Application format for Expedited Marketing Authorisation

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

COVID-19 Vaccine: [name of the vaccine]

Subject: Application for Expedited Marketing Authorisation of our vaccine [name of vaccine] in Sri Lanka

Contact person: [name of applicant's contact person]
Title
Tel:
Email:

Dear [name],

Following our pre-submission meeting on [date of pre-submission meeting]/your acceptance of our expression interest (Ref No._____), we hereby submit our applications for the below:

Name of COVID-19 vaccine:
Type of the vaccine and presentation:
The target indication for [name of vaccine] is:
Description of intended use of Vaccine:

We are submitting the following documents for your perusal:

For Vaccine approved under WHO-EUL/WHO-PQ or approved by WHO-listed SRAs:

Copy of WHO-EUL listing issued by WHO along with weblink	Yes ☐ /No ☐
Proof of deposit of applicable fees as per national legislation	Yes ☐ /No ☐
Copy of EUA/ Manufacturing License for COVID-19 Vaccines	Yes ☐ /No ☐
Manufacturer certificates of analysis for three consecutive finished product batches	Yes ☐ /No ☐
National Control Laboratory (Country of Origin) release and test reports for three consecutive batches	Yes ☐ /No ☐
Photo of vaccine presentations, copy of labels of all presentation and packing inserts	Yes ☐ /No ☐
Undertaking that information shall be provided if there is any change in the status of WHO-EUL/WHO-PQ, EUA or manufacturing license in origin country and undertaking to submit a copy of any new CTD submission to origin country NRA/WHO (Format attached)	Yes ☐ /No ☐

For Vaccine approved by WHO benchmarked NRAs as per Global Benchmarking Tools (and for Govt to Govt to agreements):

Proof of deposit of the applicable fees as per national legislation	Yes ☐ /No ☐
Copy of EUA/ Manufacturing License for COVID-19 Vaccines	Yes ☐ /No ☐

Copy of last registration dossier submitted to NRA of the origin: (soft copy in searchable PDF in CTD format as accepted by WHO/ICH)	Yes ☐ /No ☐
Manufacturer certificates of analysis for three consecutive finished product batches	Yes ☐ /No ☐
National Control Laboratory (Country of Origin) release and test reports for three consecutive batches	Yes ☐ /No ☐
Photo of vaccine presentations, copy of labels of all presentation and packing inserts	Yes ☐ /No ☐
Undertaking that information shall be provided if there is any change in the status of EUA or manufacturing license in origin country and undertaking to submit a copy of any new CTD submission to origin country NRA (Format attached)	Yes ☐ /No ☐

For vaccines approved by other NRAs

Proof of deposit of the applicable fees as per national legislation	Yes ☐ /No ☐
Copy of EUA/ Manufacturing License for COVID-19 Vaccines	Yes ☐ /No ☐
Copy of last registration dossier submitted to NRA of the origin: (soft copy in searchable PDF in CTD format as accepted by WHO/ICH)	Yes ☐ /No ☐
Manufacturer certificates of analysis for three consecutive finished product batches	Yes ☐ /No ☐
National Control Laboratory (Country of Origin) release and test reports for three consecutive batches	Yes ☐ /No ☐
Photo of vaccine presentations, copy of labels of all presentation and packing inserts	Yes ☐ /No ☐
Undertaking that information shall be provided if there is any change in the status of EUA or manufacturing license in origin country and undertaking to submit a copy of any new CTD submission to origin country NRA (Format attached)	Yes ☐ /No ☐
Common Technical Dossier (CTD) which would include GMP certificate, manufacturing license, production and stability data, product informational leaflet, primary and secondary labels, clinical study reports and quality control module.	Yes ☐ /No ☐
Summary lot protocols for four batches	Yes ☐ /No ☐
Authorization letter issued by the manufacturer for relevant supplier.	Yes ☐ /No ☐
Regulatory approval / Emergency Use Authorization issued by the National Regulatory Authority in country of origin and other countries if any.	Yes ☐ /No ☐

Signature:
Name:
Title:
Date:

Undertaking by manufacturer

TO WHOEVER IT MAY CONCERN

Reference: Undertaking for Application No._____for Expedited Marketing Authorisation of [name of the vaccine]

We, the manufacturer/importer of [name of the vaccine] undertake that relevant information shall be submitted to National Medicines Regulatory Authority [NMRA] if there is any change in the status of EUA or manufacturing license in [name of country of origin] or applicable WHO-EUL /WHO-PQ status. In addition, we undertake to submit a copy of any new CTD submission to NMRA and /or WHO-PQT.

We certify all documents submitted for review are authentic and have been verified by us.

Name of manufacturer/Importer: (“the Applicant”):
Street:
City and country:
Email:
Telephone:
Date:(dd/mm/yyyy):