RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR AUTHORIZATION FOR EMERGENCY USE OF MEDICINAL PRODUCTS, MEDICAL DEVICES AND IVDs

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to quality, safety and efficacy of medicinal products, medical devices and IVDs in order to protect public health by increasing their access and availability.
Considering the provisions of the technical Regulations No CBD/TRG/010 governing the registration of human medicinal products and Regulations No CBD/TRG/012 Governing the registration of medical devices, the Authority has to issue Guidelines No DHT/GDL/039 on Authorization for Emergency Use of medicinal products, medical devices and IVDs

The Authority has developed Guidelines for Authorization for Emergency Use of Medicinal Products, medical devices and IVDs in order to provide guidance on the submission of product dossier application and the approval of Marketing authorization during the Public health emergencies where the benefits of immediate product availability outweighs the risk of approving applications with less comprehensive data than normally required in routine procedures.
The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Dr Charles KARANGWA
Acting Director General.

1.0 TABLE OF CONTENTS

2.0 ABBREVIATIONS

PHE	Public Health Emergency
AEU	Authorization for Emergency Use
ICH	International Conference on Harmonization
CTD	Common Technical Documents
WHO	Word Health Organization
GMP	Good Manufacturing Practices
IVDs	In Vitro Diagnostics
EMA	European Medicines Agency
RMP	Risk Management Plan
GVP	Good Pharmacovigilance Practices
QPPV	Qualified Person for Pharmacovigilance

3.0 DEFINITIONS

In these guidelines unless the context states otherwise:

- **"Authority"** refers the Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under the article 2 of the Law No. 003/2018 of 09/02/2018
- **"Applicant"** is a person who applies for registration of a human medicinal product to Rwanda FDA, who must be the owner of the product. He may be a manufacturer or a person to whose order and specifications, the product is manufactured.
- **"Biological Product"** means items derived from living organisms (ranging from normal or genetically modified microorganisms to fluids, tissues and cells derived from various animal and human sources) or containing living organisms that are used to:
    - treat or prevent diseases or manage injury
    - diagnose medical condition
    - alter the physiological processes
    - test the susceptibility to diseases Such items include;
        - products of genetically modified organisms (e.g., insulin etc.)
        - traditional vaccines (bacterial, viral, combination etc.)
        - immunotherapy products (e.g., cell based tumour vaccines, human cellular vaccines etc.)
        - peptides and Polypeptides (e.g., insulin, cytokine etc.)
        - monoclonal antibodies
        - other human cell-based products (e.g., fibroblast, epithelial cells, chondrocytes)
- **"Medical Device"** any instrument, machine, appliance, material intended by the manufacturer to be used alone or in combination for the purpose of diagnosis, testing, vaccination, cure, surgery or for human or animal health protection
- **"Medicinal Products"**: any substance or mixture of substances manufactured sold or presented as capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions. It also means products used in disinfecting premises in which food and drugs are manufactured, prepared or stored, for cleaning hospitals, equipment and farm houses.
- **"Equivalent"** means equal or virtually identical in the parameter of interest. Small non-relevant differences may exist. Equivalent efficacy of two drug products means they have similar (no better or no worse) efficacy and any observed differences are of no clinical relevance.

- **"ICH"** means International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH is a project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. For more information, see http://www.ich.org/.
- **"Inadequate product"** if there are contraindicating data for special circumstances or populations (e.g., immunocompromised individuals or individuals with a drug allergy) or if the agent is or may be resistant to approved and available alternative products.
- **"Lot release":** process for the evaluation of each individual lot of vaccine submitted to be used in the market; this means independent control of each lot to guarantee that all the lots produced and used in a country are in compliance with the established quality specifications. This process can be performed by detailed review of Summary Protocols of Production and Quality Control, and includes laboratory testing when it is considered necessary.
- **"Unapproved product"** refers to a product that is not approved or registered for commercial distribution under national Law and regulations.

4.0 INTRODUCTION

These Guidelines provide the regulatory requirements for the Authorization for Emergency Use (AEU) of a medicinal product, medical devices and IVDs during a declared Public Health Emergency.

Such emergencies shall include, but not limited to, a heightened risk of affliction or outbreak on the life, health, safety and security of the general public or any incident with a significant potential to affect national security.

This Authorization for Emergency Use (AEU) will allow the expedited approval of medicinal products, medical devices and IVDs in the following conditions:

- The disease 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 AEU assessment, e.g., there are no licensed products for the indication or for a critical subpopulation (e.g., children);
- Existing products have not been successful in eradicating the disease or preventing outbreaks (in the case of vaccines and medicines); in emergency situations for the diagnosis, treatment, or prevention of serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives.

These guidelines allow the Authority to approve the use of unregistered or unapproved medicinal products, medical devices and IVDs during a Public Health Emergency.

Generally, the Authority will issue an AEU in the following conditions:

1. The disease causative agent/item specified in the declaration of Public Health Emergency can cause a serious or life-threatening disease or condition;
2. 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 a serious or life- threatening disease or condition caused by the agent specified in the declaration of emergency;
3. 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; and
4. No adequate, approved, and available alternatives to the product for diagnosing, preventing, or treating such serious or life-threatening disease or condition.

These Guidelines are intended to inform industries, government agencies, and the general public on the general requirements and procedures for issuance of an Authorization for Emergency Use (AEU).

The Authority expects that the Ministry of Health shall submit the request for consideration of an AEU. The Authority may seek additional data and information on a case-by-case basis to ensure that the statutory requirements for the issuance of an AEU are met.
These Guidelines should be read in conjunction with other published guidelines by the Authority

5.0 PURPOSE OF THE AEU

The purpose of the procedure is to define the steps that the Authority will follow to establish eligibility of unlicensed products for assessment under this procedure, the essential information required, and the process to be used in conducting the assessment to determine whether an unlicensed product can be listed on a time limited basis, while further data is being gathered and evaluated.

It is intended to provide a time-limited approval for unlicensed products in an emergency context when limited data are available and the products are not yet ready for application for marketing authorization. As part of the AEU, it is expected that the manufacturer will complete the development of the product and submit for marketing authorization approval.

The AEU is not intended to interfere with ongoing clinical trials. This means that the clinical development should proceed as planned after the initial submission and subsequent updates.
This document is intended to guide manufacturers who are willing to submit applications, with the goal of obtaining an emergency approval of their product(s) for use during public health emergencies and participation in the procedure is voluntary.

6.0 SCOPE OF THE AEU

The AEU is not equivalent or an alternative to the Marketing Authorization granted by the Authority, and should not be thought of as such. The AEU is a special procedure for unlicensed medicinal product, medical devices and in vitro diagnostics in the event of a PHE when the public health authorities may be willing to tolerate less certainty about the efficacy and safety of products, given the morbidity and/or mortality of the disease and the lack or scarcity of treatment, diagnosis/detection or prevention options

7.0 REQUIREMENTS

7.1 Mode of submission

7.1.1 Product development dossier shall be submitted in an electronic format, two (2) copies saved either on a USB flash drive, on CDs or hyperlink file sharing together with an application letter addressed to the Director General

7.1.2 The Authority recommends that an AEU application begins with a section that describes the content and organization of the application. To facilitate the evaluation of submitted data, it is recommended that a well-organized data on product Quality, Safety, Efficacy and Effectiveness is submitted with the AEU application.

7.1.3 The data should be complete as possible, and should be in a format that is globally acceptable, (preferably in the Common Technical Document (CTD) format). However, a similar format and data content shall be acceptable under the current circumstances.

7.1.4 An AEU application that is missing relevant data or that is otherwise incomplete or poorly documented will make determination of whether the product benefits outweigh its risks more difficult and may, for that reason, be more likely to result in a request for additional information. This might result in the need for a longer time period for evaluation, or a decision not to authorize emergency use of the medicinal product, medical device and IVDs. A summary of the minimum data and information requirement for an AEU application is presented in section 7.2

7.1.5 If considered necessary or desirable by the applicant and the Authority, a discussion may be held between the applicant and the Authority before the actual evaluation process starts. These pre-submission exchanges may be done via a chosen method of communication, including face-to-face meetings.

7.2 General Requirements

7.2.1 The manufacturer must submit an application letter to the Authority on the following address:

Director General
Rwanda Food and Drugs Authority
Nyarutarama Plaza, Rwanda
KG 9 Avenue, Kigali
P.O. Box 1948, Kigali, Rwanda.
E-mail: info@rwandafda.gov.rw

7.2.2 All documents submitted for the purpose of an AEU shall be in English, and must be legibly printed and not handwritten. The Authority expects material to be provided in a reviewable form and sufficiently complete to permit substantive evaluation.

7.2.3 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).

7.2.4 Identification and an explanation of what unmet need(s) will be addressed by issuance of the AEU.

7.2.5 A description of the product's global/international registration/Marketing Authorization (MA) status or whether the medicinal products, medical device and IVDs is prequalified by an international organization such as WHO. The application should include countries in which the product is registered or authorized for use (if applicable) and provide proof/evidence to establish the fact.

7.2.6 A list of each site where the product, if authorized, would be (or was) manufactured and the evidence of current Good Manufacturing Practices (cGMP) status of the listed manufacturing site(s);

7.2.7 Identification of any approved alternative products, including their availability and adequacy for the proposed use (if known);

7.2.8 Available safety, efficacy and effectiveness information/data on the medicinal product, medical device and IVDs (i.e., non-clinical and clinical data);

7.2.9 A detailed discussion of risks and benefits balance of the medicinal product, medical device and IVDs;

7.2.10 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;

7.2.11 Information on the Chemistry, Manufacture, and Controls – Quality part of the product development dossier. Data should be submitted on the product stability and conditions of storage;

7.2.12 Certificate of Analysis of the finished product;

7.2.13 Instructions for use as an AEU product (e.g., if follow-up treatment is required);

7.2.14 Proposed product labelling of the medicinal product, medical device and IVDs; Labelling should at least comply with the WHO labelling requirements for the product. It should include Packaging Insert or Patient Information Leaflet;

7.2.15 Proposed Summary of Product Characteristics (SmPC). It should at least comply with the WHO SmPC requirements guidelines;

7.2.16 Risk Management Plan (RMP). It should at least comply with the content, format and submission prescribed in the EMA RMP guidelines or the guidelines on Good Pharmacovigilance Practices (GVP), Chapter 5, Risk management systems.

Applicants will be requested to incorporate local RMP requirements in the final RMP document (refer to the Rwanda FDA Guidelines on safety and vigilance of medical products and health technologies available on the Authority website);

7.2.17 Proposed finished product handling, storage and transportation logistics necessary to maintain product integrity;

7.2.18 Name of reference substance/material (if applicable);

7.2.19 Product representative samples (where applicable);

7.2.20 Lot/Batch release certificate and a copy of the batch/lot release protocol and report for the vaccine intended to be imported into the country. Documents should be submitted to the Authority at least 4 weeks prior to the receipt of the consignment into the country.

7.3 Recommended Safety Data

Generally, the amount and type(s) of safety data that the Authority recommends to be submitted as part of a request for consideration of an AEU 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.

The Authority will interpret safety information in light of the seriousness of the clinical condition, alternative therapies (if any), and the specific circumstances of the emergency. The Authority strongly encourages any person or entity with an AEU medicinal product, medical device and IVDs to discuss with the Authority at the earliest possible time, the nature and type of safety data that might be appropriate to submit.

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, the Authority recommends that the request for consideration for an AEU reference the approved application if the requester submitted the approved application or has a right of reference.

If the new use causes 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. The Authority recommends that any request for consideration for an AEU include available preclinical/non-clinical testing data, such as in vitro and animal toxicology data.

The Authority also strongly encourages that safety information in humans from Clinical Trials and individual patient experience be provided, if available.

The Authority 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.

7.4 Recommended Effectiveness Data

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

The Authority recommends that requests for consideration of AEU include any available relevant scientific evidence regarding the following:

a) the mechanism(s) of action for the drug product to diagnose, treat, or prevent the disease or condition underlying the request;
b) re-clinical/non-clinical testing data, such as in vitro evidence for effect of the product in preventing or reducing the toxicity of the specified agent;
c) 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);
d) evidence of effectiveness in humans (e.g., in published case reports, uncontrolled trials, controlled trials, if available, and any other relevant human use experience)
e) 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.

7.5 Other Data Considerations

The Authority recommends that the request for consideration include the following types of data, as appropriate and to the extent feasible given the requirements of the circumstances;

a) Well-organized study reports that provide a complete assessment and analysis of available safety and effectiveness data and an interpretation of the findings. If final study reports are not yet available, any available interim study reports should be provided and clearly identified as such.
b) Any relevant statistical analyses; and
c) Source data for clinical studies, non-clinical 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.

7.6 Data Quality

The Authority recommends that requests for consideration for AEUs include statements on whether the non-clinical 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.

7.7 Data 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 benefit/risk assessment.
The applicant should, as much as possible, provide tentative timelines for the submission of additional/supplementary information based on the expected dates of completion/planned interim analyses of studies currently ongoing/or being initiated soon.
Submission of updates/additional data should clearly follow the section numbering system of the initial submission.

8.0 DISCUSSION OF RISKS AND BENEFITS

The Authority recommends that a request for consideration for an AEU include a discussion of the product's known and potential risks and benefits, which includes a synthesis of the data and information requested above, including:

a) Measures taken to mitigate risk or optimize benefit;
b) Limitations, uncertainty, and data gaps;

c) Description of circumstances, if any, under which the product should not be used (e.g., contraindications).

9.0 ASSESSMENT OF AUTHORIZATION FOR EMERGENCY USE (AEU) APPLICATION

This section discusses the role of the Authority in pre-AEU activities for AEU of medicinal product, medical device and IVDs, as well as the procedures which will be followed in processing a request for consideration for an AEU once the Ministry of Health has issued a declaration of Public Health Emergency.

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

The Authority recognizes that the exact type and amount of data needed to support an AEU may vary depending on the nature of the declared emergency and the nature of the candidate product. The Authority 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 assess the information and data included in the request for consideration and make recommendations to the Director General.

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 and will be issued by the Director General.

10.0 TIMELINES FOR PROCESSING AN AEU APPLICATION

The timelines for processing of an AEU will depend on the following:

a) Product profile;
b) The existing, if any, of pending applications for the AEU;
c) The nature of the emergency and
d) Other relevant factors.

Although the length of time required for action will vary, the Authority recognizes that it is likely that, in an emergency situation that is occurring or believed imminent, a request for consideration for an AEU will be processed **within 15 working days**.

11.0 CONDITIONS OF AEU

11.1Distribution of emergency use authorized Products:

As part of the conditions for issuance of an AEU, all authorized products will be distributed according to the appropriate channel of national medical supply chain.

11.2 Information for Health Care Providers

To the extent consistent with other conditions of authorization, information on the AEU of medicinal product, medical device and IVDs should be disseminated to healthcare providers through media, videos/DVDs/CD-ROMs, the internet, and direct communication from the Ministry of Health or other relevant institutions.

11.3 Information for Recipients:

The information dissemination requirements are mandatory only to the extent conditions establishing such requirements are practicable. The Authority 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 AEU, recipients must be informed that the Authority has authorized emergency use of the product, and has evaluated its potential benefits and risks. Methods of dissemination may include media (e.g., public service announcements), videos/DVDs, the internet, and direct communication from health care providers and relevant public health institutions.

Recipients must have an opportunity to accept or refuse the AEU 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.

11.4 Monitoring and Reporting of Adverse Events

The Authority requires that the applicant appoints a Qualified Person for Pharmacovigilance (QPPV) (refer to Rwanda FDA Guidelines on safety and vigilance of medical products and

health technologies available on the Authority website) from any established entity with the experience in adverse event monitoring and reporting for AEU product. The Authority expects that the primary focus of such appointments will be to capture Serious Adverse Events (SAEs) and identify appropriate mechanism(s) to be used for the collection of follow-up clinical information, identify the size of the safety database required for effective monitoring, and the types of data needed. Pre-defined mechanisms to capture adverse event data are preferred, where feasible. QPPV person may use internet site, safety monitoring Apps to appropriately execute its mandate.

11.5 Records

The Authority requires that records of unregistered product or unapproved use should be maintained and access be granted by the applicant/ manufacturers to the Authority given the circumstances of the emergency.

The Authority may impose comparable record requirements on any entity other than a manufacturer who carries out any activity for unapproved product. The Authority anticipates that such record requirements may relate to the number of doses including lot/batch number of the AEU product; the name and addresses of the facilities where the AEU product was deployed to; monitoring of patients who have been administered with the product under an AEU. The Authority also may impose conditions regarding other matters that the it determines are appropriate and practicable given the circumstances of the emergency.

11.6 Additional Conditions for Unapproved Products

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

a) Restricted distribution under the AEU -- conditions may be placed on which entities;
b) 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;
c) Information conditions may be placed on the collection and analysis of information on the safety and effectiveness of the AEU product.

The authority will establish these conditions on a case by case basis.

11.7 Additional conditions for unapproved use of an approved product

With respect to an AEU that authorizes a change in product information of an approved product, but for which the manufacturer chooses not to make such change, the AEU may not authorize a

product distributor or any other person to alter or obscure the manufacturer's product information. However, under such conditions, the Authority must authorize, to the extent practicable under the circumstances of the emergency, any person (other than the manufacturer) acting pursuant to such AEU to provide appropriate information, in addition to the manufacturer's product information, with respect to the product.

The Authority may establish conditions of distribution and administration of an approved product for unapproved use that are no more restrictive than those previously approved. Any such additional conditions will be established by the Authority 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.

12.0 COMPLIANCE WITH GMPs OR ALTERNATIVE APPROACHES

The Authority expects that an AEU product 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.

13.0 ADVERTISING

The Authority may establish conditions on advertisements and other promotional descriptive printed matter relating to the use of AEU product.

14.0 AEU VALIDITY, REVOCATION OR TERMINATION

14.1Validity

The AEU shall terminate one (1) year from the date of issuance of the Authorization letter or when the declaration of the Public Health Emergency has ceased to exist or whichever is earlier. Generally, the AEU will be in effect for the duration of the declaration, unless the AEU is revoked because the criteria of issuance above are no longer met or revocation is appropriate to protect public health or safety.

14.2 Revocation

The Authority will periodically review the circumstances and appropriateness of an AEU, including circumstances that might warrant revocation of the AEU. Such circumstances may include significant adverse monitoring findings (e.g., where an inspection of the manufacturing site and processes have raised significant questions regarding the Quality, Safety, Efficacy or Effectiveness of the AEU product that materially affect the risk/benefit assessment upon which

the AEU was based); reports of adverse events (number or severity) linked to, or suspected of being caused by, the AEU 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.

14.3 Termination

Upon termination of the declaration of the PHE, any product with AEU must be disposed 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).
A manufacturer may choose to apply to the Authority to formally register the medical product for the indication upon which the AEU was granted or apply to officially include the AEU-approved indication in the registered product data (in situations where the product was already registered with the Authority).

14.4 Continued Use

Any use of an AEU 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.

15.0 REFERENCES

1. Ghana FDA Guidelines for Emergency Use Authorization of Medical Products number: FDA/GEN/GL-EUA/2021/04 version 02
2. Rwanda FDA Guidelines on submission of Documentation for Registration of human medicinal products N°: DHT/GDL/001
3. WHO Emergency Use Listing Procedure Version 13 December 2020

16.0 DOCUMENT REVISION HISTORY

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05/05/2021	Rev_0	DAR/GDL/039	First Issue

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