MEDICINES CONTROL AGENCY

THE GAMBIA

Public Health Emergency Policy

March 2022

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1 INTRODUCTION

1.1. The regulation of medicines including vaccines and related products as well as in-vitro diagnostics (IVD) in The Gambia is governed by the provisions and requirements of the Medicines and Related Products Act, 2014. The Medicines Control Agency (MCA) was established as the regulatory body for medicines and related products (which are referred to in this document as **medical products**).

1.2. During declared Public Health Emergency (PHE) situations, MCA adopts agile and efficient regulatory pathways, in accordance with the World Health Organization (WHO) recommendations, to evaluate the quality, safety, and efficacy of new medical products as well as unapproved / “off label” use of registered medicines based on risk-benefit assessments.

1.3. A Public Health Emergency can be defined as an occurrence, or imminent threat, of an illness or health condition that poses a substantial risk of a significant number of human fatalities, injuries or permanent or long-term disability. A Public Health Emergency of International Concern is a formal declaration by the WHO Director-General of "an extraordinary event which is determined to constitute a public health risk to other countries through the international spread of disease and to potentially require a coordinated international response". This is formulated when a situation arises that is "serious, sudden, unusual, or unexpected", which "carries implications for public health beyond the affected country's national borders" and "may require immediate international action".

1.4. The national emergency preparedness and response plans include streamlined regulatory pathways that allow new medical products to be introduced following legal and orderly processes. This regulatory preparedness is key to achieving a rapid response that does not obstruct or delay access to and availability of medical products.

1.5. The pharmacovigilance activities are implemented, based on risk management plans and requirements for the issuance of import permits and customs clearance, and clinical trial authorisation are adopted accordingly.

2 PURPOSE AND SCOPE

2.1. This policy describes the principles upon which the Agency will operate in the event of a PHE.

2.2. It applies to all staff at the MCA.

3 RESPONSIBILITIES

3.1. The President of the Republic of The Gambia is the Chair of the National Disaster Governing Council (NDGC) and has representation from the Ministries and relevant Government departments.

3.2. The National Disaster Technical Committee (NDTC) is comprised of Heads of Government Departments, Security and Emergency Services, relevant

external organisations, and serves to advise the NDGC on disaster management issues.

3.3. The Minister of Health, in consultation with WHO and the appropriate authorities, declares the beginning and end of a Public Health Emergency in line with the country's regulatory framework.

3.4. The Minister of Health in close collaboration with NDGC assesses the need for emergency measures (e.g. use of legal powers to maintain essential services).

3.5. The MCA establishes the authorisation requirements, procedures and timeframes for introduction, distribution and use at the national level of medical products.

4 RISKS IN PUBLIC HEALTH EMERGENCY (PHE)

4.1. A declared public health emergency includes a heightened risk of affliction or attack on the life, health, safety and security of the general public and has the potential to affect national security.

4.2. The risks that need to be managed by the MCA in PHE may include:

- Import of products by unlicensed importers or uncontrolled import due to increased demand of certain products and porous border areas;
- Use of unregistered medicines and off label use of the registered medicines;
- Lack of essential medicines that may lead to inappropriate distribution channels and sharing of medications by patients;
- Poor quality products applied for an Emergency Use Authorisation (EUA);
- Inappropriate storage, handling, administration or use of EUA products due to increased amounts of EUA products, lack of information and training;
- Uncertainty in causality assessment of adverse events of medicines due to underlying diseases and conditions;
- Misleading or wrong information about EUA product due to e.g. lack of data or training or fear to use EUA products;
- Increased occurrence of serious adverse events in clinical trials due to underlying diseases and conditions;
- Inadequate supply of raw and packaging materials which may affect capacity of domestic manufacturers to produce medical products;
- Stretched capacity of the MCA to provide adequate regulatory oversight due to task shifting or effect of the PHE on individuals.

4.3. The MCA has established procedures for the mitigation and contingency of anticipated risks.

5 ADOPTED PROCESSES IN PHE

5.1. The MCA undertakes regular interactions with national and international

stakeholders including international partners such as WHO as part of routine preparedness activities to ensure that it will be in a state of readiness to deal with a PHE threat.

5.2. There is an abbreviated process established for the EUA of products in a PHE and the MCA conducts product-related assessments and post-authorisation surveillance activities.

5.3. The specific conditions under which each product is authorised (e.g. its exclusive use in certain population groups) will be based on risk-benefit analyses, post-authorisation safety notifications, additional information that manufacturers are obliged to submit to the MCA, and the respective risk management plans.

5.4. The pharmacovigilance activities in the situation of a PHE will be enhanced with respect to surveillance, signal management, rapid exchange of information on pharmacovigilance issues and the potential need for prompt regulatory action and communication to patients, healthcare professionals and public.

5.5. The MCA may grant exemptions or waivers with respect to documentation and fees for the import of products in emergency situations.

5.6. The Agency may expedite the application and review process for clinical trials and may make exemptions for the documents required to be submitted to the Agency for clinical trial applications.

5.7. Depending on the nature of the PHE, the Agency may carry out some or all its operations off site by using electronic and virtual platforms. Arrangements for port of entry and market inspections may be made while observing all the necessary precautions.

6 RISK-BENEFIT CONSIDERATIONS IN PHE

6.1. In the event of a PHE the community/public health authorities will ensure that products meet the standards of quality and safety using the minimum available data, given the morbidity and/or mortality of the disease and the lack or paucity of treatment, diagnosis/detection or prevention options.

6.2. The MCA decisions should be supported by reliable information on the quality, safety, and efficacy of these products; however, given the time frames and mechanisms required for a timely response in an emergency, a more prominent risk-benefit approach may be adopted compared to that used in normal market authorisation situations.

6.3. Both the nature of the products under evaluation and their origin (manufacture and procurement pathways) will be considered when defining the risk factors for regulatory decision-making and establishing differentiated mechanisms according to these parameters.

6.4. The MCA will also adopt a rolling review strategy on the applied products based on the available data at different times. Necessary modifications on the conditions for use may be made as the new information on quality and safety profile of the respective products become available.

7 REGULATORY PREPAREDNESS FOR PHE

7.1. The MCA has prepared guidance documents and procedures for PHE situation that cover:

- Emergency use authorisation of medicines and in-vitro diagnostics (IVDs);
- Import clearance permits;
- Clinical trials authorisation; and
- Pharmacovigilance.

7.2. The MCA uses Reliance in accordance with its policy and guidance documents that cover:

- Registration of medicines and variations;
- GMP inspections;
- Pharmacovigilance;
- Clinical trials authorisation; and
- Laboratory services for quality control of products.

7.3. The staff of MCA are trained and capable to respond to PHE situations.

7.4. The MCA is organised and managed in a flexible manner to respond to PHE requirements with respect to their regulatory functions (e.g. to shift priorities, to mobilise additional resources, etc).

8 TIMELINES IN PHE

8.1. The evaluation of documents for an EUA of medicines for treatment, diagnosis/detection or prevention in PHE will be processed on a case-by-case basis but will be acted upon within a matter of days, but should take no more than 15 calendar days. These number of days will encompass all marketing authorisation stages including pre-submission meetings, assessments of dossiers and consideration by the expert committees.

8.2. An import clearance permit for such products should be issued, within 24 hours whenever possible but not later than within 5 working days.

8.3. The review of clinical trial applications should be completed as soon as possible but not later than within 21 working days.

8.4. The MCA should communicate PHE related issues via the website, emails and/or text messages to relevant stakeholders within 72 hours but not later than within 5 working days of decisions.

9 REFERENCES

- EMA plan for emerging health threats (EMA/863454/2018), 10 December 2018.
- WHO Annex 5, Guidelines on import procedures for medical products. Fifty-third Report. Geneva, WHO 2019.

- The republic of The Gambia, Integrated National Emergency Preparedness and Response Plan for Avian & Human Influenza (AHI), (2015-2019), 31 October 2015.
- Public Health (dangerous infectious diseases) Protection Regulations and Orders. 2020. Presentation.

10 DOCUMENT HISTORY

Version #	Implementation Date	Reasons for Change:
1	09 March 2022	New document

Signature: ..... Date: .....