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Guideline for Emergency Use Authorisation of Medicines including Vaccines and In-vitro Diagnostics

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2	31 January 2025	Editorial changes; acknowledgement included; procedures more detailed

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Guideline for Emergency Use Authorisation of Medicines including Vaccines and In-vitro Diagnostics

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Acknowledgements

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Executive summary

The development of this guideline is based on the outcomes and consensus of the meetings convened in January / February 2020 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 document has been discussed and adapted in exchange between LMHRA, PBSL, The Gambia MCA, Ghana (FDA, Food and Drugs Authority) and the GHPP-PharmTrain project team from November 2021 to September 2022. The updated version 1 of the Guideline on Emergency Use Authorization for the National Medicines Regulatory Authorities of Ghana, Liberia, Sierra Leone, and The Gambia was finalised on 10 March 2023 for preparation of the NMRA's own guidelines.

This document should be read in conjunction with the relevant sections of other applicable guidance documents.

1 Introduction (background)

1.1. This guideline gives clarity on the regulatory requirements for an emergency use authorisation of a medicine (medicinal product) including vaccine and of an in-vitro diagnostic (IVD) 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 such as the MCA *Guideline on Medicine Donations* and *Guideline for Marketing Authorisation (Registration) of Medicines*.

1.2. The Emergency Use Authorisation (EUA) is granted by the legal provision Medicines and Related Products Regulations, 2020. The EUA empowers the MCA to permit the approval of an unauthorised product in a PHE.

1.3. This procedure takes into consideration whether 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 approved adequate, and available alternatives.

1.4. The MCA expects that a Government Ministry, Department or Agency (MDA) or any other recognised agency (e.g. the Ministry of Health or the Ministry of Defence, Ministry of Interior, an entity appointed by a Government MDA, etc.) shall submit the request for consideration for an EUA to the MCA. 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.

1.5. In the event of a PHE an applicant may apply for an EUA directly to the MCA or, a request for consideration may also be submitted by an MDA or any other recognised agency.

Objective

1.6. This Guideline on Emergency Use Authorisation seeks to expedite access to quality, safe and efficacious products to the public during a PHE.

2 Legal basis

2.1. In pursuant of legal provision Medicines and Related Products Regulations, 2020 of The Gambia, this document provides guidance on the use of products during a declared PHE.

3 Scope

3.1. This document provides guidance to industries, government agencies, and the general public on the general recommendations and procedures on the issuance of EUA process for the use of a medicine including vaccine and IVD during a PHE. This can be a repurposed product (authorised product but unapproved use), a novel product (unauthorised product) as well as a product that has been authorised by a reference institution.

3.2. The EUA is a special procedure for fast-track approvals of products 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.

3.3. To establish eligibility of unauthorised products for assessment under this procedure, this guideline defines the steps that MCA will follow, the essential information required, and the process to be used in conducting the assessment to determine whether an unauthorised product can be approved on a time limited basis, while further data is being gathered and evaluated.

4 General Requirements

4.1 Declaration of Emergency

4.1.1. The Ministry of Health shall declare a national PHE by an Executive Instrument where there is a situation that poses an immediate risk to health or life.

4.1.2. To meet the criteria for a national PHE, the incident should:

- Immediately threaten life or health;
- Have already caused loss of life or health detriments;
- Have a high probability of escalating to cause immediate danger to life or health.

4.2 Eligibility for Emergency Use Authorisation (EUA)

4.2.1. This is when an unauthorised product or an authorised product with an unapproved use can be authorised for use during a declared PHE 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.

4.2.2. These products and their uses are not authorised as per standard marketing authorisation (registration) procedure.

4.2.3. After consultation with relevant bodies and/or committees (to the extent feasible and appropriate given the circumstances of the emergency), the MCA may issue an EUA only if, the MCA concludes-

a. That the agent/pathogen/item specified in the declaration of emergency (in the following called "the agent") can cause a serious or life-threatening disease or condition.

b. 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

i. the serious or life-threatening disease or condition referred to in a. above; or

ii. a serious or life-threatening disease or condition caused by a product granted emergency use authorisation for diagnosing, treating, or preventing the disease or condition referred to in a. above.

c. 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. An approved alternative to the product for diagnosing, preventing or treating such serious or life-threatening disease or condition is not available or not adequate. A potential alternative product may be considered as:

i. "not available" if there are insufficient supplies to meet fully the emergency need

ii. "not adequate" if

- there are data contraindicating the use of any available alternative for special circumstances or populations (e.g. immunocompromised individuals or individuals with a medicine allergy) or
- if the agent is or may be resistant to available alternative products.

e. 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. The applicant undertakes to complete the development of the product and apply for full authorisation. 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.

4.2.4. MCA may consider reviewing a candidate product for an 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.

5 Instructions for the Applicant

5.1 Request for Consideration for an EUA

5.1.1. Although an EUA may not be issued until after a PHE has been declared by the Ministry of Health, 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 an actual or potential emergency.

5.1.2. 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.

5.1.3. In addition, this section of the guideline sets out the information for the MCA to allow an assessment of safety and effectiveness and to make an adequate risk-benefit determination to support issuance of an EUA. Details about the format of submissions are specified in Annex 1.

Pre-submission Meeting(s)

5.1.4. A pre-submission meeting is anticipated to facilitate the entire EUA process.

5.1.5. For both pre-emergency and emergency activities, a pre-submission meeting is recommended. These meetings should be scheduled as early as possible. Applicants intending to make submissions for an EUA may face different challenges with respect to their applications. These may vary from complying with the administrative requirements in terms of the format and the availability of data. MCA therefore encourages applicants to schedule a pre-submission meeting with the Agency by email to obtain guidance in accordance with the requirements outlined in section 5.2.1. A pre-submission meeting request form is in Annex 2.

5.1.6. A presentation should be prepared detailing the product, the technology used, the data available, specific transport/storage and labelling information. Information on whether the product has been or is intended to be submitted to WHO, or other regulators for approval and the time frame for submissions should be shared.

5.1.7. In advance to the meeting, the applicant should supply 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.

5.1.8. Additional meetings may be held during the assessment process, as requested.

5.1.9. Before the event of a PHE, the MCA should assign a group of regulators within the NMRA a so-called “Roster of expert”. They are 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 requirements, to communicate the timelines, to conduct the review in an expedited manner, e.g. as rolling review.

Pre-Emergency Activities

5.1.10. Such activities may include discussions with MCA about a prospective EUA of a product and the appropriate procedure for submitting data on the product prior to an emergency declaration. The MCA strongly recommends that an entity submitting data during a "pre-emergency" period, follows the recommendations for data submission outlined in the section "Submission of a Request for Consideration" below.

5.1.11. If, prior to the declaration of an emergency, MCA concludes that a candidate product may meet the criteria for an EUA the MCA may share appropriate information on such product with the body declaring the PHE. Prior a declaration of a PHE, the MCA may share information regarding a product candidate with the declaring body if the MCA deemed the product candidate eligible.

Emergency Activities

5.1.12. Once a determination of an actual or potential emergency has been made the Ministry of Health may declare an emergency justifying the authorisation to use an unauthorised product for an unapproved use. The Ministry will consult with the MCA and other agencies and private entities, where appropriate, to identify products that may be eligible for an EUA in light of the circumstances of the emergency and to facilitate timely submission of the EUA request by an appropriate entity.

5.2 Submission of a Request for Consideration

5.2.1. A request may be submitted 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.

5.2.2. The exact type and amount of data needed to support an EUA may depend on the nature of the declared emergency and the nature of the candidate product. According to MCA recommendations a request for consideration for an EUA shall include a well-organised summary of the available scientific evidence that evaluates the product's pharmaceutical quality, safety and efficacy.

Summary of required information

5.2.3. The information below summarises the type of data that MCA requires to be submitted to support a request for consideration for an EUA (requirements specific for vaccines are described in detail below):

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 medical need(s) would be addressed by issuance of the EUA.

c. A description of the product's international registration/Marketing Authorisation (MA) status, including also, whether the product is WHO prequalified.

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

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 (Details see Annex 3a and 3b).

g. A discussion of risks and benefits (Details see Annex 3c).

h. A description of the information for healthcare providers or authorised dispensers and recipients of the product, (e.g. two separate "Condition of

use" documents), and the feasibility of providing such information to health care providers or authorized dispensers and recipients in emergency situations.

i. Information on pharmaceutical quality (as per Module 3).

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

k. 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.

l. Proposed labelling (if applicable). Including batch number, manufacturing date and expiry date, legal status and limitations of data.

m. The MCA recommends 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.

5.2.4. **These data requirements are discussed in more detail in Annex 3.** Please note that the MCA may also issue subsequent guidance providing greater detail on these recommendations and procedures for specific products and/or public health emergencies.

5.2.5. MCA requests that the applicant submits 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 are not required to be submitted under a condition of authorisation) to the MCA as soon as such data become available.

5.3 Requirements Specific for Vaccines

Manufacturing and quality control data

5.3.1. Manufacturing and quality control data should generally comply with CTD quality requirements as per MCA *Guidance for the Application in the Common Technical Document (CTD) Format* applicable to biologicals (biotechnical products). The following are additional relevant references/requirements for consideration:

a) Full characterisation of cell banks according to WHO Technical Report Series 978, Annex 3 and any subsequent updates or related guidelines.

b) Full characterisation of master and working seed organism(s).

c) Process validation (based on quality risk assessment for the development stage of clinical batch) and demonstration of consistency of production at the production scale used for the batches to be distributed. If deemed appropriate by MCA data on clinical batches with a commitment to complete validation on production batches and to submit the data as part of lot release review may be considered.

Note: If full characterisation is not possible at the time of submission, adequate justification must be submitted as to why not, and a plan must be

presented to address the data gaps.

Validation of potency tests and other critical assays: If novel test methods have been developed, full description of the test development and qualification must be presented.

d) Justified specifications for starting material, intermediates, and final products.

e) Stability data for the vaccine produced at the scale produced for the batches to be supplied. If available, accelerated stability data must be included.

f) Inspection report(s) from the responsible NMRA or from the WHO inspection team showing compliance with GMP requirements – if available.

g) Process changes: By the time of submission, it is likely that the manufacturing process is not finalised and that numerous changes will have to be applied after the first listing. These changes should be submitted as updates.

Non-clinical and Clinical Data

5.3.2. Non-clinical data demonstrating acceptable safety, immunogenicity, and efficacy, if available, in the most appropriate animal model. The applicant must justify the choice of animal model. If the non-clinical package is not complete at the time of submission, the applicant must submit adequate justification for the lack of complete data and a plan and timeline for submitting those data.

5.3.3. Clinical data demonstrating the appropriate dose to be used and initial acceptable safety and immunogenicity in the population in which the vaccine will be used in the context of the public health emergency.

5.3.4. Preliminary data showing some efficacy, if available. If preliminary human data showing some efficacy are not available for the vaccine under consideration and if not imminently available for other vaccines being concurrently developed, MCA will consider whether the preponderance of evidence from the non-clinical, and early human studies justifies considering the immunogenicity data as a potential surrogate that is thought to be reasonably predictive of clinical efficacy. In such cases, the emergency use listing can proceed, provided there are trials underway that will ultimately provide confirmation that immunogenicity is a surrogate.

5.3.5. Safety and immunogenicity data from other vaccines made by the manufacturer using the same product platform may be considered as supportive data for review if applicable.

Plan for monitoring and reporting of adverse events

5.3.6. Since the vaccines listed under the EUA procedure have not been authorised for use in routine immunisation settings, post marketing data would not be available at the time of application.

5.3.7. Therefore, the applicant should discuss with MCA in pre-submission meetings, the plans to ensure the collection and analysis of information on the

safety and effectiveness of the product during the period when the EUA would be in effect and for a reasonable time following such period.

5.3.8. MCA encourages applicants to discuss proposals for active data collection and follow-up mechanisms to capture adverse event information under the EUA during the pre-submission meetings.

5.3.9. A Risk Management Plan (RMP) in line with MCA requirements should be in place and submitted by the applicant as part of EUA submission. The RMP may include Post-Authorisation Safety Study (PASS) and Post-Authorisation Efficacy Study (PAES) as applicable.

5.3.10. Active monitoring will be required as well as spontaneous reporting by the MCA, and frequent submission of PSURs in line with MCA requirement.

Labelling

5.3.11. The following is required for labelling:

- Summary of product characteristic (SmPC) (information for healthcare professionals);
- Patient information leaflet (PIL);
- Container labelling;
- Any other instructional materials provided to the user;
- A plan to help assure that prospective recipients and healthcare professionals are adequately informed about the uncertainties regarding both the potential benefits and risks.

Note: When the product is listed, the labelling should clearly indicate that that product is for emergency use only.

Environmental Risk Assessment (ERA)

5.3.12. If the product contains a Genetically Modified Organism (GMO), the applicant must submit a completed Environmental Risk Assessment report.

6 EUA Instructions for the MCA

6.1 Processing of an EUA

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

6.2 Pre-Emergency Submission

6.2.1. 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 submissions will be determined on a case-by-case basis and will depend on the nature of the emergency.

6.2.2. 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.

6.3 Prioritisation of Requests for Consideration for an EUA

6.3.1. The MCA intends to establish priorities for its evaluation of requests to consider an EUA, prior as well as during a declared PHE. 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 available information concerning the likelihood that the product may be safe and effective in preventing, treating, or diagnosing the condition;

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

e. whether the product is included in government strategic stockpiles, if applicable;

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, and 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;

l. the quantity of product available;

m. the feasibility of adhering to required storage conditions; and

n. the security of the supply chain, if applicable.

6.3.2. MCA intends to establish priorities for its pre-emergency activities at the Directorate level or higher and, as appropriate and feasible, will consult with the Ministry and may consult other agencies on its priority setting.

6.4 Consideration for an EUA Request

6.4.1. 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.

6.4.2. 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.

6.4.3. 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.

6.4.4. The responsible Directorate in consultation with other relevant Directorates and technical committees (as appropriate and feasible), will perform an evaluation of the information and data included in the request for consideration and make recommendations to the Executive Director (ED) of the MCA. The letter of authorisation or otherwise will be issued by the ED.

6.4.5. The letter authorising the emergency use of a product will include a description of the intended use, the indications and contraindications of the product, as well as the validity of the EUA. The conditions of the authorisation for emergency use of an unauthorised product or authorised product with unapproved use are specified in Annex 5.

6.4.6. 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.

6.5 Timelines for Evaluation of the Request

6.5.1. The timelines for evaluation and action on a request for consideration for an EUA will depend on the product's profile, the existence, if any, of pending applications for the product, the nature of the emergency, and other relevant factors.

6.5.2. Although the length of time required for action will vary, the MCA recognises that it is likely that, in a PHE that is occurring or believed imminent, a request for consideration for an EUA will be acted upon with highest priority.

6.6 Validity, Revocation or Termination of an EUA

6.6.1. The validity of an emergency use authorisation in the context of a PHE will generally be for 12 months. An EUA will be in effect for the duration of the declaration (as described in section 4.1 Declaration of Emergency), unless the EUA is revoked because the criteria of issuance (as described in section 4.2 Eligibility for an Emergency Use Authorisation) are no longer met or revocation is appropriate to protect public health or safety.

Revocation:

6.6.2. 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 or severity) 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);
- availability of a preferred product.

Termination:

6.6.3. Upon termination of the declaration, an unauthorised/ product or its labelling and product information for an unapproved use must be disposed of. A manufacturer may choose to have an unauthorised product returned after termination.

6.6.4. 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 physician).

Continued Use:

6.6.5. 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 physician.

6.7 Publication

6.7.1. MCA will promptly publish a notice of each EUA on the MCA website, including an explanation of the reasons for issuance, a description of the intended use, and any contraindications of the EUA product. MCA also will promptly publish each termination or revocation of an EUA and an explanation of the reasons for the decision.

6.7.2. By publicly releasing information on an EUA, MCA will take necessary steps to protect classified information and information otherwise protected by law, as appropriate.

6.7.3. Disclosures of information by MCA to the Ministry of Health will be consistent with applicable laws protecting trade secrets and confidential commercial or financial information.

7 7. Post-Authorisation Activities

Post EUA monitoring

7.1. After a product has been approved and used, MCA will take into consideration reports on safety surveillance, efficacy/ effectiveness/ performance monitoring, quality complaints and other relevant data that may impact the validity of the EUA.

7.2. The sources of such information will inter alia be based on existing surveillance mechanisms in The Gambia and on post-approval surveillance commitments of the manufacturer, set as conditions for the EUA. The applicant must provide a Risk Management Plan considered necessary to identify, characterise and minimise the important risks of a product.

7.3. MCA deems that the emergency use authorisation holder is not responding to a post-approval quality/safety issue in a timely and/or scientifically sound manner and if post-approval quality/safety issues are identified and cannot be resolved to MCA’s satisfaction, MCA reserves the right to restrict or revoke the EUA of the product.

Post-EUA changes

7.4. The applicant must promptly inform MCA of all changes regarding formulation, manufacturing process, testing methods, specifications, facilities and any other aspects that might result in a change of the safety and/or efficacy and/or performance of the product.

Definitions

Interpretations and abbreviations contained in the MCA Glossary can be found on the MCA Website: **www.mca.gm.**

The definitions provided below apply to the terms used in this guideline. They may have different meanings in other contexts and documents.

The interpretation of terms provided in the Act and Regulations apply, unless further defined in this guideline.

Active Pharmaceutical Ingredient (API)
Any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals. Synonym is "active substance".

Agent
Pathogen/item specified in the declaration of emergency causing a serious or life-threatening disease or condition.

Applicant
A person or entity who has applied for an Emergency Use Authorisation of a product or a change thereof. All applicants (e.g. manufacturer, marketing authorisation holder, research institution, etc) are to own the product.

Batch Number
A distinctive combination of numbers and/or letters which specifically identifies a batch or lot and from which the production history can be determined.

Biological/Biotechnical product
A diverse category of medicines that generally are large, complex molecules including vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins of human, animal, plant or microorganism origin; these medicines may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterise than small molecule medicines.

Excipient
any constituent of a pharmaceutical form that is not an active pharmaceutical ingredient.

Finished Pharmaceutical Product (FPP)
A product that has undergone all stages of production, including packaging in its final container and labelling. An FPP may contain one or more active pharmaceutical ingredients.

In-vitro diagnostic (IVD)
A medical device, whether used alone or in combination, intended by the manufacturer for the invitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Manufacturer
Any person or entity with responsibility in manufacturing activities including implementation of oversight and controls over the manufacture of the product or active ingredients or excipients to ensure quality.

Marketing Authorisation Holder (MAH)
A company or other legal entity that has the authorisation by a regulatory authority to market a medicine or related product and who is responsible for its quality, efficacy and safety and for compliance with conditions of authorisation (registration).

Medicine (Medicinal Product)
Any substance or combination of substances prepared, sold or presented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it or restoring, correcting or modifying organic functions in human beings.

The term "medicines/medicinal products" in the context of this guideline includes finished pharmaceutical products (FPPs), herbal medicinal products and vaccines. Not included are blood products and animal products.

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

Unauthorised product
A product that has no marketing authorisation (registration) by MCA or any other NMRA.

References

- USFDA. Emergency Use Authorization of Medical Products and Related Authorities. Guidance for Industry and Other Stakeholders. January 2017. FDA/SMC/BPD/GL-EUM/2019/08.
- WHO. NEW Emergency Use Listing Procedure (EUL) December 2020, Version 13 December 2020 https://extranet.who.int/pqweb/sites/default/files/documents/EUL-FINAL-13_12_2020.pdf
- WHO. Recommendations for the evaluation of animal cell cultures as substrates for the manufacture of biological medicinal products and for the characterization of cell banks, Technical Report Series No 978, Annex 3, 2013
- FDA Ghana. Guideline on Emergency Use Authorization of Medical Products. FDA/DNC/GDL - 17/02. 8th January 2024
- FDA Ghana. Guidelines For Safety Monitoring Of Medicinal Products. March 2019, FDA/SMC/SMD/GL-SMP/2015/05.
- ICH. Harmonised Tripartite Guideline the Common Technical Document for The Registration of Pharmaceuticals for Human Use: Quality – M4Q(R1), 12 September 2002.
- 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.

- Medicines and Related Products Act, 2014, The Gambia
- Medicines and Related Products Regulations, 2020
- MCA Guideline for Reliance on decisions, reports, or information from other national medicines regulatory authorities (NMRAs) or regional and international bodies (MCA-GL-109)
- MCA Guideline for Marketing Authorisation (Registration) of Medicines (MCA-GL-102)
- MCA Guidance for the Application in the Common Technical Document (CTD) Format (MCA-G-112/02)

List of Annexes

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Annex 3: Details on required information for submission (MCA-G-120/04)

Annex 3a: Recommended Safety Data (MCA-G-120/05)

Annex 3b: Recommended Effectiveness Data (MCA-G-120/06)

Annex 3c: Discussion of Risks and Benefits (MCA-G-120/07)

Annex 4: Conditions of Authorisation (MCA-G-120/08)

Annex 5a: Healthcare Provider or Authorised Dispenser Information (MCA-T-120/09)

Annex 5b: Recipients Information (MCA-T-120/10)