

Zambia Medicines Regulatory Authority

GUIDELINES ON EMERGENCY USE AUTHORISATION FOR MEDICINES AND IN-VITRO DIAGNOSTICS IN ZAMBIA

Contact details:
 Head Office, Plot No 2350/M, Off Kenneth Kaunda International Airport Road
 P.O. Box 31890, Lusaka, ZAMBIA
 Tel: +260 211 220429,
 E-mail: pharmacy@zamra.co.zm;
 Website: www.zamra.co.zm

	Name	Designation	Signature	Date
Prepared by	Mr. Lyoko Nyambe	Director-Marketing Authorisation		25/9/2026
Reviewer	Mr. Makomani Siyanga	Director-General		25/09/2026
Approver	Hon. Prof. Roma Chilengi, MP	Minister of Health		06-10-26



**TABLE OF CONTENTS**

1. INTRODUCTION.....	4
2. OBJECTIVES	5
2.1 General Objective	5
2.2 Specific Objectives	5
3. SCOPE	5
4. DEFINITIONS	5
5. ABBREVIATIONS.....	6
6. DECLARATION OF PUBLIC HEALTH EMERGENCY	7
7. TERMINATION OF A PUBLIC HEALTH EMERGENCY	8
8. ELIGIBILITY OF CANDIDATE PRODUCTS	8
8.2 Risk-Benefit Analysis.....	9
9. PHASES OF THE PROCEDURE	10
9.1 Pre-Emergency Phase	10
9.2 Emergency Phase.....	11
9.2.1 Assessment of Initial Information Received	11
9.2.2 Submission of Updates	12
9.2.3 Publication of Review Outcomes and Communications.....	12
9.2.4 Authorisation of Products in the EUA list based on Emergency Approval by Stringent Regulatory Authorities/WHO	12
9.2.5 Timelines for Evaluation of an Application and Validity	13
9.2.6 Revocation and Revision.....	14
9.3 Post Emergency phase	14
9.3.1 Importation Authorisations	14
9.3.2 Post Authorisation Monitoring	15
9.3.3 General recommendations for post-marketing monitoring plans comprise	15
9.4 Post-Authorisation Changes	15
9.5 Change in Authorisation Status	16
10. Annex 1 Criteria for Assignment of Assessment Pathways	17
11. Annex 2: Essential Data Requirements for EUA for Vaccines, Medicines and Invitro Diagnostics	19

	Document No.: MA/GUD/011 Guidelines on Emergency Use Authorisation for Medicines and In-Vitro Diagnostics in Zambia	Page 3 of 29
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12. Annex 3: Notes and Disclaimers - EUA List of Candidate Products General notes 27



1. Introduction

The Zambia Medicines Regulatory Authority (ZAMRA) has developed the Emergency Use Authorisation (EUA) regulatory mechanism to expedite the availability of medicines and allied substances needed during public health emergencies and to provide guidance to applicants and procurement entities in determining the acceptability of specific products for use on the Zambian market, based on available quality, safety, efficacy, immunogenicity, and performance data.

In accordance with Section 39 (4) of the Medicines and Allied Substances Act No. 3 of 2013, ZAMRA may apply the Emergency Use Authorisation (EUA) framework during a declared public health emergency to facilitate timely access to unregistered medicines and allied substances where there are no adequate, approved, and available alternatives, for the diagnosis, treatment, or prevention of serious or life-threatening diseases or conditions. The authorisation is based on an assessment that the available data reasonably demonstrates that the product's quality, safety, and efficacy/performance are acceptable and that the anticipated benefits outweigh the potential risks and uncertainties in the context of a national or international public health emergency. The EUA framework is not intended to interfere with ongoing clinical trials or product development studies, and clinical development should continue as planned with subsequent data updates. In view of the afore stated, the Authority may implement expedited regulatory pathways and other appropriate regulatory measures to expedite the EUA.

These guidelines provide the regulatory requirements for the authorisation of medicines and allied substances for emergency use during a declared public health emergency, including situations that pose a significant risk to public health, safety, or national security, and are intended to guide applicants, government ministries, departments, agencies, and procurement entities on the submission and assessment process for Emergency Use Authorisation (EUA). These guidelines should be read in conjunction with other relevant guidelines available on the Authority's website (<https://www.zamra.co.zm/guidelines/>), and the Authority may request additional data or information where necessary to support decision-making.



2. Objectives

2.1 General Objective

To ensure that products authorised for EUA are of the acceptable quality, safety, efficacy and performance.

2.2 Specific Objectives

- i. To determine the eligibility of products without Marketing Authorisation (MA) for assessment under the EUA.
- ii. To prescribe the essential information required for EUA.
- iii. To provide expedited mechanisms for ensuring availability of medicines/vaccines in an emergency.
- iv. To provide guidance on the assessment pathways for EUA.
- v. To provide mechanisms for monitoring the safety of products granted an EUA.
- vi. To provide procedures for importation of products authorised under the EUA.

3. Scope

This document is intended to provide guidance to applicants on the Authorisation for use, Importation and safety monitoring of products without MA in an emergency. The scope of this guideline covers medicines, vaccines and medical devices for human use.

4. Definitions

Public Health Emergency: means an occurrence or imminent threat of an illness or health condition, caused by bioterrorism, epidemic or pandemic disease, or a novel and highly fatal infectious, chemical or biological agent.

Confidential Information: This refers to confidential intellectual property, know-how, and trade secrets (including formulas, processes or information contained or embodied in a product, unpublished aspects of trademarks, patents); and commercial confidences (structures and development plans of a company).

Minister: Minister responsible for Health.

Risk-Benefit Analysis: Products are eligible for EUA if the Authority determines that the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks of the product.



The Authority: This refers to Zambia Medicines Regulatory Authority

5. Abbreviations

AEFI	Adverse Event following Immunization
CTD	Common Technical Document
DOI	Declaration of Interest
EMA	European Medicines Agency
MA	Marketing Authorisation
ERA	Environmental Risk Assessment
EUA	Emergency Use Authorisation
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMO	Genetically Modified Organisms
GMP	Good Manufacturing Practices
GCP	Good Clinical Practice
QMS	Quality Management Systems
ICH	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
IVDs	In Vitro Diagnostics
NRA	National Regulatory Authority
PHE	Public Health Emergency
MoH	Ministry of Health
PHEIC	Public Health Emergency of International Concern
PQ	Prequalification



PSUR	Periodic Safety Updated Report
R&D	Research and Development
RUO	Research Use Only
WLA	World Health Organisation Listed Authority
TCM	Technical Committee for Medicines
TRS	Technical Report Series
UN	United Nations
WLA	WHO Listed Authority
WHO	World Health Organization
ZAMRA	Zambia Medicines Regulatory Authority
ZNPHI	Zambia National Public Health Institute

6. Declaration of Public Health Emergency

The Authority may issue an EUA, following a declaration of a public health emergency by the Minister responsible for health. The declaration follows an event that causes an immediate risk to health, life, property, or the environment and can be of national and/or international concern. Such extraordinary events are determined as those that:

- Immediately threaten life, health, national security, property or the environment;
- Have already caused loss of life, health detriments, property damage or environmental damage;
- or
- Have a high probability of escalating to cause immediate danger to life, health, property or the environment.

In case of an emergency declaration, it is important to differentiate between the emergency declaration allowing for an EUA procedure and the emergency declarations issued by other governmental authorities to manage a PHE. For example, a government may put in place a “national state of disaster” to implement protecting mechanism for the management of a crisis. This “state of
Version No. 1



disaster” does not automatically allow for an EUA procedure but other measures to combat it.

7. Termination of a Public Health Emergency

When a PHE is officially declared over by the Minister responsible for health, then any EUA(s) issued based on that PHE will no longer remain in effect. The Authority will inform the stakeholders that the circumstances that precipitated the EUA have ceased. Nationally, legal provisions other than EUA may be in place for continued use.

8. Eligibility of Candidate Products

For a product to be eligible for EUA, the disease or condition for which it is intended should have been declared a public health emergency and should meet the following criteria:

- a. The disease or condition for which the product is intended is serious or immediately life threatening, has the potential of causing an outbreak, epidemic or pandemic and it is reasonable to consider the product for an EUA assessment, for example, there are products without MA for the indication or for a critical subpopulation (for instance in children).
- b. In the case of vaccines and medicines, existing products have not been successful in eradicating the disease or preventing outbreaks. There must be no adequate, approved, and available alternative to the candidate product for diagnosing, preventing, or treating the disease or condition. A potential alternative product may be considered “unavailable” if there are insufficient supplies of the approved alternative to fully meet the emergency need. A potential alternative product may be considered “inadequate” if, for example, there is contraindicating data for special circumstances or populations (children, immunocompromised individuals or individuals with a drug allergy), if a dosage form of an approved product is inappropriate for use in a special population (for example a tablet for individual who cannot swallow pills), or if the agent is or may be resistant to approved and available alternative products;
- c. The product is manufactured in compliance with current Good Manufacturing Practices (GMP) in the case of medicines and vaccines and under a functional Quality Management System (QMS) in the case of medical devices;
- d. that the known and potential benefits outweigh the known and potential risks of the product when used to diagnose, prevent, or treat the serious or life-threatening disease or condition that is the subject of a declared public health emergency;



- e. The applicant commits to complete the development of the product. For that purpose, the remaining clinical trials and other testing needed to complete the development of the product must already be underway at the time of the application for an EUA;
- f. That the products are procured by the Government of Zambia to address public health emergencies or shortages;
- g. That products for a public health emergency are caused by a highly transmissible infectious agent with high morbidity or high mortality or both, where there is no approved cure in Zambia and other countries; and
- h. That products developed and manufactured are developed in the country of origin but are not approved and used there because the target infectious disease has low endemicity and/or prevalence but still is prevalent in Zambia.
- i. Products that have been listed by WHO in the context of a Public health emergency.

Any other unforeseen circumstances where access to the medical product is justifiable and is deemed beneficial to the public.

8.2 Risk-Benefit Analysis

Products are eligible for EUA, if the Authority determines that the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks of the product. In determining whether the known and potential benefits of the product outweigh the known and potential risks, the Authority intends to assess the quality and quantity of the evidence, given the current state of scientific knowledge, of risks and benefits. The Authority intends to use this information to make an overall risk-benefit determination. To accomplish this, the Authority plans to look at the totality of the scientific evidence, which could arise from a variety of sources.

The Authority intends to evaluate and consider all evidence, including results of domestic (local) and foreign clinical trials, animal data (pre-clinical), and in vitro data, available for consideration. The Authority anticipates that, for some candidate products, data from clinical trials control will be available. For others, the Authority expects to consider clinical studies other than a controlled trial if the circumstances warrant. For others, in vivo efficacy data may only be available from animal models.



9. Phases of the Procedure

The EUA may not be issued until after a public health emergency has been declared by the responsible Minister. However, the Authority recognizes that during such exigent circumstances, the time available for the submission and review of an EUA request may be severely limited. Therefore, the Authority strongly encourages an entity with a possible candidate product, particularly one at an advanced stage (phase 2 clinical studies for medicines, comparative studies and risk analysis for medical devices) of development, to contact the Authority for the candidate product even before a determination of actual or potential emergency.

This guidance offers recommendations for both pre-emergency activities to be conducted prior to the determination of actual or potential emergency and emergency activities to be performed once the determination has been issued. In addition, this section of the guidance sets out the types of information that is important to allow an assessment of safety and effectiveness and to make an adequate risk-benefit determination to support issuance of an EUA.

There are 3 phases of the EUA procedure:

- i. Pre-emergency phase;
- ii. Emergency phase, and;
- iii. Post-Authorisation phase.

9.1 Pre-Emergency Phase

Activities in the pre-emergency phase should include engagement with the Authority on a prospective EUA product and the appropriate procedure to use when submitting data on the product prior to a determination of actual or potential emergency.

The Authority strongly recommends that an entity submitting data during a pre-emergency period follow the recommendations for data submission contained in "Essential data requirements for EUA for vaccines, medicines and medical devices," Annex 2.

If, prior to the declaration of an emergency, the Authority determines that a candidate product may meet the criteria for an EUA, the Authority may share appropriate information on such product with the Ministry responsible for Health.



9.2 Emergency Phase

In this phase, the evaluation of a specific product or group of products for a specific disease will be determined by the Authority upon declaration of a public health emergency. Once a determination of actual or potential emergency has been made, the Minister responsible for health may declare an emergency justifying the authorisation to consider an application for the use of product without MA for an unapproved use. The Minister responsible for health may consult with the Authority and other agencies and private entities, where appropriate, to identify products that may be eligible for an EUA in light of the circumstances of the emergency and to facilitate timely submission of the EUA request by an appropriate entity or applicant.

This procedure includes provisions that concentrate on most of the activities related to the submission and assessment of available data in the pre-emergency phase and emergency phase stages. Therefore, optimally the Authority will have all the necessary information to deliberate and issue a recommendation to the committee on whether or not a product should be listed, and if so, under what conditions for use, in a short period of time. The Authority may request additional information from the applicant before making a decision.

9.2.1 Assessment of Initial Information Received

All applications during public emergencies shall be received through Integrated Regulatory Information Management System (IRIMS). The Screening and Validation Unit will perform the screening of the submission to ensure that sufficient information is available to initiate the assessment based on the essential data requirements (See Annex 2). If the screening indicates that the assessment cannot start due to lack of information, this will be communicated to the applicant. A complete dossier may be submitted any time afterwards.

The criteria for selecting the assessment pathway for vaccines, medicines, and in vitro diagnostics under emergency use authorization are outlined in Annex 1. It outlines the applicable assessment approaches based on the registration status of the product, these include abridged assessments for products authorized by recognized WLA or WHO, and full reviews in accordance with the Authority's EUA Guidelines.

In addition to the EUA dossier review process, the GMP inspection team may conduct a desk review of available inspection reports. As appropriate, the GMP inspection team may also undertake on-site inspection of manufacturing sites depending on the outcome of the desk review or if the GMP



inspection team recommends so. The product may Further, the GCP inspection team may conduct onsite inspection of the clinical sites, depending on the outcome of the assessment of the clinical data.

A consolidated assessment report will indicate whether the information received is considered sufficient for a recommendation, or if additional information is needed prior to giving a recommendation. If the applicant has provided a timeline for additional results according to the product development plan, this will be indicated in the consolidated report.

9.2.2 Submission of Updates

After the initial submission of the application with all the required information for initial assessment, applicants should promptly submit any additional information on the development of the product to the Authority, particularly if it may affect the product's risk/benefit assessment.

The applicant should provide tentative timelines for the submission of additional information based on the expected dates of completion or planned interim analysis of studies currently ongoing or being initiated soon.

Submission of updates and additional data should clearly follow the section numbering system of the initial submission (see Essential Data Requirements in Annex 2).

9.2.3 Publication of Review Outcomes and Communications

The Authority will communicate the decision of the review outcomes to the Minister responsible for health and/or the relevant applicant while respecting confidentiality and other intellectual property rights.

The Authority will maintain an to date list of products issued EUA. The List will be publicly available. Annex 3 provides general notes and disclaimers relating to the Emergency Use Authorization (EUA) list of Candidate Medicines and Medical Devices.

9.2.4 Authorisation of Products in the EUA list based on Emergency Approval by Stringent Regulatory Authorities/WHO

The Authority may recognize the emergency evaluation and approval of products by regulatory authorities that apply stringent standards for quality, those recommended by the Authority such as, but not limited to, the US Food and Drug Administration (USFDA), the European Medicines Agency (EMA), Health Canada (HC) and the World Health Organisation (WHO).



Where an abridged reliance procedure is being used for a product that has been WHO listed or given EUA by a WLA, the Authority will review the assessment reports of the product. The acceptability of consideration of the EUA to be assessed under the abridged reliance procedure will depend on the applicant submitting the same information or dossier. When an abridged/reliance procedure is used, the dossiers and assessments reports will be reviewed for acceptability taking into consideration any regional or local requirements. The Authority will make a decision based on the considerations noted on the quality, safety and efficacy of the product using the abridged review procedure of the EUA. This focus means that the Authority may still undertake some extra assessment activities if deemed necessary or request the dossier that was assessed previously through other emergency mechanisms.

9.2.5 Timelines for Evaluation of an Application and Validity

The timelines for evaluation and action on an application for Emergency Use Authorisation (EUA) shall depend on the product profile, the nature and severity of the public health emergency, the availability and completeness of submitted data, the existence of any pending applications for the product, and any other relevant factors. In circumstances where complete clinical trial or supporting data are not yet available, as may occur during a public health emergency, the Authority may review and assess data as they become available from ongoing studies and other credible sources.

Screening	Reliance	Work-sharing	Full Assessment
2 working days	10 working days	10 working days	30 working days

The validity of an EUA will be 12 months or when the public health emergency ends. All decisions to list a product in the EUA will be reassessed at 12 months intervals (or sooner, if further data becomes available that could alter the original decision). When deemed necessary, the emergency use Authorisation can be extended. Products may be taken off the EUA list earlier, if new data become available that change the benefit-risk balance of the product or immediately upon termination of the public health emergency, whichever comes first.



9.2.6 Revocation and Revision

The Authority will periodically, at minimum once, prior to expiration of the validity of the EUA, review the decision concerning the circumstances and appropriateness of the EUA, including circumstances that might warrant revocation or revision of the EUA. The review will include regular assessments based on additional information provided by the EUA holder. The Authority will revise or revoke EUA if:

- i. Initial circumstances justifying the issuance no longer exist; or
- ii. Other circumstances require a revision or revocation to protect the public health or patients' safety.

Such circumstances may include:

- i. Significant adverse inspectional findings (e.g., when an inspection of the manufacturing site and processes has raised significant questions regarding purity, potency, or safety of the EUA product that may affect the risk/benefit assessment);
- ii. Reports of adverse events linked to the EUA product;
- iii. Product failure in terms of pharmaceutical quality;
- iv. Product ineffectiveness (e.g. due to newly emerging data that may contribute to a revision of the Authority's initial conclusion that the product "may be effective against a particular pathogen);
- v. Request from the EUA holder to revoke EUA;
- vi. A material change in the risk/benefit assessment based on evolving understanding of the disease or condition and/or availability of medical countermeasures; or
- vii. A change in the approval status of the product (that may render an EUA unnecessary).

9.3 Post Emergency phase

Activities After a Product Has Been Listed, Deployed and Used.

9.3.1 Importation Authorisations

Import authorisations shall be issued by the Authority in accordance with Section 39(4) Medicines and Allied Substances Act No. 3 of 2013.

The Authority shall prioritise processing of import permit applications for products granted EUA.



9.3.2 Post Authorisation Monitoring

After a product has been listed, the Authority will take into consideration reports on safety surveillance, efficacy, effectiveness, performance monitoring, quality complaints and other relevant data that may impact the validity of the Authorisation status.

The manufacturer will have the primary responsibility to provide information on active post-Authorisation surveillance based on post-Authorisation surveillance commitments. Periodic Safety Update Reports (PSUR) should be provided every six months or as soon as new data arises.

Other sources of such information will among others be based on existing surveillance mechanisms within the Country (such as but not limited to AEFI, ZNPHI, MoH).

The Authority reserves the right to issue an information notice for procurement agencies and relevant programs, if at any time, the Authority deems that the EUA holder is not responding to a post-Authorisation quality or safety issue in a timely and/or scientifically sound manner. The Authority shall continue to monitor the quality, safety and efficacy/performance of the product. If quality, safety and performance concerns cannot be resolved to regulatory requirements' satisfaction, the Authority reserves the right to restrict or revoke the emergency use Authorisation of the product(s).

9.3.3 General recommendations for post-marketing monitoring plans comprise

- i. Submission of reports of specific adverse events of interest in an expedited manner beyond required routine reporting;
- ii. Submission of adverse event report summaries (i.e. PSUR/PBRER) is at more frequent intervals (i.e every 3 months) than specified for routine reporting required;
- iii. Submission of the Authority's specific requirements on post-authorisation plans;
- iv. Further studies, e.g. pharmacoepidemiologic study may be imposed to further evaluate important identified or potential risks or study uncommon or delayed-onset adverse events of special interest; and
- v. A pregnancy exposure registry that actively collects information on use of the medicinal product during pregnancy and associated pregnancy and infant outcomes.

9.4 Post-Authorisation Changes

The EUA holder must promptly notify the Authority of all changes that may affect the quality, safety and efficacy/performance of the product. Such changes to the product(s) shall follow the Authority's



Amendment Guidelines for Marketing Authorisation and require prior approval.

Changes to products listed based on reliance procedures must be accepted for emergency use by the original WLA responsible for the oversight of the product or WHO and the Authority must be notified of the accepted changes by the applicant.

9.5 Change in Authorisation Status

In the post-EUA phase, the authorisation status of the EUA product may change depending on the circumstances and a full marketing authorisation as the ultimate goal might be obtained. There are different ways to receive a full marketing authorisation of the medical product:

1. The Authority requires the EUA holder to provide a plan for fulfilling conditions for a full marketing authorisation prior to the termination of the emergency declaration. If the emergency has been declared over before these requirements have been met, the EUA holder shall be encouraged to transition the product to the (full) marketing authorisation status.
2. In case a reference authority has granted full marketing authorisation, reliance will be used in order to grant full authorisation before the emergency ends. This approach may be applied, especially when the EUA itself was also based on a reliance mechanism.

**10. Annex 1 Criteria for Assignment of Assessment Pathways*****Vaccines***

The following criteria will be followed to determine the assessment approach

Table 1: Assessment Pathways for vaccines

Status of the Vaccine	Pathway to be used
1. Vaccine approved for emergency use by a recognized WLA, WHO for the target disease and agreement in place between WHO and the NRA for the exchange of information.	A
2. Vaccine not approved for emergency use by a WLA, WHO for the target disease or no agreement in place with the WLA	B

Key

A: Abridged assessment, consisting of initial assessment of:
Report(s) from the responsible WLA, WHO (Summary basis for the emergency use approval or equivalent).

Programmatic aspects

B: For all vaccines not listed by the WHO, or WLA. The Authority shall conduct a review according to the Authority's EUA guidelines. An Inspection report (conducted by the Authority) shall be required and programmatic aspects shall be considered.

Programmatic aspects include: indication, dosage, conservative, storage temperature, auto disable syringe, etc.

WHO prequalification includes assessment of regulatory data and inspection of site.

Medicines**Table 2: Assessment Pathways for Medicines**

Registration Status	Assessment Approach	Inspection
1. Product authorized for emergency use by the WLA or WHO for the target disease	Abridged assessment based on the WLA or WHO report	Desk review of available WLA or WHO inspection reports, and/or if required, inspection by the Authority.
2. Product not approved for emergency use by the WLA or listed by WHO for the target disease	The Authority will conduct a review to the EUA guidelines. The review will also consider available assessment reports prepared by NRAs.	Inspection by the Authority and/or desk review of available WHO or WLA inspectorate reports

*In Vitro Diagnostics***Table 3: Assessment Pathways for IVDs**

Description	Assessment approach	Inspection
1. Product assessed through another emergency mechanism of an acceptable standard	Abridged initial assessment of reports	Desk review of the QMS
2. Product not assessed through another emergency mechanism of an acceptable standard	The Authority will conduct a review according to the EUA guidelines	Desk review of the QMS and/or inspection if required

Abridged IVD/Medical Devices EUA Assessment

For IVDs, some submissions for the Authority EUA may have undergone a previous assessment through other emergency mechanisms, for example, WHO, EMA, the United States Food and Drug Administration (USFDA) Emergency Use Authorisation (EUA) process. Where this is the case, it is not the intent of the Authority to undertake duplicative work, if the review of the other emergency mechanism is deemed to be of a satisfactory standard.

The ability to waive aspects of the EUA assessment in these circumstances can be applied to any of the two steps of the review. However, the EUA is designed to provide a minimum level of assurance of the quality, safety, and performance of products without MA for the primary purpose of use in the setting of a current public health emergency. This focus means that the Authority may still undertake some extra assessment activities if deemed necessary or request the dossier that was assessed previously through other emergency mechanisms.

**11. Annex 2: Essential Data Requirements for EUA for Vaccines, Medicines and Invitro Diagnostics**

Overview of required data for an EUA at each emergency stage.

	(Pre-) Emergency Phase: Submission EUA	Emergency-Phase: Decision EUA	Post - EUA Phase
A description of the product and its intended use	√		
A description of the product's international marketing authorisation (MA) status.	√		
The need for the product including any approved alternative product(s) and their availability and adequacy for the proposed use, and the unmet medical need(s) the EUA address.	√		
All available safety and efficacy information for the product	√	√	√
A discussion of risks and benefits	√	√	√
Information on chemistry, manufacturing, controls and stability	√	√	√
A list of all sites where the product, if EUA is granted, will be (or was) manufactured and the GMP status of the manufacturer		√	√
Information about the quantity of finished product on hand and the surge capabilities of the manufacturing site(s)		√	√
Information comparable to summary of product characteristics and patient information leaflet ("Instructions for Use"-documents)	√	√	√
Proposed labeling of primary and secondary package	√	√	√
Product samples as per sampling schedule	√	√	√

The expectation is that the manufacturing or quality control and clinical development of the product submitted for EUA will continue product development and ultimately be submitted for MA, the submission for EUA of medicines and vaccines should follow the ICH CTD format. In the CTD dossier, sections for which no information is available at the time of the initial submission should be indicated as "data or information not available", "study ongoing" or "not applicable" as the case may be.

For IVDs, applicants should follow the dossier structure requirements laid down in documents *Guidelines on application for Grant of Marketing Authorisation of In-Vitro Diagnostic Devices for*

Use.

For IVDs, the dossier content requirements may differ depending on the analyte being detected and clarification of specific data requirements will require discussion between the applicant and the Authority in advance of submission.

The following requirements outline the minimum data and information to be submitted in support of an application for Emergency Use Authorization (EUA) for vaccines, medicines, and in vitro diagnostics during a public health emergency. The requirements are intended to facilitate a risk-based assessment of the quality, safety, efficacy, and performance of products, while ensuring that appropriate measures are in place for pharmacovigilance, risk management and product monitoring.

A. VACCINES

Manufacturing and Quality Control Data:

1. Full characterization of cell banks according to recognised international guidelines including WHO Technical Report Series (TRS) 978, and any subsequent updates.
2. Full characterization of master and working seed organism(s), based on reference to the most appropriate guideline (listed in the Authority's Vaccines guideline or recognised international guideline).
3. Process validation (based on quality risk assessment for the development stage) and demonstration of consistency of manufacturing at the production scale used for the lots to be distributed. If deemed appropriate, data on clinical batches with a commitment to complete validation on production batches and to submitting the data as part of lot release review may be considered. It should be noted that if full characterization is not possible at the time of submission, adequate justification must be submitted, and a plan must be presented to address the data gaps. Validation of potency tests and other critical assays should be provided. If novel test methods have been developed, full description of the test development and qualification must be presented.
4. Justified specifications for starting material, intermediates, and final products.
5. Stability studies data should be provided for the lot size to be supplied. For vaccines being assessed for emergency use, the Authority shall consider programmatic suitability. A minimum of 3 months stability data shall be required for both accelerated and long-term stability studies.
 For vaccines requiring low temperatures at less than -20°C (e.g -60°C), considerations regarding infrastructure for vaccine storage and distribution at these required temperatures for recipient countries will be made.
 Routinely, multi-dose vaccines should contain adequate preservative, unless they are live-attenuated vaccines. However, if a multi-dose vaccine submitted under this emergency



procedure does not contain a preservative, information/plans on how such a vaccine could be safely managed in the field should be submitted.

6. Recent Inspection report(s) from the responsible WLA, WHO, inspection team or the Authority inspection team showing compliance with current GMP requirements, where applicable.
7. Process changes: by the time of submission, it is likely that the manufacturing process is not finalised and that numerous changes will have to be made after the first emergency authorisation. These changes should be submitted as updates.

B. Non-Clinical and Clinical Data

Data from phase 2 shall be provided, if not available, animal immunogenicity data and data from phase 1 shall be considered. Where early phase 3 interim data are available, it should be provided as well.

Products developed under the animal rule will also be considered for review.

1. Non-clinical data demonstrating acceptable safety, immunogenicity, and efficacy – if available- in the most appropriate animal model. The applicant must justify the choice of animal model.
2. If the non-clinical package is not complete at the time of submission, the applicant must submit adequate justification for the lack of complete data and a plan and timeline for submitting those data.
3. Clinical data demonstrating the appropriate dose to be used and initial acceptable safety and immunogenicity in the population in which the vaccine will be used in the context of the public health emergency.
4. Preliminary data showing some efficacy– if available. If preliminary human data showing some efficacy are not available for the vaccine under consideration and if not imminently available for other vaccines being concurrently developed, the Authority will consider whether the preponderance of evidence from the non-clinical, and early human studies justifies considering the immunogenicity data as a potential surrogate that is thought to be reasonably predictive of clinical efficacy. In such cases, the EUA can proceed, provided there are trials underway that will ultimately provide confirmation that immunogenicity is a surrogate.
5. Safety and immunogenicity data from other vaccines made by the manufacturer using the same product platform may be considered as supportive data for review if applicable.

C. Plan for Monitoring and Reporting of Adverse Events

The Authority requires applicants to discuss proposals for active data collection and follow-up mechanisms to capture adverse event information under the EUA during the pre-submission meetings and such discussions should also be included in the Risk Management Plan (RMP). Refer to ICH E2E guideline.

D. Product Information:



Products registered under EUA shall follow the requirements of Statutory Instrument (SI). 79 of 2019. The product information shall constitute the following:

- i. Summary of product characteristics (information for healthcare provider)
- ii. Patient information leaflet
- iii. Primary and secondary container labelling
- iv. Any other instructional materials provided to the user
- v. A plan to help assure that prospective recipients and healthcare providers are adequately informed about the uncertainties regarding both the potential benefits and risks.

In addition to the above requirements, the labelling should clearly indicate that the product is for emergency use only.

E. Environmental Risk Assessment (ERA)

If the product contains a Genetically Modified Organism (GMO), the applicant shall submit a completed Environmental Risk Assessment application to National Biosafety Authority.

II. MEDICINES

A. Manufacturing and Quality Data

1. Information on the active pharmaceutical ingredient(s) and finished pharmaceutical product, including their characterization (known and potential impurities), composition, preparation, controls (specifications, analytical methods and their validation).
2. A list of intended changes for scale up, if any, along with a discussion on impact of these changes on the quality and safety or efficacy profile of the product.
3. Stability data shall be conducted as per requirements under Zone IVa/ IVb conditions, and a minimum of 3 months stability data shall be required.
4. Inspection report(s) from an WLA, WHO, ZaZiBoNa, or from the Authority inspection team showing compliance with GMP requirements for other, but similar products. Based on the acceptability of the reference Authority, WHO, report, the Authority may need to perform its own assessment of GMP compliance.

B. Non-Clinical and Clinical Data

1. All relevant *in-vitro* and *in-vivo* pharmacodynamic data shall be provided including microbiologic activity in addition to any modelling performed.
2. Data on efficacy and safety in *in-vitro* tests and in animal model(s) under well-controlled and documented conditions shall be provided. The preferred model depends on the disease and may vary according to the medicine's mechanism of action. The applicant must



- justify the choice of animal model.
- Evidence of efficacy should include improved survival and/or reduced morbidity of animals in the preferred model under relevant conditions. Surrogate markers, validated or reasonably expected to predict efficacy, would be supportive.
 - All available evidence of the medicine's activity *in-vitro* and in animals, together with pharmacokinetics and efficacy in humans, also against other diseases should be submitted.
3. A rationale should be provided for the proposed dosing in humans, with reference to drug exposures shown to be safe and effective in suitable models. Ideally, human pharmacokinetic data should be available, demonstrating similar levels of the drug following administration at the proposed dose, compared to blood levels found to be safe and efficacious in the relevant animal model.
 4. If human pharmacokinetic trials or studies in other indications at the exposure level proposed for treatment of the disease condition have been conducted, assessment of safety using standard parameters (including but not limited to, adverse events and clinical laboratory monitoring,) shall be done. This safety evaluation may be supplemented by any other non-clinical and clinical data at different exposure levels.
 5. If available, clinical data demonstrating safety and efficacy at the proposed dose for public health emergency field use should be submitted.

C. Product Information

Products registered under EUA shall follow the requirements of SI. 79 of 2019. The product information shall constitute the following:

- i. Summary of product characteristics
- ii. Patient information leaflet
- iii. Primary and secondary labelling
- iv. Any other instructional materials provided to the user
- v. A plan to help ensure that prospective recipients and health care providers are adequately informed about the uncertainties regarding both the potential benefits and risks.

In addition to the above requirements, the labelling should clearly indicate that the product is for emergency use only.

III. IN VITRO DIAGNOSTICS

A. Quality Management System (QMS)

The following requirements shall apply:

- i. Evidence of implementation of a manufacturing quality management system (including,

	Document No.: MA/GUD/011 Guidelines on Emergency Use Authorisation for Medicines and In-Vitro Diagnostics in Zambia	Page 24 of 29
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- ISO 13485 certificate and the most recent report by a certification body, quality manual, exclusions or non- applications, list of valid quality management documentation, management review report);
- ii. Details of the production workflow including QC points (in process and final release activities);
 - iii. Critical supplier list including supplied products (components or raw materials) and services;
 - iv. If the product was approved for Research Use Only (RUO), details on the performance of the product;
 - v. Details of the manufacturing capacity (maximum batch or lot size, capacity of equipment and batch manufacturing records); and
 - vi. Procedure(s) relevant to control of non-conforming goods, including but not limited to procedures for corrective and preventative actions, recalls and field safety notices.

B. Product Dossier Review

The second step is the assessment of the documentary evidence of safety and performance. It is acknowledged that many of the required studies to meet full regulatory requirements may not have been performed for IVDs undergoing EUA assessment. Based on the submitted documentation, a risk-based judgment will be made on whether there is a favourable benefit/risk profile. An initial evidence base that includes studies using banked specimens from previous studies, relevant studies in literature, and studies using contrived specimens to supplement testing of clinical specimens including representative analytes may be acceptable in the absence of complete analytical and/or clinical performance studies, if this evidence base provides a reasonable assurance of safety and performance.

The outcome of this step will determine if the application proceeds to the next step, whether further documentation should be requested, or whether the application should be terminated.

Refer to Guidelines on application for Grant of Marketing Authorisation of *In-Vitro* Diagnostic Devices for Use.

C. Plan for Monitoring and Reporting Adverse Events, Incidents, Non-Conforming Goods and Processes.

The applicant shall submit the surveillance or vigilance plan on how the adverse events or suspected quality problems will be monitored and reported.

Risk-Management Plan

A risk-management plan (RMP) to document the risk management system is considered necessary to identify, characterise and minimise the important risks of medicinal products. In general, the RMP should contain:

- i. The identification or characterisation of the safety profile of the medicinal product, with emphasis on important identified and important potential risks and missing information, and



also on which safety concerns need to be managed proactively or further studied (the 'safety specification');

- ii. The planning of pharmacovigilance activities to characterise and quantify clinically relevant risks and to identify new adverse reactions (the 'pharmacovigilance plan');
- iii. The planning and implementation of risk minimisation measures, including the evaluation of the effectiveness of these activities (the 'risk minimisation plan').

Checklist for writing or assessing an RMP:

Safety specification	
	Have all appropriate data been reviewed when compiling the safety specification, e.g. are there important (outstanding) issues which have not been discussed in the safety specification?
	If parts of the target population have not been studied, have appropriate safety concerns in relation to potential risks and missing information been included?
	Have limitations in the safety database (e.g. related to the size of the study population, study inclusion and exclusion criteria) been considered and what are the implications of such limitations on the safety profile of the medicinal product? Has reference been made to populations likely to be exposed during the intended or expected use of the medicinal product in the medical practice? Does the safety specification provide a true reflection of the safety concerns (e.g. important identified risks, important potential risks and/or missing information) with the medicinal product?
Pharmacovigilance Plan	
	Are all safety concerns from the safety specification covered in the pharmacovigilance plan?
	Are routine pharmacovigilance activities adequate or are additional pharmacovigilance activities necessary?
	Are the activities in the pharmacovigilance plan clearly defined, described and suitable for identifying or characterising risks or providing missing information?
	Are the safety studies that have been imposed by a competent authority as conditions clearly identified?
	If there are safety concerns derived from medication errors, does the RMP include appropriate proposals to monitor the correct use of the product?
	Are the proposed additional studies necessary, feasible, non-promotional and able to provide the required further characterisation of the risk(s) and address the scientific questions?



	Are timelines and milestones appropriate and feasible for the proposed actions, including those for the submission of results?
Plans for post-authorisation efficacy studies	
	Have all post-authorisation safety studies, either as conditions of the marketing authorisation or as specific obligations, been included?
Risk minimisation measures	
	Are routine risk minimisation measures sufficient or is there a need identified for additional risk minimisation activities?
	Have additional risk minimisation activities been suggested and, if so, are these sufficiently justified and risk-proportionate? Is implementation feasible in respective countries of the SADC region?
	Have criteria for effectiveness of additional risk minimisation activities been defined a priori?
	Are the methods for evaluating the effectiveness of risk minimisation activities well described and appropriate?
Summary of the Risk Management Plan	
	Is it a true representation of the RMP?
	Have the facts been presented appropriately without any elements of promotional



12. Annex 3: Notes and Disclaimers - EUA List of Candidate Products General notes

The Medicines and Medical devices Emergency Use List

1. The Medicines and Medical Devices included under EUA are products without MA.
2. This list is exclusively intended to facilitate access to Medicines and Medical devices that are required during a public health emergency.
3. The Medicines and Medical devices included in this list have been evaluated based on the minimum set of available quality, safety, and efficacy data or performance and an agreed plan for their further development.
4. This list will be updated regularly whenever a new Medicine or Medical Device is authorised under this procedure.
5. The Authority may suspend or remove Medicines and Medical devices from the list based on information that may subsequently become available.
6. Inclusion in the list does not imply final approval (Grant of Marketing Authorisation).
7. This list may not be used by manufacturers and suppliers for promotional purposes.

Publication of Medicines and Medical devices Included in the EUA

The Authority shall maintain and publish a list of Medicines and Medical devices recommended for EUA on the website.



13. REFERENCES

WHO Guideline on Emergency Use Listing Procedure, version 13, December 2020
https://extranet.who.int/pqweb/sites/default/files/documents/EUL-FINAL-13_12_2020.pdf

Food and Drugs Authority Ghana, Guidelines for Emergency Use Authorization of Medical Products

[https://www.fdaghana.gov.gh/img/organisation/Guidelines%20for%20Emergency%20Use%20A
uthorization%20of%20a%20Medical%20Product.pdf](https://www.fdaghana.gov.gh/img/organisation/Guidelines%20for%20Emergency%20Use%20Authorization%20of%20a%20Medical%20Product.pdf)

Medicines Control Authority Zimbabwe - [https://portal.mcaz.co.zw/sdm_downloads/mcaz-evr-gl-
01-rev_3_march-2025-guideline-for-emergency-use-authorization-of-medical-products/](https://portal.mcaz.co.zw/sdm_downloads/mcaz-evr-gl-01-rev_3_march-2025-guideline-for-emergency-use-authorization-of-medical-products/)

Emergency Use Authorization of Medical Products and Related
Authorities <https://www.fda.gov/media/142749/download>



Document No.: MA/GUD/011

**Guidelines on Emergency Use Authorisation for
Medicines and In-Vitro Diagnostics in Zambia**

Page 29 of 29

14. Revision History

Current Document Name:		Guidelines on Emergency Use Approval					
Change Request No.	Document No.	New Version No.	Page No. Amended	Section/Part No. Amended	Date Amended	Brief Description of the Changes to the Previous Version	Change Request Approve by (Name)
	Z/GUD/005	1				New Document	

Version No. 1