Medicines Control Authority of Zimbabwe

MCAZ/EVR/GL-01

GUIDELINE FOR EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS

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CONTENTS

1.0 APPLICATION

These guidelines apply when authorizing the emergency use of a Medical Product (allopathic medicines, complementary medicines, biological medicinal products and medical devices) during a declared public health emergency.

2.0 PURPOSE

This document provides guidance to applicants on the approval process for use during a public health emergency of an unregistered medical product.

3.0 BACKGROUND / INTRODUCTION

These guidelines publish the regulatory requirements for authorizing the emergency use of a Medical Product (allopathic medicines, complementary medicines, biological medicinal products and medical devices) during a declared public health emergency. Such emergencies shall include, but not limited to, a heightened risk of affliction or attack on the life, health, safety and security of the general public or any incident with a significant potential to affect national security. These guidelines should be read in conjunction with other guidelines on the Authority's website www.mcaz.co.zw. Those documents provide specific guidance on the labelling requirements.

The Medicines Control Authority of Zimbabwe (MCAZ) shall leverage on Section 75 of the Medicines and Allied Substances Control Act (Chapter 15:03) during a declared public health emergency to approve the use of an unregistered medical product under the Emergency Use Authorization (E.U.A) framework; - to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents when there are no adequate, approved, and available alternatives.

4.0 DEFINITIONS

The following definitions are provided to facilitate interpretation of the guidelines.

4.1 **Applicant:** Means the person or entity by, or on whose behalf, an application for emergency use authorisation is made.

4.2 **Manufacturer:** A company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of medical products.

4.3 **Risks:** Any known and potential risks relating to the quality, safety or efficacy of the medical product as regards patients' health or public health.

4.4 **Risk-benefit analysis:** An evaluation of the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, in relation to known and potential risks as defined above.

5.0 GUIDELINES

5.1 Requirements

5.1.1 Declaration of a Public Health Emergency

The Minister responsible for Health shall declare a public health emergency by a Statutory Instrument when a situation which poses an immediate threat to health, life, property or the environment arise. To meet the criteria for a public health emergency, the incident should;

i. Immediately threaten life, health, property or the environment;
ii. Have already caused loss of life, health detriments, property damage or environmental destruction; OR
iii. Have a high possibility of escalating to cause immediate danger to life, health, property and the environment.

5.1.2 Eligibility for Emergency Use Authorization (E.U.A)

Emergency Use Authorization is when an unregistered medical product can be authorized for use during a declared public health emergency involving a heightened risk of affliction or attack on the health, safety and security of the general public or a significant potential to affect national security. These products and their uses are not approved, cleared, or registered under Section 30 of Medicines and Allied Substances Control Act (Chapter 15:03).

However, MCAZ may issue an E.U.A only if, after consultation with the Ministry of Health and Child Care and/or MCAZ's technical committees (to the extent feasible and appropriate given the circumstances of the emergency), MCAZ concludes:

i. That the agent/pathogen/item/ specified in the declaration of public health emergency can cause a serious or life-threatening disease or condition;
ii. That, based on the totality of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition referred to in paragraph and there are no approved alternatives;
iii. 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 the declaration;
iv. That there is no adequate, approved, and available alternative to the product for diagnosing, preventing;
v. That the products are procured by the Government of Zimbabwe to address public health emergencies or shortages;
vi. 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 Zimbabwe;
vii. 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 Zimbabwe and other countries; and

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

5.1.3 Risk-Benefit Analysis

Products are eligible for Emergency Use Authorization (E.U.A.), if MCAZ 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, MCAZ will assess the quality and quantity of the evidence given to the current state of scientific knowledge, of risks and benefits. MCAZ will use this information to make an overall risk-benefit determination. To accomplish this, MCAZ will consider at the totality of the scientific evidence, which could arise from a variety of sources. The Authority will evaluate and consider all evidence, including results of domestic and foreign clinical trials, animal data, and in vitro data, available for consideration. MCAZ anticipates that, for some candidate products, data from controlled clinical trials will be available.

5.1.4 Alternatives to the Product

MCAZ may issue an E.U.A if it concludes that there is no adequate, approved, and available alternative to the candidate product. A potential alternative product may be considered as:

i. "Unavailable" if there are insufficient supplies to meet fully the emergency need.
ii. "Inadequate" if there are contraindicating data for special circumstances or populations (e.g., immune-compromised individuals or individuals with a medical product allergy) or if the agent is or may be resistant to approved and available alternative products.

5.1.5 Request for consideration for an E.U.A.

Although an E.U.A. may not be issued until after a Public Health Emergency has been declared by the Minister, MCAZ recognizes that during such exigent circumstances, the time available for the submission and review of an E.U.A request may be severely limited. Therefore, MCAZ strongly encourages an entity with a possible candidate product, particularly one at an advanced stage of development, to contact MCAZ 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 MCAZ believes are important to allow an assessment of safety and effectiveness and to make an adequate risk-benefit determination to support issuance of an E.U.A.

Pre-emergency activities

Such activities may include discussions with MCAZ about a prospective E.U.A product and the appropriate procedure to use, when submitting data on the product prior to a determination of actual or potential emergency. MCAZ strongly recommends that an entity submitting data during a "pre-emergency" period follow the recommendations for data

submission contained in "Submission of a Request for Consideration," below. If, prior to the declaration of an emergency, when MCAZ believes that a candidate product may meet the criteria for an E.U.A, MCAZ may share appropriate information on such product with the Ministry of Health and Child Care.

Emergency Activities

Once a determination of actual or potential emergency has been made, the Minister responsible for health may declare an emergency justifying the authorization to use an unregistered medical product for an unapproved use. The Minister will consult with MCAZ and other agencies and private entities, where appropriate, to identify products that may be eligible for an E.U.A in light of the circumstances of the emergency and to facilitate timely submission of the E.U.A request by an appropriate entity.

5.1.6 Submission of a request for consideration

Based on the totality of scientific evidence available to MCAZ (including data from adequate and well-controlled clinical trials, if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition. The exact type and amount of data needed to support an E.U.A may vary depending on the nature of the declared emergency and the nature of the candidate product. To facilitate MCAZ evaluation of such data, the Authority recommends that a request for consideration for an E.U.A include a well-organized summary of the available scientific evidence that evaluates the product's safety and effectiveness, including the adverse event profile when used for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

The information below summarizes the types of data that MCAZ recommends to be submitted to support a request for consideration for an E.U.A. For MCAZ to evaluate a request for consideration for an E.U.A, the following information should be submitted:

i. A description of the product and its intended use (e.g., identification of the serious or life-threatening disease or condition for which the product may be effective);
ii. Identification and an explanation of what unmet need(s) would be addressed by issuance of the E.U.A;
iii. A description of the product's international registration/Marketing Authorization (MA) status, i.e., whether the product is prequalified by an international organization such as WHO;
iv. A list of each site where the product, if authorized, would be (or was) manufactured and the Good Manufacturing Practices (GMP) status of the manufacturer;
v. Identification of any approved alternative products, including their availability and adequacy for the proposed use (if known);
vi. Available safety and efficacy information for the product
vii. A discussion of risks and benefits;
viii. A description of the information for health care providers or authorized dispensers and recipients of the product, (e.g., two separate "Fact Sheets"), and the feasibility of providing such information to health care providers or authorized dispensers and recipients in emergency situations;
ix. Information on chemistry, manufacturing, and controls;

x. Certificate of Analysis of the E.U.A medical product instructions for use as E.U.A product (e.g., if follow-up treatment is required);
xi. A list of each site where the product, if authorized, would be (or was) manufactured and the Good Manufacturing Practices (GMP) status of the manufacturer;
xii. Proposed labelling (if applicable). Including batch number, manufacturing date and expiry date;
xiii. Name of reference substance/material (if applicable);

These recommendations are discussed in more detail below. Please note that the MCAZ may also issue subsequent guidance providing greater detail on these recommendations and procedures for specific medical products and/or public health emergences.

5.1.7 Recommended Safety Data

In general, the amount and type(s) of safety data that MCAZ recommends be submitted as part of a request for consideration for an E.U.A will differ depending upon a number of factors, including whether the product is approved for another indication and, in the case of an unapproved product, the product's stage of development. MCAZ will interpret safety information in light of the seriousness of the clinical condition, alternative therapies (if any), and the specific circumstances of the emergency. MCAZ strongly encourages any person or entity with an E.U.A medical product to discuss with the Authority at the earliest possible time (even before a determination of actual or potential emergency) the nature and type of safety data that might be appropriate to submit to MCAZ.

In the case of previously approved products:

If the new indication uses a similar dose, duration, route of administration, and/or mechanism of action (as appropriate given the nature of the product), and the intended patient population is similar to that for which the product is approved, MCAZ recommends that the request for consideration for an E.U.A reference the approved application if the requester submitted the approved application or has a right of reference. If the new use poses a different risk to the patient population (e.g., suggesting the possibility of increased toxicity), the Authority recommends that information from relevant in vitro studies, animal toxicology studies, and (if available) human clinical data and experience be provided to support such a use.

In the case of products under development:

The range of available data for such products will differ widely. MCAZ recommends that any request for consideration for an E.U.A include available preclinical testing data, such as in vitro and animal toxicology data. MCAZ also strongly encourages that safety information in humans from clinical trials and individual patient experience be provided, if available. MCAZ further recommends that data submitted in the request attempt to link the likely patient exposure to any relevant existing preclinical data. Similarly, where animal data are used, sufficient information should be provided to link the results of these data to expected exposures related to the proposed use in humans. Any information on safety

associated with use in humans of this or related compounds or devices of a similar design also should be submitted.

5.1.8 Recommended Effectiveness Data

In general, MCAZ recognizes that comprehensive effectiveness data are unlikely to be available for every E.U.A medical product, and the information necessary to authorize emergency use of a product will depend on the circumstances of the declared emergency, as well as available knowledge about the product's safety profile. MCAZ will assess the sufficiency of the effectiveness data and the risk-benefit profile of each candidate product on a case-by-case basis.

MCAZ recommends that requests for consideration for E.U.As include any available relevant scientific evidence regarding the following:

i. The mechanism(s) of the product's action to diagnose, treat, or prevent the disease or condition underlying the request;
ii. Preclinical testing data, such as in vitro evidence of effect of the product in preventing or reducing the toxicity of the specified agent;
iii. Data to demonstrate effectiveness in diagnosing, treating, or preventing the subject disease or condition in at least one animal species expected to react with a response predictive for humans, where the animal study endpoint is clearly related to the desired benefit in humans (e.g., enhancement of survival or prevention of major morbidity);
iv. Evidence of effectiveness in humans (e.g., in published case reports, uncontrolled trials, controlled trials, if available, and any other relevant human use experience);
v. Data to support the proposed dosage (including pharmacokinetics and pharmacodynamics data, and for vaccines or antibody therapies, immunogenicity and/or achievement of protective levels of relevant parameters of immunity) for the intended use;

5.1.9 Other Data Considerations

In general, MCAZ recommends that the request for consideration include the following types of data, as appropriate and to the extent feasible given the exigencies of the circumstances:

i. Well-organized study reports that provide a complete assessment and analysis of available safety and effectiveness data and an interpretation of the findings.
ii. If final study reports are not yet available, any available interim study reports should be provided and clearly identified as such any relevant statistical analyses; and source data for clinical studies, nonclinical laboratory studies, and any animal studies demonstrating activity or effectiveness of the product in the treatment of the underlying disease or condition or a closely related disease or condition, such as case report tabulations for key studies; case report forms for all patients who died during the clinical studies and for all persons who did not complete the study due to an adverse event, regardless of causality; relevant reports in the published literature; and translations of source materials in a language other than English.

Data Quality

MCAZ recommends that requests for consideration for E.U.As include statements on whether the nonclinical laboratory studies were conducted in compliance with applicable Good

Laboratory Practice (GLP) requirements and whether the clinical studies were conducted in compliance with applicable Good Clinical Practice (GCP) standards.

Data Updates

MCAZ recommends that any data from any ongoing testing (e.g., longer term stability data) or other data or information that may change MCAZ's evaluation of the product's safety or effectiveness that become available during the period of review or the term of the E.U.A (to the extent that such data are not required to be submitted under a condition of authorization) be submitted to the Authority when such data become available.

Discussion of risks and benefits:

MCAZ recommends that a request for consideration for an E.U.A include a discussion of the medical product's known and potential risks and benefits, which includes a synthesis of the data and information requested above, including:

i. Measures taken to mitigate risk or optimize benefit
ii. Limitations, uncertainty, and data gaps
iii. A description of circumstances, if any, under which the product should not be used (e.g., contraindications).

5.1.10 Format of submissions

Submissions shall be made in an electronic format: two (2) copies, either saved on a USB flash drive or on a CDs, together with an application letter addressed to the Director-General of the Medicines Control of Zimbabwe (MCAZ). MCAZ recommends that the submission begin with a section that describes the contents and organization of the included materials. The applicant or anyone with a right of reference may refer to data or other information previously submitted to MCAZ in a registration and/or marketing authorization application.

MCAZ expects material to be provided in reviewable form and sufficiently completed to permit substantive evaluation. Nevertheless, MCAZ recognizes that, in rapidly developing or unexpected emergency circumstances, or when previously unanticipated or unavailable medical countermeasures are being considered, it may not be possible for an entity to provide all of the requested data or to provide it in the format suggested in a timely manner. In such circumstances, MCAZ will accept and evaluate the request for consideration for an E.U.A based on data in the form an entity is able to submit. However, a request for consideration that is missing data or that is otherwise incomplete or poorly documented will make determination of whether the product's benefits outweigh its risks more difficult and may, for that reason, be more likely to result in a request for additional information, the need for a longer time period for evaluation, or a decision not to authorize emergency use of the medical product.

The address for submission of a request for consideration for an E.U.A. is:

Director-General
Medicines Control Authority of Zimbabwe
106 Baines Avenues
Harare, Zimbabwe

5.2 Processing of an Emergency Use Authorization (E.U.A)

This section discusses MCAZ's role in pre-emergency activities for E.U.A medical product, as well as the procedures the Authority will follow in processing a request for consideration for an E.U.A once the Minister has issued a declaration of public health emergency.

5.2.1 Prioritization of Pre-Emergency Activities

The Authority will establish priorities for the activities it undertakes, prior to a determination of actual or potential emergency. Such prioritization may be based on the circumstances, such as:

i. the seriousness of the clinical condition;
ii. the incidence of the clinical condition;
iii. the effect use of the product may have in ensuring national security;
iv. whether the product is included in government stockpiles or whether there is a significant likelihood that the product will be included in government stockpiles if an E.U.A is granted;
v. whether the product could be used by a large population or is limited to subpopulation(s);
vi. request of another government agency;
vii. the extent to which the product would serve a significant unmet medical need in a special population (e.g., pregnant women, infants and children, and immuno-compromised persons);
viii. the availability and, where known, safety and effectiveness of other countermeasures;
ix. the urgency of the treatment need (i.e., the window of opportunity for treatment can vary between different medical conditions)
x. the available information concerning the likelihood that the product may be safe and effective in treating the condition
xi. the adequacy of the supporting nonclinical and clinical information; and
xii. the quantity of product available

5.2.2 Pre-emergency submission

To allow MCAZ evaluation process to begin before a determination of actual or potential emergency, MCAZ recommends that a pre-emergency submission be filed using existing processes to the extent feasible and appropriate. The extent of, and timelines for, evaluation of such submission will be determined on a case-by-case basis and will depend on the nature of the emergency.

Subject to exigent circumstances beyond MCAZ's control, the Authority anticipates that pre-emergency submissions for high priority activities may be evaluated in a matter of weeks to months.

5.2.3 Consideration for an E.U.A request

MCAZ will be responsible for the overall disposition of the request and will interact directly with the entity submitting the request for consideration. MCAZ will arrange for the consultations with other agencies to the extent that such consultations are feasible and appropriate given the circumstances of the emergency. MCAZ will work with the Ministry of Health and Child Care

depending on the complexity of the issues presented and the nature of the declared emergency and may seek additional scientific and technical input from outside experts or advisory committees.

MCAZ recognizes that the exact type and amount of data needed to support an E.U.A may vary depending on the nature of the declared emergency and the nature of the candidate product. MCAZ will evaluate each request in light of the circumstances and the statutory criteria for issuance. The responsible Department in consultation with other relevant Departments and technical committees (as appropriate and feasible), will perform evaluation of the information and data included in the request for consideration and make recommendations to the Director-General. The letter of authorization or otherwise will be issued by the Director-General of MCAZ. The letter authorizing emergency use of a product will include a description of the intended use, as well as the indications and contraindications of the product.

5.2.4 Timelines for evaluation of the request

The timelines for evaluation and action on a request for consideration for an E.U.A will depend on the product profile; the existence, if any, of pending applications for the product; the nature of the emergency; and other relevant factors. *In cases where complete clinical trials data is not yet available as is usually the case in a public health emergency, MCAZ will review data as they become available from ongoing studies.* Although the length of time required for action will vary, MCAZ recognizes that it is likely that, in an emergency situation that is occurring or believed imminent, a request for consideration for an E.U.A will be acted *upon within 2 weeks.*

5.3 Conditions of Authorization

5.3.1 Information for Health Care Providers or Authorized Dispensers

To the extent consistent with other conditions of authorization, information on the E.U.A of medical product should be disseminated to healthcare providers and authorized dispensers through media, videos/DVDs/CD-ROMs, the Internet, and direct communication from the Ministry of Health and Child Care.

5.3.2 Information for Recipients

Although informed consent is not required for administration of an E.U.A medical product, the information dissemination requirements are mandatory only to the extent conditions establishing such requirements are practicable. MCAZ recommends that recipients be given as much appropriate information as possible given the nature of the emergency and the conditions of the authorization. For healthcare provider carrying out any activity concerning an E.U.A, recipients must be informed that MCAZ's Director-General has authorized emergency use of the medical product and has evaluated the potential benefits and risks of the medical product. Recipients must have an opportunity to accept or refuse the E.U.A product and must be informed of any consequences of refusing administration of the product. Recipients also must be informed of available alternatives to the product and of their risks and benefits.

MCAZ recommend that some form of written information will be given to recipients in the simplest language possible and using other techniques to improve health literacy. The Authority recommends that the written information include the significant known and potential risks and

benefits of the product and the extent to which the potential risks and benefits are unknown, specific instructions for home use (if necessary), and adverse event information, including contact information should adverse events occur. Furthermore, the Authority recommends that the written information for recipients be tested (e.g., by focus groups) for clarity particularly regarding messages on uncertainty and relative risks. MCAZ acknowledges, however, that exigent circumstances may dictate the use of other, more appropriate, dissemination methods. Therefore, MCAZ expects that recipient information would be disseminated in the most effective and expeditious way possible to reach the intended audience. Methods of dissemination may include media (e.g., public service announcements), videos/DVDs, the Internet, and direct communication from health care providers and public health agencies.

5.3.3 Monitoring and Reporting of Adverse Events

MCAZ recommends that the Ministry of Health and Child Care and/or applicant to conduct adverse event monitoring and reporting for E.U.A medical product. MCAZ expects that the primary focus will be on capturing adverse events and identifying the appropriate mechanism(s) to be used for the collection of follow-up clinical information. Predefined mechanisms to capture adverse event data are preferred, where feasible. MCAZ Adverse Events forms such as the Adverse Events Following Immunisation (AEFI) forms and the Adverse Drug Reaction (ADR) forms must be completed for any suspected adverse events. These must be submitted to the Authority for causality assessment.

5.3.4 Records

MCAZ requires that records of unregistered product or unapproved use should be maintained, and access be granted by the manufacturers to the Authority given the circumstances of the emergency. MCAZ may impose comparable record requirements on any person other than a manufacturer who carries out any activity for an unapproved product. The Authority anticipates that such record requirements may relate to the number of doses including lot number of the E.U.A product; the name and addresses of the facilities where the E.U.A product was deployed; monitoring of patients who have been administered with the product under an E.U.A. MCAZ also may impose conditions regarding other matters that the Authority determines are appropriate and practicable given the circumstances of the emergency.

5.3.5 Importation authorisations

Importation authorisations will be issued in terms of section 75 of the Medicines and Allied Substances Control Act (Chapter 15:03) on a consignment basis for all unregistered medical products.

5.3.6 Additional Conditions for Unapproved Products

To the extent feasible given the circumstances of the emergency, MCAZ may establish additional conditions for unapproved products, such as the following:

i. Restricted distribution under the E.U.A: conditions may be placed on which entities
ii. Distribution of the product and how distribution is to be performed;

iii. Personnel: conditions may be placed on who may administer the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered;

iv. Information: conditions may be placed on the collection and analysis of information on the safety and effectiveness of the E.U.A product;

v. With respect to an E.U.A that authorizes a change in labeling of an approved product, but for which the manufacturer chooses not to make such labeling change, the E.U.A may not authorize a product distributor or any other person to alter or obscure the manufacturer's labeling. However, under such conditions, MCAZ must authorize, to the extent practicable under the circumstances of the emergency, any person (other than the manufacturer) acting pursuant to such E.U.A to provide appropriate information, in addition to the manufacturer's labeling, with respect to the product;

vi. MCAZ may establish conditions for distribution and administration of an approved product for an unapproved use that are no more restrictive than those established by the Authority for the distribution and administration of the product for an approved use. Any such additional conditions will be established by MCAZ on a case-by-case basis, depending on the circumstances of the emergency and the nature of the approved product authorized for an unapproved use;

vii. Compliance with GMPs or Alternative Approaches: MCAZ expects that an E.U.A products will be produced in compliance with GMP; however, limits or waivers may be granted, on a case-by-case basis, after consideration of the circumstances and of any alternative proposed approach;

viii. Advertising: MCAZ may establish conditions on advertisements and other promotional descriptive printed matter relating to the use of E.U.A product.

MCAZ will establish these conditions on a case-by-case basis.

5.3.7 Validity, Revocation or Termination of an E.U.A

An emergency use authorisation will be **valid for a period of 12 months** or when the **public health emergency ends**, whichever is shorter, unless the E.U.A is revoked because the criteria of issuance "Eligibility for an Emergency Use Authorization," above) are no longer met or revocation is appropriate to protect public health or safety. If additional satisfactory data needed for full registration are submitted in an application to the Authority, then full marketing authorisation (registration) could be granted.

Revocation

MCAZ will periodically review the circumstances and appropriateness of an E.U.A, including circumstances that might warrant revocation of the E.U.A. Such circumstances may include significant adverse inspectional findings (e.g., where an inspection of the manufacturing site and processes have raised significant questions regarding the purity, potency, or safety of the E.U.A product that materially affect the risk/benefit assessment upon which the E.U.A was based); reports of adverse events (number or severity) linked to, or suspected of being caused by, the E.U.A product; product failure; product ineffectiveness (such as newly emerging data that undermine the Authority's conclusion that the product "may be effective" against a particular agent); and availability of a preferred product.

Termination

Upon termination of the declaration, unapproved product or labeling and product information for an unapproved use must be disposed in line with appropriate Disposal guidelines in force at the time. Notwithstanding any such termination, an authorization shall continue to be effective to provide for continued use in any patient who began treatment before termination (to the extent found necessary by the patient's attending physician).

Continued Use

Any use of an E.U.A product beyond the term of a declaration is subject to investigational product regulations under clinical trials authorization, except for use by patients who began treatment when the declaration was in effect, to the extent found necessary by such patient's attending physician.

6.0 KEY RELEVANT DOCUMENTS

6.1 WHO Emergency Use Listing Procedure, December 2020. (https://cdn.who.int/media/docs/default-source/medicines/eulprocedure_a63b659c-1cdc-4cee-aa2d-ef5dd9d94f0b.pdf?sfvrsn=55fe3ab8_7&download=true)

6.2 Food and Drugs Authority Ghana. Guidelines for Emergency Use Authorisation of Medical Products.

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	**Reason for change(s).**
0	27/7/2021	**To respond to WHO GBT IDP –** Update guideline for EUA with respect to section 5.2.4 to clearly state the timelines. allowing for a rolling review and to define the role of specialised experts (e.g advisory committees) in the process*(P.S – Role of specialised experts is defined in section 5.2.3 of the guideline and is therefore not included in this amendment)* **FROM** The timelines for evaluation and action on a request for consideration for an E.U.A will depend on the product profile; the existence, if any, of pending applications for the product; the nature of the emergency; and other relevant factors. Although the length of time required for action will vary, MCAZ recognizes that it is likely that, in an emergency situation that is occurring or believed imminent,

		a request for consideration for an E.U.A will be acted upon within a matter of days. **TO** The timelines for evaluation and action on a request for consideration for an E.U.A will depend on the product profile; the existence, if any, of pending applications for the product; the nature of the emergency; and other relevant factors. *In cases where complete clinical trials data is not yet available as is usually the case in a public health emergency, MCAZ will review data as they become available from ongoing studies.* Although the length of time required for action will vary, MCAZ recognizes that it is likely that, in an emergency situation that is occurring or believed imminent, a request for consideration for an E.U.A will be acted *upon within 2 weeks*
1	January 2022	**System improvement** **FROM** **5.1.2 Eligibility for Emergency Use Authorisation** ii. That, based on the totality of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition referred to in paragraph **TO** **5.1.2 Eligibility for Emergency Use Authorisation** ii. That, based on the totality of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition referred to in paragraph and there are no approved alternatives. **ADDED** **5.1.2 Eligibility for Emergency Use Authorisation** v. That the products are procured by the Government of Zimbabwe to address public health emergencies or shortages

		vi. 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 Zimbabwe; vii. 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 Zimbabwe and other countries; and viii. Any other unforeseen circumstances where access to the medical product is justifiable and is deemed beneficial to the public