REPUBLIC OF KENYA

MINISTRY OF HEALTH

GUIDELINES ON MANAGEMENT OF HEALTH PRODUCTS AND TECHNOLOGIES IN KENYA

OCTOBER 2020

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Guidelines on Management of Health Products and Technologies in Kenya

October 2020

Recommended Citation

Ministry of Health. Guidelines on the Management of Health Products and Technologies in Kenya. 2020. Nairobi, Kenya.

ACKNOWLEDGEMENT

The Ministry of Health and in particular the Division of Health Products and Technologies (DHPT) wishes to acknowledge the support and contribution made by various partners and stakeholders towards the development of these guidelines. We greatly appreciate USAID, through Afya Ugavi, for their funding and technical support in the development process of this guideline.

Finally, we acknowledge the invaluable inputs of all experts drawn from the Government and other stakeholders. We also recognize the contribution of the reviewers who took their valuable time to review and edit the content of these guidelines to ensure they are comprehensive and meet the desired standards.

FOREWORD

The Health Sector has a mandate of providing health care services in response to the population needs in line with the goals of the *Kenya Health Policy 2014-2030*, which is, ensuring significant improvement in the overall status of health in Kenya in line with the *Constitution of Kenya 2010*.

Overall, the Health Sector strategic focus is guided by the Country's blueprint, *Vision 2030* and the *Constitution of Kenya, 2010*. The Kenya Vision 2030 aims to transform Kenya into a globally competitive and prosperous country with a high quality of life by 2030, while the Constitution of Kenya, 2010, guarantees the highest attainable standard of health as a right.

The Kenya Government is implementing Universal Health Coverage (UHC) as one of its four flagship programs dubbed *"The President's Big Four Agenda"*. This program, which is in line with *Sustainable Development Goals (SDG) 3*, has an overarching goal of ensuring that all citizens have access to safe, effective, quality essential health care services, including affordable essential medicines and vaccines without suffering catastrophic expenditure. Ensuring that effective, safe, and affordable health products and technologies are available and rationally used, is pivotal to a functioning health care system that supports the UHC agenda. As such, the policies, regulations, systems and practices regarding health products and technologies have a direct bearing on access to, quality and safety of healthcare services delivered to citizens in need.

The policy direction envisages that investments in health systems will be scaled up for improved health outcomes. Amongst its objectives are improved service quality, responsiveness, efficiency and effectiveness in the delivery of the *Kenya Essential Package for Health (KEPH)*.

The KEPH is operationalized through six levels of service:

- Level 1 - Community Units
- Level 2 - Primary Care Service Units (Dispensary/Clinic)
- Level 3 - Primary Care Service Units (Health Centre)
- Level 4 - Primary Referral Service Units
- Level 5 - Secondary Referral Service Units
- Level 6 - Tertiary Referral Service Units

These guidelines have been prepared in line with the *Health Products and Technologies Supply Chain Strategy 2020-2025* as a sound response to key challenges in the sector regarding HPT supply chain. They have been prepared in response to the need to harmonize the procedures for essential health products and technologies management throughout the various levels of service delivery under the KEPH. They are targeted at health facility staff handling HPTs in various ways, including those working under the health programs.

FOREWORD

The guidelines aim to provide them with information, procedures and tools required to ensure regular and reliable supply of HPTs, their appropriate storage, control and issuing.

Dr. Patrick Amoth, EBS
Ag Director General for Health
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ABBREVIATIONS & ACRONYMS

DHPT	Division of Health Products and Technologies
AIDS	Acquired Immunodeficiency Syndrome
ARC	Africa Resource Centre
CHMT	County Health Management Team
DAR	Daily Activity Register
GDP	Good Dispensing Practices
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HPT	Health Products and Technologies
ICC	Inter-Agency Coordination Committee
INN	International Non-proprietary Name
IRV	Issue and Receipt Voucher
KEDL	Kenya Essential Diagnostics List
KEML	Kenya Essential Medicines List
KEMSA	Kenya Medical Supplies Authority
KEMSL	Kenya Essential Medical Supplies List
KEPH	Kenya Essential Package for Health
LMIS	Logistics Management Information System
MELR	Monitoring Evaluation, Learning and Research
MTC	Medicines and Therapeutics Committee
NEMA	National Environment Management Authority
NQCL	National Quality Control Laboratory
OT	Open Tender
PMIS	Pharmaceutical Management Information System
PPADA	Public Procurement and Asset Disposal Act (2015)
PPOA	Public Procurement Oversight Authority
RIRV	Requisition, Issue and Receipt Voucher
SDG	Sustainable Development Goals
SOPs	Standard Operating Procedures
TB	Tuberculosis
UHC	Universal Health Coverage
VEN	Vital, Essential, Non-essential

CHAPTER 1:
BACKGROUND

CHAPTER 1

Good management of Health Products and Technologies (HPT) is important to ensure that the quality of these valuable commodities is maintained up to the point of use and that items required for delivery of quality health care are continuously available.

HPT management in Kenya is faced with a large number of challenges similar to those found in many other developing countries. Many of these challenges have been documented in various pharmaceutical sector surveys and reports in Kenya.

These challenges include:

1. Shortage or absence of trained staff (not necessarily pharmaceutical staff but staff trained in provision of basic commodity management of HPTs)
2. Poor or inadequate infrastructure, facilities and equipment
3. Lack of policies, guidelines and Standard Operating Procedures (SOPs) for HPTs logistics management
4. Ineffective or absent supportive supervision and mentorship
5. Poor logistics information management
6. Weak regulations, laws and poor enforcement of the same
7. Inadequate quality assurance practices

The overall consequence of these deficiencies is lack of commodity security.

Key issues to be addressed include:

- Selection of HPTs is evidence based
- HPT are procured in a timely, transparent and accountable manner
- Quality and secure stocks of HPT are maintained at all levels
- HPT are distributed in accordance with good distribution practice (GDP) at all levels
- Optimal health outcomes from appropriate use of HPTs
- Safe and environmentally friendly disposal of HPT waste

The key to improved HPT management is therefore an integrated approach with targeted interventions addressing each of the challenges listed above.

PURPOSE OF THE GUIDELINES

These guidelines are intended to provide clear practical guidance on the main procedures involved in HPT management. This will in turn result in improved availability of required items and contribute towards efforts to provide better quality of health services for clients.

CURRENT CONTEXT AND POLICY ENVIRONMENT

The Constitution of Kenya (2010) Article 43 (1) (a) provides that *'every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care'.*

In addition, Article 46 (1) provides for the following consumer rights;
a. To goods and services of reasonable quality
b. To the information necessary for them to gain full benefit from goods and services
c. To the protection of their health, safety and economic interest; and
d. To compensation for loss or injury arising from defects in goods or services

The Health Act (2017) aims to establish a unified health system, to coordinate the inter-relationship between the national government and county government health systems, to provide for regulation of health care service and health care service providers, health products and technologies and for connected purposes.

The Kenya Health Policy (2014-2030) underscores the importance or need to improve procurement processes to ensure availability of HPTs, according to essential HPT lists. The public procurement process in Kenya is generally guided by the Public Procurement and Disposal Act (2015).

Universal Health Coverage (UHC) - The objective of Universal Health Coverage is to ensure that all Kenyans have access to preventive, promotive, curative, rehabilitative and palliative health services at minimum financial burden. In the three drivers for UHC, under access to health services, HPTs are recognized as a critical component.

OBJECTIVES OF THE GUIDELINES

The objectives of these guidelines are to describe and document the processes listed below for HPTs:

Scope of these guidelines
- Product selection and quantification
- Procurement
- Warehousing and distribution
- Supply chain information management system
- Quality management and rational use of HPTs
- Monitoring, evaluation and research for HPTs

APPLICATION OF THESE GUIDELINES

The Ministry of Health has the mandate to develop policy and guidelines that will guide management of HPTs in the Country.

These guidelines will be applicable at National and County levels, and health facilities in line with their respective operational needs.

The guidelines will be used by National, County and health facility teams involved in management of HPTs.

CHAPTER 1

DEVELOPMENT PROCESS

These guidelines were developed through a consultative process.

Justification for the development

- Align to;
  - Universal Health Coverage (UHC) in attainment of the Big Four Agenda
  - The Health Act (No. 21 of 2017)
  - The Health Products and Technologies Supply Chain Strategy 2020-2025
- Widen the scope of application of *The Guidelines on Management of Medicines and Medical Supplies for Health Facilities in Kenya (2015)*

The initial meetings to define the scope and content of the guidelines were held in September 2019 and were followed by detailed background work. A workshop was convened in December 2019 to review and harmonize the process maps and develop the guidelines content. The output from the workshop provided the basis for drafting of the guidelines, which was presented to various stakeholders for technical review and input in May 2020 and September 2020. The final document was thereafter approved for dissemination and use.

CHAPTER 2:
OVERVIEW OF HEALTH PRODUCTS AND TECHNOLOGIES

CHAPTER 2

INTRODUCTION

The purpose of this chapter is to provide the necessary background information and key issues regarding HPTs

HEALTH PRODUCTS AND TECHNOLOGIES

The Health Act (2017) defines health products and health technologies.

Health products includes human and veterinary medicines, medical products, medicinal substances, vaccines, diagnostics, medical devices, blood products, traditional and alternative medicine, therapeutic feeds and nutritional formulations, cosmetics and related products

Health technologies means the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve the quality of life

REGULATORY, POLICY AND GOVERNANCE

Policy

Health products and technologies are recognized by WHO as one of the key building blocks of a health system. The Kenya Health Policy (2014-2030) outlines HPTs as one of the eight policy orientations. Investments under this policy orientation will be aimed towards ensuring that effective, safe and affordable HPTs are available and rationally used at all times, while moving towards a strategic National HPTs reserve.

Improvement of procurement and availability of essential HPT is one of the priority reform areas for the health sector in *Kenya Vision 2030*. Scaling up of investment in HPT is one of the anchors for the achievement of the six health objectives/outcomes of the *Kenya Health Policy 2014-2030 (Sessional Paper 7 of 2012)*, the overarching framework guiding the nation towards attainment of the highest standard in a manner that is responsive to the need of the population. *The Kenya National Pharmaceutical Policy (Sessional paper 4 of 2012)* is the overall guiding policy on HPT with the goal of achieving universal access to quality essential medicines, essential health technologies, and pharmaceutical services in Kenya.

Governance

The Ministry of Health continues to provide stewardship over the HPT supply chain in line with the Kenya Health Policy and Health Act, 2017. At the apex level, HPT Inter-Agency Coordination Committee (ICC) has been set up as part of the coordination structures encapsulated in the Health Sector Partnership Framework. The Framework outlines how the Ministry of Health, county governments, external and non-state partners should interact with each other. The ICC is meant to provide oversight on matters HPT and should meet on a quarterly basis.

In 2019, the MOH elevated the HPT coordination function from a unit to a division under the department of health systems strengthening in the directorate of healthcare services with a ten-items mandate cutting across policy, standards, regulation, coordination and capacity building.

Under the devolved governance, the overall governance structures for health service delivery for county governments have been established and rationalized. At county level, the health sector is headed by a County Executive Committee Member for Health, who is supported by a Chief Officer for Health who is the accounting officer. The County Director for Health oversees the technical aspects of the health sector and heads the county health management team. Most counties have designated members of CHMT, domiciled in the departments of health, to coordinate health products and technologies (HPT) functions in collaboration with the county supply chain units that are mostly centralized. In line with the *Public Financial Management Act, 2012*, the supply chain directorates for county governments, through the County Treasuries are responsible for development of consolidated county government procurement plans and quarterly reporting on implementation.

County governments have commodity security working groups designed alongside the parallel priority programs for HIV/AIDS, Malaria, TB, and Immunization. Counties and hospitals are expected to have active Medicines and Therapeutics Committees so that there is harmony in handling of HPT supply chain functions such as quantification, procurement, warehousing, and distribution. Focus on HPT at intergovernmental relations level should be strengthened through the HPT ICCs.

Regulation

The Health Act, 2017 provides for the establishment of a regulatory body to regulate the licensing, manufacturing, laboratory testing and inspection, storage and distribution facilities, clinical trials, advertising and promotion, and post marketing surveillance for quality safety and disposal of health products and technologies through an Act of Parliament. This expanded the classes of products covered to include therapeutic feeds and nutritional formulations. Additionally, the Act also requires that the procurement of HPT for public health services be undertaken in line with the *Public Procurement and Asset Disposal (PPADA) Act No. 33 of 2015* and agreed intergovernmental arrangements; KEMSA has the mandate for procuring, warehousing, and distributing essential medicines and medical supplies in Kenya under the KEMSA Act 2013. The KEMSA Act also provides guidance for procurement of health products for the public sector both at the National and county levels. The Health Act also makes a provision for the establishment of a regulatory body on the practice of traditional and alternative health practices, that shall set the minimum standards of practice and licensing for traditional medicine and alternative medicine in Kenya.

Nationally, the *Public Procurement and Asset Disposal (PPADA) Act No. 33 of 2015* guides procurement of HPT.

Other legislation applied in management of HPT supply chain include the *Public Financial Management Act, 2012 and County Government Act, 2012*. State agencies such as KEMSA, PPB, NQCL and Academic Institutions are also governed under the *State Corporations Act, Cap 446*.

A better understanding of the HPT regulations has also been outlined within the *Health Products and Technologies Supply Chain Strategy 2020-2025*.

HPT FINANCING AND PRICING

HPT financing

The Kenyan health system has evolved to incorporate the role of county governments and new national initiatives removing user fees, with both benefits and challenges for health service delivery. At the same time, the GOK is strengthening the institutions that can deliver UHC, and these goals are articulated in the KHFS (MOH). The proposed reforms to health financing arrangements, as stated in the KHFS, are intended to better mobilize and pool funds for healthcare, as a part of this process, to raise insurance coverage with the result that better access to health services will be achieved. Utilization of health services will rise, and financial protection from the costs of ill health for vulnerable families will be provided. There are 4 major sources of funding for HPTs in Kenya these include the following,

- Government - national government through MOH, County governments, parastatals, other government agencies (33%).
- Development partners - mainly in the following programs TB, Malaria, HIV, EPI vaccines, Family Planning and Nutritional supplements (22%).
- National Hospital Insurance Fund (NHIF), Private employers, private insurers and Non-profit institutions serving households (12%)
- Households thru out of pocket expenditure (OOS at 33%)

According to the 2015/2016 National Health Accounts, the Total Health Expenditure was estimated at KES 346 Billion and accounting for 5.2% of the nominal GDP while per capita health expenditure was KES 6,602. This is considered below the desired target investment of about KES 23,407 per capita for coverage of Essential Health Benefits. In terms of sources of financing, the government remains the biggest healthcare financier accounting for 33%, followed by households, donors, and corporations at 33%, 22% and 12% respectively. Donor investments are mainly concentrated on the priority public health programs. The government allocation to health has been increasing stabilizing at 7.5% of the national budget. Allocation to HPTs account for 13% of the health budget. Under the affordable health for all initiative, there are deliberate attempts to improve health financing through pooling mechanisms and strategic purchasing. Health insurance coverage is still low at 19%, an estimated 4.9% of Kenyans incur catastrophic expenditure from out of pocket healthcare payments while many others (28%) fail to seek treatment owing to affordability barriers. The proportion of Public Health Expenditures (Government and donor) spent on Health Products has stagnated at 15%. Strategic HPTs (HIV, TB, malaria, Family Planning, EPI vaccines and Nutrition commodities), except for family planning commodities, are mainly funded by Development partners. Donors invest about KES 77 billion per year in the 3 major communicable diseases meeting 92% of those HPT need, with government meeting the less than 10% difference in program HPTs needs.

Kenya Medical Supplies Authority (KEMSA) operates a revolving fund business model for the supply of Essential HPTs, having been initially capitalized in 2013, to the tune of KES 8 billion though it has not received additional seed capital for to support HPT PSM functions. KEMSA re-configured its business model to align itself with the devolved system

of government to ensure that public health facilities access medical commodities. Under the new not-for-profit self-sustaining commercial business model, the county health facilities order and pay for their medical commodities on a demand driven supply system. The funds acquired from these sales goes towards replenishing stock. Sustainability of this model is hampered by delays in payments by counties and other facilities such as national referral facilities.

Pricing of HPT in the HPT supply chain

Prices of HPT in Kenya are unregulated and generally higher than those in other EAC countries. Recent reviews, such as HAI Pricing study and KEMSA Assessments, indicate that KEMSA and MEDS have been able to negotiate for competitive prices compared to international reference prices, leveraging economies of scale. Similarly, market price surveys undertaken have also aided in negotiations of prices during tendering. Sourcing from local producers has increased. However, the prices for HPT charged to patients at the public health facilities and faith-based facilities have not always reflected these gains owing to add on charges.

In the private for-profit sector, the variations in pricing of HPTs are high. Retail prices in the low-income settlements have been noted to be higher than corresponding international reference prices, and vary across regions despite similarity in socio–economic status. Prices in the private sector have been noted to be higher than the international reference prices, and for some products more than 30 times. Various assessments and studies in the health sector have attributed the unaffordable prices for HPT to the following factors including but not limited to;

- High cost of local production
- Lack of appropriate consumer information
- Fragmentation of sources, which leads to inconsistent supply
- Lack of agreed framework of operation between private and public health facilities
- Lack of data on HPT price trends in the market
- Unjustifiable mark-ups along the distribution chain
- Lack of coherent policy guidance on pricing of HPT
- Gaps in regulation with regards to registration of products
- Lack of transparency in the whole supply chain, which encourages corruption

The following were identified as the priority gaps in HPT financing and pricing in Kenya,

- Over-reliance on external/donor resources for strategic HPTs
- Inadequate budgetary allocation for supply chain management costs
- High outstanding debt and pending bills by both MOH and Counties to suppliers including KEMSA
- KEMSA does not have sufficient resources to ensure commodity availability for all essential health commodities, due in part to funds flow delays and outstanding debts
- Lack of aggregated pricing data and inadequate sharing of pricing information and other commodity information among key stakeholders
- Lack of a pricing structure for HPTs dispensed to clients in levels 4-6 hospitals
- Delays in disbursement of funds for HPTs
- Lack of clear Resource Allocation Criteria (RAC) for HPT at the Counties

- Program Based budgeting has not yet been implemented in a way that sufficiently monitors actual spending against programmatic objectives including for HPTs
- High price disparities within and across the dealers' public including hospitals even for similar brands
- Lack of transparency and accountability

ENSURING SECURITY OF HPTS

This can be attained through the development and implementation of a national HPT policy and relevant regulatory frameworks that will further elaborate the following strategies:

I. **Defining and applying an evidence-based essential package of health products and technologies.** This shall be judiciously applied in acquisition, financing, and other access-enhancing interventions. It will incorporate national lists of essential medicines, health products and diagnostics, treatment protocols, and standardized equipment.

II. **Establishing a national appraisal mechanism for health products and technologies.** This will provide guidance on the clinical and cost-effectiveness of new health products, technologies, clinical practices, and interventional procedures.

III. **Putting in place a harmonized national regulatory framework for health products and technologies.** This shall advance quality, safety, and efficacy/effectiveness based on sound science and evidence. The regulatory framework shall be autonomous in its operations and shall encompass human drugs; vaccines, blood and its products; diagnostics, medical devices, and technologies; animal and veterinary drugs; food products, tobacco products, and cosmetics; and emerging health technologies.

IV. **Rational investment in and efficient management of health products and technologies.** This aims to ensure the most effective management of patients in line with established standards. This will incorporate cost-effective prescribing and other interventions to improve the rational use of drugs and other health products.

V. **Have in place effective and reliable procurement and supply systems.** These shall leverage public and private investments to advance patient access to essential health products and technologies and deliver value for money across the system.

VI. **Promoting local production, research, and innovations of essential health products and technologies.** This shall be done in a manner that advances universal access and promotes national competitiveness.

VII. **Ensuring availability of affordable, good quality health products and technologies.** This shall be done through full application of all options (e.g., promoting use of generics and exploiting all provisions in the trade-related aspects of intellectual property rights) and public health safeguards relating to health products and technologies, through multi sectoral interventions on trade, agriculture, food, and related sectors.

VIII. **The national government to ensure strategic reserves** for public health commodities (Tuberculosis, Vaccines, Antiretrovirals, Family Planning) and any other commodities for emerging global conditions of public health concerns.

HEALTH PRODUCTS MANAGEMENT

Health Products management has five fundamental elements that underpin supply chain activities; product selection, procurement, distribution, use and management support. These elements are outlined in the cycle below (Figure 1), and described in details in the *Ministry of Health. Quantification Handbook for Health Products and Technologies. 2020. Nairobi, Kenya.*

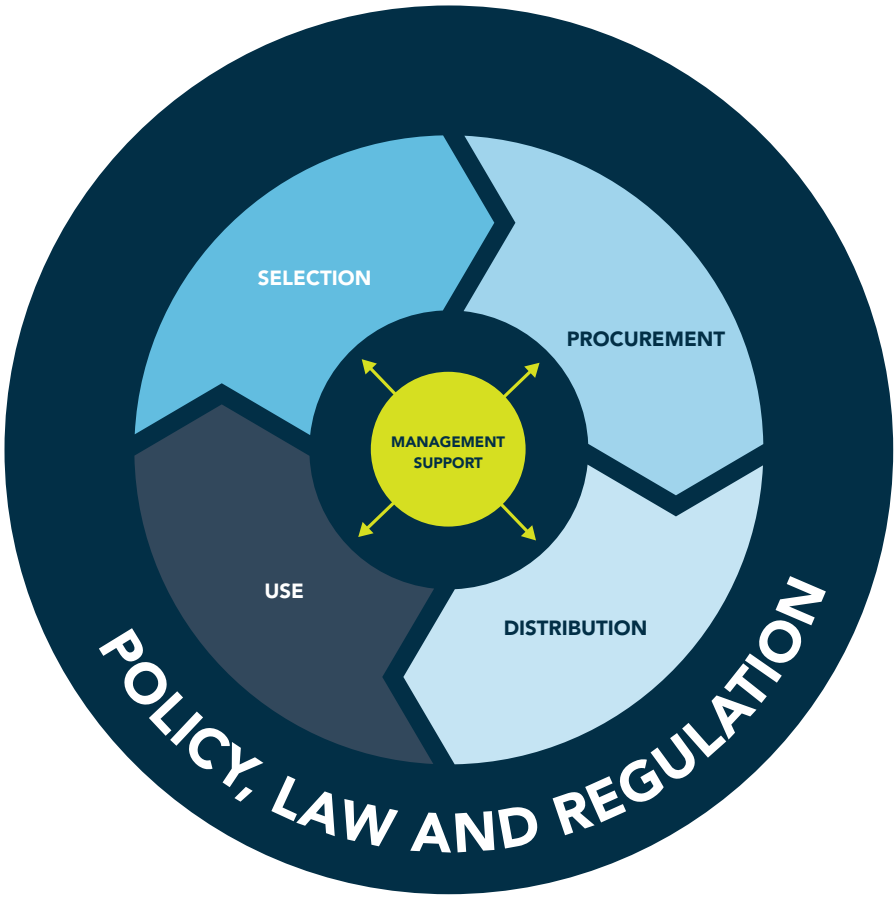

Figure 1 | ***Pharmaceutical Management Cycle***

(Source: Adapted from MDS-3-Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health)

The health products and technologies will be categorized as;

- Strategic – vaccines and drugs for TB, HIV/AIDS, epidemics
- Special and expensive – Cancer drugs, immunosuppressive agents
- Essential/Basic products

The National Government will acquire and maintain adequate stocks of the Strategic and Special/Expensive categories of products whereas county governments will focus on ensuring the availability of Essential/Basic products at county health facilities and in line with Kenya Essential Medicines List (KEML), Kenya Essential Medical Supplies List (KEMSL) and Kenya Essential Diagnostics List (KEDL).

CHAPTER 3:
HEALTH PRODUCTS AND TECHNOLOGIES MANAGEMENT

CHAPTER 3

INTRODUCTION

The purpose of this chapter is to provide the necessary background information and context to assist policy and decision makers, managers and health workers to understand why good management of HPTs is important in the provision of health services at all levels.

The following key aspects of health products and technologies management are explained in this chapter:

- Product selection and quantification
- Procurement
- Warehousing and distribution
- Quality management and rational use of HPTs
- Health products and technologies waste management
- Supply chain information management system
- Monitoring, evaluation and research for HPTs

PRODUCT SELECTION AND QUANTIFICATION

Selection

Selection is the process of identifying and choosing required HPTs.

Purpose of Selection

- To prioritize the various HPTs, in order to maximize therapeutic benefits and optimize patient outcomes, as well as leading to better supply, more rational use and lower costs
- It is a prerequisite to quantification as it identifies the products to be procured.

Selection of HPTs is based on:

- A selection criterion of HPTs in line with essential HPT lists
- Standard treatment guidelines
- Relevance
- Proven efficacy and safety
- Adequate scientific data and evidence of performance in various settings
- Quality
- Favorable cost-benefit ratio
- Desired health outcomes
- Level of use

Selection is important for the following reasons:

- A wide variety of health commodities exist for provision of health services, therefore there is need to narrow down to HPTs that a health system can provide sustainably
- Costs of items with similar use may vary widely and it is important to ensure good value for money
- The limited resources available for health commodities procurement means that systematic prioritization is vital to ensure that priority health needs are met
- To ensure good quality HPTs with sustainable supply are identified

The selection process may face challenges due to:

- Poor coordination between various departments/divisions
- Advances in technology
- Multiple funding sources with "preferred" choices
- Pressure from manufacturers and suppliers
- Local biases: schools of thought, vested interests
- Failure to systematically apply evidence-based criteria to the selection process
- Lack of standard treatment protocols to guide the selection process

The approaches used in selection of HPT in different sectors are as follows:

Public Sector

- In the public sector, the selection process is conducted at National and County level to determine which items should be available at each level of care
- Based on essential national HPT lists
- At facility level, the facility chooses it's required HPT from a predetermined list based on level of care.

Private Sector

- Selection process is internal to a facility or organization
- It should be aligned to the national policies and guidelines

Quantification

Quantification is the process of estimating quantities and costs of products required for a specific health program or service, and determining when the products should be delivered to ensure uninterrupted supply of HPT.

Quantification Methodologies

The following methodologies are used based on the type of data;

a) Using consumption data (this is the preferred method when consumption data is available)
   Use of historical consumption data to estimate future needs.

b) Using morbidity data
   Use of data on disease patterns to estimate requirements.

c) Proxy consumption method
   Use of consumption data of a similar level facility with comparable catchment population to estimate needs. Mainly used for new facilities.

d) Use of population/ demographic data
   Use of demographic data to estimate the requirements

e) Using services data
Use of service data such as patient workload, number of clients on a particular method

NB: For detailed information about quantification, refer to the *Ministry of Health. Quantification Handbook for Health Products and Technologies. 2020. Nairobi, Kenya.*

PROCUREMENT

Procurement is the process of acquiring by purchase, rental, lease, hire purchase, license, tenancy, franchise or by any other contractual means of any type of HPTs or services in the supply chain system. In Kenya, HPTs can also be acquired through donations. Value for money is the core principle underpinning public procurement.

Procurement should be carried out within the confines of applicable laws, policies, regulations and good procurement practices as provided for in the *Public Procurement and Disposal (PPAD) Act 2015* and PPAD Regulations 2020 to ensure transparency, accountability and efficiency of its processes.

The process can be done at various levels:

- National level
- County level
- Facility/organization level

KEMSA is the national procuring entity for HPTs in the public sector as provided for in the KEMSA Act 2013 and in the Health Acts amendments for May 2019.

The procuring entities should adapt the processes as outline in figure 2 below

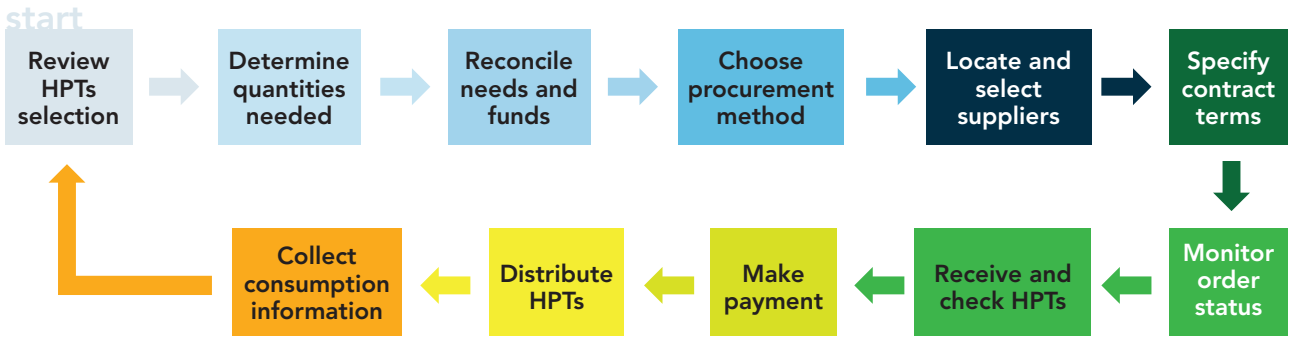

Figure 2 | The HPTs Procurement Cycle

Adapted from: Management Sciences for Health. 2012. MDS-3: Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health.

The procurement cycle describes most of the decisions and actions that guide the specific HPTs quantities, prices paid and quality of products procured. The steps in the procurement cycle can be summarized as follows:

1. **Select HPTs:** This is based on the essential HPT lists (KEML, KEMSL and KEDL and any other official list). Develop and document specifications for the products prior to the procurement

2. **Determine quantities needed:** Quantification for HPTs is mainly done through consumption method, based on reliable data. However, other methods as outlined above are also applicable. The process leads to development of a supply plan

3. **Reconcile needs and funds:** Reconciliation of needs to the available funds culminates into development of a procurement plan. One of the recommended methodologies for reconciliation is the ABC/VEN analysis, as discussed below. Procurement plans are subject to periodic review

4. **Choose procurement method:** in the public sector several procurement methods are applicable as outlined in the Public Procurement and Disposal Act 2015 i.e. Open Tender (OT), Direct Procurement, Framework Agreements, Request for Quotations, Restricted Tender, Request for Proposals, etc. In the private sector various internal mechanisms may be applied

5. **Locate and select suppliers:** Select suppliers based on value for money, quality, reliability and service. Selection of suppliers for the public sector should follow a competitive process as outlined in the Public Procurement and Disposal Act 2015 and other applicable laws.

6. **Specify contract terms:** The procuring entity develops contract terms

7. **Monitor order Status:** This is part of pipeline monitoring

8. **Receive and Check HPT:** When HPTs are delivered to the warehouse, a visual inspection, verification of quantities and documentation for the consignment is conducted.

9. **Make payment:** Once the delivered consignment is checked and it is ascertained that the HPTs meet specifications, they are received into the warehouse and payment made to the suppliers

10. **Distribute medicines:** for further details refer to the section on distribution

11. **Collect consumption information:** Having a reliable mechanism to collect, collate and report consumption information is critical in ensuring more accurate matching of demand and supply. Accurate, complete and timely consumption information will enable the Government to avoid wasting resources in procuring either excess or obsolete commodities. It also avoids extra spending on emergency orders and redistribution of commodities from one facility to another.

VEN and ABC principles

Due to scarcity of resources, it is prudent for HPT procurement to be rationalized. Some of the tools available for rationalization include VEN classification and ABC analysis.

VEN classification

This is the grouping of items into Vital, Essential and Non-essential in order to guide the allocation of resources. The vital and essential classification of items is usually by consensus of the Medicines and Therapeutics Committees (MTC)

- **Vital HPTs (V):** potentially life-saving or crucial to providing basic health services
- **Essential HPTs (E):** effective against less severe but significant forms of disease, but not absolutely vital to providing basic health care
- **Non-essential HPTs (N):** used for minor or self-limiting illnesses; these may or may not be formulary items and efficacious and they are the least important items stocked.

When procuring public sector HPTs, no resources should be allocated for non-essential HPTs.

ABC classification

ABC analysis classifies items in the order of budgetary consumption.
A, approximately 10 – 20% of items accounting for 75-80% of total value
B, approximately 10 – 20% of items which take up the next 15-20% of the total budget
C, the bulk of items (60 – 80%) which only account for the remaining 5-10% of value.

VEN/ABC analysis

In situations of budgetary constraints, rationalization is done by minimizing quantities for class A items which are not considered to be of the V class

WAREHOUSING AND DISTRIBUTION

Inventory Management

Inventory management is the process of ordering, receiving, storing and issuing of health products and technologies. It entails keeping of accurate and up to date records of receipts and issues which are critical for accountability and reliable quantification.

The basic inventory management tools are bin cards/stock control cards. It is desirable to have the same records in an electronic version with effective backup. However, an electronic system is not a substitute for the manual system. Audit systems will always make reference to hard copies of documentation tools.

Best practices for inventory management

1. Receipt - This involves the following:
   - Confirmation of the order
   - Verification of various receipts documents e.g. delivery note, invoice, waybill
   - Verification of the products by the relevant users to conformity to the specs
   - Confirmation of actual quantities
   - Signing off the documents

2. Storage - This is the keeping of the products in the designated locations in the store/ warehouse
   - Update the manual and where applicable electronic stock control cards

3. Issuing - This is the release of the products from the store to various points of use which can be to internal departments or external facilities. It involves:
   - Receipts of orders from departments or facilities
   - Processing of the orders
   - Issuing of orders through *First Expiry First Out (FEFO) or First In First Out (FIFO)*
   - Picking, Packing and labelling
   - Documentation
   - Dispatch

4. Delivery - This is the movement of the products from the point of issue to various users
   - The delivery method will depend on the nature, quantity and the point of use.
   - Available options include collection by the user, delivery by courier services, vans
   - Signing and return of proof of delivery

5. Disposal of expired, obsolete or damaged products - This is the process of getting rid of products that can no longer be used. This should comply with various statutory regulations such as the *Public Procurement and Disposal Act (2015) and the Environmental Management and Coordination Act (1999)*

All expired, obsolete or damaged products should be:
   - Documented
   - Removed from inventory cards
   - Kept away in a secure location
   - Disposed with the most appropriate method taking into account the prevailing policies and guidelines

6. Reverse logistics
   - This involves the return of products to the original source.
   - The process of issuing and documentation should be followed at the source
   - The receiving store should follow the receipt and storage procedures as described above

CHAPTER 3

REASONS FOR REVERSE LOGISTICS OF HPTs

- Wrongly supplied products
- Slow moving products
- Excess products
- Quality issues and recalls
- Too defective/damaged HPTs
- In-excess stock due to unused quantities at the end point
- Have potential hazard that may be subject to government regulation or liability concerns
- Complaints of serious adverse reactions to the product and its packaging
- Concerns that the product is or may be counterfeit
- Unregistered
- The products fail to meet quality standards
- Obsolete but still have a secondary usage or value
- It has reached the end of its service life

THE COMPONENTS OF REVERSE LOGISTICS

These processes can include repair, warranty recovery, redistribution, value recovery, end-of-life recycling or any combination of these activities. Depending on the volume, a separate reverse supply chain may be established.

There are series of activities required to retrieve HPT including the five R'S

- **Returns** - it involves receiving, sorting, inspecting and testing of the product through verification and trucking system
- **Recall** - the product is transported for replacing, reclaiming, resells and or disposition. For pharmaceuticals however, the products recalled in specific batches due to quality and safety issues are destroyed
- **Repair** - the products are refurbished, remanufactured like new, then returned to stock to be reused
- **Repacking** - in case of minor flaws found, the products are reconditioned and repacked for distribution
- **Recycling** - the products are either recycled or disposed

HPTs can also be withdrawn from the market completely when they do not meet the required standards of quality, safety and efficacy.

PRACTICES FOR REVERSE LOGISTICS OF HPTs

i. Trained store personnel.
ii. There should be a checklist and documented procedures in place to guide manufacturers, market authorization holders, store staff on recalls and withdrawals for the item so that returns are handled properly.
iii. HPT managers must have insights into the cost/benefit analysis for moving items through the reverse logistics pipeline.
iv. Established a gatekeeping function to identify how, and which, products are returned.

v. Have an efficient and rapid real time communication system to help in facilitating disposal or reused
vi. Have a packing list to assist in tracking and retrieval
vii. Have maintained current lists of HPT stocks in each area

Each item should be tracked with the same level of visibility and transparency.

QUALITY MANAGEMENT AND RATIONAL USE OF HPTs

Description

Rational use of HPTs means patients receive HPTs appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time and at the lowest cost to them and their community. Rational use criteria include:

- Appropriate indication
- Appropriate HPT considering efficacy, safety, suitability and cost
- Appropriate utilization (dosage, duration, administration)
- Appropriate patient (assess contraindications or likely adverse reactions)

Quality management encompasses managing the processes and procedures to ensure safety, effectiveness, client centered, timeliness, efficiency and equitable aspects of HPTs.

Quality control refers to the sum of all procedures undertaken to ensure the identity and purity of a particular pharmaceutical or other HPT.

Utilization (Healthcare) is the quantification or description of the use of services by persons for the purpose of preventing and curing health problems, promoting maintenance of health and well-being, or obtaining information about one's health status and prognosis.

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problem with the view to early detection of hitherto unknown adverse reactions and interactions.

Post Marketing Surveillance is the continuous process of monitoring the quality, safety and efficacy of all medical products and health technologies on the market.

Antimicrobial Resistance is the ability of a microorganism to stop or prevent the activity of an antimicrobial that was once effective against it.

Rational Use

For rational use to be achieved, HPTs are required to be available in the facility and at the service delivery point for appropriate use by the patient.

CHAPTER 3

ISSUING

HPTs need to be moved from the facility store to the places where they are used, such as treatment areas, wards, or outpatient facilities. The procedures are similar, whatever the size of the facility.

How are Commodities Issued?

- From central stores to the facilities
- Inter-facility – Issuing between health facilities within the same locality e.g. from a Sub-County hospital to a health center
- Intra-facility – Issuing between departments within a health facility e.g. from the pharmacy to the wards or satellite pharmacies
- To clients/patients at service point (e.g. when dispensing)

Guidelines for issuing commodities

- Ensure that the sites you are issuing to are authorized by the program and/or your SOPs
- Ensure proper records are used and maintained, e.g. S11 or other facility-based order/issue form
- Develop SOPs for issuing commodities

APPROPRIATE USE OF HPTs

These guidelines have used the approach of appropriate use as opposed to rational use because there are many rational uses which are not appropriate e.g. use of antibiotics in acute upper respiratory infections may be rational but not appropriate.

Appropriate use of HPTs constitutes; the right item, in the right dosage, right strength and right duration.

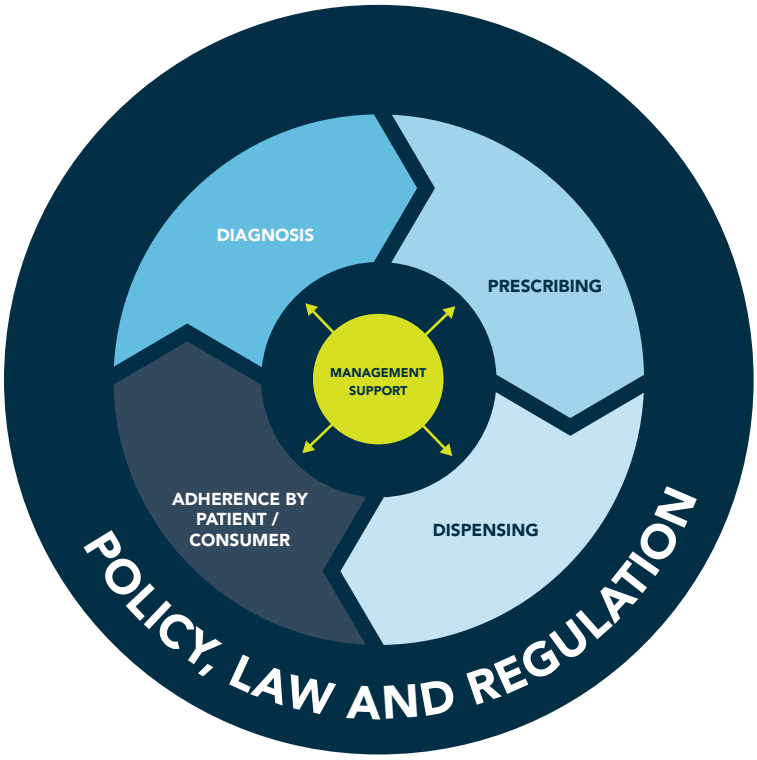

Figure 3 | Appropriate HPT Use Cycle

Principles of appropriate use are:

i. Good clinical diagnostic practices

Elements of good clinical diagnostic practices include;

- Comprehensive clinical assessment based on clinical guidelines/protocols/clinical pathways
- Comprehensive diagnostic investigations

ii. Good prescribing practices

- Should be based on correct diagnosis
- Should be compliant to clinical guidelines, protocols and clinical pathways
- Compliant to the essential HPT lists and formulary
- The prescription should be complete i.e. all details required should be provided and should be legible - date, patient name, age, weight, height, patient reference no (outpatient, inpatient no), duration of treatment (medicines)
- Should be by generic name/INN (for medicines)
- Should be by a duly qualified prescriber and within the limitations of their knowledge, skills and expertise
- Document and communicate the reasons and decisions for the prescription/requisition to the recipient/caregivers and other relevant health worker

iii. Good Dispensing Practices (GDP)

The goal is to ensure services such as dispensing, imaging and laboratory diagnostics are appropriately administered to the right patient/consumer at the right time, in the right manner, with clear instructions based on the need.

Elements of GDP:

- Based on a complete prescription/requisition
- Use of generic names/INN for medicines
- Use of effective SOPs
- Qualified staff
- Clear labelling
- Use of clean and suitable equipment
- Use of appropriate packaging material
- Clear instructions
- Good record keeping

iv. Patient/consumer adherence

The elements to achieve this are:

- Checking patient/client knowledge for the prescribed intervention
- Counseling and accountability including information on side effects and possible adverse reactions
- Proper labeling
- Self-monitoring
- Storage and handling of dispensed products
- Frequency and duration of use

MANAGEMENT SUPPORT

The support is best provided through Medicines and Therapeutics Committees (MTC) at the various levels i.e. National, County and the health facilities (Refer to the *Guidelines for Medicines and Therapeutics Committees, Ministry of Health Kenya, 2020).*

The objectives of a Medicine and Therapeutics Committee are:

- To ensure that only efficacious, safe, cost-effective and good quality medicines are used
- To ensure the implementation and adherence of recommended standard clinical/ treatment guidelines
- To maximize medicine safety through monitoring, evaluating and thereby preventing, as far as possible adverse drug reactions and medication errors
- To develop and implement interventions to improve medicine use by prescribers, dispensers and patients through the investigation and monitoring of medicine use to prevent antimicrobial resistance
- To advice on matters of medical waste management for medicines and other HPTs

Quality Management

This entails the procedures to address aspects of quality control, pharmacovigilance and post marketing surveillance of HPTs

Key guidance

- Identification of suspected adverse drug reactions (ADRs) and poor-quality HPTs
- Management of suspected ADRs

- Reporting of ADRs
- Analysis of ADR reports for decision making at policy, regulatory, and facility level
- Regulatory function as regards poor quality HPTs e.g. quarantine, future procurement sources etc.
- Perform physical quality control checks for HPTs

HEALTH PRODUCTS AND TECHNOLOGIES WASTE MANAGEMENT

Introduction

Safe management of HPT waste requires taking all practical steps to ensure that the waste is managed in a manner that protects human health and the environment against the adverse effects which may result from the waste.

Health products waste includes expired, unused, spilt and contaminated HPTs e.g. prescribed and proprietary drugs, vaccines and sera that are no longer required, and, due to their chemical or biological nature, need to be disposed of carefully. The category also includes discarded items heavily contaminated during the handling of HPTs, such as bottles, vials and boxes containing pharmaceutical residues, gloves, masks and connecting tubing.

HPTs are considered hazardous if they demonstrate one or more of the following six criteria:

- Carcinogenicity
- Teratogenicity or other developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses in humans or animals
- Genotoxicity
- New drugs that are similar to existing HDs in structure or toxicity

Genotoxic waste is highly hazardous and may have mutagenic (capable of inducing a genetic mutation), teratogenic (capable of causing defects in an embryo or fetus) or carcinogenic (cancer-causing) properties. The disposal of genotoxic waste raises serious safety problems, both inside hospitals and after disposal, and should be given special attention. Genotoxic waste may include certain cytotoxic drugs, vomit, urine or faeces from patients treated with cytotoxic drugs, chemicals and radioactive material.

WASTE SEGREGATION, TRANSPORT AND STORAGE

Guiding principles

Any person whose activities generate pharmaceutical waste has an obligation to ensure that such pharmaceutical waste is transferred to a person who is licensed to dispose of such pharmaceutical waste in an approved pharmaceutical waste disposal facility. Therefore, health-care facility managers and their supervisors have a responsibility to ensure that health products waste is always kept under control within a health-care facility and disposed of safely either onsite or offsite. Proper segregation, onsite storage and transportation systems provide a continuous sequence of safe keeping at each step in the process, from the point of generation of waste to its final treatment or disposal.

The following general principles of waste segregation, storage and transportation relate to the control of waste flow from generation to disposal:

- Dispose radioactive, cytotoxic and radiopharmaceutical waste produced in the process of the diagnosis and treatment of cancer in accordance to international and relevant local guidelines
- Have written policies and SOPs for hazardous waste describing requirements for the segregation, packaging, labeling, collection, transportation, storage and on-site treatment of waste within the facility
- HPT waste generated in a medical area should be segregated into different fractions, based on their potential hazard and disposal route, by the person who produces each waste item;
- Provide waste disposal amenities and commodities - Separate containers should be available in each medical area for each segregated waste fraction; Waste containers when filled should be labelled to help managers control waste production;
- Closed local storage inside or near to a medical area may be needed if wastes are not collected frequently;
- Hazardous and non-hazardous wastes should not be mixed during collection, transport or storage;
- Staff should understand the risks and safety procedures for the wastes they are handling. Conduct regular capacity building on waste disposal for all healthcare providers including support staff.
- Provide appropriate PPEs for handling hazardous waste.
- Incinerate hazardous waste using special incinerators and maintain documentation on the same.
- Minimize the risk of contaminating the local water supply and/or soil with hazardous drugs (HDs). Hazardous drug waste should never be discarded into waste water (sink or toilet) or into a landfill
- Specific disposal systems should be mandatory for radioactive effluents. This system should be effectively and carefully maintained to prevent contamination and exposure of personnel to the radioactive waste both within and outside the facility

Waste Segregation systems

The correct segregation of health-care waste is the responsibility of the person who produces each waste item, whatever their position in the organization. The health-care facility management is responsible for making sure there is a suitable segregation, transport and storage system, and that all staff adhere to the correct procedures.

Based on the WHO recommended color schemes, chemical and pharmaceutical waste should be segregated in brown plastic bags or rigid containers and labelled with appropriate hazard symbols using the globally harmonized system of classification and labelling of chemicals. (see annex)

Various chemical and pharmaceutical wastes should be segregated and collected separately: subcategories include mercury, batteries, cadmium-containing wastes, photo chemicals, stains and laboratory reagents, cytotoxic drugs and other pharmaceuticals. All should be clearly labelled with the type of waste and the name of the major chemicals, with any necessary hazard labels attached to corrosive, flammable, explosive or toxic chemicals.

Note that

- Liquid chemical wastes should never be mixed or disposed of down the drain but should be stored in strong leak-proof containers.
- Return of photo chemicals to suppliers should be practiced where possible
- Low-energy light bulbs (compact fluorescents) contain small amounts of mercury. Both these and batteries should be segregated and treated by recycling processes, where suitable facilities exist.
- Unused pharmaceuticals should be taken back to the pharmacy for return to the manufacturers or dispatched to specialist waste-treatment contractors
- Pharmaceuticals should be kept in their original packaging to aid identification and prevent reaction between incompatible chemicals
- Spilt and contaminated chemicals and pharmaceuticals should not be returned to the pharmacy but should go directly from the point of production to a waste store
- Typically, contaminated chemicals and pharmaceuticals are stored and transported within a health-care facility in brown cardboard boxes and must be kept dry
- Radioactive wastes should be collected and handled by specialist disposal services. Otherwise, waste may be stored in secure, radiation-proof repositories (leak-proof, lead-lined and clearly labelled with the name of the radionuclide and date of deposition) where it should be left to decay naturally.

STORAGE

HPT waste should be stored in a suitable location or facility where isolation, environmental and health protection and human control are provided in order to ensure that the waste is subsequently retrieved for disposal. All storage locations for health products waste should be clearly marked HPT WASTE STORE and be away from usable products. These storage areas should be cleaned regularly.

Storage facilities for pharmaceutical waste should be labeled on the outside with the hazard sign of a skull and 2 crossbones and with the 'No Entry for Unauthorized Persons' signage.

TRANSPORT

Health products waste should be transported in a means of conveyance that prevents scattering, escaping, flowing, spillage or leakage of the waste.

- Transport hazardous waste in a sealed container marked as hazardous
- Use a container that can contain a spill if one would occur
- Label containers to indicate the hazardous contents
- The transporter must have full instruction on the nature of the content and what to do in case of spillage or breakage
- Transporter must have access to a spill kit and be trained on how to use it
- Task of receiving and unpacking of hazardous waste delivery should be responsibility of specific individuals who are trained on safe handling of the same
- Vehicles engaged in transport of pharmaceutical waste should be licensed by NEMA, road worthy and fulfill the required design criteria. Refer to other national level guidelines on waste management for further details
- There should be an auditable trail on HPT waste detailing the products, source, transporter and recipient. The generator of the waste should receive an official confirmation that the waste was received at the expected destination.

DISPOSAL METHODS

The following are the options for disposal of small quantities of health products waste

- Return of expired pharmaceuticals to the donor or manufacturer where possible
- Encapsulation and burial in a sanitary landfill
- Inertization with subsequent
  - Production of cubes or pellets which are then transported to a suitable storage site
  - Pouring of the liquid homogenous mass onto the surface of previously landfilled municipal waste and then covering with fresh municipal waste
- Chemical decomposition in accordance with the manufacturer's recommendations if expertise and materials are available

- Discharge into a sewer with or without dilution for intravenous electrolyte solutions and water for injection
- Dilution in large amounts of water and discharge into a sewer for solutions containing vitamins and amino acids

SPECIAL CONSIDERATIONS FOR CYTOTOXIC DRUGS

Cytotoxic drugs should never be landfilled.

Receiving, Storage and Inventory Management

- Cytotoxic medicines storage must be easily identifiable and it must be a dedicated area, clearly marked, including refrigeration for quick containment and spill management
- The storage room should be secure and access limited to authorized staffs
- All the staff who are involved in receiving hazardous drugs packages must be trained on safe handling
- Damaged or package with visual sign of damage should be opened in an isolated area by workers wearing full PPE including double gloves, gown, eye protection, and respirator. Potentially contaminated items such as PPE's and damaged vials should be disposed as hazardous waste. Damaged items should immediately be quarantined and suppliers contacted
- Hazardous spill kit must be readily available, and personnel handling HDs must be trained to perform spill cleanup
- There should be work policies, SOPs, job aids etc. to ensure unintentional occupation exposure is avoided
- Staff should wash their hands with soap and running before and after handling cytotoxic medicines
- Distinctive labeling and physical separation of cytotoxics from other medicines is recommended indicating special handling and disposal precautions. The outer packaging container should display a clear warning label stating the goods are cytotoxic in nature.
- Clear visual symbols should be put on the products as well as storage area to prevent risk of error in picking

The following are the recommended disposal methods for pharmaceutical waste comprised of cytotoxic drugs such as antineoplastic agents:

- Return to original supplier
- Chemical degradation in accordance with manufacturers' instructions
- Incineration at high temperatures. Full destruction of cytotoxic drugs may require incineration temperatures up to 1200°C and a minimum gas residence time of two seconds in the second chamber.

SUPPLY CHAIN MANAGEMENT INFORMATION SYSTEMS

Description

MIS is the use of information technology, people, and business processes to record, store and process data to produce information that decision makers can use to make day to day decisions. Through use of MIS, data is extracted from varied sources and used to derive insights for decision making.

Of importance within a health supply chain system, is the Logistics Management Information System (LMIS). An LMIS is a system of records and reports – whether paper-based or electronic – used to aggregate, analyze, validate and display HPT data (from all levels of the logistics system) that can be used to make logistics decisions and manage the supply chain. LMIS data elements include stock on hand, losses and adjustments, consumption, demand, issues, shipment status, and information about the cost of commodities managed in the system.

Data collection

All staff responsible for maintaining logistics records—whether stock keeping, transaction or consumption—should be appropriately trained and have adequate time to carry out this responsibility. The forms should be clear and simple, with enough writing space. On-the-job training (OJT) and supportive supervision should be undertaken to ensure the forms are being completed correctly.
Data for decision making needs to be categorized, defined and frequently collected. Data need to be collected and recorded daily at all levels of the supply chain, compiled and reported within defined periodic intervals (monthly or quarterly). The data collected may be analyzed daily to assess stock status, monthly or quarterly to determine resupply or order, and track quantities. On annual basis, the data may be used for purposes of quantification of HPTs. From a logistics point of view, supplies in a pipeline can be stored, moved (in transit), or consumed (used). Three types of logistics records are needed to monitor products in the pipeline and track their movement. Each record type has a distinct form and use.

1. Stock keeping records. Holds information about products in storage.
2. Transaction records. Holds information about products being moved.
3. Consumption records. Holds information about products being consumed or used.

NOTE: Refer to Appendix 1 for description and examples of the above records

ESSENTIAL LOGISTICS DATA ITEMS

To make logistics decisions, a logistics manager needs three essential data items that are necessary to manage a logistics system. To ensure efficiency, the staff must use an LMIS to record and report them:
1. stock on hand,
2. consumption,
3. losses and adjustments.

NOTE: Refer to Appendix 2 for description and examples of the above records

Data reporting: Reporting Systems and Summary Reports

Data should be reported regularly, and logistics managers should review the reports to verify the quality of the data. Feedback reports and incentives can be used to motivate lower levels to turn in complete, error-free reports. Linking reporting with ordering also encourages timely reporting.

To make the collected data useful, the records must be available to HPT staff in a form useful for decision making. Data must be of the right quality (i.e. complete and accurate) and at the right cost (not spend more to collect information than spend on supplies). For informed decision-making, summary reports are prepared and relayed to the relevant HPT staff at various levels for their action (budgeting and supportive supervision)

Reporting systems

- Reports provide decision makers at various levels with the right information, at the right time, in the right place, in the right quantity, of the right quality, and the right cost
- A reporting system must be in place to ensure that this information flows correctly and consistently
- A reporting system in a supply chain may include levels outside storage and distribution points. For example, a County Health Office might not hold stock or be involved in the distribution of products, but that office still needs to receive LMIS reports to ensure that facilities are stocked appropriately to determine if additional funding and/ or resources are required.

Type of Reports

The purpose of a primary summary report is to avail all essential logistics data items for products, for a specific facility, and for a specific time (such as monthly, bimonthly, or quarterly) to decision makers. One of the most important decisions HPT staff face in collecting data on any report is determining when and at what level data is required. Important points include:

- How visible does the facility-level data need to be higher up in the system (i.e., does the central level need to know exactly what each health facility distributed and has on hand?)

- What decisions need to be made at what levels (budgetary, supervision, stock distribution, etc.) and what detail of data is needed?

- What are the current tasks and work responsibilities of staff that will be required to compile the aggregated data? Will aggregating data be too much of a burden? Which levels have tools (computers) and staff that can more easily aggregate data?

The table below summarizes the various types of reports, their description and inputs/ contents

Report Type	Description	Inputs/contents
Summary Reports	• Targeted at the decision makers • Compiled for specific set periods, i.e. monthly, bi-monthly, quarterly • It is recommended that this reporting is staggered based on the number of facilities, i.e. alternate months, such that the first half of the facilities report and followed by the other half the following month Can also be staggered based on levels, i.e. 1st – 10th of the month is for facilities; 10th – 20th is for Sub-County and 25th – 30th is for Regional / national consolidation	• Contains stock at hand, consumption, losses and/or adjustments • Recommended format includes, facility report, aggregated summary reports, request forms and combined facility reports
Aggregated Summaries	• It is high level in nature • Similar to summary report but have additional information on requisition for new supplies. • It ties reporting to ordering; orders issued if report submitted	• Contains orders and requisitions • It can be facility specific
Feedback Reports	• Reports from the HPT managers • Gives reviews and feedback of the reports reviewed • Used to identify weaknesses in the logistics system • Used to inform overall program planning and management • Use to solve problems/challenges and motivate facilities and staff members • Can be useful to other agencies such as KEMSA and other development partners	• Generated from LMIS • Contains information on trends in consumption, national stock status, % facility reporting and other routine data

Data monitoring, aggregation, and analysis

Once data is reported, it paves way for monitoring, aggregation and analysis. The data should be validated by comparing different indicators to ensure that data are accurately and consistently entered, aggregated, and reported. It is important to ensure optimal quality of the raw data that is subsequently analyzed, so that reports are reliable for decision making. This data ought to be;

- Correct: within normal ranges
- Timely: Available when needed.

- Complete: All sets of the data should be completed.
- Reliable and accurate enough to support decisions
- Consistent: within acceptable limits over time.
- Comparable: Use same definitions for data items

Wrong information can easily be reported when aggregating data, unless the procedures for aggregation are clear. It is important that staff at all levels correctly understand the data that is to be reported and how the aggregation is done – for example aggregation from source documents at the facility to summary forms (DAR, Bin Card to summary forms). For analysis purposes, below are possible indicators to review:

Indicator	Indicator Definition
Percentage of Health facilities with stock out of tracer non-pharm for 7 consecutive days in a month	% of facilities reporting more than 7 days in a month of number of days in which tracer items was not available in a specified period
Average availability of essential medicines in health facilities	% of the tracer medicines available throughout the months (averaged over all tracer drugs under the review in the month)
Average availability of basic diagnostic tracer items in facilities	% of the tracer diagnostic items available throughout the months (averaged over all tracer diagnostic items under the review in the month)
Order fill rate of tracer medicines by quantity per item as (%)	% of items ordered by health facilities from KEMSA (or other private supplier) over a period that are filled correctly at least 80% in terms of quantities requested of those items
Order fill rate of tracer non-pharmaceutical commodities by quantity per item as (%)	% of items ordered by health facilities from KEMSA (or other private supplier) over a period of time that are filled correctly at least 80% in terms of quantities requested of those items

MONITORING, EVALUATION AND RESEARCH FOR HPT

Monitoring refers to reviewing, on a continuous basis, the extent to which HPT activities are implemented consistently. It aims to know if we are undertaking interventions in the right way. Evaluation on the other hand refers to the periodic assessment of the progress towards meeting expected outcomes. Monitoring and Evaluation (M&E) relies on indicators, which are variables that measure change. They may be numerical and expressed in terms of numbers, percentages, or averages. They may also be expressed as binomials such as "yes" and "no."

Using indicators, monitoring tracks outputs such as availability of medicines and supplies, number or percentage of trained staff and quality of services. Comprehensive list of HPT indicators can be referenced from the M & E matrix of the *Health Products and Technologies Supply Chain Strategy 2020-2025*.

Evaluation on the other hand provides feedback on the overall performance and makes it possible to gauge how much has changed and provides direction for future planning in line with set objectives. Evaluation can be conducted biannually, annually or at a stipulated time in the life of a strategy. Continuous evaluation provides enough data and information

to inform research on topical areas of HPT management and provide solutions to long standing issues e.g. Adverse Drug Reactions, Rational use of medicines, prescribing habits, supply chain optimization etc.

How to Conduct Monitoring, Evaluation and Research

Monitoring and evaluation for HPTs requires the following:

i. Development of an M&E framework
ii. Establishment of tools for data capture and reporting
iii. Creating a routine for data capture mechanism
iv. Supportive supervision for continual, informal monitoring of work plan implementation and progress towards set objectives
v. Routine reporting of selected data set through the health information system
vi. Data Quality Audits (DQAs) on reported data to establish possible gaps
vii. Periodic evaluation against the HPT strategy objectives
viii. Special research studies whenever an implementation problem or planning question requires specific additional information

For M&E to be effective, we require predetermined tools to assess progress against the identified indicators. Examples of these tools include the following;

i) Supportive Supervisory visit checklists
ii) Inventory and patient/client records
iii) Management Information System (MIS)
iv) Periodic survey tools e.g. Logistics System Assessment Tool (LSAT)

Information and data use will be enhanced using research and evaluation. Operation research studies can be carried out from time to time to determine the extent to which the objectives are met.

The Monitoring and Evaluation Framework

An M&E framework is designed to establish a formal manner in which information will be collected. The framework articulates the indicators, linkages and reporting relationships used to measure inputs, outputs, outcomes and impact of the project/program/intervention. Through the framework, the implementing institution is able to establish milestones to be achieved against the targets.

The *Health Products and Technologies Supply Chain Strategy 2020-2025* has an embedded M&E framework for HPTs, and is also aligned to the larger Ministry of Health's M&E framework.

Use of Indicators in Monitoring and Evaluation

Indicators are useful tools or directional signals used by managers to track the performance of particular aspects or activities of the HPT supply system as well as the performance of the

overall system. A well-defined indicator is clearly linked to an important input, process, or outcome. Indicators can be **qualitative** - where they tend to be 'Yes' or 'No' (e.g. is there a standard treatment manual at the health facility? (Y/N)), or can be **quantitative** - in the form of counts, rates, ratios, proportions or percentages (e.g. 30% of health workers trained in commodity management).

Criteria for selecting appropriate performance indicators are:

- Clarity: the indicator is easily understood and calculated
- Usefulness: the indicator reflects an important aspect of performance
- Measurability: the indicator can be defined in quantitative terms and used within existing constraints on information quality and availability
- Reliability: the indicator permits consistent assessment over time and among different observers
- Validity: the indicator is a true measure of what it is meant to measure. Validity must also be based on the indicator's acceptance by key stakeholders and the consistency of interpretation among different stakeholders

Indicators can be used to monitor the performance of the following aspects, among others:

- Selection
- Procurement
- Distribution performance
- Financial performance
- Patient/client/user behavior/quality of care
- LMIS reporting
- Storage conditions
- Supply chain client satisfaction

Examples of indicators for use in monitoring HPTs:

- % Forecast accuracy
- % of facilities that reported on stock status *(reporting rate)*
- % of facilities/SDPs that reported on time *(on time reporting)*
- % of facilities that had their requested orders supplied in full *(order fill rate)*
- # of emergency orders
- Proportion of health supply chain budget by admin unit
- Supply chain loss ratio

ANNEXES

Annex 1: Terms of Reference for the National HPT Quantification Team

The table below outlines the different types of data collected at various levels.

National Level

Data Category	Data Elements Required	Source
Receipts Data	Date of Receipt, Source of Funds, Product Category, Product Code, Product Name, Batch No, Source of Funds, Expiry Date, UOM, Qty Received, Unit Value, Cost Value	KEMSA
Issues data	Issue Date, Delivery Note No, Facility Code/MFL No, Facility Name, Facility Level, Facility Type, Facility Category, County, Product Category, Item Code, Product Name, Batch No, Source of Funds, Expiry Date, UOM, Qty Issued, Unit Value, Cost Value	KEMSA
Pipeline data	Product Name, Supporting Agency, Quantity, Estimated Time of Arrival	KEMSA

County Based Data

Data Category	Data Elements Required	Source
Consumption & stock movement Data	County, Facility Code/MFL No, Facility Name, Product Code, Product Name, Qty Received, Qty Issued, losses & adjustments, Stock on Hand	Health Facility Bin Cards, Daily Activity Registers, Facility CDRR
Orders Data	County, Facility Code/MFL No, Facility Name, Product Code, Product Name, Qty Ordered	LMIS Order forms

Annex 2: Types of logistics records

Type of Record	Description	Examples
Stock keeping records	• Used to record information about products in storage. • Must contain the quantity of stock on hand; the quantity of losses; and the quantity of adjustments, by individual product • Completed by anyone who receives or issues stock from storage, and by anyone who takes a physical inventory of the stock, including the warehouse manager and other warehouse staff, and service delivery point (SDP) staff. For pharmacy stores, the staff should also use stock keeping records. The pharmacist and other pharmacy staff are responsible for completing these stock keeping records • Entries are recorded on the stock keeping record whenever products are received or issued. They are recorded when stock is counted during a physical inventory, or as soon as a loss is noticed. When the stock keeping record is full, a new record is started, using the ending balance from the previous record • They are organized by date and transaction reference (the unique number of the corresponding transaction record for a receipt or issue, and/or the name of the facility from which products are received and issued). They record receipts, issues, losses and adjustments, and the balance on hand. They also record the results of physical inventories (when items are counted to verify the quantity in storage) • Types of stock keeping records include stock cards (an individual stock keeping record that holds information about a single product by lot number or batch number), inventory control cards (an individual stock keeping record that holds information about all the lots of a single product), and bin cards	The most common formats for stock keeping records are individual stock cards and stores ledgers. Types of stock keeping records include stock cards, inventory control cards, and bin cards
Transaction records	• Transaction records are used to record information about the movement of stock from one storage facility to another. In addition, transaction records are proof of requisition, issue, and/or delivery • Although transaction records are essential in recording the movement of stock, they do not need to include any of the essential data items mentioned earlier. Sometimes, a transaction record will be combined with a type of report and will include data like current stock on hand and, depending on the system design, losses and consumption data. • Completed by stores/warehouse personnel at both issuing and receiving facilities. In pharmacies or SDPs, e.g. storekeepers, nurses etc. may complete the transaction records. • They are started any time a facility requests or issues supplies. They are filled in at any point in the order, issue, and receipt process when custody of the product being moved changes. They are completed when the receiving facility confirms receipt of the items shipped. • Data in a transaction record - usually organized by date and by transaction number, which helps identify the transaction. Extra copies of transaction records can be a reminder that a request was made and not yet received, or that an item was issued, but confirmation of receipt is still pending. Ideally, transaction records should include a reference number that identifies each transaction. Data on the transaction record are organized by the product requested or issued. One transaction record is usually used to request or issue any number of products. On paper transaction records, the product names may be pre-printed or written by hand.	The most common formats are Bills of Landing; receiving records; issue vouchers; receipt vouchers; and combined requisition, issue, and receipt vouchers. The content of the transaction record will depend on how many transactions and which parts of the transaction are tracked on the record. In all cases, a pre-printed voucher number on each transaction record helps track individual shipments.

Type of Record	Description	Examples
Consumption records	• They are used to record the quantity of each product used by or dispensed to end users or used at an SDP when services are provided • They contain consumption data; more specifically, the quantity of any specific product consumed in a specific period • They do not usually record stock on hand, or losses and adjustments • Service providers who dispense products to clients or use products at SDPs make the entries whenever supplies are dispensed to clients or used by service providers during service provision. The total quantity of each product used or dispensed is totalled at the end of the reporting period • Data is organized by the date of the visit, or date of dispensing or usage. They record the quantity of a specific product either dispensed to users or used by the end user • Consumption records are usually bound in a book or are printed on oversized paper. One record (perhaps consisting of several pages) is usually used per month; however, in a bound book, a new page is started each month	Common examples include daily activity registers (DARs), pharmacy dispensing registers, daily usage registers or logs, and tally/tick sheets.

Annex 3: Global harmonized system of classification and labelling of chemicals

(Symbols from the United Nations Economic Commission for Europe, UNECE)

Corrosive (C)
These substances attack and destroy living tissues, including the eyes and skin

Highly flammable (F)
These substances easily catch fire (flash point: 21–55 °C). Never store flammable substances together with explosive ones.

Toxic (T)
These substances can cause death. They may have their effects when swallowed or breathed in, or when absorbed through the skin.

Harmful (Xn)
These substances are similar to toxic substances but are less dangerous.

Explosive (E)
An explosive is a compound or mixture susceptible to a rapid chemical reaction, decomposition or combustion, with the rapid generation of heat and gases with a combined volume much larger than the original substance

Irritant (I)
These substances can cause reddening or blistering of skin.

Extremely flammable (F+)
Liquid substances and preparations that have an extremely low flash point (<21 °C) and therefore catch fire very easily.

Very toxic (T+)
Substances and preparations that, in very low quantities, cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin.

Oxidizing (O)
These substances provide oxygen, which allows other materials to burn more fiercely.

Dangerous for environment (N)
Substances that, were they to enter into the environment, would present or might present an immediate or delayed danger for one or more components of the environment.

Specific organ toxicity
These substances may cause:
- damage to organ or organs after single or repeated exposure
- respiratory sensitization
- allergy or asthma or breathing difficulties if inhaled.

GLOSSARY OF TERMS

Distribution, Issuing and Dispensing
Properly recorded issuing from the central store to the facilities and within the facility to the dispensary or other internal departments and the correct dispensing to patients including counseling where appropriate.

Inventory Management
Systematic recording of all stock movements using Stock Control Cards (Bin Cards) in order to provide a basis for quantification, ordering and receipt, and monitoring of use.

Law
Written, detailed agreed upon rule that defines appropriate behavior and consequences of illegal behavior.

Policy
Written or unwritten general framework that guides use of resources to achieve national goals.

Procurement / Ordering
Facilities order from KEMSA on a pre-determined schedule, currently every 3 months for levels 2 and 3 and every 2 months for the higher levels. Orders from the parallel programs are based on the same schedules

Quantification
Estimation of the amounts of each item required in order to cover expected consumption over the supply period plus some safety stock, and avoid overstocks/expiries and stock-outs

Regulation
Written specific statement based on existing laws to be modified/adapted to the changing needs of society.

Selection
The choice of required HPT from preprinted lists (i.e. standard order form, hospital order forms and order forms provided under the various parallel programs) in order to enable management of common conditions.

Storage
Proper storage of items in order to maintain quality and facilitate access

Note: *Use, which involves appropriate prescribing and dispensing of HPT and effective patient counseling in order to obtain maximum therapeutic benefit for the patient, is only briefly covered in these guidelines. This area will be the subject of a whole series of activities and interventions, including the preparation of guidelines, SOPs and implementation of (re)training programs.*

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