FOOD AND DRUGS AUTHORITY

GUIDELINES FOR EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS

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1. ACKNOWLEDGEMENT

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1.0 INTRODUCTION

These Guidelines publish the regulatory requirements for the Emergency Use Authorization (EUA) of a Medical Product (Allopathic Medicines, Biological Medicinal Products, including Vaccines and Medical Devices) during a declared Public Health Emergency.

In executing its mandate, the FDA takes cognizance of the powers granted the Minister of Health by Sections 169 – 173 of the Public Health Act, 2012 (Act 851) in the event of a Public Health Emergency.

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

This Emergency Use Authorization (EUA) Guideline (**FDA/SMC/BPD/GL-EUM/2019/10**) will allow the expedited approval of medical products 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. It allows the FDA to authorize the use of either an unregistered medical product or an unapproved use of a registered medical product during a Public Health Emergency. Generally, the FDA will issue an E.U.A when it concludes that:

A. that the disease causative agent/item specified in the declaration of Public Health Emergency 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 a serious or life-threatening disease or condition caused by the agent specified in the declaration of emergency;
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; and

D. there is no adequate, approved, and available alternative 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 Emergency Use Authorization (E.U.A). The FDA expects that a Government Ministry, Department or Agency (MDA) or any other recognized agency or licensed/registered company (e.g., the Ministry of Health or the Ministry of Defence, Ministry of Interior, an entity appointed by a Government MDA, pharmaceutical company, etc.) shall submit the request for consideration of an E.U.A. The FDA may seek additional data and information on a case-by-case basis to ensure that the statutory requirements for the issuance of an E.U.A are met.

These Guidelines should be read in conjunction with other guidelines on the Food and Drugs Authority's (FDA) website <www.fdaghana.gov.gh>.

1.1 SCOPE

In pursuant of Sections 118, 169, 170, 171,172 and 173 of the Public Health Act 2012, Act 851, this document would provide guidance to applicants on the approval for use during a public health emergency of an unregistered medical product.

2.0 GLOSSARY

- **"Authority"** means Food and Drugs Authority
- **"Applicant"** means the product owner or license holder. Representatives of licence holders may not hold themselves as applicants unless they own the product.
- **"Accelerated stability studies"** means studies designed to determine the rate of change of vaccine properties over time as a consequence of the exposure to temperatures higher than those recommended for storage. These studies may provide useful support data for establishing the shelf-life or release specifications but should not be used to forecast real time real condition stability of a vaccine. They could also provide preliminary information on the vaccine stability at early developmental stages and assist in assessing stability profile of a vaccine after manufacturing changes.
- **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)

- **“Drug”** means (a) a substance referred to in a publication mentioned in the fourth schedule of the Public Health Act 2012 (Act 851), (b) a substance or mixture of substances prepared, sold or represented for use in, (i) the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it, in human or animal, or (ii) restoring, correcting or modifying organic functions in man or animal, and (c)nutritional supplements.
- **“Medical Device**” means an instrument or apparatus including components, parts and accessories of it manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or the symptom of it in man or animal;
- **“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 Harmonisation 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 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.

- **License:** in some countries it is called registration. Procedure whereby the National Regulatory Authority (NRA) grants permission for the product in question to be sold and distributed in the country.
- **Master cell bank:** culture of specific cells of known origin that are distributed in a container or packages in a single operation to ensure uniformity and stability in storage. The master bank is usually kept at a temperature of -70°C or less. In some countries, it is called the primary bank.
- **Pre-E.U.A activities**: such activities may include discussions with FDA about a prospective E.U.A application and the appropriate procedure to use, when submitting data on the product prior to the submission of the actual application for an E.U.A for a medical product.
- **Product development:** all studies to show that the dose, formulation, manufacturing process and packaging system, as well as the microbiological properties, are appropriate for the proposed purpose.
- **Raw materials:** any substance used to make or extract the active ingredient but from which the active ingredient is not directly derived. For example, culture media, fetal bovine serum, etc.
- **Starting materials:** any substance of biological origin, such as microorganisms, organs and tissues of plant or animal origin, including cells or fluids of human or animal origin and recombinant cell substrates.
- **Unavailable:** if there are insufficient supplies to meet fully the emergency need.
- **Validation:** series of documented procedures or actions, consistent with good manufacturing practices, demonstrating that the processes, equipment, materials, activities and/or systems satisfy the predetermined specifications and quality attributes

3.0 REQUIREMENTS:

3.1 **Format for submission:** Product development dossier shall be submitted in an electronic format, (two (2) copies either saved on a USB flash drive or on CDs), together with an application letter addressed to the Chief Executive Officer (CEO) of the Food and Drugs Authority (FDA). The FDA recommends that an E.U.A application begins with a section that describes the content and organization of the application. To facilitate evaluation of submitted data, it is recommended that a well-organized data on product Quality, Safety, Efficacy and Effectiveness is submitted with the E.U.A application. 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). Nonetheless, a similar format and data content shall be acceptable under the current circumstance. Please note that, an E.U.A application that is missing relevant 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. This might result in the need for a longer time period for evaluation, or a decision not to authorize emergency use of the medical product. A summary of the minimum data and information requirement for an E.U.A application is presented in section 3.2.

3.2 General Requirements

3.2.1 The application should be submitted through the authorized local agent by the regulatory contact person to the following address:

The Chief Executive Officer

Food and Drugs Authority

17 Nelson Mandela Avenue

Shiashie, Accra

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

3.2.3 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)

3.2.4 identification and an explanation of what unmet need(s) will be addressed by issuance of the E.U.A

3.2.5 a description of the product's global/international license /registration/Marketing Authorization (MA) status or whether the medical product is prequalified by an international organization such as WHO. The application should list countries the product is registered or licensed or authorized for use and provide proof/evidence to establish the fact.

3.2.6 a list of each site where the product, if authorized, would be (or was) manufactured and the evidence of current Good Manufacturing Practices (GMP) status of the listed manufacturing site(s)

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

3.2.8 available safety, efficacy and effectiveness information/data on the medical product (i.e., non-clinical and clinical data)

3.2.9 a detailed discussion of risks and benefits balance of the medical product

3.2.10 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

3.2.11 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.

3.2.12 Certificate of Analysis of the finished medical product

3.2.13 Instructions for use as an E.U.A product (e.g., if follow-up treatment is required)

3.2.14 Proposed product labelling of the medical product. Labeling should at least comply with the WHO labelling requirements for the product. It should include Packaging Insert or Patient Information Leaflet.

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

3.2.16 Risk Management Plan (RMP). It should at least comply with the content, format and submission prescribed in the EMA RMP guidelines or the guideline on good pharmacovigilance practices (GVP) - Module V – Risk management systems. Applicants will be requested to incorporate local RMP requirements in the final RMP document (refer to the Guidelines for safety monitoring of medicinal products on the FDA website)

3.2.17 Proposed medical product handling, storage and transportation logistics necessary to maintain product integrity.

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

3.3 Recommended Safety Data

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

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, FDA recommends that the request for consideration for an E.U.A reference the approved application if the requester submitted the approved application or has a right of reference. If the new use poses a different risk to the patient population (e.g., suggesting the possibility of increased toxicity), the Authority recommends that information from relevant in *vitro* studies, animal toxicology studies, and (if available) human clinical data and experience be provided to support such a use.

In the case of products under development, the range of available data for such products will differ widely. FDA recommends that any request for consideration for an E.U.A include available preclinical/non-clinical testing data, such as in *vitro* and animal toxicology data. The FDA also strongly encourages that safety information in humans from Clinical Trials and individual patient experience be provided, if available. FDA 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.

3.4 Recommended Effectiveness Data

In general, the FDA recognizes that comprehensive effectiveness data are unlikely to be available for every E.U.A medical product, and the information necessary to authorize emergency use of a product will depend on the circumstances of the declared public health emergency, as well as available knowledge about the product's safety profile. FDA 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 FDA recommends that requests for consideration for E.U.As include any available relevant scientific evidence regarding the following:

a) the mechanism(s) of the product's action to diagnose, treat, or prevent the disease or condition underlying the request
b) pre-clinical/non-clinical 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 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.

3.5 Other Data Considerations

a) The FDA recommends that the request for consideration include the following types of data, as appropriate and to the extent feasible given the exigencies of the circumstances; 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.

3.6 Data Quality

The FDA recommends that requests for consideration for E.U.As 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.

3.7 Data Updates

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

3.8 Discussion of risks and benefits:

FDA recommends that a request for consideration for an E.U.A include a discussion of the drug'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).

4.0 PROCESSING OF AN EMERGENCY USE AUTHORIZATION (E.U.A) APPLICATION

This section discusses FDA's role in pre-E.U.A activities for E.U.A medical product, as well as the procedures the Authority will follow in processing a request for consideration for an E.U.A once the Minister has issued a declaration of Public Health Emergency. The FDA will be responsible for the overall disposition of the request and will interact directly with the entity submitting the request for consideration. The FDA 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 FDA 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.

FDA recognizes that the exact type and amount of data needed to support an E.U.A may vary depending on the nature of the declared emergency and the nature of the candidate product. The FDA will evaluate each request in light of the circumstances and the statutory criteria for issuance.

The responsible Department in consultation with other relevant Departments and technical committees (as appropriate and feasible), will perform evaluation of the information and data included in the request for consideration and make recommendations to the CEO. The letter of authorization or otherwise will be issued by the CEO of the FDA. 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.

4.1 Timelines for processing an E.U.A application

The timelines for processing an E.U.A will depend on the product profile; the existence, if any, of pending applications for the product; the nature of the emergency; and other relevant factors. Although the length of time required for action will vary, the FDA recognizes that it is likely that, in an emergency situation that is occurring or believed imminent, a request for consideration for an E.U.A will be acted upon within 15 working days.

4.2 Conditions for E.U.A

a) **Information for Health Care Providers or Authorized Dispensers**:

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

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

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

c) **Monitoring and Reporting of Adverse Events**: FDA requires that the applicant appoint a Qualified Person for Pharmacovigilance (QPPV) (refer to the FDA Guidelines for Qualified Person for Pharmacovigilance) from any established entity with the experience in adverse event monitoring and reporting for E.U.A medical product. The FDA 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.

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

e) **Additional Conditions for Unapproved Products**: To the extent feasible given the circumstances of the emergency, the FDA may establish additional conditions for unapproved products, such as the following:
    i. Restricted distribution under the E.U.A -- conditions may be placed on which entities
    ii. may distribute the product and how distribution is to be performed.

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

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

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

Additional conditions for an unapproved use of an approved product:

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

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

Compliance with GMPs or Alternative Approaches:

The FDA expects that an E.U.A 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.

Advertising:

The FDA may establish conditions on advertisements and other promotional descriptive printed matter relating to the use of E.U.A product.

4.3 Summary of conditions for authorization:

The following chart sets out conditions that may be imposed on an E.U.A for an unregistered product and for unapproved use of a registered product, respectively. A condition is identified as "mandatory" to the extent practicable given the circumstances of the emergency, to establish such condition when it is necessary or appropriate to protect the public health. A condition identified as "discretionary" in the chart below is one that the FDA may impose as may be deemed necessary or appropriate to protect the public health. In addition to the conditions described as "mandatory" and "discretionary" in the chart below, the FDA may establish other conditions on an authorization that may be necessary or appropriate to protect the public health.

CONDITION OF AUTHORIZATION	**UNREGISTERED PRODUCT**	**UNAPPROVED USE OF A REGISTERD PRODUCT**
Information for Health Care Providers and Authorized Dispensers	Mandatory for manufacturers and others	Mandatory for manufacturers
Information for Recipients	Mandatory for manufacturers and others	Mandatory for Manufacturers
Adverse Event Monitoring/Reporting	Mandatory for manufacturers and others	Mandatory for manufacturers

Recordkeeping/Access	Mandatroy for manufacturers and others	Mandatory for manufacturers
Compliance with GMPs	Mandatory for manufacturers and others	Discretionary for manufacturers others
Advertising	Discretionary for manufacturers and others	Discretionary for manufacturers and others
Restricted Distribution	Discretionary for manufacturers and others	Discretionary for manufacturers and others
Restricted Administration	Discretionary for manufacturers and others	Discretionary for manufacturers and others
Data Collection/Analysis	Discretionary for manufacturers and others	

* Others may include relevant agencies

4.4 E.U.A Validity, Revocation or Termination

Validity: An E.U.A. will be in effect for the duration of the declaration, unless the E.U.A is revoked because the criteria of issuance above are no longer met or revocation is appropriate to protect public health or safety.

Revocation: The FDA will periodically review the circumstances and appropriateness of an E.U.A, including circumstances that might warrant revocation of the E.U.A. Such circumstances may include significant adverse 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 E.U.A product that materially affect the risk/benefit assessment upon which the E.U.A was based); reports of adverse events (number or severity) linked to, or suspected of being caused by, the E.U.A product; product failure; product ineffectiveness (such as newly emerging data that undermine the Authority's conclusion that the product "may be effective" against a particular agent); and availability of a preferred product.

Termination: Upon termination of the declaration, unapproved product or labeling and product information for an unapproved use must be disposed of pursuant to section 132 (subsection 2) of the Public Health Act, 2012 (Act 851). 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 FDA to formally register the medical product for the indication upon which the E.U.A was granted or apply to officially include the E.U.A- approved indication in the registered product data (in situations where the product was already registered with the FDA) under section 118 of the Public Health Act, 2012 (Act 851).

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

APPENDIX 1

Health Care Provider or authorized dispenser or pharmacist information

[PRODUCT for INTENDED USE]

An emergency has been declared by the Minister of Health.

[INCLUDE A BRIEF DESCRIPTION (1-2 sentences) OF THE EMERGENCY].

The FDA has authorized the emergency use of [PRODUCT] for a use [IDENTIFY THE INTENDED USE] that has not yet obtained FDA approval or registration by usual FDA processes. This authorization will terminate when the emergency has ceased to exist, whichever is earlier.

The information in this form is the minimum information necessary to inform you of the significant known and potential risks and benefits of emergency use of [PRODUCT].

The significant known and potential risks and benefits of emergency use of [PRODUCT] are: [LIST]. The extent to which such risks and benefits are unknown is [EXPLAIN].

The available alternatives to [PRODUCT] are: [LIST]. The risks and benefits of [ALTERNATIVES] are: [LIST]. [If there is no alternative, provide an explanation of outcomes of exposure or of any special public health measures (e.g., quarantine or monitoring) that an individual who does not receive the E.U.A product may face.]

INCLUDE NAME, ADDRESS, AND TELEPHONE NUMBER FOR MANUFACTURER.]

As the health care provider or authorized dispenser or pharmacist administering [PRODUCT], please communicate the significant known and potential risks and benefits, and the extent to which such risks and benefits are unknown, to the recipient of [PRODUCT].

Please inform the recipient that he or she has the option to accept or refuse administration of [PRODUCT], and of the consequences of refusing administration. Please inform the recipient of any available alternatives to [PRODUCT], and of their risks and benefits. Please provide the “Recipients Information” to the recipient of [PRODUCT].

If providing this information before administration would delay the administration [PRODUCT] to a degree that would endanger the lives of exposed or affected individuals, the information must be provided to the recipient as soon as practicable after [PRODUCT] is administered.

FDA also recommends that E.U.A applicants include the following additional information in the Fact Sheet for Health Care Providers or Authorized Dispensers or Pharmacist if it is available.

APPENDIX 2

INSTRUCTIONS FOR USE

How to administer the product (including dose, route of intake or infusion, how long to use the product, how to take care of the infusion site), how to store the product, how it is supplied/forms that it comes in, how to constitute;

If it is an in vitro diagnostic (IVD): what type of specimens should be collected for testing with the product, how to store the specimens, how the laboratory should use the product, how to interpret the results; and instructions for use in special populations (i.e., pregnant women, infants and children, and immunocompromised individuals), including special dosing instructions (e.g., weight-based dosing), special precautions.

Known major interactions with other products or substances, including drug interactions, cross reactivity for IVDs.

Known efficacy information or performance characteristics (for IVDs)

Adverse events. Significant known adverse event information (e.g., what are the significant known side effects? Under what conditions should the recipient stop taking product?), instructions for follow up in case of an adverse event, how to report an adverse event, what to do in case of an adverse event (stop using the product? seek treatment?), whom to contact for professional advice if an adverse event occurs or if the product does

not work. Health care providers or authorized dispensers or Pharmacist also may report adverse events to the FDA.

Alternatives. If other agents (approved/licensed/cleared products or E.U.A products) may treat or prevent the same or closely related condition for [INTENDED USE], this information should be stated. If available, the relative or expected safety and effectiveness of the alternative should be provided, particularly for use in different populations or settings. Such information may include:

a) when an alternative product may be more appropriate, e.g., in the treatment of the pregnant women, infants and children, and immunocompromised individuals, or other special populations.
b) for preventive treatments, the time needed for [PRODUCT] to be administered in advance of the exposure to be effective, and alternatives that may be more effective if that time is exceeded.

Significant known and potential risks and benefits may include relevant information about the manufacturer (e.g., a waiver of Good Manufacturing Practices compliance), if known.

Consequences of not taking/using [PRODUCT], including possible health effects and quarantine, and of stopping the use of [PRODUCT] against the recommendation of the health care provider.

New findings. A statement about the fact that any significant new findings observed during or after the course of widespread use will be made available.

Approved products. For approved products being used for unapproved indications, the Fact Sheet also may include critical elements from the package insert.
Contacts. Whom to contact if you have any questions or concerns (other than an adverse event report) about the product.

APPENDIX 3

RECIPIENT INFORMATION

[PRODUCT for INTENDED USE]

An emergency has been declared by the Minister of Health

[INCLUDE A BRIEF DESCRIPTION (1-2 sentences) OF THE EMERGENCY].

The FDA has authorized the emergency use of [PRODUCT] for [IDENTIFY THE INTENDEDUSE]. This authorization will terminate when the emergency has ceased to exist.

The information in this Fact Sheet is the minimum necessary to inform you of the significant known and potential risks and benefits of emergency use of [PRODUCT].

The significant known and potential risks and benefits of emergency use of [PRODUCT] are: [LIST]. The extent to which such risks and benefits are unknown is [EXPLAIN].

The available alternatives to [PRODUCT] are: [LIST]. The risks and benefits of [ALTERNATIVES] are: [LIST]. [If there is no alternative, provide an explanation of outcomes of exposure or of any special public health measures (e.g., quarantine or monitoring) that an individual who does not receive the E.U.A product may face.]

[INCLUDE NAME, ADDRESS, AND TELEPHONE NUMBER FOR MANUFACTURER.]

You have the option to accept or refuse administration of [PRODUCT]. The consequences of refusing administration of [PRODUCT] are [LIST].

Available alternatives to [PRODUCT] are: [LIST]. The risks and benefits of these alternatives are: [LIST].

Potential adverse events for [PRODUCT] include [LIST]. Should you experience an adverse event, [INCLUDE INSTRUCTIONS].

Any significant new findings observed during the course of emergency use of [PRODUCT] will be made available [STATE HOW FINDINGS WILL BE MADE AVAILABLE].

FOOTNOTES

FDA may issue subsequent guidance providing greater detail on these recommendations and procedures.

The FDA may issue one or more E.U.A(s) on the basis of a single declaration of emergency provided that the E.U.A(s) are intended for use in the same emergency involving the same disease causative agent/item.

For purposes of this document, an "unapproved" product refers to a product that is not approved, licensed, or registered for commercial distribution under sections 118 of the Public Health Act 2012.

In publicly releasing information on an E.U.A., FDA will take necessary steps to protect classified information and information otherwise protected by law, as appropriate.

Disclosures of information by FDA to the Ministry of Health (MoH) will be consistent with applicable laws protecting trade secrets and confidential commercial or financial information.

FDA anticipates that distribution of E.U.A products will be performed according to existing response plans, as practicable and appropriate.