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MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINE FOR DEVELOPMENT, REVIEW AND APPROVAL OF REGULATORY INSTRUMENTS

JANUARY, 2022

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ABBREVIATIONS

GRP	Good Regulatory Practices
ICH	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
KAA	Kenya Airports Authority
KEBS	Kenya Bureau of Standards
KEMRI	Kenya Medical Research Institute
KENTRADE	Kenya Trade Network Agency
KPA	Kenya Ports Authority
MoH	Ministry of Health
NACOSTI	National Commission for Science, Technology and Innovation
NMRAs	National Medicine Regulatory Authorities
PICO	Population/Problem, Intervention, Comparator and Outcome
PPB	Pharmacy and Poisons Board
PQM+	Promoting Quality of Medicines-plus
RIA	Regulatory Impact Assessment
RIC	Regulatory Instruments Committee
TWG	Technical Working Group
USAID	United States Agency for International Development
USP	United States Pharmacopoeia
WHO	World Health Organization

GLOSSARY OF TERMS

The definitions given below apply to the terms as used in this document. They may have different meanings in other contexts.

Board of Directors - This consists of appointed Board members. It is the final decision making authority of PPB.

Consultation - The process of engaging with stakeholders and other interested parties to gather their inputs, views, achieve common understanding of the issues in the regulatory impact assessment

Co-regulation - A system of shared regulatory responsibilities in which an industry association or professional group assumes some regulatory functions, such as surveillance and enforcement or setting regulatory standards.

Dissemination - This shall include sensitization and conducting awareness to the other departments/Public.

Guideline - A statement by which to determine a course of action with the aim to streamline the public participation according to a set of guiding principles.

Guiding principles - Value-based statements to guide the authorities in their actions and decisions when planning and executing the public participation.

International standards and guidelines - For the purpose of this document, the term includes relevant WHO standards and guidelines and any other relevant, internationally recognized standards (e.g. International Organization for Standardization or pharmacopoeial standards) and guidelines (e.g. the International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use or guidelines of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme).

Medical product - For the purpose of this document, the term includes medicines, vaccines, blood and blood products and medical devices, including in-vitro diagnostics, food supplements, Cosmetics, Radiopharmaceuticals, Cells, Tissues and Organs, Complementary and Alternative medicines and Borderline products.

PPB Management - This forms the top management of PPB. It consists of the C.E.O, the Directors, Deputy Directors and Managers

Public health emergency - The condition that requires the Cabinet Secretary responsible for health to declare a state of public health emergency, defined as an occurrence or imminent threat of an illness or health condition, caused by bioterrorism, epidemic or pandemic disease, or (a) novel and highly fatal infectious agent or biological toxin that poses a substantial risk of a significant number of human fatalities or incidents or permanent or long-term disability.

Public participation- is a voluntary and inclusive process, where individuals or organized groups can exchange information, express opinions and articulate their interests in a fair and transparent manner with the aim to influence decisions or outcome of the matter at hand, without guaranteed or predetermined positive outcomes.

Quality management system- An appropriate infrastructure comprising the organizational structure, procedures, processes, resources and systematic actions necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality.

Recognition- Acceptance of the regulatory decision of another regulator or other trusted institution. Recognition should be based on evidence that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the PPB. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement.

Regulatory convergence - A voluntary process whereby the regulatory requirements in different countries or regions become more similar or "aligned" over time. Convergence results from gradual adoption of internationally recognized technical guideline documents, standards and scientific principles, common or similar practices and procedures or the establishment of appropriate domestic regulatory mechanisms that align with shared principles to achieve a common public health goal.

Regulatory cooperation - A practice among regulatory authorities for efficient and effective regulation of medical products. May be practised by an agency, an institution or a government. The formal mechanisms include creation of joint institutions, treaties and conventions such as mutual recognition agreements, while less formal mechanisms include sharing information, scientific collaboration, common risk assessment, joint reviews and inspections and joint development of standards. May also include work with international counterparts to build regulatory capacity or provide

technical assistance, thus contributing to improvement of international regulatory governance practices.

Regulatory harmonization - A process whereby the technical guidelines of participating authorities in several countries are made uniform.

Regulatory impact analysis - Process of examining the probable impacts of a proposed regulation and of alternative policies to assist the policy development process

Regulatory instruments - Laws, rules, regulations, manuals or guidelines

Regulatory stock - Collection or inventory of accumulated regulations.

Regulatory system - The combination of institutions, processes and the regulatory framework with which a government controls particular aspects of an activity.

Reliance - The act whereby the PPB takes into account and gives significant weight to assessments by another regulatory or trusted institution or to any other authoritative information in reaching its own decision. The PPB remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

Regulatory Impact Assessment(RIA) - This refers to the systematic process of identification and quantification of benefits and costs likely to flow from regulatory or non-regulatory options of a policy under consideration. It may be based on a cost benefit analysis, cost-effectiveness analysis, business impact analysis among other factors. (Ref:Good regulatory practises, 2016, British Standards Institution (BSI)).

Regulatory instruments Committee (RIC) - This is the committee charged with the responsibility of reviewing all guidelines and guidance documents. In doing so, the RIC is expected to ensure that the tenets of guideline development are met before their submission to management and the Board, including the CS MoH and PS MoH. In this guideline, the RIC and guideline review committee (**GRC)** can be used interchangeably.

Stakeholders - Individuals or groups on whom the regulation has direct or consequential impact or those who have interest in the effect and outcome of the regulation

Standard - Document approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for products or

related processes and production methods. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Statutory Instruments - means any rule, order, regulation, direction, form, tariff of costs or fees, letters patent, commission, warrant, proclamation, by-law, resolution, guideline or other statutory instrument issued, made or established in the execution of a power conferred by or under an Act of Parliament under which that statutory instrument or subsidiary legislation is expressly authorized to be issued.

Technical Regulation - Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Technical working Group (TWG) - This is the committee composed of the user department and resource persons put together to develop the guideline.The resource persons may be drawn from both within the PPB and outside the PPB.

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PREFACE

Regulatory authorities have a duty to ensure that they regulate in a manner that achieves public policy objectives. It is therefore critical that a coherent legal and regulatory framework is established and implemented to provide the required level of oversight while facilitating innovation and access to safe, effective and good quality medical products and professionals that are fit to practice.

The Pharmacy and Poisons Board (PPB) recognizes that effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes and regulators are an essential part of the health workforce. Consequently, this Guideline has been developed to guide developers, reviewers and approvers of regulatory instruments to produce high quality regulatory instruments that meet the minimum Good Regulatory Practices (GRP) prescribed by the World Health Organization.

Similarly, it sets out the PPB *Standards for Guidelines* and provides stepwise advice on the technical aspects of developing a PPB guideline and the methods used. It aims to provide a clear path through the process and seeks to ensure that the resulting guidelines have credibility and meet PPB's criteria for content, methods and presentation, while remaining accessible and useful. Involvement of the public is the hallmark of a regulatory system that is responsive to its environment. This guideline therefore provides a framework for the conduct of public participation in development and implementation of regulatory instruments, taking into account the Constitutional requirements and the threshold set out in the Public Service Commission Guidelines for Public Participation in Policy Formulation.

The appropriate forms and templates have been attached as appendices at the end of the guidelines to ensure standardization of PPB regulatory instruments. We hope you will find this document beneficial in ensuring good regulatory practices and quality management systems at the PPB.

We undertake to review these guidelines and incorporate up-to-date practices, as may be necessary for our setting to achieve public policy objectives.

Dr. F.M. Siyoi
CHIEF EXECUTIVE OFFICER

PART ONE: INTRODUCTION

A solid oversight system requires regulatory authorities to be backed by an effective framework of laws, regulations, and guidelines, as well as to have the competence, capacity, resources, and scientific knowledge to carry out its mandate in an efficient and transparent manner. The extent to which a regulatory framework achieves its policy objectives is determined by the quality of its formulation and implementation.

The Pharmacy and Poisons Board (PPB) is the national regulatory authority established under the Pharmacy and Poisons Act, Cap 244 Laws of Kenya ("the Act"). The Act mandates the PPB to regulate medical products, health technologies and the profession of Pharmacy. To enable performance of its regulatory functions, Section 3A of the Act empowers the Board to formulate guidelines and Section 44 of the Act empowers the Cabinet Secretary responsible for health to prescribe regulations upon the recommendation of the PPB.

A sound legal framework, adoption of international norms and standards and recruitment and development of competent staff are necessary but not sufficient conditions to ensure "good regulatory oversight". These measures must be combined with good regulatory practices (GRP) that guide all personnel in regulatory agencies in developing suitable regulatory instruments that are clear, transparent, consistent, impartial, proportionate, prompt, and scientifically sound. Regulated parties and other stakeholders are also important in maintaining a clear, efficient regulatory environment that allows patients to access quality-assured medical items and personnel, thus underscoring the importance of public participation.

This Guideline seeks to provide the framework for establishing and implementing regulatory instruments that ensure sound, affordable, efficient regulation of medical products, health technologies and the pharmacy profession as an important part of health system performance and sustainability. This will ensure a modern, science-based, responsive regulatory system in which regulations are translated into desired outcomes.

Public participation in formulation of public documents-; laws, rules, regulatory measures, guidelines and frameworks and funding priorities is a requirement by the constitution of Kenya 2010 which provides for a strong legal for public participation. It is anchored in article 10 (2) (a) and 232 (1) (d) as a key value and principle of governance.

Article 10 (1) (b) requires state officers, public officers and all persons when interpreting, enacting or applying any law, making or implementing any public

policy to agree to values and principles of public participation. Public participation is a requirement of public service commission through guidelines on public participation in policy formulation of 21/01/2015.

This guideline proposes to provide a mechanism to facilitate effective and coordinated public participation in development of the PPBs regulatory instruments. It is complemented by related guidance on best regulatory practices, including good governance practices, good review practices and quality management systems for national regulatory authorities.

1.1 Scope

This Guideline presents principles and considerations in the development, review and approval of the regulatory instruments that underpin regulatory activities, guidelines development processes, public participation and rule-making process. It shall extend to regulatory instruments that touch on administrative activities.

1.2 Objective of the Guideline

To ensure an effective and coordinated approach in the process of regulatory instruments development, review and approval.

1.3 Specific Objectives of the Guideline

The specific objectives of this guideline are as follows:

1. To provide overall guidance on the initiation, development, review, approval and revision of regulatory instruments at the PPB;
2. To provide general processes and format for PPB regulatory instruments;
3. To ensure that PPB regulatory instruments are compliant with WHO Good Regulatory Practices and international best practices;
4. To provide a framework for involvement of the public in development of regulatory instruments.

1.4 Key Considerations

In providing the necessary regulations and tools for fulfilling publicly entrusted mandates, the PPB has a duty to ensure that it regulates in a manner that achieves public policy objectives. Therefore, establishment and implementation of a coherent regulatory framework is key to provide the required level of oversight and control while facilitating innovation and access to safe, effective and high-quality medical products and competent personnel. It must also build the necessary flexibility and responsiveness into the regulatory framework, particularly for managing public health emergencies such as the COVID-19 pandemic, addressing new technologies and best practices and promoting international regulatory cooperation.

As the PPB strengthens its regulatory capacity, it must ensure that regulatory instruments are science-based, that they adhere to international standards and guidelines and that its approach leverages the work of other, trusted regulatory authorities and institutions when possible. To this end, the PPB shall also formulate and implement policies and strategies that promote international collaboration, convergence, harmonization, information- and work-sharing and reliance.

PART TWO: OVERVIEW OF THE REGULATORY SYSTEM

2.1 Components of the Regulatory Framework

In this Guideline, the terms "law", "rules" and "regulations" are used to describe the components of the regulatory framework which is binding legislation.

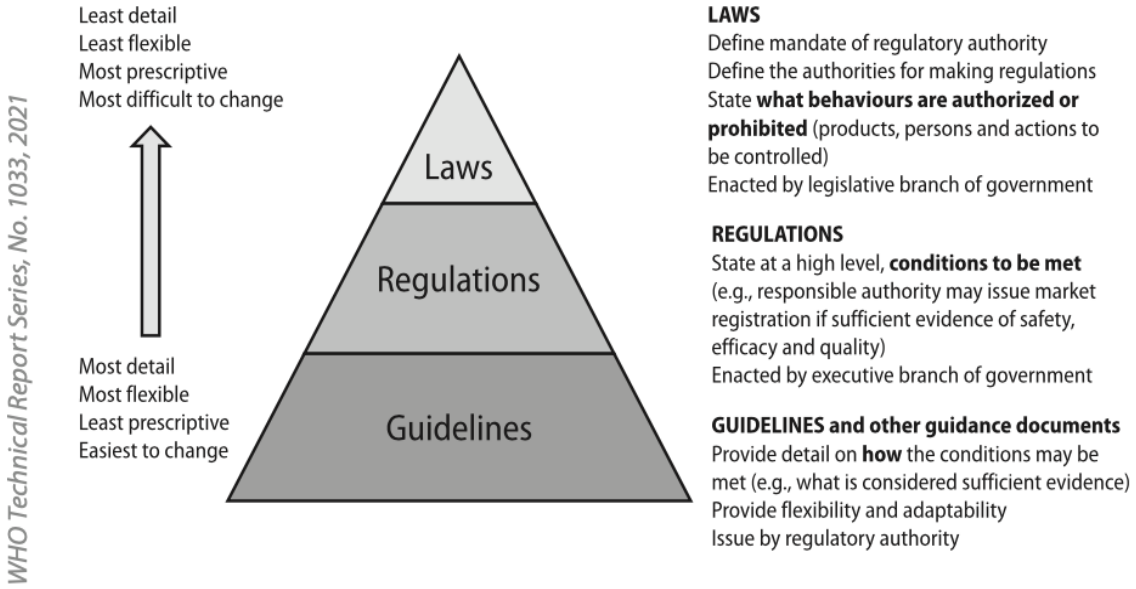
Laws generally define the roles and responsibilities of institutions, in this case, the PPB as the regulatory authority, Ministry of Health or other relevant organizations. They define the products, persons and activities that are to be regulated and state what is permitted and what is not. More importantly, laws authorize an institution to make lower-level regulations and guidelines.

Regulations also known as Rules are a diverse set of instruments by which requirements are placed on enterprises and citizens. Regulations usually state at high level the conditions to be met and the requirements defined in laws. For instance, a law may prohibit the manufacture, importation or sale of a medical product in the absence of specific authorization, while regulations would set out the conditions for obtaining authorization, such as the provision of certain types of information (the results of non-clinical testing and clinical trials, data on manufacturing and control) that allow the regulatory authority to establish the quality, safety and efficacy or performance of a medical product.

Guidelines and other guidance documents provide further detail on how the regulated stakeholders can comply with laws and regulations. Guidelines may also provide details of the processes of enforcement of the respective legislation (laws and regulations). Within a regulatory framework for medical products, such documents are generally more detailed and scientific in nature. They are thus appropriate for describing the approaches that are generally considered suitable for satisfying regulatory requirements but unsuitable for inclusion in legislation.

Figure 1 summarizes the hierarchy of the regulatory framework.

Figure 1: Summary of a Regulatory Framework



2.2 Components of the Regulatory System

In the overall regulatory system, three components (inputs) contribute most to regulatory functions and activities:

(i) the regulatory framework, composed of the legal framework (laws and regulations), guidelines and other guidance documents;

(ii) regulatory institutions, which may be represented by one or more entities, including the PPB, the National Quality Control Laboratory (NQCL), Kenya Bureau of Standards (KEBS), Kenya Medical Research Institute (KEMRI), pharmacovigilance centres and research ethics committees etc; and

(iii) all types of resources, including human and financial, infrastructure and equipment and information management systems.

The spectrum of regulatory activities for medical products includes: clinical trials oversight, marketing authorization, vigilance, market surveillance and control, licensing of establishments, regulatory inspection and laboratory testing. The PPB in addition regulation of medical products and technologies regulates the profession of Pharmacy as part of its regulatory activities.

This Guideline focuses on the regulatory framework component of regulatory systems at the PPB.

2.3 Committees to oversee development of Regulatory Instruments

The following committees shall have roles and responsibilities in regulatory instruments:

1. Technical Working Group (TWG)
2. Regulatory Instruments Committee (RIC)
3. Management Committee
4. Board of Directors

2.3.1 Technical Working Groups (TWGs)

The TWGs must include a mix of expertise and experience and be representative of those most likely to be affected by the regulatory instrument, such as consumers, researchers, clinicians, policymakers and others expected to use or implement the guideline. It is important to get the membership and functioning of the development group right, since it is their judgement that influences the interpretation of evidence and the wording and strength of recommendations.

The TWG will:

a) Be composed of an appropriate mix of expertise and experience, including relevant end users
b) Have clearly defined, documented processes for reaching consensus

Thorough documentation of the selection, composition, their affiliations and disciplines, and any conflicts of interest that were identified and how they were managed and decision making of the development group is also essential for a trustworthy guideline.

2.3.2 The Regulatory Instruments Committee (RIC)

The Board shall establish a Regulatory Instruments Committee (RIC) whose role is to ensure that PPB regulatory instruments are of high quality, aligned to other PPB documents and developed through a transparent, evidence-based decision-making process.

As a result, all PPB regulatory instruments shall receive RIC recommendation in writing before their final approval and uploading into the website. The RIC is expected to review the regulatory instrument at least twice during the development; after completion of the zero draft, before external and after external stakeholders input and before final stakeholder reviews.

To allow adequate time for review, all relevant documents must be submitted to the RIC with a notification no later than two weeks before the date of the next meeting.

The RIC will be appointed for a period of three (3) years comprising the following:

1. Chair of RIC
2. Representative from the Legal department
3. Representative from the research committee
4. Representative from QMS
5. Three (3) members with varying subject matter expertise
6. At least two (2) members from user department (secretariat)

PART THREE: PRINCIPLES FOR DEVELOPMENT OF REGULATORY INSTRUMENTS

The development, implementation and revision of all regulatory instruments and activities at the PPB shall be guided by the nine (9) overarching principles of Good Regulatory Practices (GRP) detailed in this part:

1. Legality
2. Consistency
3. Independence
4. Impartiality
5. Proportionality
6. Clarity
7. Flexibility
8. Efficiency
9. Transparency

3.1. Legality

3.1.1 The principle of legality requires that regulatory instruments are based on clear legal authority and a sound legal basis;

3.1.2 When more than one institution or level of government is involved in regulation of HPTs or pharmacy profession, the functions and responsibilities of each should be clear and complementary, and the processes for communication and coordination among them should be defined;

3.1.3 Conflict in responsibilities in the organization should be avoided in the regulatory instrument;

3.1.4 The regulatory framework should encourage regulatory cooperation, such as use of assessments and decisions of other trusted regulatory authorities and institutions in conducting its own work. This may include convergence, harmonization, information- and work-sharing, reliance and recognition;

3.2. Consistency

3.2.1 The Principle of Consistency requires the regulatory framework to be consistent with existing government policies and legislation and be applied consistently and predictably;

3.2.2 It should also be coherent with any treaties, conventions and regional or international agreements to which the country is party;

3.2.3 Any overlap or conflict with existing laws and regulations should be avoided, as this causes confusion, duplication of mandates and unnecessary regulatory work and increases the likelihood of noncompliance.

3.2.4 In instances where other institutions are responsible or involved for different, or the same, regulatory functions and products, there

should be prescribed in the regulatory instrument the cooperation and coordination mechanism;

3.2.5 The regulatory instrument should speak to existing guidelines relating to the different regulatory functions and activities in the organization to ensure the uniformity of the regulatory system.

3.2.6 The regulatory framework should provide for impartial appeal of regulatory decisions;

3.2.7 Before implementation of a Regulatory instrument, the staff should undergo orientation and training/sensitization on the instrument;

3.2.8 Prior to revision of an instrument, regular, transparent interactions with regulated parties and other stakeholders e.g. industry, health care professionals associations and other relevant government institutions. This will improve the process of identification and resolution of issues through review of regulatory instruments.

3.3. Independence

3.3.1 The principle of independence requires the PPB to operate and be seen to operate in an independent manner, discharging its duties independently from politicians, government and regulated entities e.g Industry. This should be clear in the regulatory instruments;

3.3.2 Whenever PPB incorporates the use of experts sitting on scientific and advisory committees to develop regulatory instruments, declarations of interest should be recorded.

3.4. Impartiality

3.4.1 In developing and reviewing regulatory Instruments, consideration should be given in the way regulatory parties are treated; All regulated parties should be treated equitably, fairly and without bias.

3.4.2 The principles and framework in drafting a regulatory instrument should be such that public and private bodies and domestic and foreign entities are regulated equitably to ensure competitive neutrality;

3.4.3 Regulatory instruments must be written such that the regulatory activities and decisions made on the basis of such instruments are legitimate, evidence-based and ethical;

3.4.4 Regulatory instruments on technical aspects of regulation should be based on science and evidence and be predictable;

3.4.5 Public consultation and transparency should be incorporated in the regulation instrument making process to ensure impartiality, better regulatory outcomes and greater public confidence in the use of regulated products and personnel.

3.5. Proportionality

Regulatory instruments should make provision for reaching regulatory decisions that are proportional to risk

3.6. Flexibility

Regulatory Instruments should be flexible in responding to a changing environment and unforeseen circumstances. e.g responsiveness to public health emergencies, donations

3.7 Clarity

3.7.1 Regulatory requirements should be accessible to and understood by users.

3.7.2 Regulatory instruments should be written in language that is clear, precise, unambiguous and understood by intended users;

3.7.3 In drafting regulatory instruments, the terminology used in the instrument should be defined and should be consistent with international norms, standards and harmonized guidelines;

3.7.4 The legal team should be consulted in considering the objectives of regulatory instruments;

3.7.5 Prior to review of regulatory instruments, one should identify unclear areas, inconsistencies with the instrument or with other instruments or redundancies with a view to resolving the same in the reviewed instrument;

3.7.6 The instruments should be subjected to internal and external consultation to confirm clarity of language;

3.7.7 Regulations and supporting guidelines should be reviewed periodically to ensure that they refect the authority's current practices and expectations, are adapted to scientific and technological developments and are aligned with current international standards and guidelines, when applicable.

3.8 Efficiency

3.6.1. In development of regulatory instruments, consideration should be made on ensuring the best use of resources by use of International collaborative mechanisms such as reliance.

3.6.2.

3.9 Transparency

3.6.3. The requirements provided under regulatory instruments should be made known and input should be sought on regulatory proposals.

3.6.4. The regulatory instruments should be made accessible on the organization website

3.6.5.

PART FOUR: GUIDANCE ON RULES AND REGULATION-MAKING

This part provides stepwise guidance on developing rules and regulations. It aims to provide a clear path through the process and seeks to ensure that the resulting rules and regulations are credible.

In this part, rules, regulations and statutory instruments have the same meaning and will be used interchangeably to refer to subsidiary legislation.

4.1 Decision to develop a rule/regulation

4.1.1 The decision to develop a rule is arrived at to close a gap where there exists express provision delegating the making of the instruments or, if there is an amendment in the statute necessitating development of rules to address the amendment.

4.1.2 In deciding to develop a rule, the Board will have to survey its legal mandate and then decide which issues or goals have priority for rule-making including but not limited to:

a) New technologies or new data on existing issues;
b) Recommendations from parliamentary committees;
c) Petitions from interest groups, corporations, and members of the public;
d) Lawsuits filed by interest groups, corporations, States, and members of the public;
e) Presidential directives;
f) Requests from other agencies;
g) Studies and recommendations of Board staff.

4.1.3 Upon reaching the decision to develop a rule, consideration should be given on the purpose of the rule and whether:

a) there is potential conflict with existing constitutional provisions, statutes, rules and other instruments
b) there exists potential conflict with international conventions to which Kenya is a party
c) expert guidance will be required
d) there exists resources for the development of the rules.

4.2 Public awareness

4.2.1 The Board will notify and update its stakeholders and the public of any planned rulemaking activities on pending and completed statutory actions. This decision on the form and manner of the means through which this will be achieved will depend on the area of rulemaking and may include: email, website, letters, stakeholder meetings.

4.2.2 Such notification shall be entered in the "Regulatory instruments register" in form and format annexed as Annex 1.

4.3 Stakeholder and Public involvement

4.3.1 The Board may take some preliminary steps before issuing a proposed rule; information may be gathered through unstructured processes and informal conversations with people and organizations interested in the issues.

4.3.2 If the Board receives a "Petition for Rulemaking" from a member of the public, it may decide to announce the petition in the "Regulatory Instruments Register" and accept public comments on the issue.

4.3.3 During the preliminary stages of rulemaking the Board may publish an "Advance Notice of Proposed Rulemaking" in the Regulatory Instruments Register to get more information. The Advance Notice is a formal invitation to participate in shaping the proposed rule and starts the notice-and-comment process in motion.

4.3.4 Anyone interested (individuals and groups) may respond to the Advance Notice by submitting comments aimed at developing and improving the draft proposal or by recommending against issuing a rule.

4.3.5 Depending on the issues, the proposed rules may be developed through a negotiated process. In a negotiated process, the Board shall invite members of interested groups to meetings where they attempt to reach a consensus on the terms of the proposed rule. If the participants reach agreement, the Board may endorse their ideas and use them as the basis for the proposed rule.

4.3.6 Stakeholder participation may take different forms such as attending Parliamentary committee hearings, setting up meetings with the Cabinet Secretary or departmental heads, organizing workshops, seminars or retreats, using the media to outline the issues and similar entities to lobby, publication of extracts in newspaper articles or other online platforms and making contributions during public fora and submitting written opinions and memoranda.

4.3.7 Reference Part Six on public participation.

4.4 Roles and responsibilities

A. Secretariat

4.4.1 The initiator department will propose and draft the statutory instrument.

4.4.2 The initiator department shall undertake comprehensive and comparative research on the matter to be regulated

4.4.3 The initiator department shall facilitate negotiation and public participation through preparation of discussion documents on the policy or law to facilitate debate, comments and feedback

4.4.4 The legal department shall review statutory instruments to ensure compliance with the legal provisions

4.4.5 The legal department shall submit to the committee responsible for regulatory instruments review and approval[2]

4.4.6 The Committee shall be appointed by the CEO for a term of three (3) years, drawing membership from the legal, initiator and a technical department.

4.4.7 The committee submits the approved statutory instruments to the CEO for evaluation and transmission to the Board.

B. The Board

4.4.8 The Board may review the draft statutory instrument and make the necessary changes

4.4.9 It should ensure that there was sufficient public engagement with stakeholders in development of the statutory instrument.

4.4.10 The Board, upon concurrence with the proposals, shall approve the statutory instrument and recommend publication of the same to the CS

4.5 Structure of the Proposed Rule

The proposed rule should be structured to have;

I. Preamble- includes purpose of rule
II. Preliminary
    a. Citation
    b. application
    c. Interpretation
III. Main parts
IV. Miscellaneous provisions
V. Schedules

4.6 Timelines for public to submit comments

Stakeholders and members of the public shall be accorded a period ranging from 30 to 60 days. The time may however, vary depending on the complexity of the statutory instrument which the Board will be a liberty to grant.

The Board, upon request from stakeholders or members of the public, may allow more time for submission of late filled comments. However, it is under no obligation to consider late comments but will provide information whether the same will be considered.

4.7 Reopening of the rule

The Board may re-open or extend a comment period in case it is not satisfied as to the adequacy of the comments or when the public comments have justifiable reasons for adding more time.

Similarly, the Board may establish that the stakeholders and the public have raised new issues in their comments that were not discussed in the initial proposed rule. As new issues or additional complexity arises, the Board may publish a series of proposed rules in the Register of public notification of regulatory instruments.

4.8 Submission of electronic comments

Technological advances have enabled efficient public engagement through electronic platforms, hence the Board prefers the use of electronic comments for ease of accessibility to the public.

The electronic comments can be submitted and accessed through the Boards website

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4.9 Decision on public comments

The notice and comment process enables anyone to submit a comment regarding any part of the proposed rule.

Upon considering the comments, the Board will base its reasoning and conclusions on the rulemaking record, consisting of the comments, scientific data, expert opinion and facts accumulated during the notification and proposed rule stages.

The Board must be satisfied that the proposed statutory instrument meets the outlined objectives or solve the problems identified. It must also consider whether alternate solutions would be more effective or cost less.

If the rulemaking contains persuasive new data or policy arguments, or pose difficult questions or criticisms, the Board may decide to terminate the rulemaking. Or, the board may decide to continue the rulemaking but change aspects of the rule to reflect these new issues. If the changes are major, the Board may publish a supplemental proposed rule. If the changes are minor, or a logical outgrowth of the issues and solutions discussed in the proposed rules, the Board may proceed with a final rule.

4.10 Publication; Effective date, interim rules

Upon publication, a statutory instrument becomes effective no less than thirty days after the date of publication in the Kenya Gazette. The Board may make the rule effective sooner with justifications.

The statutory instrument shall be revoked after ten years from the effective unless it is sooner repealed, expires or a regulation is made exempting it from expiry.

4.11 Publishing of the final rules

The Board shall publish the approved statutory instrument accordingly and shall give instructions how the instrument enhances the statutory mandate outlined in the main Act. A Register of Regulatory Instruments (RRI)shall be created by the Board containing all generally applicable rules. The legal department of the Board shall update the RSI on the Board's website at regular intervals indicating their respective effective dates.

Rules with delayed effective dates are placed in amendment files and linked from the main e-RRI database.

4.12 Interpretation of Rules and Regulations

Interpretive rules, policy statements and other guidance documents may be issued by the Board at any time after a final rule is published in order to help the public understand how a statutory instrument applies to them and the effects to their interests. The Board may explain how it interprets a statutory instrument and how the same may apply in a given instance including what things a person or corporation must do to comply.

The explanation must not set new legal standards or impose new requirements. The Board may however request comments on interpretive rules and other guidance document to improve the quality and clarity of the material. Interpretive rules and policy statements with broad applicability are often published in the register, but some may appear on the Board's website.

4.13 Statutory/Regulatory impact assessment

The Board shall prior to development of new rules and regulations, prepare a regulatory impact analysis or assessment. There are cases where the Board will be exempted from preparing such impact assessments reports.

For statutory impact assessments, refer to the Statutory Instruments Act No. 23 of 2013, under sections 6-9 of the Act.

http://kenyalaw.org/kl/fileadmin/pdfdownloads/Acts/StatutoryInstrumentsActNo23of2013.PDF)

4.14 Explanatory memorandum

The Board shall after the development of new rules and regulations, prepare an explanatory memorandum that shall contain

a) a statement on the proof and demonstration that sufficient public consultation was conducted as required under Articles 10 and 118 of the Constitution;
b) a brief statement of all the consultations undertaken before the statutory instrument was made;
c) a brief statement of the way the consultation was carried consultation; an outline of the results of the consultation;
d) a brief explanation of any changes made to the legislation as a result of the consultation.

Where no such consultations were undertaken as contemplated in subsection the Board shall explain why no such consultation was undertaken.

The explanatory memorandum shall contain such other information in the manner specified in the Schedule and may be accompanied by the statutory impact statement prepared for the statutory instrument.

4.15 Revision of rules

The regulatory process enters the compliance, interpretation and review phase after a final statutory instrument is published. The Board may undertake a review based on a petition from the public. With expert advise, the Board may commence review process when conditions change and the applicable statutory instrument seems outdated. If a decision to revoke or amend a statutory instrument is reached, the Board will use the notice and comment process to make the change.

PART FIVE: GUIDELINES & OTHER GUIDANCE DOCUMENTS

5.1 Planning your Guideline

The plan for Guideline development will include the following:

a. Develop a project plan
b. Constitute a guideline development group
c. Identifying and managing conflicts of interest
d. Training of document development groups
e. Engaging stakeholders
f. Stakeholder involvement
g. Scoping the guideline
h. Adopt, adapt or start from scratch
i. Transparency
j. Implementability
k. Equity

5.2 Standards for Developing Guidelines

5.2.1 Relevance for decision making

The purpose of a guideline should be clearly articulated to avoid misinterpretation of key messages, unintended application or create issues during implementation. All guidelines shall be relevant to the board's mission and useful for decision making, in that;

a) It will address a regulatory issue
b) Clearly state the purpose of the guideline and the context in which it **will be applied**
c) Be informed by public consultation
d) Be feasible to implement.

5.2.2 Transparency

Transparency refers to the inclusion of information that enables the reader to understand how the guidelines were developed and who developed them. It is necessary so that people using it can be confident about a guideline's trustworthiness. In order to ensure transparency, guidelines will be made publicly available:

a) The details of all processes used to develop the guideline
b) The source evidence
c) The declarations of interest of the Contributors and members of relevant committees
d) All sources of funding for the guideline.

To ensure a guideline's recommendations are objective and unbiased, all contributors and members of relevant committees must declare their interests and careful steps must be taken to manage any conflicts.

Policies on declaration and management of competing interests in guideline development are designed to protect the integrity of guidelines and the individuals involved in their development. To identify and manage conflicts of interest guideline developers will:

a) Require all interests of all guideline development technical working group members and RIC to be clarified and declared
b) Establish a process for determining if a declared interest represents a conflict of interest, and how a conflict of interest will be managed

5.2.3 Focused on health and related outcomes

Focusing on the right health and related outcomes ensures that guidelines will address the needs of the target population and those of other stakeholders and the general public. The Guidelines will:

a) Explicitly define the scope of regulation of pharmacy practice, Health Products and Technologies
b) Address outcomes that are relevant to the guideline's expected end users
c) Clearly define the outcomes considered to be important to the persons who will be affected by the decision and prioritise these outcomes

5.2.4 Be evidence informed

Guideline development should be based on the best available evidence. To be evidence informed, Board's guidelines will:

a) Be informed by well conducted systematic reviews
b) Consider the body of evidence for each outcome (including the quality of that evidence) and other factors that influence the process of making recommendations including benefits and harms, values and preferences, resource use and acceptability.
c) Be subjected to appropriate peer review.

5.2.5 Make actionable recommendations

The recommendations contained in a guideline must be concise and clearly worded but contain enough information to allow informed decisions about regulation of pharmacy practice, Health Products and Technologies. The guidelines will:

a) Discuss the options for action
b) Clearly articulate what the recommended course of action is and when it should be taken
c) Clearly articulate what the intervention is so it can be implemented
d) Clearly link each recommendation to the evidence that supports it

5.2.6 Guidelines should be up-to-date

The evidence in guidelines should be up-to-date to ensure that recommendations are derived from current evidence, which is critical for their ongoing relevance and reliability. The guidelines will:

a) Ensure that the recommendation is based on an up to date body of evidence
b) Propose a date by which the evidence and the guideline should be revised.

5.2.7 Accessibility

Guidelines accessibility ensure that they are easily located and accessible. To ensure accessibility, guidelines will:

a) Be easy to find
b) Ideally be free of charge to the end user
c) Be clearly structured, easy to navigate and in official languages
d) Be available online

5.3 Important considerations before initiating the development of guidelines

Before initiating the development of a guideline, the following factors are to be taken into consideration at the very outset;

5.3.1 The aim is to close a gap where there exists one

5.3.2 Survey the Board's legal mandate and then decide which issues or goals have priority for rule-making including but not limited to:

a) New laws, rules and regulations;
b) New technologies or new data on existing issues;
c) Recommendations from parliamentary committees;
d) Petitions from interest groups, corporations, and members of the public;
e) Lawsuits filed by interest groups, corporations, States, and members of the public;
f) Presidential directives;
g) Requests from other agencies;
h) Studies and recommendations of Board staff.

5.3.3 Upon reaching the decision to develop a guideline, consideration should be given on whether:

a) There exists international guidelines on the same issue from ICH, WHO, EAC or any other applicable international guidance
b) there is potential conflict with existing guidelines
c) there exists potential conflict with international conventions to which Kenya is a party
d) expert guidance will be required

A document developer/initiator shall take the following factors into consideration:

(i) The necessity of the guideline. It should meet a defined technical, regulatory or administrative need, have a mandate-related perspective and not duplicate existing guidelines/instruments. It is imperative to consult other departments as early as possible, and decide on whose primary responsibility for developing the guideline and those involved. Good planning will yield good guidelines.

(ii) Generally, a proposed guideline should meet a technical, regulatory or administrative need, have a mandate related perspective and not duplicate existing resources. It should take into consideration recommendations from WHO or other recognized organizations. If an existing guideline meets the need, a new one is not required.

(iii) The proposed guideline should be linked to a departmental programme of work. Equally, the implementation mechanisms thereof should be such that can be clearly defined.

(iv) The outcome of the proposed guideline must address a regulatory administrative or policy need.

(v) Consideration on the urgency of a situation thus if the same is of utmost urgency, a rapid advice guidelines will be considered where the timeline is 1-3 months unlike the ordinary guidelines.

(vi) The concurrence and approval from the directorate will be essential before the proposal can be considered by the GRC. The CEO will thereafter, approve the proposal and final product. The final product will need approval of the Board before implementation.

(vii) Collaboration with other function related PPB departments is critical in avoiding duplication of outputs. A decision on the department with the primary responsibility of developing the guideline will be helpful in streamlining the operations. The tasked department must undertake a preliminary research on previous published works on similar subject matter. Where necessary, Technical Working Groups (TWG) formed to develop guidelines may incorporate external experts or resource persons.

If you cannot answer all these questions, it is probably best not to start.

5.4 Adaptation and adoption of guidelines

The PPB may from time to time domesticate guidelines through adoption/ adaptation. These guidelines may include but are not limited to;

(i) Guidelines developed under collaborative framework with other speciality medical societies such as ICH, PIC/S;

(ii) Collaborative framework with WHO;

(iii) Guidelines developed by other NMRAs, Regional Blocs, WHO and other recognized institutions

The user department should explore international best practices in guideline development and is expected to apply reliance, regulatory convergence, cooperation and recognition.

5.4.1 Adaptation of Guidelines

Adaptation of guidelines must follow standard PPB procedures. The RIC will make case-by-case assessments of proposals for adaptation or adoption. In addition and taking into consideration copyright related rights, it is important to note that:

(i) adaptation or endorsement of another organization's guideline should be initiated by the PPB department concerned;
(ii) adaptation or endorsement of another organization's guideline can be considered when no PPB guideline exists or an existing PPB guideline is outdated or inadequate;
(iii) minimum standards for guidelines should be met;
(iv) the approach to reviewing and summarizing evidence should be consistent with that recommended for PPB guidelines;

In light of this therefore, the user department can visit those medical speciality societies, NMRA's and WHO and search for the information needed. Some of the links to the above speciality societies and NMRA's are listed below.

https://www.who.int/health-topics (WHO)

https://www.ich.org/lob/med (ICH)

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/search-general-and-cross-cutting-topics-guidance-documents (USFDA)

It is paramount that while adopting documents, acknowledgment of the sources should be done and where necessary and unless the guidance document sought is not a public document, necessary authorization and approvals are sought from the concerned speciality medical societies, NMRA's and WHO by the user department.

5.4.2 Adoption Of Guidelines

1. Adoption of internationally recognized technical guidelines is predicated on the fact that they form the basis for development and establishment of the Act and, the rules and regulation thereunder that govern the regulation of HPTs and Pharmacy profession ("the Act").

2. Generally, the Act defines the roles and responsibilities, the products, persons and activities that are to be regulated and state what is permitted and what is not. More importantly, the Act authorizes the Board to make rules and regulations.
3. Provision within these guidelines that specify requirements for regulated individuals (as defined under the Act) shall be considered based on their suitability for inclusion in the legislation or on their suitability in simply describing the approaches suitable for satisfying regulatory requirements.
4. For the purpose of this guidance, internationally recognized technical guidelines shall include all such guidelines that provide technical requirements in a specific regulatory area as published by:
    a. The World Health Organization (WHO) and (ICH)
    b. International Council for harmonization of technical requirements for Pharmaceuticals for human use
5. Where there exist clear provisions in the Act for development of rules and regulation, internationally recognized technical guidelines shall be adopted to form the basis on which the applicable rules and regulation are developed and established. The rules shall explain and provide clarity to the provision of the Act.
6. As far as is practicable, the Board shall adopt internationally recognized technical guidelines to explain and provide clarity on the provision in the Act and, the rules and regulations.
7. Where there is no explicit provision in the Act to develop rules and regulation, internationally recognized technical guidelines shall be adopted to explain the provision in the Act.
8. Guidelines developed to explain and clarify provisions in the Act the regulation of HPTs and Pharmacy Profession shall, as far is practicable, involve adoption of international recognized guidance
9. Guidelines (and other guidance documents) adopted from internationally recognized guidelines shall provide further detail on how the regulated stakeholders can comply with laws and regulations. These Guidelines shall, where applicable, provide details of the processes of enforcement of the respective legislation (laws and regulations).
10. PPB guidelines (and other guidance documents) shall generally be more detailed and scientific in nature. They shall thus be adopted to provide appropriate description of the approaches that are generally considered suitable for satisfying regulatory requirements but unsuitable for inclusion in legislation.
11. The Board considers of adoption of internationally recognized technical guidelines in the manner described below: (refer to initial draft on technical content/requirments)

Technical requirements

a. All preliminary information: (abbreviation, acknowledgments, preface-executive summary, legal mandate, introduction, scope etc) shall be developed based on the current context, circumstances
b. Where there exist no rules and regulations because the Act does not make the provision for the development and establishment of rules and regulations or they haven't been developed; the internally recognized technical requirements guidelines shall stand adopted without change, re-writing, paraphrasing or any altering. This will require that stakeholders are made aware.
c. Where there exist rules and regulations based on internationally recognized guidelines, the internally recognized technical requirements guidelines shall stand adopted without change, re-writing, paraphrasing or any altering. This will require that stakeholders are made aware.
d. However, in both cases, PPB guidelines representing an interpretation of the legal framework provisions (the Act and, the rules and regulations) shall be developed. You will have to cite the legal provision, and provide rationale, justification and explanatory remarks using the respective internationally recognized guidelines or, in addition, alternative internationally recognized guidelines. Alternative internationally recognized guidelines shall be cited and under foot notes for review by guidelines reviewers. This will require that stakeholders are made aware.
e. All other provisions within the technical guidelines including recommendations to regulators shall not form part of the adopted guidelines. In which case, the Board shall provide guidance based on any alternative guideline, regional guidance documents (EMEA, USFDA, MHRA, etc) and guidance of SRAs. These shall be cited and under foot notes for review by guidelines reviewers.
f. The source of all rationale, justification and explanatory remarks given shall be indicated in the draft guideline as footnotes for consideration by reviewers of the draft.
g. This foot notes of rationale, justification and explanatory remarks shall not form part of the final version of the guideline.
h. Whenever local rationale, explanation or justification is required and considered appropriate, this shall be explicitly be laid out under the provision. Such local rationale, explanation or justification on technical requirements will require that the stakeholders give their comments

Recommendations on Technical requirements

a. Where the internationally recognized guideline makes recommendation for agencies to decide the approach, provide

guidance on what the Board considers most appropriate recommendation.

b. The recommendation should be based on alternative internationally recognized guidance document, international best practice or what other agencies, SRAs recommend. This should be explicitly mentioned and cited under footnote for review by reviewers. It shall not form part of the final version.

Recommendations on Technical requirements

a. Where the internationally recognized guideline makes recommendation for agencies to decide the approach, provide guidance on what the Board considers most appropriate recommendation.

b. The recommendation should be based on alternative internationally recognized guidance document, international best practice or what other agencies, SRAs recommend. This should be explicitly mentioned and cited under footnote for review by reviewers. It shall not form part of the final version.

5.5 Types of Guidelines & their different requirements

In developing a guideline, the initiating department/unit shall identify the type of guideline. The following will not fall within the definition of guidelines;

a) Documents containing standards for manufacturing health technologies, such as pharmaceuticals and vaccines;
b) 'How to' documents, or operational manuals (e.g. how to set up a research project or how to implement a service);
c) Documents that describe standard operating procedures for organizations or systems;
d) Documents that state established principles (e.g. ethics, human rights, constitutional issues).
e) Documents that provide information on different options for interventions without recommending any particular intervention

There are different types of guidelines as indicated below

5.5.1 Rapid advice guidelines

A rapid advice guideline is produced in response to an emergency including but not limited to; public health emergency (such covid 19 pandemic), scientific advice, etc, in which the Pharmacy and Poisons Board (PPB) is required to provide quick guidance. This type of document needs to be produced within 1–3 months and will be evidence-based, but it may not be supported by full reviews of the evidence. It will be prepared mainly by the

user department with external consultation and peer review. It must be published with a review-by date that indicates when the guidance will become invalid, or when it will be updated or converted to a standard guideline.

5.5.2 Standard Guidelines

A standard guideline is produced in response to a request for guidance in relation to an emerging issue, change in practice or controversy in a policy, regulatory or administrative area. A standard guideline may not cover the full scope of the condition or regulatory problem. This guideline may take 9-12 months to complete and should be prepared after consultation on the scope of the guideline and the issue that it covers. A standard guideline may have a specified review-by date depending on the expected rate of change of evidence in the topic area. Most PPB guidelines will fall into this category.

5.5.3 Full Guidelines/Compedium

A full guideline is one that provides complete coverage of a regulatory function like process for product evaluation and registration, Good Manufacturing Practices, Pharmacy Practice. It would be expected to include recommendations in relation to all aspects of the topic (e.g. evaluation of quality, safety and efficacy section of a CTD dossier) and to be fully based on systematic reviews of the evidence for each aspect.

These are likely to take 2-3 years to complete, and will require several meetings of a guideline development group. Given the time and expense of producing full guidelines, the need for doing these in PPB needs to be carefully assessed and justified.

5.6 Development of the Guideline

The development of guidelines at the Pharmacy and Poisons Board will be cognisant of the **principles of guideline development** which may include;

1. Identifying and refining the subject area.
2. Convening and running guideline development groups.
3. Assessing evidence identified by systematic literature review.
4. Translating evidence into recommendations.
5. Subjecting the guideline to external review.

5.7 Evidence gathering in guideline development

The user department will undertake adequate literature review and document the same in a systematic manner. For further guidance on this, refer to Chapter 5 and 6 of the WHO Handbook for Guideline Development;

https://apps.who.int/iris/bitstream/handle/10665/75146/9789241548441_eng.pdf;jsessionid=CEA0F077897143A6BD48BF775FB574B4?sequence=1 ; Chapter 5. Formulating questions and choosing outcomes

5.8 Process Flow for Guideline Development

A. Rapid Advice Guidelines Process Flow

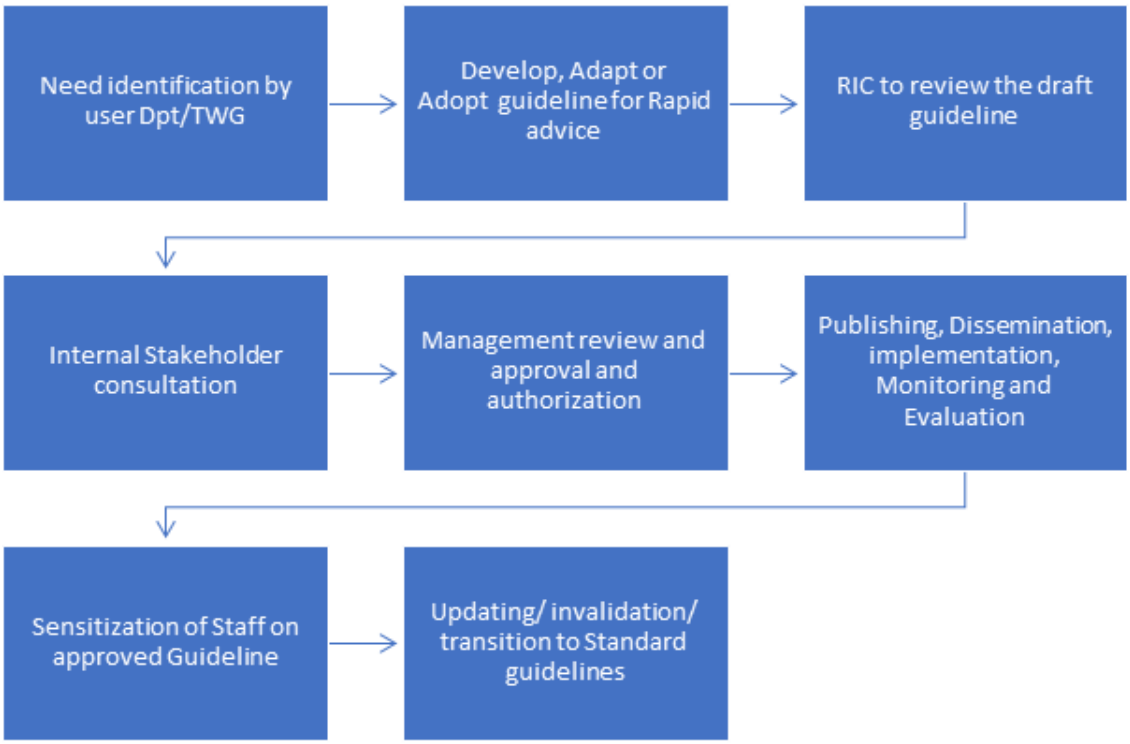
The development of Rapid Advice Guidelines at PPB will follow the process in the table 1 below.

Table 1: Process Flow for Rapid Advice Guidelines

No.	Input	Process	Output	Responsibility	Timelines
1.	Identified need	Develop, Adapt or Adopt guideline for Rapid advice	Zero Draft guideline	User department(s)/TWG	2 weeks
2.	Zero Draft guideline	RIC to review the draft guideline	Draft one guideline	RIC	21 days
3.	Draft one guideline	Internal Stakeholder consultation	Draft one with stakeholder input	User department/TWG	14 days
4.	Draft one with stakeholder input	Management review and approval and authorization	Approved Rapid Advice Guideline	Board of Directors/ Management Committee	14 days
5.	Approved Rapid Advice Guideline	Publishing, Dissemination, implementation, Monitoring and Evaluation	Published and disseminated guideline	C.E.O/User department	7 days
6.	Published and disseminated guideline	Sensitization of Staff on Approved Guideline	Sensitization/Dissemination Report	User department	1 week
7.	Rapid Advice Guideline, Monitoring & Evaluation Report Stakeholders/Users Comments	Updating as need arises and invalidation or transiting into standard guideline	Revised or standard guideline	User department to develop concept note	

	Legal & Regulatory Comments MOH Comments				

Figure 1: Process Flow- Rapid Advice Guideline Dev't



5.9 Process Flow for Standard Guidelines

The development of Standard Guidelines at PPB will follow the process in the table 2 below.

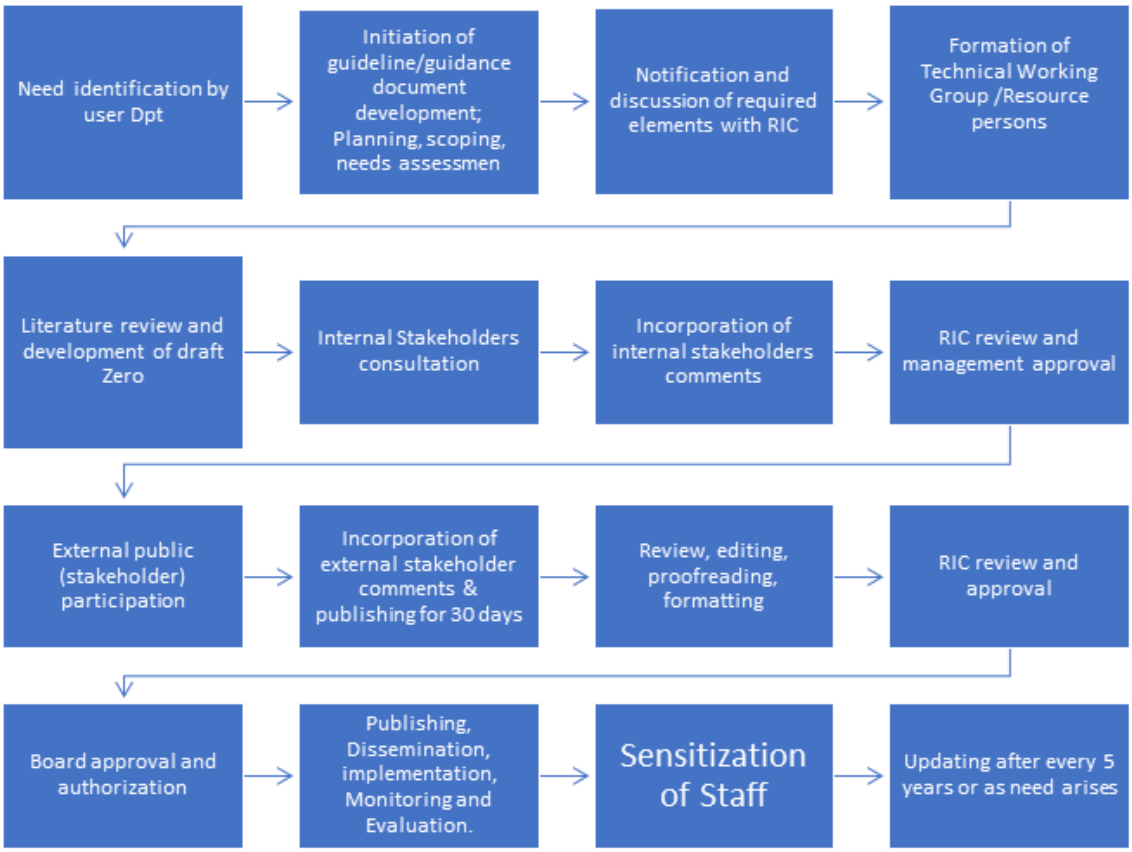
Table 2: Process Flow for Standard Guidelines

No.	Input	Process	Output	Responsibility	Timelines (Max)
1.	Identified need	Initiation of guideline/guidance document development; Planning, scoping, needs assessment	Concept note - hyperlink to template	User department(s)	2 Weeks
2.	Concept Note	Notification and discussion of required elements with RIC	Approval to develop/ Request for Information/ Decline note	User department/RIC	3 weeks
3.	Approved concept note	Formation - Technical Working Group /Resource persons	TWG	User Dep't/CEO	2 weeks
4.	TWG	Key Question formulation (PICO questions) in Literature review Development of zero draft	Zero draft	TWG	8 weeks
5.	Zero draft	Internal Stakeholders consultation	Internal Stakeholders' Comments	User Dep't/TWG	6 weeks
6.	Internal Stakeholders' comments	Incorporation of internal stakeholders comments	Draft One	TWG	3 Weeks
7.	Draft One	Review by RIC and management approval	Draft Two and/or RIC Comments	RIC/Management	4 weeks

No.	Input	Process	Output	Responsibility	Timelines (Max)
8.	Draft Two	External stakeholder Participation	External Stakeholders' Participation Report	Management	4 weeks
9.	External Stakeholders' Participation Report	Incorporation of external stakeholder comments and publishing on the PPB website for 30 days	Draft Three	TWG/RIC/Management Committee	3 Weeks
10.	Draft Three	Review, editing, proofreading, formatting	Final Draft	TWG	3 Weeks
11.	Final Draft	RIC Review & Approval	RIC-Approved Draft	RIC	4 Weeks
12.	RIC-approved Draft	Approval	Approved Guideline	Board/Management	8 weeks
13.	Final Approved Guideline	Publishing, Dissemination, Implementation, Monitoring & Evaluation	Published & Disseminated Guideline	CEO/User Department	1 week upon Approval
14.	Published & Disseminated Guideline	Sensitization of Staff on Approved Guideline	Sensitization/Dissemination Report	User Department	1 week
15.	Approved guideline/guidance document; Monitoring and evaluation report;	Updating after every 3 years or as need arises	Revised guideline	User department to develop concept note	

No.	Input	Process	Output	Responsibility	Timelines (Max)
	Stakeholders/users comments Legal and regulatory comments; MoH comments				

Figure 2:Process Flow for Standard Guidelines



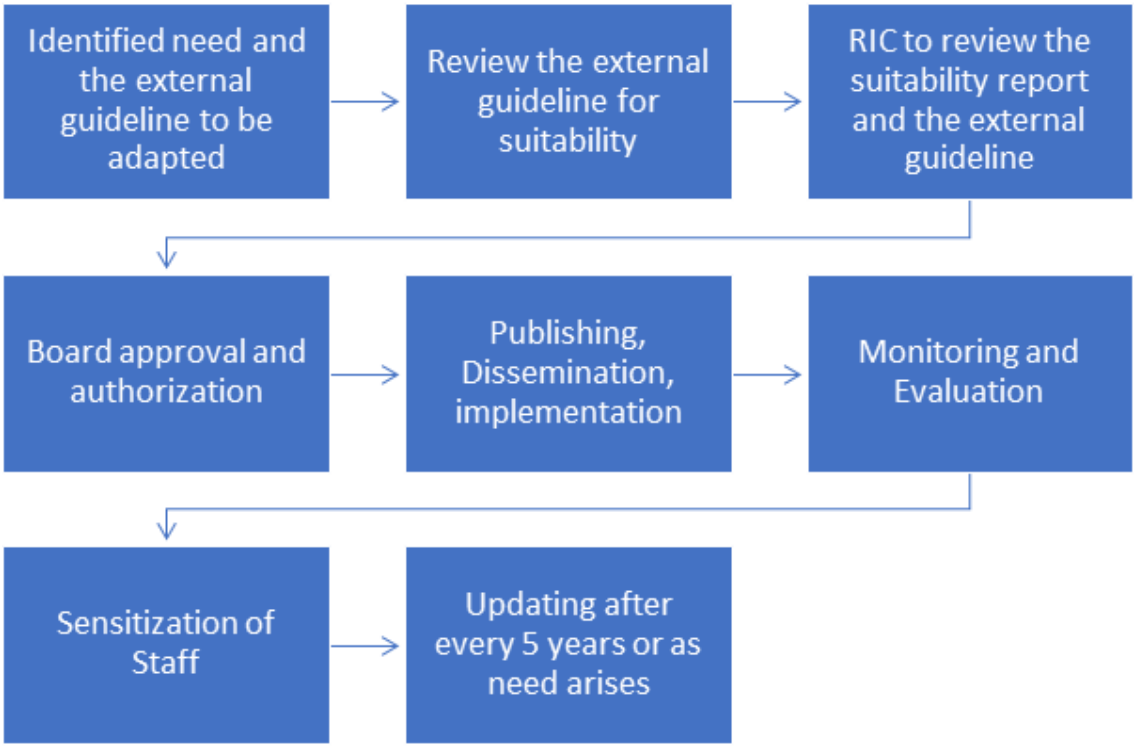
5.10Process Flow for Adaptation of External Guidelines

Table 3: Process Flow for Adaptation of External Guideline

No.	Input	Process	Output	Responsibility	Timelines (Max)
1.	Identified need and the external guideline to be adapted	Review and or customize the external guideline to PPB requirements	Zero draft guideline	User department(s)	2 weeks
2.	Zero draft and justification for adapting external guideline	RIC to review the identified need and appropriateness of the referenced external guideline	Approval for adaptation (Draft one) or Decline note	RIC	2 weeks
3.	Draft One	Management review and recommendation to the Board	Draft two	RIC	
4.	Draft two	Board approval and authorization	Approved guidelines	Board of Directors/ Management Committee	
5.	Approved guideline	Publishing, Dissemination, implementation, Monitoring and Evaluation	Published and disseminated guideline	C.E.O/User department	
6.	Published and disseminated guideline	Sensitization of Staff on Approved Guideline	Sensitization/Dissemination Report	User department	1 week

7.	Approved guideline; Monitoring and evaluation report; Stakeholders/users comments Legal and regulatory comments; MoH comments	Updating after every 5 years or as need arises	Revised guideline	User department to develop concept note	

Figure 3: Process Flow External Guidelines



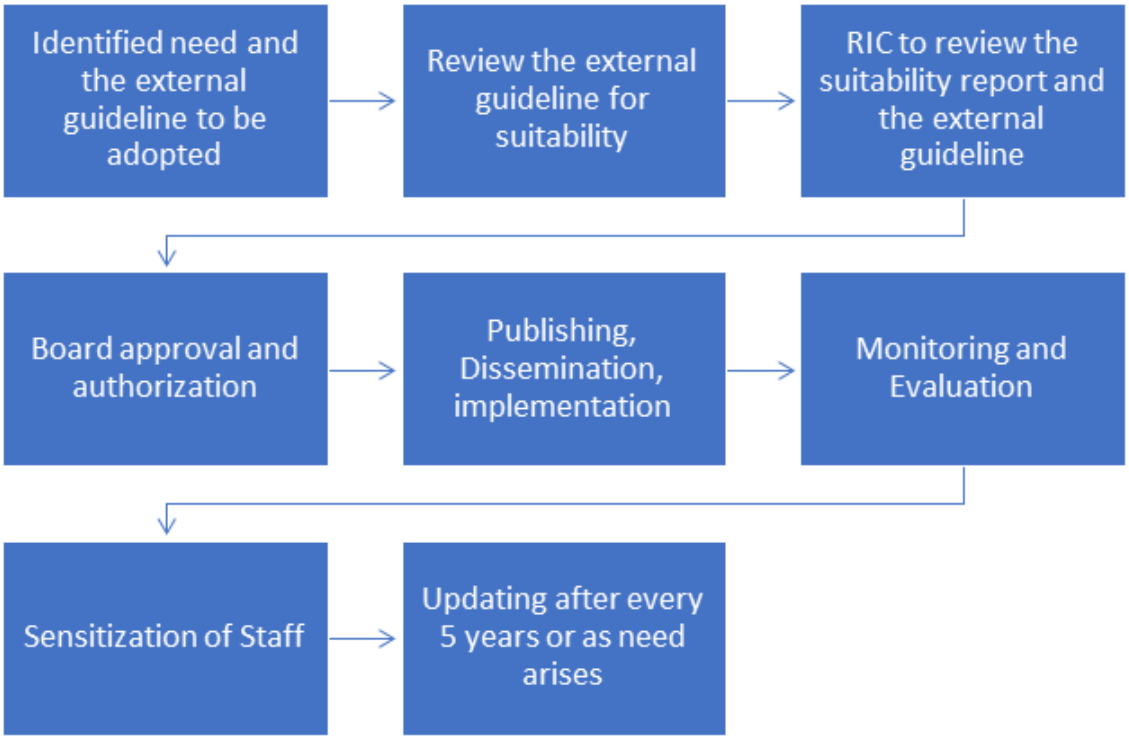
5.11 Process Flow for Adoption of External Guidelines

Table 4: Process Flow Adoption of External Guidelines

No.	Input	Process	Output	Responsibility	Timelines
1.	Identified need and the external guideline to be adopted	Review the external guideline for suitability	External guideline and suitability report	User department(s)/TWG	2 weeks
2.	External guideline and suitability review report	RIC to review the suitability report and the external guideline	Approval to adopt or Decline note.	RIC	
3.	External guideline	Board approval and authorization	Adopted external guideline	Board of Directors/ Management Committee	
4.	Adopted external guideline	Publishing, Dissemination, implementation, Monitoring and Evaluation	Published and disseminated guideline	C.E.O/User department	1 Week upon approval
5.	Published and disseminated guideline	Sensitization of Staff on Approved Guideline	Sensitization/Dissemination Report	User department	1 week
6.	Adopted guideline; Monitoring and evaluation report; Stakeholders/users comments	Updating after every 5 years or as need arises	Revised guideline	User department to develop concept note	

	Legal and regulatory comments; MoH comments				

Figure 4: Adoption of Guidelines Process Flow



5.12 PPB Guidelines, Manuals and Policies will have the following main contents

1. Table of Contents
   **This section shall provide a list of all the sections/ chapters of the document. it shall serve as an overview of the document's contents.*
2. Abbreviations and Acronyms
   **This part of the document shall provide a list of all the shortened words/ phrases as used in the document, including initials, Mixture of initials or letters representing words in another language.*
3. Glossary of Terms
   **This part of the document shall give the meanings assigned to words used in the document*
4. Preface-Executive Summary, where a need arises
   **This section will contain a brief statement of the problem covered, background information and main conclusions. It shall be made by the CEO or his designated representative.*
5. Introduction
   **Details regarding the purpose/need for the present guideline to be clearly detailed in this section. Details with regard to the guideline's presentation and use may also be provided.*
   a. Global perspective of the need

b. Regional perspective of the problem
c. Kenyan studies/situation (Situation analysis)
d. Problem statement
e. The proposal with how to undertake the proposal

6. Legal framework/Responsibility for implementation
   **Applicable/ relevant documents that include the constitution, legislation, regulations, and contracts where applicable to be listed here.*
7. Scope
   **The author to describe what the guideline is for and to whom it is meant for in this section. The scope should be specific and highlight any exclusions where applicable*

8. Main topics/Technical content
   Processes, technical standards. For adopted guidelines make reference to the relevant international guideline including the hyperlinks

9. References/Bibliography
   **A detailed list of all the reference materials used/ cited in the work are to be provided, including any relevant background readings.*

10. Acknowledgements/Contributors/Reviewers
    **This section is specifically dedicated to appreciation of persons considered helpful in the document development process. This is to be done in a concise manner and restricted to key persons involved.*

11. Annexes
    **Standalone data that cannot be placed in the main document to be listed here. These include additional information tables, references in original copy, Templates, files etc.*

PART SIX: PUBLIC PARTICIPATION

The purpose of this part is to institutionalize and support public participation in governance as ascribed to by Constitution of Kenya 2010.

6.1 Principles of public participation

Public participation is a critical element and an enabler of the Good Regulatory Practices (GRP). In applying public participation in development of regulatory instruments i.e. the Laws, the Regulations/Rules and guidelines, the regulator and the stakeholders should ensure that the principles of good regulatory practice are followed. These principles include:- legality, consistency, independence, impartiality, proportionality, flexibility, clarity, efficiency and transparency (please refer to section xxx for more information).

Further, this guideline proposes additional seven guiding principles for successful public consultation and active participation in regulatory instruments development. They represent the essential elements of good practice in the public participation in development and implementation of aspired regulations.

PRINCIPLE	WHAT IT MEANS
Service Standards	Principle of telling citizens about type of services, quality, timelines, charges and channels of communication that are provided by the institution.
Access	Citizens should have equal access to services rendered by the institution
Courtesy	It is about treating citizens with respect and dignity when they are seeking government services.
Information	The principle is about providing citizens with accurate information and in a language they understand to enable them make informed choices when they seek for services
Openness and Transparency	Informing citizens how the institution is run, the cost of various services and assigned responsibilities.
Redress	Urgent and effective remedial measures should be put in cases of poor services.
Value for Money	It is about delivering services that are economical and efficient, proper complaint management and required facilities that will ensure that citizens do not experience unnecessary difficulties and waste of time in accessing public services

Procedures for draft document release

PPB shall establish a Procedure for draft document release that will ensure the internal stakeholders are satisfied that the document is suitable for release. The line department shall bring to the attention of internal stakeholders any information or contents of the document that may be deemed sensitive or confidential for their consideration. The draft document can then be released upon endorsement and verification by the internal stakeholders.

6.2 Public Participation Process

This section provides guidance on putting the public participation exercise into operation using the process approach. The process approach is particularly relevant as it provides ease of integration into PPBs'existing quality management system (QMS), which is already in place.

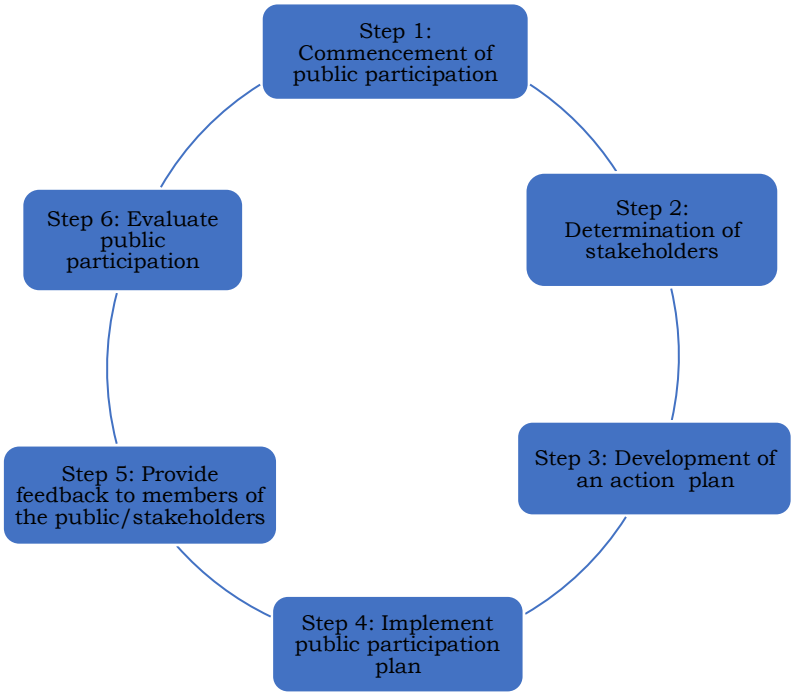


Figure 5: Public participation process flow

6.2.1 Commencement of public participation

The PPB will;

i) Adhere to provisions of Article 10 (2) (a), 35, 232 (1) (b) of the Constitution

ii) Consider legislation to the regulatory instruments and legislation applicable to service delivery
iii) Provide adequate opportunities and notice to stakeholders to voice their opinion
iv) Ensure logistical arrangements including the recording of stakeholder inputs
v) Ensure purpose of session is clearly explained to stakeholders

6.2.2 Determination of stakeholders

The PPB will;

i) Develop a clear criteria for identification of stakeholders
ii) Identify stakeholders, their interests in operation and programs of PPB, and roles and in the participation process
iii) Determine which stakeholder should be involved and the contributor expected from different stakeholders
iv) Identify appropriate methods to involve stakeholders about public participation process
v) Determine method(s) most effective of making stakeholders aware of the public participation
vi) Take all necessary measures to ensure participation of persons with disability in the public participation process.
vii) Each stakeholder shall identify persons to represent their interests in the public participation process.

6.2.3 Criteria for identification of stakeholders

A systematic stakeholder analysis will be carried out to identify the relevant stakeholders. It shall include gathering and analyzing qualitative information to determine whose interests should be considered when developing or implementing regulatory instruments.
The objective is to reach all stakeholders and interested parties including those hard-to-reach ones. It is important to ensure that there is adequate representation of stakeholders participating in the consultation.

This process shall entail analyzing the characteristics such as knowledge of the regulatory instrument, interests related to the policy/regulation, position for or against the regulation, potential alliances with other stakeholders and the ability to affect the policy/regulatory process through their power or leadership. Stakeholder analysis is a way to enable the PPB to be more prepared to detect and act to prevent potential misunderstanding, and/ or position to regulation or policy**.**

6.2.4 Identifying stakeholders

PPB will identify both it's internal and external stakeholders. Internal stakeholders include Board of directors and staff while external stakeholders are Government of Kenya, Ministry of Health, Members of public, development partners among others. (*Refer to 2020-2025 strategic plan on the detailed list of stakeholders and their roles and the list of stakeholders annexed at Annex 8 this Guideline*)

They may be classified as;

a) Staff and consultants
b) Technical interest groups
c) Organized groups including civil society
d) Active citizens
e) Public

6.2.5 Stakeholders analysis

a) Key points to consider during stakeholder analysis;

- Who are to benefit from a proposed regulation
- Who will be directly or indirectly affected by a proposed regulation
- Who has interests that may be negatively affected by a particular regulation
- Who possesses information, resources and expertise needed for strategy formulation and implementation related to a regulatory instrument
- Their level of influence

b) Processes to apply during stakeholder analysis

- Planning the process
- Selecting and defining the required regulatory instrument
- Identify key stakeholders
- Adapting the tools
- Collecting and recording information
- Filling in stakeholder table/matrix
- Analysing the stakeholder table using information

c) Stakeholder analysis matrix

A stakeholder Matrix will be applied for stakeholder analysis. This is where stakeholders are plotted against two variables. These variables will be plotted on the “importance” of the stakeholder against the “influence” of the stakeholder. This analysis will vary depending on the regulatory activity.

<table>
<tr><td></td><td colspan="5">Importance of stakeholders</td></tr>
<tr><td></td><td></td><td>Unknown</td><td>Little/ No importance</td><td>Some importance</td><td>Significance importance</td></tr>
<tr><td rowspan="4">Influence of stakeholder</td><td>Significant influence</td><td colspan="2" rowspan="2">C</td><td colspan="2" rowspan="2">A</td></tr>
<tr><td>Somewhat influential</td></tr>
<tr><td>Little/ No influence</td><td colspan="2" rowspan="2">D</td><td colspan="2" rowspan="2">B</td></tr>
<tr><td>Unknown</td></tr>
</table>

Boxes A, B and C are the key stakeholders of the organization. The implications of each box is summarised below:

Box A

These are stakeholders appearing to have a high degree of influence on the project, who are also of high importance for its success. This implies that the implementing organisation will need to construct good working relationships with these stakeholders, to ensure an effective coalition of support for the project. Examples might be the senior officials and politicians or trade unions.

Box B

These are stakeholders of high importance to the success of the project, but with low influence. This implies that they will require special initiatives if their interests are to be protected. An example may be traditionally marginalised groups (e.g. Indigenous people, youth, seniors), who might be beneficiaries of a new service, but who have little „voice" in its development.

Box C

These are stakeholders with high influence, who can therefore affect the project outcomes, but whose interests are not necessarily aligned with the overall goals of the project. They might be financial administrators, who can exercise considerable discretion over funding disbursements. This conclusion implies that these stakeholders may be a source of significant risk, and they will need careful monitoring and management.

Box D

The stakeholders in this box, with low influence on, or importance to the project objectives, may require limited monitoring or evaluation, but are of low priority.

6.2.6 Development of action plan

The PPB will;

i) Identify the public participation approach that would be most appropriate under the specific circumstances of PPB, e.g interactive websites, public meetings (face-to-face, online), workshops, public surveys, consultant interviews, print and electronic media
ii) Determine strengths and weaknesses of relevant approaches
iii) Select participation approach based on cost-effectiveness, reach and stakeholder expectations
iv) Identify organizational capacity required in terms of facilitation skills (technical and communication skills), research skills, mediation skills and interviewing skills
v) Ensure that there is a strategy to fulfill the capacity needs and that stakeholders are empowered to meaningfully participate in the process
vi) Identify capacity needs of stakeholders to participate in the process
vii) Develop a detailed action plan, indicating responsibilities, timelines, milestones, activities and resource requirements for each activity.

6.2.7 Implement the public participation plan

The following questions should guide the implementation of public participation;

i) WHAT to consult - determine the matter that need consultation from the determined stakeholders
ii) WHOM to consult – determine the stakeholders you need to consult as per the matter at hand
iii) WHEN to engage - consultation shall be initiated at all stages of regulatory instruments development and is a voluntary interactive process. It serves to incorporate, citizen values and consider views and priorities throughout development of legal instruments and regulatory instruments lifecycle management.
iv) HOW to ask them - establish the appropriate means of communicating the matter that need the stakeholders' views, inputs or considerations

6.3 Forms of Public participation

Public participation should take the following forms;

a) Public notice and comments

b) Stakeholder meetings
c) One to one interview
d) Public surveys
e) Focused Groups
f) Round table discussions
g) Web-based forums

Online consultation with adequate publicity is crucial to ensure that interested parties have the opportunity to participate in the process.

6.4 Conduct of public participation

In conducting a public participation, PPB will

i) Notify the relevant stakeholders about the regulatory instrument that requires public participation;
ii) Receive preliminary feedback from stakeholders in the feedback form Annex 7;
iii) Measure the understanding and receptiveness on the matter at hand;
iv) All participants including representatives of the PPB and all stakeholders shall be courteous, respectful and civil in public participation processes;
v) Individuals who are disruptive shall be given a warning and may be if necessary be removed from a meeting;
vi) Expression of views shall be limited to the nature of discussion;
vii) Undertake and encourage actions that build trust and credibility in the public participation process among all the participants;
viii) Be responsible for the validity of all data collected, analyses performed, or plans developed by it or under its direction;
ix) Not engage in conduct involving dishonesty, fraud, deceit, misrepresentation or discrimination;
x) Not accept any payments or gifts given contingent on an interested party's desired result where that desired result conflicts with its professional judgment;
xi) Avoid relationships or actions, which could be legitimately interpreted as a conflict of interest by clients, officials or the public; and
xii) Ensure there is no misrepresentation of facts
xiii) Request, where applicable, for advanced copies of written submissions from the identified stakeholders.

6.5 Provision of feedback to stakeholders

The PPB will;

i) Provide stakeholders feedback on the incorporation of their input in development of regulatory instruments by ensuring that the final

regulatory instrument has been publicized on the PPB website or published in the daily newspaper with wide circulation or in the gazette as appropriate

ii) Other forms of feedback, at any stage of public participation/consultation should always be provided officially through hard copy written communication, official emails, the PPB's website and any other means considered to be a recognized official communication means.

iii) prepare a report summarizing the proceedings of the Stakeholder consultations and share the same

6.6 Processing of responses/ memoranda

The PPB will ensure;

a) That all responses are carefully and independently analysed;
b) The final decision is made widely available to the public, including the reasons for the decisions taken; and
c) The disclosure of all relevant information for the public to understand and evaluate the decision made.

6.7 Timelines

The timelines for receiving responses from stakeholders should range between four (4) to twelve (12) weeks and should be specified in the notification to stakeholders. On declaration of a Public Health Emergency by the Government, the timelines may range from two(2) to four (4) weeks.

The timelines for giving feedback to stakeholders should range between four (4) to eight (8) weeks and it shall be communicated clearly to stakeholders. On declaration of a Public Health Emergency by the Government, the timelines would range from one(1) to two (2) weeks.

6.8 Decision making

It is the final process in concluding the findings and discussion from the consultation process. The conclusion should include:

i. Details on the public participation process such as mechanism used, consultation period, and the consultation results.
ii. Documenting how the views of stakeholders were considered during consultation
iii. Documenting what is the PPB feedback on the consultation results

6.9 Monitoring and Evaluation

Public participation processes will be reviewed regularly or as necessary to address challenges and constraints experienced in the process to ensure usefulness of the entity's public participation process.

PPB will ensure that;

a) Effective instruments and indicators are used to evaluate whether the public participation objectives have been achieved
b) Constraints and challenges in public participation process have been identified
c) Ways to improve public participation have been devised
d) Lessons learnt from the process have been documented

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ANNEXES

Annex 1: Register of public notification of statutory instruments

S/no.	Regulations under development	Directorate/Department/ Division	Date
1.			
2.			
3.			
4.			
5.			

Annex 2: Guideline Development Notification Form

Guideline No.	
Directorate:	
Department:	
Date:	
Name of Guideline	
Type of Guideline:	(Insert the 4 types of guidelines)
Reasons for requesting document development/revision/Change:	
Impact of guideline/revision (The need to be addressed):	
Initiator of request:	

Annex 3: Guideline approval/ decline note template

Review, assessment and Authorization			
Guideline No:			
Guideline Name & Type:			
Initiator Department:			
Assessment Panel members			
Name	**Title**	**Sign**	
Regulatory Instruments Committee Decision		**Referred**	**Declined**
If referred or declined, state reasons.			
Authorization of the proposed change			
Name	**Title**	**Sign**	**Date**
Section 3: Communication of review outcome			

Initiator of change formally notified of decision of review and Assessment (via email and/or memorandum)	**Yes**	**No**
Date notified		
Checked by: Name	**Sign**	**Date**

Annex 4: RIC Guidelines Development/Review Register

Serial No.	Name of Guideline	Guideline No.	Type of Guideline	Status	Date
1.					
2.					
3.					

Annex 5: Title and back pages for PPB Guidelines, Manuals & Policies

Title page

PHARMACY AND POISONS BOARD

KPPB

NAME OF DOCUMENT

Date of Approval
(Month and Year)

Back page

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Annex 6: Document Review Comments Form

1.	Document name;
2.	Document no;
3.	Revision number and date;
4.	Reviewer's comment(s)
	4.1. Title Page Comment(s) 4.2. Table of contents Comment(s) 4.3. Abbreviations and Acronyms Comment(s) 4.4. Acknowledgment Comment(s) 4.5. Preface – Executive summary where need arises Comment(s) 4.6. Legal framework/responsibility for implementation Comment(s) 4.7. Introduction Comment(s) 4.8. Scope Comment(s) 4.9. Main topics/Technical content

	Comment(s) 4.10. References/Bibliography Comment(s) 4.11. Authors/contributors Comment(s) 4.12. Annexes Comment(s) 4.13. Back Page Comment(s)
5.	Reviewer's recommendation(s)
6.	I hereby declare that I have reviewed the above document and provided input and comments as above
7.	Reviewer's name Signature Date

Annex 7: Stakeholder Consultation Feedback Form

Comments on the draft PPB Regulatory Instruments			
Document title	**Page number and Section**	**Proposed changes**	**Justification**

Annex 8: List of Stakeholders

- Ministry of Health (e.g. health service department, pharmaceutical units, national programmes);
- Procurement agencies, importers and distributors both from the private and the public sector (including tertiary care hospitals, primary care facilities, hospital pharmacists);
- County Governments (Departments of Health)
- National Government Representatives (Regional Coordinators, County Commissioners)
- Ministries of finance, industry and trade, National Treasury;
- Partner Government Agencies e.g KEBS, KENTRADE, KPA, KAA, NACOSTI, KEMRI etc
- Quality control laboratories;
- Audit departments (Office of Auditor General);
- Office of the Attorney General
- Prosecutions & Enforcement Departments (Office of the Director Public Prosecutions, National Police Service)
- Pharmaceutical industry (multinational and national) and associations;
- Local Manufacturers of Health Products and Technologies
- Non-governmental organizations, such as those engaged in health service activities, patient advocacy groups, "watch-dog" organizations;
- International donor organizations, such as the World Health Organization, the World Bank and the Global Fund;
- Academic institutions (colleges, universities)
- Research institutions; Ethics committees, institutional review boards
- Professional associations (medical, pharmacy, etc.);
- Media (if knowledgeable about the pharmaceutical sector);
- Health insurance funds
- Civil Society Organizations

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