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Guideline for Emergency Use Authorisation

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An agency of The Gambia

Guideline for Emergency Use Authorisation

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Executive summary

The development of this guideline (GL) is based on the outcomes and consensus of the meetings convened in January 2020 and February 2020 and additional online meetings in 2021 by GHPP PharmTrain-Project Team of the Federal Institute for Drugs and Medical Devices (BfArM, Germany) with participants from the national medicines regulatory authorities (NMRA) of Liberia (LMHRA, Liberia Medicines and Health Products Regulatory Authority), Sierra Leone (PBSL, Pharmacy Board of Sierra Leone) and The Gambia (MCA, Medicines Control Agency).

This draft document was discussed and adapted in exchange between LMHRA, PBSL, The Gambia MCA, Ghana (FDA, Food and Drugs Authority) and the GHPP PharmTrain-Project Team starting at the Workshop for Guideline development from 8th-11th November 2021 in Accra, Ghana.

The draft guideline was adopted by the MCA Technical Working Group on 10th December 2021 for release for public consultation. After consultation the suggested changes were implemented and the MCA Technical Working Group agreed on the document for finalisation on 28th December 2021. The final guideline was approved by the MCA Executive Director on 30th December 2021 for coming into effect.

1 Introduction (background)

This guideline gives clarity on the regulatory requirements for the Emergency Use Authorisation (EUA) of a medicine (both innovator and multisource (generic) finished pharmaceutical products (FPPs), and biological products including vaccines) and of in-vitro diagnostics (IVDs) during a declared public health emergency (PHE) involving (amongst others) a heightened risk of attack on the general public's life, health, safety or a significant potential to affect national security. This guideline should be read along with other guidance documents concerning information and application requirements for registration of products published on the MCA website.

The EUA empowers the MCA to permit the approval of an unregistered medicine or IVD in a public health emergency when the known and potential benefits outweigh the known and potential risks of the product when used to diagnose, treat, or prevent serious or life-threatening diseases or conditions, when there are no adequate, approved, and available alternatives.

The MCA expects that the Ministry of Health or any other relevant Ministry shall submit the request for consideration of an EUA. The MCA may seek additional data and information on a case-by-case basis to ensure that the statutory criteria for issuance of an EUA are met.

1.1 Objectives

This Guideline on Emergency Use Authorisation seeks to expedite access to quality, safe and efficacious medicines and to quality IVDs to the public during a public health emergency.

2 Scope

This document provides guidance to industries, government agencies, and the general public on the general recommendations, requirements and procedures on the issuance of EUA process for the use during a public health emergency of an unregistered medicine (both innovator and multisource (generic) finished pharmaceutical products (FPPs) and biological products including vaccines) and IVD. The EUA is a special procedure for fast-track approval of medicines in the event of a PHE when the community/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 paucity of treatment, diagnosis/detection or prevention options. This guideline defines the steps that MCA will follow to establish eligibility of unlicensed medicines and IVDs 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 approved on a time limited basis, while further data are being gathered and evaluated.

3 Legal basis

In pursuance of Part VIII Section 64 of the Medicines and Related Products Act 2014, this document provides guidance for MCA and its stakeholders through the

registration for use of medicines and in-vitro diagnostics during a declared public health emergency.

4 Requirements

4.1 Declaration of Emergency

The Ministry of Health shall declare a public health emergency by an Executive Instrument where there is a situation that poses an immediate risk to health, life, property or the environment.

To meet the criteria for a public health emergency, the incident should:

- Immediately threaten life, health, 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 and the environment

4.2 Eligibility for Emergency Use Authorisation (EUA)

This is where an unregistered medicine and IVD can be authorised for use during a declared public health emergency involving a heightened risk of affliction or attack on the safety and security of the general public or a significant potential to affect national security. These products and their uses were not approved, cleared, or registered in The Gambia. The MCA may issue an EUA only if the MCA concludes:

a. that the agent/pathogen/item specified in the declaration of emergency can cause a serious or life-threatening disease or condition;

b. 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;

c. 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;

d. that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such serious or life-threatening disease or condition;

e. that the product is manufactured in compliance with current Good Manufacturing Practices (GMP) or produced under a functional Quality Management System (QMS) in the case of IVDs;

f. that the applicant undertakes to complete the development of the product and apply for full approval. 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; and

g. that the product is either on the WHO Emergency Use Listing (EUL) or is issued an EUA by a reference institution.

MCA may consider reviewing a candidate product for EUA that does not meet all of the requirements. In such situations, the application letter and documentation provided to MCA should justify the application of the product although it does not meet all eligibility requirements.

4.3 Risk-Benefit Analysis

Products are eligible for EUA if MCA 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, MCA assesses the quality and quantity of the evidence, given the current state of scientific knowledge, of risks and benefits. The MCA uses this information to make an overall risk-benefit determination. To accomplish this, MCA looks at the totality of the scientific evidence, which could arise from a variety of sources. The Agency evaluates and considers all evidence, including results of domestic and foreign clinical trials, animal data, and in vitro data, available for consideration. MCA anticipates that, for some candidate products, data from controlled clinical trials will be available. For others, the MCA 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.

Products to be used in public health emergencies, in response to recognised health threats, may provide particularly important benefits, therefore higher risks related to the absence of some data may be acceptable. In such cases an EUA can be granted also if preclinical or pharmaceutical data are not comprehensive.

4.4 Alternatives to the Product

The MCA may issue an EUA if it determines that there is no adequate, approved, and available alternative to the candidate product. A potential alternative product may be considered as:

- “unavailable” if there are insufficient supplies to meet fully the emergency need; or

- "inadequate" if there are contraindicating data for special circumstances or populations concerned (e.g., immunocompromised individuals or individuals with a medicine allergy) or if the agent is or may be resistant to approved and available alternative products.

4.5 Request for Consideration for an EUA

Although an EUA may not be issued until after a public health emergency has been declared by the Ministry, MCA recognises that during such exigent circumstances, the time available for the submission and review of an EUA request may be severely limited. Therefore, the MCA strongly encourages an entity with a possible candidate product, particularly one at an advanced stage of development, to contact the MCA for the candidate product even before a determination of actual or potential emergency. This can be done by either one or all of the following options: phone call, email, posted letter and/or a virtual or face-to-face meeting. This guideline offers recommendations and requirements 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, the guideline sets out the types of information MCA believes are important to allow an assessment of safety and effectiveness and to make an adequate risk-benefit determination to support issuance of an EUA.

A pre-submission meeting(s) is anticipated to facilitate the entire process, and for both pre-emergency and emergency activities, a pre-submission meeting(s) is recommended. These meetings should be scheduled as early as possible.

Applicants intending to make submissions for registration may have different challenges with respect to their applications and these may vary from complying with the administrative requirements in terms of the format extending to what data are available. MCA therefore encourages applicants to schedule a pre-submission meeting with the agency by email to obtain guidance that is specific to the application concerned.

A presentation detailing the product, the technology used, the data available, specific transport/storage and labelling information should be prepared. Information on whether the medicine or IVD has been or intends to be submitted to WHO, or other regulators for approval and the time frame for the submissions should be shared. In advance to the meeting, the applicant should provide a list of questions addressed to the MCA and propose a predefined agenda for an efficient meeting structure. Such meetings are important for discussing the availability of essential data required for specific products, expected timelines for submission and updates, monitoring of safety and effectiveness after deployment, and other relevant information. Additional meetings may be held during the assessment process, as requested.

Before the event of a PHE, the MCA should assign a group of regulators within the MCA “Roster of expert” responsible to conduct the pre-emergency and emergency activities, to evaluate the eligibility of an EUA, to participate in the pre-submission meetings, to communicate the essential data requirement, to communicate the timelines and to conduct the review.

4.6 Pre-Emergency Activities

Such activities may include discussions with MCA about 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 MCA strongly recommends that an entity submitting data during a "pre-emergency" period follow the requirements for data submission contained in "Submission of a Request for Consideration," below. If, prior to the declaration of an emergency, MCA believes that a candidate product may meet the criteria for an EUA, the MCA may share appropriate information on such product with the Ministry of Health.

4.7 Emergency Activities

Once a determination of actual or potential emergency has been made, the Ministry of Health may declare an emergency justifying the authorisation to use an unregistered medicine or IVD for an unapproved use. The Ministry shall consult with the MCA 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.

4.8 Submission of a Request for Consideration

Based on the totality of scientific evidence available to the MCA (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, MCA may consider issuing an EUA. The exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product. To facilitate MCA evaluation of such data, the MCA requires that a request for consideration for an EUA includes a well-organised summary of the available scientific evidence that demonstrates 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 summarises the types of data that MCA requires to be submitted to support a request for consideration for an EUA using the request form (**Annex I**). For MCA to evaluate a request for consideration for an EUA, the following information should be submitted:

a. 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);

b. An identification and an explanation of what unmet need(s) would be addressed by issuance of the EUA;

c. A description of the product's international registration/Marketing Authorisation (MA) status, i.e. whether the product is prequalified by an

international organisation such as WHO or has an EUA by a recognised authority;

d. A list of each site where the product, if authorised, would be (or was) manufactured and the Good Manufacturing Practices (GMP) status of the manufacturer;

e. An identification of any approved alternative products, including their availability and adequacy for the proposed use (if known);

f. Available safety and efficacy information for the product;

g. A discussion of risks and benefits;

h. A description of the information for healthcare providers or authorised dispensers and recipients of the product, and the feasibility of providing such information to healthcare providers or authorised dispensers and recipients in emergency situations;

i. Information on chemistry, manufacturing, and controls;

j. Certificate of Analysis of the EUA medicine;

k. Instructions for use as EUA product (e.g. if follow-up treatment is required);

l. Proposed labelling (if applicable), including batch number, manufacturing date and expiry date;

m. Name of reference substance/material (if applicable).

These requirements are discussed in more detail below. Please note that the MCA may also issue subsequent guidance providing greater detail on these requirements and procedures for specific medicines or IVDs and/or public health emergencies.

4.9 Required Safety Data

In general:

The amount and type(s) of safety data that MCA requires to be submitted as part of a request for consideration for an EUA 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. MCA will interpret safety information in light of the seriousness of the clinical condition, alternative therapies (if any), and the specific circumstances of the emergency. MCA

strongly encourages any person or entity with an EUA medicine to discuss with the MCA 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 MCA (see 4.5 Request for Consideration for an EUA).

4.9.1 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, MCA requires that the request for consideration for an EUA references 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 MCA requires 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.

4.9.2 Products under development

The range of available data for such products will differ widely. MCA requires that any request for consideration for an EUA includes available preclinical testing data, such as in vitro and animal toxicology data. The MCA also strongly encourages that safety information in humans from clinical trials and individual patient experience be provided, if available. MCA further requires that data submitted in the request attempts 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 IVDs of a similar design also should be submitted.

4.10 Required Effectiveness Data

In general:

MCA recognises that comprehensive effectiveness data are unlikely to be available for every EUA medicine or IVD, and the information necessary to authorise 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. MCA

assesses the sufficiency of the effectiveness data and the risk-benefit profile of each candidate product on a case-by-case basis.

MCA requires that requests for consideration for EUAs include any available relevant scientific evidence regarding the following as applicable:

a. The mechanism(s) of the product's action to diagnose, treat, or prevent the disease or condition underlying the request;

b. Preclinical testing data, such as in vitro evidence of 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 studies, 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;

f. For IVDs, device performance data to support the intended use such as analytical sensitivity and analytical specificity, and data from testing fresh, contrived, banked or archived specimens.

5 Other Data Considerations

5.1 In general

MCA requires that the request for consideration includes the following types of data, as appropriate and to the extent feasible given the exigencies of the circumstances:

a. Well-organised 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 raw 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 notarised translations of materials in a language other than English.

5.2 Data Quality

The Agency requires that requests for consideration for EUA 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.

5.3 Data Updates

MCA requires that any data from any ongoing testing (e.g. longer term stability data) or other data or information that may change the MCA's evaluation of the product's safety or effectiveness that become available during the period of review or the term of the EUA (to the extent that such data is not required to be submitted under a condition of authorisation) be submitted to the MCA when such data become available.

5.4 Discussion of Risks and Benefits

MCA requires that a request for consideration for an EUA includes a discussion of the medicine’s known and potential risks and benefits, which includes a synthesis of the data and information required above, including:

a. Measures taken to mitigate risk or optimise benefit (how the anticipated benefits to public health in the context of immediate availability outweigh the risks (also taking into account the as yet missing information));

b. Limitations, uncertainty, and data gaps (risks inherent in the fact that additional data are still required);

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

d. Benefits to public health of the immediate availability of the medicine on the market.

5.5 Format of Submissions

The MCA expects material to be provided in a reviewable form in CTD format and sufficiently complete to permit substantive evaluation and that the request form (**Annex I**) is completed.

Submissions shall be made in an electronic format two (2) copies, saved on a USB flash drive, together with an application letter addressed to the Executive Director of the MCA.

MCA requires that the submission begins with a section that describes the contents and organisation of the included materials. The applicant or anyone with a right of reference may refer to data or other information previously submitted to the MCA in a registration and/or marketing authorisation application.

Nevertheless, the MCA recognises 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 required data or to provide it in the format suggested in a timely manner. In such circumstances, the MCA will accept and evaluate the request for consideration for an EUA 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 authorise emergency use of the medicine or IVD.

The address for submission of a request for consideration for an EUA is:

Executive Director, Medicines Control Agency, 54 Kairaba Avenue, P.O. Box 3162, The Gambia.

5.6 Processing of an EUA

This section discusses MCA's role in pre-emergency activities for EUA medicine, as well as the procedures the MCA will follow in processing a request for consideration for an EUA once the Ministry has issued a declaration of emergency.

Prioritisation of Pre-Emergency Activities:

The MCA establishes priorities for the activities it undertakes, prior to a determination of actual or potential emergency. Such prioritisation may be based on the circumstances, such as:

a. the seriousness of the clinical condition;

b. the incidence of the clinical condition;

c. the effect the use of the product may have in ensuring national security;

d. whether the product is included in government stocks or whether there is a significant likelihood that the product will be included in government stockpiles if an EUA is granted;

e. whether the product could be used by a large population or is limited to subpopulation(s);

f. request of another government agency;

g. the extent to which the product would serve a significant unmet medical need in a special population (e.g. pregnant women, infants and children, or immunocompromised persons);

h. the availability and, where known, safety and effectiveness of other countermeasures;

i. the urgency of the treatment need (i.e. the window of opportunity for treatment can vary between different medical conditions);

j. the available information concerning the likelihood that the product may be safe and effective in treating the condition;

k. the adequacy of the supporting nonclinical and clinical information; and

l. the quantity of product available.

MCA establishes priorities for its pre-emergency activities at the central or regional level, as appropriate and feasible, and will consult with the Ministry of Health and other institutions, where applicable, on its priority setting.

5.7 Pre-Emergency Submission

To allow MCA evaluation process to begin before a determination of actual or potential emergency, the MCA 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 MCA's control, the MCA anticipates that pre-emergency submissions for high priority activities may be evaluated in a matter of weeks to months.

5.8 Prioritisation of Requests for Consideration for an EUA During a Declared Emergency

Once the Ministry has declared an emergency justifying the authorisation to use an unregistered product or an unapproved use of an approved product, the MCA prioritises its evaluation of requests for consideration for an EUA based on factors such as:

a. the seriousness of the clinical condition;

b. the incidence of the clinical condition;

c. the likelihood that the product may be effective in treating the condition;

d. the effect use of the product may have in ensuring national security;

e. whether the product is included in government strategic stocks;

f. whether the product could be used by a large population or is limited to subpopulation(s) (unless such use may be critical in managing a public health threat or in protecting a subpopulation with no other suitable measures available);

g. request of another government agency;

h. the extent to which the product would serve a significant unmet medical need in a special population (e.g. pregnant women, infants and children, or immunocompromised persons);

i. the availability and, where known, safety and effectiveness of other countermeasures;

j. the urgency of the treatment need (i.e. the window of opportunity for treatment can vary between different medical conditions);

k. the adequacy of the supporting nonclinical and clinical information; and

l. the quantity of product available.

5.9 Consideration for an EUA Request

The MCA will be responsible for the overall disposition of the request and will interact directly with the entity submitting the request for consideration. The MCA 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 MCA will work with the Ministry 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.

MCA recognises that the exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product. The MCA 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/groups (as appropriate and feasible), will perform evaluation of the information and data included in the request for consideration and make recommendations to the Executive Director of the MCA. The letter of authorisation or otherwise will be issued by the Executive Director. The letter authorising emergency use of a product will include a description of the intended use, as well as the indications and contraindications of the product.

5.10 Timelines for Evaluation of the Request

The timelines for evaluation and action on a request for consideration for an EUA 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, the MCA recognises that it is likely that, in a public health emergency that is occurring or believed imminent, a request for consideration for an EUA will be acted upon within a matter of days.

5.11 Conditions of Authorisation for Emergency Use of an unregistered or unapproved use of a registered medicine and IVDs

Information for Healthcare Providers or Authorised Dispensers:

To the extent consistent with other conditions of authorisation, information on the EUA of medicines and IVDs should be disseminated by MCA to healthcare providers and authorised dispensers through media, videos/DVDs/CD-ROMs, the Internet, and direct communication from the Ministry.

Information for Recipients:

Although informed consent is not required for administration of an EUA medicine, the information dissemination requirements are mandatory to the extent practicable. MCA requires that recipients be given as much appropriate information as possible given the nature of the emergency and the conditions of the authorisation. For healthcare providers carrying out any activity concerning an EUA, recipients must be informed that the MCA has authorised emergency use of the medicine, and has evaluated the potential benefits and risks of the medicine. Recipients must have an opportunity to accept or refuse the EUA 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.

MCA requires that some form of written information will be given to recipients in the simplest language possible and using other techniques to promote public health awareness. The MCA requires that the written information includes 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 MCA recommends that the written information for recipients be tested (e.g. by focus groups) for clarity, particularly regarding messages on uncertainty and relative risks. MCA acknowledges, however, that exigent circumstances may dictate the use of other, more appropriate, dissemination methods. Therefore, MCA 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 healthcare providers and public health agencies.

Monitoring and Reporting of Adverse Events:

The Ministry of Health appoints focal persons from any established entity with the experience in adverse event monitoring and reporting for EUA medicines. MCA expects that the primary focus will be on capturing serious adverse events and identifying the appropriate mechanism(s) to be used for the collection of follow-up clinical information, the size of the safety database, and the types of data needed. Predefined mechanisms to capture adverse event data are preferred, where feasible. In certain circumstances, other mechanisms also may be considered, such as using stickers or labels on the product, and any other information that refers the healthcare provider or authorised dispenser and recipient to a toll-free number and Internet site to report adverse events. Such information could be included as part of the recipient information.

Records:

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

Importation authorisation:

Once the MCA has issued an EUA there should be an application and approval for import by using the MCA Import Clearance Permit form (MCA-F-113/01), available from the MCA website. The MCA requires the following documents and information to be submitted for importation:

- Full name, telephone number, email, postal address and premises physical address of the exporter and importer;
- Name of port of shipment and port of entry into The Gambia and the dates;
- Total CIF value;
- Name (brand and generic names, compositions, strengths and dosage forms, where applicable), and description of products;
- Total quantity of products and units of issue;
- Name of manufacturer and country of origin; and
- Batch numbers and Expiry Dates.
- For pharmaceutical companies and health institutions, the full name, registration number and signature of the Supervising Pharmacist or duly authorised senior health official, where applicable.

In applying for a permit, the following documents shall be submitted, where applicable:

- Three (3) copies of the supplier's invoice(s);
- Three (3) copies of the packing list;
- Three (3) copies of the completed import clearance permit form;
- Three (3) copies of airway bill/bill of lading, where applicable;
- One (1) copy of the stamped customs entry form; and
- For medicines, one (1) copy of the Certificates of Analysis (CoA) for each batch to be imported.

Additional Conditions for Unapproved Products:

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

- Restricted distribution under the EUA;
- How to store and distribute the EUA product;

- 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;
- Conditions may be placed on the collection and analysis of information on the safety and effectiveness of the EUA product.

The MCA will establish these conditions on a case-by-case basis.

Additional Conditions for an Unapproved Use of an Approved Product:

With respect to an EUA that authorises a change in labelling of an approved product, but for which the manufacturer chooses not to make such labelling change, the EUA may not authorise a product distributor or any other person to alter or obscure the manufacturer's labelling. However, under such conditions, the MCA must authorise, to the extent practicable under the circumstances of the emergency, any person (other than the manufacturer) acting pursuant to such EUA to provide appropriate information, in addition to the manufacturer's labelling, with respect to the product.

The MCA 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 MCA for the distribution and administration of the product for an approved use. Any such additional conditions will be established by the MCA on a case-by-case basis, depending on the circumstances of the emergency and the nature of the approved product authorised for an unapproved use.

Compliance with GMPs or Alternative Approaches:

The MCA expects that EUA 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.

Advertising:

MCA may establish conditions on advertisements and other promotional descriptive printed matter relating to the use of EUA product.

5.12 Laboratory Tests for IVDs under an EUA

If issuing an EUA for an IVD, MCA will indicate whether the test can be performed at a point-of-care setting or only in a laboratory able to handle more complex tests. MCA may also establish appropriate conditions on the performance of the test.

5.13 Revocation or Termination of an EUA

An EUA will be in effect for the duration of the declared emergency (see 4.1 above) unless the EUA is revoked because the criteria of issuance (see 4.2 above) are no longer met or revocation is appropriate to protect public health or safety.

Revocation:

The MCA will periodically review the circumstances and appropriateness of an EUA, including circumstances that might warrant revocation of the EUA. 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 EUA product that materially affect the risk/benefit assessment upon which the EUA was based), reports of adverse events (number and seriousness) linked to, or suspected of being caused by, the EUA product, product failure, product ineffectiveness (such as newly emerging data that undermine the MCA'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 labelling and product information for an unapproved use must be disposed of. A manufacturer may choose to have unapproved product returned after termination for registration. Notwithstanding any such termination, an authorisation 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 healthcare provider).

Continued Use:

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

Definitions

Authority means the national medicines regulatory authority (NMRA)

Applicant means the product owner or licence holder. Representatives of licence holders may not hold themselves as applicants unless they own the product

Biological product means items derived from living organisms

Manufacturer is a company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of medicines

Risks are any known and potential risks relating to the quality, safety or efficacy of the medicine as regards patients' health or public health

Risk-benefit analysis is 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

Public health emergency (national and international) is an emergency need for health care services to respond to a disaster, significant outbreak of an infectious disease, bioterrorist attack or other significant or catastrophic event, which can be national or international. A Public Health Emergency of International Concern is a formal declaration by the WHO of "an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response", formulated when a situation arises that is "serious, sudden, unusual, or unexpected", which "carries implications for public health beyond the affected state's national border" and "may require immediate international action"

References

- WHO. NEW Emergency Use Listing Procedure (EUL) December 2020 https://extranet.who.int/pqweb/sites/default/files/documents/EUL-FINAL-13_12_2020.pdf
- FDA Ghana. GUIDELINES FOR EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS https://fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/BPD/GUIDELINES%20FOR%20EMERGENCY%20USE%20AUTHORIZATION%20OF%20MIDICAL%20PRODUCTS.pdf
- USFDA. Emergency Use Authorization of Medical Products and Related Authorities. Guidance for Industry and Other Stakeholders. January 2017.

- EMA. Guideline on the scientific application and the practical arrangements necessary to implement Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004. 25 February 2016, EMA/CHMP/509951/2006, Rev.1, Committee for Medicinal Products for Human Use.
- SAHPRA. INFORMATION AND GUIDANCE ON APPLICATION FOR REGISTRATION OF CANDIDATE COVID-19 VACCINE, COMMUNICATION TO INDUSTRY. Version1 Nov 2020.
- Medicines and Related Products Act, 2014, The Gambia
- Medicines and Related Products Regulations, 2020

Annex

Annex I _Request for Consideration for EUA form (MCA-F-120/01)