HPT/PER/GUD/092

Revision No:03

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINE ON EVALUATION AND AUTHORIZATION OF UNREGISTERED HEALTH PRODUCTS AND TECHNOLOGIES

JUNE, 2026

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Table of Contents

ABBREVIATIONS AND ACRONYMS

PPB	Pharmacy and Poisons Board
PV/PMS	Pharmacovigilance/ Post Market Surveillance
SmPC	Summary of product characteristics
HPT	Health Product and Technology
CPRO	Chief Principal Regulatory Officer
DPER	Product Evaluation and Registration Department
GMP	Good Manufacturing Practice

GLOSSARY OF TERMS

For the purposes of this guideline any word or expression to which a meaning has been assigned in the Act or General Rules shall have the meaning so assigned and, unless the context otherwise indicates.

An unregistered health product refers to any finished product whose active ingredient (s) has not been granted marketing authorization in Kenya, but has been granted marketing authorization from the country of origin.

The Board- Pharmacy and Poisons Board

Confidentiality / Secrecy

The confidentiality of information submitted to PPB is governed by Section 34 of the Act. The Authority, advisory committee members or staff of the Authority may NOT:
Disclose to any person, any information acquired in the exercise of powers or performance of functions under the Act and relating to the business affairs of any person, except for the purpose of exercising his / her powers, or for the performance of his/her functions under the Act, or when required to do so by any competent court or under any law, or with the written authority of the CEO, or use such information for self-gain or for the benefit of his employer.
PPB may insist on written confirmation of the identity and affiliation of an individual inquiring telephonically, or in person, about a medicine.

No information shall be disclosed telephonically unless the Authority staff member knows the enquirer is entitled to receive the information.

Language

In terms of these guideline, all applications and supporting data submitted to Pharmacy and Poisons Board should be presented in English. Original documents not in English should be accompanied by an English translation.

1.0 INTRODUCTION

This document is intended to clarify the mandate, intent and scope of access to unregistered medicines for human use through the provisions of Rule 16 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022, and clarifies the mandate, intent and scope of this Rule published in terms of the Act (CAP 244). It outlines the process to be followed when requesting an unregistered health product, as well as the information required to comply with the provisions of CAP 244 and the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022.

1.1 Purpose

The objective of this guideline is to ensure that requests for access to unregistered medicines are received, processed, and decided upon efficiently, consistently, and in a timely manner, in full compliance with legal provisions.

1.2 Scope of the document

The Board in its mandate under section 3(b) of CAP 244 Laws of Kenya is responsible for regulating the safety, efficacy, and quality of all medicines manufactured in, imported into or exported from the country. In certain circumstances, and in accordance with Rule 16 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022, the Board may authorize the sale of an unregistered medicine for a specified period to a specified person or institution for specific purposes, in the manner and period as determined by the Board.

Where adherence to the guideline (HPT Routine Registration) is not feasible, a justification and motivation must be provided along with the application for authorization to sell unregistered medicines under Rule 16 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022. Each application will be assessed individually to ensure that patient safety and well-being are not compromised.

The primary aim of any authorization granted under Rule 16 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022

is to provide access to quality, safe and effective medicines on an exceptional basis, particularly where conventional therapies have been ruled out, proven ineffective, or are unavailable.

It is important to note that the importation of unregistered medicines for exhibition purposes is outside the scope of this guideline.

1.3 Objectives

This document is intended to clarify the mandate, intent and scope of access to unregistered medicines in terms of Rule 16 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022 according to the scope of the document described in 1.2 and outlines:

a) the process to be followed to enable access to a medicine that is not registered for sale in Kenya;
b) the responsibilities of sellers of unregistered medicine including health care providers, persons submitting an application on behalf of a health establishment, and the holders of a license to manufacture, import or to act as a wholesaler of or distribute a medicine or Scheduled substance, issued in terms of the Pharmacy and Poisons Rules 2022.
c) the role and responsibilities of the organizational unit (committee) responsible for managing applications submitted in terms of Rule 16 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022.
d) the information required to comply with Rule 16 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022 made in terms of the Act.

1.4 Legal Provision

Rule 16 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022 States:

1) The Board may, in writing, authorize a person to import or distribute for a specified period to a specified person or institution a specified quantity of a particular health product that is not a registered product.

2) A health product distributed pursuant to authorization granted under subrule (1) may be used for such purposes and in such manner and during such period as the Board may in writing determine.
3) A person who intends to obtain the authorization under subrule (1), for purposes other than a clinical trial, shall apply to the Board, in Form 8 set out in the First Schedule.
4) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who shall be a citizen of Kenya, a person who has permanent residence or a company incorporated in Kenya.
5) The application made under subrule (3) shall be accompanied by—
    a) a product brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human or animal pharmacological and clinical data with the health product concerned;
    b) witnessed informed written consent document, where applicable;
    c) details of registration or pending registration of the health product with any other regulatory authority, if available;
    d) evidence of compliance of the manufacturer of the health product with Good Manufacturing Practice standards as determined by the Board;
    e) reasons why a registered health product cannot be used;
    f) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;
    g) proof that the applicant holds—
        i. a valid practicing licence issued in accordance with section 9A of the Act;
        ii. a valid wholesale dealer's licence issued in accordance with section 27 of the Act;

iii. a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;

iv. a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or

v. a valid manufacturing licence issued in accordance with section 35A of the Act; and

vi. the fees specified in the Second Schedule.

6) The Board shall grant authorisation under subrule (1) if the applicant has—

a) a valid practicing licence issued in accordance with section 9A of the Act;

b) a valid wholesale dealer's licence issued in accordance with section 27 of the Act;

c) a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;

d) a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or

e) a valid manufacturing licence issued in accordance with section 35A of the Act.

7) Where the Board issues an authorisation under subrule (1), the person to whom the authorisation is issued shall submit to the Board—

a) progress reports after every six months from the date when the authorisation was issued;

b) any adverse event report, whenever an adverse event occurs; and

c) a progress report within thirty days after the completion or termination of the use of the health product.

8) The Board may, if the Board is of the opinion that the safety of any patient or animal is compromised or the scientific reasons for administering the unregistered health product have changed:-
    a) impose any additional conditions;
    b) request additional information;
    c) inspect the site where the unregistered health product is manufactured, stored or administered; or
    d) withdraw the authorisation to treat the patient or animal.

9) The Board may, by notice in writing withdraw the authorisation issued under subrule (1) if the any of purposes or the manner specified in subrule (2) is contravened.

10) A health product authorised under this rule shall be labelled in accordance with section 41 of the Act.

11) An applicant shall notify the Board of any variation to the agreement appointing the local representative within seven days of the variation.

1.5 General Principles

Authorisation for the sale of an unregistered health product in terms of Rule 16 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022 must be granted prior to any such medicine being imported into the Republic of Kenya.

No person may sell any unregistered health product unless they have been so authorised as under Rule 16 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022.

Conditions associated with the authorisation for the sale of an unregistered health product may be imposed at the time of authorisation or during the authorisation as additional conditions in line with the provisions of Rule 16 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022 and CAP 244 Laws of Kenya.

2.0 POSSIBLE ACCESS SCENARIOS

2.1 Individual named patient

This scenario considers access to unregistered health product for the treatment, diagnosis, or prevention of conditions, diseases or disorders when conventional therapies have been considered and ruled out, have failed, are unsuitable or unavailable as marketed products.

2.2 Bulk stock held by a health establishment

In exceptional circumstances, certain unregistered medicines need to be available urgently and an individually named patient application is not possible. In such circumstances, bulk stock of the unregistered medicine may need to be maintained at a health establishment for use in, for example, an intensive care unit or theatre. An application may be submitted for authorization to hold a certain amount of emergency stock in the pharmacy of the health establishment for use when an emergency arises.

2.3 Bulk stock held by the holder of a licence issued in terms of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022.

In exceptional circumstances, certain unregistered medicines may need to be maintained at a single point of storage for distribution on an urgent basis to one or more health care providers or health establishments.

2.4 Additional information required

The applicant may apply for a certain quantity of emergency stock to be held on their premises, for distribution when required in accordance with the conditions of the authorisation granted.

2.5 Co-applicants

In such circumstances, co-applicants shall include health establishments and prescribers, where these are known. Where these are not known, the

applicant is required to keep adequate records in accordance with any conditions of the authorization.

Despite any authorization provided by the Board, the sale of any medicine may only be permitted after compliance with any other legislative or policy requirements that may be required outside of the mandate of the Board.

3.0 ROLES AND RESPONSIBILITIES

The scenarios outlined in section 2 require that various persons and/or institutions need authorization in accordance with section 16 of the Pharmacy and Poisons Rules 2022 to sell unregistered medicines.

3.1 Applicant:

Applicants are required to assume responsibility for the application process and submission thereof, including provision of accurate information for submission with an application.

Applicants must: -

a) ensure that the medicine for which authorisation is granted is sold, prescribed and dispensed in compliance with the provisions of the Act;

b) ensure that the medicine for which authorisation is granted, is used for the purpose, in the manner and for the duration for which authorisation is granted; and

c) comply with any other conditions imposed by the Board.

Following the granting of authorisation by the Board, the applicant is responsible for deciding whether or not to sell the medicine. An applicant is under no obligation to sell an unregistered medicine and cannot be compelled to do so, however, the Board must be notified by the holder of authorisation when the authorised medicine will not be sold.

Applicants are expected to ensure that significant new information about the safety, quality and efficacy of a medicine for which authorisation has been granted in terms of Rule 16 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022 is made available to relevant role-players and in accordance with the conditions and guidelines issued by the Board.

3.2 Authorisation of sale of an unregistered medicine for certain purposes

The person under whose supervision the unregistered medicine or substance is prescribed shall submit to the Board-

(i) any adverse event report;

(ii) progress reports after every six months from the date following commencement of the use of the unregistered medicine; and

(iii) progress report 30 days after the completion or termination of the use of the medicine.

The provisions of Pharmacy and Poisons (Pharmacovigilance and Post Market Surveillance) Rules, 2022, which place an obligation on health care providers or any other person to report suspected adverse drug reactions or new or existing safety, quality or effectiveness concerns, shall apply equally to unregistered medicines for which authorisation has been granted.

a) Vigilance

A health care provider, or any other person should inform the Board, in the manner as determined by the Board in the Guidelines on the Safety and Vigilance of Health Products and Technologies in Kenya (**HPT/PDS/VMS/GUD/022**) of any-

(i) suspected adverse events; or

(ii) new or existing safety, quality or effectiveness concerns, occurring as a result of the use of any medicine or scheduled substance, or

(iii) suspected quality defects

3.3 Assessment Committee

The Evaluation Committee undertakes the following activities:

a) While evaluating applications, the committee shall check that applicants have provided the information required in terms of Rule 16 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022;

b) Emphasising to health care providers that registered medicines should always be considered and/or used before considering the use of an unregistered medicine;

c) Monitoring the compliance of applicants with the provisions of Rule 16 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022 and Pharmacy and Poisons (Pharmacovigilance and Post Market Surveillance) Rules, 2022 regarding the reporting of adverse events;

d) Monitoring the compliance of applicants with any conditions imposed in terms of CAP 244 and the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022;

e) Monitoring safety issues and concerns pertaining to medicines accessed in terms of CAP 244 and the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022;

f) Monitoring the frequency and extent of requests for a specific unregistered medicine, to enable the Board to determine whether a recommendation should be made that application for registration of the medicine be considered; and

g) Monitoring trends in the use of unregistered medicines accessed in terms of CAP 244 and the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022.

4.0 APPLICATION PROCESS

4.1 Initiation of application

To initiate an application an applicant shall complete the Application Form. The latest fee schedule and relevant instructions may be accessed and downloaded from the Board website www.pharmacyboardkenya.org.

A completed application form must be accompanied by the prescribed fee and must contain at least the information as prescribed by the Board.

These applications can be submitted electronically/manually to the Board.

The following supporting documents must be submitted as part of the application:

a) A need assessment letter shall be submitted for **each** health institution and healthcare provider in support of Local Purchase Orders (LPOs) and patient prescriptions. The letter shall be **product-specific** and shall, at a minimum, contain the following:
   i. A declaration confirming that the respective health institution or healthcare provider is fully aware that the requested product is **unregistered in the Kenyan market.**
   ii. Name of the unregistered health product, including brand name, International Non-proprietary Name (INN), dosage form, and strength.
   iii. Number of patients who will be prescribed the product.
   iv. Patient code names (for data privacy)- to be verified by PPB at/from the hospital before approval
   v. Pack size.
   vi. Detailed dose calculations and therapy outline for each patient, specific to the unregistered health product. For antineoplastic agents and any other health products requiring patient-specific doses based on a dosing range, such calculations shall be provided for each patient (e.g., Body Surface Area [BSA] calculations).
   vii. Duration of treatment corresponding to the requested quantity.

viii. Total quantity requested, justified by points (iii), (vi), and (vii)

ix. A written commitment to submit progress reports for each patient at six-month intervals from the date of issue.

x. A written commitment to submit a final progress report within thirty (30) days following completion or termination of product use.

xi. A written commitment to report any adverse reactions and quality defect concerns to the Pharmacy and Poisons Board (PPB) through the established pharmacovigilance reporting system.

xii. Commitment to Submit treatment protocols for high-risk products from the health institution and/or healthcare provider's practice, when requested by the Board.

xiii. Full names of the healthcare provider including the KMPDC number. In situations where the clinical pharmacist is applying on behalf of the institution, then the PPB registration number of the clinical pharmacist.

b) **Justification for Request** : Where an alternative brand or therapeutic option exists in the market, the applicant shall provide a valid justification:

i. Brand preference shall not be accepted as a justification.

ii. Claims of short supply must be supported with verifiable evidence

c) Valid wholesale dealer's license

d) Primary and secondary artworks

e) SmPC and/or PIL

f) Brand name, pharmaceutical form and strength, pack size and total quantity requested.

g) Supporting LPOs, valid patient prescriptions and/or letters from HCPs and Health institutions officially requesting for a defined

quantity. All of these documents should be valid and authorized.

h) Proof of registration of the brand requested for import in the country of origin.

Following consideration of the application, the Board may either authorize the sale of the unregistered medicine, request additional information from the applicant, or deny the application.

The Board reserves the right to request for additional documentation based on evaluation outcomes.

4.2 Timeline for review.

The timelines for this process shall be in accordance with the Board's Service Charter which can be accessed on the website www.pharmacyboardkenya.org.

5.0 EVALUATION PROCESS

Evaluation is the process by which the Evaluation committee decides whether authorisation is appropriate and justified. Each request represents a unique set of circumstances and is supported to varying degrees by information provided by the applicant.

A decision to authorise or deny a request is made on a case-by-case basis taking into consideration the nature of the unmet medical need, the availability of marketed alternatives and the information provided in support of the request regarding the use, safety and efficacy of the medicine.

Screening of one application shall not exceed two (2) rounds. If all deficiencies are resolved within the first or second screening response round, the procedures will apply. If the applicant fails to respond or sufficiently address the screening queries, the application will be processed and presented to the plenary, with all deficiencies outlined, for rejection.

Evaluation of one application shall not exceed three rounds of evaluation with the exception of administrative queries or minor clarification requests. If the applicant fails to address the queries raised in the three rounds, the application shall be considered closed and claims rejected.

The allowable quantities of product being requested shall primarily be based on the physician prescription/LPO, submitted treatment protocol and/or patient dose calculations. The maximum allowable quantities/period of use shall be determined by pharmacy and poisons board on case-by-case basis. In any situation the maximum use period shall not exceed 6 months

Evaluation takes into account the information supplied and balances the following factors to ensure that an unmet medical need exists and there is credible data to support the request:

a) Seriousness of disease based on a description of the unmet medical need for which the medicine is requested;
b) Clinical status of the patient/s, including prognosis for patient-

specific applications;

c) Other therapies that have been tried and failed, or have been considered and ruled out, or are unavailable

d) Other current/concomitant medication whether for diagnosis, treatment or concomitant disease;

e) Prior patient experience with the medicine, including evidence of efficacy and adverse drug reactions;

f) Data provided with the application including quality and relevance of data regarding the unmet medical need. A hierarchy of available evidence may range from prescribing information/professional information from the jurisdiction where the medicine may be marketed, preferably a regulatory Board with which PPB aligns itself; published data to support the application; or unpublished reports;

g) Data available from medical literature, treatment guidelines, investigator's brochures, information obtained from the manufacturer, clinical trial reports, consultations with experts;

h) Regulatory status of the medicine; and

i) Medicine shortages and discontinued medicines.

5.1 Special Considerations

Medicine shortages and discontinued medicines

In circumstances where a medicine is in short supply or is discontinued from the market, the Board will consider authorising access to an alternative source in circumstances where:

a) the medicine is considered to be medically necessary for the treatment, diagnosis or prevention in an area of unmet medical need;

b) there are no other dosage forms of the medicine on the market that would be considered a reasonable alternative;

c) there are no other medicines or therapies that would be considered to be reasonable alternatives.

5.2 Communication of the Outcome of the Application

Following consideration of the application, the Board will either authorize or deny the application, with reasons provided if denied. Authorized applications will be issued with an approval letter and rejected applications will be issued with a letter of rejection.

The Board will inform applicants through PRIMS of any queried applications. Responses to queries may also be addressed through PRIMS.

5.3 Appeals against PPB's decisions on Unregistered Health Products and Technologies Authorization

In instances where the Pharmacy and Poisons Board (PPB) has rejected a request for an unregistered HPT, the applicant may submit a formal written appeal to the PPB, requesting a review of the decision taken.

All notice of appeals must be made within thirty (30) calendar days from the date of the notification.

The applicant shall make appeal by giving grounds for review for each reason given for the rejection of the request for the unregistered product. The grounds for the request shall be based on the information that was submitted in the product dossier. Any additional or new information that was not earlier submitted will not be accepted. PPB may review or uphold its earlier decision.

6.0 RENEWAL OF APPLICATIONS

An applicant may submit a request for renewal of an applciation that was previously authorized through the unregistered Health Products and technologies.

A completed application form must be accompanied by the prescribed fee and must contain at least the information as prescribed by the Board.

These applications can be submitted electronically/manually to the Board.

The following supporting documents must be submitted as part of the the renewal application:

a. A current product-specific needs assessment letter
b. Confirmation of product and Manufacturing details (Product information including primary and secondary artworks, and labeling information for the unregistered brand). These details should be the same as those previously authorized.
c. Proof of GMP compliance
d. Pharmacopoeial Reference Standards
e. **Submission of Progress Reports** – Progress reports from the health institutions and healthcare providers shall be submitted in accordance with the requirements stipulated in the *Pharmacy and Poisons (Registration of Drugs) Rules, 2022*
f. **Submission of Distribution Logs** – Applicants shall provide distribution logs demonstrating that supply of the health product(s) has been limited strictly to the facilities and healthcare providers previously approved under the initial authorization

Following consideration of the application, the Board will either authorize or deny the application, with reasons provided if denied. Authorized applications will be issued with an approval letter and rejected applications will be issued with a letter of rejection.

The Board will inform applicants through PRIMS of any queried applications. Responses to queries may also be addressed through PRIMS.

7.0 RECORD KEEPING

All records relating to unregistered medicines sold must be maintained in accordance with applicable legislation (recommended to be no less than five years), in a manner that permits rapid retrieval if necessary. The Board may at any time request that applicants account for all quantities of medicine received or supplied i.e. reconciliation of the quantities for which authorisation is granted, procured and used.

The holder of a licence issued in terms of the CAP 244 and the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022 is required to maintain complete and accurate records of all transactions in a manner that permits rapid response to specific requests to verify the distribution of medicine supplies to health establishments or health care providers.

8.0 REPORTING

Applicants must provide reports to the Board on the use of the unregistered product, suspected quality defects and any adverse drug reactions (ADRs) encountered, using the channels provided by the Board, and are listed in the Guidelines on the Safety and Vigilance of Health Products and Technologies in Kenya.

The guideline must be followed regarding what should be reported, and the associated timeframes. Any suspected Adverse Drug Reaction and /or Adverse Event shall be reported as soon as possible to the National Pharmacovigilance Centre at the Board. The following timelines for reporting apply to spontaneous cases encountered by health care professionals and the patients/ public:

a) Fatal cases - The Board shall be notified immediately and a report submitted within 48 hours.

b) Serious (non-fatal) cases shall be reported within 15 calendar days.

c) Non-serious local cases shall be reported within 30 calendar days.

9.0 UNUSED MEDICINES

As a general rule, unused supplies of a medicine should be returned to the holder of a license issued in terms of the Act.

Unused medicines for which authorization has been granted must be disposed of in terms of The Pharmacy and Poisons (Pharmaceutical Waste Management) Rules, 2022.

10.0 MARKETING AND ADVERTISING

Advertising and marketing of unregistered medicines accessed through this route of authorization is strictly prohibited. This includes:

a) Supply of health products as marketing samples

b) Advertisement of health products authorized through this route in any manner or form, across all platforms including and not limited to online advertisement and physical display.

c) Promotion of health products authorized through this route to healthcare providers and patients.

d) For use and supply in Government Hospital tenders.

The holder of a license issued under the Act and the Pharmacy and Poisons Rules, 2022, is responsible for ensuring that health establishments are adequately informed about the prohibition on advertising health products authorized through this pathway.

11.0 REGULATORY CONSEQUENCES OF NON-COMPLIANCE

Failure to comply with the stipulated conditions and regulations will result in regulatory action, which may include, but is not limited to:

a) Suspension or revocation of the non-routine authorization.

b) Product recalls as deemed necessary.

c) Prohibition from utilizing this authorization pathway for future applications.

d) Withdrawal of Practice and Wholesale Dealers License

e) Additional penalties as prescribed by law under CAP 244.

12.0 REFERENCES

1. SAHPRA Guideline for Section 21 Access to Unregistered Medicines.
2. EFDA Guideline for Conditional Approval of Medicines.
3. CAP 244 and the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022
4. Guidelines on the Safety and Vigilance of Health Products and Technologies in Kenya

13.0 REVISION HISTORY

Revision No	Date	Author/ Reviewer	Section (s) Revised	Decription of Change
0	01/01/2024	QAO	Initial Issue	Initial Issue
1.	10/08/2025	QAO	Section 4.1	Introduction of (a) Needs Assessment letter which requests for dose calculations (b) Justification for request
			Section 5.0	Duration of approval.
			Section 6.0	Renewal of applications
2.	18/02 2026	QAO	Section 15.0	Update to the process flow chart to capture service charter timelines
3.	16/06/2026	QAO	Section 5.0	Inclusion of maximum limit of 2 screening rounds and 3 evaluation rounds and clarification that an application may be closed if outstanding issues remain unresolved after the agreed evaluation rounds.
			Section 5.2	Update to communicaion of outcome: Inclusion of issuance of rejection letters
			Section 5.3	Addition of Appeals Process

14.0 LIST OF CONTRIBUTORS AND REVIEWERS

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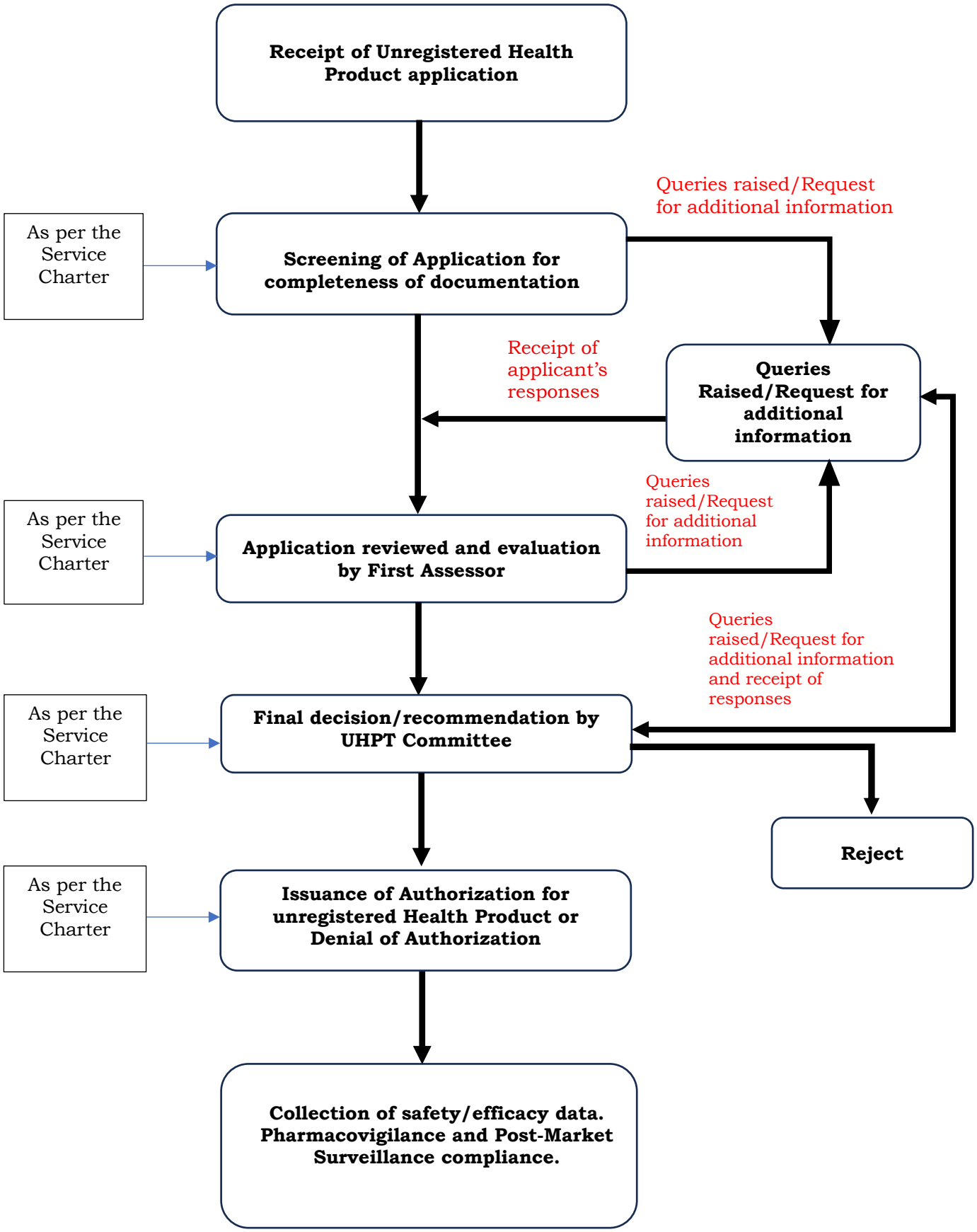
15.0 ANNEXES

Annex I: Unregistered Health Products and technologies Process Flow:



Annex 2: Application Form Form 8 (r. 16(3))

Application Form for Unregistered Health Product and Technologies <Date>	
Application No.	
Active substance[s]	
Orphan indication	

1. Description of the condition under which the HPT is to be used

1.1 Details of the condition

Definition

Aetiology

Specific characteristics; pathophysiological, histopathological, clinical characteristics

Classification

Diagnosis and sympyoms

1.2. Proposed indication

1.3. Medical plausibility

1.3.1. Active substance: description of the medicinal product, pharmacological class and mode of action

1.3.2. Plausibility of the condition; data with the specific product as applied for designation in specific models or in patients affected the condition

1.4. Justification of the life-threatening or debilitating nature of the condition

2. Prevalence of the condition

2.1. Prevalence of the disease or condition in the Kenya

2.2. Prevalence and incidence of the condition in the Kenya

3. Other methods for diagnosis, prevention or treatment of the condition

3.1. Details of any existing diagnosis, prevention or treatment methods

3.2. Justification as to why methods are not satisfactory *or* Not applicable. *(delete as appropriate)*

Note that sections 3.2 and 3.3 are mutually exclusive.

3.3. Justification of significant benefit *or* Not applicable. *(delete as appropriate)*

4. Description of the stage of development

4.1. Summary of the development of the product

Quality aspects

Non-clinical aspects

Proof-of concept in relevant model Pharmacology

Pharmacokinetics

Toxicology

Clinical aspects

Pharmacokinetics

Pharmacodynamics

Clinical efficacy

Dose-response studies and main clinical studies Clinical studies in applied condition

Planned clinical studies

Clinical safety

Adverse events

Serious adverse events and deaths

4.2. Details of current regulatory status and marketing history in the Kenya and other countries
Applicant's position:

Please delete any paragraph above that does not apply.

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