Republic of Kenya
Ministry of Health

PHARMACY AND POISONS BOARD

GUIDELINES FOR EMERGENCY AND COMPASSIONATE USE AUTHORISATION OF HEALTH PRODUCTS AND TECHNILOGIES

APRIL 2020

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Pharmacy and Poisons Board

VISION

To be a global leader in promoting and protecting public health

MISSION

To protect and promote the health of the public by regulating the profession of pharmacy and ensuring access to quality, safe efficacious and affordable health products and technologies

CORE VALUES

Commitment to Public health, Professionalism, Accountability and Transparency, Integrity and Respect, Quality and. Diversity and inclusion

Prepared by Quality Assurance Officer – PER Dep.

Sign.....

DR. ALI ARALE

Date...15/03/2020.....

Checked by Director, Product Evaluation and Registration

Sign.....

DR. RONALD INYANGALA

Date.....18/03/2020.....

Checked by Head, Quality Management

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Date.....20/03/2020.....

Authorized by Chief Executive Officer

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Date.....24/25 March 2020.....

ACKNOWLEDGEMENTS

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FOREWORD

The Emergency and Compassionate Use Authorization (ECUA) Guidelines have been developed in response to the COVID-19 (SARS-COV 2 Virus) pandemic. The guidelines describe the Pharmacy and Poisons Board procedure applicable to the authorization of the emergency use/compassionate use of health products and technologies (HPTs) as prescribed under Section 3B(2)(e) of the Pharmacy and Poisons Act, Cap 244; and, amended by the Health Laws (Amendment) Act, 2019. The recommendations under these guidelines will enhance the Board's preparedness to deal with public health emergencies including chemical, biological, radiological, nuclear agents and emerging infectious threats, such as, COVID-19. The ECUA is a risk-based procedure for assessing 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 procedure is to allow rapid authorization decision once an emergency is declared.

This guideline has been developed to provide guidance to industry (Manufacturers), stakeholders and local technical representatives on the documentation requirements and procedure for emergency use/compassionate use Authorization of health products and technologies (HPTs).

The goal of the guideline is to define the steps Pharmacy and Poisons Board (PPB) would use to establish the eligibility of the unregistered products (including unregistered indication of a registered product) for assessment under this procedure, mandatory information required and the process to be used in conducting the assessment to determine whether the unregistered product would be approved to be listed on time limited basis, while further data is being gathered and evaluated. In addition, the guidelines provide for conditions for importation of HPTs from non-traditional sources. The ECUA is not an alternative to product registration. It is to be used only during

declared emergencies where the Board would tolerate less certainty about the quality and safety of products given the mortality and/or morbidity of the disease and the lack of treatment, diagnostic or prevention options. The ECUA 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 document has been developed by Experts on Medicines Evaluation and Registration, Pharmacovigilance and Clinical Trials and Legal Department from Pharmacy and Poisons Board. The guidelines have been developed in reference to WHO emergency use Listing procedure, WHO Guidelines on regulatory preparedness for provision of marketing authorization of human pandemic Influenza vaccines in non-vaccine producing countries(WHO TRS No 1004, 2017 annex 7) and USFDA Guidance on Emergency Use authorization of medical products.

INTRODUCTION

Pharmacy and Poisons Board is mandated under the Pharmacy and Poisons Act to regulate Health products and Health Technologies.

Before a product is considered for approval, sufficient scientific and clinical evidence must be collected to show that it is safe, efficacious and of suitable quality. The scientific evidence includes quality data, safety and efficacy results from human clinical trials or non-clinical studies; it should be evident that the benefits of the product outweigh risks associated. This notwithstanding, 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.

When all above is in place, additional mechanisms like: Risk-management plan, Post-market surveillance for compliance verifications as well as investigations of potential health hazards should 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 Manufacturing Practices (GMP). Alternatively, available and reliable evidence of compliance and non- compliance with good practice requirements can be leveraged as part of the risk-based inspection planning process as prescribed in the WHO guidance on good practices for desk assessment. These guidelines prescribe data, which is required to be submitted to Pharmacy and Poisons Board to demonstrate the safety, efficacy and quality of the product being applied for market authorization.

Applications for emergency use and/or compassionate use shall follow product specific guidelines and the general guidance included in this guideline.

Compassionate use shall be applied for in isolated cases of sub-populations or individual (s)where a medicinal product is made available to “patients with a chronically or seriously debilitating disease, or a life-threatening disease or condition, including chemical or radiologic attack and who cannot be treated satisfactorily using a registered product. Thus, this does not require a declaration of public health emergency to be applied rather it can be implemented whenever a situation occurs. However, it should be noted that all procedures for Emergency Use Authorization shall apply for compassionate use authorization.

It is noted that for emergency and compassionate use products, there may exist limited data, including clinical data; the Board may accept reduced data requirements with commitment by the manufacturer/applicant to submit more data once available.

These guidelines should be read in conjunction with other international guidelines on quality, safety and efficacy as cited in this guideline namely the World Health Organization (WHO), USFDA and European Medicines Agency (EMA) on emergency Health products and Technologies and PPB’s product specific guidelines.

LEGAL FRAMEWORK

The Board is statutorily empowered to undertake various duties in execution of her mandate regarding regulation of health products and health technologies. This includes regulation of clinical trials, marketing authorization and post marketing surveillance. The regulation for the conduct of clinical trials is governed under the provisions of the Pharmacy and Poisons Act, Cap 244 Laws of Kenya as amended by the Health Laws (Amendment) Act, 2019 (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 3 of the Pharmacy and Poisons Act as amended by the Health Laws (Amendment) Act, 2019 to;

a) Grant or withdraw authorization for conducting clinical trials of medical products
b) Grant or withdraw marketing authorization for medical 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
e) Approve the use of any unregistered medicinal substance for purposes of clinical trials and compassionate use
f) Collaborate with other national, regional and international institutions on medicinal substances regulation.
g) Advise the Cabinet Secretary on matters relating to control, authorization and registration of medicinal substances;

Additionally, the Board is obliged under Section 25A (4) of the said Act to prescribe guidelines for 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 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 inform the approval of the use of any unregistered medicinal substance for purposes of compassionate use.

ABBREVIATIONS AND ACRONYMS

AMA	African Medicines Agency
AVAREF	African Vaccines Regulatory Forum
CP	Convalescent sera/Plasma
COVID-19	Corona Virus Disease 2019. Also known as SARS COV-2
DPER	Directorate of Product Evaluation and Registration
EAC	East African Community
EUCUA	Emergency Use & Compassionate Use Authorization
FDA	US Food and Drug Administration
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HPT	Health Products and Technologies
IMDRF	International Medical Device Regulators Forum
PHEIC	Public Health Emergency of International concern
PPB	Pharmacy and Poisons Board
PS	Product Safety Department
PV/PMS	Pharmacovigilance/ Post Market Surveillance
SRA	Stringent Regulatory Authority
WHO	World Health Organization

GLOSSARY

For the purposes of these guidelines, the following definitions shall apply:

- *Compassionate use* means approval for use in isolated cases of subpopulations or individual (s) i.e. where a medicinal product is made available to "patients with a chronically or seriously debilitating disease, or a life-threatening disease or condition, including chemical, or radiologic and who cannot be treated satisfactorily using a registered product.

- *Emergency use* means approval for use when 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, radiologic 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 procedure may also be applied in extreme situations such as during war.

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

- *The Board*- Pharmacy and Poisons Board

- *The National Pandemics Response Committee:* the national organ responsible for mitigation of effects of Infectious disease epidemics or pandemics.

- *The National Security Council:* the national organ responsible for national security.

SCOPE

These guidelines are intended to provide general considerations and guidance on content and format for regulatory submission of applications **for emergency/compassionate use** authorization of health product and technologies in Kenya. Emergency use products are those used in public health emergencies that include; emerging infectious diseases such pandemic influenza, Ebola, Corona virus pandemic and any other public health emergency/pandemic as declared by the Cabinet Secretary Ministry of Health.

ELIGIBILITY OF CANDIDATE PRODUCTS

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

(a) Medicines (therapeutics)
- Blood and Blood Product e.g. Convalescent sera/Plasma.
- Biotherapeutics products

(b) Vaccines

(c) In- Vitro diagnostics & Medical devices

(d) Health products and technologies from non-traditional sources

Examples of ECUA applications may include: -

- Use of registered product for prophylaxis or treatment of a condition not included in the indications and usage section of product information.

- Substitution of a critical agent of in vitro diagnostic with another reagent that has not been approved for use with the device.

- New Investigational product under ECUA (refer also to Clinical Trials Guidelines).

- Products from other countries or manufacturing facilities that are not registered by PPB

The four product categories would each have specific requirements for eligibility for evaluation under the ECUA procedure.

In order to qualify for assessment under the ECUA 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

pandemic and there are no registered products for the indication or for a critical subpopulation.

b) Existing products have not been successful in eradicating the disease or preventing outbreaks. Potential ECUA product may also be an antidote that may be effective to mitigate disease or condition caused by use of an already registered product.

c) The potential benefits of the product must outweigh 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) 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.

PPB may consider reviewing a candidate product for ECUA that does not meet all the requirements; this must be justified (e.g. in case it is the only option available at the time).

PHASES OF THE PROCEDURE

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

1.1. PRE-EMERGENCY PHASE

Pre-emergency Phase will include activities that can be done in advance (pre planned activities to tackle emergencies) thus reducing the time required to make final decisions for ECUA Authorization of a product. Pre-emergency phase should be in place, for instance, where an infectious disease 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 should be implemented in the subsequent phase.

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

A sponsor submitting data as part of Pre-emergency phase (pre-ECUA) activities should include a well-organized summary of the available scientific evidence of the product's safety and effectiveness/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 (when applicable, particularly blood and blood products) for specific products. This is critical as

it is very likely that in emergency circumstances that might be no existing standards that are fully applicable to a specific unregistered 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 Team.

1.1.1.Submission of Applications

The applicant (MAH) must submit an application with a cover letter to the Directorate of Product Evaluation and Registration, Pharmacy and Poisons Board. The cover letter should include details of the country of origin, sites of manufacture, proposed presentations for the product and information on whether or not an authorization for emergency use or equivalent has been issued by the national competent authority. The application shall be accompanied with a dossier in the appropriate format for each product category (Please refer to the product specific guidelines).

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

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

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

1.1.2.Regulatory Pathway for Evaluation

The applicant will indicate in the cover letter and the application form the proposed Regulatory pathway applicable to their product.

For Purposes of ensuring that quality, safety and efficacious/effective performance products for emergency use are assessed by the Kenyan public in a timely manner, three regulatory pathways have been designed for authorization of products under ECUA procedure.

1.1.2.1. Assessment of Initial Information (Full Assessment)

Product yet to be authorized for use by any regulatory agency or for products although approved by SRA but the assessment reports are not available to PPB will undergo initial evaluation by PPB and regulatory decision made. In addition to the ECUA 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 inspection of manufacturing and clinical sites, respectively.

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

The report shall include documented outcome of the evaluation of quality, safety, efficacy/immunogenicity/performance of the product by the DPER assessors and the Director, DPER or designate. 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 should 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. Please refer to timelines under the regulatory timelines section.

1.1.2.2. 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 the ICH member countries, EMA, USFDA and EAC member state, AMA or AVAREF and the assessment report is available to PPB will undergo Abridged evaluation and regulatory decision through reliance mechanisms. The applicant will be required to submit quality and abridged clinical data together with evidence of authorization in SRA. Please refer to timelines under the regulatory timelines section.

1.1.2.3. WHO COLLOBORATIVE PROCEDURE:

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

1.2. EMERGENCY PHASE

Most of the assessment activities shall be concentrated in the pre-emergency phase. The Board may request further information from the applicant before making its final regulatory decision.

1.3. POST AUTHORIZATION PHASE

The Board shall endeavor 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 surveillance mechanisms shall be applied in effecting collection and dissemination of 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)

- An outline of the post marketing pharmacovigilance plan for the product.
- Periodic benefit-risk evaluation report in accordance with ICH Guideline E2C(R2) Clinical Safety Data Management: Periodic benefit risk evaluation report
- Applicant should provide information on any on-going phase II/III/IV studies or on any active monitoring of the safety profile that is taking place.
- Risk management plan.

Once a product has been authorized under the EUCUA procedure, the development of the product must, if possible, continue to completion for attainment of marketing authorization.

The applicant shall inform the board in case of any post Authorization changes that may include but not limited to :-

Changes in formulation, manufacturing process, testing methods, specifications, facilities and any other aspect that might result in a change of 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.

Advertisements and/or promotions shall adhere to the legal and regulatory requirements.

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 SRA or WHO.

ECUA APPLICATION(S) PROCESS

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

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 ECUA is for an unapproved or off-label 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 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 will depend on whether the product is already registered for other indications or a New Investigational product, it will depend on the stage of development. Clinical Trials may be mandatory although this can be provided on Phase by Phase approach as the data accumulates from clinical trials. In other circumstances, a 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 EUCUA 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 experience, if available. If only animal data (including data on non-human primates) is available an extrapolation to humans should 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 EUCUA 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 EUCUA.

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

c) Data on activity or effectiveness in animals that would enhance understating 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 Non-clinical laboratory studies and whether the clinical studies were conducted in compliance with Good Clinical Practices. If the nonclinical laboratories studies were not conducted under GLP, evidence of quality systems put in place to ensure the quality and integrity of data from animal studies should be provided.

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

13. A discussion on Risk-benefit analysis should include the following:-

a) Measures taken to mitigate risks

b) Uncertainties and data gaps

c) Contraindications

d) Information concerning threats posed by the Chemical, Biological, Radiological, 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 documentations as part of the pre-emergency case.

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

16. **NOTE 1:** The guidelines provide for authorization for emergency use of health products and technologies from non-traditional sources on condition that the following requirements are met;

    a) The product is authorized for use in the exporting country and any of the stringent regulatory authority (SRA), like the ICH member countries, EMA, USFDA and EAC member state and AMA;
    b) The manufacturing facility is in compliant with Good Manufacturing Practices requirements of the exporting country and any of stringent regulatory authority (SRA), like the ICH member countries, EMA, USFDA and EAC member state and AMA;
    c) The products meet the quality, safety and efficacy requirements of PPB

17. **NOTE 2:** The following requirements may be waived by this ECUA procedure: Current good manufacturing practice requirements, including the quality system requirements with respect to the design, manufacture, packaging, labeling, storage, and distribution of the eligible product.

1.4. FORMAT OF SUBMISSIONS

An EUCUA application shall include the following:-

1. Cover Letter

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

2. Comprehensive Table of Contents for all Modules

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

3. The Application Body

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

- Guidelines for registration of Human medicine
- Guidelines for Registration of Human Vaccine
- Medical devices and Invitro diagnostic Guideline
- Biotherapeutic Guideline
- Blood and Blood product Guideline
- Guidelines on herbal and Complementary/alternative medicines.

Additionally, the applicant shall be required to provide Pharmacovigilance plan and Risk management plan (Guidelines on the safety and vigilance of

medical products and health technologies (https://pharmacyboardkenya.org/pharmacovigilance)

REGULATORY PROCESS

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

After the initial submission of the ECUA procedure, 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 unsatisfactory response. An applicant may request for withdrawal of the application after screening, before first evaluation, during query response and after unsatisfactory query response. Applicants of rejected applications may appeal to the board upon payment of prescribed fee.

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

1. The emergency use authorization shall terminate upon declaration of end of public health emergency.

2. For cases affecting individuals following a public health emergency, the use of products shall continue under the compassionate use authorization clause.

3. The applicant shall adhere to all commitments including additional data updates, continued clinical studies, safety reports, risk management plans and adherence to advertisements and/or promotions legal, regulatory requirements and safety and vigilance guidelines on MPHTs.

4. After declaration of the end of the public health emergency and based on the outcome of the continued studies, the applicant will be expected to submit a complete dossier for the evaluation for marketing authorization.

1.5. REGULATORY PROCESS TIMELINES

Approval timelines shall be determined on a case by case basis and maybe as short as in a matter of an hour or few hours. However, in general, the approval timelines for abridged and WHO EUL listed products applications shall be evaluated within 7 calendar days of submission of complete documentation. For initial assessment application, an application shall be reviewed within 30 calendar days. Any subsequent additional information shall be reviewed within 7 calendar days. Screening for eligibility shall be accomplished within 7 calendar days.

TERMINATION OF EUCUA

The duration of ECUA shall be up to when the emergency declaration is terminated as determined by the Cabinet secretary, Ministry of Health and the National Security Council or the Pharmacy and Poisons Board as advised by the National Committee on Pandemics Response. The National Security Council takes precedence. The applicants of products under ECUA shall be encouraged to transition them to the marketing authorization status i.e. registration.

PUBLICATION

The Board shall publish on the Board's website and make publicly available the following information of products authorized through EUCUA procedure:-

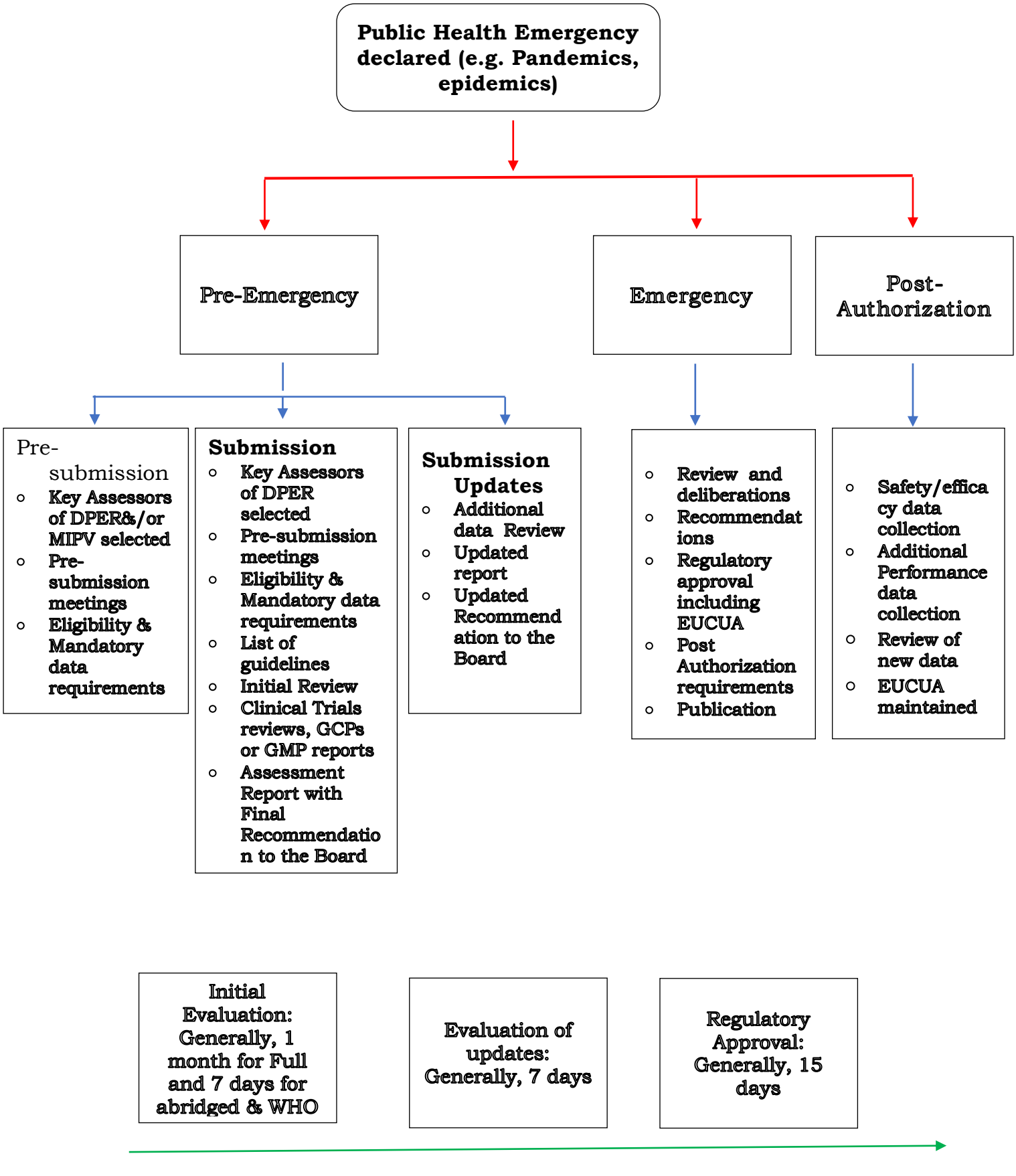
- The name of the products, the applicants and the manufacturers that have applied for EUCUA.
- A PPB EUCUA public report summarizing the findings of the EUCUA assessment.
- Include any negative outcomes of the EUCUA assessment.

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

ANNEXES

Annex 1. Flow chart of the Regulatory process timelines

Annex 2. Flow chart of the EUCUA process.



Annex 3. Emergency use/Compassionate use authorization template.

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

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PHARMACY AND POISONS BOARD HOUSE
LENANA ROAD
P.O. BOX 27663-00506
NAIROBI

When replying please quote

Ref. No.

Date:

Applicant/Sponsor.

Dear Sir/madam,

Re: Emergency use/Compassionate use Authorization of "Therapeutic /Vaccine /in-vitro Diagnostic/device" in Treatment/Diagnosis of "Disease /Condition".

Name of the product (brand Name):

INN name:

Name of the FPP manufacturer:

FPP site/s:

LTR:

Ongoing or planned clinical studies/performance studies:

Conditions of authorization:

Yours Sincerely,

The office bearer & Signature

Title

References

1. WHO Emergency Use Authorization procedure (version 9 January 2020)
2. Guidance on Emergency Use authorization of medical products by USFDA (January 2017)
3. WHO Guidelines on regulatory preparedness for provision of 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)

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