

MINISTRY OF HEALTH

Guidance for Establishment of Health Products and Technologies (HPT) Units

March 2022



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Recommended Citation

Ministry of Health, March 2022. *Guidance for Establishment of Health Products and Technologies (HPT) Units*

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Acronyms

ADR	Adverse Drug Reaction
AG	Attorney General
ARV	Anti-Retroviral
CEC	County Executive Committee
CECM	, County Executive Committee Member of Health
СНМТ	, County Health Management Team
COG	Council of Governors
СоН	Chief Officer of Health
COVID	Coronavirus Disease
DHIS2	District Health Information Software
DPs	Development Partners
EHPT	Essential Health Products and Technologies
EMMS	Essential Medicines and Medical Supplies
EVMA	Effective Vaccines Management Assessment
FBO	Faith-Based Organization
FCDRR	Facility Consumption Data Report and Request
GDP	Good Dispensing Practice/Good Distribution Practices/Gross Domestic Product
GoK	Government of Kenya
HF	Health Facility
HPT	Health Products and Technologies
HPTU	Health Products & Technologies Unit
HRIO	Health Records & Information Officer
ICT	Information and Communication Technology
JD	Job Description
KNPP	Kenya National Pharmaceutical Policy
LMIS	Logistics Management Information System
M&E	Monitoring and Evaluation
МОН	Ministry of Health
MTC	Medicines and Therapeutics Committee
MTEF	Medium Term Expenditure Framework
NCDs	Non-Communicable Diseases
0&M	Operation and Maintenance
PCV	Pharmacovigilance
PMS	Post Marketing Surveillance
PPDA	Public Procurement and Disposal Act
PPB	Pharmacy & Poisons Board
PPRA	Public Procurement Regulation Authority
PvERS	Pharmacovigilance electronic reporting system
QA	Quality Assurance
QC	Quality Control
RMNCAH	Reproductive Maternal Neonatal Child and Adolescent Health
SCHMT	Sub-County Health Management Team
TOR	Terms of Reference
TWG	Technical Working Group
UHC	Universal Health Coverage
UNICEF	United Nations Children Fund
USAID	United States Agency for International Development
WHO	World Health Organization

Foreword

The inaugural Health products and Technologies (HPT) Supply Chain Strategy 2020-2025 flagged off several persistent concerns set to be addressed over a five-year period in the HPT investment area among them inadequate transparency and accountability across the entire HPT supply chain. The strategy commits to strengthen the capacity for HPT governance, regulation and quality assurance for improved oversight and accountability at all levels of the supply chain.

Accountability refers to the ownership of responsibilities and the obligation to report on the discharge of those responsibilities. It is a critical tool in improving the health supply chain performance, from a health systems perspective, through reducing excesses, wastages and leakages, fortifying compliance with procedures and standards and embedding value for money. Specifically, the accountability framework has four basic components – Commitments, Review, Actions, Monitoring and Reporting. It defines who is accountable as individuals, facilities, departments and/or agencies including at the various levels of the HPT supply chain. It also stipulates what they are accountable for in terms of commitments and actions and how they will be held accountable through reviews and monitoring and reporting.

The overarching goal in the development of the accountability framework is to fortify the country's supply chain transparency and accountability capabilities for a sustainable impact in saving lives through improvement in accessibility, affordability and availability of essential HPT. This will ensure that resources are optimally utilized.

It is my sincere hope that counties will use this guidance in establishing, operationalizing and maintaining governance structures to ensure that all efforts are geared towards ensuring that HPT are available for provision of healthcare services in implementation of Universal Health Coverage in Kenya.

Omphi and

Dr. Patrick Amoth, EBS Ag Director General for Health MINISTRY OF HEALTH

1. Introduction

1.1 Background

Access to affordable and quality HPT is critical in the delivery of health care and attainment of desired health outcomes for the citizens of Kenya as envisaged by the Constitution of Kenya, 2010 and various national and county government policies and strategies on health. The Kenya Health Policy 2014-2030, the overarching national health policy, provides direction on required investments for improving access to and quality health services including those required in the HPT supply chain front. The policy direction is further elaborated through the Kenya National Pharmaceutical Policy (KNPP) 2012, the national health sector strategic plan 2019-2023, the Health Products and Technologies (HPT) Supply Chain Strategy 2020-2025, and various county health sector strategic plans.

On the legislative front, several Acts of the parliament and county assemblies have provisions governing various aspects of the health products and technologies supply chain from procurement, quality assurance, warehousing and distribution, rational use, to inventory management and accounting. These legislations include the Health Act 2017; Kenya Medical Supplies Authority Act 2013; Pharmacy and Poisons Act; Public Procurement and Assets Disposal Act 2015; Public Financial Management Act 2012; and County Health Services Acts enacted by most county governments. Although these legislations have been instrumental in guiding implementation in the health supply chain at various levels of the healthcare system, there are gaps that have been highlighted in terms of slow pace of implementation of policy interventions, inadequacies in governance and regulation, inadequate technical capacity, and accountability challenges.

The need to address these gaps is more than urgent bearing in mind renewed focus to attain Universal Health Coverage (UHC). Strengthening of the governance and management structures for health supply chain at the national and county level is one of the interventions in the HPT Supply Chain strategy that seeks to fill the gap. Recent experiences in revitalisation of the HPT function at the Ministry of Health and deliberations held with county teams undertaken during dissemination of the HPT supply chain strategy underline the need for guidance for county governments in strengthening their coordination structures for effective and efficient delivery of the health products and technologies mandate and improving overall commodity security. All these efforts are aligned to the requirements of the Constitution of Kenya 2010 in terms of assignment of functions in the devolved context; and fully acknowledge the mandate of individual county governments in determining the organisation of the county and their functions in accordance with the County Government Act 2012.

County governments are at different stages in the journey to having fully functional HPT Units. A variety of implementation structures have been established by counties, ranging from HPT committees, assignment of HPT coordination to focal persons or coordinators, to most recently counties setting up formalized units with dedicated staff to deliver HPT functions. The latter direction has been informed by the realization that strong governance and coordination structures for HPT at the county and sub-county level address accountability challenges, provide stronger leadership in the implementation of the National HPT policies, laws, guidelines, and strategies. Imperatively, the need for enhancement of existing structures for coordinated resource mobilization, selection, quantification, procurement, distribution, and financial management has been underlined.

1.2 Rationale and Objectives

This document provides guidance to county governments as they discharge their mandates in the HPT supply chain. County governments have established various structures dealing with the HPT functions and face different challenges in their health supply chains. Significant challenges include establishment of appropriate governance structures for effective coordination and sustainable delivery of unique aspects of the health products and technologies supply chain whilst appreciating the significance of budgetary spending in this area. The rationale for this guidance is to provide appropriate standards for consideration by county governments as they establish/streamline their HPT supply chain functions. The specific objectives are:

- Strengthen county stewardship/leadership role in HPT supply chain including improved coordination and partnership structure.
- Provide a viable oversight, HPT planning, and monitoring and supervision system from the county level to the facility level.
- Refocus HPT supply chain on the essential HPT concept for effective selection, quantification, procurement, distribution, and rational use.
- Coordinated resource mobilization and financial management for county HPT supply chain system.
- Strengthen the HPT management capacity of all county health facilities through training and the provision of appropriate supporting environment.
- Strengthen mechanisms for monitoring/addressing pharmacovigilance-related information.
- Establish appropriate structures for the promotion of essential HPT concept to ensure safety, efficacy, quality, availability, affordability, accessibility, and rational HPT use.
- Establish dynamic interactions between stakeholders in county health supply chain including, health care providers and consumers, to improve the quality, accountability, and responsiveness of services.

This guidance provides basic principles for establishment of an effective county HPT function that is essential for effective management of HPT in the county.

The guidelines provide amongst other aspects: the basic principles of an elaborate health products and technologies function; roles and responsibilities of the HPT function; required skills and competences; accountability and anchorage; and steps in setting up a fully functional HPT unit.

Strengthened **County Health** Products and **Technologies** functions will ensure that effective, safe, and affordable health products and technologies are available and rationally used, while maintaining harmonious relationships with relevant stakeholders in the health supply chain for sustainability.

2. Guidance Framework

2.1 Principles

The following principles were considered and adopted in the development of this guidance:



Responsiveness

There will be an aspiration to meet the changing needs of clients for quality health care services by providing direction on appropriate medicines use, and coordination and strengthening of HPT management. All issues related to health products and technologies and their use, shall be responded to in a timely manner.

Accountability

There shall be an endeavour to provide information, reports, data, and feedback to stakeholders regarding activities and various interventions in ensuring availability and access to quality health products and technologies.

Clarity

It will be ensured that activities and interventions are well elaborated so that there is a clear understanding of mandate, roles and responsibilities, activities and interventions, challenges, and opportunities in ensuring quality health products and technologies are available and accessible.

Quality orientation

Efforts will be made towards ensuring provision of health products and technologies, services as well as related information of the highest standard attainable.

Participation

In principle, a participatory approach will be encouraged and enhanced, where key stakeholders are involved in decision making for delivery of HPT related services and interventions.

Sustainability

Interventions or activities will be designed, and functions carried out, in a manner that can be sustained, replicated and scaled-up without the need for over-reliance on external support. As much as possible internal resources (human, infrastructural and financial) should be explored to support the HPT units.

Intersectoral approach

A system that incorporates various sectors will be adopted to enhance synergies thus avoiding duplications. The sectors will share responsibilities, information, lessons, and experiences to enrich interventions.

Flexibility and adaptability

Structures, systems, and approaches that are able to change with time and circumstances, to best suit the situation and for implementation of their mandate, functions and activities shall be adopted.

2.2 Terms of Reference of HPT Units

The roles and responsibilities of the HPT units are anchored on the overarching goal of ensuring access to HPT of assured quality, safety, efficacy, and cost effectiveness. This is in appreciation of health products as a significant investment area in the framework for health systems. In defining the specific terms of reference for the county HPT units, county governments should consider the following:

- a) Implementation of national policies, standards, guidelines and regulations on HPT
- b) Coverage of various components of HPT including medicines, vaccines, medical supplies, laboratory supplies, radiology supplies, dental supplies, rehabilitation supplies and technologies.
- c) Aspects of affordability including gathering information on prices and building capacity to negotiate prices.
- d) Aspects of production practices and quality assessment of priority products
- e) Aspects of procurement, supply, and storage and distribution systems for minimising leakages and other waste
- f) Support for rational use of essential medicines, medical supplies, and equipment, through strategies for adherence, reducing resistance, maximising patient safety and training.
- g) Support in improving transparency and reducing potential vulnerability to corruption especially in selection and procurement of HPT.

Roles and responsibilities presented in the table that follows are categorized into five - those relating to policy, organization and supply chain management; those relating to core supply chain management of selection, procurement, distribution and use; roles linked to the patient and community; roles linked to research, monitoring and evaluation & learning; and those relating to planning, resource mobilization and partnerships.

The county Health Products and Technologies Unit will be responsible for, but not limited, to the following:

	Category	Roles and Responsibilities
1	Roles related to health policies, organization and supply chain management	 <i>Health Policies</i> Provide strategic direction in HPT supply chain delivery through development of supply chain policies, guidelines, operational procedures and standards.
		• Participate in and carry out the formulation, implementation, and evaluation of HPT policies, within the area of influence of the service.
		• Establishing standards for the county HPT supply chain staff and ensure there is compliance
		Organization
		 Participate in the development and updating of the legislation and setting of norms for HPT services and complying with active legislation (including ethical/ bioethical aspects)
		• Facilitate the actions of the regulatory agencies for HPT through enforcement of legal/regulatory framework; best practice standards; monitoring mechanisms; supportive supervision and other mechanisms.
		• Plan, implement, manage, and evaluate HPT services in ways that are integrated national and county health system.
		 Promote access, quality, safety, and rational use of HPT
		• Contribute to the protection of health and safety of the population and the environment.
		• Implement and coordinate or participate in Medicines and Therapeutic Committees (selection of medicines) or other committees related to HPT services.
		Supply Chain Management
		 Coordinate administration and manage the supply of HPT.
		• Determine and make recommendations for the development expenditure to improve efficiency of HPT supply chain services.
		• Manage the availability and promote rational use of HPT in situations of disaster mitigation and prevention and emergencies.
		Ensure product security and risk management
2	Roles related to	a) Manage the appropriate storage and distribution (including redistribution) of HPT.
	HPT (medicines, medical supplies, diagnostics) management	b) Monitoring effective storage of specialized medical supplies.
		c) Implement the necessary measures to guarantee the quality of HPT throughout the county health supply chain.
		d) Implement the necessary measures for the appropriate regulation of waste from HPT.
		e) Promote pharmacovigilance within the county.
		 f) Coordinating resolution of health supply related issues through interventions such as redistribution of stocks among facilities, recommending therapeutic alternatives and use of alternative pack sizes or dosage strengths working in close collaboration with the county MTC
		g) Facilitate coordination of ordering, purchasing, storing, dispensation and distribution of HPT for countywide health services delivery.

3	Roles directly linked to the patient, community, and citizens	 a) Develop and support programmes and activities for health prevention, health promotion, protection and rehabilitation. b) Develop activities for the promotion of rational use of HPT aimed at the public and the other members of the county health team. c) Develop and participate in pharmacovigilance, pre-market and post market surveillance programmes
4	Roles to research, monitoring and evaluation and learning	 Research Conduct research in HPT related matters and adopt new technologies and innovations <i>M & E</i> Promote and participate in the design, monitoring and evaluation of HPT. Reviewing reports from county health facilities to determine utilization rates and trends. Promote information sharing on HPT <i>Learning</i> Promote continuous learning of human resources for health Promote implementation and sharing of best practices Coordinate mentorship and on-the-job training in HPT management
5	Planning, Resource Mobilization and Partnerships	 Planning Adopt demand and supply planning for HPT Align HPT budgeting, implementation and expenditure monitoring for HPT in line with strategic goals and policy direction. Implement resource planning and utilization at health facilities Facilitate health supply chain optimisation within the county Resource mobilization Develop funding proposals for HPT supply chain Undertake resource mobilization for HPT Oversight of utilization of mobilized resources Prepare utilization reports to donors Partnerships Stakeholders coordination and engagement Liaison between the County, DHPT and partners Alignment of stakeholder support for HPT capacity building

Partnerships

The current health sector partnership framework is guided by the Kenya Health Sector-strategic and Investment plan 2019-2023, and is intended to improve effectiveness of health activities. The framework aims at providing an enabling environment to achieve harmony and synergy among all health stakeholders to improve health of the population. The partnership principles focus on country ownership, alignment, harmonization, managing for results, and mutual accountability. This approach is anchored on joint planning, budgeting and monitoring frameworks for service delivery. These principles are harmonized by the constitution of Kenya, 2010 across health system. A common monitoring and evaluation is one of the key elements of the partnership framework.

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Benefits of HPT Partnerships

The benefits of HPT partnerships include; well-structured partnership arrangement, increased communication and shared accountability; coordination of efforts, harmonization and aligned reporting procedures; description and mobilization of technical and financial support for implementing HPT priorities; commitment to regularity of sharing consolidated feedback within shorter time frame; and developing strategies to explore possible solutions to challenges and provide support for the Health Sector.

Aligning stakeholders to support HPT capacity building

Stakeholder coordination is one of the critical drivers of convergence in the health sector currently articulated through the "three ones" principle – which requires all stakeholders to operate within one planning framework, one funding mechanisms and One M & E framework. It is important that policy makers are engaged more at macro-level to avoid more challenges and win the political commitment which may have an effect on developing and implementing the three ones. These will also ensure the health sector is supported through allocation of sufficient resources, securing national and county support and increasing the participation level of national and county implementers.

Monitoring & Evaluation

The M & E partnerships support communication, coordination and harmonization of efforts to achieve the ideals of quality service delivery in the health sector. The HPT partnerships should be aligned to the Kenya Constitution 2010 for access to health. The following milestones should be monitored during the establishment and operationalization of the HPT units:

- Inception meeting with County Leadership
- Feedback to County Department of Health
- Sensitization of the larger CHMTs and SCHMTs
- Develop concept paper and TORs for HPTU
- Develop the HPTU structure, roles and organogram
- Sensitize S/CHMT on HPTU organogram & TORs
- Advocacy meetings for buy-in and institutionalization
- Appointment of HPTU members
- Launch & Operationalize the HPTU
- HPTU stakeholders progress review meeting, M & E

Sustainability of the HPT units is critical to effective supply chain management and counties should therefore ensure there is:

- 1) A quarterly/annual HPTU work plan with key performance indicators
- 2) Periodic capacity assessment of the HPT unit
- 3) Annual resource mobilization plan
- 4) HPTU anchorage in county legislation
- 5) Continuous supervision, auditing, and feedback for both public and private health facilities on appropriate HPT use.

Research

Research plays an important role in informing policy changes and identification of capacity gaps in the supply chain. HPT units will be expected to undertake regular research within the county to inform decision making and create new knowledge in the supply chain space. The HPT Unit should therefore:

- Identify a focal person for HPT research within the County to build the capacity and ensure effective coordination and priority setting among research institutions/stakeholders.
- Establish County Health Observatory for assuring comprehensive analysis of Health Information linked with other key research institutions such as KEMRI and universities.
- Enhance investment on research and evidence generation to guide practice and implement innovations
- Link research and capability for local production of essential HPT

2.3 Accountability

The HPT structures will strengthen coordination of the county health supply chain system. The structure will support the county health departments and the county government at large in accountability for HPT. In this regard, the functional structure adopted will seek to advance accountability in various dimensions including the following: Clarity on who is accountable as individuals, health facilities, county teams and technical committees for various aspects of the county health supply chain; clarity on commitments and actions; and mechanisms for reviews, monitoring and reporting.

In view of the significance of the investments that county governments commit to the HPT area, the diversity of the products, and also the complexity of health supply chain it is important that the functional structure adopted also effectively supports: compliance with the rules, laws and regulations, standards applicable to the various health products from medicines, medical supplies to medical devices; professional accountability through ensuring that the health workers involved with various components of the health supply chain including inventory management uphold the set standards; mutual accountability including relationships with the key stakeholders such as regulatory institutions, development partners, implementation partners, suppliers and the citizens as users of the health products.

To effectively support and synergize existing structures, the county HPT function should be established as a Directorate/ Department/Division within the Department of Health Services.

- The HPT unit will serve as the Secretariat for the County Medicines and Therapeutics Committee
- The HPT unit should also have linkages with the Ministry of Health, Directorate/Department of Health Products and Technologies
- The HPT unit should have linkages with the regulatory institutions in the health supply chain space.

2.4 Requisite Skills and Competencies

For effective and efficient delivery of the county health supply chain functions elaborated above, there is need for county governments to ensure that the HPT functions are equipped with requisite skills, knowledge, and technical capacity to implement HPT supply chain related activities. Staff in the unit should have and be able to undertake the following:

- Have broad knowledge on health products and technologies.
- Possess sound knowledge of legislation relating to health products and technologies as well as supply chain in Kenya.
- Develop and implement health procurement and supply chain plans.
- Develop and implement health products and technologies quantification plans and forecasts.
- Managing HPT purchasing systems
- Identify, develop, monitor and evaluate indicators for health supply chain.
- Collect, analyse, manage and interpret health supply chain data.
- Communicate and disseminate HPT and supply chain services information.
- Manage and lead the teams at the various levels of the of the county health supply chain.
- Manage HPT inventory, requisitioning, storage and distribution methods.
- Uses and application of information technology in health supply chain operations and optimization.
- Appreciation of quality assurance and improvement in the management of HPT
- Preparation of HPT budget estimates
- Establishing and maintaining effective working relationships with HPT supply chain stakeholders

2.5 Composition

Based on the functions and requisite skills and competences, the county health products, and technologies (HPT) units should have at least four full time persons to effectively deliver the mandate. This team should be effectively linked to the sub-county health sector structures.

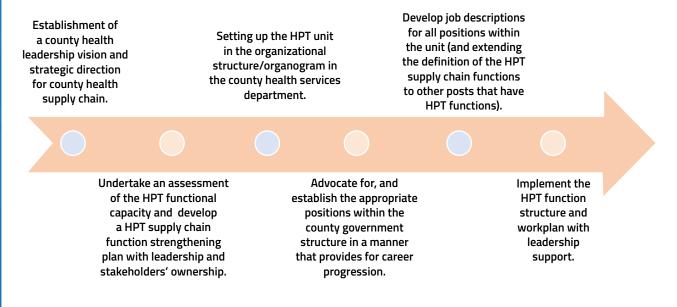
The core team should have the following.

- Head/Coordinator/Manager: responsible for overall coordination, liaison, policy/guidelines issues and serving as the chair for the county HPT security technical working group
- **Quality Assurance Lead:** Acts as Deputy Head of HPT function, coordinates capacity building, product inspections and surveillance, pharmacovigilance and rational use activities
- **Supply Chain Lead:** responsible for sub-counties coordination, budgeting and resource mobilization for HPT, quantification, procurement and accountability monitoring
- Logistics Management Information System (LMIS) Lead: responsible for information management systems for HPT, M & E, data reviews, monthly commodity reporting, data quality assurance (DQAs)

2.6 Road map for establishment of the HPT Units

A functional county HPT Unit should have a clear mandate, clear leadership structure, job descriptions for the HPT unit staff and adequate number of skilled staff in health supply functions. The following steps are proposed in establishing the HPT functions at county level.

- 1) Establishment of a county health leadership vision and strategic direction for county health supply chain. The support of the County Health Executive Committee Member (CECM) for Health is critical in establishing the unit and anchoring it at the appropriate level.
- 2) Undertake an assessment of the HPT functional capacity (guided by the functions elaborated in this document). The findings then support development of a clear HPT supply chain function strengthening plan with leadership and stakeholders' ownership.
- 3) Setting up the HPT unit in the organizational structure/organogram in the county health services department ensuring proper alignment, positioning for leadership support, availability of skills and competences, clear linkages within the health and other departments, and resources preferably through dedicated budget lines.
- 4) Advocate for establishment of appropriate positions within the county government structure in a manner that provides for career progression.
- 5) Develop job descriptions for all positions within the unit (and extending the definition of the HPT supply chain functions to other posts that have HPT functions) even though at different levels of the county structure. The job descriptions should embed clear reporting lines.
- 6) Implement the HPT function structure with leadership support.



Step 1:

Development of the county health supply chain vision and strategic direction The vision for the county health supply chain would ordinarily be captured in the overall county health sector plan, the county integrated development plan, and county health department's strategic plan. A clear understanding of the strategic direction will facilitate identification of priorities and thus focusing the establishment of the appropriate structures for the health supply chain to support the delivery of overall objective and desired outcomes. It will also facilitate identification of the metrics (performance indicators and targets) that the county government applies in monitoring the effectiveness and efficiency of the county health supply chain. The support of the County Health Executive Committee Member (CECM) for health is critical in establishing the unit and anchoring it at the appropriate level.

Step 2: Assessing the HPT Functional Capacity

It is important that county governments undertake an assessment of the county health supply chain so that they have a clear understanding of the performance, operational capacity, and capability of the heath products supply chain at all levels in the county. The assessment will support the identification of the progress made in implementation and the attendant gaps. Further, it will also support establishment of appropriate baselines and targets for monitoring progress of implementation including baselines for monitoring HPT stock availability and logistics data quality. The assessment will also assist in providing evidence for crafting the county health supply chain strategic interventions. The assessment should generally cover the functional areas of an effective health supply chain including:

- Core functions such as forecasting and supply planning, procurement, warehousing, storage and distribution, logistics management information system (LMIS), quality management and rational use and waste management.
- Similarly, supportive aspects strategic planning and management, governance, human resource, and financing should be assessed and documented. County governments could consider applying assessment tools¹ that are comprehensive enough to capture capacity and performance in these areas.

In undertaking these assessments, it is important also for quantitative data to be obtained on key health supply chain indicators such as stock out rates for tracer commodities at health facilities, forecasting accuracy, extent of functionality/ effectiveness of technical committees such as the Medicines and Therapeutics Committee (MTCs at county, sub-county and facility levels); facility reporting rates on HPT; budgetary allocation and expenditure performance on health commodities and related systems strengthening components.

County governments should strategically and thoughtfully undertake assessments to identify opportunities for improving performance. Adaptation of tested tools and approaches will help counties in focusing attention and reducing duplications. Joint assessments could be undertaken with stakeholders such as development and implementation partners, Public Procurement Regulatory Authority (PPRA) and Ministry of Health. The critical consideration in undertaking the assessments is ensuring that they are fit for the purpose and relevant. For instance, in assessing the county health supply chain aspects for immunization, counties can leverage on the Effective Vaccines Management Assessment (EVMA).

¹Such assessment tools include the Supply Chain Maturity Assessment Tool (SMAT), the EVMA Tool, and the NSCA Tool

Step 3:

Setting up the HPT unit in the organizational structure/organogram in the county health services department ensuring proper alignment, positioning for leadership support, availability of skills and competencies, clear linkages within the health and other departments, and resources preferably through dedicated budget lines. The setting up of the HPT unit should be informed by the results of the county health supply chain assessment and the implementation plan adopted by the county government. The overarching priority in the set up should be to ensure that all necessary supply chain functions are covered by the functional structure chosen. Further, it is critical that the existing county entities carrying out the supply chain functions are empowered, and that the respective roles, responsibilities, and relationships among the various actors in the county health supply chain are well understood. The responsibilities considered should also include those for capacity building in health supply chain to improve performance as well as staffing for the supply chain functions such as storage and inventory management of health commodities, dispensing, waste management, pharmacovigilance and reporting. Acknowledgement of the importance of quality management functions such as quality testing of health commodities, enforcement of guidelines and standard operating procedures for various aspects of the county health supply chain is critical in support of the county government goals of reducing risks associated with poor quality, unusable and expired commodities in the county health supply chain.

Step 4:

Advocate for establishment of appropriate positions within the county government structure in a manner that provides for career progression

Step 5:

Develop job descriptions for all positions within the unit (and extending the definition of the HPT supply chain functions to other posts that have HPT functions) even though at different levels of the county structure As clarity is obtained in the relevance and appropriateness of HPT functional unit, the health department leadership should advocate for the creation of the positions in the county public service establishment. The County Human Resources Advisory Committee (CHRAC) and the County Public Service Board should be engaged in this regard. County governments should also obtain the approval of the County Executive Committee of Health. Where county governments deem it fit to establish the units and anchor them as critical service delivery components in their legislation governing health services, then the further engagements with the County Assembly through the County Assembly Health Committee should be pursued. Some suggested provisions are included in Appendix II.

Once the positions have been established, job descriptions that aptly capture the roles of the positions established in the HPT functional structure are developed and/or reviewed. Job descriptions document the duties, responsibilities, reporting relationships, critical performance areas and working conditions in relation to the established positions. They may also detail the minimum qualifications, experience, and competences (skills, knowledge, and behaviour) that the holders of those positions are expected to possess.

The development and/or review of the job descriptions should be undertaken after job analysis so that county teams are able to make appropriate determinations on whether to develop new or update the contents of existing job descriptions to reflect changes arising from the positions created. The job descriptions should be validated by the county health management team and the county health leadership team to ensure that they truly reflect the duties, tasks, responsibilities and specifications of the jobs in the HPT units.

The job descriptions should be shared with the Human Resources Department for review, confirmation, and presentation at the County Human Resources Advisory Council (CHRAC). The CHRAC approves the job descriptions that have been validated by the Department of Health leadership with the guidance of the Human Resources Department. The approved Job Descriptions are signed off by the Head Human Resources and the Chief Officer of the Department of Health as the authorized/accounting officer.

Step 6: Implement the HPT function structure with leadership support The established HPT Units should have elaborate work plans and dedicated budgets developed on annual basis and reviewed quarterly. Progress made by the units in terms of delivery of their mandates will be monitored through quarterly reviews and reports.

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27	Susan Njogo	Africa Resource Centre
28	Tom Menge	MOH - Division of Health Products & Technologies
29	Tracy Njonjo	MOH - Division of Health Products & Technologies
30	Victor Sumbi	Afya Ugavi

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Appendix I: Sample Job Descriptions

Job Title: Head/Coordinator/Manager/Director of HPT Unit

Directorate/Division/ Unit/Section	County Health Products and Technologies Directorate/ Division/Unit	
Reporting Relationships	Reports to the County Director of Health Services.	
	• Direct reports to this position from: Quality Assurance Lead, LMIS lead and Supply Chain Lead.	
	• Indirect reports from the sub-county coordinators or focal persons for HPT, health facility in-charges, procurement/supply chain officer	
Job Purpose	Responsible for overall coordination, liaison, policy/guidelines issues and serves as the chair for the county HPT security technical working group	
Key Responsibilities/ Duties/Tasks	• Developing the HPT unit's strategic operating plans, which reflect the long-term objectives, vision, mission, values and priorities.	
	• Aligning and mobilizing stakeholder, staff time, energy, material and financial resources to support the HPT Unit's goals and priorities.	
	• Motivating staff for commitment and continuous learning for adaptation and continuous improvement.	
	 Maintaining ongoing dialogue with technical officers in the health depar as a lead technical health products and technologies advisor and implement 	
	 Implementing adequate operational strategic planning; management (structure processes, and procedures); and financial control systems 	
	 Ensuring that the operating objectives and standards of performance understood and followed by the implementing HPT unit staff to achieve def results. 	
	• Closely monitoring and evaluating achievements and results against plans; continuously updating information from M & E and the LMIS; using feedback to adjust plans, structures, systems and processes for future results.	
	• Taking remedial action where necessary and informing the department of health services of significant changes	
	Maintaining the operational performance of the HPT Unit	
	• Providing guidance in formulating all health products and technologies related laws and regulations for the county department of health services.	
	• Participating in the development of all other health-related policies and laws that have or may affect HPT.	
	• Encouraging public-private partnerships to improve access to affordable HPT.	
	• Ensuring adherence to the national HPT policy and guidelines in the county health facilities	
	• Advising and championing county programs for appropriate and safe use of HPT	

Job Title: Quality Assurance Lead

Directorate/Division/Unit/Section	County Health Products and Technologies Directorate/ Division/Unit	
Reporting Relationships	 Reports to the County Head of the HPT Unit. Direct reports to this position from: Pharmacovigilance coordinator, MTC Chair & Secretary, Disease surveillance coordinator. Indirect reports from the sub-county coordinators or focal persons for HPT, HPT leads at hospitals, health facility in-charges. 	
Job Purpose	 Responsible for capacity building in HPT, product inspections and surveillance, pharmacovigilance and rational use activities. Acts as Deputy Head of the HPT Unit. 	
Key Responsibilities/Duties/Tasks	 In terms of rational Use, the Quality Assurance Lead will: Manages the review and updating of National Essential HPT List(s) in collaboration with the relevant stakeholders. Ensures compliance with standard treatment guidelines. Collaborates with training institutions to incorporate problem-based HPT training. Coordinate program for consumer awareness about appropriate HPT use Develop a mechanism for empowering communities to practice HPT rational use. Collaborate with the regulatory agencies including Pharmacy and Poisons Board (PPB) to enforce regulations that will ensure quality, safety, efficacy, and accountability for HPT. Coordinate the establishment of the county and hospital Medicines and Therapeutics Committee (MTC)². Coordinate design and conduct of operational research on matters relating to rational HPT use, affordability and HPT benefits. Ensure periodic updating of formularies, guidelines, policies, and other reference materials to promote rational HPT use. Coordinate development of HPT quality assurance and rational utilisation tools for use in county health facilities Monitoring of manufacturing of therapeutic commodities by county health facilities Ensuring adherence to the national HPT policy and guidelines within the county Serving on policy making committees within the county, such as the County MTC, to influence rational use within the county. 	

²Medicines and Therapeutics Committee (MTC) are multidisciplinary bodies that coordinate medicines and therapeutics use policies and implement and evaluate interventions to promote rational medicine use in the county and county health facilities.

Job Title: HPT Supply Chain Lead

Directorate/Division/Unit/Section	County Health Products and Technologies Directorate/ Division/Unit		
Reporting Relationships	 Reports to the County Head of the HPT Unit. Direct reports to this position from: County and Sub-county commodi managers. Indirect reports from the sub-county coordinators or focal persons for HPT, HPT leads at hospitals, health facility in-charges. 		
Job Purpose	Responsible for sub -counties coordination, budgeting and resource mobilization for HPT, quantification, procurement, accountability monitoring		
Key Responsibilities/Duties/Tasks	 Ensure maintenance of appropriate HPT inventory levels, order, and refill levels Ensuring placement and expediting of orders; verification of HPT receipts and appropriate segregation of expired HPT Participates in supply chain supervision from county to sub-county and county health facilities to aid in mentoring HPT staff and ensuring good storage practices, proper inventory, management, and good quality data. Supporting procurement of health commodities for county health facilities to assure an adequate supply of quality products. Ensuring that security and proper storage conditions are in place for all HPT. Ensuring that proper records, such as consumption data, stock status, procurement, and costs of HPT are in place. Conducting training on the HPT supply management for health staff Supporting evidence-based quantification of HPT for the county and following national HPT quantification guidelines for procurement decisions Coordinating the timely delivery and distribution of commodities to health facilities based on needs that are determined using health facility data. Monitoring storage conditions for HPT in the county and formulating recommendations to create appropriate conditions for storage and distribution Advising on risk control management during distribution of health products and commodities to county health facilities Conducting training on the HPT supply management for health staff within the county 		

Job Title: Logistics Management Information System (LMIS) Lead

Directorate/Division/Unit/Section	County Health Products and Technologies Directorate/ Division/Unit		
Reporting Relationships	 Reports to the County Head of the HPT Unit. Direct reports to this position from: County and Sub county HRIOs. Indirect reports from sub-county coordinators or focal persons for HPT, HPT leads at hospitals, health facility in-charges. 		
Job Purpose	Responsible for information management systems for HPT, M & E, Data review, monthly commodity reporting, data quality assurance		
Key Responsibilities/Duties/Tasks	 Responsible for processing the data into information for use in planning activities, estimating demand, allocating resources, and monitoring and evaluating HPT management operations. 		
	 Promote use of appropriate HPT indicators to monitor performance to improve accountability. 		
	• Support implementation of LMIS with end-to-end visibility		
	 Establish a mechanism to provide feedback to the reporting facil and to stakeholders. 		
	 Coordinate integration of HPT data collection, processing, and presentation of information on health commodities 		
	 Developing, producing, and providing HPT information products such as bulletins, fliers, and other resources 		
	 Undertaking ongoing review of the extent of implementation of HPT activities and achievement of targets 		
	 Analysing progress toward meeting established county health supply chain objectives, goals, and results 		
	 Supervising regular data collection and ensuring data quality through random verification and validation 		
	• Analysing and discussing findings based on regular monitoring data.		
	 Supporting and/or collaborating with partners to conduct baseline and key performance indicator surveys. 		
	 Liaising with other units within the county health department as well as county health facilities for operational research 		

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Appendix II: Legislative Provisions

It is expected that the County Health Products and Technologies Units will support the County Health Management Teams in the achievement of their objectives as assigned the County Executive Committee Member for Health. The suggested provisions are therefore meant to elaborate the role of HPT Units in this endeavour.

Establishment of Health Products & Technologies Units

Proposal One

Health Products and Technologies Unit

- XX. 1) There shall be established in the Department, The Health Products and Technologies Unit
 - 2) The unit shall comprise of technical officers with background, skills and competences in management of medicines, medical supplies and diagnostics and health supply chain
 - 3) The Health Products and Technologies Unit shall
 - (a) ensure that essential Health Products and Technologies are available and accessible in each county health facility.
 - (b) ensure that the Health Products and Technologies are of good quality and are rationally used within the health facilities, meeting the standards prescribed under any written law.
 - (c) adopt appropriate measures for ensuring cost effectiveness in product selection, quantification, warehousing and storage and supply chain management information systems for Health Products and Technologies.
 - (d) collaborate with the county and sub county health management teams and officers in charge of county health facilities.
 - 4) Officers in charge of county health facilities shall provide the necessary support and information to the Health Products and Technologies Unit to enable it carry out its functions.
 - 5) The Health Products and Technologies Unit shall prepare and submit, a report on quantification of all health products and technologies to the County Executive Committee Member annually

Proposal Two

- (1) The Department shall
 - (a) develop and implement a system which ensures that essential medical supplies are available and accessible in each county health facility.
 - (b) ensure that the medical supplies are of good quality and meet the standards prescribed under any written law; and
 - (c) adopt appropriate measures for ensuring cost effectiveness in procurement, supply, storage, and distribution systems for medical supplies.
 - (d) ensure there is deliberate focus on the essential HPT concept for effective selection, quantification, procurement, distribution, and rational use.

2) The Executive member shall establish structures for health products and technologies supply chain coordination, monitoring and management, including.

- i) county health products and technologies unit,
- ii) county health commodities security technical committees,
- iii) county Medicines and Therapeutics Committee
- iv) hospital Medicines and Therapeutics Committees

Proposal Three

 XX. (1) The County Executive member shall in consultations with the County Health Management Team establish a Health Products and Technologies Unit whose functions shall include, but not limited to: -

- a) Ensuring that essential Health Products and Technologies are available and accessible in each county health facility.
- b) Ensuring that the Health Products and Technologies are of good quality and are rationally used within the health facilities, meeting the standards prescribed under any written law, and for the user departments to be involved in meeting this objective.
- c) Adopting appropriate measures for ensuring cost effectiveness in product selection, quantification, warehousing and storage and supply chain management information systems for Health Products and Technologies.
- (2) In establishing the unit under (1), the Executive member shall ensure that the unit is appropriately and adequately equipped with technical staff to handle all core aspects of county health products and technologies supply chain

General Section on the Health Products and Technologies

(1) The County Executive Member for Health shall —

- (a) establish appropriate structures for the promotion of essential health products and technologies concept to ensure safety, efficacy, availability, affordability, accessibility, and rational use
- (b) establish a county essential medicines and medical supplies list as per level of care which shall be reviewed from time to time as may be determined.
- (c) establish a system which ensures that the county essential medicines and medical supplies are available and accessible as per the level of care in each county health facility.
- (d) ensure that the medical supplies are quality-assured and meet the standards prescribed under any written law
- (e) adopt appropriate measures for ensuring cost effectiveness in procurement, supply, storage and distribution systems for essential medicines and medical supplies.
- (f) establish a catalogue of medical equipment with clear technical specifications to guide procurement which may be reviewed from time to time as may be determined.
- (g) ensure that donations of medicines and medical supplies meet the prescribed national standards of quality and safety
- (h) ensure that disposal of medical supplies, medical and non –medical equipment is as per the prescribed laws and regulations

Appendix III: HPT Unit Functionality Checklist

	Description	Yes/No	Comments
1	Established in County Department of Health with approval of the County Executive Committee (CEC) and County Public Service Board (CPSB)		
2	HPT Unit Charter with clear Vision and Mission		
3	Terms of Reference and Organogram in place		
4	Job Descriptions Developed/Revised		
5	HPT Unit staff deployed		
6	HPT Unit developed and implementing Annual Work plan with clear performance matrices		
7	Has an updated stakeholder's inventory		
8	Holds quarterly/bi-annual/annual review meetings		
9	Holds annual stakeholders meeting		
10	HPTU has budget allocation from county		



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