MEDICINES CONTROL AGENCY

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Conditions of Authorisation

1. Information relating to the EUA product

To the extent consistent with other conditions of authorisation, information on the EUA of medicine (medicinal product) should be disseminated to healthcare providers and authorised dispensers through media, videos/DVDs/CD-ROMs, the Internet, and direct communication from the Ministry of Health.

For an unapproved product and for an unapproved use of an approved product, MCA must (to the extent practicable given the circumstances of the emergency) establish conditions to ensure that healthcare professionals who administer the EUA product are quickly informed:

- that MCA has authorised the emergency use of the product (including the product name and an explanation of its intended use);
- of the significant known and potential benefits and risks of the emergency use of the product, and the extent to which such benefits and risks are unknown; and
- of available alternatives and their benefits and risks.

Therefore, MCA recommends that a request for an EUA. includes a "Condition of Use " document for healthcare professionals or authorised dispensers that includes essential information about the product. In addition to the required information, this document should include:

- a description of the disease/condition;
- any contraindications or warnings;
- dosing information (if applicable), including any specific instructions for special populations; and
- contact information for reporting adverse events and additional information about the product.

Annex 5a provides a template for the "Information for Healthcare Providers or Authorised Dispensers or Pharmacists" as well as "Instructions for use".

b. Information for Recipients:

Although informed consent is not required for administration of an EUA medicine, the information dissemination requirements are mandatory only to the extent conditions establishing such requirements are practicable. MCA recommends that recipients be given as much appropriate information as possible given the nature of the emergency and the conditions of the authorisation. For healthcare provider carrying out any activity concerning an EUA, recipients must be informed that the MCA's Executive

Director has authorised emergency use of the medicine, and has evaluated the potential benefits and risks of the it.

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.

MCA requests that some form of written or verbal/pictural information will be given to recipients in the simplest language possible and using other techniques to improve health literacy. The MCA recommends that the written or verbal/pictural 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 or verbal/pictural 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.

Annex 5b provides a template for the "Information for Recipients".

2. Monitoring and Reporting of Adverse Events

MCA recommends that the Ministry appoints a person responsible for pharmacovigilance from any established entity with the experience in adverse event monitoring and reporting for EUA.

MCA expects that the primary focus of such conditions 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 postage-paid postcards or stickers added to the product, labelling, 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.

3. Records:

MCA requires that records of an unauthorised product or unapproved use should be maintained and access be granted by the applicant to the MCA given the circumstances of the emergency.

The MCA may impose comparable record requirements on any person other than an applicant who carries out any activity for an unauthorised 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, 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.

4. Importation authorisation

5. Additional Conditions

a. for Unauthorised Products

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

- Restricted distribution under the EUA-conditions may be placed on which entities;
- may distribute the product and how distribution is to be performed;
- 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;
- information-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.

b. for an Unapproved Use of an Authorised Product

With respect to an EUA that authorises a change in labelling of an authorised product, but for which the applicant chooses not to make such labelling change, the EUA may not authorise a product distributor or any other person to alter or obscure the applicant'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 applicant) acting pursuant to such EUA to provide appropriate information, in addition to the applicant'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.

6. Compliance with GMPs or Alternative Approaches

The MCA expects that EUA medicines 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.

7. Advertising

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

8. Summary of Conditions for Authorisation

The following chart sets out conditions that may be imposed on an EUA for unapproved products and for unapproved uses of approved products, 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 MCA 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 MCA may establish other conditions on an authorisation that may be necessary or appropriate to protect the public health.

EUA.	**Unauthorised Product**	**Unapproved Use of an authorised Product**	**Product authorised by another NMRA**
Information for Healthcare Providers and Authorised Dispensers	Mandatory for applicant	Mandatory for applicant	Mandatory for applicant and others
Information for Recipients	Mandatory for applicant	Mandatory for applicant	Mandatory for applicant and others
Adverse Event Monitoring/Reporting	Mandatory for applicant	Mandatory for applicant	Mandatory for applicant and others
Recordkeeping/Access	Mandatory for applicant	Mandatory for applicant	Mandatory for applicant and others
Proof of Compliance with GMPs	Mandatory for applicant and others	Mandatory for applicant and others	Mandatory for applicant and others
Advertising	Only after Approval by NMRA	Approval by NMRA	
Distribution	As determined by the MCA	As determined by the MCA	Discretionary for applicant and others
Post-E.U.A. Data Collection/Analysis	Mandatory for applicant	Mandatory for applicant and others	Mandatory for applicant and others