Eligibility Criteria for 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 following eligibility criteria.

(i) Criterion 1: The vaccine has been selected for procurement through the COVID-19 Vaccines Global Access (COVAX) facility on behalf of its participating countries; or
(ii) Criterion 2: The vaccine manufacturer is prequalified by the World Health Organization; or
(iii) Criterion 3: The vaccine is authorized by a stringent regulatory authority (SRA) for manufacture in an SRA country, or the SRA has authorized its manufacture in a non-SRA country.

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 16 February 2021.

Manufacturer	Criterion 1: Selected for procurement through COVAX	Criterion 2: Vaccine Manufacturer Prequalified by WHO	Criterion 3: Vaccine Authorized by a SRA for manufacture in an SRA country, or SRA has authorized the vaccine's manufacture in a non- SRA country
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 Republic of Korea or SK Bio)	World Health Organization (WHO) has included AstraZeneca vaccines manufactured by SII) and SK Bio in its Emergency Use Listing (EUL) with COVAX expected to immediately procure and distribute them. Once procured, they will meet Criterion 1 and therefore be eligible for Asian Development Bank (ADB) financing.		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) and Australia's Therapeutic Goods Administration (TGA). If the project procures these vaccines, they will meet

[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 document in Appendix 2 of the report and recommendation of the President).

Manufacturer	Criterion 1: Selected for procurement through COVAX	Criterion 2: Vaccine Manufacturer Prequalified by WHO	Criterion 3: Vaccine Authorized by a SRA for manufacture in an SRA country, or SRA has authorized the vaccine's manufacture in a non- SRA country
			Criterion 3 and therefore be eligible for ADB financing. For AstraZeneca vaccines manufactured by SII and SK Bio: review process by an SRA has not been initiated.
SII (manufacturing Covovax using technology licensed from Novavax)	AMC signed by SII for Covavax with COVAX. Formal procurement is awaiting inclusion of Covovax vaccine in 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-PQ by manufacturers of the vaccines has not been initiated.	Initial Phase 3 results were announced in media last week and submission for EUAs by stringent regulatory authorities (SRAs) expected before end of Q1 of 2021. In addition to this, in order to meet Criterion 3, the SRA would need to authorize SII's manufacture of Covovax.
Janssen (Johnson & Johnson or J&J)	AMC signed by J&J with COVAX. Formal procurement is awaiting inclusion of the J&J vaccine in 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-PQ by manufacturers of the vaccines has not been initiated.	Initial Phase 3 results were announced in media last week and submission for EUAs in SRAs expected before end of Q1 of 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.

Q = quarter

4. In addition to the above 3 vaccines, other vaccines under consideration by the Philippines and which may still be financed by the project are vaccines manufactured by Moderna and Pfizer/BioNTech, which currently meet Criterion 3 and are therefore eligible for ADB financing as both have been granted emergency use authorizations (EUAs) by several SRAs namely Canada, Switzerland, United Kingdom, and the United States, and they would be procured from manufacturing sites in SRA countries. In addition, Pfizer/BioNTech is a COVAX-procured vaccine. Other vaccines that are under consideration by the Philippines include SinoVac and Gamaleya and if they meet one of the three eligibility criteria above, they will be eligible for ADB financing. In this regard, both SinoVac and Gamaleya would need to be selected for procurement through

COVAX, or prequalified by WHO, or authorized by an SRA for manufacture in a non-SRA country. Currently, it does not satisfy any of these 3 criteria.

5. **Philippines' Regulatory Approval.** Besides satisfying any one of the above eligibility criteria, there is a need for the vaccines to be authorized by the Philippines Food and Drug Administration (PFDA)—the national drug regulatory authority. Executive Order No. 121 has been issued to allow the FDA to grant EUAs to COVID-19 vaccines. The vaccine from AstraZeneca was granted an EUA last 28 January 2021 while the vaccine of Pfizer/BioNTech received its EUA on 13 January 2021. Covovax/Novavax and Johnson & Johnson vaccines have not applied for EUA from PFDA as they are required to submit EUAs from SRAs or other PFDA-acceptable non-SRA national regulatory agencies before processing their applications for EUA. SinoVac and Gamaleya have both already applied for EUA from PFDA.