REPUBLIC OF KENYA

MINISTRY OF HEALTH

Malaria Health Products and Technologies Management Handbook



NATIONAL MALARIA CONTROL PROGRAM
MINISTRY OF HEALTH, KENYA

Komesha Malaria
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1ST EDITION, APRIL 2026

MALARIA HEALTH PRODUCTS AND TECHNOLOGIES MANAGEMENT HANDBOOK

A Practical Guide for the Management of Malaria Health Products and Technologies in Kenya

1st Edition, April 2026

Citation

Ministry of Health, Kenya. (2026).

Malaria Health Products and Technologies Management Handbook.

National Malaria Control Programme (NMCP), Directorate of Primary Health Care.

Ministry of Health, Nairobi, Kenya.

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Disclaimer

This handbook is intended to guide the management of malaria Health Products and Technologies (HPT) within Kenya's health system. While every effort has been made to ensure the accuracy and completeness of the information contained in this document, the Ministry of Health does not assume responsibility for errors or omissions.

The guidance contained in this handbook should be implemented in conjunction with existing national policies, guidelines, and regulatory frameworks governing the management of health products and technologies in Kenya.

Distribution

This handbook is intended for use by the National Malaria Control Programme (NMCP), county and sub-county health management teams, health facility staff, and other stakeholders involved in the management of malaria Health Products and Technologies across Kenya.

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Foreword

Malaria remains a major public health challenge in Kenya, particularly in endemic regions where it continues to cause significant illness and loss of life. Despite this burden, the Government of Kenya, through the Ministry of Health, has made commendable progress in reducing malaria morbidity and mortality through sustained investments in prevention, timely diagnosis, effective treatment, and strengthened health systems.

A critical pillar of these efforts is the continuous availability and proper management of malaria Health Products and Technologies (HPT), including diagnostics, medicines, and vector control commodities. Ensuring that these essential products are available at the right place, in the right quantity, and at the right time is fundamental to achieving our national malaria control and elimination goals.

This Malaria Health Products and Technologies Management Handbook has been developed by the National Malaria Control Programme (NMCP), in collaboration with key stakeholders, to provide clear and practical guidance for the management of malaria commodities across all levels of the health system. It offers standardized approaches for forecasting, procurement, distribution, inventory management, reporting, monitoring, and quality assurance, while promoting the use of routine supply chain data for informed decision-making.

Aligned with the Kenya Malaria Strategy 2023–2027 and the National Malaria Policy, this handbook reinforces our commitment to strengthening commodity security and ensuring uninterrupted access to quality-assured malaria interventions at county, facility, and community levels.

I urge all stakeholders, including national and county health managers, healthcare workers, implementing partners, and community health teams, to embrace and utilize this handbook as a practical tool for improving supply chain performance and enhancing malaria service delivery across the country.

Together, through coordinated action and commitment, we can sustain the gains made and move closer to a malaria-free Kenya.



Dr. Patrick Amoth, CBS
Director General for Health
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Preface

The effective management of malaria Health Products and Technologies (HPT) is fundamental to ensuring uninterrupted access to quality malaria prevention, diagnosis, and treatment services across Kenya. As the country continues to implement the Kenya Malaria Strategy 2023–2027, the need for strong, efficient, and responsive supply chain systems remains central to reducing malaria morbidity and mortality.

This Malaria Health Products and Technologies Management Handbook was developed in response to the need for standardized and practical guidance on the management of malaria commodities across all levels of the health system. Variations in forecasting, procurement, storage, distribution, reporting, and inventory practices can lead to stock imbalances, wastage, and service interruptions, thereby affecting the quality of malaria service delivery.

The handbook was developed through a consultative process led by the National Malaria Control Programme (NMCP) in collaboration with key stakeholders, including national and county health teams, supply chain experts, implementing partners, and relevant regulatory and technical institutions. The development process included a review of existing policies, operational guidelines, routine program data, and best practices in commodity management, to ensure that the guidance provided is evidence-based and aligned with national priorities.

The handbook provides practical guidance on forecasting, procurement, distribution, inventory management, reporting, monitoring, and quality assurance of malaria HPT. It further promotes the use of routine data systems, including the Kenya Health Information System (KHIS), to strengthen decision-making and improve supply chain performance.

This document is intended for use by stakeholders at national, county, facility, and community levels involved in malaria commodity management and service delivery. It is our expectation that this handbook will serve as a practical reference tool to strengthen malaria HPT management and contribute to improved health outcomes across the country



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Acknowledgements

The National Malaria Control Programme (NMCP) wishes to express its sincere appreciation to the many institutions and individuals whose invaluable contributions made the development of this Malaria Health Products and Technologies Management Handbook possible.

The Programme is particularly grateful to the Office of the Director General for Health for providing overall policy direction and strategic leadership throughout the development process. We further acknowledge the Directorate of Primary Health Care, and the Directorate of Health Products and Technologies for their technical guidance, oversight, and support during the drafting and review of this handbook.

Special appreciation is extended to the technical teams and NMCP staff who coordinated the consultative process, compiled evidence, and led the technical review and finalization of the document.

The Programme also acknowledges the important contributions of key national institutions, including the Kenya Medical Supplies Authority (KEMSA) and the Mission for Essential Drugs and Supplies (MEDS) for their expertise in procurement and supply chain management. We equally recognize the Pharmacy and Poisons Board (PPB) and the Pest Control Products Board (PCPB) for their regulatory guidance on malaria health products and technologies.

We deeply value the contributions of County Governments, particularly county and sub-county health products and technologies managers, whose practical implementation experience and field insights greatly informed the development of this handbook.

Finally, we convey our sincere gratitude to our development and technical partners, including the Global Fund, the United States Government, the World Health Organization (WHO), and Amref Health Africa, among others, for their sustained technical and financial support in strengthening malaria programme implementation and commodity management systems in Kenya.

To all who contributed in diverse ways, we extend our heartfelt appreciation.



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Abbreviations and Acronyms

Abbreviation	Full Meaning
ACT	Artemisinin-based Combination Therapy
ADR	Adverse Drug Reaction
AL	Artemether–Lumefantrine
AMC	Average Monthly Consumption
ANC	Antenatal Care
ASAQ	Artesunate–Amodiaquine
AWPs	Annual Work Plans
CCMm	Community Case Management of Malaria
CWC	Child Welfare Clinic
CHA	Community Health Assistant
CHP	Community Health Promoter
CHU	Community Health Unit
CSTWG	County Supply Chain Technical Working Group
CWC	Child Welfare Clinic
DAR	Dispensing/Daily Activity Register
eCHIS	Electronic Community Health Information System
EMR	Electronic Medical Record
FASP	Forecasting and Supply Planning
FEFO	First Expiry First Out
FIFO	First In First Out
GPHF	Global Pharma Health Fund
GSDP	Good Storage and Distribution Practices
HMIS	Health Management Information System
HPT	Health Products and Technologies
HPTUs	Health Products and Technologies Units
IPC	Infection Prevention and Control
IPTp	Intermittent Preventive Treatment in Pregnancy
iLMIS	integrated Logistics Management Information System
KDHS	Kenya Demographic and Health Survey
KEPH	Kenya Essential Package for Health
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Authority
KHIS	Kenya Health Information System
KMS	Kenya Malaria Strategy
KNBS	Kenya National Bureau of Statistics
LMIS	Logistics Management Information System
LLIN	Long-Lasting Insecticidal Net
MedRS	Medicines Risk-based Surveillance Tool
MEDS	Mission for Essential Drugs and Supplies

MFT	Multiple First-Line Therapy
MOH	Ministry of Health
MOS	Months of Stock
mRDT	Malaria Rapid Diagnostic Test
NEMA	National Environment Management Authority
NMCP	National Malaria Control Programme
NQCL	National Quality Control Laboratory
NPC	National Pharmacovigilance Centre
PCPB	Pesticides Control Products Board
PPB	Pharmacy and Poisons Board
PPADA	Public Procurement and Asset Disposal Act
PV	Pharmacovigilance
PvERS	Pharmacovigilance Electronic Reporting System
QA	Quality Assurance
RDT	Rapid Diagnostic Test
SOH	Stock on Hand
SP	Sulfadoxine–Pyrimethamine
WHO	World Health Organization

Definition of Terms

Average Monthly Consumption (AMC): The average quantity of a product used or dispensed per month, calculated using historical consumption data.

Health Products and Technologies (HPT): Medicines, diagnostics, medical devices, vector control products, and related technologies required for the prevention, diagnosis, and treatment of diseases.

Inventory Management: The systematic process of ordering, receiving, storing, issuing, and tracking HPT to ensure their availability and proper use.

Lead Time: The period between placing an order for HPT and the time the products are received and available for use.

Logistics Management Information System (LMIS): A system used to collect, analyze, and report data on HPT supply chain operations, including stock levels, consumption, and distribution.

Months of Stock (MOS): The quantity of stock available expressed in the number of months the stock is expected to last based on consumption.

Post-Market Surveillance (PMS): Monitoring of medicines and medical products after they have been introduced to the market to ensure their quality, safety, and effectiveness.

Stock Availability: The presence of a product in sufficient quantity at a facility, warehouse, or outlet to meet current demand without interruption

Stock on Hand (SOH): The physical quantity of HPT available in stock at a specific point in time.

Stocked According to Plan: Measures the percentage of time, or number of facilities/items that maintain inventory levels within a designated range.

Substandard and Falsified Products: Medical products that fail to meet quality standards or deliberately misrepresent their identity, composition, or source.

Supply Chain: The system of organizations, people, activities, information, and resources involved in moving HPT from manufacturers to end users.

Shelf Life: which refers to the length of time a product may be stored without compromising its safety, quality, or effectiveness.

Pipeline: which refers to the chain of procurement, storage, and distribution through which HPT move from manufacturers to service delivery points.

Order Fill Rate: This is the proportion of the quantity of malaria HPT supplied against the quantity ordered within a given period.

Chapter 1: Introduction

1.1 Background

Kenya's commitment to improving access to quality health services is anchored in the Constitution of Kenya (2010), which guarantees every citizen the right to the highest attainable standard of health. This commitment is reinforced through key policy and legal frameworks, including the Health Act (2017), the Kenya Health Policy (2014–2030), and the Health Laws (Amendment) Act (2021) which supports the implementation of Universal Health Coverage (UHC). These frameworks emphasize the need for strong health systems, including effective management of HPT to ensure their availability, quality, and rational use.

To operationalize these commitments, the Health Products and Technologies Strategy (2020–2025) provides the national framework for strengthening supply chain systems for essential health products. Complementary national HPT management guidelines harmonize procedures for the procurement, storage, distribution, and monitoring of health products within the Kenya Essential Package for Health (KEPH). Within the devolved health system, county governments play a critical role in planning, budgeting, and managing malaria HPT to ensure their availability and continuity across health facilities.

The National Malaria Control Programme (NMCP) provides leadership in malaria prevention, diagnosis, treatment, and surveillance. The Kenya Malaria Strategy (2023–2027) outlines the country's roadmap for malaria control and elimination, with targets to significantly reduce malaria incidence and deaths and interrupt transmission in selected counties. Achieving these targets depends on sustained availability of key malaria HPT.

Effective malaria HPT management therefore requires coordinated processes for forecasting and supply planning, procurement, storage, distribution, reporting, and rational use of these products. Strengthening these systems - supported by health management information systems - improves data visibility, enhances stock management, and supports timely decision-making. This handbook provides practical guidance to support standardized and effective management of malaria HPT across all levels of the health system.

1.2 Justification

Effective malaria control depends on the continuous availability and proper management of malaria HPT across all levels of the health system. These products - including prevention tools, diagnostics, medicines, and related supplies - are essential for delivering effective malaria services. Weaknesses in supply chain management, inconsistent documentation and reporting, and limited use of routine data for decision-making can compromise the availability and rational use of these critical interventions.

Mention of first handbook, following best practices which vary from HPT to HPT; silo management.

This handbook has therefore been developed to provide standardized guidance on the management of malaria HPT, including forecasting, ordering, receipt, storage, distribution, rational use, and reporting. It aims to promote consistent practices across national, county, sub-county, facility, and community levels, thereby strengthening supply chain efficiency, reducing stock-outs and wastage, and improving accountability.

The handbook also supports the country's transition to Multiple First-line Treatment (MFT) to slow the emergence of antimalarial drug resistance and preserve treatment effectiveness. In addition, it promotes sustainable procurement approaches that consider economic efficiency, equitable access to quality medicines, and environmentally responsible sourcing and supply practices.

By strengthening data use through systems such as KHIS and LMIS, this handbook supports evidence-based decision-making and improved visibility of malaria HPT across the supply chain. Ultimately, it contributes to

the continuous availability and effective use of malaria HPT, supporting Kenya's progress toward malaria control and elimination.

1.3 Goal and Objectives

Goal

To provide a standardized and practical guide to effective malaria HPT management for continuous availability, rational use and accountability across all levels of the health system.

Broad Objective

To guide stakeholders at national, county, sub-county, facility, and community levels in implementing consistent, efficient, and data-driven malaria HPT management practices through standardized procedures, tools, and monitoring mechanisms.

Specific Objectives

1. Provide a practical guide on the ordering, storage, distribution, and rational use of malaria HPT.
2. Standardize documentation and reporting using national tools for malaria HPT management.
3. Strengthen malaria HPT data quality and the use of dashboards for evidence-based decision-making.
4. Leverage electronic medical records (EMRs) and other digital platforms to enhance real-time, end-to-end visibility of the malaria HPT supply chain.
5. Align malaria HPT management with national policies, treatment guidelines, and management standards.

1.4 Scope of the Handbook

This handbook covers the end-to-end management of malaria HPT used for prevention, diagnosis, and treatment within Kenya's health system. It outlines the key standards, procedures, and tools for managing malaria HPT across the supply chain - from selection and procurement to receipt, storage, distribution, dispensing, and documentation - at national, county, sub-county, facility, and community levels.

It also describes the reporting processes and data systems, including MoH tools, the KHIS, and iLMIS (integrated logistics management information system) used to ensure visibility, accountability, and effective monitoring of malaria HPT across the health system.

1.5 Target Users

This handbook is intended for stakeholders involved in the management of malaria HPT across the health system. Primary users include personnel responsible for procurement, storage, distribution, dispensing, reporting, and oversight of malaria HPT at national, county, sub-county, health facility, and community levels.

These include officers in HPT Units, health facility in-charges and pharmacy personnel, Community Health Assistants (CHA) and Community Health Promoters (CHP) involved in CCMm, as well as monitoring, evaluation, records, and reporting officers who support data capture and use for decision-making.

Chapter 2: Overview of Malaria Health Products and Technologies

This section provides a summary of the main categories of malaria HPT, including products for prevention, diagnosis and treatment, and related supplies.

2.1. Malaria Prevention Products

These are HPT used to reduce human exposure to infectious mosquito bites and lower the risk of malaria transmission across different ecological settings. Key prevention HPT used in Kenya include long-lasting insecticidal nets (LLIN), insecticides used in indoor residual spraying (IRS), biolarvicides used in larva-source management (LSM), mosquito repellents for personal protection, intermittent preventive treatment in pregnancy (IPTp) medicines such as sulfadoxine-pyrimethamine. These products play a critical role in protecting vulnerable populations and reducing malaria transmission at community level. The complete list of nationally approved malaria prevention HPT is provided in Appendix 2: Malaria HPT List.

2.2. Malaria Diagnostic Products

These include the HPT used to detect malaria parasites and confirm diagnosis. Diagnostic HPT commonly used in Kenya include malaria rapid diagnostic tests (mRDTs), microscopy equipment and supplies. These are complemented by quality assurance materials and verification tools used to ensure accuracy and reliability of diagnostic results. The full list of nationally approved malaria diagnostic HPT is provided in the Appendix 2: Malaria HPT List.

2.3. Malaria Treatment Products

They are products used in the management of uncomplicated and severe malaria as per the national malaria treatment guidelines. Malaria treatment HPT used in Kenya include artemisinin-based combination therapies (ACT), injectable artesunate, and other medicines used in malaria case management. The complete catalogue of nationally approved malaria treatment HPT is provided in Appendix 2: Malaria HPT List.

Chapter 3: Malaria Supply Chain

Kenya's malaria supply chain is a coordinated network of organizations, people, technologies, and supply chain activities involved in the planning, procurement, storage, and distribution designed to guarantee timely availability, accountability, and efficient use of malaria HPT across the health system. The following sections describe the governance arrangements and key components that underpin the effective functioning of the malaria supply chain.

3.1. Supply Chain Levels, Roles and Responsibilities

Malaria HPT are managed through a robust multi-level supply chain**.**

3.1.1 National Level

The NMCP provides strategic oversight of malaria HPT management, development of policies and guidelines. It coordinates forecasting, quantification and supply planning, and procurement of malaria HPT through designated national supply agencies, and reviews supply chain performance indicators. It accomplishes these roles through the technical and financial support from partners and other government entities.

3.1.2 County Level

County HPTUs coordinate malaria HPT management within their jurisdictions. They review and submit orders from sub counties, monitor stock status, report and review supply chain performance indicators, and conduct capacity building on malaria HPT management. It accomplishes these roles through the technical and financial support from partners and other government entities.

3.1.3 Subcounty Level

Subcounty HPT managers verify and validate facility and CHU data, rationalize facility orders, monitor stock status, report and review supply chain performance indicators, and conduct capacity building on malaria HPT management.

3.1.4 Health Facility Level

Health facilities are responsible for ordering, receiving, storage, issuing, dispensing, and stock management. They maintain stock records, report on consumption and stock status through monthly reporting tools, and supply HPT to their linked CHU(s). Facilities must maintain optimal stock balances and ensure accuracy of HPT data.

3.1.5 Community Health Unit Level

CHAs order malaria HPT from the link facility and issue to CHPs to support community malaria case management (CCMm). The CHPs record stock movements using designated community tools and submits them to the CHA for consolidation and submission to the link facility.

Chapter 4: Malaria HPT Selection

In Kenya, malaria HPT are selected and managed in alignment with national treatment policies and product standards outlined in the Guidelines for the Diagnosis, Treatment and Prevention of Malaria in Kenya (7th Edition, 2026), the MFT Implementation Plan (2026–2030), and other Ministry of Health guidance. Product specifications are further detailed in the Malaria HPT Specifications Catalogue (2026), which provides standardized descriptions of approved malaria products used within the programme.

Selection and stocking of malaria HPT should be guided by disease burden, consumption patterns, and programmatic needs to ensure efficient supply chain management and minimize wastage. High-burden counties may stock the full range of ACT weight bands to support effective case management, while low-risk counties may limit stocking - often to artemether–lumefantrine (AL) 12s in selected facilities - to reduce the risk of expiry, wastage, and pilferage. Where necessary, redistribution of near-expiry HPT to higher-burden counties should be undertaken to optimize use and prevent losses.

Commodity selection should also include other essential malaria case-management HPT such as mRDTs, microscopy reagents and supplies, and injectable artesunate for severe malaria management. Under the MFT implementation plan, selection of ACT should support the planned rotation of treatment options to maintain therapeutic effectiveness and delay the emergence of drug resistance. In specific contexts, such as Turkana County where sulfadoxine–pyrimethamine plus amodiaquine (SPAQ) is used for seasonal malaria chemoprevention (SMC), artesunate–amodiaquine (ASAQ) should not be selected to avoid overlapping exposure to amodiaquine.

Chapter 5: Forecasting and Supply Planning

Forecasting and supply planning (FASP) are key components of the quantification process for malaria HPT. Quantification involves estimating the quantities and costs of malaria HPT required for programme implementation and determining when these products should be procured and delivered to ensure an uninterrupted supply across the health system.

Forecasting uses available data - such as consumption trends, morbidity patterns, programme targets, and stock status - to estimate future HPT requirements. Supply planning then translates these estimates into procurement and distribution schedules that consider lead times, funding availability, pipeline supplies, and stock levels. Together, these processes support efficient resource allocation and continuous availability of malaria HPT.

5.1. Importance of Forecasting and Supply Planning

Forecasting and supply planning aim to:

- Ensure continuous availability of malaria HPT at service delivery points for client use.
- Minimize wastage resulting from overstocking, expiry, or poor storage conditions.
- Prioritize critical HPT requirements based on available funding and manufacturer capacity.
- Support planning, advocacy, and mobilization of financial resources for malaria programmes.
- Guide timely procurement and efficient supply planning to maintain commodity security.

5.2. Data Sources for Quantification

Quantification of malaria HPT relies on multiple data sources to estimate product requirements and guide supply planning. Key data types include consumption data, service data, morbidity data, and demographic data, which may be complemented by programme targets and planned interventions. Table 1 below gives a summary of the types and sources of data that can be used:

Table 1: Sources of data for malaria HPT Quantification

Types of data	Sources of data
Programmatic Data	Program progress and evaluation reports, policy and strategic planning documents e.g., Kenya Malaria Strategy (KMS) 2023-2027, technical reports, AWPs, MFT implementation plan, Standard Treatment Guidelines (STGs), Kenya essential HPT Lists
Demographic	National population census (KNBS), Demographic health surveys (KDHS 2022), population growth rate, target population e.g., malaria in pregnancy, children under 1
Morbidity	Surveys (Kenya Malaria Indicator Survey), Malaria incidence or prevalence data, testing rate, test positivity rate
Services	HMIS reports, M&E reports e.g., MOH 705A/B, MoH 706, 748, LLIN coverage, Surveillance indicators
Consumption	LMIS reports, stock control cards, dispensing records (DARs - MoH 645, Lab register), KHIS (MoH 743), MoH 748, eCHIS, EMR

5.3. Forecasting Methods

Forecasting for malaria HPT uses diverse standard methods to estimate future requirements which are applied individually or in combination depending on data availability and programme needs.

5.3.1 Consumption method

Uses verified historical consumption data to project future HPT needs, assuming stable service delivery and consistent reporting.

5.3.2 Morbidity method

Estimates requirements based on expected malaria cases derived from disease burden, test positivity rates, and national testing and treatment protocols.

5.3.3 Service-level method

Forecasts HPT needs using expected service outputs such as ANC attendance, outpatient visits, or planned testing targets.

5.3.4 Demographic method

Uses population data and target-group estimates to determine HPT needs for specific interventions or age cohorts.

5.3.5 Proxy consumption method

Uses consumption patterns from comparable facilities or periods where reliable consumption data are unavailable.

5.4. Pipeline Monitoring

Pipeline monitoring is the routine tracking of malaria HPT as they move through procurement, shipment, warehousing, and distribution stages. It provides visibility of quantities on order, expected delivery timelines, and potential supply gaps, enabling timely corrective action.

Key elements include:

- **Tracking procurement and shipments:** Monitoring quantities ordered, supplier confirmations, dispatch dates, and expected arrival times.
- **Reviewing stock status:** Comparing available stock with pipeline deliveries to assess whether target months-of-stock levels will be maintained.
- **Identifying risks:** Detecting delays, short-expiry supplies, or quantities insufficient to meet projected needs.
- **Informing supply decisions:** Using pipeline data to rationalize orders, plan redistributions, and update quantification assumptions.

Effective pipeline monitoring supports timely supply decisions and helps maintain continuous availability of malaria HPT across the health system.

Chapter 6: Procurement

This is the process of acquiring malaria HPT to ensure their continuous availability and appropriate use across the health system. Procurement must be conducted in accordance with national legal and regulatory frameworks, including the Public Procurement and Asset Disposal Act (PPADA), 2015 (Revised 2022), its subsidiary regulations, and the Facility Improvement Fund (FIF) Act, 2023. Adherence to these frameworks ensures transparency, accountability, value for money, and efficiency in the acquisition of malaria HPT.

Procurement of malaria HPT is largely coordinated at the national level through designated procurement and supply agencies to ensure standardization, quality assurance, and economies of scale. However, counties may procure limited quantities of selected HPT to address immediate service delivery needs.

6.1 Procurement Planning

Procurement planning ensures that malaria HPT are acquired in a timely manner to meet programme needs. Planning should consider procurement lead times, contract management requirements, supplier performance monitoring, and compliance with quality standards.

Procurement plans are informed by quantification results and available resources, and should align with programme priorities and national treatment guidelines. Effective procurement planning helps prevent stock-outs, minimizes procurement delays, and supports efficient use of financial resources.

6.2 Procurement Processes

Procurement of malaria HPT follows a structured and legal framework designed to ensure quality, transparency, and timely supply. The process includes preparation of procurement plans, development of technical specifications, tendering and supplier selection, contract award and management, and receipt and verification of HPT.

Upon delivery, malaria HPT must undergo inspection and verification to confirm compliance with approved specifications, quantities, and quality standards before acceptance into the supply chain system.

6.3 Lead Times

Lead time refers to the period between initiation of procurement and the availability of malaria HPT at service delivery points. Lead times vary depending on procurement procedures, supplier capacity, manufacturing timelines, and shipping arrangements.

Effective management of procurement lead times is essential to ensure continuous availability of malaria HPT. Programme managers should consider factors such as average monthly consumption (AMC), stock on hand (SOH), minimum–maximum stock levels, disease burden, and seasonal malaria transmission patterns when planning procurement timelines to prevent stock-outs and ensure adequate supply.

Chapter 7: Warehousing and Distribution

Warehousing and distribution are essential functions in the management of malaria HPT and ensure that products are safely stored, properly handled, and delivered to service delivery points in a timely manner. Effective warehousing and distribution systems help maintain product quality, support efficient inventory management, and ensure continuous availability of malaria HPT across the health system.

Warehousing functions are primarily undertaken at central and regional warehouses, where malaria HPT are received from suppliers, inspected, recorded, and organized for onward distribution. These facilities serve as key points for consolidating inventory, maintaining stock visibility, and preparing HPT for dispatch to counties, sub counties, and health facilities. Warehouse operations must comply with national regulatory standards and Good Storage and Distribution Practices (GSDP) to safeguard the integrity of malaria HPT throughout the supply chain. (Appendix 9)

7.1 Warehouse Organization

Effective warehouse organization ensures orderly storage, easy access, and accurate tracking of malaria HPT. Products should be arranged systematically according to product type, batch number, and expiry date to facilitate stock monitoring and efficient distribution.

Warehouses should maintain clearly designated areas for receiving, storing, and dispatching HPT. Adequate space should be available for safe handling of bulky products such as LLIN and other large supplies. Appropriate racks and pallet systems should be used to protect products from damage and allow proper airflow.

Warehouse personnel are responsible for verifying deliveries, recording inventory movements, and ensuring that malaria HPT are stored and handled according to established procedures.

7.2 Temperature and Humidity Monitoring

Warehouses must be equipped with calibrated thermohygrometers to monitor temperature and humidity levels within storage areas equipped with Heating, Ventilation, and Air Conditioning (HVAC) systems to continuously regulate temperature and humidity for a conducive environment for malaria HPTs. Continuous monitoring ensures that environmental conditions remain within acceptable ranges required to maintain product stability.

Temperature and humidity monitoring records, including calibration documentation, should be maintained and made available for inspection in accordance with regulatory requirements such as PPB Public Notice (03/10/2025) (Appendix 10: PPB Public Notice).

7.3 Distribution of Malaria HPT

Distribution refers to the movement of malaria HPT from central warehouses to counties, sub counties, and health facilities. An efficient distribution system ensures that malaria HPT reaches service delivery points on time and in quantities that meet programme needs.

Distribution planning should be guided by stock status, consumption trends, minimum–maximum stock levels, disease burden, and seasonal variations in malaria transmission. Regular distribution schedules and redistribution mechanisms should be established to address stock imbalances and prevent stock-outs or overstocks across facilities.

During transportation, appropriate handling procedures must be followed to maintain product quality. This includes protecting HPT from excessive heat, humidity, and light exposure, and ensuring that any products

requiring special handling conditions are transported accordingly. Adherence to GSDP during distribution helps ensure that malaria HPT arrive at their destination in safe and usable condition.

Chapter 8: Inventory Management

8.1 Overview of Inventory Management

Inventory management refers to the systematic process of receiving, recording, monitoring, and controlling malaria HPT to ensure that the right products are available in the right quantities at the right time and place. Effective inventory management minimizes losses due to expiry, damage, or pilferage while ensuring uninterrupted malaria prevention, diagnosis, and treatment services across the health system.

A well-functioning inventory management system strengthens accountability, improves stock visibility, and supports data-driven decision-making for forecasting, procurement, and distribution of malaria HPT. By maintaining accurate inventory records and routinely monitoring stock movements, health facilities and supply chain managers are able to maintain optimal stock levels and respond promptly to supply challenges.

8.2 Key Components of Inventory Management

Inventory management for malaria HPT involves several interrelated activities that ensure effective stock control throughout the supply chain. These include stock control, stock level management, stock rotation, stock verification, and reporting.

Stock control focuses on monitoring stock quantities and movements while maintaining accurate inventory records to prevent stock-outs and overstocking. Stock level management ensures that facilities maintain stock within the recommended minimum and maximum thresholds and calculate months of stock (MOS) to guide timely replenishment.

Stock rotation ensures that products with earlier expiry dates are issued first through the application of the First Expiry First Out/First In First Out principle. Regular stock verification through physical stock counts allows facilities to confirm the accuracy of recorded stock balances and identify discrepancies arising from losses, damages, or recording errors.

Accurate reporting and documentation of stock movements support accountability and provide essential data for forecasting, procurement planning, and supply chain monitoring.

8.3 Key Inventory Management Terms

Several standard terms are used in inventory management to guide stock monitoring and replenishment decisions.

AMC refers to the average quantity of malaria HPT consumed per month based on historical consumption data. **SOH** refers to the quantity of malaria HPT physically available in the store and dispensing areas following a stock count.

MOS expresses the quantity of stock available as the number of months the stock will last based on AMC. **Lead time** refers to the time interval between placing an order and receiving the HPT for use, while the **review period** refers to the routine interval between stock assessments used to determine whether a new order should be placed.

The **minimum stock level** represents the lowest quantity of stock that should be maintained before initiating a new order, usually equivalent to approximately three months of stock. The **maximum stock level** represents the highest quantity of stock that should normally be maintained, usually equivalent to six months of stock.

Other important terms include **shelf life**, which refers to the length of time a product may be stored without compromising its safety, quality, or effectiveness, and the **pipeline**, which refers to the chain of procurement, storage, and distribution through which HPT move from manufacturers to service delivery points. **Stock-out days** refer to the number of days during which a particular HPT is unavailable at a facility. **Order Fill Rate** is the proportion of the quantity of malaria HPT supplied against the quantity ordered within a given period.

8.4 Stock Control Principles

Stock control refers to the procedures used to monitor and regulate the movement and quantities of malaria HPT within the supply chain. Effective stock control ensures that facilities maintain accurate inventory records and can quickly detect and address supply gaps.

Accurate record keeping is a fundamental component of stock control. Health facilities must ensure that all stock transactions are recorded immediately using approved inventory tools such as stock cards, bin cards, stock ledgers, or digital systems. These records should capture all receipts, issues, adjustments, losses, damages, and expiries. Stock records must be updated after every transaction to maintain accurate SOH balances.

Monitoring consumption patterns is equally important. Health workers should routinely review consumption data to calculate AMC and use this information to support forecasting, quantification, and resupply decisions. Facilities should monitor stock levels regularly and submit replenishment requests in a timely manner to prevent stock shortages.

Preventing stock-outs requires facilities to track stock levels carefully, maintain adequate safety stock, and initiate replenishment when stock approaches the minimum threshold. Indicators of possible stock-out risk include declining stock levels, increasing consumption, or delayed resupply.

Overstocking should also be avoided, as it may lead to expiry, storage constraints, and increased risk of losses. Orders should therefore be based on reliable consumption data and should maintain stock within the recommended stock level limits.

Maintaining accountability for malaria HPT is essential. Facilities must record all transactions accurately, investigate discrepancies, and document any losses, damages, or expiries. Routine supervision, inventory audits, and stock reconciliation processes help strengthen accountability and maintain the integrity of the HPT supply chain.

8.5 Ordering and Replenishment

Health facilities should place orders for malaria HPT on a quarterly basis or as required during emergencies. Orders are submitted through the LMIS, which is integrated with KHIS.

Consumption data captured in KHIS are used to calculate reorder quantities using the following formula:

Quantity to Order = (aAMC × Review Period) − SOH

Note: Adjusted average monthly consumption (aAMC), is adjusted in case of stockouts of some weight bands and non-reporting

This approach ensures that facilities maintain stock within recommended minimum and maximum levels while preventing both shortages and overstocking.

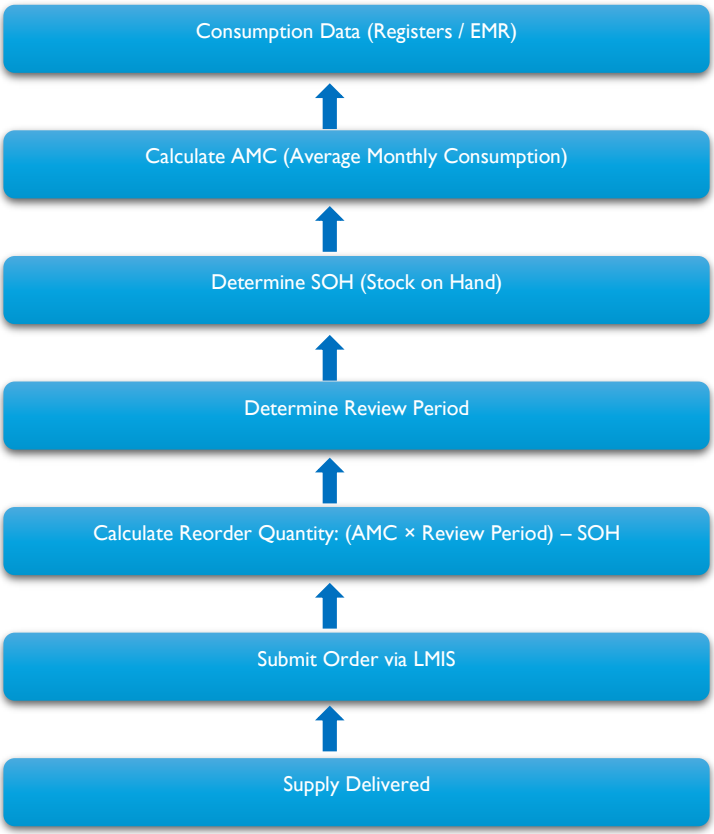


Figure 1: Facility Resupply Calculation

Facility Malaria HPT Resupply Cycle

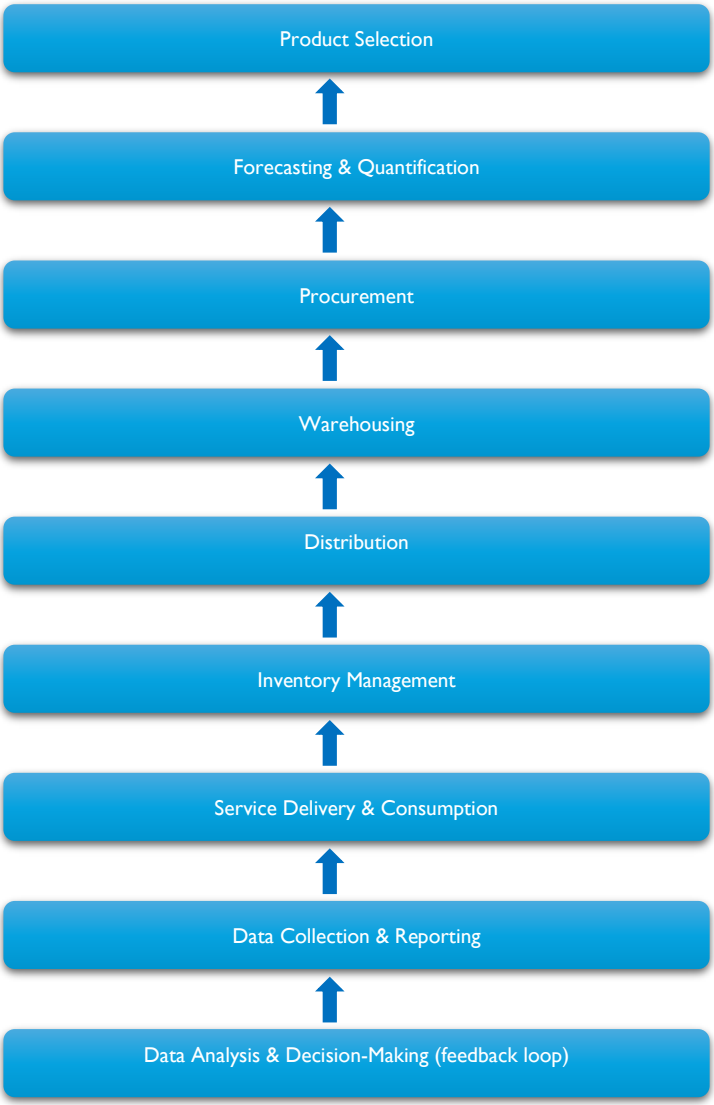


Figure 2: Facility Malaria HPT Resupply Cycle

8.6 Receiving

Malaria HPT should be received by a designated health facility staff who verifies the delivery against the order form and delivery note. During receipt, quantities and product specifications must be checked to ensure they match what was ordered.

Any discrepancies, shortages, or evidence of tampering should be recorded on the delivery documentation. All received quantities must then be recorded in the facility inventory records, such as stock cards or digital systems, to ensure accurate tracking of stock movements.

8.7 Issuing

Malaria HPT are issued from the store to service delivery points using approved requisition and issue forms such as S11 and S12. All issues must be recorded in the relevant inventory management tools to maintain accurate stock balances.

Proper documentation of issued quantities ensures traceability of HPT movements within the facility and strengthens accountability in stock management.

8.8 Dispensing

Dispensing refers to the process of providing malaria HPT to clients at service delivery points in accordance with national treatment and prevention guidelines. Health workers shall ensure that the correct product, quantity, and dosage are issued based on the client's clinical needs. During dispensing, staff must verify product integrity, observe FEFO principles, and provide clear instructions on proper use, adherence, and storage. All dispensed quantities shall be documented immediately in the relevant data capture tools to maintain accurate consumption data, support timely replenishment, and strengthen accountability for malaria HPT.

8.9 Physical Stock Counts and Reconciliation

Physical stock count refers to the process of counting the actual quantities of malaria HPT available in storage and comparing them with the quantities recorded in inventory records. This process helps confirm stock accuracy and identify discrepancies resulting from recording errors, losses, or damages.

Health facilities should conduct physical stock counts regularly, preferably on a monthly basis. Additional verification may occur during supervisory visits or inventory audits.

Stock reconciliation involves comparing physical stock counts with recorded inventory balances. If discrepancies are identified, facilities should review stock transaction records, investigate possible causes, and correct stock records accordingly. All adjustments must be documented, authorized, and recorded in the relevant inventory management tools.

Regular stock verification and reconciliation improve inventory accuracy and strengthen accountability in the management of malaria HPT.

Regular stock verification and reconciliation improve inventory accuracy, strengthen accountability, and support effective management of malaria HPT across the health system.

Chapter 9: Data Management and Reporting

9.1 Overview of Data Management and Reporting

Effective data management is essential for monitoring the availability, utilization, and performance of malaria HPT across the health system. Health facilities and Community Health Units (CHU) routinely collect and report data on key indicators related to malaria HPT management as part of routine service delivery.

These indicators include Stock on Hand (SOH), quantities received, quantities dispensed or consumed, losses, expiries, and stock-out days. The data are recorded using standardized tools developed by the NMCP and captured at the point of service delivery.

The reported data are analyzed at facility, county, and national levels to monitor the availability and use of malaria HPT, identify stock-outs or overstocking, and inform decisions related to forecasting, procurement, distribution, and redistribution. Reliable and timely reporting therefore plays a critical role in strengthening malaria HPT supply chain management. (Appendix 3)

9.2 Malaria HPT Data Capture Tools

Standardized tools are used at both community and facility levels to capture malaria HPT consumption and stock information. These tools ensure consistent documentation of service delivery activities and enable aggregation of data for reporting and supply chain monitoring.

9.2.1 Community Health Unit (CHU)

At the community level, malaria HPT data are recorded through the following tools:

Table 2: CHU Malaria HPT Data Capture Tools

Tool	Purpose
MoH 648 – CHU Daily Activity Register for Malaria Commodities	Records daily use of malaria HPT including mRDT and ACT
MoH 748 – CHU Monthly Summary Report for Malaria Commodities	Summarizes monthly consumption of malaria HPT
eCHIS	Digital platform used for community health service delivery, reporting and commodity tracking

These tools support monitoring of malaria case management activities conducted by CHPs.

9.2.2 Health Facility Level

At the facility level, malaria HPT data are captured using the following tools:

Table 3: Malaria HPT data capture tools in health facilities

Tool	Purpose
MoH 645 – Daily Activity Register	Records daily service delivery and malaria HPT consumption
MoH 743 – Facility Malaria Summary Form	Reports monthly malaria HPT consumption
MoH 643 – FCDRR (Laboratory HPT)	Reports monthly laboratory HPT including malaria diagnostics
MoH 706 – Laboratory Summary Tool	Captures malaria diagnostic testing data
Health Facility EMR	Digital system for recording service and inventory data

These tools provide the primary data used to monitor malaria HPT consumption, track stock status, and inform supply chain decision-making. (Appendix 4 and 12)

9.3 Reporting and Data Flow

Malaria HPT reporting follows a structured reporting pathway from the community and facility levels to the national level.

CHUs compile their monthly reports using the CHU monthly summary tool and submit them to their link health facilities by the 3rd day of the following month. The link facility consolidates CHU data together with facility reports.

Health facilities then compile their monthly malaria reports and submit them to the Sub-County Health Management Team (SCHMT) by the 5th day of the following month. Sub-county teams review and validate the reports for completeness and accuracy before uploading them into the KHIS by the 15th day of the same month.

This reporting structure ensures that malaria HPT data are available for timely monitoring and decision-making across all levels of the health system. (Appendix 5 and 6)

9.4 Digital Systems for Malaria HPT Management

Digital information systems play an important role in strengthening the management and visibility of malaria HPT across the supply chain.

The KHIS serves as the national platform for routine health data reporting and analysis. Malaria HPT data submitted through facility and sub-county reports are entered into KHIS, where they can be analyzed and visualized through dashboards to support programme monitoring and decision-making.

The KEMSA iLMIS supports ordering and supply management of malaria HPT. Counties use the system to place orders and monitor supply status.

The platform utilizes indicators such as SOH and adjusted Average Monthly Consumption (aAMC) to compute rational resupply quantities when counties place orders. Integration between facility reporting systems, KHIS, and the KEMSA supply chain platform provides end-to-end visibility of malaria HPT across the supply chain.

The roll out of Taifa Care EMR in public health facilities aims to strengthen commodity management by digitizing supply chains, promoting availability of HPTs, integrating HPT tracking into the national health system and eliminating counterfeit medicines through a "track-and-trace" mechanism.

In addition, eCHIS enables digital reporting of community-level malaria HPT data and strengthens data integration between community and facility reporting systems.

9.5 Data Quality Assurance

Ensuring high-quality data is essential for effective malaria HPT supply chain management. Data quality assurance mechanisms help ensure that reported information is accurate, complete, timely, and reliable.

Data quality should be routinely assessed at facility, sub-county, county, and national levels through processes such as data verification, supervision, and periodic data quality audits.

Key data quality assurance practices include:

- Routine review of data for completeness and consistency
- Verification of reported figures against source documents such as registers and stock records
- Reconciliation of consumption data with inventory records
- Supportive supervision and mentorship of facility staff

- Periodic data quality assessments and validation exercises

Strengthening data quality ensures that malaria HPT supply chain decisions are based on reliable information and supports effective programme monitoring and continuous improvement.

Chapter 10: Monitoring and Performance Tracking

Monitoring and performance tracking are essential for ensuring the continuous availability and effective management of malaria HPT across all levels of the health system. Routine monitoring enables programme managers to assess supply chain performance, identify operational gaps, and implement timely corrective actions.

Effective monitoring supports accountability and strengthens data-driven decision-making at facility, sub-county, county, and national levels. Regular review of HPT data helps improve supply chain responsiveness, detect risks such as stock-outs or overstocking, and ensure that malaria prevention, diagnosis, and treatment services are not disrupted.

10.1 Key Malaria HPT Supply Chain Indicators

A core set of indicators is used to monitor malaria HPT availability, reporting performance, data quality, and supply chain efficiency. These indicators provide a minimum framework for assessing system performance and identifying areas requiring corrective action.

Health facilities should generally maintain 3 - 6 MOS for routine malaria HPT unless otherwise specified by national supply planning guidelines.

10.1.1 Reporting Performance Indicators

Reporting performance indicators measure the completeness and timeliness of malaria HPT reporting. These include:

- **Percentage reporting rate for facility malaria summary forms**, which measures completeness of monthly reporting.
  Percentage of facilities reporting on time, which measures the proportion of reports submitted within the designated reporting period.

Strong reporting performance ensures that supply chain decisions are based on accurate and timely data.

10.1.2 Stock Availability Indicators

Stock availability indicators measure whether facilities maintain adequate stock levels to support service delivery. Key indicators include:

- Percentage of facilities with malaria HPT within the recommended MOS range, which reflects balanced stock levels at facility level.
- **Percentage of facilities experiencing stock-outs**, which measures continuity of malaria service delivery for key HPT.

Monitoring these indicators helps identify facilities requiring urgent resupply or redistribution.

10.1.3 Consumption and Documentation Quality Indicators

Consumption and documentation indicators assess the quality and consistency of HPT reporting and stock documentation. Examples include:

- Percentage of facilities capturing ACT weight-band consumption data in summary forms, which supports accurate forecasting and quantification.
- **Variance between malaria cases and ACT quantities dispensed**, which assesses the relationship between service delivery and HPT utilization.

- Percentage of facilities where opening SOH equals the previous month's closing SOH, which verifies continuity of stock documentation.
- **Percentage of facilities demonstrating internal stock balance consistency**, which validates correct calculation of stock movements based on receipts, issues, losses, and adjustments.
- Variance between LLIN issued to ANC/CWC clients and LLIN reported in HPT summary forms, which ensures accurate documentation of routine LLIN distribution.

These indicators help identify potential data quality or inventory management issues that may affect supply chain planning. (Appendix 5)

10.1.4 Additional Supply Chain Risk Indicators

Additional indicators help identify emerging supply risks and support proactive supply chain management. These include:

- **Percentage of HPT below minimum stock level**, which serves as an early warning indicator of potential stock-outs.
- Percentage of HPT above maximum stock level, which indicates potential overstocking.
- **Number of facilities with HPT expiring within six months**, which signals potential expiry risks requiring redistribution.
- Percentage of HPT expired or damaged, which monitors wastage.
- Average lead time between order placement and delivery, which measures supply chain responsiveness.

Monitoring these indicators enables early identification of supply risks and supports timely corrective action.

10.2 Use of the Malaria HPT Dashboards

The malaria HPT dashboards provide a consolidated digital platform for visualizing stock status, consumption trends, reporting performance, and supply chain risks across the health system. These dashboards integrate routine facility, community, sub-county, and county data to enhance visibility of malaria HPT and support timely, evidence-based decision-making. By presenting indicators such as SOH, AMC, MOS, stock-out days, quantities dispensed, and reporting completeness, the dashboards enable programme managers and supply chain personnel to identify stock-outs, overstocking, short-expiry products, and reporting gaps and take corrective action promptly. Routine use of dashboards during review meetings strengthens accountability and coordination of stock management activities and enhances end-to-end performance monitoring of malaria HPT.

10.2.1 Key Functions of the Malaria HPT Dashboards

Stock Status Visualization

Dashboards display facility and county stock levels, including SOH, MOS, stock-outs, overstocking, and short-expiry products. This enables rapid identification of facilities requiring redistribution or resupply.

Supply Planning Support

The dashboards show order status, expected deliveries, and pipeline quantities, allowing programme managers to align replenishment decisions with actual needs and anticipate supply gaps.

Reporting Performance Monitoring

Dashboards track completeness and timeliness of facility reports and flag missing or late submissions to guide follow-up and strengthen reporting discipline.

Alerts and Exception Flags

Systems highlight inconsistencies, repeated stock-outs, abnormal consumption patterns, and other risks requiring attention, enabling early corrective action.

Comparative Performance Analysis

Dashboards enable comparison of performance across facilities, sub-counties, and counties, supporting targeted supervision, tailored mentorship, and prioritization of support.

By integrating data from multiple reporting systems, the malaria HPT dashboards provide end-to-end visibility of commodity performance and strengthen data-driven planning, distribution, and monitoring of malaria interventions.

10.3 Data Analysis and Decision-Making

Routine analysis of malaria HPT data supports proactive supply chain management and ensures timely resolution of operational gaps. NMCP, Counties and sub-counties should regularly analyze reporting performance, stock status, data consistency, and consumption trends.

10.3.1 Elements of Data Analysis

Key analytical activities include:

- **Trend analysis:** Examining patterns in consumption, stock levels, stock-outs, and reporting performance over time.
- **Data quality review:** Assessing internal consistency and verifying alignment between inventory records and service delivery data.
- **Variance analysis:** Identifying discrepancies between expected and reported values, such as mismatched stock balances or inconsistencies between malaria cases and HPT consumption.
- **Exception identification:** Detecting facilities that consistently experience stock-outs, overstocking, reporting delays, or data inconsistencies.

10.3.2 Decision-Making Actions

Findings from data analysis should inform practical actions, including:

- Adjusting resupply quantities
- Redistributing HPT between facilities
- Initiating corrective actions for facilities experiencing stock management challenges
- Conducting targeted supportive supervision visits
- Addressing reporting gaps and strengthening data quality

Regular facility, sub-county, county review meetings should be used to review performance indicators, validate data, and agree on follow-up actions. National review forums and bi-annual malaria programme review meetings should also be used to align county-level improvements with national commodity security priorities.

10.4 Supportive Supervision and Performance Improvement

Monitoring results should inform supportive supervision, mentorship, and performance improvement activities across the health system.

NMCP and Counties should prioritize supervision visits to facilities experiencing:

- Repeated stock-outs
- Poor reporting performance
- Data inconsistencies
- Weak inventory management practices

Monitoring of malaria HPT performance should also be integrated within routine malaria programme review meetings at facility, sub-county, county, and national levels. Reviewing commodity indicators alongside malaria epidemiological data helps ensure alignment between disease burden and HPT availability.

Facilities facing persistent supply chain challenges should receive targeted capacity building, supportive supervision visits, and follow-up action plans to strengthen HPT management and reporting performance.

11. Quality Assurance and Safety

Quality assurance (QA) of malaria HPT is essential to ensure that all products used in malaria prevention, diagnosis, and treatment are safe, effective, and meet the required performance standards. In Kenya, QA for malaria HPT is implemented through a comprehensive system that includes regulatory oversight, product registration, quality testing, procurement and post-market surveillance. The quality assurance system, therefore, ensures that only quality-assured, safe, and effective products are available within the supply chain and at service delivery points.

11.1 Regulatory Framework and Oversight

The Pharmacy and Poisons Board (PPB) serves as the national regulatory authority responsible for ensuring that all medicines, diagnostics, and medical products used in Kenya meet established quality, safety, and efficacy standards.

National QA systems are guided by the Kenya Malaria Strategy (KMS) 2023–2027 and the National Malaria Policy (2024), which emphasize universal access to quality-assured malaria interventions.

11.2 Quality Assurance of Malaria HPT

All malaria HPT used within Kenya's malaria programme must comply with nationally approved technical and regulatory standards. These standards guide product selection, procurement, storage, distribution, and use across the health system.

Before a malaria HPT can be legally marketed or used in Kenya, it must undergo a regulatory evaluation and registration process by the PPB. This process assesses the product's quality, safety, efficacy, and compliance with international standards. In exceptional circumstances, unregistered products may be authorized by the PPB through special regulatory provisions to address urgent public health needs.

11.2.1 Quality Assurance of Malaria Medicines

Kenya employs both proactive and reactive quality monitoring systems to prevent the circulation of substandard or falsified malaria medicines.

The Malaria HPT Specifications Catalogue (2026) provides the authoritative reference for approved malaria HPT specifications. The catalogue outlines the approved product types, formulations, performance criteria, packaging requirements, and labelling standards. All malaria HPT procured and distributed under the national malaria programme must meet these specifications.

The PPB conducts routine post-market surveillance (PMS) to monitor the quality of malaria medicines circulating within public, private, and informal sectors. During these surveillance activities, samples of antimalarial medicines are collected and subjected to laboratory testing to verify their quality.

Quality testing follows a tiered approach. Initial screening may be conducted at sentinel sites using portable screening technologies such as the Global Pharma Health Fund (GPHF) Minilab™, Raman spectroscopy, or near-infrared (NIR) spectrophotometry. These technologies allow rapid identification of suspected substandard or falsified medicines in the field.

Products that fail preliminary screening, as well as selected samples of products that pass screening, undergo confirmatory compendial analysis at accredited laboratories such as the National Quality Control Laboratory (NQCL), the PPB Quality Control Laboratory, or the Mission for Essential Drugs and Supplies (MEDS) Quality Control Laboratory.

This multi-layered system helps ensure that malaria medicines circulating within the Kenyan health system meet required quality standards.

11.2.2 Quality Assurance of Malaria Diagnostics

Accurate diagnosis is a critical component of malaria case management and helps prevent unnecessary treatment with antimalarial medicines. Quality assurance systems therefore extend to malaria diagnostic tools, including microscopy and mRDTs.

Microscopy quality assurance programs include periodic refresher training for laboratory personnel, supportive supervision visits, and cross-checking of blood slides to verify diagnostic accuracy.

For mRDTs, quality assurance begins during product selection and registration, where products undergo validation processes to confirm their performance characteristics. In Kenya, validation and evaluation of diagnostic tests may involve institutions such as the Kenya Medical Research Institute (KEMRI).

Routine monitoring and quality checks help ensure that diagnostic tools maintain their sensitivity and specificity during routine use.

11.2.3 Quality Assurance of Vector Control Products

Quality assurance also applies to malaria vector control products such as long-lasting insecticidal nets (LLIN). LLINs used in Kenya's malaria programme must meet internationally recognized standards and are typically WHO prequalified or recommended under the WHO Vector Control Prequalification Programme.

Quality assurance for Long-Lasting Insecticidal Nets (LLINs) includes verifying compliance with product specifications, insecticide content, durability, packaging integrity, and labelling before procurement. After distribution, nets are monitored through durability surveys at 6, 12, 24, and 36 months to assess their physical condition, insecticidal effectiveness, and chemical content under real household conditions. The findings help determine the actual lifespan of the nets, guide the timing of replacement campaigns, and inform policy decisions on selecting more durable LLIN types.

Quality assurance of insecticides used in indoor residual spraying in Kenya involves strict regulatory approval, laboratory testing, proper storage and transport, trained personnel, calibrated equipment, field monitoring, environmental management, and programme evaluation. These measures ensure that IRS interventions remain safe, effective, and capable of reducing malaria transmission.

11.3 Pharmacovigilance of Malaria HPT

Pharmacovigilance (PV) refers to the monitoring and evaluation of the safety of medicines and other health products after they have been introduced into routine use. In Kenya, pharmacovigilance for malaria HPT is coordinated by the National Pharmacovigilance Centre (NPC) within the Pharmacy and Poisons Board.

The pharmacovigilance system aims to detect, assess, and prevent adverse drug reactions (ADR) and other HPT-related problems to ensure that malaria treatments maintain a favorable benefit-risk balance for patients.

The PPB maintains several reporting channels to facilitate reporting of suspected adverse drug reactions and poor-quality products. These include:

PvERS (Pharmacovigilance Electronic Reporting System): An online reporting platform used by healthcare workers, manufacturers, and the public to report safety concerns related to medicines and HPT. The system is integrated with the WHO global safety monitoring database.

mPvERS Mobile Application: A mobile reporting application available on Android and iOS platforms that allows healthcare workers and the public to submit pharmacovigilance reports in real time.

USSD Reporting Platform (*271#): A mobile reporting option that enables users to submit reports using basic mobile phones in both English and Kiswahili.

Standardized Reporting Forms: To facilitate standardized pharmacovigilance reporting, the PPB uses color-coded reporting forms that categorize different types of safety events. These include:

- **Yellow Form:** Used for reporting suspected adverse drug reactions associated with medicines.
- **Pink Form:** Used for reporting suspected poor-quality HPT, including substandard or falsified malaria medicines and diagnostics.
- **Other Specialized Forms:** Used for reporting medical device incidents, medication errors, or adverse events following immunization.

These standardized forms allow health workers to document and report safety concerns systematically.

12. Waste Management and Disposal

Effective waste management is essential for ensuring that malaria HPT waste is handled safely and in a manner that protects human health and the environment. Waste generated from malaria prevention, diagnosis, and treatment activities - including used diagnostic materials, damaged products, and expired HPT - must be managed in accordance with established national guidelines and regulatory requirements.

12.1 Waste management

Safe waste management involves several key practices, including waste minimization, controlled generation, proper segregation, safe storage, and appropriate disposal. Health facilities and community service delivery points should implement these practices to prevent environmental contamination and reduce potential risks to patients, health workers, and the community.

Special attention should be given to the management of waste generated from mRDTs and related materials, which may include sharps, biological materials, and chemical reagents. Community Health Promoters (CHP) and health facility staff should therefore be sensitized and trained on proper waste management practices in line with procedures established by the Ministry of Health (MOH).

Additional guidance on the safe management of pharmaceutical and medical waste is provided in the PPB pharmaceutical waste management guidelines and the national guidelines on management of HPT in Kenya.

12.2 Management of Expired, Damaged, or Obsolete HPT

Expired, damaged, or obsolete malaria HPT must be managed carefully to prevent accidental use and ensure safe disposal. Health facilities and warehouses should establish procedures for identifying, documenting, and removing such products from usable inventory.

When expired or damaged malaria HPT are identified, they should be:

- Documented in inventory records and relevant reporting tools
- Removed from active stock records and inventory systems
- Clearly labelled to prevent accidental dispensing or use
- Segregated from usable stock and placed in a designated quarantine area
- Reported through routine facility reporting systems, including the health facility monthly summary report where expired HPT quantities are recorded

These procedures ensure accountability and support monitoring of losses and wastage within the HPT supply chain.

12.3 Disposal Procedures

Disposal of malaria HPT must follow established national procedures to ensure compliance with public health, environmental, and regulatory standards.

12.3.1 Identification and Documentation

Expired, damaged, or obsolete malaria HPT should first be identified and documented in facility or warehouse inventory systems. Proper documentation ensures traceability and accountability during the disposal process.

12.3.2 Waste Segregation

Malaria HPT waste should be segregated at the point of generation. Different categories of waste - such as pharmaceutical waste, diagnostic waste (e.g., used mRDT), and general waste - should be separated using color-coded containers in accordance with national healthcare waste management guidelines.

12.3.3 Safe Storage

Expired or unusable HPT should be stored in a designated quarantine area, clearly labelled and secured to prevent accidental use while awaiting disposal authorization.

12.3.4 Authorization for Disposal

Disposal of malaria HPT waste must be conducted in accordance with national regulatory procedures and applicable legal frameworks, including the PPADA, 2015, and other relevant regulations. Disposal should only be undertaken after obtaining the necessary authorization from PPB, the National Environment Management Authority (NEMA), and other relevant regulatory authorities, to ensure compliance with national environmental, public health, and pharmaceutical waste management standards.

12.3.5 Approved Disposal Methods

Malaria HPT waste should be disposed of using environmentally safe and approved methods. These may include:

- High-temperature incineration at approved facilities
- Encapsulation for certain pharmaceutical products
- Controlled disposal of diagnostic materials, including used mRDT and sharps

The choice of disposal method should comply with national waste management regulations and environmental protection standards.

12.3.6 Supervised Destruction

Destruction of expired and damaged malaria HPT should be officially supervised and documented. The destruction process may involve representatives from health facilities, county health authorities, and regulatory bodies to ensure transparency and accountability.

Appendices

Appendix 1: List of Contributors

No.	Name	Organization	Designation
1	Antony Wechuli	Pesticides Control Products Board	RO
2	Dr. Alex Mungai	MOH, Samburu County	Pharmacist
3	Dr. Carol Asin	MOH/Primary Healthcare	Pharmacist
4	Dr. Dorothy Memusi	USAID/ Afya Ugavi	Consultant
5	Edith Ramaita	MOH/ National Malaria Control programme	Programme Office
6	Dr. Edward Abwao	USAID/ Promoting Quality Medicines	Technical Advisor
7	Dr. Edwin Onyango	MOH/ National Malaria Control programme	Programme Officer
8	Dr. Emma Nyadigisi	MOH/ National Malaria Program: Procurement and Supply Management	PSM Manager
9	Dr. Evans Sagwa	USAID/ Promoting Quality Medicines	Chief of Party
10	Dr. Gathai Mundia	Zihi Institute	Director
11	Dr. George Otieno	MOH/ Nyamira County	County Pharmacist
12	Gladys Mberia	MOH/ National Malaria Control Programme	Program Officer
13	James Mwangi	USAID/ Afya Ugavi	Technical Officer
14	Joan Manji	Kenya Medical Supplies Authority	Customer Service Analyst
15	Johana Too	MOH/ Kericho County	County Medical Laboratory Coordinator
16	Dr. Joseph Muriu	Mission for Essential Drugs and Supplies	Quality Assurance Manager
17	Dr. Kibor Keittany	MOH/ National Malaria Program: Head of Unit	Head of Program
18	Dr. Meera Shah	USG, GHSC-PSM	Technical Officer
19	Melda Nelima	MOH/ Bungoma County	County Medical Laboratory Coordinator
20	Dr. Nancy Olunga	MOH/Siaya County	County Pharmacist
21	Dr. Nazilla Ganatra	MOH	DHPT
22	Nicholas Ojwando	Kenya Medical Supplies Authority	Procurement Officer
23	Dr. Onesmus Saidimu	Pharmacy and Poisons Board	Pharmacist
24	Otieno Steve	MOH/ National Malaria Program: Program Management	Planning Officer
25	Patrick Mburugu	MOH/ National Malaria Control Programme	Program Officer
26	Paul Rumosia	MOH/ National Malaria Control programme	Global Fund Focal person
27	Dr. Pauline Duya	MOH/DHPT	Pharmacist
28	Dr. Peter Ngumo	MOH/ National Quality Control Laboratory	Pharmacist
29	Regina Kandie	MOH/ National Malaria Program: Case Management	Program Officer
30	Richard Gatukui	MOH/ DHPT	Program Officer
31	Robert Mwaura	MOH/ National Malaria Program: Procurement and Supply Management	Logistician
32	Rosebella Kiplagat	MOH/ National Malaria Reference Laboratory	Laboratory Officer
33	Dr. Samwel Kola	MOH/ Migori County	County Pharmacist
34	Sammy Gatigwa	Kenya Medical Training College	Medical Laboratory Officer
35	Dr. Sammy Mahugu	MOH/ National Malaria Program: Case Management	Program Officer
36	Tedd Atsulu	Amref Health Africa	Project Associate
37	Dr. Victor Sumbi	US State Department, Nairobi	Project Management Specialist
38	Dr. Welby Chimwani	MOH/ National Malaria Program: Program Management	Pharmacist
39	Dr. Ndinda Kusu	Jhpiego	Project Lead

Appendix 2: Malaria HPT List

The following table provides an indicative list of malaria Health Products and Technologies (HPT) used in malaria prevention, diagnosis, and treatment within Kenya's malaria programme. The definitive specifications are provided in the Malaria Programme Specifications Catalogue (2023).

Category	Product	Typical Formulation / Specification	Level of Use
Prevention	Long-Lasting Insecticidal Nets (LLIN)	WHO-prequalified LLIN	Community / Facility
Prevention	Sulfadoxine-Pyrimethamine (SP)	Tablets for IPTp	Community / Facility
Diagnosis	Malaria Rapid Diagnostic Tests (mRDT)	HRP2 / combo RDT kits	Community / Facility
Diagnosis	Microscopy Supplies	Slides, stains, reagents	Laboratory
Treatment	Artemisinin-based Combination Therapy (ACT)	AL, DHA-PPQ, ASAQ (per MFT policy)	Community / Facility
Treatment	Injectable Artesunate	60 mg vial	Facility
Treatment	Quinine	Tablets / Injection	Facility
Case Management Supplies	Syringes, gloves, sharps boxes	Standard IPC supplies	Community / Facility

The complete and approved list should be referenced from the **national malaria commodity catalogue**.

Appendix 3: Stock Management Tools

The following tools are used for inventory management of malaria HPT across the health system.

Tool	Purpose	Level
Bin Card / Stock Card/Health facility EMR	Track stock receipts, issues, and balances	Store / Pharmacy
Stock Ledger	Detailed inventory records	Store
Delivery Note	Confirms receipt of supplies	Facility
Issue Voucher (S11 / S12)	Records issuance of HPT to service points	Facility
Expiry Tracking Chart	Monitor upcoming expiries	Facility
Temperature Monitoring Log	Monitor storage conditions	Store

These tools support accurate stock control and accountability of HPT.

Appendix 4: Reporting Templates

Standard reporting tools are used for capturing malaria HPT consumption and stock data.

Level	Tool	Purpose
CHU	MOH 648 – CHU Daily Activity Register for Malaria Commodities	Capture daily service and commodity use
CHU	MOH 748 – CHU Monthly Summary Report for Malaria Commodities	Monthly HPT consumption reporting
Facility	MOH 645 – Daily Activity Register	Capture daily malaria services
Facility	MOH 743 – Facility Malaria Summary Form	Monthly malaria HPT reporting
Facility	MOH 643 – FCDRR Laboratory HPT	Laboratory commodity reporting
Facility	MOH 706 – Laboratory Summary Form	Malaria diagnostic reporting
Digital	EMR Systems	Electronic inventory and service records
Digital	eCHIS	Community health service delivery and data capture

These reports are submitted through the Kenya Health Information System (KHIS).

Appendix 5: Supply Chain Indicator Reference Guide

This appendix provides definitions of key malaria HPT supply chain indicators.

Indicator	Definition	Purpose
Reporting Rate	Percentage of facilities submitting reports	Monitor reporting completeness
On-Time Reporting	Percentage of reports submitted within reporting period	Monitor timeliness
Stock-Out Rate	Percentage of facilities with stock-out of key HPT	Monitor service continuity
Months of Stock (MOS)	Quantity of stock expressed in months of consumption	Monitor stock adequacy
Overstock Rate	Percentage of facilities above maximum stock level	Detect oversupply
Expiry Rate	Percentage of HPT expired	Monitor wastage

These indicators are monitored through KHIS malaria dashboards.

Appendix 6: Malaria HPT Data Flow

Malaria HPT data flows through the following levels:



Data sources include:

- CHU Daily Activity Registers
- Facility Daily Activity Registers
- Monthly Summary Forms
- EMR systems
- eCHIS

This data is aggregated and analyzed through KHIS dashboards.

Appendix 7: Malaria HPT Supply Chain Flow

The malaria HPT supply chain follows the structure below:



This structure ensures end-to-end visibility and efficient distribution of malaria HPT.

Appendix 8: Key Inventory Management Formulas

Average Monthly Consumption (AMC)

$$\text{AMC} = \frac{\text{Total Quantity Consumed}}{\text{Number of Months}}$$

Months of Stock (MOS)

$$\text{MOS} = \frac{\text{Stock on Hand}}{\text{Average Monthly Consumption}}$$

Quantity to Order

$$\text{Quantity to Order} = (\text{AMC} \times \text{Review Period}) - \text{Stock on Hand}$$

Appendix 9: Storage and Distribution Job Aids

Recommended job aids for malaria HPT management include:

- Good Storage Practices checklist
- Temperature monitoring chart
- Expiry tracking chart
- Redistribution request form
- Stock reconciliation checklist

These job aids support health workers in maintaining product quality and accurate inventory records.

Appendix 10: Pharmacovigilance Reporting Channels

Suspected adverse reactions or poor-quality HPT should be reported through:

System	Description
PvERS	Online pharmacovigilance reporting system
mPvERS	Mobile reporting application
USSD *271#	Mobile reporting platform
PPB Reporting Forms	Yellow and Pink reporting forms

Reports submitted through these channels are analyzed by the National Pharmacovigilance Centre.

The **Pharmacovigilance Electronic Reporting System (PvERS** is a suite of software applications designed to collect and process reports on suspected Adverse Drug Reactions (sADRs), suspected Poor Quality Health Products and Technologies (sPQHPT), Adverse Events Following Immunization (AEFIs), medication errors, incidents related to medical device use, and suspected reactions to blood and blood products. It receives reports on all products regulated by the PPB and improves report quality by supporting timely causality assessment and signal detection, providing data for evidence-based policy decision-making. This System **(PvERS)** is accessible through **Pv.pharmacyboardkenya.org** and once logged in, you can do either:

- Log in if already registered in the system
- Register as a new user
- Submit and send a report as a guest user

The platform enables users to report the following safety issues related to malaria HPT:

1. Adverse events following immunization (AEFI)
2. Suspected adverse drug reactions
3. Medical device incidents
4. Medical errors
5. Blood transfusion reactions

To use the Mobile Pharmacovigilance Electronic Reporting System (mPvERS) for reporting Adverse Drug Reactions (ADRs) and other safety events, you can access it through several official channels provided by the Pharmacy and Poisons Board. **Download the mPvERS Mobile App**. You can install the **mPvERS app** on your smartphone:

- Android**:** Available on Google Play Store
- iPhone: Available on Apple App Store.

Search for "mPvERS" (Mobile Pharmacovigilance Electronic Reporting System) and install it. The app allows you to report ADRs, AEFIs, medication errors, medical device incidents, and suspected poor-quality medicines.

Appendix 10: PPB Public Notice

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

PUBLIC NOTICE

MANDATORY INSTALLATION OF CALIBRATED THERMOHYGROMETERS WITH DOWNLOADABLE DATA CAPABILITY AS A REQUIREMENT FOR ANNUAL LICENSING

The Pharmacy and Poisons Board (PPB), established under the Pharmacy and Poisons Act (Cap 244, Laws of Kenya), is mandated to regulate the manufacture, importation, distribution, and sale of health products and technologies (HPTs) to ensure their quality, safety, and efficacy throughout the supply chain.

In line with the provisions of the PPB Guidelines for Good Distribution Practices (GDP) for Health Products and Technologies in Kenya, all stakeholders involved in the handling, transportation, storage, and distribution of HPTs are reminded that maintaining appropriate storage conditions—particularly temperature and humidity—is critical to safeguarding product integrity and protecting public health.

During recent Post-Marketing Surveillance (PMS) activities conducted by the Board, it has been observed that a significant number of facilities have not installed thermohygrometers in their storage areas. This gap compromises the assurance of the quality, safety, and efficacy of HPTs stored under such conditions. Consequently, and to address this compliance gap, the PPB reminds stakeholders of this mandatory requirement to strengthen quality assurance across the pharmaceutical supply chain.

Page 1 of 3

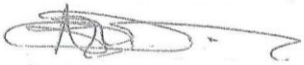
As part of ongoing efforts to strengthen PMS and promote compliance with GDP requirements, the Board hereby directs all transporters, dealers, wholesalers, distributors, and retailers to:

1. Install calibrated thermohygrometers with downloadable data capability in all transportation, storage, and handling areas used for Health Products and Technologies (HPTs) and maintain verifiable records of continuous temperature and humidity monitoring and calibration for inspection by Pharmacy and Poisons Board (PPB) officers.
2. Use pallets for storage of products to prevent direct contact with floors and to facilitate proper air circulation and protection against contamination and moisture.
3. Ensure adequate shelving to allow proper organization, identification, and segregation of products, and to avoid overcrowding or stacking that may compromise product integrity.
4. Handle all pharmaceutical products strictly in accordance with manufacturers' recommendations, including adherence to specified storage conditions, temperature ranges, and handling precautions.
5. Provide protection from light and other environmental factors that may degrade product quality, particularly for light-sensitive products.
6. Implement adequate transportation controls, including the use of appropriate vessels, monitoring gadgets, and record-keeping systems, to ensure that products are transported under conditions that maintain their quality, safety, and efficacy.
7. Ensure that all personnel involved in the handling, storage, and transportation of HPTs are adequately trained on Good Distribution Practices (GDP), proper product handling, and monitoring procedures.

These requirements apply to all facilities engaged in the distribution, wholesale, retail, or storage of health products and technologies. Compliance will ensure the integrity of HPTs across the supply chain and uphold the Board's commitment to public health protection.

For further clarification or guidance, stakeholders are encouraged to contact the Board through gdp@ppb.go.ke , pms@ppb.go.ke

Thank you for your continued cooperation in protecting public health.



Dr. Ahmed I. Mohamed
Ag. CHIEF EXECUTIVE OFFICER

03 OCTOBER 2025

Appendix: 12: MOH 645

Republic of Kenya - Ministry of Health — **Health Facility Daily Activity Register for Malaria Commodities** — **MOH 645**

Page number:

Health Facility Name: _____ Receipt date: _____

KHMFL code: _____ Ref No. _____

Qty. of RDTs (tests)	AL 20/120mg treatments				ASPY		DHAP tablets			ASAQ tablets			Inj. Artesunate 60mg (Vials)
	AL 6S	AL 12S	AL 18S	AL 24S	30/ 60 mg sachet	60/ 180 mg tabs	20/ 160 mg disp tabs	40/ 320 mg disp tabs	40/ 320 mg tabs	67.5/ 25 mg tabs	135/ 50 mg tabs	270/ 100 mg tabs	
Balance b/f from previous page (A):													
Quantities Received (B):													
Total Stock (C) = (A) + (B):													

TESTING SECTION

Date	Patient's Age Group (Tick)		TP / OP number	Malaria Test Type (Tick)						Qty of RDTs used (Indicate 1,2 etc, do not tick)
				Microscopy		mRDTs			malaria test NOT done	
	<5 years	≥5 years		POS	NEG	POS	NEG	INV		
Totals (F):										
									Losses (D):	
									Balance end of this page (F):	

TREATMENT SECTION 1 - Artemesinine-Combination Therapies (ACTs)

ACT weight/ age category (Tick only for patients given an ACT)										Qty of ACT dispensed (Indicate 1,2, 2.5 etc, do not tick)									
										AL (treatments)				ASPY		DHAP (tablets)		ASAQ (tablets)		
5 to <10 kg	10 to <15 kg	15 to <20 kg	20 to <25 kg	25 to <30 kg	30 to <35 kg	35 to <60 kg	60 to <80 kg	≥80 kg		AL 6S	AL 12S	AL 18S	AL 24S	30/ 60 mg sachet	60/ 180 mg tabs	20/ 160 mg disp tabs	40/ 320 mg disp tabs	40/ 320 mg tabs	67.5/ 25 mg tabs	135/ 50 mg tabs	270/ 100 mg tabs

Appendix: 12: MOH743

Republic of Kenya - Ministry of Health

Health Facility Monthly Summary Report for Malaria Commodities — **MOH 743**

County: _____ **Sub-county:** _____

Facility Name: _____ **KMHFL Code:** _____

Facility Type: Level 2 ⬭ Level 3 ⬭ Level 4 ⬭ Level 5 ⬭ Level 6 ⬭

Period of Reporting: Beginning: _____ (Day/ Month/ Year) **Ending:** _____ (Day/ Month/ Year)

Item Description	Basic Units	Beginning Balance	Quantity Received this Period	Total Quantity Dispensed	Losses (Excluding Expiries)	Positive Adjustments	Negative Adjustments	Physical Count	Quantity of Expired Commodities	Commodities with ≤ 6 months to Expiry	Days out of stock this month
		A	B	C	D	E	F	G	H	I	J
Malaria commodities											
Rapid Diagnostic Test (RDT)	Tests										
Artemether + Lumefantrine 20/120mg (AL) blister	6s										
Artemether + Lumefantrine 20/120mg (AL) blister	12s										
Artemether + Lumefantrine 20/120mg (AL) blister	18s										
Artemether + Lumefantrine 20/120mg (AL) blister	24s										
Artesunate + Pyronaridine (ASPY) 20/ 60mg sachet	Satchets										
Artesunate + Pyronaridine (ASPY) 60/ 180mg tablet	Tabs										
Dihydroartemesinin + Piperaquine (DHAP) 20/ 160mg dispersible tab	Tabs										
Dihydroartemesinin + Piperaquine (DHAP) 40/ 320mg dispersible tab	Tabs										
Dihydroartemesinin + Piperaquine (DHAP) 40/ 320mg tab	Tabs										
Artesunate + Amodiaquine (ASAQ) 67.5/ 25mg tab	Tabs										
Artesunate + Amodiaquine (ASAQ) 135/ 50mg tab	Tabs										
Artesunate + Amodiaquine (ASAQ) 270/ 100mg tab	Tabs										
Injectable Artesunate 60mg	Vials										
Sulphadoxine + Pyrimethamine (SP) 500/ 25mg tab	Tabs										
Long Lasting Insecticidal Net (LLIN)	Pieces										
Primaquine 7.5mg tab	Tabs										

Total Patients by Age

<5 years	≥5 years

Total Patients Given an ACT by Weight Band Category

	5 to <10 kg:	10 to <15 kg:	15 to <20 kg:	20 to <25 kg:	25 to < 30 kg:	30 to < 35 kg:	35 to < 60 kg:	60 to < 80 kg:	80 kg+
<5 years:									
≥5 years:									

Patients given inj artesunate by weight/ age

	<20 kg (<5 yrs):	20 to <50 kg (5 to <15 yrs):	50+ kg (≥15 yrs):
<5 years:			
≥5 years:			

Malaria Diagnosis Summary

	Microscopy		RDT			Total (microscopy + RDT)			Not Tested	Grand Total (Tested + Not Tested)
	Pos	Neg	Pos	Neg	Invalid	Pos	Neg	Invalid		
<5 years:										
≥5 years:										

Number of pregnant women receiving IPTp:

Number of new ANC clients:

Number of DPT/Hep+HiB1 doses Administered <1 Years:

Number of days facility was stocked out of ALL the ACTs:

Comments (including explanations of losses and adjustments):

_____

_____

Report Prepared by: _____ (Name of Reporting Officer) _____ (Signature) _____ (Designation)

Contact Telephone: _____ **Date:** _____

Report reviewed by: _____ (Sub-County Pharmacist) _____ (Signature) _____ (Designation)

Contact Telephone: _____ **Date:** _____

To be Submitted to the Sub-County by the 5th Day of Every Month

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MALARIA HEALTH PRODUCTS AND TECHNOLOGIES MANAGEMENT HANDBOOK

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