

## Responses to Bidders' Questions

### REQUEST FOR PROPOSAL RFP-DAN-2020-503209 in support of the COVAX Facility for COVID-19 Vaccines of assured quality for use against the pandemic caused by SARS-CoV-2 virus

<https://www.ungm.org/public/Notice/117711>

Topic	Question	Answer
	1. What if certain manufacturers have an APC with the COVAX Facility which includes tiered pricing? How would they reflect that in the RFP?	As indicated in the RFP, manufacturers should provide access to the lowest price during the pandemic phase for all COVAX Participants. COVAX is aiming to achieve the lowest price on the market given the financing and de-risking provided by the push and pull contracts, indemnity and liability provisions, and the pooled COVAX volumes.  If a manufacturer has already signed an APC prior to the release of this RFP, the offer to the RFP should be aligned with the terms offered to Gavi for the APC.
	2. Are UNICEF and PAHO the only bodies in charge of the procurement and supply arrangements for the COVAX Participants?	While UNICEF and PAHO are designated procurement agencies for the AMC92 countries, SFCs have two options: i) they may choose to self-procure allocated doses from manufacturers with an agreement with the COVAX Facility; or ii) they may choose to benefit from the procurement services of PAHO for Member States in the Region of Americas or UNICEF in the rest of the world.
	3. Would it possible to send a bid in response to the RFP issued by UNICEF & PAHO if the development of the vaccine is still at an early stage and hasn't reached phase 2 yet?	Please refer to the procurement objectives of the tender on page 4 of 41 of the RFP document. The RFP aims to secure access to Covid-19 vaccines which meet the quality, safety and efficacy requirements for delivery in 2021. If a developer/manufacturer considers that it is realistic to meet this target based on the current clinical development plan and regulatory pathway, please submit a Proposal. Page 34 of 41 of the RFP document states the minimum package of documents that would be required in order for the IPG to consider the proposal for further evaluation. A summary of this information may be provided as a PowerPoint presentation
	4. Would it be possible to send a bid in response to the RFP if the first doses could not be supplied before 2022?	Please refer to the procurement objectives of the tender on page 4 of 41 of the RFP document. This tender aims to secure access to Covid –19 vaccines which meet the quality, safety and efficacy requirements for delivery in 2021.

	<p>5. Once an LTA is signed, and provided that all conditions are met, aren't there any guarantees for the manufacturers that the volumes stated in the LTA would be purchased by UNICEF &amp; PAHO? Manufacturers will have to block volumes to honour the commitment with COVAX and therefore not accept additional requests from other countries. What mechanism would be put in place to reduce the risk for manufacturers to end up with unsold capacities?</p>	<p>Any guarantee to procure doses by the COVAX Facility will be established in the Advance Purchase Commitment (APCs) signed between the COVAX Facility and the manufacturers. The Long-Term Agreements established by UNICEF and PAHO do not constitute a commitment or guarantee to procure. Quantities set forth in Long-Term Agreements are provided as good faith estimates of potential requirements.</p>
	<p>6. We understood that participants have the option to select between two participation arrangements upon joining the COVAX Facility: Committed Purchase Arrangement or Optional Purchase Arrangement. Therefore, is it possible for manufacturers to opt for "Committed Purchase Arrangement" only to reduce the risks?</p>	<p>These arrangements only refer to Self-Financing Self-Procuring Countries, so a subset of the COVAX participants. Regardless of the arrangement chosen by participants, the volume guarantee under the APCs will apply. Furthermore, allocation decisions are made by the WHO allocation Platform. One of the primary objectives of the COVAX Facility and WHO allocation platform is to ensure equitable access to COVID-19 vaccines and allocation mechanism will make decisions independently, without any additional constraints placed by manufacturers.</p>
	<p>7. In the Committed Purchase arrangement it seems that self-financing countries will pay US\$10.55 per dose to COVAX Facility – hence, is</p>	<p>Please kindly note that \$10.55 per dose is a weighted average projection, may not be the actual amount of cost or price in conventional terms. The COVAX Facility will be investing in portfolio of vaccine candidates with involvement of risks at multiple stages. The initial financial estimate of \$10.55 is used in COVAX Country Agreements as a commitment reference and budgeting purposes.</p>

	<p>this amount considered as the maximum price per dose that should be proposed by manufacturers? Is there a pricing threshold that manufacturers should not overpass? What percentage of the US\$10.55 per dose would be allocated to the manufacturer ?</p>	<p>The estimated average per dose cost of \$10.55 composed of three elements: (1) an estimated ex-factory cost (around 80%) + (2) “speed &amp; access premiums” (around 17%) + (3) financing/risk mitigation and operating costs for the facility (3%). Self-financing countries are requested to make a binding financial commitment based on the estimated cost per dose multiplied by a number of doses that the country would like to receive (i.e. 20% of the country’s population) during the initial allocation Phase 1. At a later stage, the actual procurement price (adjusted cost per doses) of the vaccines will be clarified depending on the success of the invested vaccine candidates and negotiations with the suppliers. The COVAX Facility hopes that actual price of vaccines to be much lower than \$10.55 per dose, however, there is no established price threshold at this moment.</p>
	<p>8. In the Optional Purchase Arrangement it seems that SFCs will pay US\$3.50 per dose to COVAX Facility – in such case, how would this lower contribution cover the vaccine price?</p>	<p>As above, down payments are different between Optional Purchase Arrangements and Committed Purchase Arrangements and they are only a share of the estimated procurement value per dose.</p>
	<p>9. How would down payments for Advance Purchase Agreements be made to manufacturers to accelerate investments and developments? Are there any milestones? What would be the financial structure? (upfront Payment and financial guarantee)</p>	<p>Minimal down payments may be considered in certain circumstances for specific activities and situations. The COVAX Facility would be open to consider such requests.</p>
	<p>10. If unfortunately, the development of the vaccine fail, would the selected manufacturers who received upfront payments, need to reimburse partially or totally the amount?</p>	<p>This will depend on the specific terms and conditions of the upfront payments.</p>

	<p>11. In Annex D, there are items on the labelling, barcodes and serialization that appear to be generic requests for any vaccine and not reflecting the more recent WHO guidance on these topics. Is the intent for these requirements to evolve as the draft WHO guidance evolves</p>	<p>Proposers are requested to follow the guidance set out in WHO working position on model packaging <a href="https://www.who.int/teams/regulation-prequalification/eul/covid-19/covid-19-model-packaging">https://www.who.int/teams/regulation-prequalification/eul/covid-19/covid-19-model-packaging</a></p>
	<p>12. Manufacturer signed SOI with the facility however since their vaccine expected to be ready for delivery in 2nd half of 2021 and also their proposals would need to be cleared at several levels, they will not meet the phase 1 deadline which was intended for all those with APC,MOU, SOI. Is this acceptable for the facility that the proposer submits the proposal by the phase 3 deadline?</p>	<p>In this case the manufacturer qualifies for both the first and third phase. The proposal will be accepted by the deadline of Phase 3 however all bidders are encouraged to make every reasonable effort to submit before the target deadline.</p>
	<p>13. What is supplier's ability to set Minimum Order Quantities for PAHO? Will Minimum Order Quantities be strictly prohibited, or is there flexibility (i.e., at least more than a single package or shipper)?</p>	<p>For both PAHO and UNICEF, order quantities will be defined by the allocation mechanism, which will take into consideration the population in each country and territory and the principles of the COVAX Facility. Quantities can be adjusted to meet packaging sizes, but Minimum Order Quantities are not allowed. Small quantities may be required for small countries/territories where population is small but please propose solutions in order to achieve delivery. The tender aims to secure access to vaccines for all participants, irrespective of market size. Minimum order volumes will be defined by the validated packaging configuration as part of the regulatory approvals.</p>