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REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR EMERGENCY USE AUTHORIZATION (EUA) OF HEALTH PRODUCTS AND TECHNOLOGIES

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ABBREVIATIONS

AMA	African Medicines Agency
AVAREF	African Vaccines Regulatory Forum
COVID-19	Coronavirus Disease 2019
DPER	Department of Product Evaluation and Registration
EAC	East African Community
EMA	European Medical Agency
EUA	Emergency Use Authorization
EUL	Emergency Use listing
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GxP	Good Practices e.g., GCP, GLP
ICH	International Council on Harmonization of requirements of Pharmaceuticals for Human Use
IGAD	Intergovernmental Authority on Development
IMDRF	International Medical Device Regulators Forum
IMP	Investigational Medicinal Product
ISO	International Organization for Standardization
IVD	In-vitro diagnostics

MOH	Ministry of Health
MTaPS	Medicines, Technologies, and Pharmaceutical Services
PHEIC	Public Health Emergency of International concern
PPB	Pharmacy and Poisons Board
PS	Product Safety Department
PV/PMS	Pharmacovigilance/ Post Market Surveillance
RRA	Reference Regulatory Authority
SAE	Serious Adverse Events
SmPC	Summary of product characteristics
SRA	Stringent Regulatory Authority
SUSAR	Suspected Unexpected Serious Adverse Reaction
US FDA	US Food and Drug Administration
USAID	United States Agency on International Development
WHO	World Health Organization
WHO TRS	WHO Technical Report Series
QAO	Quality Assurance Officer

GLOSSARY

For these guidelines, the following definitions shall apply:

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. Off-label use means the utilization of a registered product for unregistered indication, dosage, dosing frequency, duration of use, route of administration, or patient groups i.e., outside the approved indication contained in section 4.1 of the approved summary of product characteristics (SmPC).

Marketing Authorization means approval i.e., license/ certificate of registration for a product to be marketed in a country. The term product registration may be used synonymously.

Cabinet Secretary- the Secretary at the time being in charge of the Ministry responsible for Health.

The Board- Pharmacy and Poisons Board

The National Security Council: The National Organ responsible for National security

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FOREWORD

The Emergency Use Authorization (EUA) guideline has been developed to address public health emergencies including emerging epidemics and pandemics to ensure timely access to life-saving health products and technologies. It explains the Pharmacy and Poisons Board procedures applicable to the authorization of the emergency use of Health Products and Technologies as prescribed under the Pharmacy and Poisons Act Cap 244 Laws of Kenya.

The recommendations under this guideline shall enhance Kenya's preparedness to deal with public health emergencies including chemical, biological, radiological and nuclear agents, and emerging infectious threats, such as COVID-19.

The guideline provides a risk-based procedure for assessment and authorization of unlicensed medicines, vaccines, and in vitro diagnostics (IVDs) and any critical healthcare product or technology for use primarily during public health emergencies. The purpose of the guideline is to allow expedited non-routine authorization decisions once an emergency is declared.

This guideline has been developed to guide industry (Manufacturers), local technical representatives, Importers, Health facilities, National Health Programs, and other stakeholders on the documentation requirements for emergency use Authorization of Health Products and Technologies.

This EUA is not a routine marketing authorization; it is applicable during declared emergencies where the Board shall accept fewer comprehensive data about the quality, safety, and efficacy of products. This is taking into consideration the mortality and/or morbidity of the disease and the lack of treatment, diagnostic or prevention options. The EUA is not intended to interfere with ongoing clinical trials and thus clinical trials would be expected to proceed as planned after initial submission and subsequent updates.

The guideline has been developed with reference to the WHO emergency use Listing procedure, WHO Guidelines on regulatory preparedness for provision

of the marketing authorization of human pandemic Influenza vaccines in non-vaccine producing countries (WHO TRS No 1004, 2017 annex 7), and US FDA Guidance on Emergency Use Authorization of medical product.

1.0 INTRODUCTION

The Pharmacy and Poisons Board (hereinafter referred to as "the Board") is mandated under the Pharmacy and Poisons Act Cap 244 Laws of Kenya (hereinafter referred to as "the Act") to regulate Health Products and Technologies.

Ordinarily, before any consideration for the Marketing Authorization of a product, sufficient scientific and clinical evidence must be collected to demonstrate that it is safe, efficacious, and of suitable quality. The scientific evidence includes quality data, and safety and efficacy result from human clinical trials or non-clinical studies; it should be evident that the benefits of the product outweigh the risks associated. However, less sufficient information on quality, safety, efficacy/immunogenicity/performance may be accepted in times of public health emergencies where there is no other available treatment/intervention. In such circumstances, additional mechanisms like; a risk-management plan, pharmacovigilance, and post-market surveillance for compliance verifications as well as investigations of potential health hazards shall be implemented.

Furthermore, where necessary, inspections of manufacturers, packagers/labelers, testing laboratories, importers, distributors, and wholesalers of the product may be conducted to ensure that they comply with Good Practices (GXPs). Alternatively, available, and reliable evidence of compliance or non- compliance with good practice (GXPs) requirements can be leveraged as part of the risk-based inspection planning process as prescribed in the Board's guideline on desk review assessment and WHO guidance on good practices for desk assessment. These guidelines prescribe data, which is required to be submitted to the Board to demonstrate the safety, efficacy, and quality of the product being applied for market authorization.

Emergency use Authorization shall be applied when a public health emergency has been declared 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 in which there is no sufficient time to obtain product registration. Emergency use authorization procedures may also be applied in extreme situations such as during war.

It is noted that for emergency use products, there may exist limited data, including clinical data hence the Board may accept reduced data requirements with the commitment by the manufacturer/applicant to submit more data once available. Applications for emergency use (EUA) shall follow product specific guidelines and the general guidance included in this guideline.

This guideline shall be read with international guidelines on quality, safety, and efficacy, such as the international council on Harmonization of requirements of Pharmaceuticals for Human Use (ICH) guidelines and as cited in this guideline namely the World Health Organization (WHO), US FDA and European Medicines Agency (EMA) on emergency Health products and Technologies and PPB's product specific guideline

1.1 Legal Framework

The Board is statutorily empowered to undertake various duties in the execution of its mandate regarding the regulation of health products and technologies. This includes regulation of clinical trials and marketing authorization. The regulation for the conduct of clinical trials is governed under the provisions of the Pharmacy and Poisons Act Cap 244 Laws of Kenya (hereinafter referred to as "the Act"), and the Subsidiary Legislation thereunder.

With respect to Marketing Authorization and Clinical Trials, the Board is empowered amongst others, under Section 3A of the Act to:

a) Grant or withdraw authorization for conducting clinical trials of medical products.
b) Grant or withdraw marketing authorization for medicinal products subject to appropriate conditions and revise such conditions for marketing as necessary.
c) Prescribe the standards appropriate for new medical products; new uses, dosages, and formulations of existing medical products; and such other categories as may be appropriate.
d) Constitute technical and expert advisory committees.

Further Section 3B of the Act mandates the Board to undertake the following with respect to clinical trials and compassionate use:

a) Approve the use of any unregistered medicinal substance for purposes of clinical trials and compassionate use.
b) Collaborate with other national, regional, and international institutions on medicinal substance regulation.
c) Advise the Cabinet Secretary on matters relating to the control, authorization, and registration of medicinal substances.

Additionally, the Board is obliged under Section 25A (4) of the Act to prescribe guidelines for the evaluation of applications for clinical trials on a product to

be implemented for accelerated evaluations during emergency situations, epidemics, and outbreaks.

Furthermore, Rule 14 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022 States

a) The Board may, where it considers it necessary to protect public or animal health or in the event of a threat to human or animal life or health, the Board, issue a provisional certificate of registration for a health product or technology.

b) A person who intends to obtain the provisional certificate of registration for a health product or technology under subrule (1) shall apply to the Board, in Form 2 set out in the First Schedule.

c) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who shall be a citizen of Kenya, a person who is has permanent residence or a company incorporated in Kenya.

d) An application under subrule (2) shall be accompanied by—

   i. such documents as may be necessary to support the application;

   ii. where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

   iii. proof that the applicant holds—

      a) a valid practicing licence issued in accordance with
      b) section 9A of the Act;
      c) a valid wholesale dealer's licence issued in accordance
      d) with section 27 of the Act;
      e) a valid licence to deal in poisons for mining or
      f) agricultural purposes issued in accordance with section
      g) 28 of the Act;
      h) a valid licence to sell Part II poisons issued in
      i) accordance with section 32 of the Act; or
      j) a valid manufacturing licence issued in accordance

k) with section 35A of the Act;

e) When determining an application under subrule (1), the Board shall consider the facts established from the valid marketing authorization for the health product or technology and the report on the assessment of the health product or technology obtained from the authority competent for medicinal products, if available.

f) The person to whom the certificate of registration is issued under subrule (1) shall be responsible for the labelling, packaging, advertising and pharmacovigilance system of the health product or technology.

g) The Board shall issue a provisional certificate of registration under subrule (1) if the person has—
   i. a valid practicing licence issued in accordance with section 9A of the Act;
   ii. a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;
   iii. a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or
   iv. a valid manufacturing licence issued I accordance with section 35A of the Act.

h) A provisional certificate of registration issued under subrule (1) shall be valid for two years from the date of issue or until the declaration made under section 35 of the Public Health Act is revoked.

i) Any variation to the agreement appointing the local representative to the application made under subrule (2) shall be notified to the Board within seven days of the variation.

This Guideline shall also be applicable upon the declaration by the Cabinet Secretary responsible for the health of any disease to be a formidable epidemic disease pursuant to Section 35 of the Public Health Act, Cap 242 of the Laws of Kenya, and/or a declaration by the World Health Organization of a Public Health Emergency.

1.2 Scope

This guideline is intended to provide general considerations and guidance on content and format for required information for regulatory submission of Health products and Technologies for Emergency use authorization in Kenya. Emergency use products are those used in public health emergencies that include; emerging infectious diseases such pandemic influenza, Ebola, Coronavirus pandemic, and any other public health emergency/pandemic as declared by the Cabinet Secretary Ministry of Health in accordance with section 35 of the Public Health Act.

This guideline does not cover the off-label use of health products and technologies.

1.3 Eligibility Of Candidate Products

The product categories to be reviewed under emergency use shall include but are not limited to:

a) Medicines (therapeutics)
    1. Blood and Blood Product
    2. Biotherapeutics products
    3. Chemical products
b) Vaccines
c) Medical devices & In-vitro diagnostics (IVDs)

The product categories shall each have specific requirements for eligibility for evaluation under the EUA procedure.

To qualify for assessment under the EUA procedure the following criteria must be met: -

a) The disease for which the product is intended is serious, immediately life-threatening, or has the potential of causing an outbreak, an epidemic, or a pandemic and there are no registered products for the indication or a critical subpopulation.
b) Existing products have not been successful in eradicating the disease or preventing outbreaks. A potential EUA product may also be an antidote that may be effective to mitigate disease or condition caused by the use of an already registered product.
c) The potential benefits of the product must outweigh the potential risks.
d) The product is manufactured in compliance with Good Manufacturing Practices (medicines & Vaccines) and under a functional Quality Management system (ISO standards) in the case of IVDs and Medical devices, and
e) Where applicable, the applicant undertakes to complete the development of the product (clinical trials in case of medicines & vaccines and validation and verification in case of IVDs) and subsequently apply for registration of the product.

2.0 PHASES OF THE PROCEDURE

1. Pre-emergency
2. Emergency
3. Post Authorization

2.1 Pre-Emergency Phase

Pre-emergency Phase shall l includes activities that can be done in advance (pre-planned activities to tackle emergencies) thus reducing the time required to make final decisions for EUA Authorization of a product. Pre-emergency phase shall be in place, for instance, where infectious disease is a potential public health emergency or has been declared a public health emergency in neighboring countries or when the WHO has declared a disease a Public Health Emergency of International Concern (PHEIC). In case such activities are not implemented in the pre-emergency phase, they shall be implemented in the subsequent phase.

Pre-emergency phase activities shall include but not be limited to the selection of key experts within the PPB and section of advisory or consultants from other organizations, strategic planning, and oversight of systems to support the implementation of EUA (assessment team). Further, the determination of the eligibility of products shall be done through pre-submission meetings. Selection of products for assessment will be in line with the laid-out eligibility criteria, assignment of evaluation pathway, and assessment of submitted data.

An applicant submitting data as part of Pre-emergency phase activities shall include a well-organized summary of the available scientific evidence of the product's quality, safety and efficacy/performance, risks (including adverse events profile) and benefits, and any available approved alternatives to the product.

Consensus must be built on essential requirements on quality, safety, efficacy/immunogenicity/ performance, and lot release (where applicable, particularly vaccines and blood and blood products) for specific products.

This is critical as it is very likely that in emergency circumstances there might be no existing standards that are fully applicable to a specific unregistered product or investigational medicinal product. However, the existing general guidelines (WHO, ICH, and PPB guidelines) may be used for the assessment of products that are under development and for which there are no published product specific guidelines. The WHO, ICH, PPB guidelines, or scientific literature from peer-reviewed journals or anecdotal literature may be used to support a scientific opinion/consensus on aspects related to the specific product. This should be considered and discussed by the Product evaluation and registration department.

2.1.1 Submission of applications

The applicant shall submit an application with a cover letter to the Pharmacy and Poisons Board, Department of Product Evaluation and Registration. The cover letter shall include details of the country of origin, sites of manufacture, proposed presentations for the product, and information on whether or not authorized for emergency use or equivalent has been issued by the national competent authority and a focal qualified person for pharmacovigilance (QPPV) to conduct surveillance and actively report on the quality safety and efficacy of the product. The application for EUA shall be accompanied by a dossier in the appropriate format for each product category (Please refer to the product specific guidelines).

In addition to the requirements set forth in this guideline, applicants must also comply with the conditions and submit documentation requirements outlined in the Pharmacy and Poisons (Registration of Health Products and Technologies) rules, Part III (Miscellaneous) regarding registration during emergency.

The Board shall acknowledge receipt through automated email for online submissions; this shall be immediate on online submission or within two working days for manual submission.

The Board shall issue a rejection letter for applications that do not meet eligibility criteria.

Once an application is accepted under EUA procedure, the Deputy Director (Department of Product Evaluation and Registration or the designate) shall assign the product to a particular assessment pathway and assessors (1st and 2nd assessor) for review of the application.

A fee shall be charged for emergency use authorization if the health product and technologies are to be commercialized. This shall not apply for products donated or managed through access programs i.e., Ministry of Health (MoH) or Non-governmental Organizations. Therefore, there shall be two types of EUA i.e., a) Commercial EUA; issued to private entities, and b) Government/Donations EUA; issued to the Ministry of Health (refer to Annex III).

2.1.2 Regulatory pathway for evaluation of EUA

The applicant shall indicate in the cover letter and the application form the proposed Regulatory pathway applicable to their product. For purposes of ensuring that products of good quality, safety, and efficacy/effective performance for emergency use are accessed by the Kenyan public in a timely manner, three (3) regulatory pathways have been designed for authorization of products under this guideline

2.1.3 Assessment of initial Information (Full assessment)

Products yet to be authorized for use by any regulatory agency or products approved by SRA but whose assessment reports are not available to PPB shall undergo initial evaluation by PPB. In addition to the EUA dossier review process, the PPB GMP inspection department may conduct a desk review of available inspection reports. If appropriate, the GMP & GCP inspectors may conduct on-site inspections of manufacturing and clinical sites, respectively.

An assessment report by the DPER which shall be compiled in recognition of the GMP and GCP inspection reports shall be used to make a regulatory decision.

The report shall include documented outcomes of the evaluation of quality, safety, efficacy/immunogenicity/performance of the product by the DPER

assessors, and the deputy director, DPER, or designate shall communicate the outcome to the applicant. The report shall also indicate when the next set of data e.g., Clinical Trials Report for subsequent Phase or additional product performance data is expected. The applicant shall provide tentative timelines for the submission of additional data based on the expected dates of completion or planned interim analyses of studies currently ongoing or being initiated.

The submission of additional data should be clearly numbered as per the respective product specific guidelines.

In instances where external expertise is needed, the Board may use its prerogative to form ad-hoc committees under DPER that shall also include the internal regulatory experts for accelerated review of data.

2.1.4 Abridged evaluation Pathway

Any product that has been approved for use under extraordinary circumstances, such as public health emergency, by a national regulatory authority (NRA), particularly by a stringent regulatory authority (SRA) like EMA, USFDA, and other ICH member countries, an approval by EAC partner states and the assessment report is available to PPB, the EUA application shall undergo an abridged evaluation and regulatory decision through reliance mechanisms. Any application that has undergone work-sharing mechanisms such as under EAC, IGAD, AMA, or AVAREF shall be considered under this pathway. The applicant shall be required to submit quality and abridged clinical data together with evidence of authorization or acceptance from the reference regulatory Authority or organization.

2.1.5 Who Collaborative Procedure

Any product (Medicine, vaccine, In-vitro diagnostic) that has been accepted by WHO under the Emergency Use listing (EUL) procedure and IMDRF member states shall be authorized through the reliance mechanism.

2.2 Emergency Phase

Most of the assessment activities shall be concentrated in the pre-emergency phase. In instances where preparations were not done in the pre-emergency phase to prop up the regulatory system, including the selection of experts, the activities under section 1.1 shall be carried out or continued in the emergency phase to ensure access to the investigational medicinal products or unregistered health products and technologies does not impinge. Upon assessment (s), the Board may request further information from the applicant before making its final regulatory decision.

2.3 Post Authorization Phase

The Board shall continually review submitted quality and safety reports submitted by the QPPV appointed by the applicant to collect and analyze reports on safety surveillance, efficacy/effectiveness/ performance monitoring, quality complaints, and other relevant data that may impact the validity of the Authorization.

The existing Pharmacovigilance and Post-marketing surveillance mechanisms shall be applied in effecting collection and dissemination of quality and safety surveillance, efficacy/effectiveness/ performance monitoring, quality complaints, and other relevant data.

The applicant should provide the following post-approval commitments in addition to meeting other Pharmacovigilance obligations as stipulated in the Guidelines on the safety and vigilance of medical products and health technologies (https://pharmacyboardkenya.org/pharmacovigilance)

1. An outline of the post-marketing pharmacovigilance plan for the product.
2. Periodic benefit-risk evaluation report in accordance with ICH Guideline E2C(R2) Clinical Safety Data Management: Periodic benefit-risk evaluation report
3. Applicants shall provide information on any ongoing phase I/II/III/IV studies or on any active monitoring of the safety profile that is taking place i.e
    a) Risk management plan.
    b) Vigilance reports to be frequently provided;

1. Suspected unexpected Serious Adverse Reactions (SUSARS) including Adverse events following Immunization (AEFIs) shall be reported within 24 hours.
2. Serious Adverse Events (SAEs) shall be reported within seven (7) days.
3. The Board may institute active Surveillance or targeted Spontaneous reporting.

Once a product has been authorized under the EUA guideline, the development of the product should, if possible, continue to completion for the attainment of marketing authorization.

The applicant shall inform the board in case of any post Authorization changes that may include but are not limited to: Changes in formulation, manufacturing process, testing methods, specifications, facilities, and any other aspect that might result in a change in the safety and/or efficacy/performance of the product or change the basis for authorization. The post Authorization changes shall follow the Specific Variations guidelines. (Refer to Pharmacy and Poisons Board product variation guideline). Promotions shall adhere to the legal and regulatory requirements (refer to the guideline for the advertisement and promotion of medicines and medical devices in Kenya).

In case of a reliance mechanism (abridged procedure & WHO collaborative procedure), changes to the authorized products must be first accepted for emergency use by the reference regulatory Authority (RRA) or WHO.

3.0 EUA APPLICATION PROCESS

3.1 EUA Application

In general, the following minimum information shall be submitted in any application for an EUA: -

1. A description of the product and its intended use (the serious or life-threatening disease, how the product is anticipated to be used, and /or the populations for which the product is to be used.
2. Description of PPB's registration status i.e., whether the product is NOT registered or if registered the requested EUA is for an unapproved use. Whether the product or intended use is under an Investigational application (with PPB or SRA country), whether the product is authorized in an SRA country or WHO.
3. The need for the product i.e. if there are any alternatives or not.
4. Available safety and effectiveness information.
5. A discussion of risks and benefits.
6. Information on chemistry (as applicable), manufacturing, and controls, including a list of all manufacturing sites and the cGMP status of the manufacturing site (s).
7. Information on the quality and quantity of the FPP in stock and the surge capabilities of the manufacturing site(s).
8. Product information equivalent to the Product information requirements as per established product specific guidelines.
9. Information on product stability, anticipated storage, and handling conditions.
10. With regard to safety information;
    a) In general: It shall depend on whether the product is already registered for other indications or a New Investigational product, and it shall depend on the stage of development. Clinical Trials may be mandatory although this can be provided on a Phase-by-Phase approach as the data accumulates from clinical trials. In other circumstances, clinical experience from case studies may be used. Sponsors are encouraged to apply for Clinical Trials

authorization from the Board (please see https://pharmacyboardkenya.org/clinical-trials).

b) For Unapproved uses of already registered products. If the new indication uses a similar dose (or dose range as established through previous clinical trials), duration, route of administration, or mechanism of action, and the intended patient population is similar to the approved product, a right of reference to the registered product is applicable.

c) Unapproved products. The available data may vary considerably. It is recommended that an EUA application should include preclinical testing data i.e., in vitro testing and animal toxicology data. The applicant is also encouraged to submit human safety information from clinical trials and individual patient experiences, if available. If only animal data (including data on non-human primates) is available an extrapolation to humans shall be provided. Any safety information on humans on related compounds or devices should be provided

11. It is appreciated that comprehensive effectiveness data are unlikely to be available for every EUA candidate product. The effectiveness data shall be assessed on a case-by-case basis.

The following minimum information should be provided: -

a) Product(s) mechanisms of action to diagnose, treat or prevent a disease or condition identified in the EUA.

b) For Medicines, preclinical testing data on the effectiveness in treating the identified agent.

c) Data on activity or effectiveness in animals would enhance understanding of the drug's potential effects in humans (Animal efficacy studies).

d) Evidence from human experience, particularly published case reports, uncontrolled trials, or clinical trials.

e) Data to support the proposed dosage (Pharmacokinetics and Pharmacodynamics data) for Medicines and Immunogenicity or achievement of protective levels of immunity using other

parameters (for vaccines) and device performance data e.g. analytical method sensitivity and specificity and data from testing fresh, banked, or archived specimens.

f) Evidence to show that nonclinical studies were conducted in compliance with Good Laboratory Practice (GLP) for nonclinical laboratory studies and whether the clinical studies were conducted in compliance with Good Clinical Practices (GCP). If the nonclinical laboratory studies were not conducted under GLP, evidence of quality systems put in place to ensure the quality and integrity of data from animal studies shall be provided.

12. Ongoing studies e.g., Long-term stability studies shall be provided promptly whenever available

13. A discussion on Risk-benefit analysis shall include the following: -
    a) Measures are taken to mitigate risks.
    b) Uncertainties and data gaps.
    c) Contraindications.
    d) Information concerning threats posed by the Chemical, Biological, Radiological, and Nuclear agents, including infectious agents and anticipated responses.

14. The applicant must in the case of in-vitro diagnostics, avail the reagents reference material along with the instruments for use with the diagnostics documentation as part of the pre-emergency case.

15. The applicant shall provide a Pharmacovigilance plan and Risk management Plan.

16. The applicant/facility/program shall obtain informed consent from the patient(s), individual(s), or Guardian.

17. Any additional conditions/requirements as per the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, Part III (Miscellaneous) regarding registration during emergency.

3.2 Format of submissions for EUA

An EUA application shall include the following:

1. Cover Letter

Applicants shall include a cover letter with all applications. A copy of the letter shall be placed at the beginning of the application. The applicant should also indicate the regulatory pathway applicable to each product. The cover letter should include a list of all the documents submitted including their version numbers and date. Additionally, the cover letter shall include the statement to confirm that the material provided is true and accurate and shall be signed and dated.

2. Comprehensive Table of contents for all Modules

Module 1 shall include a comprehensive table of contents for the entire application. The comprehensive table of contents shall include a complete list of all documents provided in the application by module. In the table of contents, the location of each document shall be identified by referring to the volume numbers that contain the relevant documents.

3. The application body

The EUA application body shall be aligned to the product specific guidelines as listed below:-

a) Guidelines for registration of Human Medicine.
b) Guidelines for Registration of Human Vaccine.
c) Medical devices and Invitro Diagnostic Guidelines.
d) Biotherapeutic Guideline.
    i) Blood and Blood Product Guidelines
    ii) Guidelines on herbal and Complementary/alternative medicines.
e) Guidelines on reliance mechanisms for marketing of health products and technologies in Kenya.

Additionally, the applicant shall be required to provide a Pharmacovigilance plan and Risk management plan (Guidelines on the safety and vigilance of medical products and health technologies (https://pharmacyboardkenya.org/pharmacovigilance)

4.0 REGULATORY PROCESS

Upon submission of the application, screening of the application shall be conducted for acceptance of the application. Screening shall be done within three days. Successful applications shall proceed for evaluation under the EUA. If no queries are raised the application shall be recommended for Emergency use authorization.

After the initial submission of the EUA application with all the mandatory information for initial assessment, applicants are requested to promptly submit any additional information on the development of the product to the Board. Any unsatisfactory application may be rejected upon screening or an unsatisfactory response and feedback provided to the applicant. An applicant may request for withdrawal of the application after the screening, before the first evaluation, during query response, or after an unsatisfactory query response. Rejected applications may appeal to the Board upon payment of the prescribed fee.

The emergency use authorization shall be subject to but not limited to the following conditions: -

1. The applicant shall adhere to all commitments including additional data updates, continued clinical studies, safety reports, risk management plans, and adherence to promotional requirements, regulatory requirements, and safety and vigilance requirements on health products and technologies.
2. After the declaration of an end to a public health emergency and based on the outcome of the continued studies, the applicant shall be expected to submit a complete dossier for evaluation for marketing authorization.

4.1 Regulatory Process Timelines

The timelines for this process shall be in accordance with the PPB Service Charter.

4.2 Termination Of EUA

The validity of EUA shall terminate at the end of the emergency or as determined by the Board as per the Pharmacy and Poisons (registration of drugs) rules].

5.0 PUBLICATION

The Board shall publish on its website and make publicly available the following information on products authorized through EUA procedure:

I. The name of the products, the applicants, and the manufacturers that have applied for EUA.
II. A PPB EUA public report summarizing the findings of the EUA assessment; subject to availability of resources.
III. Include any negative outcomes of the EUA assessment.

The Board reserves the right to share full assessment reports with partners, particularly, the East African Community partner states.

6.0 REFERENCES

1. WHO Emergency Use Authorization procedure (version 9 August 2022).
2. Guidance on Emergency Use authorization of medical products by USFDA (January 2017).
3. WHO Guidelines on regulatory preparedness for provision of the marketing authorization of human pandemic Influenza vaccines in non-vaccine producing countries (WHO TRS No 1004, 2017 annex 7).
4. WHO collaborative procedures (WHO TRS 996- Annex 8).

7.0 REVISION HISTORY

Revision No:	Date	Author/Reviewer	Section(s) revised	Description of change
Rev 1	12-18 Dec 2021	QAO		The Rev 0; was only for covering the COVID-19 To include any emergency infectious diseases
Rev 2	15/07/2022	QAO	The word "Investigational" in the definition.	Changes of word "Investigational Medicine" to "Unregistered Medicine" in the definition of a compassionate use
Rev 2	15/07/2022	QAO	Regulatory process	Additional statement: The allowable quantities of product being requested for compassionate use shall be based on the number of patients in need and the duration of treatment
Rev 3	9/01/2024	QAO	Regulatory process	The maximum allowable CUA quantities/period of use shall be determined by pharmacy and poisons board on case-by-case basis to a maximum of one year
Rev 4	15/05/2025	QAO	Regulatory Process	Separation of EUA/CUA guidance. This guidance document has been amended to reflect the EUA procedure. A new guideline will be drafted for the CUA procedure.
		QAO	Regulatory Process	Removed provision allowing use of the compassionate use pathway after expiry of EUA authorization.
		QAO	Regulatory Process	Inclusion of the PPB rules 2022 that govern EUA as part of the legal framework of the guideline
		QAO	Annex I	Process flow charts for EUA procedures
		QAO	Revision of Annex I and Regulatory process timelines.	The timelines for this process shall be in accordance with the PPB Service Charter. Consequently, Annex I has been revised, and this statement has been incorporated into the guideline to ensure alignment and harmonization with the Service Charter.

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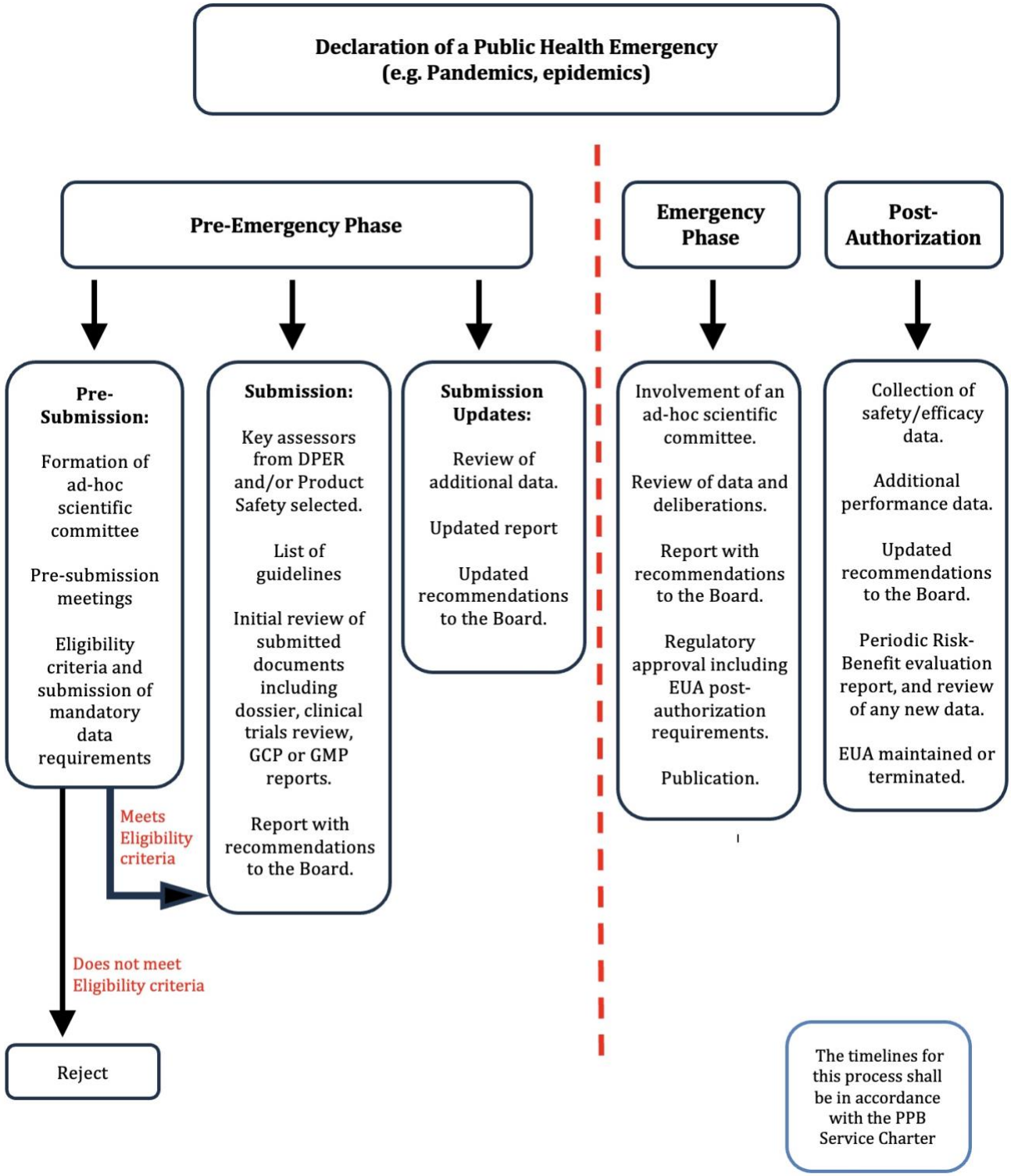
9.0 ANNEXES

Annex I. Flow Chart of the EUA process



Annex II. Emergency Use Authorization template

REPUBLIC OF KENYA

THE PHARMACY AND POISONS ACT

THE PHARMACY AND POISONS (REGISTRATION OF DRUGS) RULES

EMERGENCY USE AUTHORIZATION (EUA)

EUA Number: Hxxx/CTDxxxx/xxxxxEUA

It is hereby certified that the drug as described hereunder, has been issued emergency use authorization subject to the conditions indicated hereunder:	
Trade name	
Approved name	
Form of preparation (Dosage form)	
Active ingredients and quantities per unit	
Condition(s) under which is registered	
Name and business address of manufacturer (FPP)	
Registered in the name of (EUAH)	
Local Technical Representative (LTR)	
Date of EUA	
Date of Issue	
Expiry date of EUA	

Kindly note that this does not constitute a Marketing Authorization

Signed: _____

Signatory Name

CHIEF EXECUTIVE OFFICER

Name and business address of other manufacturer (FPP) 0	
Diluent Suppliers	
Storage condition	
Approved Shelf Life	
Approved in use Shelf life	
Indication	
API/DS Manufacturing Sites0	

Conditions

Mandatory

1. This is NOT a marketing Authorization
2. Batch release/Lot release certificates and summary lot protocol shall accompany all batches imported into Kenya.

Optional

E.g.

1. The applicant shall report on all adverse events in accordance with the timelines as prescribed in the Guidelines on Safety and vigilance of Medical Products and Health Technologies 2019. The reports shall be

sent in E2b format via Email at pv@pharmacyboardkenya.org. The first PSUR of this product shall be submitted within 6 months following the Emergency Use Authorization (EUA) by PPB.

2. The Emergency Use Authorization Holder (EUAH) shall submit a monthly line list of all AEFIs and AESIs to pv@pharmacyboardkenya.org.
3. Pharmacovigilance plan: As part of the routine activities, "Traceability and Vaccination Reminder cards" the EUAH shall ensure the tools and process to implement this is available.
4. The Risk Mitigation measures plan shall include: Guidance should be provided that the vaccine should only be administered in facilities equipped with trained staff to attend to cases of anaphylactic shock.

   i. A proposal for educational materials for healthcare professionals to administer the vaccine.

   ii. A minimum period of 15 minutes of observation of each vaccinee after vaccination is given

   I v. The risk of potentially life-threatening anaphylactic/anaphylactoid reactions.

Conditions Related to Advertising and Promotion

Please note that all descriptive printed matter, including advertising promotional material relating to the use of COVID-19 Vaccine Janssen (Ad26.COV2-S [recombinant]) shall be consistent with the authorized labeling as well as terms applicable as per the Guidelines for Emergency and Compassionate Use Authorization of Health Products and Technologies, Guidelines for Advertisement and Promotions of Medicines and Medical Devices in Kenya and the Pharmacy and Poisons Act (*CAP 244*).

Emergency Use Authorization - H2021/CTD8692/20203EUA

All WHO-accepted drug substance and drug product manufacturing sites are hereby Authorized by the Board. Pharmacy and Poisons Board to be notified on any sites not specified in this EUA.

***Amendment I:* 27th August 2021

Annex III: Safety Monitoring guidance.

PHARMACY AND POISONS BOARD	REQUIREMENTS FOR SAFETY MONITORING	FOM 002/PER/MED/GUD/024
		Rev. No.2

Objective

The objective of the safety monitoring plan is to outline procedures for active pharmacovigilance during treatment of [condition] to ensure that healthcare professionals report all suspected adverse events (AEs) associated with medicines issued with Emergency Use Authorization to facilitate early detection of safety signals to promote patient safety.

Monitoring Aspects

1. All adverse events shall be documented and reported as detailed in the National Pharmacovigilance guideline: (https://pharmacyboardkenya.org/pharmacovigilance)
   a. Suspected unexpected Serious Adverse Reactions (SUSARS) including Adverse events following Immunization (AEFIs) should be reported within 24 hours
   b. Serious Adverse Events (SAEs) should be reported within seven (7) days.

2. Any such reports should include concomitant medication(s) used. These reports shall be submitted through the Pharmacy and Poisons Board Pharmacovigilance electronic reporting system at https://pv.pharmacyboardkenya.org/. In addition, information on patients treated with any of the medicines during pregnancy shall also be reported with follow-up on the outcome of the pregnancy. To assist the PPB in the assessment of suspected adverse events reports, as much information as possible should be provided in the initial report, particularly under listed information (use the Adverse events reporting tools in the Pharmacovigilance Electronic Reporting System)

   Suspected drug

   I. The age and gender of the patient

II. Description of the adverse reaction (including an indication of seriousness)
III. Patient's medical history (including any previously diagnosed/recently diagnosed conditions) e.g. diabetes, heart disease, chronic liver disease, asthma, HIV, active tuberculosis.
IV. Any concomitant medications, whether supportive or already prescribed
V. The outcome of the reaction (resolved, revolving, death)
VI. State whether the medicine was discontinued as a result of the adverse reaction

3. A line list of all the reported AEs should be prepared on an excel sheet using the format on the table below and submitted monthly.
4. All necessary laboratory parameters monitored must be documented and a list of out-of-range parameters reported before and after commencement of the use of [Medical Product and Health Technology].
5. Cumulative summary of the total number of patients (Including full demographic data) put on the Medical Product and Health Technology and the outcomes, e.g., negative conversion rate, time to body temperature normalization, death, need for ventilation, and radiological progression where monitored shall be submitted on a fortnight basis to Pharmacovigilance Division.
6. Information on product accountability shall be maintained and reported.
7. Your [Emergency Use] of this medicine should be well documented in the routine patient registry.
8. Adherence by the hospital to Good Records and Documentation practices to facilitate the reconstruction of the history of any related data in case of any regulatory decision and other GxP inspections.

LINE LIST FOR ADEs REPORTED WITH USE OF PRODUCT

No	Case Number	Case Report Type	Facility of Occurrence	Reporter Type	Age	Gender	List of Suspect Product Names	List of Concomitant Product Names	List of events	Case Level Serious	Case Relatedness	Case Narrative/ Description of the reaction	Case Outcome	Treatment Outcome
1														
2														
3														
4														
5														
6														
7														
8														
9														
10														

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