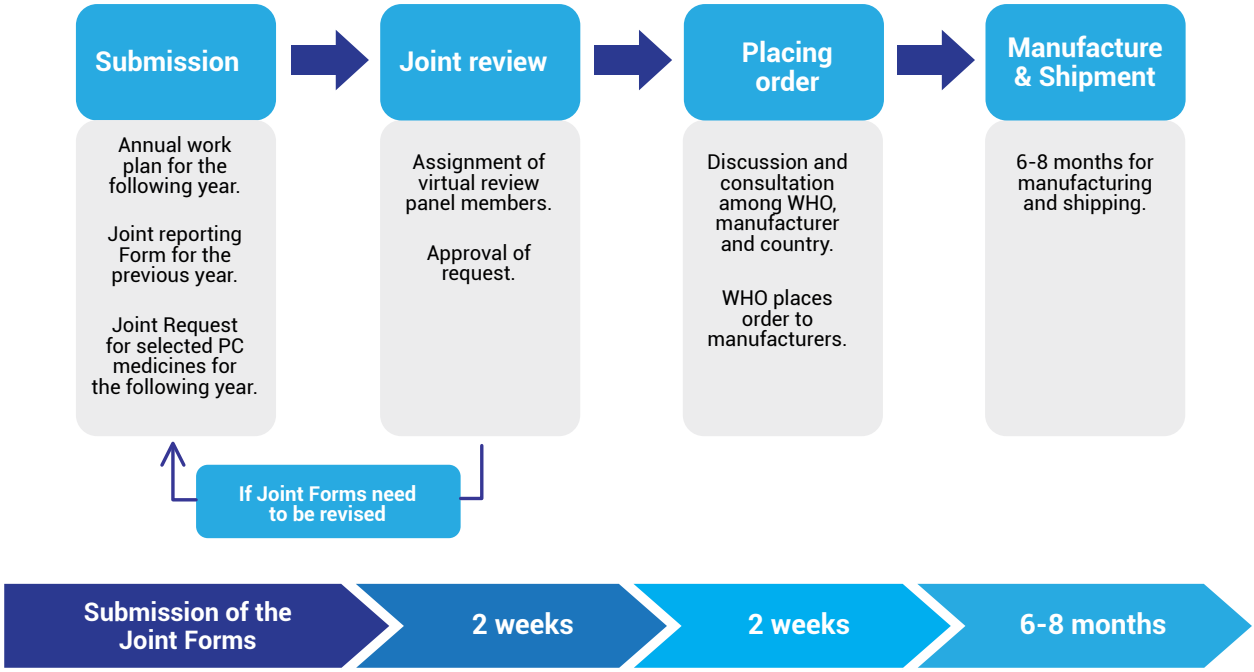
Once the forms are finalized, the summary page of the final copy must be printed, signed, stamped, scanned, and submitted to the WHO Country Office along with the full version of the form. Additionally, soft copies of the Joint Reporting Form (JRF) and Epidemiological Reporting Form (EpiRF) should be submitted to expedite the application process.

Summary of Process:

See Figure 2 for a summary of the processes from submission to shipment.

[9] Standard operating procedures for supply chain management of health products for neglected tropical diseases amenable to preventive chemotherapy. Geneva: World Health Organization; 2022

Figure 2: Joint Application Package Submission Process



Note: The JAP should be submitted at least 10 months ahead of the planned MDA.

3.2.1. Joint Request for Selected Medicines (JRSM)

JRSM is used to quantify selected HPTs required to reach the planned target population of the Implementation units (IUs), in a coordinated and integrated manner for the preventive chemotherapy NTDs (PC-NTDs) for the subsequent year. This form is sent to the Head, VBNTDU by WHO. This form should be populated and submitted by the Head, VBNTDU (or appointed designate), 10 months before the planned date(s) of MDA.

To complete the JRSM:

- Convene a meeting with stakeholders to present all the required country NTD information necessary to complete the JRSM.
- Complete the JRSM using accurate information compliant with the country's NTD context and status.
- Review the completed JRSM and submit it to the WHO country and regional offices for regional review and clearance.
- If requesting HPTs for triple HPT (IDA), verify eligibility guidelines.

The data required to fill the JRSM is as follows:

- Forecasted target population
- Forecasted HPT quantities required
- Inventory of PC HPTs in the country
- Available funding
- Up-to-date prevalence data

Note: The JRSM does not apply to azithromycin for trachoma and ivermectin for onchocerciasis. A separate application process is used for these; WHO sends the pre-populated Azithromycin application to the national trachoma program manager (or the NTD program trachoma focal point in an integrated program) for the upcoming year.

3.2.1 (b) Ivermectin (IVM) Application Process for Triple (IDA) Therapy

The JRSM (JRSM-IDA) form is used to apply for Mectizan® for IDA and must be submitted to both the NTD Unit of the WHO Regional Office and the Mectizan® Donation Program (MDP) along with the following supporting documents:

a) Revised master plan with IDA adopted by the MOH to eliminate LF.
b) The AWP including county's targeted for IDA, implementation strategy and post M&E.
c) Epidemiological evidence of eligibility for IDA for each county.
d) Signed agreement with MDP to receive and distribute Mectizan.

Note: Applications for Mectizan® follow the WHO JAP review mechanism.

3.2.2. Joint Reporting Form (JRF)

The Joint Reporting Form (JRF) is a standardized electronic tool used to report annual progress on the integrated and coordinated distribution of drugs across Neglected Tropical Diseases (NTDs) for the reporting year. The JRF should be completed and submitted within three months after the conclusion of the last scheduled Mass Drug Administrations (MDAs) in the calendar year.

To complete the JRF:

- Convene a meeting with stakeholders to gather all the treatment data from the field.
- Generate the JRF using the data received from the field and other available sources, e.g. the servers used.
- Review the final JRF and submit it for approval.

The data required to fill the JRF is as follows:

- Actual MDA treatment data.
- Actual number of tablets used.
- Inventory of PC HPTs in the country.
- Up-to-date prevalence data, including:

    ◊ Administrative structure
    ◊ Population by age group
    ◊ Endemicity status
    ◊ Planned interventions
    ◊ Interventions implemented

3.2.3. Epidemiological Reporting Form (EpiRF)

The EpiRF helps standardize national epidemiological data reporting on LF, ONCHO, STH, and SCH. Ministries of Health are required to submit the completed form to WHO every year, along with the JRF.

The EpiRF should report new mapping data of completed recent/survey results from sentinel surveys and morbidity-related data. This data is used to monitor progress and estimate the population requiring PC. The submitted form should remain blank if epidemiological surveys have not been conducted during the reported year.

3.2.4. Annual Work Plan (AWP)

The AWP is a comprehensive Excel document outlining planned activities carried out by MOHs at the national and county levels. Planned interventions to be implemented are indicated to capture the ones whose HPTs are requested. HPT logistics, monitoring and evaluation, and funding details are included. These activities aim to control and eliminate NTDs such as LF, ONCHO, SCH, and STH in the year of use of the requested HPTs. This document helps ensure efficient resource allocation and coordination in the fight against these diseases and must be completed at least 10 months before the planned MDA.

To complete the Annual Work Plan (AWP) and ensure that it is aligned with the government AWP:

a) Download the AWP from the ESPEN Portal or the NTD section of the WHO website.
b) Fill out the AWP and share it for review.

3.3 Pfizer donates Non-WHO Donated Items for PC NTDs Azithromycin Application Process

Azithromycin through the International Trachoma Initiative (ITI), and Tetracycline Eye Ointment (TEO) is procured in the country. A separate annual application process requires information on every Implementation Unit (IU) where treatment is planned and the scheduled timelines. The Azithromycin application has two parts that must be prepared by the Head, VBNTDU, in collaboration with the National Trachoma Implementation Team, and submitted to the ITI.

It is vetted by the Trachoma Expert Committee (TEC). ITI Program Liaison uses national program information to advocate for the country at TEC meetings. The Trachoma Elimination Monitoring Form (TEMF) and the Azithromycin application are pre-populated by ITI with past and projected IUs population figures.

The Azithromycin application is approved, and the national program reviews and updates TEMF and Azithromycin applications. Based on the data presented for each IU, TEC makes the following recommendations:

a) Approve Azithromycin to be allocated for the upcoming year.
b) Approve Azithromycin with contingency:

- Pending confirmation of available funding, and/or
- Pending results from population-based prevalence surveys, and/or pending resolution of a special situation (either outside the control of the national program, i.e. signing of the memorandum of understanding between MOH and ITI or insecurity, or requiring intervention by the national program).
- Does not meet criteria.

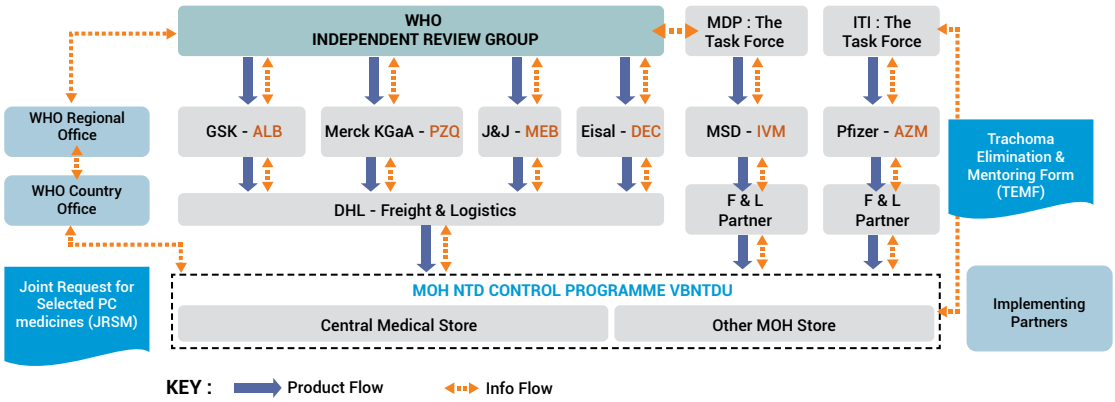
Table 2: Azithromycin Application Timeline

Month	Activity
January	WHO sends Azithromycin application to national trachoma programme (or national NTD programme trachoma focal point for integrated programmes) for the upcoming year
March	National trachoma programme submits the application to WHO and ITI
June to November	Trachoma Expert Committee decides on the allocation of Azithromycin ITI sends notification to the MOH of the Committee's decisions and either enters a new memorandum of understanding or updates the current 3-year memorandum with an addendum
1-2 months before MDA	ITI ships Azithromycin to the country depending on the MDA schedule)
March following year	MOH reports to WHO and ITI on treatments distributed during the past year in the Trachoma Elimination Monitoring Form, which includes the Azithromycin application
Before shipment	MOH reports to ITI on remaining inventory from the previous year

Azithromycin Memorandum of Understanding (MoU)

ITI and MOH sign an MOU for three years outlining the legal obligations of the MOH and ITI regarding the donation and management of Azithromycin. An addendum to the existing MoU is sent to the MOH in subsequent years. Failure to comply with the terms may result in the suspension of the Azithromycin donation.

Table 3: Summary of International Process for acquisition of NTD HPTs



3.4 WHO Donated HPTs for NTD Case Management

In Kenya, the NTDs receiving donations from WHO for case management include;

- Leishmaniasis
- Human African Trypanosomiasis (HAT)

Leishmaniasis HPTs Application Process

The Leishmaniasis focal point person at national level should use the WHO extranet DHIS2 platform to summarize all reported cases in the country for the previous reporting year (calendar year January-December). This data is then used to quantify HPTs for the following year. The application process involves the following steps:

1. Transfer and submit data from the WHO quantification tool to the Data Collection Tool for Leishmaniasis procurement.
2. Review and approve data at the WHO Country Office, WHO AFRO Office, and WHO HQ.
3. WHO HQ consolidates data and submits purchase orders to manufacturers.
4. WHO ships HPTs periodically based on warehouse stock or upon request during low stock levels.
5. WHO HQ sends shipping documents to the WHO Country Office to process the green light.
6. WHO HQ processes an AWB and shares it with the WHO Country Office for HPT shipment.
7. Counties request additional HPTs through the national Leishmaniasis focal point and KEMSA for further distribution.

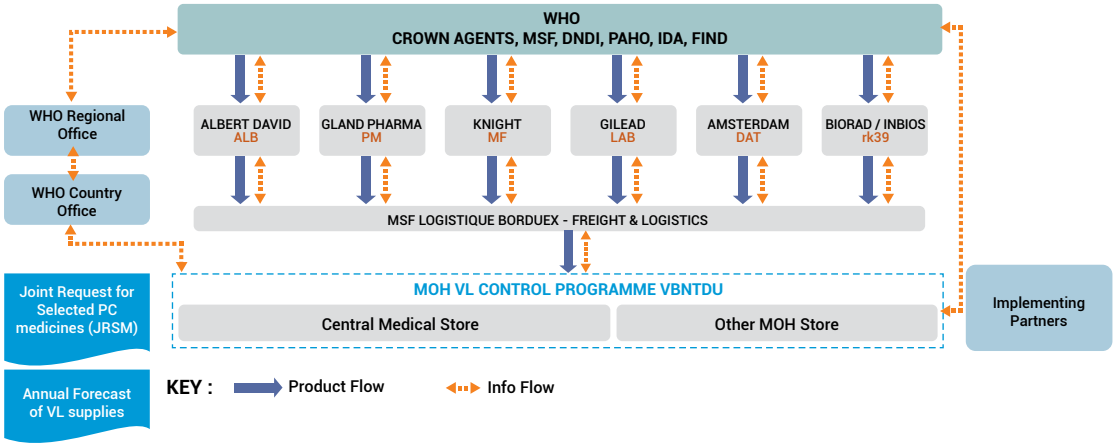
Supply of Leishmaniasis HPTs through KEMSA Procurement

Counties can also acquire the Leishmaniasis HPTs through the KEMSA procurement system.

Supply of Leishmaniasis HPTs through Other Partners

Other Partners may purchase the HPTs directly from the manufacturers and donate to the Ministry of Health for distribution through the existing mechanisms. Alternatively, partners can consider pooled procurement of HPTs with other partners to support the Ministry of Health in ensuring regular access to HPTs.

Table 4: Summary of International Process for acquisition of VL HPTs



Human African Trypanosomiasis (HAT) HPTs Application Process

The Program Manager conducts an audit of HPTs in the central medical stores every quarter to ensure that enough quantities are available and that none have expired. If the country has less than a 6-month supply of HPTs, the Program Manager raises a requisition through the WHO Country Office for additional HPTs. The Program Manager also alerts WHO about available HPTs and their expiry dates every quarter to ensure that short-expiry HPTs are collected by WHO for redistribution.

HPTs are released to counties on a need basis once a case is reported. Reconciliation of HPTs used is done through treatment sheets at health facilities, and the Program Manager reconciles remaining balances. Any expired HPTs are returned to the WHO Country Office for replacement.

3.5 County Procured HPTs for NTD Case Management

Snakebite Envenoming HPTs Ordering process

Snakebite Envenoming HPTs comprise of Polyvalent antivenom and Monovalent antivenom (for specific snakes; boomslang and carpet viper). The sub county pharmacist conducts a needs assessment to determine the number and type of snakebite antivenoms required. Adjusted consumption (from daily activity registers) at the facility level are ordered to maximum months of stock. Facilities, through the facility in-charge, submit their request through the KEMSA LMIS tool (https://lmis3.kemsa.co.ke). The sub county pharmacists rationalize, approve, and upload (forward to the county pharmacist) all sub county facility orders tthough the KEMSA LMIS online platform. The county pharmacist consolidates orders from the sub county pharmacists and submits to KEMSA through the KEMSA LMIS Tool 3.

3.6 WHO Donated Laboratory HPTs

Laboratory HPTs supported by WHO include;

- FTS kits for Lymphatic Filariasis
- rk39 and DAT for Leishmaniasis.

WHO assists specific disease areas in obtaining laboratory HPTs for use during field surveys and laboratory tests. Procurement and reporting of the rk39 and DAT are done alongside Leishmaniasis HPTs. Not all laboratory HPTs are requested from WHO for the Units' disease areas; some are procured locally. See Chapter 5 for details on the procurement of laboratory supplies.

Standards and Procedures

Filarial Test Strips (FTS)

The filariasis test strip is a rapid diagnostic tool designed to detect the presence of antigens of the primary filarial worm species *(Wuchereria bancrofti)* in human blood, which causes Lymphatic Filariasis. Diagnostic tests are essential for conducting surveys to determine disease prevalence, as recommended by WHO, to compare with target threshold levels.

The program manager for lymphatic filariasis completes the WHO TAS Eligibility and Reporting form, which includes the following information:

- The year in which the previous transmission assessment survey was conducted.
- The number of implementation units in which the surveys are planned.
- The estimated number of kits needed for the surveys, determined from the following data:
- The population in each implementation unit.
- The MDA coverage in each implementation unit over the required period of time (4-6 consecutive years).
- The results from baseline pre-transmission assessment surveys or earlier TAS surveys conducted in each implementation unit.

The completed TAS Eligibility and Reporting form[10] is submitted to the WHO country office and the regional office (AFRO) for ratification. This form helps decide whether it is the appropriate time to conduct a TAS.

The form is reviewed by the RPRG before the survey is planned. Upon approval, the form is submitted to WHO HQ, which then places the order with the manufacturer of the test kits. The test kits go through the green light process to enter the country.

Once in the country, the test kits are sent to the central warehouse for storage. When disease areas like LF are conducting surveys, the LF program writes to request the test kits from the warehouse. The kits are then transported to the respective counties and stored there seven days before the start of the exercise.

The sub-county teams share the kits as per their requirements. Any leftover kits are transported back to the VBNTDU stores, awaiting the next LF survey or disposal.

[10] https://apps.who.int/neglected_diseases/ntddata/forms/tas/WHO_TAS_EPF.xlsm

Responsible Persons

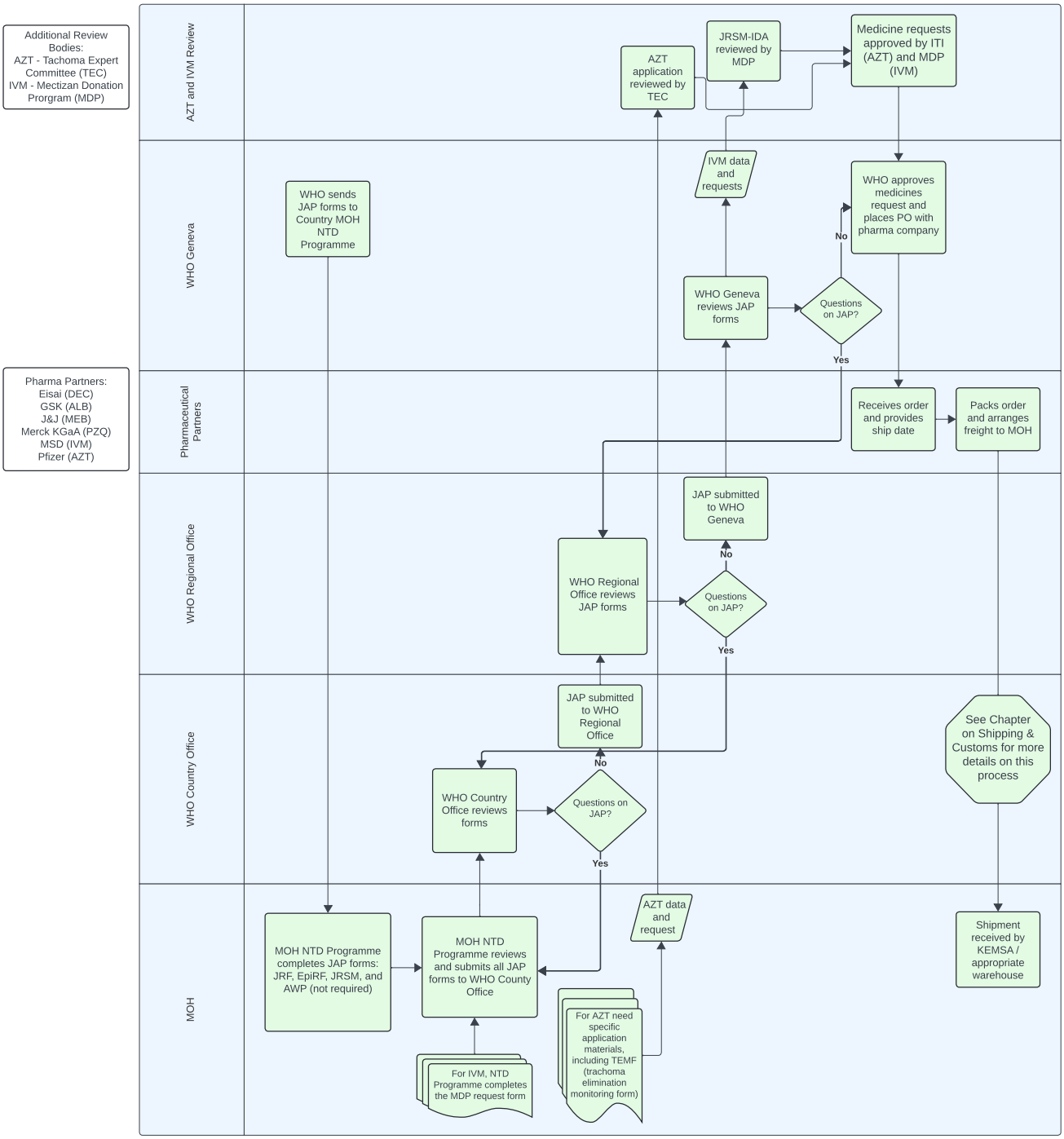
Name of Officer	Role and Responsibility
Head, VBNTDU	Overall responsible to receive the final application forms for approval and onward submission to WHO, ITI or the relevant partners
Program Managers of each targeted disease	Coordinates the completion of HPTs application process
M&E Manager at VBNTDU	Develop and implement the AWP. Provides updated program data Review of the completed request and report forms
Program Pharmacist	Completion of request and report forms and management of HPTs
Program epidemiologist	Completion of the epidemiological forms

Reference Document

Standard operating procedures for supply chain management of health products for neglected. tropical diseases amenable to preventive chemotherapy. Geneva: World Health Organization; 2022

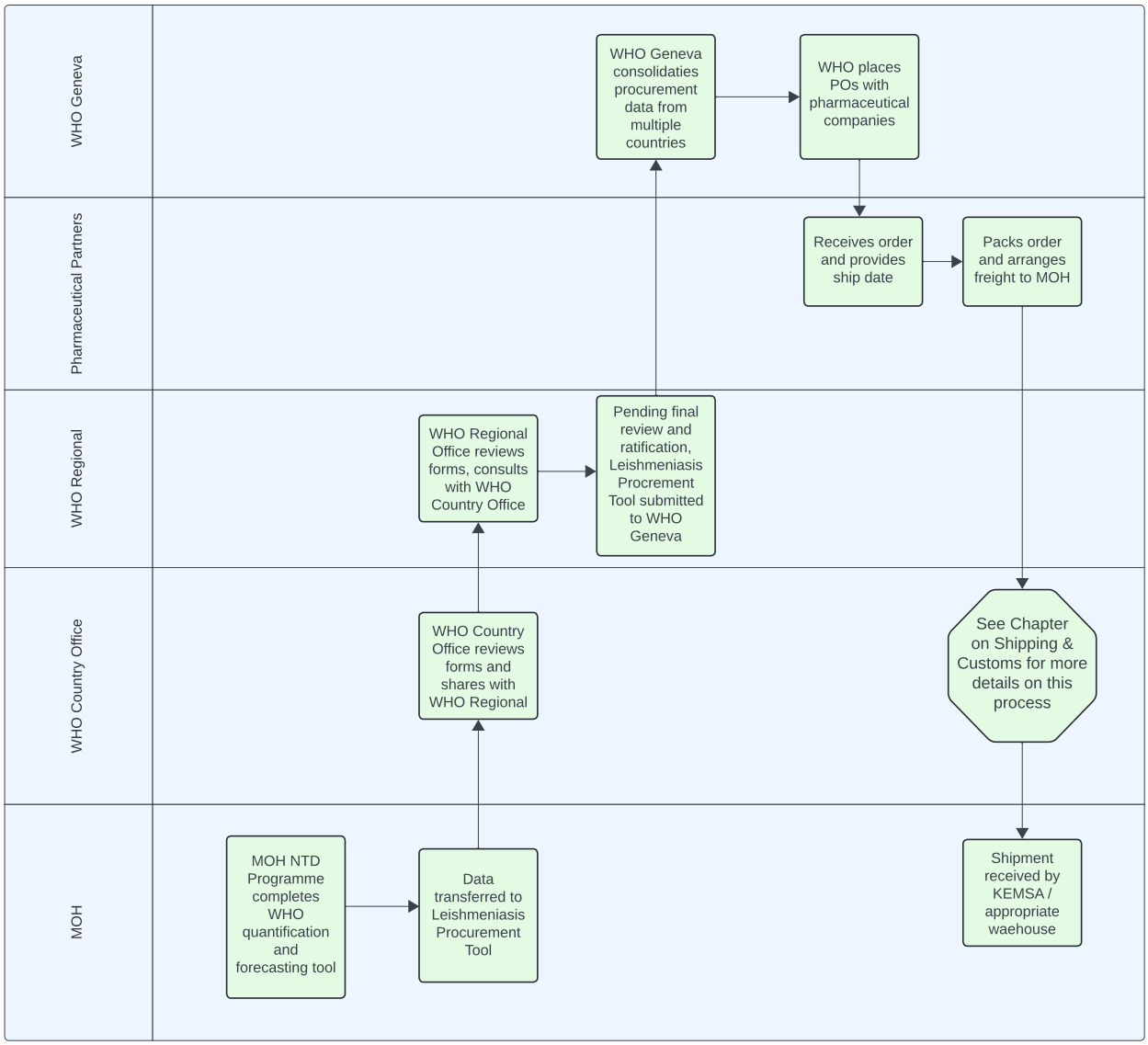
Flow Chart Diagram

First Mile Process Flow for NTDs



Flow Chart Diagram

First Mile Process Flow for VL Commodities



CHAPTER 4: SHIPPING AND CUSTOMS

4.1 Introduction

HPTs that are either donated or procured from abroad require to be shipped or air freighted into the country. These HPTs then must be cleared from customs. This process starts from the shipment of HPTs from the donor or manufacturer's plant or warehouse to the country's Port of Entry (PoE) or Central Medical Store (CMS)/warehouse. Upon arrival, these HPTs require clearance from customs to ensure timely and efficient distribution across the country. The initial steps in this process include the shipping notification, green lighr procedure, and maintaining an updated contact list.

The procedures are essential to:

a) Minimize time required to ship NTD HPTs from their origin to the destination country, ensuring that they reach the intended recipients without unnecessary delays.
b) Minimize or eliminate demurrage charges or other penalties that may arise from delays at customs or other points in the supply chain..
c) Minimize shipping delays that affect country-wide HPT distribution and the mass HPT administration (MDA) schedule.
d) Ensure mandated documentation, clearances or approvals are available at the right time, facilitating a smooth and efficient clearance process.
e) Ensure stakeholders know their responsibilities and complete activities to minimize shipment delays.

4.2 Standards and Procedures for Planning a Successful Green Light Process

To ensure a successful green light process for the importation and distribution of HPTs, the following standards and procedures must be adhered to:[11]

4.2.1 Responsible Authorities

VBNTDU should engage the following:

a) Persons responsible for decisions on HPT import permits or duty-free waivers with the power to prioritize, especially when HPTs arrive at different times.
b) The National Treasury & Economic Planning, Ministry of Health (MOH), Pharmacy and Poison Board to obtain Signature of authority.

4.2.2 Security

Ensure HPT safety at all levels, from receipt to distribution, since NTD HPTs are valuable and may be targeted for other uses, such as for livestock.. Ensure no damage or theft along the supply chain since this affects MDA coverage and NTD elimination and control goals.

4.2.3 Documentation

The Program Pharmacist should:

- Ensure all appropriate documentation is obtained before shipment.
- Identify in advance all administrative procedures for receiving and clearing NTD HPTs.
- Inform the donor/importer in advance about country regulations and documentation.
- Ensure shipping process monitoring systems are in place.
- Ensure verified and accurately filled documents accompany the shipment.

Documents Required before Green Light is Given:

- Bill of lading (BOL) / airway bill (AWB).
- Commercial Invoice with at least a value of Minimum 10 USD with the HS codes.
- Packing List with the expiry dates and batch numbers of the shipment with specified tonnage and volume - where applicable.
- Certificate of Donation.
- COO-Certificate of Origin (COO).
- COA-Certificate of Analysis (COA)- where applicable.
- COC- Certificate of conformity-where applicable.

[11] Standard operating procedures for supply chain management of health products for neglected tropical diseases amenable to preventive chemotherapy. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

- For the kits-complete table showing the contents.
- Tax exemption waiver-where applicable.
- The National Treasury & Economic Planning waivers.
- Ministry of Health stamp of approval of shipping documents.
- Letter to the KEMSA/appropriate warehouse from VBNTDU with expected delivery dates and quantitiesof NTD HPTs with 2 weeks' notice.
- Import declaration form.
- Pharmacy and Poisons Board (PPB) import permit.
- Letter of tax payment sent to KEMSA where applicable (Approved by the PS).
- Indication of shipment quantity.
- Confirmation of committed warehouse space.
- Distribution plan

4.2.4 Distribution Plan

The program should develop a comprehensive distribution plan to help the donor/manufacturer initiate the production and shipping based on the planned MDA date in the country. The National Program Coordinator and WHO must communicated the expected delivery time of NTD HPTs, factoring in the lead time required to complete all formalities and transport the HPTs to communities.

4.2.5 Budget

Ensuring smooth and efficient logistics for HPTs is critical to the success of our health initiatives. A clear budget outlines the necessary expenses to cover the logistics involved in the receipt, clearance, and transportation of NTD HPTs. These logistics are vital for maintaining the supply chain and ensuring the timely delivery of essential health products to the designated locations.

1. Customs clearance fees that covers the process of clearing shipments from customs,
2. Transportation and fees associated with freight (either through the WHO or government medical supply systems) or other aspects linked with receipt of NTD HPTs in place

4.2.5(a) Customs Clearance

Customs clearance refers to the "accomplishment of the customs formalities necessary to allow goods to enter home use, to be exported or to be placed under another customs procedure." Here, clearance for home use refers to the "customs procedure, which provides that imported goods enter into free circulation in the customs territory upon the payment of any import duties and taxes chargeable and the accomplishment of all the necessary customs formalities."

Customs clearance and delivery are the final steps in the receipt of NTD HPTs:

- Customs clearance deals with releasing NTD HPTs at the PoE or border to the recipient.
- Delivery involves moving NTD HPTs from the port (after release) to Central medical stores.

The process for preparing and executing tasks of customs clearance and delivery of NTD HPTs involves three key stages:

- Before HPT shipment arrival.
- Upon arrival of cargo at the port or border.
- Upon delivery to Central medical stores.

4.2.5(b) Key Considerations

a) Factoring in the time required for clearances can minimize or avert avoidable costs and delays for both the donor and the country.
b) Ensure documents required for clearances are in place during delivery of NTD HPTs via multiple shipments over a long period of time to mitigate the chances of delays in customs clearance.
c) Ensures timely delivery of stock to the KEMSA for onward distribution.
d) This involves:

- In-country cleared document(s) for customs clearance.
- Personnel to offload shipments at the central medical store

4.3 Before Shipment Arrival

This is before the HPT shipment arrives at the port/border or as soon as the donor initiates the shipment (weeks to months ahead of arrival, depending on shipment mode).
WHO should initiate the process of obtaining the required documentation upon receipt of all the documents necessary for the shipment from the HPT donor and should identify and gather required documents, signatures, and approvals in the country.

WHO also provides the required country documentation to the donor or the WHO's freight forwarder for the clearance of the NTD HPT. Documents, permits, tax exemptions, and import permits may be required from different channels, depending on the contents and value of the cargo. It is important to know the appropriate channel(s) ahead of time to avoid clearance delays while pursuing approvals.

The documents required may include:

- Tax exemption/waiver.
- Import permits.
- HPT distribution plan.
- Marketing authorization.
- Approval from the National Treasury & Economic Planning.
- MOH stamped copies of documents such as invoices, packing list, and shipping slip, certificate of origin, certificate of donation or certificate of analysis and contact list.

Forwarders may also approach customs services to confirm required documentation and inquire about additional requirements or process changes in Kenya.

If necessary, the forwarder informs WHO, in time for obtaining the additional documents or meeting new requirements to avoid clearance delays..

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d) This involves:

- In-country cleared document(s) for customs clearance.
- Personnel to offload shipments at the central medical stores.

Table 5: Stakeholders Involved

Responsible organization for importation	Product	Incoterm	Document required	Organization responsible for customs clearance
Trachoma program	Azithromycin	CIP	• Import declaration form. • Pharmacy and Poisons Board (PPB) import permit • Letter of payment of taxes sent to KEMSA (Approved by the PS) • BOL/AWB- Bill of lading/ airway bill • Commercial Invoice • Customs duty waiver • Indicate shipment quantity. • Warehouse space • Distribution plan	MOH through KEMSA
STH	Mebendazole	CIF	• BOL/AWB- Bill of lading/ airway bill • Invoice with at least a value of a Minimum of 10 USD with the HS codes • Packing List with the expiry dates and batch numbers of the shipment-where applicable • Donation Certificate (COD)-Certificate of Donation • COO-Certificate of Origin • COA-Certificate of Analysis-where applicable • COC- Certificate of conformity-where applicable • For the kits-complete table showing the contents • Tax exemption waiver-where applicable • The National Treasury & Economic Planning waivers (Pro 1b) • Ministry of Health stamp of approval of shipping documents • Letter to the central medical • stores from VBNTDU	WHO
SCH	Praziquantel			
Leishmaniasis program	Paramomycin, Ambisome, SSG, DAT, rk39			
Lymphatic Filariasis	Ivermectin, Diethylcarbamazine, and Albendazole			
Human African Trypanosomiasis (HAT)	Suramin and Melarsopol and Diagnostic kit			

4.4 Upon Arrival of Shipment

This is upon arrival and within three days after arrival – (Customs clearance is carried out).

The forwarder informs the relevant parties (donor/ Head, VBNTDU) of the shipment's arrival and provides a forecast timetable for customs clearance and delivery to KEMSA by email or telephone.

The donor/ Head, VBNTDU, provides the above information to the NTD programs officer and NTD Program Pharmacist, as designated in the country.

The forwarder ensures all required documents are submitted with appropriate signatures/seals, as the customs regulations require.

The forwarder communicates the arrival time to the central medical stores to the donor/ Head, VBNTDU, and Program pharmacist or designate.

4.5 Delivery

Before delivery to central medical stores

a) The program pharmacist or designee provides clear instructions for the delivery of the NTD HPTs to the central medical stores.
b) Forwarder clears the cargo and informs the donor/ Head, VBNTDU, and program pharmacist of the planned arrival time at the central medical stores.
c) The program pharmacist or designee provides the forwarder with details about Central Medical Stores, including the exact route and instructions on the offloading process.

During delivery to KEMSA or the appropriate warehouse:

a) Forwarder transports the cargo to Central medical stores in its original shipping container/package.
b) The program Pharmacist or designee coordinates offloading into central medical stores.
c) Program Pharmacist or designee checks to verify that the seal on the container/package is not broken. If the seal is broken:

    - Have the driver write down the broken seal on the delivery voucher.
    - When possible, take a picture of the broken seal so that there is a time stamp and to create visual proof (A broken seal may indicate that some HPTs have been removed from the cargo)

After delivery is received and confirmed

a) The program pharmacist or designee conducts a physical inventory of all the NTD HPTs received and confirms that all pallets and boxes are present and in good condition, in accordance with the shipping documents.
b) If HPTs are not in good condition, or if medications are missing, the Program pharmacist or designee completes the following:

i. If pallets are damaged, open all damaged boxes on the pallet and verify that HPTs are in good condition. Good condition means that the bottles are not damaged, and their seals are not broken.
    - Report on the delivery note any unusable HPTs due to damage and keep a copy of the record.
    - If possible, take pictures of all damaged goods so that there is a time stamp and visual proof of the damage.

ii. If pallets are missing, have the driver note any missing pallets and the batch or lot number of HPT(s) associated with that pallet on the Proof of Delivery (PoD) form,
    - The shipping slip (packing list) and invoice contain the lot or batch number.
    - If possible, take pictures of each received pallet to help confirm the missing pallet(s).
    - Report the damaged or missing HPTs to the Forwarder and request that they file a formal report.

c) The Head, VBNTDU, is responsible for requesting replacement HPTs per the requirements of the NTD HPT Application.
d) The program pharmacist, through the Head of VBNTDU, prepares and submits official reports to the supplier/Donor within ten (10) days.
e) The program Pharmacist or designee signs the delivery order from the forwarder.

f) The copy of the PoD form provided to the program pharmacist must be clear and legible. A legible copy will allow the country to receive replacements for missing or damaged HPT.
g) Forwarder provides the PoD to the donor and WHO NTD Programme Coordinator.

4.6 Tracking Shipments

NTDeliver (https://www.ntdeliver.com/) is a supply chain information system that centralizes and coordinates information from a variety of sources to better monitor and evaluate the NTD supply chain at the global level. It centralizes data that are currently spread across organizations in numerous spreadsheets, emails, and databases. The system allows WHO, HPT donors, shipping partners, and local key stakeholders like MOH and implementing partners to work collaboratively in a single system. It uses KPIs to identify why purchase orders were running late, providing the information needed to diagnose problems and implement solutions. It generates standard reports for use at various levels of the supply chain.

Table 6 : Responsible Persons

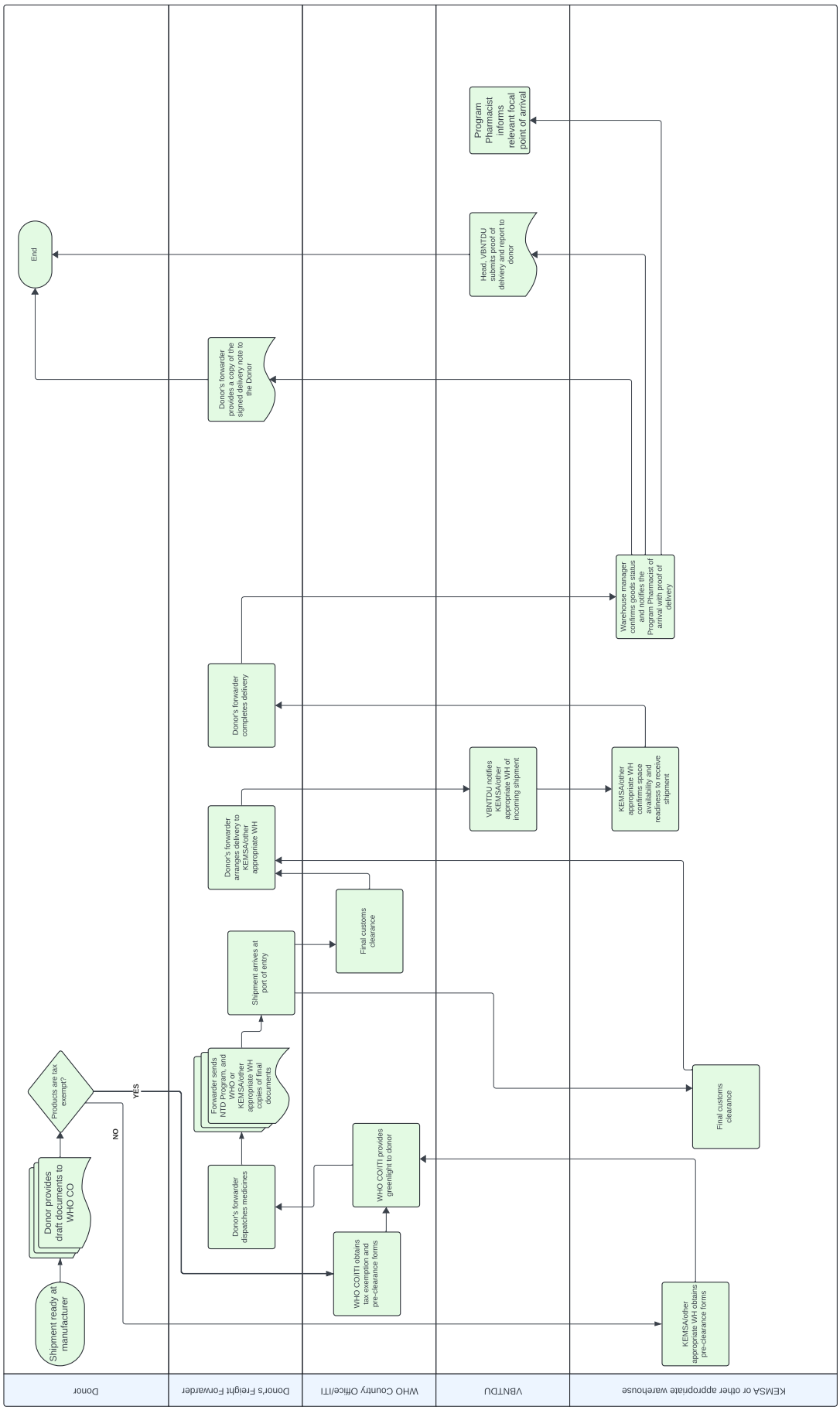
Name of Officer	Role and Responsibility
Head, VBNTDU	Receives and approves reports
Warehouse Manager	Verifies and documents HPTs received
WHO NTD Programme Coordinator	Informs of the shipment status
Forwarder	Provides Proof of Delivery to donor
Program pharmacist	Coordinates with central medical stores, WHO program coordinator and disease focal points

Reference Document

Standard operating procedures for supply chain management of health products for neglected tropical diseases amenable to preventive chemotherapy. Geneva: World Health Organization; 2022.

Flow Chart Diagrams

Shipping and Customs



CHAPTER 5: PROCUREMENT BY IMPLEMENTATION PARTNERS

5.1 Introduction

Procurement is the process of locating and agreeing to terms and purchasing goods, services, or other works from an external source, often with the use of a tendering or competitive bidding process. When a government agency buys goods or services through this practice, it is referred to as government procurement or public procurement.[12]

Procurement for VBNTDU can be done by implementing partners mandated to purchase/procure items on behalf of the unit.

Some activities that necessitate the procurement of goods and services include, but are not limited to:

- Mass Drug Administration (MDA) Campaigns: These large-scale health interventions require substantial quantities of medications and related supplies to treat or prevent NTDs across wide populations.
- Surveillance Studies: These studies are essential for monitoring and evaluating the prevalence and impact of NTDs. They require specialized equipment, lab consumables, and diagnostic tools.
- Advocacy, Communication, and Social Mobilization (ACSM): Effective communication strategies and community engagement are vital for the success of NTD programs. This includes procuring Information, Education, and Communication (IEC) materials to educate and inform the public.

The VBNTD program procures goods and services as listed in Annex 1, broadly classified into;

- Information, Education, and Communication (IEC) Materials: These tools are crucial for raising awareness and educating the public about NTDs and the importance of prevention and treatment.
- Laboratory Consumables: Items needed for conducting tests and analyses in the lab, which are essential for accurate diagnosis and research.
- Equipment: Medical and laboratory equipment is necessary for various health interventions, ensuring that healthcare providers have the tools to deliver effective care.
- Diagnostics: Tools and kits used for detecting NTDs are fundamental in promptly identifying and treating these diseases.

The procurement process is intended to ensure that the VBNTDU receives goods and services or works at the best possible price when aspects such as quality, quantity, time, and location are compared. This process is intended to promote fair and open competition for bidders while minimizing risks such as exposure to fraud and collusion while offering value for money.

5.2 Standards and Procedures

5.2.1 Procurement Planning

Procurement planning is the process of identifying and consolidating requirements and determining the timeframes for their procurement/acquisition with the aim of having them as and when they are required. VBNTDU shall endeavor to develop a procurement plan for each calendar year. This should be done during the last quarter of the preceding year.

5.2.2 Request Creation

VBNTDU will share its request with implementing partners at least 3 months before the activity/campaign.

For laboratory HPTs to be used in surveys, the HPTs request should be sent at least 1 year to the activity to allow sourcing as some of the items are sourced externally (imported) and have extended lead times. The request will include detailed specifications i.e., a list of items, quantity, quality, timelines, specific brands, where applicable, and the proposed prices as allowable by the budget. Samples of the HPTs may be provided for reference to the partners to ensure consistency in the quality of work and HPTs.

The following documents will be required for IEC materials: the IEC materials quantification list, tender committee approved minutes (signed by all members), Local Purchase Order (LPO), and MOH S11.[13]

[12] Public Procurement and Asset Disposal Regulations https://www.treasury.go.ke/wp-content/uploads/2020/11/Public-Procurement-and-Asset-Disposal-Regulations-2020.pdf
[13] S11 form for Counter Requisition and Issue Voucher https://hivpreventioncoalition.unaids.org/wp-content/uploads/2020/02/Form-S11.pdf

5.2.3 Sourcing/ Bid Solicitation

The implementing partners are fully responsible for the Request for Quotations (RFQ) process and should ensure that the Unit gets value for money and cost savings, ensuring the program's effectiveness and efficiency.

VBNTDU may recommend or propose suppliers they have worked with previously for partners to consider in the RFQ process. However, it will be solely at the partners' discretion whether to work with these suppliers.

To make the evaluation process as seamless and short as possible, the RFQs must be submitted in sealed and well-labelled envelopes, and a sample must be provided while quoting.

The RFQ window should be time bound to avoid delays in the actual delivery of the HPTs. Time is a key factor in this part of the process. This process should take place at least 3 months to the activity/campaign for IEC materials and at least 1 year to the activity for laboratory HPTs.

5.2.4 Bid Analysis

Upon receipt of all the RFQs, the partner should hold a tender opening committee meeting to analyze them. At least three representatives from VBNTDU should form the tender opening committee. This must include the program officer for whose activity the HPTs are being purchased or their appointee and any other two program representatives with technical knowledge of the HPTs being purchased.

The formed committee should analyze the RFQs by comparing both the technical aspects (quality) and the cost aspect. Its intent is to ensure that the program receives goods, services, or works at the best possible price when aspects such as quality, quantity, time, and location are compared.

Following analysis of the RFQs, the committee will decide on the best bidder to be awarded the job. The proceedings of this meeting should be captured in minutes, signed, printed, and filed together with all the bids received. This process should take place at least 3 months to the activity / campaign for IEC materials and at least 1 year to the activity for laboratory HPTs.

5.2.5 Award

The selected bidder from the analysis is awarded with a purchase order (PO) to supply the materials and/or HPTs. The PO should clearly state the quantity, detailed specifications, and brand, where applicable, delivery timeline, place of delivery (including working hours and days where applicable), packaging instructions, and terms and conditions of supply and delivery.

The award should be done at least 2 months to the campaign for locally sourced items with short lead times (specifically IEC materials and HPTs) and within adequate and sufficient timeline for other HPTs with longer lead times e.g., 1 year for laboratory HPTs.

5.2.6 Delivery

Before delivery, a pre-delivery sample of goods to be delivered is provided for checking of compliance with the specifications. The delivery of the HPTs should be done at least 8 weeks to the campaign to the central stores for verification, inspection, and receipt. A delivery note should be issued by the supplier and verified by an MOH official.

The HPTs should meet the required quality as per sample provided, be packaged in the right quantities, and well labeled as per the packaging instruction given on award. The total quantities received must match the quantities on the award PO.

Any variances noted between the actual number delivered versus the number indicated on the delivery note and PO must be noted, and the relevant persons informed. The supplier must endeavor to rectify any shortcomings within the shortest time possible to ensure that there are no delays which disrupt the onward distribution of the HPTs to the respective counties.

After satisfying the above, the goods shall be received at the storage facility.

5.2.7 Distribution

Distribution of HPTs from the National level to the Subnational level should be done together with the HPTs being distributed and should follow the distribution process in place for the HPTs.

For surveys and ACSM activities, the distribution will follow the set distribution process from national to county, from county to sub-county and from sub-county to the peripheral facilities or directly to a health facility of choice as the program may deem fit. This should be done at least 7 weeks to the actual campaign / activity to allow adequate time for distribution within the counties and sub-counties.

Any excess, extras or buffer stock should be held at a central point for easy redistribution to areas where they may experience shortages or areas where they may need top ups.

5.2.8 Actual Campaign

During the actual campaigns / activities, there might be redistribution of materials and / or HPTs on a need basis. This may occur within the first 2 days of the campaign or activity or throughout the campaign / activity period.

After the campaign, any extra HPTs and any HPTs that can be reused e.g., dosing poles, should be brought back to a central warehouse for storage and future use.

5.2.9 Post Campaign Review

After the campaign, the tender committee/implementing partner should hold a meeting with the stakeholders involved in the campaign/activity to have a review of the HPTs supplied.

This review should assess the overall performance in terms of quality, quantity, cost, responsiveness, and any other aspects of performance that may be key to that specific campaign.

The outcomes of the review process will inform future purchases for campaigns. This review should happen at least two weeks after the campaign / activity.

Table 7: Responsible Persons

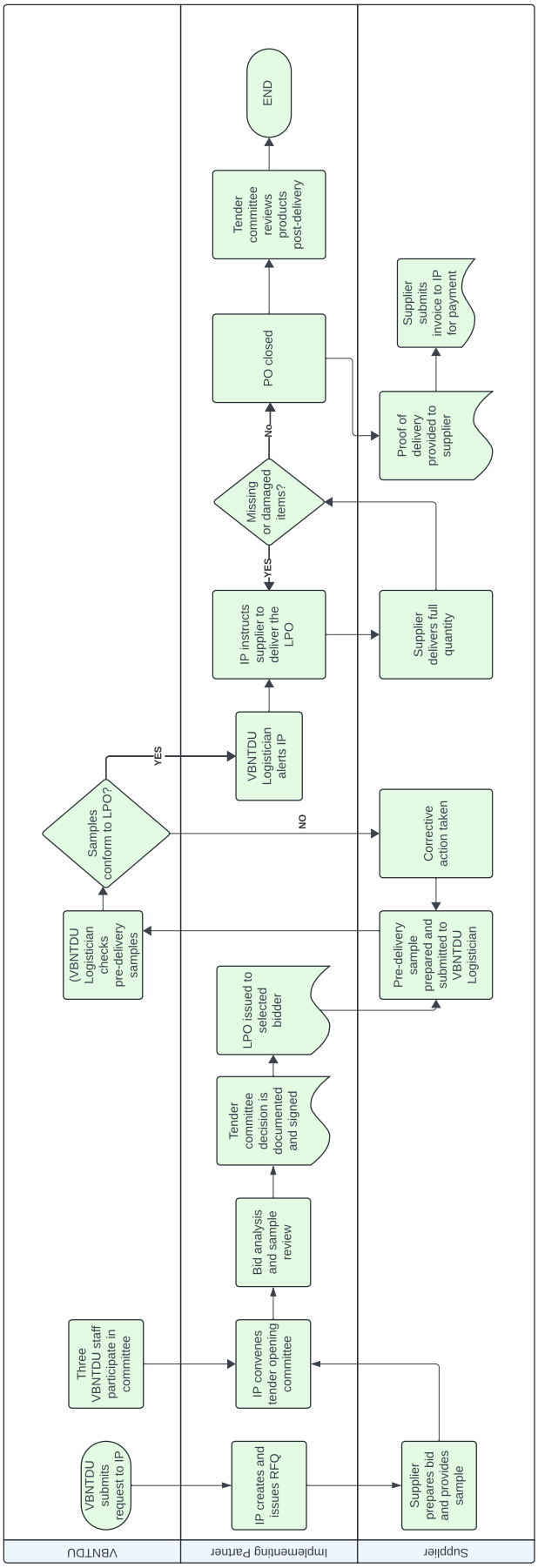
Name of Officer	Role and Responsibility
Head, VBNTDU	Validates requests for the goods and services on behalf of the program
ACSM manager	Pre-testing of IEC materials and participates in the tender committee
Focal points of each targeted disease	Makes requests for the goods and services on behalf of the program.
M&E focal person	Provides updated program data and supply chain tools.
Logistician	Ensures efficient quantification, procurement and distribution of IEC materials, data tools, lab consumables & equipment.
Program Pharmacist	Support

Reference Documents

1. The Public Procurement and Asset Disposal Act, No. 33 of 2015 (Revised Edition 2022)
1. ACSM Strategy 2023-2027

Flow Chart Diagram

Procurement



CHAPTER 6: INVENTORY MANAGEMENT

6.1 Introduction

Inventory management is a critical process in the healthcare supply chain, encompassing the ordering, receiving, storing, issuing, and dispensing of HPTs. Effective inventory management ensures that HPTs are available when and where they are needed, in the right quantities, and in optimal condition. This process is essential for maintaining the integrity and efficacy of healthcare services, minimizing costs, and optimizing resource allocation. By implementing robust inventory management practices, healthcare systems can ensure that accurate information on stock levels is readily available across all locations, facilitating efficient distribution and minimizing the risk of stockouts.

Proper inventory management is vital in ensuring accountability and transparency, particularly for procured or donated HPTs. It involves meticulous record-keeping to track inventory levels, usage, and movements, thereby reducing the potential for losses, damage, expiry, and misuse of products.

Furthermore, by balancing the costs of carrying and ordering stock, inventory management helps minimize the total cost of inventory, ensuring that resources are used effectively. This comprehensive approach supports the health system's operational efficiency and builds donor confidence by demonstrating responsible and efficient use of contributions.

6.2 Standards and Procedures

The warehousing/storage facility should comply with good warehousing practices.
The levels of warehousing include:

a) Central/National (KEMSA or Private Facility)
b) County stores
c) Sub-county stores
d) Peripheral health facility stores

6.2a Warehousing/ Storage Requirements

The warehouse should have the following requirements in place:

a) Adequate storage space and monitoring procedures.
b) Adequate number of well-trained human resources/personnel.
c) Adequate security procedures.
d) Adequate storage procedures and systems.
e) Adequate firefighting equipment and protocols.
f) Availability of appropriate systems and job aids.
g) Adequate waste/damage prevention and management protocols.
h) Provision of first aid facilities and other worker safety procedures and protocols.
i) Suitable Storage conditions:

- Provision of pallets and shelves
- Provision of temperature and humidity monitoring equipment (Thermohydrometers)
- Adequate room is needed to allow for the segregation of HPTs by type.
- Cold room/ cold chain should not be filled beyond 75% capacity

j) Storage operation protocols.

6.2b Warehousing Procedures

a) All HPTs received should be stored in good condition.
b) The physical stock should match the stock balances documented.
c) Monthly inventory reports should be shared with the program pharmacist on available balance, batch numbers and their expiry dates.
d) Regular inspection of the storage conditions should be carried out. This includes:

- cold chain is in place and not filled beyond 75% capacity, if needed.
- power maintenance (power backup systems)
- adequate and appropriate storage.
- a daily temperature and humidity log is maintained.

e) There should be designated areas for commodity segregation during warehousing and transport as assigned.
f) Ensure NTD HPTs are kept in a cool, dry place, away from direct light or following any other prescribed/special storage conditions.
g) Fill in stock control forms.
h) Conduct daily monitoring to maintain temperature control, security, and proper stacking of boxes.
i) Log monitoring results on appropriate forms such as bin cards and batch transactional records

6.2c Receipt Procedure

- Ensure there is adequate storage once communication on a expected delivery date is done
- Receive shipment(s) and relevant accompanying documentation.
- Supervise offloading of consignments for verification.
- Verify and identify the quantity of each product received against the documentation.
- Physically count sealed/complete cartons.
- Physically count the number of bottles/ packages in open cartons.
- Document any discrepancies

6.2d Documentation Procedure for NTD HPTS Received

- Once received, the delivery note and packing list should be signed and stamped with the authorized stamp and a copy returned to the clearing agent/ accompanying MoH officer.
- Notify the supplier of the delivery and any discrepancies.
- Update records with quantities received using appropriate records (e.g., bin cards, inventory logs,).
- Utilize electronic records or systems for receipt where viable or available.
- Handling discrepancies:
- Contact the supplier for assistance/verification if any documentation is incomplete or missing.
- If documentation does not match the quantities received, accept the delivery, record any shortages or excesses on the delivery note and submit to the supplier.

6.2e Storage of the Consignment

- Sort the consignment according to KEMSA or the appropriate warehouse SOP by batch and expiration date.
- Move HPTs with the nearest expiry date to the front of the storage rack.
- For open tins (leftover from past MDA), reorganize to ensure the oldest stock or stock with the nearest expiry date is at the front.
- Clearly mark the date received from reverse cascade and expiry date with large, dark numbers on the front of each open tin, ensuring all markings face forward

6.2f Stock Taking

Stock taking is the physical verification of the quantities and condition of HPTs held in a warehouse. It requires the use of bin cards or stock control cards.

- A date should be selected for stock taking.Prefereably before the 5th of every month
- Compare the quantities on hand with the quantities entered in stock-keeping records.[14]
- During the count, verify the HPT description, quantity available, batch number, and expiry date.
- Central medical stores should conduct a physical inventory count at least quarterly.
- Peripheral stores should conduct a physical inventory count at least once every month or after MDA
- Follow the KEMSA Warehouse SOP or the SOP of another appropriate warehouse for the stock taking procedure.

[14] John Snow, Inc. 2020. The Supply Chain Manager's Handbook, A Practical Guide to the Management of Health Commodities. Arlington, Va.: John Snow, Inc.

Table 8: Responsible Persons

Name of Officer	Role and Responsibility
NTD Program Pharmacist	• Liaises with Customs and KEMSA/ appropriate warehouse on arrival and receipt of consignment from customs. • Notifies the Head, VBNTDU and disease focal points of stock quantities at national and sub national level • Coordinates Inventory Management and Quality Control activities at national level
County pharmacists	Custodians of NTD Inventory at county level
Program disease focal points	• Inventory management at subcounty level • Designate health facilities at ward level. • Updates NTD HPT on time

Reference Documents

1. KEMSA Standard Operating Procedures for HPT receipts, physical and electronic put-away, March 2023.
2. KEMSA Standard Operating Procedures Warehouse Department. March 2023.[15]
1. Snakebite envenoming: a strategy for prevention and control. Geneva: World Health Organization; 2019. https://iris.who.int/bitstream/handle/10665/324838/9789241515641-eng.pdf?sequence=1

[15] KEMSA Standard Operating Procedures for Warehouse Department. KEMSA/SOP/WH/1202. March 2023

CHAPTER 7: DISTRIBUTION (LAST MILE)

7.1 Introduction

Last mile distribution is the act of getting Health Products and Technologies from central medical stores to peripheral stores. It involves planning, clear communication with peripheral stores, actual dispatch, safe transport, timely delivery, and receipt of the HPTs service level agreements with secondary transporters.

7.2 Standards and Procedures

The NTD programme pharmacist through the Head, VBNTDU will issue a distribution plan as per the supply plan to KEMSA/appropriate stores.

The distribution plan will include specific service delivery points (SDPs), the HPTs, quantities as per the specific SDPs, and expected time of delivery.

The Head, VBNTDU will specify the authority to prioritize security, distribution and the signatory authority to receive. VBNTDU in collaboration with partners, should ensure funding availability for transporting vehicles, drivers, off loaders, per diems for MOH officers accompanying the HPTs and security for the HPTs during transport.

Documentation

Electronic stock-keeping unit (SKU) tracking is valuable for supply chain management from the central stores to health facility levels i.e., service delivery points (SDPs); however, paper-based systems are adequate if managed appropriately with detailed processes and signed forms returned to their origin for filing (closing the loop).

The program pharmacist should:

- Ensure there are appropriate forms to document the transport process.
- Ensure systems are in place to monitor stocks at every step—correctly filled out documents should accompany the delivery at every stage.
- Prepare transport arrangements to the counties.
- Share the distribution list to the receiving peripheral stores or SDPs before dispatch of the HPTs.
- Prepare delivery notes and packing list (categorized by batch number and expiry date) for receipt at the County Medical Store for total tins for each sub county.

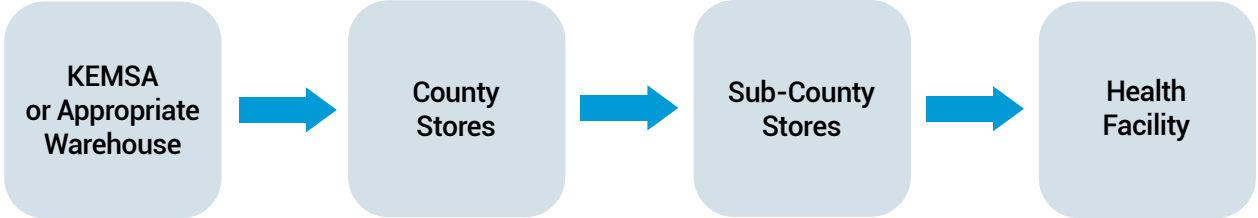
Environmental Conditions

HPTs are often transported in unpredictable weather (e.g., warm/dry season vs. wet season) or on bad roads and can be easily damaged, so it is essential to ensure that the transport mechanisms used are adequate to protect stocks from damage or deterioration and to ensure that the HPTs arrive intact and undamaged upon arrival.

To ensure commodity safety, ensure the following:

- Fill voids in cartons with packing material.
- Load vehicles carefully and systematically (First In, Last Out).
- Secure vehicle doors.
- Protect supplies from sun or rain.
- Start early in the day and drive with care, especially on hazardous roads.
- Ensure safe and timely delivery.
- Prevent breakages.
- Save time while offloading.
- Prevent physical damage.
- Prevent or guard against losses or thefts.
- Minimize deterioration of pharmaceuticals during transit.
- Avoid nighttime driving.
- Prevent accidents.

Transportation Flow Diagram



7.3 Dispatch & Distribution Procedures at National Level

The program pharmacist should:

- Regularly check when HPTs are due at subnational level and check that this is accurately reflected in the HPT distribution schedule. Have subnational pharmacists and NTD coordinators' contact information on hand.
- Confirm the subnational team is aware of the planned delivery and that space is available.
- Identify calendar restrictions for delivery (e.g., deliveries not accepted on weekends in health facilities).
- Create a quantity and distribution schedule to ensure safe, efficient transport and send it to the subnational team beforehand.
- Determine the total quantities to be delivered and prepare delivery notes.
- Quantification for requirements on quantity allocation should include approximate travel times for each subnational delivery.
- Ensure the MOH officer accompanying HPTs returns signed delivery notes to the program pharmacist for filing.
- Ensure transport service providers are licensed by PPB and meet acceptable standards for transfer of VBNTD HPTs (e.g., working condition, appropriate cover from weather, theft, or other risks).
- Ensure that transport is arranged for the necessary date two weeks prior.
- Notify the county team on the dates transport is being done in advance.
- Liaise with county pharmacist to ensure arrival.

1. Reassemble Stock

- Organize stock based on quantity needs identified in the distribution schedule.
- Fill voids in cartons with packing material to prevent damage.
- Label each carton by destination (county and sub-county names) for secondary verification.
- Load the vehicle in First in Last Out
- Prioritize the oldest and previously opened stock.
- Document and remove any damaged or expired stock.

2. Preparation for Delivery

- Prepare delivery notes or S11 forms for each county store or drop-off zone.
- Create a distribution list with quantities for each destination.
- Use pallets to protect cartons from physical damage.
- Secure vehicle doors against theft and weather, and confirm access controls.

3. Routing and Security

- Plan routes to allow sufficient time for rest and safety.
- For shipments longer than one day, secure and visually inspect the shipment at every overnight stop and in the morning, documenting each inspection.

4. Arrival and Offloading

- Upon arrival, offload according to the distribution schedule using the Last In First Out (LIFO) method.
- The driver should present the delivery note to the recipient at each county store, including the recipient's title, name, signature, and date (dd/mm/yyyy).
- The county pharmacist should inspect and count both sealed and unsealed cartons and sign the delivery notes.
- Document and remove any damaged or expired stock.

5. Record Keeping

- The MOH officer or designee should file a copy of the signed receiving form with VBNTD as a record of delivery, including the date (dd/mm/yyyy).

7.4 Receipt Procedure at the County Level

County pharmacist should:

- Ensure delivery and receipt of HPTs at SDPs is scheduled to happen on working days. However, in unforeseen circumstances there should be concurrence between the receiving and delivering officer.
- Ensure there is sufficient storage space at subcounty level and confirm arrival date from the Central stores.
- Ensure the HPTs are stored appropriately in a pharmaceutical store.
- Accurately allocate appropriate HPTs and quantities to distribution points.
- Keep buffer stock for MDA

7.5 Receipt Procedure at Subcounty and Peripheral Health Facilities

Subcounty Pharmacist should:

- Ensure sufficient space and confirm arrival date to ensure access to storage,
- Ensure appropriate space and pallets are available and that the necessary tools and registers/stock cards are on hand.
- Have the contact information for the County NTD coordinator and County pharmacist on hand.
- Liaise with the NTD program and regularly check the delivery status..
- Ensure staff offload the truck(s) and store stock is available.
- Receive and document shipment(s).
- Conduct visual inspection of sealed/complete cartons received.
- Physically count sealed/complete cartons.
- Physically count the number of bottles in the open cartons.
- Verify and identify the quantity of each product received against transport documentation.
- If the documentation does not match quantities received, accept delivery, record the shortage or excess received on the delivery note, and send a scanned copy to the NTD Program Pharmacist as applicable.
- Sign and stamp the delivery note for total cartons from each destination.
- Identify who will have access to the stock in each designated health facility.

Stack New Inventory

- Sort according to HPT type, then batch and expiry date, moving first to expire bottles already in stock to the front of the storage rack.
- Ensure all markings with expiry dates face forward.
- Ensure (as much as possible) that HPTs are kept in a cool, dry place, away from direct sunlight and at an appropriate height for access and avoiding damage.
- Fill in stock and bin cards as applicable.
- Ensure that the open bottles are issued first during the next round of MDA.
- If HPTs will remain at central storage until the next MDA, send a final tally with expiry dates to NTD program pharmacist for use in preparing drug request forms.
- If HPTs will be redistributed or destroyed, notify the NTD Program pharmacist, with details of HPTs and quantities for each health facility or subcounty.
- If an SDP runs out of HPTs, it is encouraged for SDPs to first seek redistribution within the sub county before requesting additional HPTs.

Storage conditions maintenance & monitoring

- Daily monitoring of storage temperature and humidity, security and proper storage of stacked boxes.
- Log monitoring results on an appropriate form.

7.6 Reverse Logistics

Reverse logistics is the process of moving HPTs from their point of deployment (health facility, community) after an intervention or campaign back to subcounty stores for either storage, reuse in the next MDA or disposal. Batch tracking of HPTs should be done as per the WHO guidelines.9 This will ensure integrity of the NTD HPT supply chain in the country, both donated and procured HPTs and the country does not waste resources by procuring or requesting too much or too little from MDA needs, and from the WHO, procurement agencies or other providers. It prevents theft and commercialization of NTD HPTs.

The expected results of the reverse logistics are:

- No diversion of NTD HPTs from designated repositories before and after the MDA.
- No expired HPTs.
- No wastage of HPTs.
- NTD HPTs are appropriately stored for use in the next round of MDA.
- Unusable NTD HPTs are directed for disposal according to the country's policy.

Immediately after MDA

- Collection should be done at a designated health facility, typically at the subcounty level.
- Plan to complete this task immediately after the MDA.
- Collect all containers post MDA.
- Count open bottles/containers separately from unopened (sealed) bottles/containers.
- Provide a count of total HPT stock balance or HPT return/transfer forms to the County Pharmacist along with the leftover HPTs.
- The subcounty store or health facility contact takes temporary custody of returned HPTs and keeps records of quantities received, including batch numbers.
- If the facility is a formal storage location where MDA HPTs will remain, update the stock ledger and prepare a stock status report of available quantities, expiry dates, and waste for the NTD program monthly using the Tablet Accountability Form (Annex 1).
- Deface labels of empty containers (using a dark marker or lighter) for destruction per country waste management policy.
- Clearly label and package damaged, expired, or otherwise unusable HPTs separately for disposal per country waste management policy..

Subcounty Pharmacist Responsibilities:

- Ensure collection of HPTs from all HPT distributors to subcounty stores if HPTs are to be moved to higher-level storage facilities.
- Plan to complete this task within three days after MDA.
- Make note of any discrepancies and/or missing stock for follow-up and send a report to the County Pharmacist or County NTD Coordinator.
- Take custody of returned HPTs and keep records of quantities received from each HPT distributor in subcounty tablet accountability forms and NTDeliver.
- Verify numbers of damaged, expired HPTs against reports and separate those HPTs for destruction.
- Dispose of any reconstituted oral solutions of HPTs immediately.
- Follow the pharmaceutical company's policies regarding the future use of opened bottles. Generally, close the tins tightly for reuse in next MDA except DEC

County Pharmacist Responsibilities:

- Keep records of quantities in all subcounties using the county tablet accountability forms.
- Communicate to the program pharmacist upon completion of the reverse cascade with quantities cascaded back.

NTD program pharmacist Responsibilities:

- should ensure all leftover HPTs post-MDA should be returned to central medical stores for the next MDA.
- Plan to complete this task within 7 days post- MDA.
- Confirm receipt of returned HPTs from all sub-counties.
- Update the stock ledger, including batch numbers and prepare the stock status report with subnational inventory.
- For Re-distribution of Leishmaniasis HPTs;

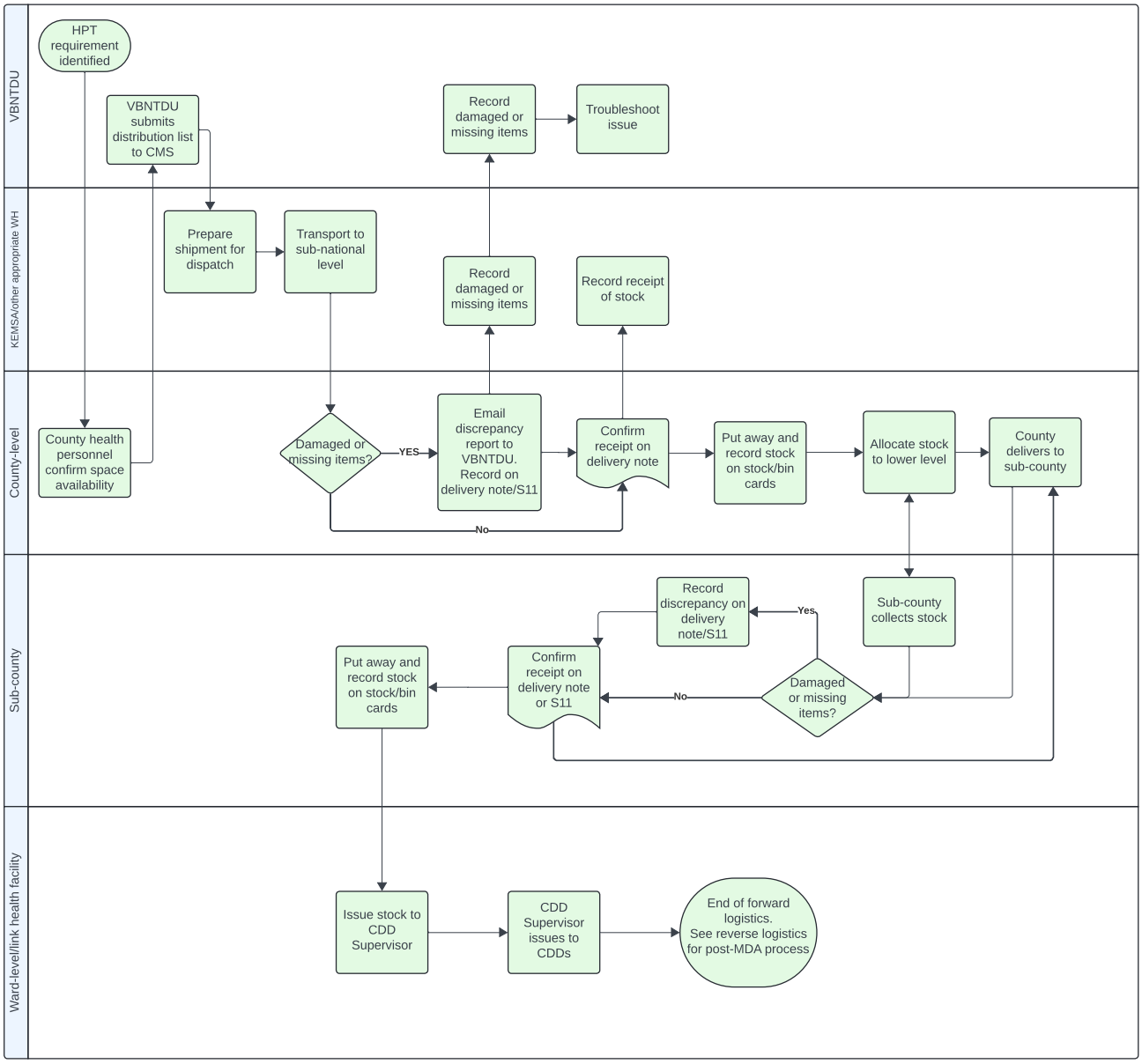
    - ◊ The facility in charge / pharmacist should ensure monthly stock reporting of the VL stock HPTs on the available reporting systems (KHIS, WHO Extranet).
    - ◊ The county pharmacist should note on the stock status taking note of short expiries (anything with 6 months to expiry) and surplus stock and redistribute within the county. In cases where redistribution is not possible within the county, S/he will then notify the National Leishmaniasis focal point to advice on possible redistribution to other counties or send back to the national program for redistribution.

Responsible Persons

Name of Officer	Role and Responsibility
Program pharmacist	Overall coordination for distribution from central stores to last mile and reverse logistics
KEMSA	Dispatch to designated f=health facilities
County Pharmacist	Overall responsibility for distribution within the county and reverse logistics
Subcounty pharmacist	Distribution and reverse logistics within the subcounty and reverse logistics

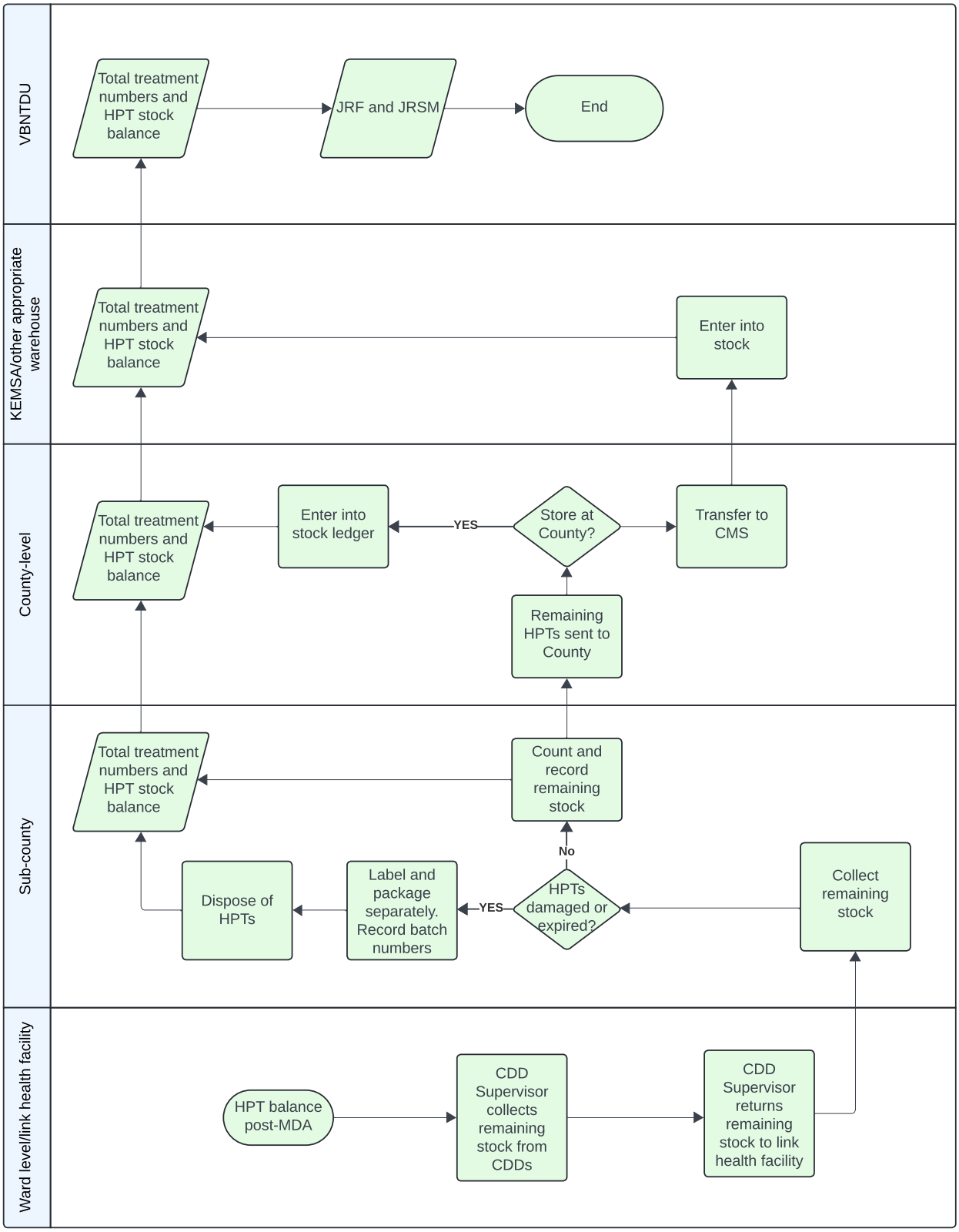
Flow Chart Diagram

Forward Logistics



Flow Chart Diagram

Reverse Logistics



CHAPTER 8: EXPIRIES AND WASTE MANAGEMENT

8.1 Introduction

The safe management of pharmaceutical and laboratory waste is vital in protection of public health and the environment. Pharmaceutical waste refers to HPTs that can no longer be used due to several reasons, e.g., they are expired, contaminated, or damaged and therefore not fit for human consumption. Laboratory wastes include blood and body fluids, sharps, pathological and anatomical waste, and other possibly infectious and potential reservoirs for pathogenic microorganisms. Healthcare generated waste includes general waste and equipment effluent. In VBNTDU, laboratory waste is found during epidemiological surveys used to determine endemicity or during routine surveys at the hospital.

In the supply chain cycle for NTD HPTs, some may expire, be damaged or contaminated during transportation, storage, and/ or handling, thereby becoming unsafe for use. It is prudent for a waste management plan to be in place to guide the documentation, collection, segregation, packaging, storage, transportation, and disposal of HPT waste.

The provisions of the Public Procurement and Asset Disposal Act (PPADA)[16]need to be considered in all protocols and at all levels during the disposal of HPT waste whether infectious or not.

8.2 Purpose

This chapter articulates the most appropriate methods and practices for safe management of NTD HPT waste. The purpose of proper waste management includes:

a) Prevention of potential accidents within health facilities and/or the community.
b) Ensure minimal wastage through efficient forecasting and supply planning.
c) Ensure safe disposal of HPT waste including infectious material.
d) Prevent the spread of infection within health facilities and/ or the community.
e) Prevent possible re-entry of expiries into the supply chain of HPTs.

8.3 Standards and Procedures

Waste Minimization

It is preferable to minimize the generation of waste than to generate the waste and manage its disposal. Any person whose activities generate waste, should follow the steps below:

a) Check the expiry date of all HPTs at the time of delivery to ensure they have acceptable shelf life.
b) Do not accept short-dated (less than 75% of shelf life / 6 months to expiry)[17] HPT from a supplier except when complete consumption is assured by the end user.
c) Implement a First In First Out (FIFO) or otherwise First Expiry First Out (FEFO) stock control system.
d) Avoid overstocking HPTs by utilizing proper forecasting and supply planning protocols.
e) Do not accept donations of HPTs you do not plan to use.
f) Dispose of waste on time to avoid stockpiling.

Damaged or expired HPTs should NOT be administered under any circumstances. This includes:

a) Tablets, injectables or POS that have expired.
b) Punctured or leaking bottles, tins, vials, or ampoules.
c) Broken, crushed, or wet tablets.
d) Hard or cakey POS that will not mix.
e) Open bottles of reconstituted POS remaining after the completion of the MDA campaign.
f) Containers without any expiry date or with a label that is illegible.

[16] The Public Procurement and Asset Disposal Act No. 33 Of 2015 (revised edition 2022)
[17] Kenya Donations Policy 2024 (draft). From Personal Communication.

Pharmaceutical Waste Segregation and Packaging

Pharmaceutical waste shall be segregated from other categories of healthcare waste. Efforts should be made to ensure that pharmaceutical waste is in its original packaging to aid identification and prevent reaction between incompatible molecules.

All pharmaceutical waste shall be securely packaged for storage or transportation in brown plastic bags or brown rigid containers15 which shall be labeled legibly in English or Kiswahili with the following information:

a) The identity of pharmaceutical waste.
b) The name, physical address, and telephone contact of the source of pharmaceutical waste.
c) Quantify the HPTs and the kits that are segregated and withdrawn from the general storage area to quarantine area.
d) The total weight and volume of the pharmaceutical waste to aid logistics planning.
e) Fill in a disposal form (F58, name of item, date of expiry, value of the expired item, reasons for expiry and counter signed by the Program Pharmacist or County/Sub County Pharmacist) and the relevant accounting officer or their designee
f) Warning or caution statements which may include any of the following as appropriate:

    i. the words **"WARNING"**, **"CAUTION"**, **"POISON"** or **"DANGER! KEEP AWAY FROM UNAUTHORIZED PERSONS"**
    ii. a pictogram of a skull and 2 crossbones

Transportation of Pharmaceutical Waste

Pharmaceutical waste shall be transported in such a way to prevent scattering, flowing, spillage or leakage. Onsite transportation of pharmaceutical waste should be separate from infectious waste.

Drivers engaged in offsite transportation of pharmaceutical waste should have appropriate training on risks and the handling of pharmaceutical waste. The training should cover the following topics:

a) Relevant local and international legal regulations on disposal.
b) Safe handling of pharmaceutical waste.
c) Pharmaceutical waste labeling and documentation.
d) Emergency and spillage procedures.

A consignment note should be prepared before offsite transport of pharmaceutical waste. This consignment note should be carried by the driver and should have the following information in case of accidents or official inspection:

a) Pharmaceutical waste source.
b) Pharmaceutical waste pick-up date.
c) Destination.
d) Driver's name.
e) Number of containers.
f) Total weight and volume of pharmaceutical waste.

On completion of a journey, the consignee shall affirm receipt of the pharmaceutical waste and the driver shall return the consignment note to the pharmaceutical waste generator.

Pharmaceutical Waste Treatment and Disposal Methods

The following are the recommended disposal methods for pharmaceutical waste:

a) Return to the original supplier.
b) Incineration at high temperatures (800 – 1450 °C).

Supervision of Disposal of Pharmaceutical Waste

All disposal of pharmaceutical waste (with the exception of returning to the donor or manufacturer) shall be done under the supervision of a PPB Inspector and at NEMA approved pharmaceutical waste disposal sites.

Application to the PPB for supervision of pharmaceutical waste disposal shall be in the prescribed form (Application for Disposal of Pharmaceutical Waste – available online: https://prims.pharmacyboardkenya.org/)[18]

The applicable fee payable to the PPB for supervision disposal and issuance of a Certificate of Safe Disposal of Pharmaceutical Waste shall be payable at the time of application for disposal of pharmaceutical waste.

A supervision disposal form shall be filled in and signed by representatives of the Pharmacy and Poisons Board and the pharmaceutical waste disposal facility.
The Certificate of Safe Disposal of Pharmaceutical Waste shall be in the prescribed format (Certificate of Safe Disposal of Pharmaceutical Waste – available online https://prims.pharmacyboardkenya.org/).

Waste Disposal Procedure

The authorized officer in charge of the HPTs store separates damaged or expired HPTs from the rest of the stock, labels them and makes the necessary adjustments to the bin/stock control cards. The staff member/warehouse manager in charge of dispensing HPTs separates and removes damaged or expired HPTs (including patient returns) from the dispensing area and makes the necessary adjustments in the daily activity register.

The staff member/warehouse manager in charge of facility stores raises an S13 or other appropriate document for receipt of the damaged or expired HPTs and endorses the document as the receiving officer.

The staff member in charge of the facility store keeps all HPTs stocks set aside for destruction and completes the Survey on Stores form (Form F.0. 58).

The Sub- County Pharmacist and Accountant endorse the F.0. 58 with their signature, official designation, and date.

The facility in charge forwards the original copy of the completed F.0. 58 through the County pharmacist to the County Chief Officer for Health or the Principal Secretary, Ministry of Health, as appropriate, through the relevant channels and awaits feedback on authorization for disposal.

All HPTs (expired, damaged or waste) that require destruction, should be disposed of according to their respective material safety data sheets, PPB regulations, WHO guidelines, or NEMA guidelines. This may include incineration or diluting.

Laboratory Waste disposal

The laboratory manager should:

a) Ensure waste does not accumulate at the point of generation and are well labeled.
b) Ensure waste bags and sharps containers are disposed off at 75% full and are well-sealed.
c) Waste bags should be sealed by tying a knot.
d) Ensure sharps containers are puncture resistant, leak proof and should be sealed.
e) The bags and containers should be replaced immediately with new ones of similar specifications.
f) Waste should be segregated by placing it in clearly marked color coded bags supported in bind of matching colors to minimize damage and retain spillage.
g) Ensure contaminated or visibly soiled waste containers are clearly labeled and cleaned once they are emptied.

[18] eb.pharmacyboardkenya.org/procedure-for-safe-management-of-pharmaceutical-waste/

Table 6: Color Coded Waste Management

Highly infectious (Anatomical)	General Non infectious Waste	Infectious Waste	Sharps Waste
			

Packaging and Transport Procedure

a) During transport and storage, always place bags upright to avoid spillage.
b) Never push or pack regulated waste with your feet or hands.
c) Store regulated waste in approved impervious red bags that display the biohazard symbol and ensure that it's properly sealed with tape.
d) Personnel protective equipment should be donned, dand disinfectant used in case of spillage.
e) Decontaminate and clean heavy-duty utility gloves between uses.
f) Records should be kept when transporting regulated waste.

Disposal Procedure

Incineration, i.e. burning waste at very high temperatures to destroy pathogens and reduce the volume, is highly recommended. It is important for the personnel doing disposal to ensure:

a) The incinerator is not overloaded.
b) The temperature gauge is functioning properly.
c) The incinerator is serviced annually and is in good condition.
d) The accumulated ash is removed frequently and buried on time.
e) That both chambers are functioning.
f) That the following items do not go through the incineration process:

   i. Aerosol cans.
   ii. Reactive chemical waste.
   iii. Waste with large contents of mercury or cadmium e.g. used batteries.
   iv. Waste containing plastics that have polyvinyl chloride e.g. blood bags, IV sets, disposable syringes.

Responsible Persons

Name of Officer	Role and Responsibility
Warehouse Manager/Program pharmacist	Overall responsibility for disposal at KEMSA/ appropriate warehouse
Laboratory Manager	Overall responsibility for disposal of laboratory wastes
County Pharmacist	Overall responsibility for disposal within the county
Sub County pharmacist	Overall responsibility for disposal within the subcounty

Reference Documents

1. Guidelines for Safe Management of Pharmaceutical Waste. Poison and Pharmacy Board, January 2022.
1. Standard Operating Procedure for Quality Assurance Department. KEMSA, March 2023.
2. Guidelines for the safe disposal of expired HPTs. Geneva: World Health Organization, May 2006.https://www.emro.who.int/images/stories/pakistan/documents/pak_documents/Guidelines_for_Expired_HPTs.pdf
3. Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies; Geneva: World Health Organization, 1999. https://iris.who.int/bitstream/handle/10665/42238/WHO_EDM_PAR_99.2.pdf?sequence=1
4. Laboratory biosafety and biosecurity policy guidelines. Ministry of Health, Kenya.

Annex 1: List of NTD HPTs by Disease

Focal area	HPT	Diagnostics and Consumables
Leishmaniasis	Sodium stibogluconate, paromomycin, AmBisome, Miltefosine	Diagnostic Kits - rk39, DAT **Consumables:** DAT-Antigens and controls Whatmann's 3 filter paper V-shaped microtitration plates Yellow tips (1-200 ul) Blue tips (200-1000 ul) Freeze dried antigen Positive control sera Negative control sera 2% Mercaptoethanol PBS (Phosphate Buffer Saline)
Lymphatic filariasis	Ivermectin, Diethylcarbamazine, and Albendazole	ICT, Filariasis test strip (FTS)
STH	ABZ, MBZ	Kato katz Templates 47.1 mg, Microscope Glass slides (non-frosted), Nylon mesh/sieve(ROLLS), Malachite green, Ultra clear Cellophane (40-50mm) rolls, Distilled water, Cup, Poly pots Sample with (snap cap/lid) 25ml, Glycerol, Notebooks, Slide boxes, Gloves, Latex Medium powder free NS 100/pkt, Gloves, Latex Medium powdered NS 100/pkt, Jik solution, Waste paper bags (black); 50/pkt, Tissue paper, Liquid soap , Dettol soap/Medicated soap, Forceps, Cleaning basin, Bucket 20 Litre, Cleaning brushes, Microscope lens, Cleaning tissue, Tongue Depressors 100/pk, Petri dish, Spatula, Activated charcoal, Cotton wool gauze (8 layers – non-sterile, 100% cotton) of 5x5 cm), Wooden applicator stick, 50 mL falcon tubes, Microscopic slide, Cover slip, Timer, Iodine, Test tube racks, Plastic Jar, Laboratory tissue paper, Labels
Schistosomiasis	PZQ	Kato katz Templates 47.1 mg, Microscope Glass slides (non-frosted), Nylon mesh/sieve(ROLLS), Malachite green, Ultra clear Cellophane (40-50mm) rolls, Distilled water, Cup, Poly pots Sample with (snap cap/lid) 25ml, Glycerol, Notebooks, Slide boxes, Gloves, Latex Medium powder free NS 100/pkt, Gloves, Latex Medium powdered NS 100/pkt, Jik solution (5L), Waste paper bags (black); 50/pkt, Tissue paper, Liquid soap, Dettol soap/Medicated soap, Forceps, Cleaning basin, Bucket 20 Litre, Cleaning brushes, Microscope lens, Cleaning tissue, Tongue Depressors 100/pk, Urine containers with cap, Newspapers, Syringes 20 mls BD, Urine filter Membrane (100 membrane per packet), Urine filter holders, POC-CCA kits
Onchocerciasis	Ivermectin	

Human African Trypanosomiasis	Melarsoprol, Suramin	**Equipment:** Compound light Microscope, Portable microhematocrit centrifuge (above 2000 r.p.m), PCV reader, Portable generator, Foldable table and chair, Diamond Knife, GPS Set,Capillary holding board, Liquid nitrogen tank, Refrigirator -2 to 6, PCR machine **Materials:** Heparinized capillary tubes (100 µl), Sterile lancet, Cover Slips, Slides, Plastercine, Cotton wool, Surgical gauze, Surgical spirit, Disposable gloves, Disposable syringes and needle, Mice and Mice food, Vacutainers, Staining racks, Slide boxes **Reagents:** Absolute alcohol, Methanol, Absolute ethanol, Giemsa stain or Field stain.
Trachoma	Azithromycin Azithromycin Azithromycintabs, Azithromycin Powder for oral suspension (POS) and 1% Tetracycline Eye Ointment (TEO)	**Consumables:** Silica gel 1gm, 1.5ml sterile tethered cap tubes, Puritan sterile swabs, Contact activated lancets, TropBio filters, Sample bags 3x3, Humidity indicator (1 tin of 100 pcs), A4 size zip lock bags (1pkt of 100 pcs), Barcodes (K3_0001) **For Nucleic Acid Amplification Tests (NAATs):** ZeptoMetrix NATtrol Chlamydia trachomatis Negative Controls, ZeptoMetrix NATtrol Chlamydia trachomatis Positive Controls, **For MBA Analysis:** Beads (trachoma), Biotinylated mouse anti- human IgG, Biotinylated mouse anti-human IgG4, Phycoerythrin-conjugated streptavidin SAPE S-866(PE Protein ratio >3.6) , E.coli lysate extract, 0.45 micron filter flasks, Millipore multiscreen 96 -wells assay plates, 96 well conical bottom P.P plate 0.45ml well, Calibration Kits, Validation Kits, Single Tab Sealing Foil.
Rabies	PEP Anti-Rabies vaccine, RIG	
Snakebites	Polyvalent antivenom, mono specific antivenom (for specific snakes like boomslang and echis)	Hematology, Coagulation, Biochemistry, 20 minute whole blood clotting time (20WBCT), Enzyme Linked Immunosorbent Assay (ELISA), Western Blot Analysis and Urinalysis.
		Equipment: hamatology analyser, cetrifuge, stago machine, biochemistry analyser, dry glass or plastic test tube, ELISA plate reader, polyacrylamide gel, elecrophoresis equipment and gel, urine dipstick, PCR machine.

IEC Materials	Posters, Brochures, T-shirts (round neck and polos), Job Aids, Street Banners, Bags, Reflector Jackets, Lanyards, Caps, Stickers, Tally sheets, MDA Household registers, Summary forms, Tablet Accountability Forms, TOT manuals, Documentaries, Skits, Radio spots, Short Video skits, Bulk messaging, and Media Mentions	Artwork (Design, pre-test, validate, develop, distribute, M&E)

Annex 2: Tablet Accountability Form

DEVELOPMENT OF SUPPLY CHAIN MANAGEMENT GUIDELINES.

	NAME	ORGANIZATION
1	Agnes Kithinji	MOH-VBNTDU
2	Blevin Ian	AIHD-VBNTDU
3	Charles Oduor	MOH-SIAYA
4	Cherinet Adera	DNDi
5	Christine Othim	AMREF
6	Clare Amuyunzu	AIHD
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9	Donna Ogeto	MOH-VBNTDU
10	Dr. Abdi Hadun	KEMSA
11	Dr. Bedan Maina	MOH-THARAKA NITHI
12	Dr. Bob Agwata	MOH
13	Dr. Cecilia Ngari	KSRIC-KIPRE
14	Dr. Felix Kimotho	MOH-TAITA TAVETA
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17	Dr. Johnson Nyaga	MOH- NAROK
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21	Dr. Kefa Bota	DHPT
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23	Dr. Nkatha Mutungi	MOH-MACHAKOS
24	Dr. Paul Kibati	CHAI
25	Dr. Tina Patel	MERCK
26	Dr. Tracy Njonjo	DHPT
27	Edith Ramaita	MOH-VBNTDU
28	Elizabeth Kimiri	CHAI
29	Esther Kinyeru	WHO
30	Esther Mwaura	MOH-VBNTDU
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37	Julius Kalenda	MOH-VBNTDU
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40	Loise Ndung'u	FELTEP
41	Metrine Kwamboka	AIHD
42	Murithi Oliver	MOH-VBNTDU
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44	Patricia Njiiri	CHAI
45	Patrick Gitahi	MOH-VBNTDU
46	Rebecca Nyankieya	END FUND
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Notes

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