



THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

**DEPARTMENT OF PHARMACEUTICALS AND
NATURAL MEDICINES**

**HEALTH COMMODITIES SUPPLY CHAIN POLICY
DEVELOPMENT FRAMEWORK (A GUIDE TO DEVELOPING
AND IMPLEMENTING HEALTH COMMODITIES SUPPLY CHAIN
POLICIES)**

2021



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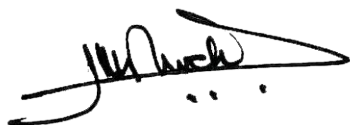
FOREWORD

The development of this health commodities supply chain policy development framework has been informed by the WHO guidelines for policy formulation, and other literature in the global health policy discourse. The framework domesticates the policy formulation process in the context of Uganda and particularly, the Ministry of Health's pharmaceutical sub-sector.

The framework was developed through a consultative process involving Ministry of Health departments of Pharmaceuticals and Natural Medicines, and Planning, Finance and Policy, Representatives of the Regional Referral Hospitals, and National Drug Authority.

The framework describes step-by-step process of formulating, implementing, monitoring, reviewing and reforming the health supply chain -related policies, regulations and guidelines. Specifically, the framework (i) provides the principles which guide the formulation and review of health supply chain policies, guidelines, regulations and reforms; (ii) establishes standardized procedures to ensure consistent formulation, approval, monitoring, and review of health supply chain policies, guidelines, regulation and reforms; and (iii) provides a comprehensive, single point of reference for information relating to health supply chain policy formulation, approval, implementation, monitoring, evaluation, review and analysis.

I wish to thank the policy and governance technical team at the USAID/ Uganda Strengthening Supply Chain Systems (SSCS) Activity for the invaluable technical input they provided in the development process of this supply chain policy development framework.



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**Director General of Health Services,
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I want to thank all the staff of the Ministry of Health department of pharmaceuticals and natural medicines for their commitment and dedication toward the development of this policy framework amidst their very busy schedules. I would like to particularly recognise the commitment and dedication of Dr. Fred Sebisubi, Ms. Martha Ajulong, and Mr. Thomas Ocwa Obua for ensuring that the process remained on track and that the policy document framework was delivered on time.

A vote of thanks to all our partners and colleagues in the Ministry of Health department of planning, finance and policy; regulatory agencies particularly National Drug Authority; sub- national teams particularly from the Regional Referral Hospitals of Jinja and Lira who contributed to this process in one way or another.

Finally allow me in a special way, to thank Mr. Moses Mukundane, the Strategy and Program Innovation Director and the the policy and governance technical lead of the USAID/ Uganda Strengthening Supply Chain Systems (SSCS) Activity for providing the technical leadership in the development process of this framework, and accommodating all our observations, comments, inputs and requests, and staying with the process to the very end.



Ms. Neville Okuna Oteba

Commissioner Health Services / Pharmaceuticals and Natural Medicines Ministry of Health

LIST OF ACRONYMS

DPNM	Department of Pharmaceuticals and Natural Medicines
EMHS	Essential Medicines and Health Supplies
GOSPOR	Governance, Standards, Policy and Regulations
HCSC	Health Commodities Supply Chain
HPAC	Health Policy Advisory Committee
HSC	Health Supply Chain
LTIA	Long term institutional arrangement
MoH	Ministry of Health
MPM	Medicines Procurement and Management
NPSSP	National Pharmaceutical Sector Strategic Plan
PARU	Policy Analysis and Review Unit
SSCS	Strengthening Supply Chain Systems Activity
TWG	Technical Working Group
USAID	United States Agency for International Development
WHO	World Health Organization

1. Introduction

1.1. Introduction

Health is a fundamental human right. Access to health care, including access to essential medicines and health supplies (EMHS), is critical in realizing that right. EMHS play a pivotal role in many aspects of health care. If available, affordable, of good quality and properly used, EMHS can offer a simple, cost-effective answer to many health challenges (WHO, 2001)¹. Costs of EMHS in Uganda account for a large share of the total health budget. Whereas EMHS have obvious medical and economic importance, there are still widespread problems with lack of access, poor quality, irrational use and wastage (ibid).

The Ministry of Health's mission is "to provide the highest possible level of health services to all people in Uganda through delivery of promotive, preventive, curative, palliative, and rehabilitative health services at all levels." (MOH, 2010)². An important aspect in the realization of this mission is the availability and proper use of EMHS. Consistent with the above, the overall goal of the National Medicines Policy is to contribute to the attainment of the highest standard of health for the population of Uganda, by ensuring the availability, accessibility, affordability and appropriate use of essential medicines of appropriate quality, safety and efficacy at all times (MoH, 2015)³. An efficient and effective supply chain system of EMHS is, therefore, of paramount importance.

One of the essential functions of government is public policy development and review to match the ever changing environment. A policy is pivotal to every action the government takes and it provides a framework within which all actions for the achievement of the national objective are carried out.

This Health commodities SC policy development and review framework is designed to support the Department of Pharmaceuticals and Natural Medicines (DPNM) of the Ministry of Health (MoH) in formulating policies, regulations, guidelines, and reforms in the health supply chain system. It includes steps to collect pertinent data to make evidence-based decisions on policy making, costing and use survey results to assess whether policies are working properly or not.

¹ World Health Organization (2001). *How to develop and Implement a national drug policy*. 2nd Edition.

² Ministry of Health (2010). *The Second National Health Policy. Promoting People's health to enhance socio- economic development*.

³ Ministry of Health (2015). *National Medicines Policy*.

The resultant supply chain structures should convey a high level of accountability and transparency that facilitates optimal coordination and communication among stakeholders. In addition these should provide solutions to identified gaps in the supply chain systems aligned with the priorities in the NPSSP IV.

The Health Commodities SC Policy Development and Review Framework comprises essential principles and procedures used for the development, monitoring, analysis and review of policies related to the health supply chain system. The Policy Development steps are essential components of this framework. They outline the core elements that are critical to the successful development, approval, implementation, and review of policies, procedures, directives, standards, protocols and guidelines.

1.2. Purpose

The Health Commodities supply chain policy development framework seeks to: Provide the principles which guide the development and review of health supply chain policies, guidelines, regulations and reforms. Establish standardized procedures to ensure consistent development, approval, monitoring, and review of SC policies. Provide a comprehensive, single point of reference for information relating to SC policy development, review, analysis, monitoring and evaluation.

1.3. Scope of the Framework

This HCSC framework presents the principles and procedures for the development, review, analysis, monitoring and evaluation of the health supply chain policies, guidelines, regulations and reforms. It also guides development of service or function specific policies for the different actors along the supply chain.

1.4. Structure of the HCSC Framework

The Framework document provides the governing principles in the development and review of policies and the key procedural stages (Initiation; Development; Approval; Implementation and Monitoring & Review).

1.5. Key HCSC Framework definitions

This Policy Development and Review Framework document specifically focuses on Steps to follow during the development of a SC policy/guidelines/regulatory framework as defined below. Definitions are also provided for other tools that may be used to support a policy in order to achieve a specific objective.

1.5.1. Policy

A policy is a formal, concise, and an accessible statement on how an entity, in this case the MoH- DPNM intends to conduct business and deliver services. Generally, it is a statement

of intent with guidelines that provide a direction for decision making and taking action. It is a series of decisions as to what shall be done and how, where, by who and when?. A policy is a product of conscious effort, a relationship of government unit to its environment, and shows whether the government is in action or inaction.

Policy is a never ending series of communicative and technical act by which all kinds of policy actions collectively engage themselves in the construction of inter-subjective political meaning and at the same time transform these meanings to construct them into collective actions. It is thus, both the input and the output of the same decision making process. A policy statement reduces the risk of conflict, and removes the opportunity for unfair selective application of rules.

1.5.2. Regulation

A Regulation is developed by an entity to operationalize provisions of the principal law. It must be approved by the relevant designated authorities. A regulation provides a framework for implementing a specific aspect of an entity's business and would normally apply to every employee and any individual or organization acting on its behalf. More often, an entity may not develop its own regulations, but it is rather obliged by law to follow regulations associated with specific legislation and governed by the existing laws.

1.5.3. Procedure

A procedure is a written statement that describes how a policy or specific legislation will be put into action within an entity. A procedure does not require approval by policy or area committee but should be approved by the relevant Leadership Team. Where linked to a policy, a procedure can be amended in isolation from the associated policy.

1.5.4. Protocol

A protocol is a system of internally agreed rules that explains the correct conduct and procedures to be followed in identified situations.

1.5.5. Guideline

A guideline is a document that outlines best practices in implementation of a policy or procedure. Guidelines are not mandatory, but help employees follow the rules while allowing for flexibility and common sense in different scenarios. Guidelines do not require approval by policy or area committee and can be reviewed and refreshed as required.

1.5.6. Strategic plan

A strategic plan is a document that establishes the direction of an organization. Plans and strategies exist at every level in the organization and they identify principles and actions required to deliver the vision and outcomes stated by the organization. There are certain

types of strategies and plans that may include a policy statement – for example the Health Sector Development Plan – and these must be approved by the responsible Minister. It is likely that specific processes and procedures will exist for these types of plans that will ensure appropriate governance. A strategic plan should not be used to identify a statement of intent without seeking the appropriate consultation and approval.

2. Principles of the policy development process

Principles are fundamental to guiding the development, approval, implementation, and review of policy documents across ministries. The following principles are consistent with best practice and are written to support and align with the mandate of the Ministry of Health. When consistently incorporated, the following principles will assist with achieving the Framework Outcomes.

Principles of Policy Development Process

1. Strategic alignment
2. Commitment and collaboration
3. Consistence with the laws, regulations and standards
4. Comprehensive decision-making
5. Change management
6. Resource use efficiency
7. Responsiveness
8. Accessibility
9. Monitoring and evaluation
10. Knowledge Transfer

2.1. Strategic alignment:

This involves identification and prioritization of policies that align with the Ministry of Health's vision, mission, values and priorities. No supply chain policy should be in conflict with or contravention of the Ministry of Health strategic direction.

2.2. Commitment and collaboration:

Development, approval, implementation, and review of HSC policies are built upon the technical commitment and political will coupled with multi-sectoral, stakeholder, and partner collaboration.

2.3. Consistence with the existing laws, regulations and standards:

The content of supply chain policies must adhere to legislation (Acts and Regulations) and organizational requirements, expectations and standards, and take into account what is both practical and reasonable.

2.4. Comprehensive decision-making:

The level of support and the approach taken for development, approval, implementation, or review of policies is a negotiated decision, based on urgency, rationality, organizational

readiness, available resources, sensitivity to stakeholder's and emerging changing trends. Decision making is preceded by a comprehensive and systematic analysis of the policy problem and followed by specification of alternative courses of action, and the selection of a course of action to be taken that will maximize benefits and minimize costs.

2.5. Change management:

Change management concepts are incorporated into the overall planning and development, approval, implementation, and review processes. It connotes appreciating the need for change from the status quo and developing the strategies for smooth transition from the status quo to the desired direction.

2.6. Resource use efficiency:

Resources needed for development, initial implementation and the transition to full scale operations are part of the considerations and decisions made prior to starting policy development activities. Accountability and resources use efficiency must be taken into consideration.

2.7. Responsiveness:

Policies must be relevant to stakeholder needs, demonstrate consideration of feedback, and are based on accepted or evidence-based practice. In addition, they should be flexible and adaptive to the emerging challenges and trends.

2.8. Accessibility:

Policies must be easily accessible, widely disseminated to the right stakeholders and implemented. They should also be easily interpreted and/or translated for proper comprehension.

2.9. Monitoring and evaluation:

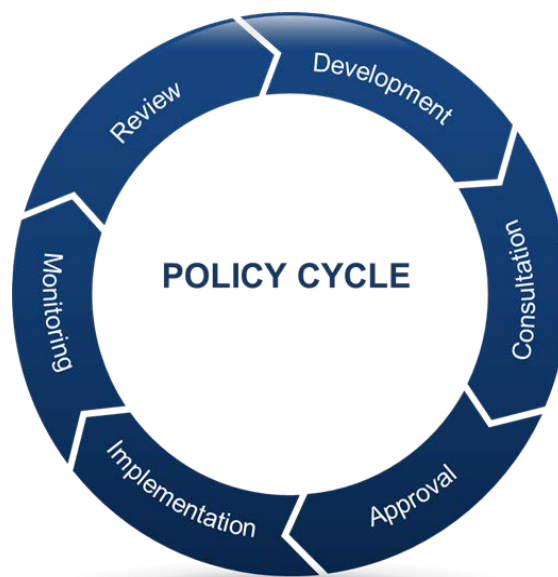
Monitoring and Evaluation is a key mechanism for sustainability of the policy development process and ongoing improvement, leading to long-term benefit for the organization. The policies must have specific, measurable, attainable, reliable, and time bound (SMART) objectives and targets.

2.10. Knowledge transfer:

This involves training and capacity building for the staff to foster understanding, build organizational capacity, and improve compliance with the Policy Development and Review Framework and Policy Development Steps.

3. Policy Development Process (Policy Cycle)

The policy development process follows a broader six-stage model. This ensures that the policy cycle is continuous with regular monitoring and review, allowing the adaptation to change. This section outlines each stage of the policy cycle. The cyclic nature of the policy development process implies that policy development is a dynamic and flexible process.



3.1. Policy formulation/development

3.1.1. Identify a policy need /problem.

This is a stage at which an issue is identified as a policy need /problem. This requires a collective participation of actors if government is to act on the policy need. The actors can range from technocrats to politician, researchers, community and or service consumers, interest groups (youth, women, and elderly) and external and internal SC performance reviewers.

Health Supply Chain policy issues or ideas may arise at any level along the supply chain system- upstream, midstream and lower stream to include national, sub-national and communitylevels

- ministry of health DPNM and her agencies, warehouses, health facilities , community, private sector players, Traditional and Complimentary/Natural Medicines (TCM) stakeholders and general SC service delivery.

Identifying a policy need may be influenced by one or more of the following:

Day-to-day practices and experiences. Health supply chain practitioners / technocrats/ policy implementers in their day-to-day routine activities interact with healthsupply chain actors, processes, and decisions which may reveal a gap that necessitates a policy action. Emerging practices from use of dietary supplements, lay/traditional herbal medicines, spiritual healing/anointing liquids, homeopathic medicines can also trigger a policy action. Recommendations from health supply chain studies. Health supply chain scientific / applied studies as well as monitoring and evaluation performance studies usually make practice and policy recommendations that can trigger certain policy direction /action.

1. **Audit, and Safety Reviews:** Recommendations or requirements that arise from an internal audit review or a safety review (such as a Patient Safety Review or the supply chain efficiency Review etc) or other quality improvement initiatives, may reveal a need to create a new policy or amend an existing policy in order to reduce risk to consumers of a service, staff, and/or the ministry.
2. **Accrediting and Quality Control Bodies:** Accrediting and quality control bodies such as the World Health Organization often include specific requirements for policies in order to meet quality standards.
3. **Colleges, Professional Associations, and Public Agencies:** The DPNM may be influenced to align with organizations that develop professional practice requirements, such as the Uganda Medical and Dental Practitioners Council, Allied Health Professionals Council, Pharmaceutical Society of Uganda, Uganda Medical Association, Uganda Law Society, among others. The ministry may as well desire to align with industry best practice, or National or International standards, such as those developed by the International Organization.
4. **Interest groups** can identify loopholes in the existing policies and advocate for a new policy or policy reforms that can address their particular health supply chain interests (e.g women, youth, elderly, PWDs,etc)
5. **Public / community perception:** The community and general public perception of various issues and concerns may influence the actions of the Ministry of Health. In many instances, policies for a specific topic area may not be mandated; however, the sensitivity and/or severity with which the public perceives these topics may warrant a policy action.
6. **Laws, Acts, Regulations:** Compliance with laws and regulations is a crucial component of policy development and risk management for the organization. The ministry of Health is guided by many Acts, regulations, and applicable laws.
7. **Government Directive:** The Government of Uganda, other government or quasi-judicial bodies may identify requirements that are specific to the Ministry of Health DPNM or to a particular

program or department that eventually require policy action.

8. Global and Regional experiences and trends. Global and regional supply chain experiences and trends can influence certain home country policy actions in line with international and regional compliance.

3.1.2. Policy research

In order to establish precedent and inform the policy process, research must be conducted into existing internal policies or similar external examples. This ensures that problems can be identified early on in the process and improve the quality of the final document. Policy research involves literature review, benchmarking and primary data collection and analysis to generate sufficient data (evidence) to support the justification for the policy action but also to generate sufficient data needed during policy consultation and engagement processes. Policy research can be done by internal and external supply chain actors beyond the Ministry of Health. These may include DPNM staff, Ministry of Health Policy unit and analysis staff, social workers, independent researchers / Research consultants, NGOs, International agencies and Development partners.

There are two categories of research that are of particular importance in the development and implementation of policies in the health supply chain system.

Operational research is aimed at better understanding of factors affecting medicines management, and identifying the best methods of selecting, procuring, distributing and using EMHS. Its results help to identify and implement practical and cost-effective measures, and should underpin management decisions.

Drug research and development includes a broad range of activities, including research into new drugs, drugs for neglected infectious diseases, new dosage forms and manufacturing processes; basic research in chemistry and molecular biology; and clinical and field trials of drugs and vaccines.

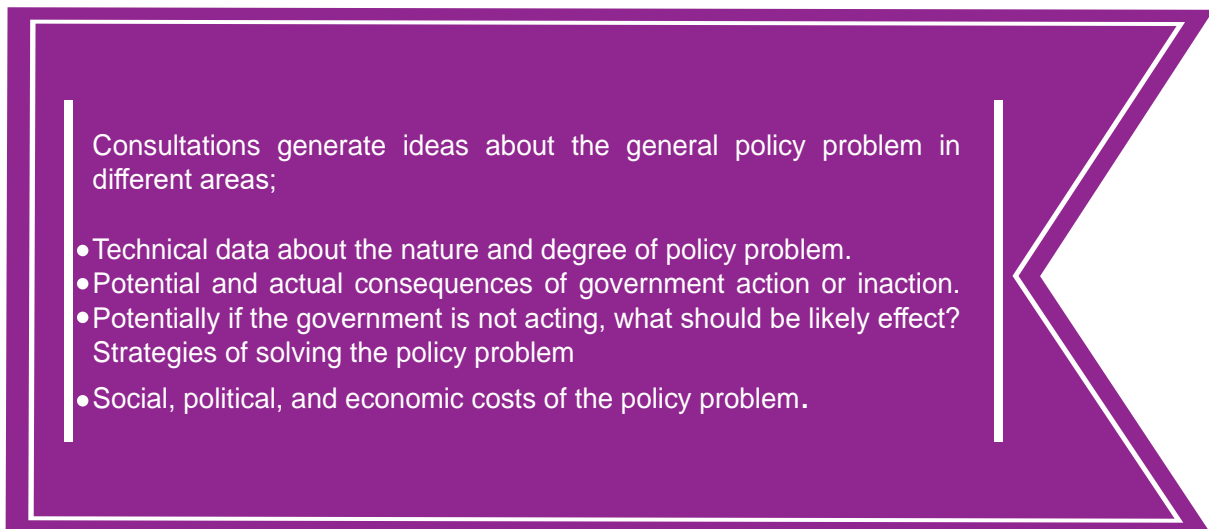
3.2. Policy consultations

A department / unit formulating a policy has to consult internally and externally with key decision makers. Consultations should be undertaken early on in the process whilst ideas are being formulated and before decisions on options have been taken. Members from the locality (department / unit) both senior and junior staff and peers as well as other senior authorities in the Ministry should be involved in this consultative process. A detailed stakeholder mapping and analysis is necessary to establish who to consult. The process of consultation involves introducing the policy idea for action (new policy, or policy reform) to the key stakeholders, seeking their views, consensus building, and ownership of policy actions / decisions.

The person/ unit/ department should prepare a document / brief summary of an idea prior consultations. This can be in form a problem statement, summary sheet of findings of the

policy research, concept note or other policy development instruments such as information paper, position paper, policy brief etc.) depending on the level of consultations / who to consult. Preparations of these documents helps to properly conceptualize the policy idea, aggregate information from the needs assessment and policy research and have the ready information suitable for different audiences and fit for purpose.

The consultations can be in form of inter-personal face-to-face interaction, organized meetings either physical or virtual, key informant interviews and even structured questionnaires.



3.3. Policy drafting

This is the stage of developing the policy content after getting a 'green light' from the consulted stakeholders on the strategic direction. It is a collaborative and iterative activity but also technical. It involves gathering and organizing all the necessary information for policy development. It involves organizing the policy content chronologically according to Ministry of Health policy development templates and guidelines. Focus is placed on the MoH Vision, Mission, policy objectives, principles to guide policy implementation, policy strategies (policy provisions), and implementation plan, among others.

The process of drafting the policy may involve benchmarking of the experiences and practices from other sister ministries or other governments that have had previous experience of developing a similar or related policy. It may also involve the use of a consultant or involving subject matter experts to take the lead in the drafting of the policy. Usually, a policy drafting taskforce is also constituted to provide oversight of the consultant's TOR and shaping the draft policy document.

Timelines for content confirmation and validation of a draft policy is influenced by operational needs (e.g. timeline for completion), correlate to the ability of subject matter experts to reach and achieve consensus, and will depend on available resources and stakeholder familiarity and/or knowledge with the policy development process.

Policies reflect an organization's position, principles, standards, and processes on key

issues. They guide the organization's operations and set out the expectations for its employees, medical and other professional staff, volunteers, students, contracted providers, and individuals who act on behalf of, or in conjunction with the Ministry of Health.

Policies may be developed to address a clinical or a corporate need;

Clinical Policies: The key components of clinical policies encompass quality of care and patient safety, and focus on a systematic and integrated approach to ensure a high standard of patient care. Clinical policies do not replace, but are in addition to professional self-regulation and individual accountability for clinical judgment that are an integral part of the healthcare system. Clinical policies are primarily concerned with patients and how they receive care and services, and set out the responsibilities and expectations for the health care and associated professional teams in the delivery of clinical care.

Corporate Policies: Within the Ministry of Health, corporate policies are fundamental to the strategic business direction of the organization and the operation of non-clinical areas such as human resources, financial management, expectations of conduct, and resource allocation and management. The focus of corporate policies is on corporate accountability, financial stewardship, procurement, human resources, and asset management to promote risk management strategies, to ensure legislative and legal compliance, and to establish sound business practices. Together, clinical and corporate policies share the common goal to fulfill the ministry's vision, mission, and values.

3.4. Policy engagement

The unit within the department, formulating a policy should engage the stakeholders to be affected by the same policy. Strategic stakeholder mapping is necessary to identify the most relevant and influential stakeholders to engage in the policy development process particularly those that are outside the technical department. The policy development process must be highly intensively engaging so as to obtain views from a wider spectrum of stakeholders. - Community leaders, district technical and political leaders, private sector, non-state actors (CSOs and NGOs) as well as technical and political leaders at ministry and agency levels.

Policy engagement provides an opportunity for public policy debate where various dimensions and aspects of policy problem is extensively discussed on several fora both informally and formally, face-to-face or virtually by key / strategic stakeholders. The fora can be task force meetings, stakeholder consultative meetings, among others. The policy engagement provides an opportunity to strategic policy stakeholders to appreciate the scope of the draft policy, the roles of relevant stakeholders in policy implementation, the potential promoters / partnerships, and build consensus on the draft policy provisions. During the policy engagement process, the draft policy must to be reviewed and polished by a highly competent team in the Ministry and / external subject area specialists. After intense stakeholder engagements on the draft policy, a department / unit formulating a policy should prepare a final draft for approval. The final version of the policy has to be submitted to multi-stage approving authorities.

3.5. Policy Approval

3.5.1. Policy approval process

Public policy is not implemented until it is duly approved by relevant authorities at different levels. Policy approval is essentially a multi-stage process and it is imperative that these approval stages are clearly mapped out in line with the long term institutional arrangement (LTIA) framework that is also consistent with the Guidelines for Governance and Management Structures of the Ministry of Health (2013).

The first approval is at the Departmental level where Pharmaceutical and Natural Medicines staff feel confident that after all the consultations and engagements are done with key stakeholders, the draft policy in the current form is good enough and it should proceed to the next level of approval- the Senior Management level. The draft policy is presented to a relevant technical working Group (TWG) meeting e.g Medicines Procurement and Management (MPM), Governance, Standards, Policy and Regulations (GOSPOR) etc for further scrutiny and advice. The draft policy is further presented to the Senior Management for scrutiny and discussion. At this level, several other observations are made that require changes in the first draft. Once these changes are made in the draft policy to the satisfaction of the senior management meeting of the Ministry, the team endorses the policy in its current form and recommends it for the next level of approval- the Health Policy Advisory Committee (HPAC). This is a forum for the Government, Health Development Partners (HDPs) and other stakeholders established to receive and discuss health policy and to advise on the implementation of the policies. HPAC may also make some observations on the draft policy document, proposes changes and recommendations moving forward.

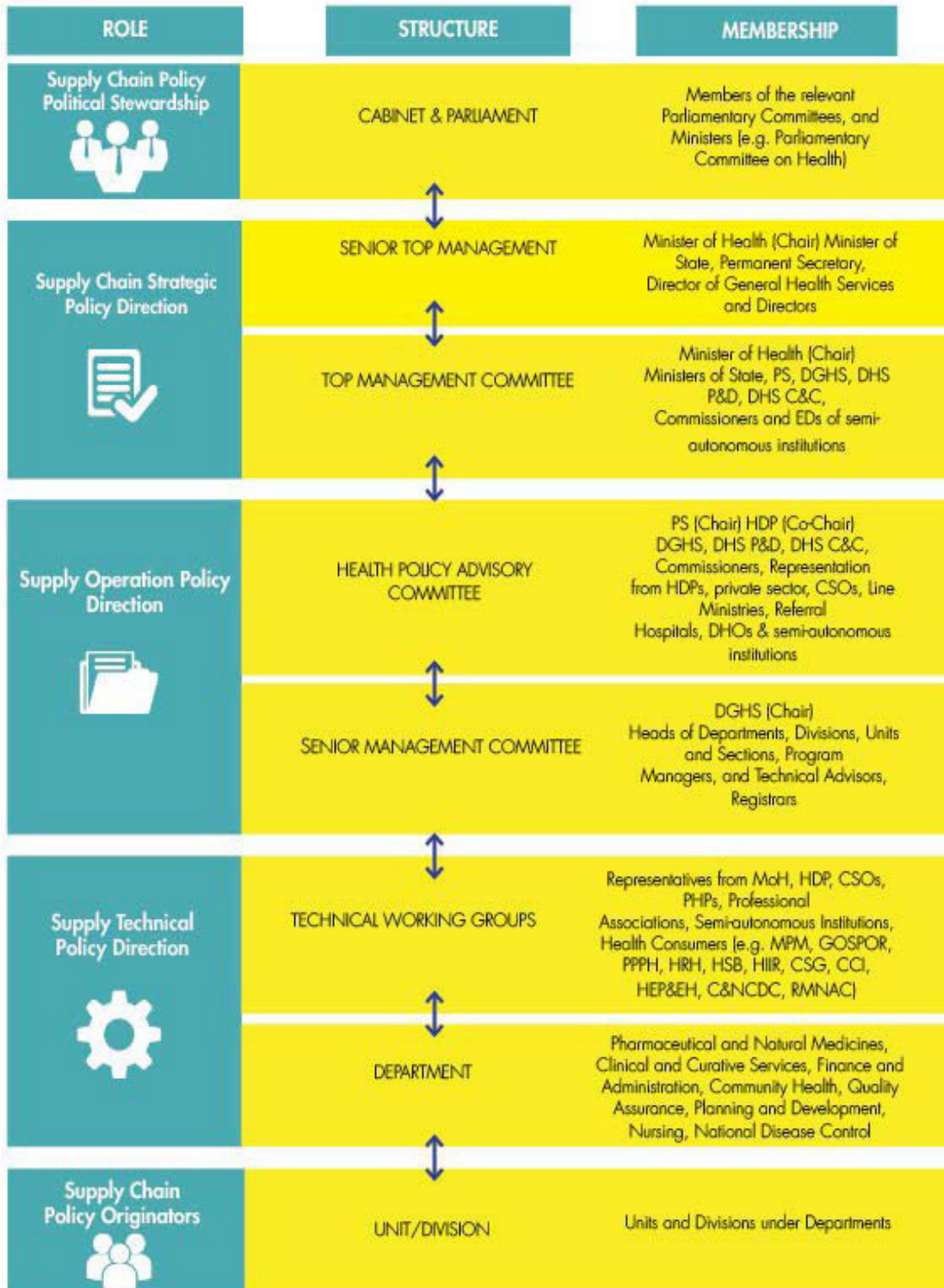
Once these changes are made in the draft policy to the satisfaction of the HPAC, members endorse the policy in its current form and recommends it for the next level of approval- Top Management. The Top Management is the highest level organ in the Ministry of Health responsible for policy decisions. It critically reviews the provisions of the draft policy and may also propose changes to the draft policy. Again, once the proposed changes are made in the draft policy to the satisfaction of the Top Policy Management, the latter approves the policy. In case of any controversial issues in the draft policy, the Top Management may refer the draft policy to the Senior Top Management for discussion and once it is addressed, the policy can be finally approved at that level.

It is imperative to note that some policies may require parliamentary and cabinet approvals depending on their sensitivity to public safety as well as public expenditure. In parliament, the draft policy is presented to the responsible Parliamentary committee for further scrutiny (such as Parliamentary Health) and it is subsequently discussed at the floor of Parliament by the members of parliament. Once the Parliament approves the policy, it is forwarded to Cabinet for final approval. Cabinet has three options to consider in passage of the policy;

- If existing policies and legislative framework are sufficient to address the issues in the policy proposals – Cabinet may decide to do nothing and therefore dismiss the policy. The Cabinet may decide that the proposals made in the policy feed into already existing policy frameworks and can be improved to cover aspects being proposed.
- The Cabinet may maintain the status quo and instead enhance on-going implementation of the existing policies and strengthen the aspects related to the subject matter of the proposed policy and other strategies without necessarily having a new policy in place; and
- The Cabinet may decide to adopt the policy and implement the proposal in the policy under a new policy framework. This will depend on the merits for the policy and the urgency to act on issues it raises.



Health Supply Chain Policy Approval Process



3.5.2. Other key issues in the policy approval process

The Commissioner for the Department of Pharmaceuticals and Natural Medicines or a designated policy development focal person in the department needs to:

Make consistent follow-ups and track the progress of the policy approval at different stages to the logical conclusion.

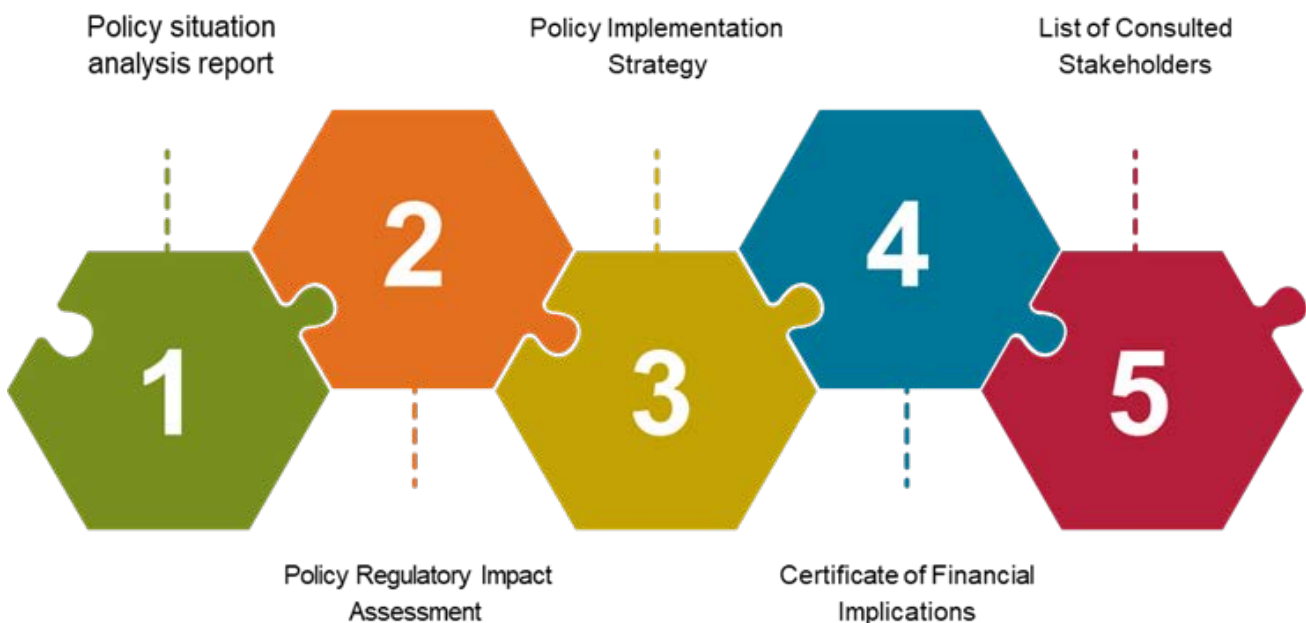
Lobby and influence the meeting agendas to have the draft policy discussed at the successive approval stages.

Identify bottlenecks to the smooth policy approval process and proactively craft the best ways to address them.

Share constantly with the team in the unit/department and other stakeholders, the information/feedback on the progress/status of the policy approval.

Prepare to submit all the supporting documents that may be required during the policy approval process.

3.5.3. Supporting documents for policy approval process



3.6. Policy Implementation

Upon the approval, a public policy is implemented according to its implementation strategy. One critical aspect of policy implementation is dissemination to the general public for purposes of publicity and ensuring a high degree of conversance among the policy implementers. This involves organizing dissemination workshops, sharing copies of the policy online as well as

printing and distributing hard copies of the policy to ministry officials, staff, and all other key stakeholders. It also involves building the capacity of policy implementers at different stages and clarifying on their roles for a smooth policy implementation process.

At this stage, policy decisions lead to specific actions at the level of programs and projects, policy ideas are translated into proper projects intended to achieve policy valued objectives, strategies are developed to implement these programs and projects. Public policy actions lead to defined outcomes that are tangible and measurable. At this stage, policy impact begins to be visible, but also unintended consequences of public policy can be analyzed.

3.7. Policy Monitoring and Evaluation

3.7.1. Policy Monitoring

Policy monitoring seeks to establish whether provisions and associated programs and projects are implemented so as to achieve the stated goal and objectives. It involves determining whether or not the observed events are consistent with the policy provisions and planned activities. If not, then a revised plan or other course of action must be initiated to correct the position. It is a checking process to correct weaknesses during the implementation.

Policy monitoring helps to exercise provision and control and from this process, it can be identified that the policy is not going according to plan or it appears the policy is not on course to achieve its targets. This helps policy managers to review if implementation of strategies are achieving intended outcomes to inform appropriate modification and establish a new plan on which right actions can be taken.

Monitoring relies on three things:-

1. Quality of data - systematic collection of specific data about the policy and the information system.
2. Proper interpretation and analysis of data
3. Application / use of data to make the right decisions, continue, modify, implement the decision taken (modifications), etc.

There are also three important issues must be considered during policy monitoring

1. The involvement of relevant actors who are key to consult in policy implementation process
2. Recognizing differences in attitudes, competencies, intelligence, personality during data collection.
3. Continuous systematic collection and analysis of data with reflections of the situation analysis / baseline data that formed monitoring indicators.

Forms of monitoring

1. Process monitoring (ongoing monitoring). It is done throughout the policy implementation
2. Impact monitoring – this provides information on the progress of the policy implementation at given points in time. As a checking process, impact monitoring provides information for policy evaluation to be done. Policy evaluation ascertains whether or not;
 - The intended policy goals and objectives have been achieved;
 - The policy implementation process has been cost effective;
 - The policy problems and the implementation strategies were identified correctly;
 - The policy outcomes have generated other host of problems that require policy actions;

3.7.2. Policy evaluation

Policy evaluation involves a comprehensive assessment of whether or not the policy has had any impact. The interest is to match outcomes with the objectives. If the intended Health commodities and services have been produced to the public, then the policy is said to be effective; If Health commodities and services are delivered at a minimum cost, the policy is said to be efficient and effective; and If policy outcomes are delivered at a maximum cost, then the policy is likely to be a bad one and should therefore be reformed or abandoned.

Key issues to note in policy monitoring and evaluation

- Policy monitoring and evaluation are different activities with different purposes but are mutually reinforcing in the policy implementation process.
- Policy is monitored to track its implementation progress and to establish whether or not it is on course in line with its goal and objectives. While Policy is evaluated to establish whether it has achieved its intended goal and objectives.
- Policy monitoring is continuously conducted both formally and informally while policy evaluation is evaluated periodically and usually formal (e.g mid-term evaluation /impact monitoring, or end-line / summative evaluation).
- Policy monitoring and evaluation can be conducted by a designated technical person – Policy M&E specialist or any other designated technical person in the department (e.g Policy development focal person).
- Policy monitoring and evaluation data (report) is important to inform appropriate actions to be taken in the course of policy implementation as well as in the designing of new policies that are more effective, efficient, and responsive.

3.8. Policy review and analysis

Policy review and analysis is the activity involving studying, gathering, processing, ordering and presenting specific information for policy making. Policy analysis contributes to reaching policy decision or advice on the implications of alternative actions on the existing policies. Analysis is an important phase in policy making and it is essential for making critical policy decisions. Policy analysis and review helps to inform policy makers on the implications of the options presented and enables them to know whether the existing policy is in tandem with the current national and international trends or whether it is still relevant in the ever changing circumstances. Policy evaluation, review and analyses provide sufficient data on the performance of existing policy to guide decisions and course of action regarding the policy in question. This can either be making reforms in the existing policy or formulating a new policy that is more relevant to the prevailing circumstances.

Key issues to note in policy analysis and review

- *Policy analysis and review is a deliberate and targeted activity towards a certain existing policy. It is informed by data generated during monitoring and evaluation activities.*
- *Policy analysis and review is a continuous activity in the policy cycle. However, as a targeted activity, it is conducted towards the end of the life of the policy or even after the implementation period.*
- *Policy analysis and review is done in response to the emerging issues from monitoring and evaluation but importantly to respond to the current national and international trends.*
- *Policy review and analysis can be conducted by a designated technical person – Policy review and analysis specialist in the Policy Analysis and Review Unit of the Ministry of Health or any other designated technical person in the department (e.g Policy development focal person).*
- *Policy review and analysis leads to the reforming of the existing policy or formulating a new policy that is more relevant and responsive to the prevailing circumstances.*

3.8.1. The role of Ministry of Health policy analysis and review unit (PARU)

In performing the task of supply chain policy analysis and review, the designated technical person in the department of Pharmaceuticals and Natural Medicines must work closely with the Ministry of Health policy analysis and review unit. The unit is manned by specialized personnel who can critically analyze and review health policies on a continuous process. The differentiated roles of the designated technical person in the department of Pharmaceuticals and Natural Medicines and Ministry of Health's PARU are tabulated below;

Role of departmental focal person for policy analysis and review	Role of MoH's PARU
<ol style="list-style-type: none"> 1. Work hand in hand with the substantive Ministry level policy analysis and review unit staff on policy matters. 2. Lobby and ensure that the department- related policies are included (or given priority) on the list of the proposed policies in the ministry. 	<ol style="list-style-type: none"> 1. Work hand in hand with the technical person(s) in the departments designated to analyze and review policies that are specific to their domain. 2. Ensure that the departmental- specific drafted policies are included on the list of the proposed policies in the ministry. 3. Analyze problems, issues and directives related to

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| <ol style="list-style-type: none"> 3. Analyze problems, issues and directives related to policy and advice on rational policy choices. 4. Analyze policy proposals within the department and advise on their rationality and viability. 5. Keep all department-related policies under review on a continuing basis and work while working closely with the MoH's PARU. 6. Monitor all department-related policies being implemented and appraise policy initiators and policy implementers on their current progress in achieving the policy's objectives. 7. Review the old policies to determine if they have relevance to present day situations trend and thinking. 8. Assemble and maintain basic data on all department-related policies (both old and new) and ensure that the data is accessible to policy makers and implementers whenever they need it. 9. Write periodic and annual reports on overall departmental policy performance and highlighting areas needing specific attention or improvement. | <ol style="list-style-type: none"> policy and advice on rational policy choices. 4. Analyze policy proposals within the Ministry and advises on their rationality and viability. 5. Keep all policies under review on a continuing basis and work with policy initiators / policy makers on issues requiring their attention or intervention? 6. Analyze policy proposals submitted by departments /units while identifying linkages with the existing policies and advise the concerned policy initiators and policy makers accordingly. 7. Monitor all policies being implemented and appraise policy initiators and policy implementers on their current progress in achieving the policy's objectives. 8. Review the old policies to determine if they have relevance to present day situations trend and thinking. 9. Advise policy initiators and policy makers about the success or failure of ministerial or departmental policies that are being implemented and present views about their being maintained, their being successful and or their being terminated. 10. Assemble and maintain basic data on all policies (both old and new) and ensure that the data is accessible to policy makers and implementers whenever they need it. 11. Serve as a "think -tank" among existing policy initiators and policy makers to resolve urgent policy related crises. 12. Write periodic and annual reports on overall departmental policy performance and highlighting areas needing specific attention or improvement. |
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4. A lay-out of a public policy document

1. *CoverPage*
2. *Abbreviations*
3. *Glossary*
4. *Acknowledgements*
5. *Background*
6. *SituationAnalysis*
7. *Guiding Principles and FocusAreas*
8. *Overall PolicyGoal*
9. *Policy Objectives andStrategies*
10. *PolicyProvisions/Issues*
11. *Annexes (if any)*

