Expression of Interest (EOI) to National Medicines Regulatory Authority by Applicant (Manufacturer/Importer) of COVID-19 Vaccines

To,

Chief Executive Officer, National Medicines Regulatory Authority
Address: 120, Norris Canal Road, Colombo 10, Sri Lanka

Reference: Application for Expedited Marketing Authorisation of COVID-19 Vaccines

We, the manufacturer/importer of the COVID-19 vaccines with following details express our interest to register and import our vaccines in your country:

Name of manufacturer/importer: ("the Applicant")
Street:
City and country:
Email:
Telephone:
Date of application (dd/mm/yyyy):
Product name in national system:
National reference EUA number/License number in origin country:
Date of EUA or first registration in origin country:

COVID-19 Vaccine Details:

Vaccine Type (Inactivate, VLP or mRNA or DNA etc):
Dosage form and strength:
Packaging:
Manufacturing site(s), including block(s)/unit(s):
WHO-EUL/WHO-PQ details:
WHO- EUL/ WHO-PQ reference number:
Date of EUL/PQ (dd/mm/yyyy):
WHO EUL/PQ holder:
Government to Government agreement Reference:
NRA to NRA agreement Reference:

1. We undertake to adhere to and collaborate with your esteemed office, NRA of the manufacturing country WHO/ PQT in accordance with the terms of the referred procedure on your website.

2. We will also authorize the NRA of the manufacturing country for verifying the submitted data with you for successful registration of our vaccine.

3. We also authorize the NRA of the manufacturing country and WHO- PQ team (if required) for freely discussing submitted documents as per the referred procedure related for the sole purpose of registration of our vaccine in your country as below:

A. WHO/PQT authorisation issued under WHO-EUL procedures
B. Results of laboratory testing of our company and the testing results provided by National Control Laboratory of our origin country.
C. Status of your manufacturing license or Emergency Use Authorisation till vaccine is registered or used in your country.

D. AEFI and pharmacovigilance data of relevant authorities in your country.

4. We submit an authorization letter for our local representative or importer of COVID-19 vaccine who is not the direct holder of license or EUA in origin country or WHO-EUL.

Applicant signature or authorised representative

Name:
Title:
Place:
Date (dd/mm/yyyy):

Template for Authorization letter for local representative or Importer of Vaccine

(To be provided if the Applicant is not original manufacturer or license holder or WHO-EUL holder)

This is to confirm that (Name of applicant/representative) is seeking registration for COVID-19 vaccines with following details:

1. Vaccine name and presentation:
2. License Number/ EUA number and or WHO-EUL number:

in Sri Lanka under the Expedited Marketing Authorisation Procedure, is acting for, or pursuant to rights derived from (Company name) and that we agree with the application of the procedure in Sri Lanka.

For (company name):

Signature:
Name:
Title:
Date: