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MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINES ON RELIANCE MECHANISMS FOR MARKETING AUTHORIZATION OF HEALTH PRODUCTS AND TECHNOLOGIES IN KENYA

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FOREWORD

The guidelines on reliance mechanisms for marketing authorization of health products and technologies in Kenya developed by the Pharmacy and Poisons Board (PPB) of Kenya represents a significant step towards optimizing the country's regulatory processes for health products and technologies. This guidance is a result of a collaborative effort between PPB staff, development partners, and key stakeholders, drawing on insights from international, regional, and local dialogues. The central objective is to maximize the effective use of limited resources while ensuring timely and robust regulatory outcomes.

The concept of reliance enables National Regulatory Authorities (NRAs) in Low and Middle-Income Countries (LMICs) to utilize the regulatory decisions of Stringent Regulatory Authorities (SRAs), such as those recognized by the World Health Organization (WHO). This approach allows LMICs to conserve valuable resources by relying on the comprehensive evaluations conducted by SRAs, thereby reducing the need for duplicative assessments and accelerating approval timelines for essential health products and technologies.
It also provides a resource-efficient alternative to the traditional, full assessment pathway for product approval. It focuses on products that have already been verified for quality, safety, and efficacy/performance in the case of Medical Devices. This is particularly beneficial for LMICs, as it allows them to prioritize national-specific regulatory activities, ensuring quicker access to quality health products and technologies without compromising safety.

While Marketing Authorization (MA) is the most prominent regulatory function of focus, reliance extends beyond this to include other key areas including: Pharmacovigilance, Post-market surveillance, Clinical Trials and Good Manufacturing Practices (GMP) oversight.

The implementation of reliance principles will significantly enhance the efficiency and effectiveness of Kenya's regulatory system. The anticipated benefits include; improved regulatory efficiency: Reliance reduces the time and resources required for local product assessments, thus enabling faster

access to life-saving medications and technologies, stronger public health systems: With a streamlined regulatory process, Kenya's preparedness and response capabilities during public health emergencies will be significantly enhanced. Consistency in decision-making: Reliance practices ensure uniformity and consistency in regulatory decisions, leading to more predictable and transparent outcomes in product approvals. With regards to global collaboration and by adopting international best practices, Kenya can strengthen its alignment with global regulatory standards, fostering greater cooperation within the global health ecosystem.

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Chief Executive Officer

ABBREVIATIONS AND ACRONYMS

ABRF	African Blood Regulators Forum Biomolecular
AMA	African Medicines Agency
AESI	Adverse event of special interest
AVAREF	African Vaccine Regulatory Forum
API	Active Pharmaceutical Ingredient
BE	Bioequivalence
BTP	Biotherapeutic products
COA	Certificate of analysis
CEP	Certificate of Suitability from the European Pharmacopeia
CPP	Certificate of Pharmaceutical Product
CTD	Common Technical Document
CV	Curriculum Vitae
CPQ	Confirmation of Prequalification
CRO	Clinical Research Organization
EAC	East African Community
EAC- MRH	East Africa Medicines Registration Harmonization
EDQM	European Directorate for the Quality of Medicines and Healthcare
EFTA	European Free Trade Association
EMA	European Medicines Authority
EU	European Union
EUA	Emergency Use Authorization
EUL	Emergency Use Listed
EU-M4ALL	European Union Medicines for all
EUCU	Emergency use and compassionate use
EPAR	European Public Assessment Report
DPER	Directorate of Product Evaluation and Registration
FPP	Finished Pharmaceutical Product
GCP	Good Clinical Practices
GMP	Good Manufacturing Practice
HPT	Health Products and Technologies
ICH	International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human use)
IFU	Instructions For Use
ILAC	International Laboratory Accreditation
IR	Immediate Route
IVDs	In Vitro Diagnostics

Japan (MHLW /PMDA)	Japan, Ministry of Health Labour and Welfare/ Pharmaceuticals and Medical Devices Agency.
IGAD	Intergovernmental Authority on Development
LMIC	Low- and Middle-income country
LTR	Local technical representative
NCL	National control laboratory
NMRA	National Medicines Regulatory Authorities
MA	Marketing Authorization
MAGHP	Swiss medic Marketing Authorization for Global Health Products
MAH	Marketing Authorization Holder
MHRA	Medicines and Health Products Regulatory Agency
MRH	Medicines Regulatory Harmonization
PASS	Post authorization safety studies
PIDM	Program for International Drug Monitoring
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PIL	Patient information leaflet
PPB	Pharmacy and Poisons Board
PQT	Pre-Qualification Team
PRIMS	PPB Regulatory Information Management System
PV	Pharmacovigilance
QC	Quality Control
QIS	Quality information summary
REC	Regional economic communities
RI	Reference institution
RMNCH	Reproductive, Maternal, Newborn and Child Health
RMP	Risk management program
RRA	Reference Regulatory authority
SF	Substandard and Falsified
SmPC	Summary of Product Characteristics
SRA	Stringent Regulatory Authority
UHC	Universal Health Coverage
UMC	Uppsala Monitoring Centre
US FDA	US Food and Drug Administration
WHO	World Health Organization
WHO-PQ	World Health Organization Prequalification
WLA	WHO -listed Authorities

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In particular, the Board appreciates its staff from the Product Evaluation and Registration for their efforts in ensuring these guidelines was completed and effective implementation to ensure efficient registration of Health Products and Technologies.

GLOSSARY

Definitions listed below are essential to ensure a common understanding of concepts and clarity in interpreting guidance on reliance.

Abridged regulatory pathways	Regulatory procedures facilitated by reliance, whereby a regulatory decision is solely or partially based on application of reliance. It is expected that use of reliance in these pathways will save resources and time as compared with standard pathways, while ensuring that the standards of regulatory oversight are maintained
Assessment	For this document, this term covers any evaluation conducted for a regulatory function (e.g., evaluation of a clinical trial application or of an initial marketing authorization for a medical product or any subsequent post-authorization changes, evaluation of safety data, evaluation as part of an inspection).
Authority	Refers to Pharmacy and Poisons Board, also referred to as the Board.
Emergency Use Authorization:	Emergency use means a mechanism to facilitate the availability and use of medical countermeasures upon declaration of public health emergencies i.e. the use of a medicine (therapeutic), vaccine, or in vitro diagnostic or medical device) on patients in a life-threatening situation or condition, including chemical, biological, radiological, or nuclear attack, in which no standard treatment or diagnostic is available, and there is no sufficient time to obtain product registration.
Equivalence of regulatory systems:	Implies strong similarity between two regulatory systems, as mutually established and documented through objective evidence. Equivalence can be established using criteria and approaches such as similarity of the regulatory framework and practices, adherence to the same international standards and guidelines, experience gained in use of assessments for regulatory decision making, joint activities and exchanges of staff. It is expected that equivalent regulatory systems will result in similar standards and levels of regulatory oversight or "control".
Expedited Pathway	Reliance pathway designed for higher-risk devices that have prior approvals from multiple reference regulatory agencies and meet specific criteria. They are fast-tracked for urgent or breakthrough treatment or diagnostics.

Immediate Pathway	This pathway allows for automatic or near-instant recognition of a medical device or IVD if it has been approved by a stringent regulatory authority.
International standards and guidelines:	For this document, the term includes relevant WHO standards and guidelines and any other relevant internationally recognized standards (e.g., International Organization for Standardization or pharmacopeial standards) and guidelines (e.g., International Council on Harmonization of Technical Requirements for Pharmaceuticals for Human Use [ICH] or guidelines of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme [PIC/S]).
In Vitro Diagnostics	A medical device, used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.
Joint assessment/ Work-sharing:	A process by which NRAs of two or more jurisdictions share activities to accomplish a specific regulatory task. The opportunities for work- sharing include joint assessment of applications for authorization of clinical trials or marketing authorizations, joint inspections for good practices, joint post marketing surveillance of the quality and safety of medical products, joint development of technical guidelines or regulatory standards and collaboration on information platforms and technology.
Medical Device	Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purposes (s) of: a. diagnosis, prevention, monitoring, treatment or alleviation of disease, b. diagnosis, monitoring, treatment, alleviation of or compensation for an injury, c. investigation, replacement, modification, or support of the anatomy or of a physiological process, d. supporting or sustaining life, e. control of conception, f. disinfection of medical devices, g. providing information by means of in vitro examination of specimens derived from the human body; h. disinfection substances, i. aids for persons with disabilities, devices incorporating animal and/or human tissues, i. k. Devices for in-vitro fertilization or assisted reproduction technologies.

Mutual recognition agreement:	A principle of international law whereby states party to mutual recognition agreements recognize and uphold legal decisions taken by competent authorities in another member state. Mutual recognition is a process which allows conformity assessments (such as, of qualifications and product) carried out in one country to be recognized in another country.
Recognition:	Acceptance of the regulatory decision of another regulator or 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 relying authority. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement.
Reference Regulatory Authority:	A regulatory authority whose regulatory decisions and/or regulatory work processes are relied upon by another regulatory authority to inform its own regulatory decisions.
Reference Institution	Continental/Regional authority or a trusted institution such as WHO prequalification (WHO PQ) whose regulatory decisions and/or regulatory work processes are relied upon by another regulatory authority to inform its own regulatory decisions.
Regional regulatory system:	A system composed of individual regulatory authorities, or a regional body composed of individual regulatory authorities, operating under a common regulatory framework but not necessarily under a common legal framework. The common framework must at least ensure equivalence among the members in terms of regulatory requirements, practices and quality assurance policies. The system or regional body may have enforcement powers to ensure compliance with the common regulatory framework.
Reliance:	The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.
Reliance Pathways	An alternative application or assessment pathway used by the authority in its regulatory decision-making regarding marketing authorization of a product based on assessment outcomes of Reference regulatory authority (ies) or institutions.
Sameness of product:	For this document, sameness of product means that two products have identical essential characteristics (i.e., the product being submitted to the relying authority and the product approved by the reference regulatory authority should

	be the same). Sameness does not need to be represented by identical manufacturing sites but rather product should be under same quality system. All relevant aspects of drugs, medical devices and in vitro diagnostics, including those related to the quality of the product and its components, should be considered to confirm that the product is the same or sufficiently similar (e.g. same qualitative and quantitative composition, same strength, same pharmaceutical form, same intended use, same manufacturing process, same suppliers of active pharmaceutical ingredients, same quality of all excipients). Additionally, the results of supporting studies of safety, efficacy and quality, indications and conditions of use should be the same. The impact of potential justified differences should be assessed by the manufacturer (for the purpose of this document, manufacturer also means marketing authorization holder) and the relying national regulatory authority (NRA) in determining the possibility of using foreign regulatory assessments or decisions. This could also be applied when assessing Medical Devices and IVDs whereas the performance of the medical device should confirm for sameness.
Secondary Review:	Refers to where NRAs may perform secondary reviews of the shared assessment and inspection outcomes from the PQT or reference NRA. Moreover, this approach may be essential where the NRA is involved or participates in the initial reviews, for example, joint reviews between the NRA and the PQT or in special access mechanisms by reference SRAs that have provisions for NRA participation. As a result, the NRA's input may be incorporated into the final decision of the PQT or the reference SRA, thereby facilitating a concurrent regulatory decision where a parallel submission has been made.
Stringent regulatory authority:	A regulatory authority which is: a. a member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or b. an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or c. a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement,

	including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015)
Trusted Institution:	Means a regional or international institution that is involved in assessment and approval (prequalification) of medicines for human use such as WHO prequalification (WHO PQ), IGAD, AMA, EMA, EAC etc whose assessment outcomes or regulatory decisions are relied upon by the Pharmacy and Poisons Board
Unilateral Recognition:	When a country chooses to rely on or formally recognize an assessment from another country unilaterally and without reciprocity.
Verified review	A streamlined review based primarily on verifying, instead of evaluating, information submitted in the application against information which has already been approved by WHO or a Recognised Regulatory Authority. Note that un-redacted reports are required for verified reviews as a fall-back option for evaluators.
WHO listed authorities	A WHO Listed Authority (WLA) is a regulatory authority (RA) or a regional regulatory system (RRS) that complies with all the relevant indicators and requirements specified by WHO for regulatory capability as defined by an established benchmarking and performance evaluation process. A regulatory authority provides the framework that supports the WHO recommended regulatory functions. This is the authority and affiliated institutions that are responsible for regulatory oversight of medical products in a given country or region and in charge of assuring the quality, safety and efficacy of medical products as well as ensuring the relevance and accuracy of product information.
Reference Regulatory Authority for Medical Devices	A reference regulatory Authority (RRA) is a regulatory authority or a regional regulatory system such as the European union that complies with all the relevant indicators and requirements for the regulation of medical devices. This authority and affiliated institutions are responsible for regulatory oversight of medical devices in a given country or jurisdiction and responsible for ensuring the quality, safety and performance. The RRA is a member of the International medical devices regulators forums, and whose regulatory decisions can be relied upon by the PPB.

1.0 INTRODUCTION

This document provides guidance on the modalities, processes, and procedures employed by the Pharmacy and Poisons Board (PPB) to implement reliance and/or utilize relevant Marketing Authorization (MA) decisions, reports, or information from other National Regulatory Authorities (NRAs), regional, and international bodies.

The PPB, recognizing the principles of Good Reliance Practices as outlined by the World Health Organization (WHO), strives to strengthen its regulatory system through efficient and effective reliance strategies. This approach enables the PPB to leverage the expertise and resources of other competent authorities while focusing its efforts on value-added activities crucial for the Kenyan market, such as, Vigilance by monitoring the safety and effectiveness of medicines post-market, Market Surveillance by ensuring the quality and authenticity of HPTs in the Kenyan market, Local Manufacturing and Distribution by supporting and overseeing the growth of local pharmaceutical industries, and Quality Control that enhances the quality assurance of HPTs through robust laboratory testing and inspection programs.

Reliance approaches facilitate timely access to safe, effective, and quality-assured HPTs for the Kenyan population. They are particularly valuable during public health emergencies, enabling rapid regulatory responses.

In today's dynamic global healthcare landscape, NRAs face numerous challenges, including: globalization of markets, rapid advancements in health products and technologies, evolving regulatory science, Complex supply chains and growing public expectations and resource constraints including limited human, financial, and infrastructural resources.

These challenges underscore the critical need for international cooperation to ensure the safety, quality, and efficacy/effectiveness of HPTs in Kenya. By embracing enhanced collaboration and reliance strategies, the PPB aims to:

a) Optimize resource utilization by avoiding unnecessary duplication of efforts and focus resources on areas of greatest need.
b) Leverage on international expertise by gaining access to the knowledge and experience of other competent authorities.
c) Facilitate timely access to medicines by ensuring timely availability of essential and innovative medicines for the Kenyan population
d) Strengthen regulatory capacity by enhancing the PPB's scientific and technical capabilities through knowledge exchange and training.

The attainment of Universal Health Coverage (UHC) in Kenya hinges on the availability of quality-assured medicines and health technologies. PPB is committed to strengthening its regulatory system through strategic reliance partnerships to ensure access to quality, safe, efficacious medicines and effective medical devices and IVD's for all Kenyans.

1.1 SCOPE

This guidance provides a framework to marketing authorization holders on the requirements for registration using the reliance principles for medicines, vaccines, blood and blood products, food supplements, herbal products, cosmetics, medical devices, and in-vitro-diagnostics.

The guideline is applicable to evaluations for initial marketing authorization, post-approval changes, and renewals of applications submitted under both routine and non-routine (EUCU) procedures in Pharmacy and Poisons Board.

This guidance is not applicable to applications for donations and unregistered HPTs.

Reliance practices can also be used for quality audits of medical devices using the medical devices single audit program (MDSAP).

2.0 PRINCIPLES OF RELIANCE

The adopted principles of reliance are in line with the WHO recommendations and PPB will use these to optimize innovative and more effective forms of collaboration to make the best use of the available resources and expertise, avoid duplication to ensure quality, safe and efficacious Health Products and Technologies.

For further guidance, please refer to “Good reliance practices in the regulation of medical products: high level principles and considerations” Annex 10 contained in Fifty-fifth report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations.

There are six (6) high level principles of reliance that are intended to complement and extend the basic principles of good reliance practices. These principles are: Sovereignty of decision making, respect for national and regional legal bases, transparency, universality, consistency and competence.

2.1 Sovereignty:

Reliance is a sovereign decision. The Board will decide when and how to use reliance and in which circumstances. In implementing reliance, the Board shall maintain its independence, sovereignty and accountability in regulatory decision making.

2.2 Legal basis:

The legal basis for reliance procedure is anchored under Sections 3A(c) and 3B(r) of the Pharmacy and Poisons Act CAP 244, the pharmacy and poisons (registration of health products and technologies) rules, 2022 -rule No 7 on Collaborative measures when processing application for registration and the EAC Corporation Protocol for Medicines Harmonization Program 2018.

2.3 Transparency

The board will implement reliance mechanisms through unselective application of the law, guidelines and procedures by all the parties involved in regulation. The Board, as relying on NRA, shall provide to all parties clearly defined standards, processes and approaches adopted in implementing reliance measures.

The approaches undertaken by the Board in implementation of the reliance system shall include all aspects of quality and transparency including screening, evaluation by first Assessor, second Assessor and quality assurance steps as defined in PPB quality management system. Regulatory decisions made through reliance shall be published and made available by PPB for purposes of information sharing.

The Board shall make use of published information from the websites of reference NRAs or other relevant organizations where applicable as primary sources of information for assessment of applications.

In some cases, the Board may request manufacturers or applicants to provide assessment reports and any other information that may make it easier for the implementation of reliance approach. The Board may ask a manufacturer or an applicant to give consent, for a reference agency to provide it with assessment reports that may not be already published.

2.4 Competency

The Board shall use its available technical competencies to undertake critical decision making for the proper implementation of the reliance guidelines.

The competency framework and curricula are useful tools to identify and develop training programmes for regulators at different levels. At PBB, all training programmes will incorporate tools that facilitate regulatory reliance, such as mutual recognition agreements, regulatory reliance principles and the WHO prequalification process.

The adoption of common competence requirements and performance standards at the national, regional and continental level, using standardized assessment tools, will enable regional, continental and international collaborations and reliance among NRAs as per the Global Competency Framework for Regulators of Medicines.

These competencies shall be built through the following but not limited to;

i. Training programmes
ii. Benchmarking against the reference authorities processes to build trust on capacities
iii. Induction training of new assessors by experienced assessors
iv. On job training for assessors
v. Attachment of assessor at WHO dossier assessment sessions
vi. Participation of assessors in WHO dossier assessment activities
vii. Participation of assessors in EAC dossier assessment activities
viii. Participation of assessors in IGAD dossier assessment sessions

ix. Bilateral engagement with sister NRAs

x. Involvement of technical experts in dossier assessment

xi. Participation of assessors in WHO-Collaborative registration Procedures for In-Vitro Diagnostics.

2.5 Consistency:

The Board shall implement a clearly defined process for practising reliance that will be transparent and predictable. The Board plans to develop an online for tracking reliance applications and timelines to market authorization. Reliance shall be applied consistently for products/ processes in the same predetermined categories.

2.6 Universality

Reliance applies to all NRAs irrespective of their levels of maturity or resources. Reliance is relevant for all resource settings and different NRAs use reliance for different reasons. For example, some use it to increase technical in-house capacity. Others use to get expertise they do not have locally.

3.0 PART 1: HEALTH PRODUCTS RELIANCE FRAMEWORK

3.1 RELIANCE EVALUATION PATHWAYS

Reliance-based evaluations are based on the level of risk that the agency is prepared to accept. The implementation of this risk-based evaluation shall consider criteria such as the number and location of prior approvals, the length of time a product may have been on the market, the quality (similarity) of the product, local public health needs and priorities, level of resources and expertise available in a NRA and unmet medical needs.

Reliance based applications are reviewed by the board through the following Four (4) types of assessment pathways: Verification, Abridged, Joint assessment or work sharing and recognition

3.1.1 Verification

In verification reviews, the agency recognises a previous authorisation of a product by a reference or benchmark agency. In this process, the agency validates this prior review while ensuring that the product conforms to local requirements and authorised product specifications.

Verification is based primarily on verifying, instead of evaluating, information submitted against information which has already been approved by a reference regulatory authority.

The board shall undertake verification assessment of the product information/dossier submitted for registration to ensure that the HPT is the same as the one that has been approved by the reference regulatory authority.

Sameness of a product shall be confirmed as follows:

i. The submitted product for marketing authorization shall have the same qualitative and quantitative formulation as the one approved by the reference regulatory authority.

ii. The products seeking approval shall have the same manufacturing site(s) for API and FPP including specific block(s)/unit(s), chain, processes, control of materials and final product, and in the case of vaccines also by the same batch release scheme. Any additional sites, regardless of their GMP status, are not acceptable under this procedure. Any

changes or variations to include additional sites should be approved by the reference regulatory authority before inclusion in the dossier application.

iii. The product seeking marketing authorization with the board should have the same specifications for excipient, API and FPP as the one approved in the reference regulatory authority.

iv. The two products should have the same essential elements of product information. (The essential elements of product information will include the indications, contraindications, posology (dosing), special warnings and precautions for use, adverse reactions, storage conditions, primary packaging, and shelf life.

v. For pharmaceutical products, differences in brand name, the name of the applicant, language, format, and degree of detail of the product information, labelling of primary, secondary, and tertiary packaging, among others, are not considered essential for the purposes of this Procedure.

vi. The manufacturer should consider country specific requirements such as product stability data according to the stability zone and the local product labelling requirements.

Verification is particularly applicable for products approved under WHO-CRP, those assessed and accepted under EAC, IGAD and AMA.

3.1.2 Abridged

When using an abridged review, the agency conducts a more detailed assessment, relies on prior evaluations to inform local decisions, evaluating the product under local conditions and regulatory requirements.
This review is based primarily on full assessment reports (if available) from RRAs, replacing the need to evaluate all data (and summaries thereof) submitted in support of an application.

In case where full assessment report from the reference regulatory authority is not available, the Board may accept the decisions of these authorities or

institutions based on a partial review of selected sections and/or modules of the application dossier.

This approach applies to products evaluated and approved by SRA, WLA, and regional economic communities (such as Zazibona, WAHO, NAMRH) etc.

Additionally, abridged assessment will be conducted for products (Vaccines, In-Vitro Diagnostics or treatments that are yet to be licenced but have been listed under the WHO-EUL (WHO-emergency use Listing procedures) whose information is not yet fully available due to the nature of the procedure being to facilitate availability of information during a public health emergency of international concern (PHEIC).

Documentation and guidance for application required for Emergency use are available in PPB guideline HPT/PER/GUD/024 Rev. 3.

3.1.3 Joint assessment or work-sharing

Under this pathway, the Board will engage in joint assessments or work-sharing arrangements with one or more regulatory authorities. This process will involve a primary review conducted by one authority, a secondary review by another authority, and a collaborative joint assessment session to finalize the assessment report and address any comments.

This approach applies to products evaluated and approved by the African Medicines Regulatory Harmonization Initiative (AMRH), the African Medicines Agency (AMA), East African Community Medicine Regulatory Harmonization (EAC-MRH), the Intergovernmental Authority on Development (IGAD), EU Medicines for All (EU-M4ALL) procedure and Swiss medic's Marketing Authorization for Global Health Products (MAGHP).

3.1.4 Recognition:

Recognition, is the routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B.

Under this pathway, the board shall undertake registration/approval process, based on directly recognizing the outcome of review from a reference

regulatory authority with which the pharmacy and poisons board shares a recognition agreement.

Also, the Board may choose to rely on or formally recognize an assessment from another reference regulatory authority unilaterally and without reciprocity. Similarity between the local context is important for this pathway/approach.

Pharmacy and Poisons Board may specify the NRA(s) or institutions whose decision it recognizes.

Note: PPB is currently in the process of negotiating recognition agreements with reference regulatory authorities and will thereafter develop mutual recognition agreements.

The abridged and verification review processes do **NOT** involve an abbreviated application – **all data and information required for a full review should be submitted, i.e. the full CTD module structure.** Evaluators may still need to review data in the dossier as required.

3.2 ELIGIBILITY CRITERIA FOR SELECTION OF REFERENCE REGULATORY AUTHORITY OR REFERENCE INSTITUTIONS

Regulatory authorities or institutions shall fulfil the following criteria to be included in the list of PPB recognized reference regulatory authorities/reference institutions.

a) Shall publish detailed information on the approved medicines (like public assessment report, labelling information and regulatory action, deferred or rejected product information) on its website or include in the approved or qualified list of medicines throughout the product life cycle as applicable
b) Member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), and/or an ICH observer,
c) National regulatory authority or institution that has signed memorandum of understanding or legally binding agreement with PPB. The institution for bilateral agreement must have attained WHO ML3 and above

d) World Health Organization collaborative registration procedures (WHO-CRP, SRA-CRP and WHO-EUL).

e) WHO Listed Authorities (WLAs)/SRA

f) WHO Transitional WLAs (Category A, B and C)- *Category A - ML3 & ML4 NRAs for vaccines only, Category B- SRA and Category C- Highly performing NRA (Vaccines)*

g) Continental assessment forums (e.g., AMA, AVAREF, ABRF,).

h) Regional Economic communities Regulatory Harmonization (e.g., EAC-MRH, IGAD, ZAZIBONA, West African Medicine Regulatory Harmonization (WA-MRH)).

i) Global health programs such as EMA under article 58 and through the Swiss medic's Marketing Authorization for Global Health products or the International Generic Drug Regulatory Programme (Swissmedic, Health Canada and EU Medicine for all)

j) Member of the International Medical Devices Regulators Forum as a founding member country.

Note: The list of Reference Regulatory Authorities shall be reviewed from time to time based on WHO updates of WLA, changes in regulatory environment and adoption of best practices.

3.2.1 General Documentation Required for Reliance Applications

a) Application dossiers should be only for products assessed and accepted by the reference regulatory authorities or reference institutions.

b) The applicant should declare the "sameness" of the reference regulatory authority or reference institution-approved medicine with the one applied for marketing authorization of medicine by the authority. These shall include, but not limited to:

   i. qualitative and quantitative formulation,
   ii. manufacturing site(s) for API and FPP including specific block(s)/unit(s),
   iii. processes, control of materials and final product,
   iv. in the case of vaccines, batch release/ lot release scheme,
   v. specifications for excipient, API and FPP,

vi. essential elements of product information (SMPC, PIL, Primary packaging and secondary packaging).

c) If any differences exist between the dossier submitted to PPB and the dossier submitted to a recognized regulatory authority or institution, all such differences should be clearly indicated and justified.

d) The submitted product should be prequalified and/or registered and marketed in the market of at least one of the reference regulatory authority's countries, except for products prequalified by WHO jointly assessed products.

e) The applicant should provide the "Quality information summary" together with the dossier.

f) The reference regulatory authority(s)or reference institutions assessment reports or at least access or link to the portal on the web site of the reference regulatory authority should be provided.

g) Commitment letter to notify the Board when there is pending variation, withdrawal from the market or banned by reference regulatory or reference institution due to any notice of concern.

h) Copy of valid GMP issued by PPB, laboratory testing report (where applicable), and safety report (where applicable).

i) Full modules with CTD document as per the Guideline for Registration of Medicines.

j) A declaration indicating that any post approval changes were reported and accepted by the reference regulatory authority or reference institution. This declaration should include the list of variations not yet accepted by reference regulatory authority or reference institution and section of the dossier affected by the accepted variations.

k) A copy of the marketing authorization, or the equivalent thereof, issued by the reference NRA or institution to demonstrate that the product is registered or licensed in accordance with the reference NRA or institution requirements. If applicable, a copy of the latest renewal of the marketing authorization should also be provided.

l) Public assessment report(s) and/or final acceptance letter issued by the NRA or institution such as the Scientific Discussion of the European Public Assessment Report (EPAR), issued by the reference NRAs or

institution. Assessment report(s) issued by the reference SRA that are not publicly available may be requested.

m) Written confirmation of permission for sharing confidential information generated by the RRA/RI with the relying authority (the PPB (see **Annex II**)).

n) Samples of the medical product from commercial batches, to be submitted to support the application.

3.2.2 For biologics including vaccines, reliance on testing carried out by the National Reference Laboratory and/or Reference Institutions shall serve as a basis for Marketing Authorization.

o) Submission of the application dossier should be through PPB product's portal.

3.2.3 Specific Requirements for Reliance Pathways

3.2.3.1 WHO Collaborative Registration Procedure (WHO-CRP/SRA-CRP)

Applicants wishing to use this registration route should proceed as follows:

a) The medicines for which application is submitted to PPB should be in the list of WHO prequalified products on the WHO website (https://extranet.who.int/prequal/content/prequalified-lists)

b) Notify WHO/the SRA of their intention to use this Procedure for registration of a particular product by sending the appropriate notification form (Appendix 2/Appendix 3, Part A) to WHO/the SRA, as outlined on the WHO website. If the applicant for national registration is different from the manufacturer with a prequalified product/SRA-approved product, the mutual agreement between the applicant and the manufacturer is necessary and the notification to WHO/the SRA has to be sent by the manufacturer.

c) Follow the national guidance to applicants for registration as provided for by PPB registration guidelines. More importantly, the following should be considered:

   i. The PPB-prescribed Application form

ii. "WHO Collaborative Procedure"/"SRA Collaborative Procedure" should be indicated as the proposed registration pathway in the PPB product online portal and in the covering letter.

iii. Must submit the Expression of Interest form (Appendix 3 Part A), as outlined on the WHO website.

iv. The technical content of the dossier has to correspond exactly to that submitted and currently approved by the PQT/SRA and as specified in the corresponding Procedure guidelines. The dossier has to be updated to reflect all post-prequalification variations approved by the PQT/SRA and accompanied by the appropriate current quality information summary (QIS) (Annex III). All variations still pending at the PQT/SRA have to be notified, and deviations from the prequalified product have to be clearly declared in the Expression of Interest form (Appendix 3 Part A).

v. Additional requirements are:

(i) A valid GMP certificate from PPB.

(ii) Application fee per product.

(iii) Stability data as per ICH climatic conditions for zone IVb

(iv) The requirements on samples stays in place

(v) Labelling requirements as per PPB guidelines.

d) Pre-registration QC testing by the PPB recognised Laboratory is not required for this procedure. Instead, post-registration risk-based testing will be carried out by the applicant.

e) In situations where the applicant wishes to apply the Procedure to an application that is already pending with PPB (applied through the National pathway), the applicant should first update the dossier to ensure that the technical part of the information is the same as that currently approved by the PQT/SRA, as applicable.

f) The post-prequalification variations should be submitted to PPB within 90 working days from the PQT/SRA approval. The PQT/SRA approval letter should be attached.

In case of questions/requests related to the CRP, the PPB's focal person's contact information is as follows, reliance@ppb.go.ke

Note: Applications submitted for products assessed and approved by WHO-CRP shall undergo verification/Abridged assessment.

3.2.3.2 WHO Listed Authority (WLA)/ Stringent Regulatory Authority (SRA)

Applicants wishing to use this registration route should proceed as follows:

a) The PPB-prescribed Application form
b) "SRA Pathway" should be indicated as the proposed registration pathway in the PPB product online portal.
c) Must submit the Expression of Interest addressed to the Chief Executive Officer.
d) The technical content of the dossier has to correspond exactly to that submitted and currently approved by the WLA/SRA and as specified in the corresponding Procedure guidelines. The dossier has to be updated to reflect all post-approval variations approved by the WLA/SRA and accompanied by the appropriate current quality information summary (QIS). All variations still pending at the WLA/SRA have to be notified, and deviations from the approved product have to be clearly declared in the Expression of Interest letter.
e) Submit the RRA detailed assessment reports, inspection reports and endorsed or validated quality information summary (Annex 4) as well as bridging reports (Appendix 6 ; Refer to WHO) if applicable.
f) Additional requirements are:
    i. WLA/RRA Approval letter/Marketing authorisation
    ii. A valid GMP certificate from PPB.
    iii. Application fee per product.
    iv. Stability data as per ICH climatic conditions for zone IVb
    v. The requirements on samples stays in place
    vi. Labelling requirements as per PPB guidelines.
g) Pre-registration testing from a PPB recognized Laboratoty or a WHO prequalified laboratory is a requirement for this procedure.
h) In situations where the applicant wishes to apply the Procedure to an application that is already pending with PPB (applied through the National pathway), the applicant should first update the dossier to

ensure that the technical part of the information is the same as that currently approved by the WLA/SRA, as applicable.

i) The post-marketing Authorization variations should be submitted to PPB within 90 working days from the WLA/SRA approval. The WLA/SRA approval letter should be attached.

In case of questions/requests related to the CRP, the PPB's focal person's contact information is as follows:reliance@ppb.go.ke

Note: Applications submitted for products assessed and approved by WLA/SRA shall undergo Abridged assessment.

3.2.3.3 WHO Listed Authority (WLA)/ Reference Regulatory Authority (RRA) with which PPB has a mutual recognition agreement.

Pharmacy and Poisons Board will continuously publish a list of NRAs that Kenya has signed mutual or bilateral agreement in the PPB website

Applicants to confirm from the list of NRAs from the PPB website that have mutual or bilateral agreement with PPB.

The applicants shall then submit applications based on the documentation required as follows:

a) The PPB-prescribed Application form
b) "SRA Pathway" should be indicated as the proposed registration pathway in the PPB product online portal.
c) Must submit the Expression of Interest addressed to the Chief Executive Officer.
d) The technical content of the dossier has to correspond exactly to that submitted and currently approved by the WLA/RRA and as specified in the corresponding Procedure guidelines. The dossier has to be updated to reflect all post-approval variations approved by the WLA/RRA and accompanied by the appropriate current quality information summary (QIS). All variations still pending at the WLA/RRA have to be notified, and deviations from the approved product have to be clearly declared in the Expression of Interest letter.

e) Submit the RRA detailed assessment reports, inspection reports and endorsed or validated quality information summary (Annex 4) as well as Bridging reports (Appendix 6 ; Refer to WHO) if applicable.

f) Additional requirements are:

   i. WLA/RRA Approval letter/Marketing authorisation
   ii. A valid GMP certificate from PPB.
   iii. Application fee per product.
   iv. Stability data as per ICH climatic conditions for zone IVb
   v. The requirements on samples stays in place
   vi. Labelling requirements as per PPB guidelines.

g) In situations where the applicant wishes to apply the Procedure to an application that is already pending with PPB (applied through the National pathway), the applicant should first update the dossier to ensure that the technical part of the information is the same as that currently approved by the PQT/SRA, as applicable.

h) The post-marketing Authorization variations should be submitted to PPB within 90 working days from the WLA/SRA approval. The WLA/SRA approval letter should be attached.

i) In case of questions/requests related to the CRP, the PPB's focal person's contact information is as follows: reliance@ppb.go.ke

Note: Applications submitted for products assessed and approved by WLA/SRA that have mutual agreement with PPB shall undergo verification assessment.

3.2.3.4 Regional joint assessment (AMA, EAC-MRH, IGAD, ZAZIBONA, West African Medicine Regulatory Harmonization (WA-MRH))

a) A letter of approval from AMA, EAC-MRH, IGAD, ZAZIBONA, West African Medicine Regulatory Harmonization (WA-MRH))

b) The technical content of the dossier has to correspond exactly to that submitted and currently approved by EAC/IGAD and as specified in the corresponding Procedure guidelines. The dossier has to be accompanied by the appropriate current quality information summary (QIS).

c) In situations where the applicant wishes to apply the Procedure to an application that is already pending with PPB (applied through the National pathway), the applicant should first update the dossier to ensure that the technical part of the information is the same as that currently approved by the EAC/IGAD, as applicable.

d) Additional requirements are:

   i. A valid GMP certificate from PPB.
   ii. Application fee per product.
   iii. The requirements on samples stays in place
   iv. Labelling requirements as per PPB guidelines.

e) Pre-registration testing from a PPB recognized laboratory or a WHO prequalified laboratory is a requirement for this procedure.

Note: Applications submitted for products assessed and approved by IGAD/EAC joint assessment shall undergo verification assessment.

3.2.3.5 For products accepted by MAGHP, EU-M4ALL joint assessment

a) A letter of positive opinion to PPB2) The technical content of the dossier has to correspond exactly to that submitted and currently approved by the MAGHP, EU-M4ALL and as specified in the corresponding Procedure guidelines. The dossier has to be accompanied by the appropriate current quality information summary (QIS).

b) Additional requirements are:

   i. A valid GMP certificate from PPB.
   ii. Application fee per product.
   iii. The requirements on samples stays in place.
   iv. Labelling requirements as per PPB guidelines.

c) Pre-registration testing from a PPB recognized laboratory or a WHO prequalified laboratory is a requirement for this procedure.

3.2.4 RELIANCE MECHANISMS IN HANDLING VARIATIONS.

a) For variation applications to be assessed through reliance, the change must be approved by WHO listed authority (WLA)/SRA/WHO,
The following conditions and documentation shall be fulfilled by the

applicant;

All Conditions and documentation will be required as per the PPB Guidelines for submission of variation applications for registered medicines (HPT/PER/GUD/015 Rev No. 4) selected along with a copy of the reference SRA/ WHO decision or other document confirming the final decision of the reference SRA/WHO.

b) Confirmation letter that the information (variation dossier) submitted to the PPB is the same as that submitted to reference SRA/WHO for the variation.
c) Whenever FPPs have been registered on the basis of approval by a WHO listed authority (WLA) (innovator products or generic products) or WHO prequalification, subsequent applications for variations should also be approved by the same WLA and WHO PQP, respectively, and the Board shall be notified of the approval of the changes and the applicant shall submit proof of approval of such changes from the respective agency, if applicable.
d) For products formerly registered by PPB and subsequently approved by WLAs, the variation(s) shall be approved based on submission of letter of approval of the variation(s), from the WLAs.
e) For further guidance and application requirements regarding variations, please consult the procedures and processes as laid out in PPB Guidelines for submission of variation applications for registered medicines, Vaccines and Biotherapeutics.

3.2.5 ASSESSMENT TIMELINES

The assessment target timelines will depend on submission pathways as follows:

a) WHO Prequalified products registered through CRP/SRA-CRP and regional expedited pathways:
    i. Screening and initial evaluation phase (10 working days)
    ii. Evaluation of additional screening questions (10 working days).
    iii. First review (70 working Days)

b) Products approved by Reference Regulatory Authorities including (WLA/SRA).

i. Screening and scheduling (10 working days)
ii. Evaluation of additional information (30 working days)
iii. First review (90 working days)
iv. Decision phase (15 working days)

Time taken by applicant to respond to questions pauses the clock and is not included as part of PPB regulatory timelines

4.0 PART 2: RELIANCE FRAMEWORK FOR MEDICAL DEVICES AND IVDs.

4.1 RELIANCE MECHANISMS USED IN REGISTRATION OF MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS

Reliance mechanisms for medical devices and invitro diagnostic follow the risk classification and public health impact assessment, whilst also remaining cognisant of emergency situations. The risk classification will influence the reliance evaluation pathway to be adopted, the documentation required and the turnaround time as outlined below

4.2 RELIANCE PATHWAYS FOR MEDICAL DEVICES AND IVD'S

a) Abridged Pathway

This pathway is prescribed for a medical device that has obtained at least two reference regulatory agency approval for a labelled use identical to that intended for marketing in Kenya at the time of submission. It typically employed in lower-risk categories or when there's a demonstrated equivalence to an already approved device. This pathway is to be used for all risk classification of medical devices except class A.

Immediate pathway

This route facilitates immediate market access for medical devices. The process facilitates a faster review and submission of less documentation than typical approval procedures, but still requires adherence to basic safety and effectiveness standard. This pathway is to be used by Class A&B medical devices

b) Expedited

Medical devices that qualify for this method of reliance that fast-tracks marketing authorisation of medical devices for emergency use or during disease outbreaks and Class C medical devices. The criteria for consideration for emergency use shall consider the following:

1. The medical device is needed:

- to treat or diagnose any medical condition resulting from a public health emergency;

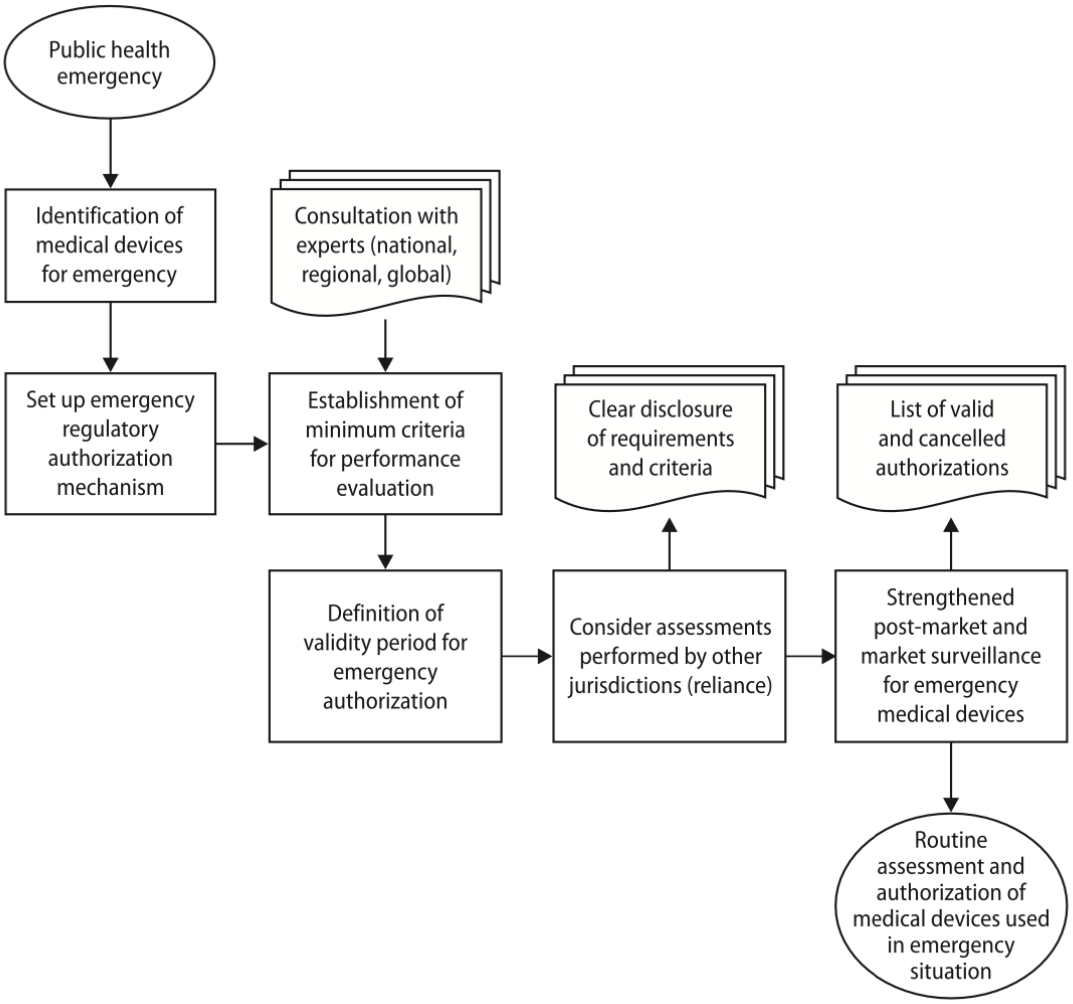
- to prevent the spread or possible outbreak of an infectious disease;
- to treat or diagnose an infectious disease or any medical condition associated with an infectious disease, where the medical condition or infectious disease is potentially serious or life threatening; and
- no safe and effective alternatives have previously been authorized or are reasonably available.

2. In the understanding of the NRA, there is:

- preliminary scientific evidence that the medical device has the potential:
  - – to treat or diagnose the medical condition resulting from the public health emergency,
  - – to prevent the spread or possible outbreak of an infectious disease, and
  - – to treat or diagnose an infectious disease or any medical condition associated with an infectious disease.
- continued scientific evidence that the potential benefits of the medical device outweigh the known risks of the medical device to a person on whom the medical device is used, and;
- a strong post-market surveillance structure and market surveillance system to monitor product safety and performance, update the benefit–risk assessment and reduce the chance of SF products reaching the market.

  The applicant is required to actively seek and submit more evidence as it becomes available.

The diagram below represents the Process for emergency use authorization



4.3 RECOGNITION OF Market Authorization FOR MEDICAL DEVICES

Under this pathway, the Board shall undertake the registration/approval process by directly recognizing the outcome of the review conducted by a reference regulatory authority with which the Pharmacy and Poisons Board has a formal mutual recognition agreement.

Furthermore, the Board may, at its discretion, choose to rely on or formally recognize an assessment from another reference regulatory authority on a unilateral basis, without requiring a reciprocal agreement.

The availability of assessment reports shared by the reference regulatory authority will form the basis for which this recognition will be issued.

4.4 REFERENCE REGULATORY AUTHORITIES FOR RELIANCE EVALUATION FOR MEDICAL DEVICES AND IVD'S.

These are set out according to a confidence-based approach, leveraging on the approvals by listed medical device reference regulatory agencies and/or prior safe marketing history of the medical devices. The types of approvals that qualify for the abridged, expedited and immediate evaluation routes are:

a) *Australia* Therapeutic Goods Administration (TGA) Device Registration License
b) Health Canada (HC) Device Registration License
c) Japan Ministry of Health, Labor and Welfare (MHLW), Pharmaceutical and Medical Devices Agency (PMDA)
    i. Pre-Market Certification from a Japanese Registered Certification Body
    ii. Pre-Market Approval from MHLW
d) US Food and Drug Administration (US FDA)
    i. 510K clearance
    ii. Premarket Approval (PMA)
e) European Union Notified Bodies (EU NB) via EC certificates issued according to
    i. Regulation (EU) 2017/745 on medical devices (MDR)
    ii. Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices
f) Health Products Regulatory Authority of Ireland
g) Swiss Medic
h) Saudi Arabia Food and Drugs Authority
i) Therapeutic Goods Administration of Australia

The following additional procedures can be used for reliance/ collaborative review, which are not strictly regulatory authorities:

a) World Health Organization (WHO) collaborative registration process

4.5 RELIANCE EVALUATION PATHWAYS FOR MEDICAL DEVICES

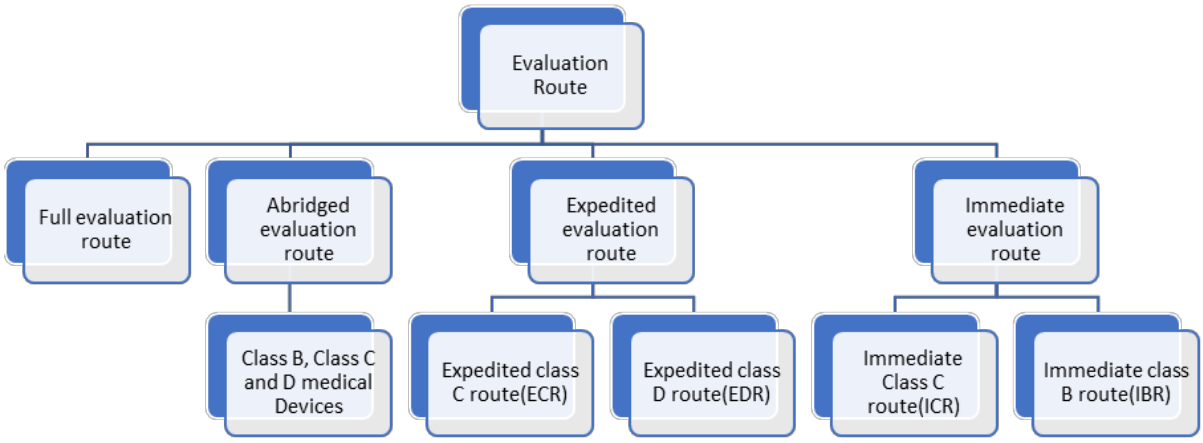
Applications for reliance are assessed by the board for granting market authorization (MA) through the following three (3) assessment reliance pathways:

a) **Abridged Evaluation Route**- This route applies to medical devices that have obtained approval from at least one of the reference regulatory agencies for a labelled use identical to that intended for marketing in the target country. It allows for a streamlined review process by leveraging existing evaluations. Applies to class B, C and D medical devices.
b) **Expedited Registration (ER) Evaluation Route**-This route is designed for higher-risk devices that have prior approvals from multiple reference regulatory agencies and meet specific criteria. They are fast-tracked for urgent or breakthrough treatment or diagnostics. Applies to class C and D medical devices
c) **Immediate Registration (IR) Evaluation Route**-This pathway allows for **automatic or near-instant recognition** of a medical device or IVD if it has been approved by a stringent regulatory authority. Applies to class B and C

Note: A medical device that has **not obtained any prior** approval from any of the listed medical device reference regulatory authorities at the point of application will be subject to the full evaluation route.

4.6 ELIGIBILITY CRITERIA AND REQUIRED DOCUMENTS FOR RELIANCE EVALUATION.

Figure 1: Summary of evaluation routes for medical devices



4.6.1 Conformity assessment process as determined by the device class

The quality, safety and performance of a medical device regardless of its classification are determined by systemic controls applied by the manufacturer to its design, development, testing manufacture and distribution and use over the device's life-cycle. This process is done by the manufacturer through implementation of a quality management system, coupled with technical documentation showing that the medical device conforms with essential principles. Thus, in considering the reliance practices, conformity assessment by the manufacturer are to be considered.

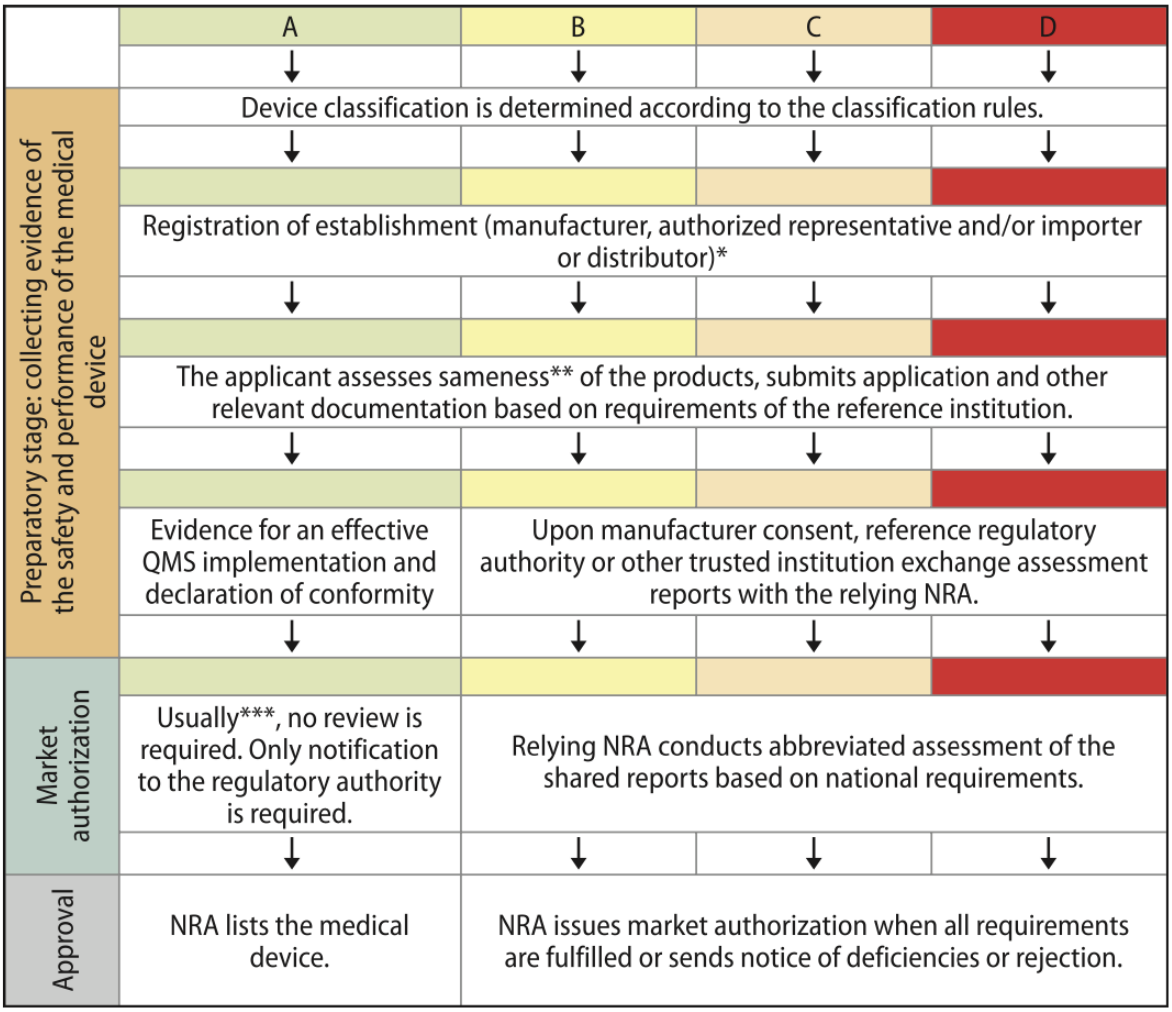
The table below provides for this consideration depending on the risk classification of the medical device.

Conformity assessment element	Class A	Class B	Class C	Class D
Quality management system (QMS)	Regulatory audit normally not required, except where assurance of sterility or accuracy of the measuring function is required.	The NRA should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to market authorization.	The NRA should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to market authorization.	The NRA should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to market authorization.
Technical documentation	Pre-market submission normally not requested.	Not normally reviewed pre-market. The NRA may request and conduct a pre-market or post-market review sufficient to determine conformity with essential principles.	The NRA will undertake a review sufficient to determine conformity with essential principles prior to the device being placed on the market.	The NRA will undertake an in-depth review to determine conformity with essential principles, prior to the device being placed on the market.
Declaration of conformity	Submission normally not requested.	Review and verify compliance with requirements by the NRA.	review and verify compliance with requirements by the NRA.	Review and verify compliance with requirements by the NRA.

4.7 Regulatory pathways for pre-market conformity assessment of medical devices based on reliance

For medical devices, reliance can take the form of assessment of technical dossiers or reports of inspections or audits performed by another NRA or a conformity assessment body, and on the evaluation of incidents made by another NRA whereas such incidents also affect the domestic market.

The table below outlines the considerations for steps to market authorization for a medical device based on reliance.



Class A Medical Devices

The Board shall not apply reliance mechanisms to Class A Medical Devices.

Reliance Evaluation Pathway for Class B, C and D Medical Device is as per Table 1 below;

Table 1: Reliance evaluation pathways for Classes B, C & D Medical Devices

Reliance Evaluation Pathway	**Class B medical devices**	**Class C medical Device**	**Class D medical Device**
Abridged	**Eligibility criteria** Must have approval from at least 1 of PPBs reference regulatory agencies. **Required Documents** 1.Proof of reference agency's approval(s). 2.Proof of registration from the above reference agency for a minimum of 3 years. 3.Declaration of safety of the device. 4.IFU/Technical manual. 5.Proof of sterility (If applicable). 6.Risk analysis.	**Eligibility criteria** Approval from at least 1 of PPBs reference regulatory agencies. **Required documents** 1.Proof of registration from the reference regulatory agencies. 2.Instruction for use (IFU)/Technical manual identical to the registered device 3.Duly filled the Essential principle checklist.	**Eligibility criteria** A medical device that has obtained **at least one** reference regulatory agency approval for a labelled use identical to that intended for marketing in Kenya at the point of submission will qualify for the abridged evaluation route. **Required documents** 1.Proof of registration from the reference regulatory agencies. (1) 2.Instruction for use (IFU)/Technical manual identical to the registered device 3.Dulfilled Essential principal checklist.
Expedited	N/A	**Eligibility criteria** **Condition 1** 1.Approval from at least 1 of reference regulatory agency. 2.Marketed for ≥ 3 years in the above independent reference regulatory agency's jurisdictions. 3.No safety issues globally.	**Eligibility criteria** 1.Obtained approvals from at least two of PPBs <u>independent</u> reference regulatory agencies for a labelled use identical to that intended for marketing in Kenya 2.No rejection/withdrawal of the medical device by/from any reference regulatory agency/that foreign jurisdiction(s) or

Reliance Evaluation Pathway	Class B medical devices	Class C medical Device	Class D medical Device
		4.No prior rejection/ withdrawal by/from any independent reference regulatory agencies or other NRA (e.g. withdrawal/rejection/ refusal to register specific models in an application) due to quality, performance/efficacy or safety issues. OR **Condition 2** 1.Approvals from at least 2 reference regulatory agencies 2.No safety issues globally 3.No prior rejection/ withdrawal by/from any independent reference regulatory agencies or other NRAs. (e.g. withdrawal/rejection/ refusal to register specific models in an application) due to quality, performance/efficacy or safety issues. **Required documents** 1.Proof of registration from the reference regulatory agencies. 2.Proof of registration from the above reference regulatory agency for a minimum of 3 years (For-Condition 1). 3.Instruction for use (IFU)/Technical	PPB due to quality, performance/efficacy or safety issues. This includes non-registration such as refusal to register specific models in an application. **Required documents.** 1.Proofof registration from the reference regulatory agencies. (2) 2.Instruction for use (IFU)/Technical manual identical to the registered device 3.Duly filled Essential principles checklist

Reliance Evaluation Pathway	Class B medical devices	Class C medical Device	Class D medical Device
		manual identical to the intended use of the device to be marketed in the Kenya market. 4.Safety declaration. 5.Duly filled Essential principal checklist.	
Immediate	**Eligibility criteria Condition 1** 1.Approval from at least 1 of reference regulatory agency. 2.Marketed for ≥ 3 years in the above independent reference regulatory agency's jurisdictions. 3.No safety issues globally. 4.No prior rejection/ withdrawal by/from any independent reference regulatory agencies or other NRA (e.g. Withdrawal/rejection/refusal to register of specific models in an application)due to quality, performance/ef	**Eligibility criteria** 1.Obtained approval from at least one of PPBs independent reference regulatory agencies for a labelled use identical to that intended for marketing in Kenya; 2.No safety issues globally associated with the use of the medical device(s) when used as intended by the product owner, in the last three years, defined as; a). no reported deaths; b).no reported serious deterioration in the state of health of any person; and c).no open field safety corrective actions (including recalls) point of submission. 3. No prior rejection/withdrawal	

Reliance Evaluation Pathway	Class B medical devices	Class C medical Device	Class D medical Device
	ficacy or safety issues. **OR** **Condition 2** 1.Approvals from at least 2 reference regulatory agencies 2.No safety issues globally 3.No prior rejection/ withdrawal by/from any independent reference regulatory agencies or other NRAs. (e.g. withdrawal/rejection/refusal to register specific models in an application) due to quality, performance/efficacy or safety issues. **Required documents.** 1.Proof of reference agency's approval(s). 2.Proof of registration from the above reference agency for a minimum of 3 years.	of the medical device by/from any reference regulatory agency due to quality, performance/efficacy or safety issues. This includes non-registration such as refusal to register specific models in an application. **Required Documents** 1.Proof of registration from the reference regulatory agencies. 2.Instruction for use (IFU)/Technical manual identical to the device intended for marketing in Kenya 3.Duly filled Essential principle checklist. 4.Safety declaration.	

Reliance Evaluation Pathway	Class B medical devices	Class C medical Device	Class D medical Device
	3.Declaration of safety of the device. 4.IFU/Technical manual. 5.Proof of sterility (If applicable). 6.Risk Analysis.		

4.8 RELIANCE MECHANISMS USED IN REGISTRATION OF IN-VITRO DIAGNOSTICS.

The reliance mechanism for the registration of In Vitro Diagnostics (IVDs) is designed to streamline regulatory pathways by leveraging prior approvals from recognized regulatory authorities while ensuring product quality, safety, and performance. Recognizing the critical role of In Vitro Diagnostics (IVDs) in disease diagnosis, monitoring, and public health surveillance, and acknowledging the need for timely access to essential diagnostics, particularly during health emergencies, this reliance mechanism is established to facilitate efficient registration processes. This approach leverages the assessments of stringent regulatory authorities, considering the risk classification of IVDs (from low-risk to high-risk) and prioritizing diagnostics for significant public health concerns.

IVDs are categorized based on their risk to patients, users, and public health, with higher-risk devices requiring more stringent evaluation.

4.9 Requirements for IVDs Reliance Applications

1) A full unredacted assessment report.
2) Evidence/proof of product registration/granting of market authorization in RRA: the product should have been registered,

prequalified and/or granted marketing authorization and is, in the latter case, on the market of the reference authority.

3) Permission for data sharing (Annex II) from the applicant (for WHO prequalified products)
4) A formal written request from the applicant/MAH.
5) A declaration letter from the applicant stating full compliance with eligibility requirements
6) For products with post-approval changes/variations all assessment reports and/or documents concerning the post-approval variations, including a tabulated summary of variation approvals from the RRA, shall also be provided.
7) All annexes of the assessment report shall be submitted.

There's only one reliance evaluation route for registration of IVDs**:** The abridged evaluation route

4.9.1 Abridged Evaluation of IVDs

An abridged assessment considers available evidence that an eligible IVD meets certain requirements as a result of the product's previous stringent/reference regulatory assessment and approval. This applies to class B, C and D IVDs.

When considering whether a product qualifies for an abridged prequalification assessment procedure, PPB takes into account the following two factors:

a) Whether the regulatory version of the IVD submitted for PPB registration has been assessed and approved by any of the reference regulatory authorities and,
b) If so, whether the regulatory version of the product submitted for PPB registration is the same (or is not substantially different) as the regulatory version that was stringently assessed and approved by the Recognized RRA

Required Documents

a) Class B IVD

i. Proof of reference agency's approval(s).
ii. Proof of registration from the above reference agency for a minimum of 3 years.
iii. Declaration of safety of the device.
iv. Instruction for use (IFU)/Technical manual.
v. Sterility report (If applicable).
vi. Risk analysis.
vii. Design and validation report.

b) Class C AND D IVD.

viii. All the above documents in class B and C plus a Dully filled Essential Principles Checklist.

4.10 Turnaround time for Medical Devices and IVDs

Risk Class	TURN AROUND TIME (WORKING DAYS)		
	Abridged	**Expedited**	**Immediate**
Class B	60		14
Class C	90	30	14
Class D	90	30	

5.0 IMPLEMENTATION MECHANISM

For the successful implementation of this guidance, PPB shall;

a) Appoint Reliance Implementation Champions tasked with overseeing and promoting the adoption of reliance practices. Their TORs shall include the following;
   - Identify reliance applications as per the RRAs/RI.
   - Act as liaison officers for reliance mechanisms.

- Undertake tracking of reliance applications using the design-thinking approach.
- Offer training to staff and sensitization of stakeholders/applicants via webinars, exchange programmes, etc.
- Collaborate and communicate with reference agencies.
- Keep the assessment team engaged in the science and keep them challenged.
- Get buy-in from senior leadership.
- Any other duties that relate in promotion of reliance mechanisms within the organisation and stakeholders.

b) Develop of an Online System: A dedicated digital platform will be set up to manage reliance applications, ensuring that the process is seamless, transparent, and traceable.
c) Ensure Resource Allocation and Monitoring: To track the success and impact of the reliance initiative, PPB will implement monitoring and evaluation systems, assessing both regulatory outcomes and public health impacts.

6.0 REFERENCES

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2. FDA. (2019). FDA Ghana reliance policy
3. FDA, Rwanda Reliance guideline
4. GMP Quality Manual.
5. Africa Regulatory Reliance Framework
6. Ethiopian FDA, Guidelines on Reliance for Medicine Marketing Authorization
7. Achieving effective regulation of medicines and vaccines by national regulatory authorities with very limited resources.
8. Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products (Working document QAS/24.956 August 2024)
9. WHO, Collaborative procedure between the World Health Organization and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics.
10. South Africa, SAPHRA, Reliance guideline (SAHPGL -BAU-01_v4
11. Health Science Authority, Singapore, Guidance on medical device product registration.
12. Brazilian Health Regulatory Agency, ANVISA, Good Reliance Practices in MDR.
13. WHO Global Model Regulatory Framework for Medical Devices Including In Vitro Diagnostic

7.0 REVISION HISTORY

Revision Number	Date	Author	Section(s) Revised	Description of Change

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9. Dr Kauthar Bajaber
10. Dr Beatrice Cheruiyot
11. Dr Anushree Patel
12. Dr Shellan Omondi
13. Dr. Anne Tibin
14. Dr. Francis Letipila

9.0 List of Annexes

Annex I _ List of RRAs

Annex II _ Documentation abridged procedure

Annex II _ Confirmation of data sharing

Annex III _ Quality Information Summary

10.0 Links to Appendices:

WHO PQ- CRP:

a) Appendix 1A: NMRA participation agreement
b) Appendix 1B: NMRA focal point(s)' confidentiality undertaking
c) Appendix 2: Prequalification holder's consent to information-sharing
d) Appendix 3: Part A Applicant's expression of interest in application of the procedure

e) Appendix 3: Part B Acceptance by the NMRA to apply the procedure
f) Appendix 3: Part C Notification of outcomes of national registration procedure
g) Appendix 4: Report on post-registration actions

WHO SRA CRP:

a) Appendix 1: Agreement of the national regulatory authority to participate in the collaborative procedure in assessment and accelerated national registration of pharmaceutical products and vaccines by stringent regulatory authorities
b) Appendix 2: Example of information included in the list of participating reference stringent regulatory authority(ies)
c) Appendix 3A: Manufacturer's consent for information sharing with participating national regulatory authority(ies) and the World Health Organization
d) Appendix 3B: Manufacturer's request for SRA permission for sharing SRA-owned non-public information with participating NRAs and the World Health Organization

e) Appendix 4: Quality information summary of the FPP or vaccine approved by the reference SRA (QIS-SRA (crp))

f) Appendix 5: Proposed documentation for collaborative procedure for reference SRA-approved FPPs and vaccines

g) Appendix 6: Requirements for provision of a bridging report for reference SRA-approved pharmaceutical product and vaccines for consideration of registration in participating countries

h) Appendix 7: Expression of interest to national regulatory authority

i) Appendix 8: Confidential disclosure agreement

j) Appendix 9: Notification of an outcome of the national registration provided by the participating manufacturer to the World Health Organization

Annex I: List of RRAs/RIs

a) WHO collaborative registration procedures (WHO CPQ and SRA CRP)

b) Regional and international reference institutions (e.g. by IGAD, EAC, Swiss MAGHP, EU-M4ALL).

c) Continental/ regional bodies/ forums (e.g., AMA, AVAREF, ABRF).

d) National Regulatory Authorities with mutual or bilateral recognition agreement with PPB.

e) Institutions for reliance on Active Pharmaceutical Ingredient (API) assessment: WHO (Certificate of a Pharmaceutical Product (CPP)), WHO Prequalification Team - Medicines (PQTm) (Confirmation of Prequalification (CPQ)) or European Directorate for the Quality of Medicines and Healthcare (EDQM) (Certificate of Suitability to the monographs of the European Pharmacopoeia (CEP)).

f) WHO Listed Authorities (WLAs)

g) WHO Transitional WLAs (Category A, B and C)- Category A - ML3&ML4 NRAs for vaccines only, Category B- SRA and Category C- Highly performing NRA (Vaccines)

h) European Medicines Agency (EMA)

Annex II: Confirmation of data sharing

Manufacturer's request for reference institution's (RI) permission for sharing RI owned non- public information with <PPB>

Date:_____*dd/mm/yyyy* **_____**
<manufacturer>

RE: Request to <RRA/RI> for a permission to <manufacturer> to share <RRA/RI>'s non-public information concerning <Product> with <PPB>.

Dear <REFERENCE REGULATORY AUTHORITY /REFERENCE INSTITUTION>,

<Manufacturer> as a <Marketing Authorization Holder> of the <RRA/RI> authorized <Product>, hereby requests the <RI's/RRA'S> permission to share <RI/RRA>-owned non-public information concerning <Product> for the purpose of the procedures of verification or abridged/abbreviated review and accelerated national registration of medicinal products based on reliance on recognized reference institutions.[6] The information to be shared consists of

<RI/RRA> final GxP inspection reports for Product <date; version>;
<RI/RRA> Product assessment reports; and

<RI/RRA> <other, please specify> documents/reports that may be needed in the context of this Procedure.

The information will be shared with the <PPB>.
Yours sincerely,
Name: _____
Title: _____
RRA: _____ Address: __
Email: _____
Telephone number: _____ cc:
_____

Annex III: QIS-RRA-FPP

Quality Information Summary of The Finished Pharmaceutical Product Approved By The Reference Institution (RRA) (QIS-RRA-FPP)

INTRODUCTION

(a) Summary of product information:

Non-proprietary name(s) of the finished pharmaceutical product(s) (FPP)	
Proprietary name(s) of the finished pharmaceutical product(s) (FPP)	
International non-proprietary name(s) of the active pharmaceutical ingredient(s) (API(s)), including form (salt, hydrate, polymorph)	
Applicant name and address	
Dosage form	
Application Number	
Strength	
Route of administration	
Proposed indication(s)	

(b) Administrative Summary:

Applicant's date of preparation or revision of the QIS	
Version and/or date of acceptance	***(official use only)***

Related dossiers (e.g. FPP(s) with the same API(s) submitted to EMP TC by the applicant):

Application number ( )	**Registration status (Y/N)**	**API, strength, dosage form (e.g. Irinotecan (as chloride) 20mg per ml Solution)**	**API manufacturer (Including address if same manufacturer as current dossier)**

2.3.S DRUG SUBSTANCE (or ACTIVE PHARMACEUTICAL INGREDIENT (API)) (NAME, MANUFACTURER)

Indicate which option applies for the submission of API information: <check one only>

Name of API:	
Name of API manufacturer:	

□	Certificate of suitability to the European Pharmacopoeia (CEP) Option 1.
□	Confirmation of API prequalification document: Option 2
□	API approval number _____. Option 3a.
□	Active pharmaceutical ingredient master file (EMP-TC APIMF) procedure: APIMF number assigned by EMP TC (if known): _____ ; version number(s) including amendments (and/or date(s)) of the open part: _____ ; version number(s) including amendments (and/or date(s)) of the restricted part: : _____. Option 3b.
□	Full details in the PD Open part DMF version number_____ Restricted part DMF version number_____ Identifier of current module 3.2.S: _____ Option 4.

2.3.S.2 Manufacture (name, manufacturer)

2.3.S.2.1 Manufacturer(s) (name, manufacturer)

(a) Name, address and responsibility (e.g. fabrication, packaging, labelling, testing, storage) of each manufacturer, including contractors and each proposed production site or facility involved in these activities:

Name and address (including block(s)/unit(s))	Responsibility	CEP number/ WHOAPI-PQ number /WHO APIMF/ EMP TC Listing No./Approved APIMF/ if applicable)	Letter of access provided?

2.3.S.2.3 Control of Materials (name, manufacturer) – <u>for API option 4 only</u>

(a) Name of starting material:

(b) Name and manufacturing site address of starting material manufacturer(s):

2.3.S.4 Control of the API (name, manufacturer)

2.3.S.4.1 Specification (name, manufacturer)

(a) API specifications of the FPP manufacturer:

Standard (e.g. Ph.Int., Ph.Eur., BP, USP, in-house)		
Specification reference number & version effective date		
Test	**Acceptance criteria**	**Analytical procedure (Type/Source/Version)**
Description		
Identification		
Impurities		
Assay		
etc.		

2.3.S.6 Container Closure System (name, manufacturer)

(a) Description of the container closure system(s) for the storage and shipment of the API:

2.3.S.7 Stability (name, manufacturer)

2.3.S.7.1 Stability Summary and Conclusions (name, manufacturer)

(a) Proposed storage conditions and re-test period (or shelf-life, as appropriate):

Container closure system	**Storage statement**	**Re-test period***

* Indicate if a shelf-life is proposed in lieu of a re-test period (e.g. in the case of labile APIs)

2.3.P DRUG PRODUCT (or FINISHED PHARMACEUTICAL PRODUCT (FPP))

Indicate which option applies for the submission of FPP information: <check one only>

Name of API:		
Name of API manufacturer:		
□	Full details	
□	WHO collaborative procedure	
□	SRA Abridged procedure	
□	EU Article 58 procedure	
	Any other recognized regulatory or QA procedure	

2.3.P.1 Description and Composition of the FPP

(a) Description of the FPP (in signed specifications):

(b) Composition of the FPP:

(i) Composition, i.e. list of all components of the FPP and their amounts on a per unit basis and percentage basis (including individual components of mixtures prepared in-house (e.g. coatings) and overages, if any):

Component and quality standard (and grade, if applicable)	**Function**	**Strength (label claim)**					
		Quant. per unit	**%**	**Quant. per**	**%**	**Quantity per**	**%**

		or per mL		**unit or per mL**		**unit or per mL**	
<complete with appropriate titles e.g. Core tablet (Layer 1, Layer 2, etc. as applicable), Contents of capsule, Powder for injection>							
Subtotal 1							
<complete with appropriate title e.g. Film-coating >							
Subtotal 2							
Total							

(ii) Composition of all *components purchased as mixtures* (e.g. colourants, coatings, capsule shells, imprinting inks):

(c) Description of accompanying reconstitution diluent(s), if applicable:

2.3.P.2.2.1 Formulation Development

(a) Information on primary (submission, registration, exhibit) batches including comparative bioavailability or biowaiver, stability, commercial:

(i) Summary of batch numbers:

Batch number(s) of the FPPs used in			
Bioequivalence	**<e.g. bioequivalence batch A12345>.**		
Biowaiver	**<e.g. biowaiver batch X12345>**		
For proportional strength biowaiver: the bioequivalence batch of the reference strength			
Dissolution profile studies			
Stability studies (primary batches)			
‹Packaging configuration I›			
‹ Packaging configuration II›			

‹*Add/delete as many rows as necessary*›			
Stability studies (production batches)			
‹ Packaging configuration I›			
‹ Packaging configuration II›			
(Add/delete as many rows as necessary)			
Validation studies (primary batches)			
‹ Packaging configuration I›			
‹ Packaging configuration II›			
(Add/delete as many rows as necessary)			
Validation studies (at least the first three consecutive production batches) version(s) for process validation protocol(s)			

Summary of formulations and discussion of any differences:

Component and quality standard (e.g. NF, BP, Ph.Eur, in-house)	**Relevant batches**							
	Comparative bioavailability or biowaiver		**Stability**		**Process validation**		**Commercial (2.3.P.1)**	
	<Batch nos. and sizes>		**<Batch nos. and sizes>**		**<Batch nos. and sizes>**		**<Batch nos. and sizes>**	
	Theor. quantity per batch	**%**	**Theor. quantity per batch**	**%**	**Theor. quantity per batch**	**%**	**Theor. quantity per batch**	**%**
<complete with appropriate titles e.g. Core tablet (Layer 1, Layer 2, etc. as applicable), Contents of capsule, Powder for injection>								
Subtotal 1								
<complete with appropriate title e.g. Film-coating >								
Subtotal 2								
Total								

2.3.P.3 Manufacture

2.3.P.3.1 Manufacturer(s)

(a) Name, address and responsibility (e.g. fabrication, packaging, labelling, testing) of each manufacturer, including contractors and each proposed production site or facility involved in manufacturing and testing:

Name and address (include block(s)/unit(s))	**Responsibility**

2.3.P.3.2 Batch Formula

Largest intended commercial batch size:

Other intended commercial batch sizes:

<information on all intended commercial batch sizes should be in the QIS>

(a) List of all components of the FPP to be used in the manufacturing process and their amounts on a per batch basis (including components of mixtures prepared in-house (e.g. coatings) and overages, if any):

Strength (label claim)			
Master production document reference number and/or version			
Proposed commercial batch size(s) (e.g. number of dosage units)			
Component and quality standard (and grade, if applicable)	**Quantity per batch (e.g. kg/batch)**	**Quantity per batch (e.g. kg/batch)**	**Quantity per batch (e.g. kg/batch)**
<complete with appropriate titles e.g. Core tablet (Layer 1, Layer 2, etc. as applicable), Contents of capsule, Powder for injection>			

Subtotal 1			
<complete with appropriate title e.g. Film-coating >			
Subtotal 2			
Total			

2.3.P.3.3 Description of Manufacturing Process and Process Controls

(a) Flow diagram of the manufacturing process:

(b) Narrative description of the manufacturing process, including equipment type and working capacity, process parameters:

2.3.P.3.4 Controls of Critical Steps and Intermediates

(a) Summary of controls performed at the critical steps of the manufacturing process and on isolated intermediates:

Step (e.g. granulation, compression, coating)	**Controls (parameters/limits/frequency of testing)**

Proposed/validated holding periods for intermediates (including bulk product):

2.3.P.3.5 Process Validation and/or Evaluation

(a) Summary of the process validation and/or evaluation studies conducted and/or a summary of the proposed validation protocol for the critical steps or critical assays used in the manufacturing process (e.g. protocol number, parameters, results):

Document code(s) for the process validation protocol(s) and/or report(s) (including reference number/version/date):

2.3.P.5 Control of FPP

2.3.P.5.1 Specification(s)

(a) Specification(s) for the FPP:

Standard (e.g. Ph.Int., BP, USP, in-house)			
Specification reference number and version			
Test	**Acceptance criteria (release)**	**Acceptance criteria (shelf-life)**	**Analytical procedure (type/source/version)**
Description			
Identification			
Impurities			
Assay			
etc.			

2.3.P.7 Container Closure System

(a) Description of the container closure systems, including unit count or fill size, container size or volume:

Description (including materials of construction)	**Strength**	**Unit count or fill size (e.g. 60s, 100s etc.)**	**Container size (e.g. 5 ml, 100 ml etc.)**

2.3.P.8 Stability

2.3.P.8.1 Stability Summary and Conclusions

(a) Proposed storage statement and shelf-life (and in-use storage conditions and in-use period, if applicable):

Container closure system	Storage statement	Shelf-life

2.3.P.8.2 Post-approval Stability Protocol and *Stability Commitment*

(a) Stability protocol for Primary stability batches (e.g. storage conditions (including tolerances), batch numbers and batch sizes, tests and acceptance criteria, testing frequency, container closure

Parameter	Details	
Storage condition(s) (◦C, % RH)		
Batch number(s) / batch size(s)	<*primary batches*>	
Tests and acceptance criteria	Description	
	Moisture	
	Impurities	
	Assay	
	etc.	
Testing frequency		
Container closure system(s)		

(b) system(s)):

(c) Stability protocol for Commitment batches (e.g. storage conditions (including tolerances), batch numbers (if known) and batch sizes, tests and acceptance criteria, testing frequency, container closure system(s)):

Parameter	Details	
Storage condition(s) (◦C, % RH)		
Batch number(s) / batch size(s)	***<not less than three production batches in each container closure system>***	
Tests and acceptance criteria	**Description**	
	Moisture	
	Impurities	
	Assay	
	etc.	
Testing frequency		
Container closure system(s)		

(d) Stability protocol for Ongoing Batches (e.g. storage conditions (including tolerances), number of batches per strength and batch sizes, tests and acceptance criteria, testing frequency, container closure system(s)):

Parameter	Details	
Storage condition(s) (◦C, % RH)		
Batch size(s), annual allocation	***<at least one production batch per year (unless none is produced that year) in each container closure system >***	
Tests and acceptance criteria	**Description**	
	Moisture	
	Impurities	

	Assay	
	etc.	
Testing frequency		
Container closure system(s)		

2.3.P.8.3 Stability Data

(a) Bracketing and matrixing design for commitment and/or continuing (i.e. ongoing) batches, if applicable:

WRITTEN COMMITMENTS OF THE MANUFACTURER – for NRA use

API

If applicable (primary stability study commitment):

The Applicant (or API manufacturer) undertook in writing (date of letter of commitment) to continue long-term testing of <INN of API> for a period of time sufficient to cover the whole provisional re-test period (period ending month/year) and to report any significant changes or out-of-specification results immediately to EMP TC for the following batches :

<Batch numbers, manufacturing dates, batch size, primary packing materials>

If applicable (commitment stability studies):

Since stability data on three production scale batches were not provided with the application, the remaining number of production scale batches should be put on long-term stability testing. Any significant changes or out-of-specification results should be reported immediately to EMP TC. The approved stability protocol should be used for commitment batches.

API option 1 – CEP

The Applicant provided a commitment in writing (date of letter of commitment) to inform EMP TC in the event that the CEP is revised or withdrawn, and that revisions to the CEP will be handled as per variation guidelines. Note that revisions or withdrawal will require additional consideration of the API data requirements to support the dossier.

API option 2 – WHOAPI-CPQ

The Applicant provided a commitment in writing (date of letter of commitment) to inform EMP TC in the event that the WHOAPI-CPQ is revised or withdrawn,

and that revisions to the WHOAPI-CPQ will be handled as per variation EMP TC Variation guidelines. Note that revisions or withdrawal will require additional consideration of the API data requirements to support the dossier.

API option 4 – full details in the PD (ongoing stability study commitment)

The Applicant undertook in writing (date of letter of commitment) a commitment regarding ongoing stability studies. Unless otherwise justified, at least one batch per year of the product will be included in the stability programme (unless none is produced during that year). The stability protocol will be that which was approved for primary batches (or the protocol was submitted for assessment). Out-of-specification results or significant atypical trends will be investigated. Any confirmed significant change or out-of-specification result will be reported immediately to EMP TC. The possible impact on batches on the market will be considered in consultation with GMP inspection.

FPP

If applicable (primary stability study commitment):

The Applicant undertook in writing (date of letter of commitment) to continue long-term testing of < FPP reference number, trade name (INN of API), strength, pharmaceutical form> for a period of time sufficient to cover the whole provisional shelf-life (period ending month/year) and to report any out-of-specification results or significant changes immediately for the following batches :

<Batch numbers, manufacturing dates, batch size, primary packing materials >

If applicable (commitment stability studies):

Since stability data on three production scale batches was not provided with the application, the Applicant undertook in writing, (date of letter of commitment) to put the remaining number <e.g. additional two (2)> production scale batches of < FPP reference number, trade name (INN of API), strength, pharmaceutical form, primary packing material> on long-term stability testing. Any out-of-specification results or significant changes during the study will immediately be reported to EMP TC. The approved stability protocol will be used for commitment batches.

If applicable (when the proposed largest commercial batch size is 200 000 units (x units) or less)

The Applicant undertook in writing (date of letter of commitment) to place the first three batches of any production size larger than x units on stability. The stability protocol will be that which was approved for primary batches (or the

protocol was submitted for assessment). Out-of-specification results or significant atypical trends will be investigated. Any confirmed significant change or out-of-specification result will be reported immediately to EMP TC.

Ongoing stability study commitment

The Applicant undertook in writing (date of letter of commitment) a commitment regarding ongoing stability studies. Unless otherwise justified, at least one batch per year of the product manufactured in every primary packaging type will be included in the stability programme (unless none is produced during that year). The stability protocol will be that which was approved for primary batches (or the protocol was submitted and found acceptable). Out-of-specification results or significant atypical trends will be investigated. Any confirmed significant change or out-of-specification result will be reported immediately to EMP TC. The possible impact on batches on the market will be considered in consultation with GMP inspection.

If applicable (validation of production batches)

Validation data on production scale batches of not less than three (3) consecutive batches of <FPP reference number, trade name (INN of API), strength, pharmaceutical form, primary packing material> was not provided with the application. Therefore, the Applicant submitted a written commitment (date of letter of commitment) that three consecutive production batches would be prospectively validated and a validation report —in accordance with the details of the validation protocol provided in the dossier— would be made available as soon as possible for evaluation by assessors or for verification by the GMP inspection.

Annex 1V: Health Products Reliance Screening Checklist

	Information required *(Please put a tick √ as applicable. If requirement not fully met, please comment below)*	***YES***	***NO***
1.	Has the applicant submitted consent form to WHO and SRA to share information with PPB under the procedure.		
Comment			
2.	Has the applicant submitted the Expression of Interest form.		
Comment			
3.	Has the applicant submitted the mutual agreement between the applicant and the manufacturer, if the applicant for national registration is different from the manufacturer with a prequalified product/SRA-CRP approved product.		
Comment			
4.	Has the applicant submitted the declaration of sameness of the product as approved.		
Comment			
5.	Has the applicant provided a declaration that the dossier has been updated to reflect all post-prequalification variations approved.		
Comment			
6.	Has the applicant attached the current approved Quality Information Summary (QIS).		
Comment			
7.	Has the applicant submitted the product's approval letter.		
Comment			
8.	Has the applicant submitted assessment report (Public or non-public)		
Comment			

Change History

Date of preparation of original QIS:

Date of revised version	**Section (e.g. S.2.1)**	**Revision**

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