Guidelines on procedure for expedited Marketing Authorization for Emergency Use Permission, Registration/Licensing of COVID-19 Vaccines in Sri Lanka.

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Introduction

This document provides guidance on the process and the criteria that should be followed to register COVID-19 vaccines for expedited Emergency Use Permission and/or Marketing Authorization (MA). It describes the procedure for requesting Emergency Use Permission of vaccines by an individual or an institution and the reviewing procedure followed by National Medicines Regulatory Authority (NMRA). The guidance aims to ensure that required vaccines are introduced to the country with requisite urgency and necessary precautions based on scientific evidence.

The World Health Organization (WHO) declared the novel coronavirus (2019-nCoV) outbreak a public health emergency of international concern on 30 January 2020, and subsequently characterized the outbreak as a pandemic on 11 March 2020.

Based on the WHO pandemic declaration and provisions in Section 109 of the National Medicines Regulatory Authority Act No. 5 of 2015, the Authority may grant Emergency Use Permission to vaccines used in the prevention of COVID-19.

Purpose

1. To grant Emergency Use Permission for vaccines to be imported and supplied during emergency situations such as global pandemics for specified quantities or a specified period of time without the need for registration. Such permission will be granted after carefully considering the need of the product in the country.

2. To expedite marketing authorization / licensing of COVID-19 vaccines.

Scope

This Emergency Use Permission has been implemented as an interim measure in response to the current public health need for timely control of COVID-19 pandemic. If an applicant wishes to supply in the long-term/for commercial use, it must be registered with the NMRA as per the relevant guidelines issued by the Authority. The rule also applies to candidate vaccines that may be developed in Sri Lanka.

Procedure for granting permission for emergency use: -

The procedure regarding granting of permission for emergency use set out herein applies to COVID 19 vaccines:

i) Submitted with a request from the Ministry of Health.
ii) Submitted by an individual or an organization recommended by the Ministry of Health.

The Emergency Use Permission shall be granted based on a risk-based review process. A person who intends to apply for Emergency Use Permission shall make an application in the form as determined by the Authority with relevant documentation as required by the Authority. The Authority has powers to request for more details for a complete review.

a. All submitted requests will be reviewed by a panel of independent experts appointed by the NMRA.
b. It is the responsibility of the NMRA to verify the authenticity of submitted documents and the current registration status of the requested product(s) to guide the panel of experts.
c. The final decision on the request is taken by the independent panel of experts after considering relevant documents, clinical development, and registration status of the product. The panel will advice the Authority on the suitability of a vaccine to be granted Emergency Use Permission.
d. If the vaccine has received Emergency Use Listing (EUL) status from the WHO or at least one Stringent Regulatory Authority (SRA), the Authority shall inform the decision on the application within five working days to the applicant.
e. Once approval is granted, the applicant should make the relevant payment as per the gazette No 2052/33 dated 05.01.2018 to obtain the relevant document.
f. The NMRA shall have the discretion of waiving this payment, which will be decided on a case-by-case basis.
g. This Emergency Use Permission approval is addressed to the Local Agent and copied to the Controller of Import and Export and Sri Lanka Customs and other relevant parties where necessary.
h. The validity period of Emergency Use Permission will be mentioned in the said letter.
i. In cases where the request for Emergency Use Permission is rejected, the reason for such rejection will be informed to the applicant in writing.

Conditions: -

a. The importer or manufacturer shall be responsible for the accountability and management of the product imported under Emergency Use Permission.
b. The manufacturers, importers and wholesalers shall maintain records of all the details of products imported under Emergency Use Permission and submit such data to the Authority within 28 calendar dates providing information pertaining to quantities of vaccine manufactured, imported and distributed by them and details of persons / organizations to whom the vaccine was distributed.
c. Periodic reports on specific data on the safety and/or performance of these vaccine will be required to be submitted to the Authority.
d. Post authorization reports to ensure continued performance of these vaccine as prescribed under Part VI National Medicine (Registration and Licensing) Regulation 2019 published by Gazette Extraordinary 2145/1 of 14/10/2019 need to be submitted on a regular basis.
e. If any safety or performance issues are observed, NMRA will require relevant follow up actions from the manufacturer.
f. No person shall label, package, treat, process assemble, sell, distribute any vaccines covered under this Guideline in a manner that is false, misleading, deceptive or likely to create an erroneous impression regarding its safety and efficacy.
g. No person shall advertise or promote any vaccines covered under this Guideline without prior written approval of the Authority.
h. An Emergency Use Permission granted under section 109 of the NMRA Act may be suspended or revoked by the Authority in case of non-compliance with the prescribed rules/regulation and guidelines issued by the Authority.

Procedure for granting permission for emergency use / expedited Marketing Authorization (MA): -

1. The expedited permission for emergency use /marketing authorization (MA) procedure for registration is a fast-track, risk-based procedure for assessing and approving vaccines licensed under Emergency Use Approval (EUA) by producing countries.

    a. This expedites the availability of these vaccines to people affected by this public health emergency caused by Covid-19 pandemic.
    b. The goal of the procedure is to clearly define the steps that the manufacturer and importing entity will have to follow to establish eligibility of these vaccines and evaluate the essential information for marketing authorisation. It also lays down the process which is used in conducting the assessment to issue the registration and approval of the vaccine on a time- limited basis, while further data is being gathered by manufacturers, producing countries NRA and WHO.
    c. However, it is very important to note that the expedited MA is not equivalent or an alternative to full marketing authorization.
    d. The MA decision shall be reviewed periodically and converted to regular MA when feasible.
    e. The expedited MA is a special procedure to conditionally license vaccines such as Covid-19 vaccines in the event of a public health emergency when the community/public health authorities may be willing to tolerate less certainty about the efficacy and safety of vaccines, given the morbidity and/or mortality of the disease and the lack or paucity of treatment or prevention options.
    f. It is intended to provide a time-limited and conditional approval for unlicensed vaccines in an emergency context when limited data are available and the vaccines are not yet ready for a full marketing authorization application.
    g. It is also recommended to have common, harmonized and well documented systems for vaccines for expedited MA procedure.

2. In order to qualify for assessment under this procedure, the following criteria must be met:

    a. The disease for which the vaccine is intended is serious or immediately life threatening, has caused an outbreak, epidemic or pandemic in the country. And it is reasonable to consider the vaccine for an expedited MA assessment based on risk benefit analysis (e.g., there are no treatment or licensed vaccines for the indication or for a critical sub-population).
    b. The vaccine is manufactured in compliance with current Good Manufacturing Practices (GMP) of WHO in the case vaccines under a functional Quality Management System (QMS) of NRA as assessed by WHO using Global Bench Marking Tools.
    c. The manufacturer has been allowed to market the vaccine in country of origin under Emergency Use Authorisation. The manufacturer also undertakes to complete the clinical development of the vaccine and apply for full Marketing Authorization in the country of origin.

3. Eligibility of vaccines candidates for expedited permission for emergency use / MA:

In context of the COVID-19 vaccines, the vaccines shall be eligible for an expedited permission for emergency use / MA if they meet the following criteria:

a. The vaccine should have completed phase III studies and results published in scientific journals with high impact factor.
b. The vaccine has been granted WHO Emergency Use Listing (EUL) post-EUA by the NRA in the country of origin.
c. The vaccine has been granted EUA by at least one SRA as per list published by the WHO.
d. The vaccine is manufactured in a country with Stringent NRA as per list published by WHO.
e. The vaccine is coming from the COVAX Facility which is an umbrella mechanism through which demand and resources are pooled to support procurement of, and equitable access to, COVID-19 vaccines.
f. NRA/manufacturer of country of origin of the vaccine is ready to share information with the NMRA with agreement for testing, lot release, EUA, licensure and post-approval changes/commitment from applicants (manufacturers/importers).

Procedure:

The procedures for expedited permission for emergency use / MA for COVID-19 vaccine commences with an expression of interest (EOI) by the applicant (manufacturer/importer) followed by pre-submission meetings/activities with the NMRA. The procedure clearly defines the essential data requirements, submission of the application and technical documentation including dossier if required. Its reliance is based on WHO-EUL listing of the vaccine candidate by at least one SRA.

The expedited MA procedure will be risk-benefit based, involving simplified procedures for regulatory activities which have no risk or minimum risk, including fast-track import, simplified application, and submission procedures such as e-submissions, risk-based review of the submitted dossier and risk-based approach on lot release.

Steps Involved in Expedited Marketing Authorisation Procedures:

1. Expression of interest (EOI) by Applicant (manufacturer/importer)

Submission of EOI shall be only open to the candidate vaccines as mentioned in eligibility criteria. Priority will be given to candidate vaccines that are expected to meet all or most of the NMRA and WHO guidelines especially related to WHO-EUL and WHO-PQ. Interested manufacturers may submit expressions of interest for vaccines evaluation by a letter to the Chief Executive Officer, NMRA. The letter should include the following information:

a) Name of the product
b) Contact person with email and phone number
c) Address of manufacturing sites, email address of the company with phone number etc
d) Description of the vaccine, presentation and indication
e) Current phase of clinical trial with date of initiation and completion
f) Proof of Emergency Use Authorisation in country of origin

g) Proof of registration in other countries if available.
h) Approximate doses produced so far and doses available for supplies in next two years.
i) Status of WHO and/or SRA Emergency Use Listing or plan for its application.
j) Status of agreement with COVAX to supply vaccine through it or plan for application to it.

2. Optional pre-submission meetings

Applicants that meet the criteria of EOI and whose EOI has been accepted, may be contacted to schedule a pre-submission meeting if deemed necessary by the Authority.

These pre-submission exchanges may be done via a chosen method of communication, such as online meetings including face-to-face meetings with the local representative.

Pre-submission meetings can play an important role in Expedited MA procedure. They provide an opportunity for the Authority to meet the applicant. A pre-submission meeting allows NMRA to have an overview of the vaccine and the extent of documentation available with applicant.

The NMRA head may invite subject matter experts, WHO representatives or other relevant individuals for the pre-submission meeting.

3. Submission and processing of applications

The manufacturer/importer must apply to the NMRA in the stipulated format. The application should include details of country, sites of manufacturing and the presentations proposed for the vaccine. NMRA will acknowledge the receipt of the application by e-mail.

4. Publication of review outcomes and communications

Upon making a decision whether or not to grant an expedited marketing authorization (acceptance or non-acceptance of the evaluated vaccine), the CEO of the NMRA will (without prejudice to any confidential information of the applicant) publish information about the vaccine evaluation in a public report available on the NMRA website. This may also include negative assessment outcomes. As NMRA is responsible for the assessment process, the ownership of the reports arising from or relating to the assessment process lies with NMRA. Thus, NMRA shall be entitled to use and publish such reports, however always subject to, the protection of any commercially sensitive confidential information of the manufacturer.

In addition, NMRA reserves the right to share decision and its evaluation reports with WHO and interested United Nations agencies including COVAX. The validity of an expedited permission for emergency use / MA in the context of the public health emergency will generally be for 12 months and it may be extended by NMRA subsequent to an extension request. Expedited MA for the vaccine may be withdrawn earlier, if new data become available that change the benefit-risk balance of the vaccine or immediately upon termination of the public health emergency.

5. Submission of updates by the Applicant

After the initial submission of the application and grant of expedited marketing authorisation, applicants should promptly submit any additional information on the vaccine candidate such as update on clinical trials, WHO-EUL, WHO-PQ, incorporation in COVAX, registration in other countries, AEFI and safety information.

6. Withdrawal or Suspension of MA

Based on the safety and efficacy data, which is collected post MA, a vaccine candidate may be suspended or withdrawn. The withdrawal or suspension may also be based on decision of WHO for delisting the vaccines from WHO-Emergency Use Listing. This may also be based on incorporation or suspension of the vaccine from COVAX facility listing.

Expected timelines:

Under the expedited permission for emergency use / marketing authorization procedure, the evaluation and decision to register a vaccine, which has not received Emergency Use Listing (EUL) by the WHO or at least by one Stringent Regulatory Authority (SRA), may be expected within 15 working days if a complete dossier in the CTD format has been submitted to NMRA. If additional information is requested from the applicant by the NMRA, the 'stopped clock' approach will be used to adhere as much as possible to stated timelines.