# ELIGIBILITY CRITERIA FOR USE OF FUNDS UNDER THE RAPID RESPONSE COMPONENT

1. The Asian Development Bank (ADB) and the Government of Sri Lanka agreed on an indicative master list of eligible items, and an agreed list of acceptable expenditure items ('positive list'), for ADB-financing under the Rapid Response Component, which will be financed by the project.[1] To be eligible for ADB financing under the rapid response component, the vaccines must meet one of the eligibility criteria outlined in ADB's policy on Support to Enhance COVID-19 Vaccine Access.[2]

(i) Criterion 1: The vaccine has been selected for procurement through COVID-19 Vaccines Global Access (COVAX) on behalf of its participating countries; or
(ii) Criterion 2: The vaccine has received World Health Organization (WHO) prequalification or WHO emergency use listing (EUL); or
(iii) Criterion 3: The vaccine has received regular or emergency licensure or authorization by a stringent regulatory authority (SRA).

2. The financing of vaccine doses over and above the free vaccines that the COVAX facility will provide to up to 20% of the population that will be procured from the said facility will be deemed eligible as these vaccines comply with the first criteria.

3. In addition, the Government of Sri Lanka has initiated discussions for vaccines under: (i) direct procurement, (ii) bilateral donation, and (iii) COVAX donation. As of 2 June, the following vaccines are considered. The assessment of their status of compliance with the three eligibility criteria are given in the table below.

**Table: Eligibility Assessment of the Vaccines Considered by Sri Lanka with the Three Eligibility Criteria of APVAX** (as of 2 June 2021)

| Manufacturer of the Vaccine | Availability/ Access to Vaccine in Sri Lanka | APVAX Eligibility Criterion 1 | APVAX Eligibility Criterion 2: | APVAX Eligibility Criterion 3: |
|---|---|---|---|---|
| Serum Institute of India (AstraZeneca/ Oxford vaccine) (eligible for ADB financing) | Sri Lanka NMRA approval received on 22 January 2021.<br>28 Jan 2021: 500,000 doses donation from Government of India received.<br>Feb 2021: 500,000 doses received via direct contract with Serum Institute of India.<br>7 March 2021: 264,000 doses | WHO has included AstraZeneca vaccines manufactured by SII in its Emergency Use Listing on 15 February 2021.<br><br>COVAX has started procuring and distributing them. Hence, it meets Criterion 1 and is therefore eligible for ADB Financing. | WHO has included AstraZeneca vaccines manufactured by SII in its Emergency Use Listing on 15 February 2021. Hence it meets Criterion 2 and is therefore eligible for ADB Financing. | Review process by stringent SRA has not been initiated. |

[1] Indicative Master List of Eligible Items, and Agreed List of Acceptable Expenditure Items ('Positive List'), for ADB-Financing under the Rapid Response Component (accessible from the list of linked documents in Appendix 2).
[2] ADB. 2020. *ADB's Support to Enhance COVID-19 Vaccine Access*. Manila; ADB. 2021. *Amendment to ADB's Support to Enhance COVID-19 Vaccine Access*. Manila.

| Manufacturer of the Vaccine | Availability/ Access to Vaccine in Sri Lanka | APVAX Eligibility Criterion 1 | APVAX Eligibility Criterion 2: | APVAX Eligibility Criterion 3: |
|---|---|---|---|---|
| | received via COVAX facility. Further 1,000,000 doses pending delivery confirmation by Serum Institute of India and 4,136,000 doses pending delivery confirmation by COVAX. | | | |
| Pfizer/ BioNTech (eligible for ADB financing) | Government of Sri Lanka has procured 5 million doses. Emergency use of Pfizer/BioNTech vaccine was approved by Sri Lanka NMRA on 8 May 2021. | WHO has included Pfizer/BioNTech vaccines in its EUL on 31 December 2020. COVAX has started procuring and distributing them. Hence it meets Criterion 1 and is therefore eligible for ADB Financing. | WHO has included Pfizer/BioNTech vaccines in its EUL on 31 December 2020. Hence it meets Criterion 2 and is therefore eligible for ADB Financing. | The vaccine is authorized by SRAs including US Food and Drug Administration, Medicines and Healthcare products regulatory Agency of UK and European Medicines Agency. Hence it meets Criterion 3 and is therefore eligible for ADB Financing. |
| AstraZeneca Institute UK and contract manufacturers in UK and EU (eligible for ADB financing) | Discussions initiated by the SPC, Government of Sri Lanka but no confirmation received as yet.<br><br>Under review by Sri Lanka NMRA. | The vaccine has not yet selected for procurement through COVAX | The vaccine manufacturer is granted EUL by WHO on 16 April 2021. Hence it meets Criterion 2 and is therefore eligible for ADB Financing. | Secured emergency use authorization from Medicines and Healthcare Products Regulatory Agency of UK, the European Medicines Agency and Australia's Therapeutic Goods Administration. Hence it meets Criterion 3 and is therefore eligible for ADB Financing. |
| Sinopharm by Beijing Bio- | The first consignment of | Might be selected for procurement | The vaccine manufacturer is | Not yet granted regular or |

| Manufacturer of the Vaccine | Availability/ Access to Vaccine in Sri Lanka | APVAX Eligibility Criterion 1 | APVAX Eligibility Criterion 2: | APVAX Eligibility Criterion 3: |
|---|---|---|---|---|
| Institute of Biological Products Co-Ltd. (eligible for ADB financing) | 600,000 doses as a donation from the People's Republic of China arrived on 31 March 2021. The second consignment of 500,000 doses arrived on 25 May 2021. NMRA has approved the use of Sinopharm vaccine on 20 March 2021.<br><br>Contract signed with Sinopharm on procuring 14 million doses. | through COVAX soon. | granted EUL by WHO on 7 May 2021. Hence it meets Criterion 2 and is therefore eligible for ADB Financing. | emergency licensure or authorization by any of SRAs |
| Gamaleya Research Institute of Epidemiology and Microbiology (Sputnik V vaccine) (not eligible for ADB financing currently) | Procurement of 13 million doses finalized.<br><br>65,000 doses arrived in May 2021.<br><br>Sri Lanka NMRA approval received on 4 March 2021. | The vaccine has not yet selected for procurement through COVAX | Review process for WHO EUL is ongoing. | European Medicines Agency has initiated a rolling review[1] of the Sputnik V vaccine. |
| Sinovac Biotech, Ltd. (eligible for ADB financing) | Discussions initiated.<br><br>Under review by Sri Lanka NMRA. | The vaccine has not yet selected for procurement through COVAX | The vaccine manufacturer is granted EUL by WHO on 1 June 2021. Hence it meets Criterion 2 and is therefore eligible for ADB Financing. | None of SRAs has approved or granted emergency use authorization to the vaccine |
| Bharat Biotech (not eligible for ADB financing currently) | Under review by Sri Lanka NMRA. | The vaccine has not yet selected for procurement through COVAX | Documents submitted for WHO EUL, but initial meeting to be held. | None of SRAs has approved or granted emergency use authorization to the vaccine |

ADB = Asian Development Bank, COVAX = COVID-19 Global Access Facility, EUL = Emergency Use Listing, NMRA = National Medicines Regulatory Authority, SPC = State Pharmaceuticals Corporation of Sri Lanka, SRA = stringent regulatory authority, WHO = World Health Organization.

[1] A rolling review is a regulatory tool that European Medicines Agency (EMA) uses to speed up the assessment of a promising medicine during a public health emergency. Normally, all data on a medicine or vaccine's effectiveness, safety and quality and all required documents must be ready at the start of the evaluation in a formal application for marketing authorization. In the case of a rolling review, EMA's human medicines committee reviews data as they become available from ongoing studies. Once the committee decides that sufficient data are available, the company

can submit a formal application. By reviewing the data as they become available, the committee can come to an opinion on the medicine's authorization sooner.

Sources: World Health Organization; WHO Country Office Sri Lanka; Landscape and Tracker of COVID-19 candidate vaccines from World Health Organization; and State Pharmaceuticals Corporation of Sri Lanka.

4. In addition to the above vaccines, other vaccines which may still be considered for financing by the project are vaccines manufactured by Moderna and Janssen vaccine manufactured by Johnson and Johnson and authorized manufacturer. Both of vaccines currently meet Criterion 3 and are therefore eligible for ADB financing.

5. **Sri Lanka Vaccine Regulatory Approval.** In addition to satisfying any one of the above eligibility criteria, there is a need for the vaccines to be authorized by the Sri Lanka National Medicines Regulatory Authority. Regulatory approval status of each candidate vaccine is in the table above.