MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

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

JANUARY 2023

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HPT/PER/GUD/024	**Guidelines on Submission of Documentation for Emergency Use & Compassionate Use Authorization (Eua/Cua) of Health Products and Technologies**	**Revision No. 3**	**Effective Date:** 01/02/2023 **Review Date:** 31/01/2028

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ABBREVIATIONS

AMA	African Medicines Agency
AVAREF	African Vaccines Regulatory Forum
COVID-19	Coronavirus Disease 2019
CUA	Compassionate Use Authorization
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

GLOSSARY

For these guidelines, the following definitions shall apply:

Compassionate use means approval for use in isolated cases of the individual(s) or subpopulations i.e., where an unregistered medicinal product is made available to "patients with a chronically or seriously debilitating disease, or life-threatening disease or condition, including chemical, biological or radiological harmful exposure and who cannot be treated satisfactorily using a registered product and who are not eligible or participant(s) in a clinical trial.

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 and Compassionate Use Authorization (EUA/CUA) 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 or compassionate 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 and compassionate use Authorization of Health Products and Technologies.

The goal of the guideline is to outline the steps the Pharmacy and Poisons Board "the Board" shall use to establish the eligibility of investigational medicinal products or unregistered products for assessment under this procedure.

The guideline also gives guidance on mandatory information required and the process to be used in conducting the assessment to determine whether the

investigational medicinal product or unregistered product shall be approved to be listed on a time-limited basis, while further data is being collected and evaluated.

The EUA/CUA is not marketing authorization; it is applicable during declared emergencies where the Board shall accept less 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/CUA 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.

This document has been developed by experts on product evaluation and registration, pharmacovigilance, clinical trials, regulatory inspections, trade affairs, and legal department, from the Pharmacy and Poisons Board and Ministry of Health with technical support from USAID-MtaPs. 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

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) or compassionate use Authorization (CUA) shall follow product specific guidelines and the general guidance included in this guideline.

Compassionate use Authorization shall be applied for use in isolated cases of individual (s) or subpopulations where an investigational medicinal product is made available to "patients with a chronically or seriously debilitating disease, or life-threatening disease or condition, including chemical, biological or radiological attack and who cannot be treated satisfactorily using a registered product. Notably, this does not require a declaration of public health emergency to apply rather, it can be implemented whenever a situation occurs.

Products for compassionate use may be allowed to be used outside of clinical trials when: the disease is serious and life-threatening, no alternative treatment for the disease, the individual is not part of or eligible for the clinical trial, and the doctor justifies that there are no other options, and the experimental treatment may be of help. The Board may grant compassionate use authorization, based on evidence of such approval by an SRA or WHO whenever the Board may not be in possession of the data on the proposed product. In case the investigational medicinal product is undergoing clinical trial studies within the country and where there has been no authorization

by SRA or acceptance by WHO, the Board may approve for compassionate use upon advice from the mandated advisory scientific committees and/ or WHO.

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

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.

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.

Further, this guideline shall be applicable to investigational medicinal products or technologies for purposes of compassionate use.

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/compassionate 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.

ELIGIBILITY OF CANDIDATE PRODUCTS

The product categories to be reviewed under emergency and compassionate 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/CUA procedure.

To qualify for assessment under the EUA/CUA 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/CUA 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.

PHASES OF THE PROCEDURE

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

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/ CUA 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/CUA (assessment team). Further, the determination of the eligibility of products shall be done through pre-submission meetings. Selection of products for assessment 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.

1.2 Submission of applications

The applicant (for either EUA or CUA) 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). For the compassionate Use Authorization application process please refer to the application form (Annex IV). Additionally, the applicant shall be required to submit an informed consent form (Annex V).

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 / CUA 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 including the compassionate use authorization for health products and technologies. 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).

1.2.1 Regulatory pathway for evaluation of EUA/CUA

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

1.2.2 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.

1.2.3 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 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.

1.2.4 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.

NOTE:

For CUA, the applicant/sponsor/requesting physician shall fill out the CUA application form (Annex IV and the consent form (Annex V) together with the cover letter and submit it to PPB electronically or via hard copy.

In some instances, a CUA authorization may be granted with minimal information provided there is evidence of authorization by an SRA, acceptance by WHO, or authorization by the NRA of the country of origin. Such information may include but is not limited to; product details, product information, manufacturing site, country of release/country of origin, requesting institution, and individual (s) for whom the medicine is to be used.

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.

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/CUA guidelines, 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.

EUA/CUA APPLICATION PROCESS

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 or CUA 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.

CUA application

For compassionate use authorization, the applicant should provide information as per clauses 1-5,8, 10 (b),13 and 15 above.

Format of submissions for EUA/CUA

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.

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)

For CUA application format refer to Annex IV

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/CUA. If no queries are raised the application shall be recommended for Emergency use/ Compassionate use authorization.

After the initial submission of the EUA/CUA 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/ compassionate use authorization shall be subject to but not limited to the following conditions: -

1. For cases affecting individuals after a public health emergency has ended, the use of products may continue under the compassionate use authorization clause. The allowable CUA quantities of product being requested shall be based on the physician prescription. The maximum allowable CUA quantities/period of use shall be determined by pharmacy and poisons board on case by case basis to a maximum use period one year.
2. 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.

3. 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.

REGULATORY PROCESS TIMELINES

Approval timelines shall be determined on a case-by-case basis. In general, the approval timelines for abridged and WHO EUL-listed products applications shall be evaluated within Seven (7) calendar days of submission of complete documentation. For the initial assessment application (undergoing full assessment pathway), an application shall be reviewed within 30 calendar days. Any subsequent additional information shall be reviewed within Seven (7) calendar days. Screening for eligibility shall be accomplished within Seven (7) calendar days.

TERMINATION OF EUA/CUA

The validity of EUA shall terminate at the end of the emergency or as determined by the Board rule 8 of the Pharmacy and Poisons (registration of drugs) rules]. A CUA has a one-off use validity; renewable whenever applicable.

PUBLICATION

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

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

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

REFERENCES

- WHO Emergency Use Authorization procedure (version 9 January 2020).
- Guidance on Emergency Use authorization of medical products by USFDA (January 2017).
- 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).
- WHO collaborative procedures (WHO TRS 996- Annex 8).

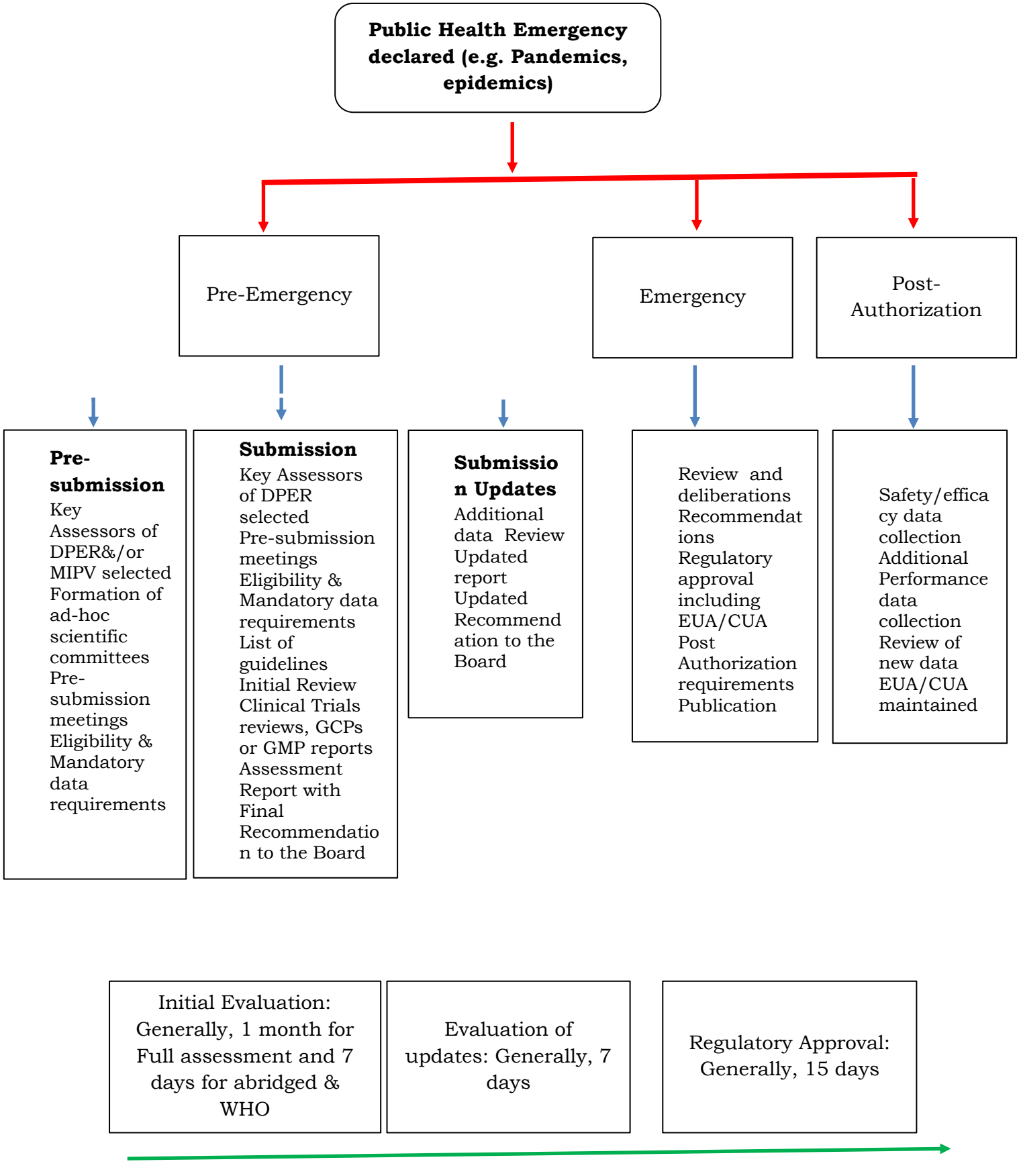
REVISION HISTORY

Revision No:	**Date**	**Author/Reviewer**	**Section(s) revised**	**Description of change**
Rev 0	12-18 Dec 2021	Pharmacy and Poisons Board		The Rev 0; was only for covering the COVID-19 To include any emergency infectious diseases
Rev 1	15th July 2022	Pharmacy and Poisons Board	The word "Investigational"	Changes of word "Investigational Medicine" to "Unregistered Medicine" in the definition of a compassionate use
Rev1	15th July 2022	Pharmacy and Poisons Board	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 2	9th January	Pharmacy and Poisons Board	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

ANNEXES

Annex I. Flow chart of the Regulatory process timelines

Annex II. Flow chart of the EUA/CUA process.



Annex III. 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 and Compassionate Use Authorization (EUCUA) 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*).

Po Box 27663-00506 Nairobi, Kenya

Serial No: 701df7b874ea6eae443cb81e9e069735

Date: July, 16th 2021

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 IV. Application Process form for CUA

PHARMACY AND POISONS BOARD	FORM FOR COMPLETING THE COMPASSIONATE USE AUTHORIZATION APPLICATION	FOM 001/PER/MED/GUD/024
		Rev. No.2

PLEASE READ THIS SECTION CAREFULLY BEFORE COMPLETING THIS FORM

I. The application form must be completed by an applicant (medical officer, pharmacist, or any authorized person by the respective Hospital Ethics Committee)

II. Every application must be accompanied by the relevant supporting documents

III. The Complete Application form shall be filled out for each request for Compassionate Use of a medicinal product, including Renewals.

SECTION A:

APPLICANT, PHYSICIAN, AND SHIPPING INFORMATION

Applicant's Details: First and last name of the applicant, designation, contact information (for group CUAs)

……

……

……

Physician's Details: If different from the applicant (for group CUAs), the first and last name of the responsible physician, and contact information. For an individual patient CUA, the applicant is the responsible physician.

……

……

……

Note: *The physician must be authorized by law to treat patients with any drug or drug substance intended for human use and requiring a prescription.*

Hospital or Clinic Name: Full name of clinic or hospital where the investigational medicinal product (IMP) or unregistered novel product is to be delivered when imported.

……

……

……

Address: Address of the physician's office/clinic or hospital pharmacy where the IMP/un-registered novel product is to be delivered, including the city, and postal code.

……

……

……

Contact Person: Full name and position (e.g Pharmacist,) of the person completing the form, if other than the requesting physician.

……

……

……

Contact Telephone number: A telephone number including an area code and extension (if applicable) where the practitioner or a contact person can be reached if further information or follow-up is required.

……

……

……

Contact's email address: An email address for the contact person should they need to be reached if further information or follow-up is required.

……

……

……

SECTION B:
UN-REGISTERED NOVEL PRODUCT AND MANUFACTURER INFORMATION

Brand Name/INN: Full name of an un-registered novel product, including international nomenclature (INN) and company designated code.

……

……

……

Name of Manufacturer: Full name of the manufacturer and location. Name and contact details (telephone number and email address) for the manufacturer or sponsor's contact person. The manufacturer or sponsor's contact person has agreed to supply the unregistered novel product to the requesting physician. Evidence of this acceptance by the manufacturer/ sponsor should be attached to the application form.

……

……

……

Route of Administration/Dosage Form: Key in the relevant information

SECTION C:
PATIENT INFORMATION FOR INDIVIDUAL OR GROUP REQUEST

1. Individual Request

Initials: First, middle (if applicable), and last initials of the patient. Note: To ensure confidentiality, indicate the inpatient number, outpatient number, or the unique patient identifier

……

……

DOB: specify the date of birth in order of date, month, and year order (i.e. DD/MM/YYYY).

.....

Sex: Check off the applicable box for the specified patient- Male or Female.

☐ Male ☐ Female

Indication: Exact medical indication for which the drug is being requested.

.....

.....

.....

New or Repeat Patient: Check the applicable box indicating whether this represents an initial or repeat. request for the patient for the specific IMP/ un-registered novel product.

☐ New ☐ Repeat Patient

Dosage and Duration: Prescribed dosage including planned duration of therapy. Strength: Required strength or combination of strengths.

.....

.....

.....

Quantity: Precise number of tabs, vials, etc. requested for each patient.

.....

.....

.....

1. Group Request

Identity of the group: with approximate number and age range, and any distinctive details.

.....

.....

.....

Indication: Exact medical indication for which the drug is being requested.

.....

……

……

New or Repeat Group request: Check the applicable box indicating whether this represents an initial or repeat request for the group for the specific IMP/ un-registered novel product.

☐ New ☐ Repeat Patient(s)

Dosage and Duration: Prescribed dosage including planned duration of therapy.

……

……

……

Strength: Required strength or combination of strengths.

……

……

……

Quantity: Precise number of tabs, vials, etc. requested for the group.

……

……

……

Total: Sum of the quantities for all patients. Note: Specify the exact amount requested (e.g., number of tabs, vials, units, etc.). *Your request will be returned if the quantity is not clearly stated.*

……

……

……

SECTION D: CLINICAL RATIONALE

Question 1a) New Patients: Provide information about the patient(s)'s medical history, including the severity of their condition, prognosis as well as

treatments considered, failed, unsuitable, or unavailable to achieve an adequate response. Include a rationale indicating what about the requested IMP/ un-registered novel product makes it the best choice for your patient(s) (i.e., mechanism of action, dosage form, drug class)

……

……
.

……

NB: Provide as attached the detailed information

Question 1b) Repeat Patients: Provide information on your patient(s) condition since treatment was initiated, including a rationale for continued access. Note: this section should be updated each time a renewal is requested to ensure that the patient(s)'s current medical state is well described.

……

……
.

……

NB: Provide as attached the detailed information

Question 2) References: Provide specific data/references with respect to the safety and efficacy of the product that supports the requesting physician's decision to prescribe the IMP/un-registered novel product for the specified indication. This can be in the form of medical literature, clinical protocols, investigator brochures, etc. *Append copies of the reference(s) to the request form.*

……

……
.

SECTION E:

PHYSICIAN'S ATTESTATION

This section consists of three attestations for the requesting and /or responsible physician to acknowledge and sign.

Physician's Signature: Requesting/ responsible physician's signature

……

License number: Requesting/responsible physician's license number (i.e. license to practice medicine as issued by the KMPDC)

……

Date:

……

SECTION F:

INFORMED CONSENT

The application should be accompanied by a consent form for each patient.

Processing of CUA Requests

The applicant/requesting physician should submit the complete application form to the PPB with a brief cover letter addressed to the Board's CEO.

The Board shall make every effort to process a request as rapidly as possible. Group requests may require additional time. After consideration of a request, approval may be granted. The Board shall send an approval letter or notice of decline to the applicant /sponsor or requesting physician.

Due to the urgency of CUA requests, applications shall ideally, be submitted to, and approval letters received from the Board electronically/through hard copy. It is the responsibility of the applicant/requesting physician to contact the Board in advance for related administrative information including submission options, the procedure, and applicable fees.

Annex V. Consent form for CUA

PHARMACY AND POISONS BOARD	INFORMED CONSENT FORM FOR COMPASSIONATE USE AUTHORIZATION	FOM 002/PER/MED/GUD/024
		Rev. No.2

INFORMED CONSENT FORM FOR COMPASSIONATE USE

If the patient in this compassionate use is under 18 years of age, the parental/guardian consent will be required.

1. Information about Compassionate Use Treatment and this Document

It has been determined that you have [Condition] which is of public health importance/life threatening/ severely debilitating. We believe that the [Health Product and Technology] may help you. There is currently no other available treatment that we believe would be as helpful for you.

[Health Product and Technology] is an investigational product. An investigational product is one that researchers are still studying to find out whether it is safe and effective. Because [Health Product and Technology] is under investigation, the Pharmacy and Poisons Board (PPB) has not yet registered it for general use.

[Health Product and Technology are not registered by the Pharmacy and Poisons Board (PPB) for your condition and therefore the use is under Compassionate Use.

The purpose of this consent form is to give you information about [Health Product and Technology] and to allow you to decide whether you want us to use it to treat you.

Please read this information carefully. It provides you with important information about the use of [Health Product and Technology]. This

information shall be reviewed with you and if you have any questions, you can ask at any time.

To help you decide if you want to take part, you should know:

I. Consent for use of [Health product and technology] is voluntary.
II. You can choose to say NO.
III. You are free to change your mind at any time even after you have accepted.
IV. Your decision won't cause any penalties or loss of benefits to which you are otherwise entitled to.
V. Your decision won't change the access to the medical care you get now or in the future if you decide to say "NO or YES" now but change your mind later.

If you agree to the use of [Health Product and Technology], you need to sign this consent form to show that you want to take part. We shall give you a signed copy of this form to keep. A copy of this form shall be put in your medical records, and another copy shall be submitted to the Pharmacy and Poisons Board.

Include the below information for cognitively impaired adults taking part in this compassionate use:

I. The person being asked to take part in this compassionate use may not be able to give consent for the use. You are therefore being asked to permit this person as his/her decision maker.
II. While you are taking [Health Product Technology], we shall tell you if we learn of any new information that may cause you to change your mind about allowing this compassionate use.

NB: *Before you sign this form, be sure you understand how [Health Product Technology]relates to your condition, as well as the risks and possible benefits of using it.*

2. Information about the treatment

Dr. [Include name, address, phone] would like to treat your [condition] using the [Health Product and Technology], [if the medical device, include a description of the device]. However, [Health Product and Technology] is not registered by the PPB for use in treating [condition]. Dr. [Name] is recommending the use of [Health Product and Technology] because S/he believes this is the best option to treat/manage your [condition] currently.

What will happen to you?
[Add information – in lay terms – of any procedures, blood tests, etc. that the patient will undergo as part of the treatment. Include an estimation of how long the treatment and any related follow-up shall last (e.g., duration of participation).]

3. Risks, Benefits, and other Alternatives

What are the risks of being treated with [Drug /Medical Device]?
[Describe reasonably foreseeable risks (including any risks to fetuses, if applicable). Include a statement that some risks may be unforeseeable. Include a statement about who to notify/what to do if side effects occur for example reporting to the PPB Pharmacovigilance reporting details] in case of ADRs.

What are the possible benefits of being treated with [Drug /Medical Device]?
[Describe anticipated benefits (e.g., cure of condition, minimizing severity/effects of a condition). Include disclosure that it is possible that the patient may not benefit]

What are the options if one does not want to allow compassionate use with (Drug/Medical Device)?

Inform the patient that s/he does not have to allow the compassionate use of the drug/medical device and that if s/he decides not to allow the use of the drug/medical device, his or her care at the hospital will not be affected.

What is usually done for patients who have this type of disease or condition? Standard treatments for [Condition] include [list and describe standard treatments, if any]. We shall be glad to talk to you about your other treatment options.

You are free to stop using this [Health Product and Technology] at any time, and your treatment with it is voluntary. Before stopping, you should discuss your choice with your doctor, as stopping its use may pose additional risks to you that your doctor may need to manage. If you stop treatment before it is finished, there shall be no penalty or loss of benefits to which you may otherwise be entitled. If you decide to stop treatment before it is finished, please tell one of the persons listed in Section 6 "Contact Information" (below).

4. Costs associated with this treatment

[Select one of the following then delete the other option as well as all bracketed instructions:]

[if manufacturer is providing free Health Product and Technology:]

The [Health Product and Technology] shall be provided to you at no cost. You or your insurance company shall be responsible for the remaining costs related to this treatment,

including the cost of treatment if the [Health Product and Technology] makes you sick or causes you injury. You shall be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company.

(if the patient will be responsible for ALL costs)
You or your insurance shall be responsible for the cost of all care associated with the procedure[s] and the [Health Product and Technology] itself. This includes the cost of treatment. If [Health Product and Technology] makes you sick or causes you injury, it is possible that your insurance shall not pay for the cost of the *[include as applicable* Health Product and Technology*, the procedure to implant the device]* because the [Health Product and Technology] is considered CUA. If that occurs, you shall be responsible for all costs, and these costs may be substantial.

By signing this form, you do not give up your right to seek compensation in case of professional negligence if you are harmed in the process of this treatment.

Shall you be paid to take part in this procedure?
You shall not be paid for taking part in this procedure.

5. Sharing of your information

If you give us permission to use [Health Product and Technology], we shall need to provide information about you, your condition, and your treatment to [Sponsor/Manufacturer Name], which is the manufacturer or supplier of the [[Health Product and Technology]] and to the Pharmacy and Poisons Board (PPB).

[Sponsor/Manufacturer Name] and the PPB require this information as part of the approval process for treatment use of [Health Product and Technology] and to monitor safety.

[Hospital Name], the Pharmacy and Poisons Board (PPB), and/or other ministry of health officials may also need to review your medical records to make sure that the [Health Product and Technology] is used in a safe and proper manner.

6. Contact Information

Who can I contact about this treatment?

Please contact the doctor to get the information listed below:

I. Obtain more information about the [Health Product and Technology]

II. Ask a question about the [Health Product and Technology].

III. Any adverse events that may be related to the use of the drug/device.

IV. Talk about treatment-related costs to you or your health plan.

V. Report an illness, injury, or other problem.

VI. Stop the treatment before it is finished.

VII. Express any concern.

(you may also need to tell your other doctors)

Doctor Overseeing Compassionate Use: [Name]

Mailing Address: [Address]

Telephone: [Phone]

When you call or write about a concern, please provide as much information as possible, including the name of the doctor providing treatment with the [HealthProduct and Technology], the title (at the top of this form), and details about the problem. This will help us look into your concern. When reporting a concern, you do not have to give your name unless you want to.

7. Signature

Consent

I have read (or it has been read to me) and fully understood the information in this consent document. I have had an opportunity to ask questions and all of my questions thus far have been answered to my satisfaction. If I have more questions or concerns, I may contact the person (s) listed in Section 6 of this consent document. I voluntarily agree to the use of [Health Product and Technology] for my treatment and understand that I can change my mind at any time. I do not give up any of my legal rights by signing this consent document.

Name:

_____

Signature:

_____

Date(dd/mm/yy):

_____

If the patient is not able to consent themselves to the use of this investigational/ CUA, use the following signature block to obtain permission from a legally authorized representative or a parent

Guardian or Parent Permission

I have read (or it has been read to me) and fully understood the information in this consent document. I have had an opportunity to ask questions and all of my questions thus far have been answered to my satisfaction. If I have more questions or concerns, I may contact the person (s) listed in Section 6 of this consent document. By signing this form, I am voluntarily providing permission for the use of [Health Product and Technology] to treat [Patient Name] and understand that I can change my mind at any time. I do not give up any legal rights by signing this consent document.

Name:

_____

Signature:

_____

Date (mm/dd/yy):

_____

Relationship to patient: ☐ Parent ☐ Spouse ☐ Child

☐ Sibling ☐ Legal Guardian ☐ Other (*specify*)

If "Other," explain the reason the patient is unable to consent:

_____

Doctor

I have provided this patient and/or his/her legally authorized representative(s) with information about this compassionate use that I believe to be accurate and complete. The patient and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the treatment, including the risks and benefits of its use.

Name:

_____

Signature:

_____

Date(dd/mm/yy):

_____

Annex VI: Approval Letter for CUA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Telegrams: "MINIHEALTH", Nairobi
PHARMACY AND POISONS BOARD HOUSE
Telephone: Nairobi 020 2716905/6 , 3562107
LENANA ROAD
Cellphone: 0733 – 884411/0720608811
P.O. BOX 27663-00506
Fax: 2713409
NAIROBI

When replying please quote
Ref. No.
Date:

Applicant/Sponsor/secretary hospital ethics committee

Dear Sir/Madam,

Re: **Compassionate use Authorization of ["health product and technology]" in Treatment/Diagnosis of [Disease /Condition**].

Reference is made to the above and your letter dated [].

The Board is cognizant that currently there is no registered medication or vaccine for treatment or prophylaxis of [Condition].

In view of this, the Board has considered and granted your request for Compassionate Use of (Product Name & strength) in [condition] cases in Kenya. The product details are hereby listed as follows:
Name of the product (brand Name):
INN name:
Name of the FPP manufacturer:

FPP site/s:

API site/s:

Yours Sincerely,

The office bearer & Signature

Title

Conditions of authorization [page 2]:

The Local Technical Representative (LTR):

1. The LTR shall ensure that all Adverse Events relating to the product, both at the authorized hospitals and out of the country are reported to the PPB promptly. Any such reports shall include any clinical data, including clinical trial data obtained in and out of the country.
2. The LTR shall maintain all such information and records in compliance with good records and documentation practice in case of any regulatory and other GXP inspections.

Authorized Hospitals:

1. The hospital shall ensure that all the patients or legal guardians sign the PPB-prescribed informed consent forms and as approved by the ethics committee in your institution, before administration of the product (Refer to Annexure V).
2. All adverse events shall be documented and reported every week, taking note of the requirement to report all fatal cases within 48 hours. Any such reports shall 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 to the individual case safety reports (ISCRs) submitted, a summary line list shall be submitted to the PV department (Refer to Annexure VI);

3. A cumulative summary of the number of patients given the product, patient outcomes, including negative conversion rate, time to body temperature normalization, death, need for ventilation and radiological progression where monitored, shall be submitted on a fortnight basis.
4. The hospital shall maintain and report information on product accountability.
5. Compassionate use of this medicine shall be well documented in the routine patient registry.
6. The quantities imported shall be aligned to the number of prescriptions or LPO submitted.
7. If a different therapy is registered (i.e., a marketing authorization has been issued) by the Board or there is compelling evidence against the use [health product and technologies] in treatment of [condition] the Board reserves the right to terminate this authorization.
8. Kindly note that this does NOT constitute a marketing authorization for the use of ((Product Name & strength).

Annex VII: 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/Compassionate 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/Compassionate 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														

P. O. Box 27663 - 00506 Lenana Road Opposite Russian Embassy Nairobi,
Tel: +254-02-12345/6789, Fax: +254-02-12345,
Website: www.Pharmacyboardkenya.org.ke,
Email: info@pharmacyboardkenya.org.ke