

Response to Bidders' Questions

REQUEST FOR PROPOSAL RFP-DAN-2020-503209 in support of the COVAX Facility for COVID19 Vaccines of assured quality for use against the pandemic caused by SARS-CoV-2 virus

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

Question	Answer
<p>1. For any manufacturer to offer any quantities of significance, we believe that this would be only possible by doing at risk manufacturing before EUL and this “at risk manufacturing” has been supported by COVAX/GAVI/BMGF for a few companies. Given the long lead time of key raw and packing materials, we would like to get a clarification if we can submit an offer which would entail getting an advance to procure these long lead items that would support at risk manufacturing.</p>	<p>Manufacturers are encouraged specify in their proposals if they require any support such as down payment/prepayment etc. in order to meet the volumes at the prices they are proposing. Such requests will be included in the evaluation of the offers</p>
<p>2. If a company has 2 products, should they submit 2 proposals?</p>	<p>Yes, please submit a complete proposal for each vaccine candidate.</p>

<p>3. In a scenario where 2 companies are partnering where one company has rights for GAVI 93 countries, is it preferable to submit one proposal or 2 separate proposals.</p>	<p>It is acceptable to receive separate proposals per company indicating which countries will be covered and its price, but a note should be made in the proposal that this is a agreed approach.</p>
<p>4. We understand that self-financing countries will have the option to self-procure or procure via UNICEF or PAHO. We would like to know how this mechanism works and what exactly is the difference between the procedure in procurement of vaccine by UNICE/PAHO for GAVI countries and SFCs.</p>	<p>The procurement process for UNICEF/PAHO is the same for GAVI (AMCs) and SFCs. The self-procurement process will be guided by the terms and conditions define in the APCs and agreed to in Summary Term sheets between Manufacturers and UNICEF as the Procurement Coordinator for the COVAX facility. The Self Procuring country would be expected to engage directly with the manufacturer to place the purchase order against the term sheet. Countries procuring via UNICEF/PAHO would have their purchase orders placed by UNICEF/PAHO against the agreed LTAs</p>
<p>5. Any specific guidance for submission to the WHO for pre-qualification review? Assuming this is part of our normal regulatory submissions process for vaccine manufactures.</p>	<p>Please refer to WHO EUL procedure (https://www.who.int/teams/regulation-prequalification/eul and https://www.who.int/teams/regulation-prequalification/eul/covid-19)</p>
<p>6. We will only have limited capacity in the 2nd half of 2021. But an increased capacity for both 1H and 2H of 2022. If we only able to supply</p>	<p>While it would be of interest to understand the availability beyond 2021, the main objective of the tender is to secure deliveries in 2021. Please submit proposal for the monthly quantity available in 2021 and the availability for 2022.</p>

**minimal doses in 2021
(meaning 1 to 2M doses)
would our doses be
accepted for 1H 2022?
(we anticipate being able
to supply 50M doses in
2022)**