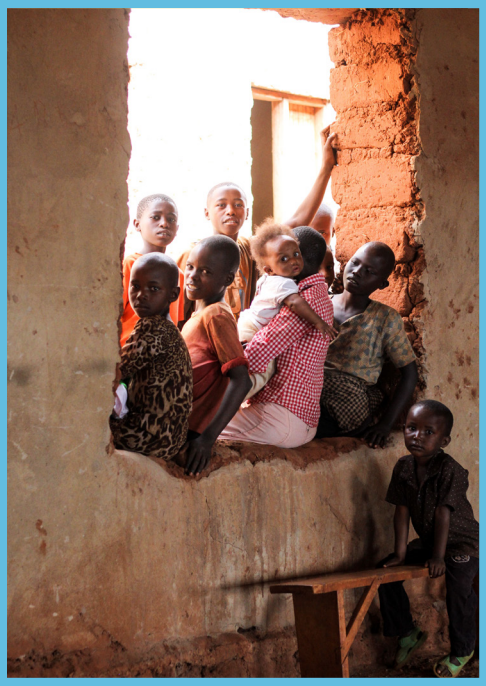
REPUBLIC OF KENYA

MINISTRY OF HEALTH

GUIDELINES FOR THE ESTABLISHMENT AND OPERATIONALIZATION OF MEDICINES AND THERAPEUTICS COMMITTEES

OCTOBER 2020



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Guidelines for the Establishment and Operationalization of Medicines and Therapeutics Committees

October 2020

These Guidelines are a revised edition of the Guidelines of Medicines and Therapeutics Committee of 2015

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FOREWORD

The goal of the Kenya Health Policy (KHP) 2014-2030 is 'to attain the highest possible standard of health in a responsive manner'. The health sector aims to achieve this by supporting *equitable, affordable and quality health and related services at the highest attainable standards to all Kenyans".*

The KHP is committed to ensuring Universal Health Coverage (UHC), whereby everyone who needs health services is able to access them, without undue financial hardship. One of the key components of UHC is that of universal access to Essential Health Products and Technologies of which Essential Medicines is a key component.

Essential medicines are critical to the healthcare system as they provide cost effective solutions to most common health problems and thus help to save lives and improve the health of the population. However, in order to maximize the benefits of essential medicines they must be used appropriately by both the health care providers and the community. However, inappropriate use of medicines continues to be a widespread problem in many developing countries, leading to wastage of resources and compromising the achievement of desired therapeutic outcomes. Various strategies have been employed to improve on appropriate use by health professionals, including development and implementation of medicines use policies through medicines and therapeutics committees (MTCs). Although MTCs have been in existence in Kenya for many years, there is need to review their establishment at various levels and to enhance their roles so that they may provide the desired technical advice and oversight within the devolved structure.

The Kenya Health Sector Strategic Plan of 2018-2023 highlights the important role of medicines and therapeutics committees which should be at all healthcare levels. The National Medicines and Therapeutics Committee was inaugurated and inducted in September 2019 and is supposed to provide oversight to County and Facility MTCs on the mandate of selection and appropriate use of medicines. These guidelines will go a long way in providing a standardized approach to achieving this objective.

It is my sincere hope that utilization and implementation of these Guidelines at the County and Institutional levels will go a long way in ensuring more appropriate and cost effective use of medicines and subsequently enhance the quality of health care delivery especially as we fully implement Universal Health Coverage in Kenya.

Dr. Patrick Amoth, EBS
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MINISTRY OF HEALTH

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ABBREVIATIONS & ACRONYMS

ADR	Adverse Drug Reaction
AE	Adverse Event
AMR	Antimicrobial Resistance
AMU	Appropriate Medicine Use
CCO	County Clinical Officer
CDH	County Director of Health
CHMT	County Health Management Team
CMLC	County Medical Laboratory Coordinator
CMTC	County Medicines and Therapeutics Committee
CNO	County Nursing Officer
CP	County Pharmacist
CPD	Continuing Professional Development
EHPT	Essential Health Products and Technologies
EML	Essential Medicines List
EMMS	Essential Medicines and Medical Supplies
FBO	Faith Based Organization
HEML	Hospital Essential Medicines List
HF	Health Facility
HPT	Health Products and Technologies
HTA	Health Technology Assessment
IGF	Inter-Governmental Forum
KEDL	Kenya Essential Diagnostics List
KEML	Kenya Essential Medicines List
KEMSL	Kenya Essential Medical Supplies List
KFDA	Kenya Food and Drugs Authority
KHP	Kenya Health Policy
KHSSP	Kenya Health Sector Strategic Plan
KNPP	Kenya National Pharmaceutical Policy
MOH	Ministry of Health
MTC	Medicines and Therapeutics Committee
MUE	Medicines Use Evaluation
MUR	Medicines Utilization Review
NMTC	National Medicines and Therapeutics Committee
STG	Standard Treatment Guidelines
TWG	Technical Working Group
WHO	World Health Organization

PURPOSE OF THE GUIDELINES

Inappropriate use of medicines and other Health Products and Technologies (HPT) is a widespread problem at all levels of Health Care Systems in many Countries. This poses a major challenge because resources are generally scarce and always inadequate. On the other hand, inappropriate practices are widely copied and entrenched amongst health workers, forming very bad precedencies for routine. Consequently, the inappropriate practices results in losses and wastage which ultimately reduce access. Reduced access manifests in increased morbidity and mortality.

However, more often than not, challenges are encountered in applying effectively across board the good management principles due to the multidisciplinary nature of the health care workers involved, and the different professional backgrounds. To address these challenges, a governance structure for the Medicines and Therapeutics Committee (MTC) has been shown globally to be suitable and effective in creating a forum where the different professionals and cadres of health workers can work together to develop/adopt customized policies, strategies, guidelines and standard operating procedures/protocols for improving appropriate use of medicines and other HPT. In this regard, the Ministry of Health aims at ensuring that MTCs are established and operationalized at the National and, County levels and in all the Public Hospitals (Levels 4-6).

These guidelines provide guidance on how to establish and operationalize MTC at all levels.

Users of the Guidelines

The guidelines target health professionals and health managers who are involved in MTC activities at all levels of the healthcare system. Additionally, Senior Management for MOH, County Health Management Teams (CHMT), Sub County Health Management Teams (SCHMT) and the Hospital Management Teams (HMT) should also be conversant with the guidelines as the appointing and supervising authorities for MTCs.

CHAPTER 1:
INTRODUCTION

CHAPTER 1

1.1 MEDICINES AND THERAPEUTICS COMMITTEE

The Medicines and Therapeutics Committee (MTC) is a multidisciplinary committee responsible for overseeing policies and procedures related to all aspects of medicines and other HPT use. It evaluates the clinical use of medicines, formulates policies for managing medicines and other health products and technologies use and administration, Pharmacovigilance and safety aspects and manages the formulary system. It also has broad responsibilities in determining which essential HPT will be available in the area under jurisdiction and how they will be used. MTC may exist at various levels of the healthcare system; Hospital, County and National.

1.2 SCOPE FOR THE MEDICINES AND THERAPEUTICS COMMITTEES

Medicines and other HPTs save lives and improve the quality of life by alleviating suffering. In many developing Countries (Kenya included), HPT constitute a significant percentage of the health budget. However, arising from increasing and high costs and scarcity of resources, more often public health systems are unable to procure enough essential HPT to meet patients and other consumer demands. In addition, HPT inputs are often managed inefficiently through inappropriate use, often resulting in losses and wastage of the already scarce and inadequate resources. The end result is compromised quality of healthcare, with poor therapeutic outcomes. Some of these inefficiencies arise from lack of a forum that brings together pharmacists, clinicians and administrators to discuss on how to strike a balance between the demand, quality of care and the available financial resources. The scope of MTC goes beyond medicines and includes all HPTs, encompassing; Surgical, Medical, Dental, Radiological, Nutritional, Physiotherapy, Orthopedic, Diagnostic, Environmental Health Supplies and Medical Devices.

The scope for HPT is that of those categorized and listed as 'Essential' in the Essential Lists and they are those which satisfy the priority healthcare needs of the majority of the population. No public healthcare system of any Country can afford to procure and stock all HPT in a particular market for service delivery. Secondly, it's neither necessary nor desirable to procure and stock all HPTs in the market for the public healthcare system. This therefore calls for the focus of MTC to be on the Essential HPT only.

1.3 GOAL AND OBJECTIVES OF THE MTC

1.3.1 Goal

The goal of the MTC is to ensure that patients and other consumers receive the best possible quality of care, through deciding what Essential HPT will be available, at what cost, and how they will be used.

1.3.2 Objectives

- Ensure that only efficacious, safe, cost-effective and quality EHPTs are used.
- Ensure adherence to the recommended standard clinical/treatment guidelines and protocols.

- Maximize HPT safety through monitoring, evaluating and thereby preventing, as far as possible adverse drug reactions and medication errors.
- Develop and implement interventions for improving HPT use by prescribers, dispensers and patients/consumers through the investigations and monitoring of use.
- Advice on matters of waste management and safe disposal for unwanted HPT.

1.4 FUNCTIONS OF THE MTC

MTC have many functions depending on the level of healthcare. Certain functions may require liaison with other committees/teams, e.g. Infection Prevention/Control Committee (IPC), Procurement Planning Committee (PPC), etc.

The most important MTC functions are as summarized below:

1.4.1 Advisory on Issues Pertaining to EHPT Management and Use

The MTC should advise on all issues, policies and guidelines, SOP concerning the selection, quantification, procurement, distribution, inventory, storage, prescribing and dispensing of EHPT.

1.4.2 Development of EHPT Use Policies

- The MTC is the most appropriate and relevant body for developing HPT use policies at the various levels of the health care system. The policies would in turn inform strategies, guidelines, standard operating procedures and protocols. The HPT use policies may vary from Country to Country, but should for a minimum contain the following: Guideline for the selection of EHPT for listing in the EHPT Lists; Essential Medicines List (EML), Essential Medical Supplies List (EMSL) and Essential Diagnostic List (EDL)
- Outline for Standard Treatment Guidelines and Protocols
- Outline for the National/County/Institutional Formulary
- Guidelines for restricted use of EHPT because of specialty, high costs, potential for abuse/misuse, safety or any other reasons of concern.
- Guidelines for generic and therapeutic substitutions, if not covered by a regulatory framework
- Guidelines for management of HPT promotions and advertisement, if not covered by a regulatory framework
- Guideline for safe disposal of HPT waste, if not covered by regulatory framework
- Guideline for donations of HPT

Selection of EHPT for listing in the EHPT Lists

This should be based on the items covered in the standard treatment guidelines and protocols, which are updated regularly to keep them in tandem with the clinical management practices.

The selection of the items should be evidence-based and should ensure efficacy, safety, quality and cost-effectiveness. The assessment for these parameters is best done through Health Technology Assessment (HTA).

1.4.3 Development of Standard Treatment Guidelines (STGs) and Protocols

STGs and Protocols are proven instruments/tools for promoting and supporting appropriate use of HPT. They should be easy to use, widely disseminated, monitored and evaluated to ensure adherence. STG and protocols also help to optimize clinical management and improve therapeutic outcomes.

1.4.4 Assessments for HPT Use

This helps MTC to identify problems and make appropriate recommendations.

There are several methods for identifying HPT use problems including:

- Aggregated HPT consumption data review
- Monitoring HPT use indicators such as adherence to STG, Protocols, EML, EMSL and EDL
- HPT use evaluation, also known as HPT utilization review
- Monitoring adverse events (adverse medicines reactions, adverse events following e.g. immunizations and medication errors)
- Conducting Surveillance on Anti-Microbial Resistance

1.4.5 Effective Interventions for Improving HPT Use

MTC should ensure that health care workers, patients and consumers have access to unbiased information on EHPT. These go a long way in improving appropriate use.

The interventions include:

- Monitoring, supervision, audits and obtaining feedback
- HPT Use education programs
- In-service capacity building on good HPT management
- Provision of key HPT management instruments/tools - STG, EHPT lists, and Formularies
- Adequate dissemination of the instruments/tools mentioned above
- Keeping to good inventory management practices

1.4.6 Management of Adverse Drug/Medicines Reactions (ADR)

ADR pose a serious risk of causing harm which may increase both morbidity and mortality and bring about increased economic costs. ADR may be due to unknown effects of new (or older) medicines/drugs, unknown medicines/drug combinations and interactions, or poor product quality. The MTC have a responsibility of ensuring that ADR are closely monitored to minimize harm effects.

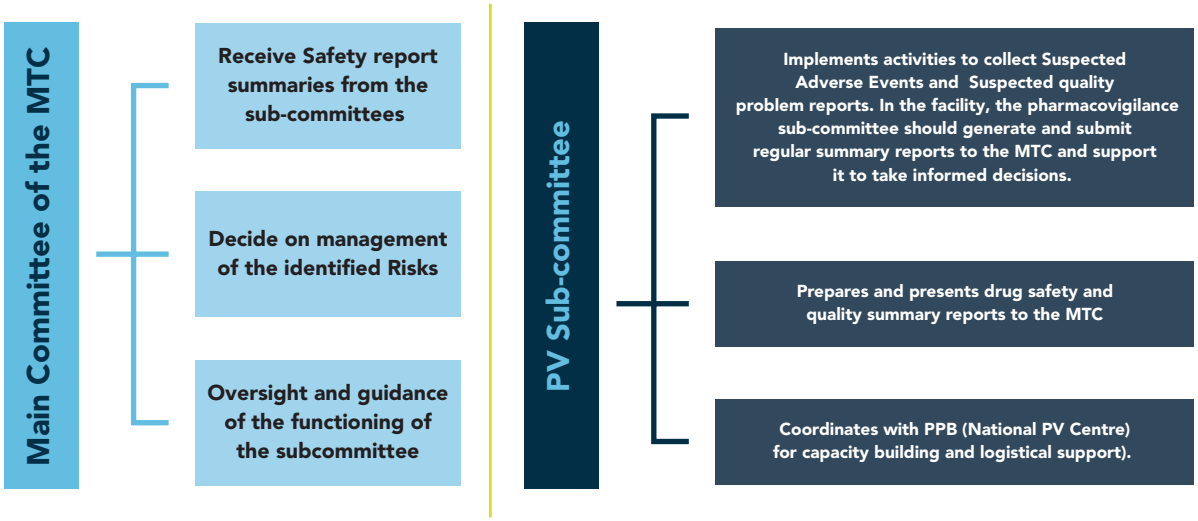

Figure 1.1 | Role of MTC in Pharmacovigilance

1.4.7 Management of Medication Errors

Medication errors occur in all health-care settings, no matter how well the healthcare workers are at prescribing, dispensing and administering medicines and other HPT. At times, there may be no errors on the part of healthcare workers, but consumers end up using medicines incorrectly.

There are numerous causes for medication errors, which include: information and knowledge gaps, staff fatigue/burnout, wrong attitudes, inadequacy in procedures, lack of policies, unfamiliar dosage forms/strengths and human error.

MTC should always strive to minimize medication errors by monitoring, analyzing, and implementing corrective actions.

There should be written Standard Operating Procedure (SOP) for reporting and managing medication errors.

1.4.8 Health Products and Technologies Management Cycle

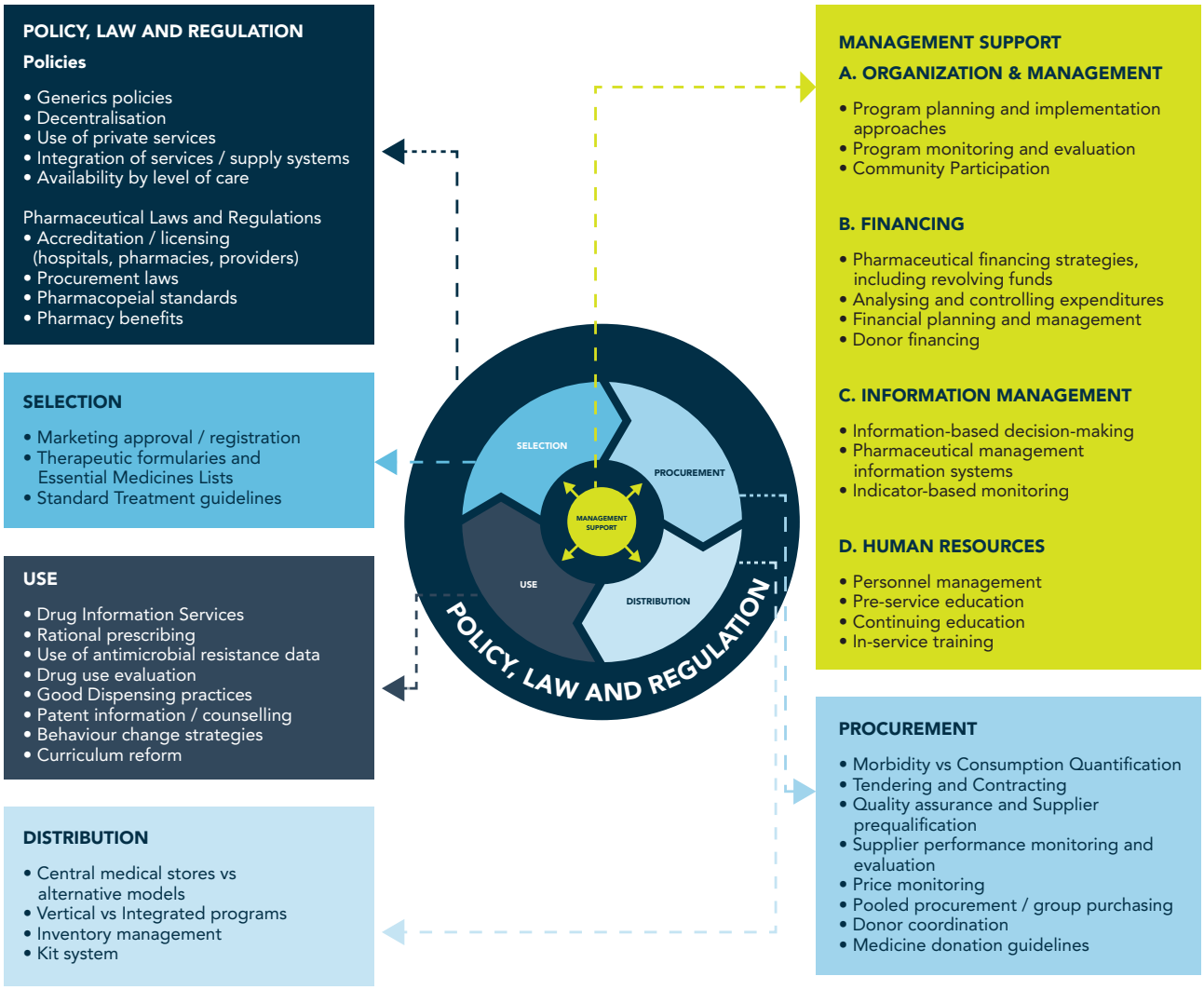

Figure 1.2 | The Essential Health Products and Technologies Management Cycle

Effective HPT management takes the above cyclic steps.

For effectiveness, all the steps of the cycle have to be operationalized.

MTC have some roles in all the steps. However, the role is more pronounced in some steps than others e.g. selection, procurement and use.

1.5 MANDATE OF THE MTC

The Kenya Health Policy 2014-2030, The Kenya Health Sector Strategic Plan 2018-2023 and The Sessional Paper No. 4 of 2012 on the National Pharmaceutical Policy (NPP) (under its Policy Imperative 122) provide for the establishment of Medicines and Therapeutics Committees in health facilities for purposes of promoting appropriate use of medicines and other health products.

Against that policy back ground, the Ministry of Health has been reconstituting through appointment, the National Medicines and Therapeutics Committee (NMTC) every three (3) years. The last appointment was in July 2019.

A few Counties and levels 4-6 hospitals have also been able to establish and operationalize MTC in their set ups. However, across board, MTC function sub-optimally where they exist. Deliberate actions needs to be taken to correct that situation.

CHAPTER 2:
RATIONALE AND CONTEXT OF MTCs

The establishment of MTC in Kenya is supported by various policies and strategic plans in the Health Sector, including; the Kenya Health Policy (2014 - 2030), Kenya Health Sector Strategic Plan (2018 - 2023), the HPT supply chain strategy (2020 -2025) and Sessional Paper No. 4 of 2012 on the National Pharmaceutical Policy.

2.1 THE KENYA HEALTH POLICY (KHP), 2014-2030

Policy Orientation 6: Health Products and Technologies (HPT): "is geared towards ensuring that effective, safe, and affordable health products and technologies are available and appropriately used at all times, while moving towards maintaining a strategic national health products and technologies (HPT) reserve. This will be attained through the development and implementation of a national HPT policy and relevant regulatory frameworks. It outlines the strategies for use as:

- 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.

- 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.

- Appropriate 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 appropriate use of drugs and other health products".

2.2 KENYA HEALTH SECTOR STRATEGIC PLAN (KHSSP), 2018 -2023

To achieve UHC, HPT security is identified as critical because most services cannot be rendered without them. This requires an effective and efficient public health supply chains that would deliver quality HPT in a reliable, cost-effective and uninterrupted manner. The entire scope of EHPT is necessary to support the UHC benefits package, which focuses on responsiveness to the population needs by expanding primary care services e.g. to cover diagnostic supplies for screening, as well as coverage for non-communicable diseases. In addition, price reduction strategies, and prudent HPT management including rational use are identified as strategies for improving access.

Investment/inputs in the area of HPT is expected to give the following Key Outputs:

- Increased capacity and access to all EHPT
- Enhanced quality of all EHPT
- Prudent/Improved HPT Management
- Enhanced support supervision with resultant improved HPT Management
- Strengthened legal identity and advocacy of KNBTS.
- Adequate safe and equitable supply of blood and blood products

- Enhanced quality of blood transfusion service and products

2.3 SESSIONAL PAPER NO. 4 OF 2012 ON THE NATIONAL PHARMACEUTICAL POLICY (NPP)

The NPP provides for establishment of MTC at National, County and Health Facility level. Policy imperative 122 states the following:

"The Government will promote evidence-based selection of medicines to meet public health needs. To facilitate the attainment of this objective the Government will:

- Restructure and support the National Medicines and Therapeutic Committee (NMTC) to advise Government and stakeholders on the appropriate use of medicines.

- Through the NMTC, collect, evaluate and disseminate systematic data on medicines utilization to monitor and act on policy adherence.

- Review and regularly update the following standard therapeutics tools, at least every 2 years and promote their use at all levels of the health system. The Essential Medicines Concept as defined by WHO will be the basis for medicines selection.
  - The Kenya Essential Medicines List (KEML)
  - The Kenya Essential Medical Supplies List (KEMSL)
  - Kenya Essential Diagnostics List (KEDL)
  - Standard Clinical Guidelines for management of health conditions in the country.

- Promote the Essential Medicines Concept and evidence-based selection of medicines in all sectors and in training programmes for health workers.

- Mandate health facilities and counties to establish Medicines and Therapeutic Committees (MTCs), with membership drawn from pharmacists, physicians, nursing staff, specialists and health administrators. Each MTC will be required to:
  - Adapt from the KEML a list of EMMS to be procured, prescribed and dispensed within the facility, based on the local disease patterns and the best available evidence on therapeutic efficacy and cost-effectiveness.
  - Monitor therapeutic trends and other medicines use practices in the facility; and institute corrective measures to ensure appropriate prescribing and dispensing.
  - Develop institutional policies, guidelines and advocacy initiatives aimed at improving use of medicines.
  - Provide feedback to the national MTC on evidence and trends in therapeutics, to guide review of the national STG and EML.

2.4 HEALTH PRODUCTS AND TECHNOLOGIES SUPPLY CHAIN STRATEGY, 2020-2025

The HPT Supply Chain Strategy 2020-2025 is amongst other documents developed to address shortcomings in the management and utilization of HPT at all levels of healthcare. The increased demand arising from the need to attain affordable Universal Health Coverage (UHC) initiative, changing epidemiological patterns and improved health education for Kenyans creates more compelling needs for functional Medicines and Therapeutic Committees.

Some of the gaps identified in the HPT supply chain strategy in the area of MTCs include:

- Inactive MTC at County and Facility levels
- Poor prescribing practices
- Inadequacy in regulatory framework with regards to regulations governing prescription only medicines and advertising
- Weak/lack of regulatory framework for traditional and alternative medicines
- Inadequate post-market surveillance and pharmacovigilance systems

To address the above gaps, the HPT supply chain strategy 2020-2025 recommends:

- Establishment and operationalization of medicines and therapeutic committees (MTC) at National, County and Hospital levels.
- Strengthening of the National Medicines and Therapeutic Committee (NMTC)
- Support to County and Hospital MTC to carry out operational research on management and use of HPT.
- Development and implementation of a program for strengthening rational use of HPT amongst health workers.

CHAPTER 3:
STRUCTURE AND ORGANIZATION OF MTC

CHAPTER 3

3.1 PRINCIPLES FOR SETTING UP MTC

Effective functioning of MTC is dependent on goodwill for support from Senior Management and abiding by the following principles:

3.1.1 Multidisciplinary Approach

Different cadres of health professionals are involved in MTC activities, each with different backgrounds, experiences, beliefs, skills, practices, motivations, attitudes and status. The MTC will often have to manage conflicts arising between clinicians, pharmacy and management arising from especially prescribing restrictions guided by guidelines, protocols and SOP. However, such conflicts would be reduced, if staffs are adequately sensitized on all decisions; there is multidisciplinary representation in the MTC; documenting and disseminating decisions made in addressing problems associated with use of HPT. This helps in wining confidence of the whole team. Further, providing feedback and expressing appreciation enhances trust and cooperation.

3.1.2 Transparency, Accountability and Commitment to Service

The success of any MTC will depend on members being active, committed and making sound decisions in a transparent and accountable manner. This is especially important in HPT selection and procurement policies. The members should not be influenced by biased and skewed HPT advertisements/promotional activities and personal motivation for financial gains. To manage such conflict of interests, all MTC members are supposed to declare and sign a 'declaration of interest' form which binds them to the principles and ethics required of their roles and responsibilities.

3.1.3 Technical Capacity

MTC at all levels should strive to have the requisite technical capacity. This should be through harnessing and riding on the diversity of technical expertise and competencies of the members and promoting team work. MTC must always endeavor to ensure that all decisions are based on/ backed by scientific evidence.

3.1.4 Administrative Support

Administrative support is important for facilitation of implementation of MTC decisions. It also provides the financial and material support required to undertake many of the MTC's activities.

This support should be mobilized as much as possible from the operations budget of the hosting entity. Establishment of a line budget on MTC operations would be the most desirable and sustainable route to take.

3.1.5 Information Dissemination

MTC should develop a clear dissemination mechanism for activities, decisions and recommendations within the organization for information and implementation.

MTC should also have a robust M & E framework for the work plans for purposes of tracking performance and progress.

3.2 STEPS FOR ESTABLISHING AND OPERATIONALIZING MTC

Steps for Establishment of MTC in Health Facilities:

STEP 1: Organization of the Committee and Selecting of Members

The size and composition of MTC may vary. Small committees may be appropriate for small hospitals while larger ones may be more useful in big hospitals with greater variety and scope of health services. Few members may allow consensus agreements to be reached more easily, while many members may provide for greater expertise, reduce the workload per individual members, and increase the ease of implementation of decisions. Nevertheless, all committees should have sufficient members to represent all critical areas of operations as far as HPT use are concerned, which includes representation from; Clinical Departments, Nursing, Administration, Medical Diagnostics and Pharmacy.

Members should be nominated with reference to their positions and responsibilities, and officially appointed by the highest authority in the institution. The Terms of Reference (ToR) of the appointed members should be clearly defined in the letters of appointment.

By virtue of MTC membership being by appointment, delegation of attendance for meetings should not be allowed.

The **Chairperson** and **Secretary have to go an extra mile for MTC to achieve and maintain vibrant status of operation**. In most hospitals, a Senior Medical Specialist, ordinarily well-known and respected is preferably appointed as the Chair and the Pharmacist in-Charge/ Clinical Pharmacist as the Secretary. The responsibilities of the Chair and Secretary should be recognized in their duties and responsibilities to the hospital for purposes of being accorded time to attend to MTC activities.

STEP 2: Determine the Objectives and Functions of the Committee

It is not possible for the MTC to do everything. The ToR defines the goals, objectives, functions and responsibilities. Refer to the key functions and roles for MTC in health facilities as described under section 3.3.3.

The MTC is responsible for maintaining and improving standards for health care within the health facility. Some standards are developed at the National level and implemented at the facility level e.g. Standard Treatment Guidelines and Essential Medicines List.

Other standards may be developed by the MTC at the facility level e.g. a Hospital Formulary. However, these facility specific standards must be adopted from the National Standards.

The MTC cycle of activities includes definition of standards, assessment of performance, diagnosis of poor performance and introduction of measures to improve performance. The figure below illustrates the interrelation between the different possible functions and activities of the MTC.

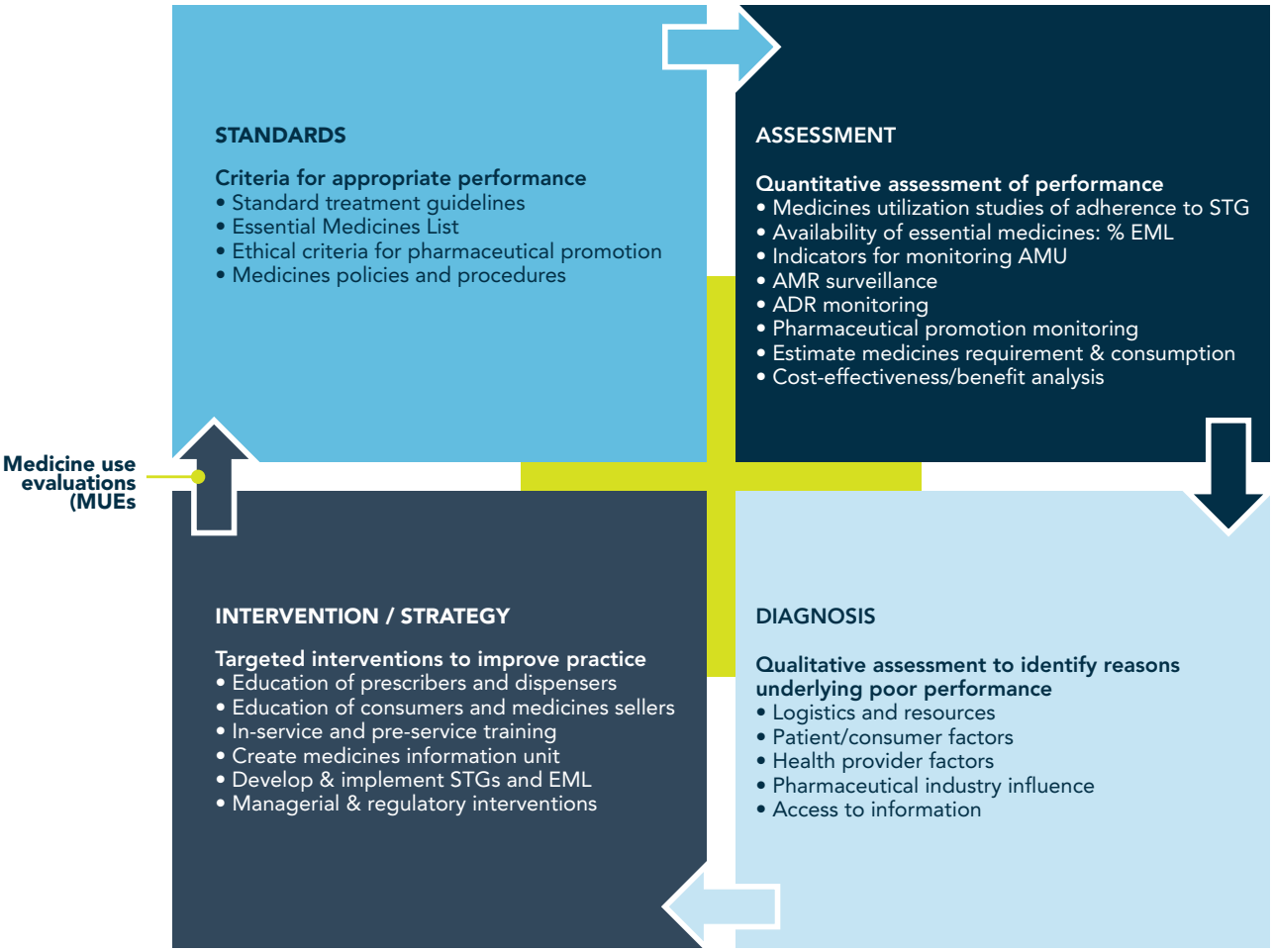

Figure 3.1 | MTC Management Cycle for Activities and Functions

STEP 3: Operations of MTC

- The MTC should have regular meetings for a minimum quarterly but preferably monthly depending on the workload. Hospital MTC meetings are recommended for monthly, while County and National are quarterly. Special meetings should be convened whenever necessary

- The length and timing of meetings should be carefully determined so as to encourage regular attendance and participation of members

- The Agenda, resource materials and minutes of the previous meeting should be prepared by the Secretary and distributed to the members for review in sufficient time before the meeting. These documents should be kept as permanent records of the hospital and should be circulated to the heads of all relevant departments. For information and action.

- MTC recommendations should be disseminated to all the relevant staff, departments and authorities in the hospital. Regular hospital activities such as ward rounds and clinical discussions should be used as venues for discussing and disseminating MTC recommendations.

- MTC operating guidelines, policies and decisions should be documented. Documentation should include sanctions for any non-compliance. The documentation must be easily accessible to relevant staff and other persons such suppliers for HPT, those carrying out promotional activities etc.

- Liaison other Hospital Committees, County and National MTC. This is important, for two reasons:
  i. Harmonization of related activities e.g. surveillance of antimicrobial resistance (AMR) and antimicrobial use
  ii. Share information concerning common activities e.g. monitoring of adverse drug reactions and strategies for educational activities such as continuing medical education.

STEP 4: Mandate

Only with the mandate conferred through appointment from the most senior authority in the hospital is the MTC credible and sustainable.

The mandate of the MTC as earlier said should be spelt in the ToR and should specify:
- Roles, Responsibilities and Functions
- Organizational structure
- Membership
- Scope and lines of authority

In the future, the policy position for MTC is planned to be strengthened through the backing of enabling regulatory framework.

STEP 5: Identifying budgetary sources

MTC must be able to mobilize resources to support own activities (such as meetings or incentives for its members), and the activities for implementation e.g. continuous medical education, health promotion programs, development of treatment protocols and clinical pathways, medicine utilization reviews assessments and supportive supervision activities.

Responsibilities for members of MTC should be reflected in the job descriptions of all the relevant staff. Budget requirement is usually not high and can be justified to the hospital management on the basis of the cost savings from effective utilization of the HPT through the MTC activities.

MTC should be always attempt to demonstrate cost-effectiveness when requesting for the regular budget allocation from the hospital management. MTC should always have a costed annual work plan. It is good to always bear in mind that budgetary requests are more admissible when backed with past or potential future cost savings.

STEP 6: Constitution of Sub-committees to address specific issues

More often, there are specific areas of functionality which may need extra work or/and expertise that the MTC may not be able to effectively address through the routine meetings. For such tasks, the MTC may deal with them by constituting sub-committees, which would work on the specific areas and report back.

A few areas suggested for establishing sub-committees are; supply chain and logistics; antimicrobial stewardship; safety and pharmacovigilance among others.

Sub-committees should be chaired by members of the MTC and can be established on ad hoc, temporary or permanent basis. Minutes for meetings of the sub-committees should always be shared and discussed by the full meeting of the MTC.

Sub-committees can also be used for implementing MTC decisions/activities.

STEP 7: Assessment of the MTC's performance

Continuous assessment and evaluation of the MTC are important if performance and impact are to be improved. The organizational development and performance of the MTC should be monitored continuously and documented, especially if the MTC is to expect the hospital management to provide continuing funding and other resources necessary for them to function.

Some of the key indicators that can be used in the assessment for MTC are shown in Annex 2. Those indicators are considered to be core for assessment for MTC. However, the MTC can develop other additional indicators and measures that would enhance to serve the purpose. Assessments through the indicators should be used to evaluate the impact of the MTC, in terms of achieving the goal and objectives and justifying the continued support by the hospital management.

3.3 ORGANIZATION OF MTCs

Medicines and Therapeutics Committees have existed in Kenya since 2000, when the first National Medicines and Therapeutics Committee (NMTC) was established as defined in the first policy in the area of pharmacy, the National Drug Policy(NDP) of1994. Since then, there has been a significant increase in the number of MTC established at hospitals level.

Under the Devolved System of Governance, MTC are supposed to be established at three levels of the health care system:

- National Medicines and Therapeutics Committee (NMTC)
- County Medicines and Therapeutics Committee (CMTC)
- Hospital Medicines and Therapeutics Committee (MTC)

3.3.1 National Medicines and Therapeutics Committee (NMTC)

The National Medicines and Therapeutics Committee (NMTC) is the highest level medicines management and therapeutics advisory body in the Country. It is supposed to be a multi-disciplinary committee comprising clinical and pharmaceutical expertise and is the body that should authoritatively guide on the appropriate use of HPT, in order to achieve the desired public health outcomes, with limited resources

3.3.1.1 Membership of the NMTC

1. Nominee of the Director General of Health as the Chairperson
2. Director of Pharmaceutical Services/Head of HPT in MoH as the Secretary
3. Nominee from Nursing Services in MoH
4. Nominee from the Pharmacy and Poisons Board/KFDA
5. Nominee from Kenya Medical Supplies Authority(KEMSA)
6. Nominee from Council of Governors(CoG)
7. Nominee from Kenya Medical Practitioners and Dentists Council
8. Head, Laboratory and Diagnostics Services in MOH
9. Head/Nominee Clinical Services in MOH
10. Head, Preventive and Promotive Health Services in MoH
11. Head, Research in MoH
12. Head, Non-Communicable Diseases in MoH
13. Head, Strategic Programs in MoH
14. Head, Oral Health Services in MoH
15. Nominee from Mission for Essential Drug Supplies (MEDS)
16. Infectious disease specialist(Microbiologist)

There should be an induction and orientation for a new NMTC to make members fully conversant with the terms of reference for the appointment.

3.3.1.2 Generic Terms of Reference of the NMTC

1. Coordination of policies on clinical governance and use of HPTs.

2. Develop Standards and Guidelines on:
   - Establishment and operations of MTCs at various levels (National, County and Institutional).
   - Appropriate prescribing, dispensing and requisition.
   - Safe and cost-effective use of HPTs:
     - Evidence based standardized approaches, ADR monitoring and reporting, HPT information, HPT safety and quality assurance.
   - Clinical audits and HPTs use evaluation studies.

3. Formulate, review and update all the relevant appropriate use guidelines e.g. National Clinical Guidelines, National Formulary, National Essential Health Products and Technologies lists, and other specific/specialized treatment guidelines.

4. Review relevant research findings and recommend appropriate interventions.

5. Identify and propose areas requiring innovative and operational research.

6. Collaborate with the relevant National and County levels to implement mitigation measures in the event of emergency disease outbreaks or health threats.

7. Collaborate with relevant Departments during the introduction of disease-based or vertical programs in which selection and use of HPT is a significant component.

8. Advocate for NMTC, its activities and adequate funding.

9. Facilitate communication regarding use and safety of HPT between stakeholders including consumers, health care professionals, County and National Agencies.

10. Support county, sub-county and hospital MTCs through development and dissemination of guidelines, training materials, and capacity building.

11. Actively participate in the development, review and revision as necessary of:
    - Pre-service health professional programs in management and use of HPT.
    - In-service training and CPD courses in management and use of HPT.

12. Support National referral hospitals and County health facilities on medical waste management.

13. Co-option of other members as the committee may find necessary.

3.3.2 County Medicines and Therapeutics Committee (CMTC)

The CMTC is an advisory body for the County Health Management Team (CHMT) for clinical governance and use of HPTs.

3.3.2.1 Membership of the CMTC

The recommended membership of the CMTC is as follows:
1. County Director of Health(CDH) or his/her Nominee as the Chairperson
2. County Pharmacist (CP) as the Secretary
3. Pharmacovigilance and medicine safety focal person
4. County Nursing Officer (CNO)/County Commodity Nurse
5. County Health Administrator
6. Head of Oral Health Services
7. Internal Medicine Specialist from a County Referral Hospital
8. County Medical Laboratory Coordinator (CMLC)
9. County Clinical Officer (CCO)
10. Representative from Medical Training Institution/research institution in the County

3.3.2.2 Generic Terms of Reference of the CMTC

The CMTC has the following terms of reference:
1. Ensure dissemination and distribution of National Guidelines and other documents for supporting appropriate use of HPT; Standard Treatment Guidelines, Program Specific Treatment Guidelines, Protocols and Clinical Pathways, Essential Health Products and Technologies lists, e.g. KEML,KEMSL,KEDL, and any other relevant documents.

2. Ensure adherence and implementation of National Policies, Standards and Guidelines in the area of HPT.

3. Establishment of MTC at County and hospital level.

4. Promote appropriate prescribing and dispensing practices.

5. Promote safe and cost-effective use of medicines and other HPTs, evidence based standardized approaches, adverse events monitoring and reporting, HPT information, HPT safety and quality assurance.

6. Systematically collect, collate and share information for review and update of Standard Treatment Guidelines (STGs) and HPT lists.

7. Facilitate and coordinate identification and implementation of priority research and dissemination of research findings as well as implementation of recommendations

8. Disseminate and implement guidelines for clinical audits and Medicines Use Evaluation (MUE) studies.

9. Collaborate with National and inter-County levels to implement mitigation measures in the event of emergency disease outbreaks or health threats.

10. Collaborate with National level during introduction of disease based or vertical programs in which there are new management protocols.

11. Collaborate and engage with other stakeholders in HPT utilization management.

12. Mobilize and allocate financial resources for MTC activities.

13. Supportive supervision for hospital MTC.

14. Monitoring & Evaluation of MTC activities in the county.

15. Facilitate information sharing between Hospitals, County and National MTC.

16. Facilitate communication at County level regarding medication safety between stakeholders including consumers and health care professionals.

17. Support establishment and operationalization of hospitals MTC through implementation of guidelines and dissemination and use of training materials, and capacity building.

18. Ensure systematic continuous medical education forums on health products and technologies and therapeutic activities.

19. Provide oversight for pharmacovigilance activities.

20. Guide the CHMT on selection of all HPT requirements for the county based on Essential HPT lists.

21. Ensure regular availability of the required HPT inventory control tools and other documents of accountability, e.g. prescription pads, treatment sheets, stock control cards and their proper use.

22. Support County health facilities on medical waste management.

23. Co-option of other members as the committee may find necessary

3.3.2.3 Meetings of the CMTC

The CMTC should meet quarterly for a minimum, but may do so more frequently if there is need. The recommended quorum should be at least two-thirds (2/3) of the members and the chairman shall have an additional tie-breaker vote to be used in case of a tie during voting.

3.3.2.4 Linkages between NMTC and CMTC

Appropriate linkages are crucial for the smooth function of medicines and therapeutics activities throughout the healthcare system. The following mechanisms support the process:

- Coordination will be through the health inter-governmental forum (IGF) and direct between the various committees

- Communications will be channeled through the relevant IGF mechanisms and offices between the various committees chairpersons and secretariats

- Regular consultative fora should be held between the national and county levels to facilitate structured information flow and feedback, resource mobilization, capacity building & technical assistance.

3.3.3 Hospital Medicines and Therapeutics Committee (HMTC)

Hospital Medicines and Therapeutics Committees (HMTC) should be multi-disciplinary and established within the health institutions designated as hospitals (Levels 3 and above). They serve as advisory bodies to the Hospital Health Management Team.

3.3.3.1 Membership of Hospital MTC

The membership should include:
1. The Medical Superintendent or his/her nominee as the Chairperson
2. Pharmacist in Charge as the Secretary
3. One(1) Senior clinician from major specialty; surgery, obstetrics and gynaecology, internal medicine, paediatrics, infectious diseases
4. Senior clinical officer
5. Clinical pharmacologist or clinical pharmacist or pharmaco-epidemiologist and PV specialist (if available)
6. The Nursing Officer in Charge/Commodity Nurse
7. An administrator representing administration and finance
8. Medical laboratory officer in charge
9. In-charge Medical records Department

3.3.3.2 Terms of Reference of the Hospital MTC

1. Implement policies for selection and use of medicines and other HPT including:
   - Standard Treatment Guidelines (STG)
   - Development the institutional HPT essential lists customized from the National lists
   - Develop the generic substitution and therapeutic interchange policy

2. Develop policy for use of items not on the essential HPT due to individualized need e.g. antimicrobial resistance, investigational products etc.

3. Assess HPT use to identify problems through:
   - Medicines utilization reviews
   - Review of aggregate HPT consumption data
   - Monitoring indicators of HPT use, including adherence to standard treatment guidelines
   - Antimicrobial resistance surveillance

4. Develop and implement strategies to address identified HPT use problems.

5. Encourage and support prescribers to use unbiased HPT information.

6. Monitor and analyze expenditure on HPT.

7. Advice on HPT for procurement by the hospital.

8. Undertake continuous medical education and other activities aimed at promoting appropriate use for HPT.

9. Undertake Pharmacovigilance activities in areas of medication errors, adverse HPT reactions, treatment failure, monitoring HPT quality and medication errors and actions to prevent re-occurrence.

10. Control activities of HPT promotion within the hospital by medical representatives

11. Provide regular feedback to the County MTC.

12. Provide technical support in the management of medical waste.

13. Co-option of other members as the committee may find necessary.

ANNEXES

Annex 1: Conflict of Interest Declaration Form

Name …… Position ……

1. Do you, or anyone in your family, have any financial or other interest in any pharmaceutical manufacturer or supplier, which may constitute a real, potential or apparent conflict of interest? Please tick : Yes ☐ No ☐

2. Have you had, during the past 4 years, any employment or other professional relationship with any organization or person that is a pharmaceutical manufacturer or supplier or represents such organizations? Please tick: Yes ☐ No ☐

If you answered 'yes' to question 1 or 2, please give details in the table below.

Type of interest (see notes below)	Name of company or business	Relationship to you	Current interest? Or year when interest ceased

3. Is there anything else which could affect, or be perceived to affect, your objectivity or independence in carrying out your duties in the MTC? If so, please state below:
……
……
……

I hereby declare that the disclosed information is correct and that no other situation of real, potential, or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances.

Signature…… Date……

Notes: Types of financial or other interests

- Any payment for performance of work or research or educational grants during the past four years by any company or business which may have an interest in the MTC's work (amounts do not need to be declared).
- Current proprietary interest in any substance, technology or process being considered by the MTC or otherwise related to the MTC's work.
- Current financial interest (e.g. shares, bonds) in a company or business with an interest in the MTC's meetings or work (shareholdings where the person has no control over the selection of shares, are exempt).
- Any employment, consultancy, directorship, or other position during the past 4 years or presently under negotiation, whether paid or not, in any company or business which has an interest in the MTC's work.

Annex 2: Core Indicators for Assessing Hospital MTC Performance & Impact

1. Is there a Hospital MTC document showing terms of reference, including goals, objectives, functions and membership?

2. Is the MTC in the organizational chart of the hospital?

3. Is a budget allotted for MTC functions?

4. Does the MTC have established criteria and authority concerning selection of medicines?
   - How many medicines are there in the Hospital Essential Medicines List (HEML)?
   - Are there documented criteria for addition to and deletion from the list and requests for the use of non-HEML medicines?
   - What percentage of prescribed medicines is on the HEML?

5. Has the MTC been active in the development and implementation of STGs?
   - Has the hospital developed/adopted its own STGs?
   - Have drug utilization studies been performed to assess adherence to STGs?

6. Has the MTC organized educational activities about medicines?
   - Have there been any organized training and lectures for health-care staff?
   - Is there an established library accessible to staff?
   - Is there continuing medical education?
   - Is there a medicines information service available to staff?

7. Have any intervention studies to improve medicine use been undertaken?

8. Have there been any Pharmacovigilance activities or addressed medicine safety issues by the MTC?
   - Number of MTC meetings that have addressed Pharmacovigilance and medicine safety issues?
   - Number of staff/public education activities on medicines safety?

9. Has the MTC been involved in medicines budget allocation?
   - Was the MTC consulted during medicines budget allocation?
   - Was MTC clearance needed prior to medicines budget approval?

10. Has the MTC developed a policy for controlling the access of medical representatives and promotional literature to hospital staff?

GLOSSARY

Adherence / Compliance to treatment	The degree to which patients adhere to medical advice and take medicines as directed. Adherence depends not only on acceptance of information about the health threat itself but also on the practitioner's ability to persuade the patient that the treatment is worthwhile and on the patient's perception of the practitioner's credibility, empathy, interest and concern
Drug / Medicine	Any substance in a pharmaceutical product that is used to modify or explore physiological systems or pathological states for the benefit of the recipient. In this guideline, the words 'drug' and 'medicine' are used interchangeably.
Drug / Medicine use	The process of diagnosis, prescribing, labeling, packaging, and dispensing and of adherence to drug treatment by patients
Drug / Medicine use evaluation	A system of ongoing, systematic, criteria-based evaluation of drugs that will help ensure that appropriate medicine use (at the individual patient level) is provided. It is the same as drug utilization review
Evaluation	A periodic assessment of progress toward achieving long-term objectives and goals
Formulary manual	A manual containing clinically oriented summary pharmacological information about a selected number of medicines. The manual may also include administrative and regulatory information pertaining to medicine prescribing and dispensing
Formulary system	The principles, criteria, procedures, and resources for developing, updating and promoting the formulary (essential medicines) list
Generic name	The approved or nonproprietary name of a drug. It is generally the international nonproprietary name given by WHO
Health Products and Technologies (HPT)	The application of organized knowledge and skills in the form of medicines, devices, vaccines, procedures, and systems developed to solve a health problem and improve the quality of lives.
Inappropriate prescribing	Prescribing that does not conform to good standards of treatment – for example, extravagant prescribing, overprescribing, incorrect prescribing, multiple prescribing, or under prescribing of medication
Indicator	Criterion used to measure changes, directly or indirectly, and to assess the extent to which the targets and objectives of a Programme or project are being attained. Indicators should meet the criteria of clarity, usefulness, measurability, reliability, validity and acceptance by key stakeholders
Monitoring	The ongoing process of reviewing the degree to which Programme activities are completed and objectives are being met, to allow for corrective action to be taken during implementation
Objectives	Results that a program or work plan seeks to achieve. A well-formulated objective fits the SMART mnemonic: specific, measurable, appropriate to overall objectives or goals, realistic in terms of available resources, time-bound (there is a deadline)
Prescribing	The act of determining what medication the patient should have and the correct dosage and duration of treatment
Standard treatment guidelines	Agreed-upon treatment practices for a diagnosed illness; may include more than details of drug treatment
Therapeutic substitution	Interchange of one pharmaceutical product with another that differs in composition but is considered to have similar pharmacologic and therapeutic activities in accordance with written protocols previously established and approved

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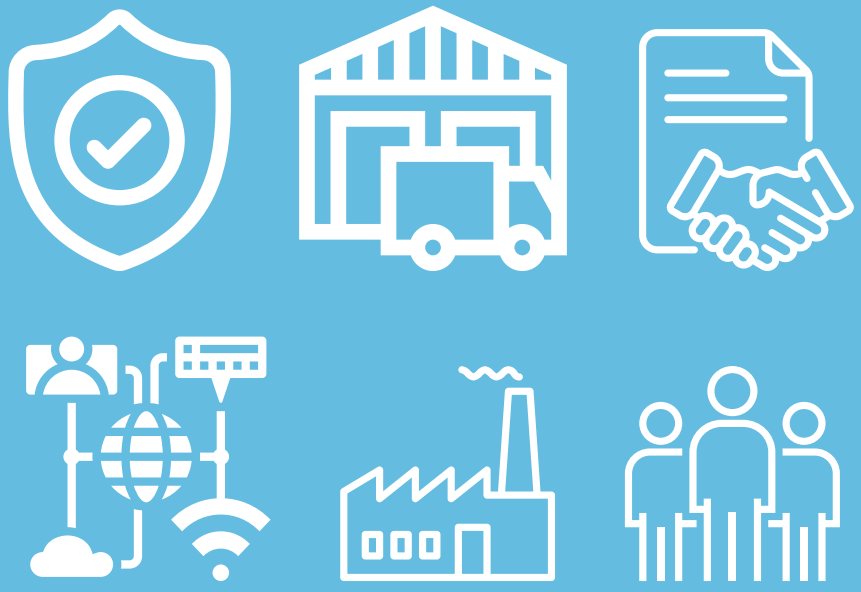

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