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

1. The Asian Development Bank (ADB) and the government agreed on an indicative list of items that 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[3]; 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)[4].

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. The indicative vaccines which are planned to be directly procured from vaccine manufacturers or distributors are set out below, along with an assessment of their current status of compliance with the three eligibility criteria above. The assessment is based on available information as of 8 June 2021.

Manufacturer	Criterion 1: Selected for procurement through COVAX	Criterion 2: Received WHO prequalification or WHO emergency use listing (EUL)	Criterion 3: Received regular or emergency licensure or authorization by a stringent regulatory authority (SRA).
AstraZeneca (as manufactured by its manufacturing plants and contract manufacturers in United Kingdom (UK), European Union (EU), Australia, Serum Institute of India (SII) and SK Bioscience of the	World Health Organization (WHO) has included AstraZeneca vaccines manufactured by SII and SK Bio in its Emergency Use Listing (EUL) on 15 February 2021. COVAX has started procuring and distributing them. Hence it meets Criterion 1 and is	Vaccine data, including clinical studies data, was submitted for WHO EUL and was, including clinical studies data, submitted for WHO EUL and was, including clinical studies data, submitted for WHO EUL and received on 15	For AstraZeneca vaccines manufactured in UK, EU and Australia: Secured emergency use authorization (EUA) from UK's Medicines and Healthcare Products Regulatory Agency (MHRA), the European Medicines Agency (EMA)

[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 of the report and recommendation of the President).

[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.

[3] Footnote 29 of the APVAX paper is modified as follows: "A vaccine procured under the COVAX facility will be required to meet at least one of the following regulatory standards: (i) WHO emergency use listing or WHO prequalification; or (ii) emergency licensure or authorization from a stringent regulatory authority (SRA), or marketing authorization from an SRA. In addition, GAVI shall have entered into an advance purchase commitment, or other legally binding agreement, for the procurement of such vaccine".

[4] Footnote 30 of the APVAX paper is modified as follows: "A stringent regulatory authority is any one of the SRAs identified by the WHO for vaccines procured and/or supplied under the COVAX facility, as may be amended from time to time by the WHO. In addition, an SRA's endorsement, or other functional equivalent of an SRA authorization, of (a) the vaccine's safety and efficacy; and (b) the good manufacturing practices of the manufacturer of such vaccine, shall constitute satisfaction of this criterion."

Manufacturer	Criterion 1: Selected for procurement through COVAX	Criterion 2: Received WHO prequalification or WHO emergency use listing (EUL)	Criterion 3: Received regular or emergency licensure or authorization by a stringent regulatory authority (SRA).
Republic of Korea or SK Bio)	therefore eligible for Asian Development Bank (ADB) Financing.	February 2021. Hence it meets Criterion 2	and Australia's Therapeutic Goods Administration (TGA). If the project procures these vaccines, they will meet Criterion 3 and therefore be eligible for ADB financing. For AstraZeneca vaccines manufactured by SII and SK Bio: review process by stringent regulatory authority (SRA) has not been initiated.
Sinopharm/Beijing Institute of Biological Products	Might be selected for procurement through COVAX soon.	Vaccine data, including clinical studies data, was submitted for WHO EUL and received on 7 May 2021. Hence it meets Criterion 2	Not yet granted regular or emergency licensure or authorization by any of SRAs
SII (manufacturing Covovax using technology licensed from Novavax)	Advance market commitment signed by SII for Covovax with COVAX. Formal procurement is awaiting inclusion of Covovax vaccine in the WHO EUL. Once procurement is initiated, this will meet Criterion 1 and therefore be eligible for ADB financing.	Vaccine data including clinical studies data has been submitted for WHO EUL review. Review process for WHO prequalification by manufacturers of the vaccines have not been initiated.	Initial Phase 3 results were announced in media on 28 January 2021. Covovax has applied for EUA to Food and Drug Administration (FDA) on 2 March 2021 and is expected to get clearance by May 2021. In addition to this, in order to meet Criterion 3, the SRA would need to authorize SII's manufacture of Covovax (Novavax).
Johnson & Johnson or J&J)	AMC signed by J&J with COVAX. J&J received WHO EUL on 12 March 2021. COVAX procurement will start soon and will meet Criterion 1 and therefore be eligible for ADB financing.	Vaccine data including clinical studies data has been submitted for WHO EUL and was received on 12 March 2021. Hence it meets Criterion 2	Initial Phase 3 results were announced in media on 28 January 2021. FDA granted EUA on 26 February 2021. In addition to this, in order to meet Criterion 3, the SRA would need to authorize the manufacture of the vaccine if it will be manufactured in a non-SRA country.
Sinovac (Beijing Kexing Bioproducts)	Might be selected for procurement through COVAX soon.	WHO EUL received on 1 June 2021.	Not yet granted regular or emergency licensure or authorization by any of SRAs

Source: Asian Development Bank.

4. In addition to the COVID-19 vaccines manufactured by above manufacturers, other vaccines that the Government of Nepal may consider including COVAXIN vaccine manufactured by Bharat Biotech International Limited and Sputnik V vaccine manufactured by Gamaleya Research Institute of Epidemiology and Microbiology or by Dr. Reddy's Laboratories, and others if they meet one of the three eligibility criteria and eligible for ADB financing. In this regard, these vaccines would need to be selected for procurement through COVAX, or prequalified or granted EUL by the WHO, or received regular or emergency licensure or authorization by SRA. Currently, they do not satisfy any of these 3 criteria.

5. **Nepal's Regulatory Approval**. Besides satisfying any one of the above eligibility criteria, there is a need for the vaccines to be authorized by the Department of Drug Administration (DDA)—the national drug regulatory authority of Nepal. As of 11 May 2021, DDA has approved emergency use of COVISHIELD vaccine manufactured by the Serum Institute of India, Sinopharm vaccine manufactured by Beijing Bio-Institute of Biological Products, COVAXIN vaccine manufactured by Bharat Biotech International Limited and Sputnik V vaccine manufactured by Gamaleya Research Institute of Epidemiology and Microbiology.[5]

[5] Department of Drug Administration. 2021. Regarding the permission for Emergency Use Authorization of Covid-19 Vaccine (COVISHIELD). Kathmandu; Department of Drug Administration. 2021. EUA of covid 19 vaccine (Vero cell), inactivated manufactured by BIBP(under Sinopharm). Kathmandu; Department of Drug Administration. 2021. Regarding the permission for Emergency Use Authorization of Covid-19 Vaccine (COVAXIN); and Department of Drug Administration. 2021. EUA (Emergency Use Authorization) for SPUTNIK-V - COVID-19 Vaccine. Kathmandu.