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
Scope	1. How does the role/objective of the tender differ as it relates to the 92 AMC countries, versus self-financing countries (SFCs) using UNICEF as a procurement agent, versus SFCs which are not using UNICEF as a procurement agent?	Objectives would be the same. For AMC92 who are procuring through UNICEF/PAHO, the tender will allow UNICEF and PAHO establish LTAs to ensure supply and delivery to AMC92 countries. Same for SFCs procuring through PAHO and UNICEF. For self-procuring SFCs, the tender will allow UNICEF as the Procurement Coordinator in collaboration with Gavi to establish a supply term sheet with each manufacturer that has signed an APC with Gavi, to inform and guide the establishment of procurement arrangements between these countries and manufacturers.
	2. In Section 1.1, how should a manufacturer with an MOU refer to the terms agreed upon with Gavi in the MOU for this tender submission?	We expect alignment with the terms offered to Gavi for an APC or MoU, and the terms offered as part of the proposal in response to this RFP. The terms offered to Gavi should not conflict with any of the T&Cs or requirements of this RFP, and so there should be no reason to present these terms differently as part of the RFP response.
	3. In Section 2, to what extent will the Key Basic Terms be binding for SFCs wanting to procure	Objective of the Key Basic Terms will be to guide and inform SFCs that decide to self-procure and engage directly with manufacturers for procurement arrangements. Procurement by SFCs via UNICEF or PAHO will be issued against theUNICEF/PAHO LTAs.

	via UNICEF and PAHO?	
	4. Do Gavi APC and SOI also need to be evaluated through the formal submission of UNICEF? What is the mechanism of this part of COVAX works? What is the link between the above mechanism and WHO EUL on COVID 19 vaccines?	The RFP's aim is both to identify further candidates for APCs, but also help establish supply agreements between COVAX buyers and manufacturers on the back of APCs (since APCs do not go into any supply and procurement details). All manufacturers need to respond to the tender to be considered for an award for COVAX supply in 2021, regardless of having APCs, MOUs or SOI with Gavi.
	5. Should bidders provide two different offers per INCOTERM requested in the RFP?	Only one offer is expected in response to this joint RFP (UNICEF/PAHO). As requested in RFP Part VI, Answering Sheets, Quantitative Proposal Sheet, page 40, price should be offered based on INCOTERMS (2020) FCA, Nearest International Airport (Name Airport). FCA prices will be the base for evaluation of the commercial offers. For procurements through PAHO, before issuing the purchase order and according to the quantities and the country, the supplier will provide the freight and insurance cost at that time, under INCOTERMS (2020) DPU. However, alternative INCOTERMS that support the achievement of the RFP objectives, provide best value for money and are considered in the best interests of the COVAX Facility, may exceptionally be considered, in addition to the FCA price.
	6. Please comment on award process and timing	This is a rolling RFP meaning that offers will be received, evaluated and awards made in a phased manner. Please refer to Page 9 or 41 of the RFP document.
	7. Will UNICEF and PAHO publish the awards?	RFP Part III, Article 2.5 page 17 of 41 refers. Awarded LTAs and pull contracts will be made public per the normal UNICEF, PAHO and Gavi process, respectively. When all LTAs and pull contract awards have been made, a summary of prices and relevant terms will be made public.

	8. Is there a scope of demand for 2022?	This RFP only covers anticipated demand for 2021.
	9. Is there a preference for non-injectables (i.e. nasal delivery)?	Any route of administration is acceptable, if vaccine is safe and effective – please see the Target Product Profile at https://www.who.int/publications/m/item/who-target-product-profiles-for-covid-19-vaccines Product characteristics will be addressed in the EUL process. Refer to WHO EUL procedure (https://www.who.int/teams/regulation-prequalification/eul and https://www.who.int/teams/regulation-prequalification/eul/covid-19)
	10. How will the Self-Procuring Countries interact in consideration of the tender requirements and response?	For Self-Procuring SFCs, the tender will allow UNICEF as the Procurement Coordinator in collaboration with Gavi to establish a supply term sheet with each manufacturer that has signed an APC with Gavi, to inform and guide the establishment of procurement arrangements between Self-Procuring SFPs and manufacturers.
	11. Can you share the list of countries outside of the AMC92 which will be using UNICEF or PAHO as the procurement agency?	As of end of October 2020, 66 SFC signed commitment agreements with the COVAX Facility, plus Team Europe covering 29 Member countries. Please see the link: https://www.gavi.org/news/document-library/covax-commitment-agreements SFCs, participating in the COVAX Facility will have the option to buy vaccines themselves through their national mechanisms or through UNICEF or PAHO to benefit from the COVAX Facility vaccine portfolio. PAHO will purchase on behalf of all interested Member States from the Americas. As of end of October 28 SFCs from the Region of Americas have signed agreements with the COVAX Facility. In the coming period, PAHO will clarify the interest of its Member States and Territories to utilize the Revolving Fund mechanism for procurement. UNICEF and Gavi is currently reaching out to SFCs in other Regions, to clarify their preferred procurement channel, i.e. through UNICEF or national mechanisms.
Product Presentation	12. Vial Label	Proposers are requested to follow the WHO guidance as set out in the working position on model packaging

	What is the evolving UNICEF perspective on a dynamic expiry date? Given that the tender does not take a clear stance, when approximately could we be expected to hear a final answer on this?	https://www.who.int/teams/regulation-prequalification/eul/covid-19/covid-19-model-packaging
	13. If a dynamic expiry date (anticipated to be 3 months at 2-8°C; based on existing platform data) is not acceptable we might consider applying the Shelf Life of 2 years at -20°C. Shipping at -20°C might be very beneficial to some countries (as the Shelf Life at -20°c is 2 years). Can we have a conversation on this topic ?	Refer to WHO EUL procedure (https://www.who.int/teams/regulation-prequalification/eul and https://www.who.int/teams/regulation-prequalification/eul/covid-19)
	14. Carton What exactly is the requirement for statement of active [substances] on the secondary packaging?	Proposers are requested to follow the guidance set out in WHO working position on model packaging https://www.who.int/teams/regulation-prequalification/eul/covid-19/covid-19-model-packaging
	15. There are requirements in the RFP on serialization,	The requirements of the RFP are not considered to be inconsistent with the WHO working position at this point in time.

	barcodes and labels that do not appear to be aligned with the draft WHO guidance on these items. Will the RFP requirements be updated as this guidance evolves?	Proposers are requested to follow the guidance set out in WHO working position on model packaging https://www.who.int/teams/regulation-prequalification/eul/covid-19/covid-19-model-packaging
Regulatory Requirements	16. What's UNICEF Position on NCL testing with regards to the different countries. Will NCL/OMCL testing be required? Will there be reliance on other NCL testing?	WHO actively promotes the principles of reliance for interactions with NRAs based on facilitated regulatory pathways. There is significant work going on with regards to regulatory alignment, but this effort does not preclude countries from adhering to their own domestic regulations and requirements. WHO is working with regulators and with the International Coalition of Medicines Regulatory Authorities on alignment of regulatory requirements.
	17. In terms of technical details, would the manufacturer no longer need to provide very detailed data after EUL says "yes"? Because once we are accepted into the EUL evaluation, it means that the technical information (design, preclinical and clinical) of relevant products shall be submitted to WHO, and this part of content is also suitable for the	Refer to WHO EUL procedure (https://www.who.int/teams/regulation-prequalification/eul and https://www.who.int/teams/regulation-prequalification/eul/covid-19) Details for information to be provided to WHO after approval under the WHO Emergency Use Listing procedure will be provided by WHO.

	content of Quality sheet.	
	18. As mandatory criteria, WHO EUL was highlighted in RFP, there will be different process including the applying, the acceptance for next evaluation and the final approval, we wonder which of those parts would mean being shortlisted in UNICEF's consideration?	Refer to WHO EUL procedure (https://www.who.int/teams/regulation-prequalification/eul and https://www.who.int/teams/regulation-prequalification/eul/covid-19) In order for a vaccine to be procured under the COVAX Facility as a minimum it will need to be approved under the WHO Emergency Use Listing procedure
	19. As an important output link of COVAX, will UNICEF also obtain corresponding information sharing from WHO?	Refer to WHO EUL procedure (https://www.who.int/teams/regulation-prequalification/eul and https://www.who.int/teams/regulation-prequalification/eul/covid-19)
Logistics	20. How flexible is supplier's ability to set Minimum Order Quantities for UNICEF? For instance, would it be acceptable to have different Minimum Order Quantities given different population sizes of	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.

	countries? Can the MOQ be increased over time (i.e., after 3% targets are hit in the first phase of shipments)? 21. 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)?	
	22. How flexible is supplier's ability to cap number of shipments in a year (i.e., shipping a maximum of two times in 2021 to each member country)?	The number of shipments to countries are dependent on the total quantities available as well as quantities allocated to the country by the WHO Allocation Framework Mechanism. Therefore, at this point, the Procurement Agencies can't forecast the number of shipments per recipient country, and capping the number of shipments per country is not allowed.
PAHO	23. While the tender is for PAHO and UNICEF, and two specific PAHO annexes are attached, there isno reference to the PAHO direct delivery to countries	Suppliers responding to purchase orders issued by PAHO are responsible for the delivery up to the airport of destination (Incoterm 2020 DPU) including insurance charges. Before issuing the purchase order and according to the quantities and the country of destination, the supplier will provide the estimated cost of freight and insurance at that time.

	in the Quantitative Proposal Sheet. How will deliveries be financed? Where are the incoterms for PAHO, and what volumes are expected? How is supplier expected to estimate delivery costs for PAHO countries, without more specific destination/quantity breakdowns ahead of time?	Quantities to be procured by PAHO will be determined by the Allocation Team in a later stage.
	24. How flexible are cost-sharing requirements for PAHO (i.e., supplier's paying for transportation or last-mile shipments)? How likely is it that PAHO ends up deducting certain costs from supplier's final invoice (a practice that Supplier finds fairly unacceptable)?	Suppliers responding to purchase orders issued by PAHO are responsible for the delivery up to the point of destination (Incoterm 2020 DPU) including insurance charges (110% of their DPU value). Purchase orders will include the cost of the vaccine, freight and insurance charges. Any transportation cost should be included in the freight charges. Suppliers are urged to find the best possible routing that will maintain the cold chain requirements of the vaccine. Before issuing the purchase order and according to the quantities and the country, the supplier will provide the cost at that time.
	25. How will pharmacovigilance activities be managed between UNICEF/PAHO and Suppliers?	Countries are working in their preparedness plans for vaccines deployment including their pharmacovigilance plans for covid-19 vaccines. WHO has been supporting countries to identify gaps and strengthen these capacities (1, 2). In the context of the covid-19 pandemic vaccine development, monitoring of vaccines safety is not only a priority but an unavoidable function that should accompany the authorization of use and introduction of the covid-19 vaccines in countries (2, 3). The monitoring of

covid-19 vaccines safety will pose challenges for both the National Regulatory Authorities and the Immunization programs. The failure of the safety monitoring and risks management of the new vaccines could be extremely deleterious in terms not only of the seriousness of the adverse events and the failure to control the pandemic, but in terms of people's trust in all vaccines. Post surveillance commitments by manufacturers are part of the EUL process, and information provided to WHO will be shared with procurement agencies and relevant programs (4). To support countries in Pharmacovigilance activities regarding covid-19 vaccine it is then required that RFP requirements are followed considering more specifically:

The provision by manufacturers of at least preliminary formats of Periodic Safety update reports and proposals for Risk management plans that could be fully shared with WHO and Health authorities participating in the Manufacturer's vaccine acquisition. These formats should consider and follow the recommendations of guidelines on the field (5, 6).
A commitment to provided updated monthly safety reports on serious events in accordance with these guidelines and other safety information as requested by the WHO or the Health Authorities involved.
The collaboration in Post-authorization safety studies (PASS), passive and active surveillance as requested and agreed with WHO and the Health authorities.

1. WHO. The push for a Covid-19 vaccine. (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines ,accessed 14 November 2020).

2. WHO. Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine_deployment-2020.1 ,accessed 18 November 2020).

3. WHO. Safety surveillance manual. Geneva: World Health Organization; 2020 (https://www.who.int/vaccine_safety/committee/covid_vaccine_safety_manual/en/ ,accessed 12 November 2020).

		4. WHO. Emergency use listing procedure, version 9 January 2020 (https://www.who.int/publications/m/item/emergency-use-listing-procedure ,accessed 18 November 2020). 5. European medicines agency. Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 Vaccines; 2020 (https://www.ema.europa.eu/en/documents/other/pharmacovigilance-plan-eu-regulatory-network-covid-19-vaccines_en.pdf accessed 18 November 2020). 6. European medicines agency. Consideration on core requirements for RMPs of COVID-19 vaccines; 2020 (https://www.ema.europa.eu/en/documents/other/consideration-core-requirements-rmps-covid-19-vaccines_en.pdf , accessed 18 November 2020).
Country Readiness	26. What does the supply chain look like beyond the delivery point (i.e., after reaching the member country)?	Consignee will oversee the distribution at the country level. What the national supply Chain looks like would differ depending on the national procedures for customs clearance, nationalization, cold chain transportation and storage capacity. Vaccine allocation and placement of purchase orders will be subject to country assessed readiness.
	27. How is UNICEF planning on ensuring recipient country readiness for receiving the vaccine? Can UNICEF or supplier collaborate	Vaccine allocation and placement of purchase orders will be subject to country readiness. There are various working groups by WHO, UNICEF and partners existing at the global, regional and national levels to support readiness of countries. There are two main tools being released in collaboration with WHO, UNICEF, World Bank and other partners to support country to prepare for receiving these vaccines. 1. The Vaccine Readiness Assessment Tool (VIRAF) which provides a roadmap for countries to plan for COVID-19 vaccine introduction and a structured framework to self-monitor readiness progress against key milestones 2. Guidance on National Deployment and Vaccination Planning (NDVP) https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine_deployment-2020.1

	with national health organizations to support readiness efforts?	Other guidance documents are under development and will be released in due course.
	28. Is the NRA readiness included in the VIRAF?	Yes. As per references below, regulatory readiness is included as part of the COVID-19 Vaccine introduction readiness assessment tool. Additional information on VIRAF is available at: 1) https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery 2) https://apps.who.int/iris/bitstream/handle/10665/336187/WHO-2019-nCoV-Vaccine_introduction-2020.1-eng.pdf?sequence=1&isAllowed=y
Data sharing	29. At various points in the tender (i.e., in the "Manufacturing, supply, and market considerations" section in "Product Profile" and questions regarding "volumes offered" and "production scale-up" in the "Qualitative Proposal Sheet"), UNICEF requests specific manufacturing data. Supplier has never been asked to share this level of detail in previous tenders, and for privacy reasons will unfortunately likely not be able to answer all the questions in full	In previous tenders UNICEF has requested to procure vaccine that is already WHO Prequalified (and hence no need to request this information) This is not the case of this tender where the tender seeks proposals for candidate vaccines that are still under development. As such, the detailed Manufacturing Data is required in order for an informed decision on whether or not to include the candidate in the COVAX portfolio. PLEASE NOTE Information shared is treated as confidential and would only be shared with the parties outlined in section 1 page 4 of 41 of the RFP document.

	detail. Will that be a disqualifier?	
	30. As supplier is already directly in contact with IPG and providing certain data at their request, can we note as such rather than answering relevant individual questions?	All manufacturers need to respond to the tender should they want to be considered for COVAX supply in 2021, regardless of having an APC, MOU or SOI with the COVAX Facility. Manufacturers should provide all relevant information as requested by the RFP.
	31. Given the lower level of detail in the data that we are providing to IPG in the status quo, is it better to not provide an additional, higher level of detail directly to them?	The information listed in the RFP for submission is required regardless of having an APC, MOU, SOI or any communication with the COVAX Facility
Requirements	32. Currently, the main candidate vaccines are still in the stage of clinical stage, and the phase III is as among the fastest. The assessment of EUL is in the beginning from no long. There would be a fact that the RFP at this stage will cause great difficulties for many suppliers. Therefore, please help us to understand the purpose of this RFP,	The RFP's aim is both to identify further candidates for APCs, but also help establish Long Term Arrangements and Supply agreements between COVAX buyers/Procurement Agencies and manufacturers on the back of APCs (since APCs do not go into any supply and procurement details). The RFP further aims to secure supply for 2021.

	we wonder if there will be different phased strategies for different suppliers/ manufacturers, please give us specific plan suggestions;	
	33. Submission time. According to the requirements of RFP, the submission time of formal proposal is closely related with the supplying prediction of the manufacturer. However, there is a question: the EUL evaluation conducted by WHO also depends on the Regulatory Administration of the host country and the arrangement of PQT at the same time, the overall progress of evaluation does not depend on the supplier's own behavior, what would be the solution once there are wide variation caused by differences between the forecast and the	UNICEF is encouraging Proposals from suppliers with products in development and acknowledges that supply forecasts for such products may need further iterations (and/or confirmations) later in time. Efforts are currently ongoing amongst regulators to accelerate regulatory timelines provided sufficient data are available to document quality, safety and efficacy of the vaccines.

	real situation of the manufacturer? How to deal with the standard proposed by UNICEF? The suggestion is in this moment, the manufacturers only need to provide a clear intention or basic plan, Gavi, UNICEF track progress, and a formal negotiation can be started when the candidate product obtains EUL or other acceptable license.	
	34. Release. According to the current regulations, Release means that the products must be approved for market by the regulatory authorities in the host country. In the RFP, the standards for supply also refer to regulatory agency registration and release certificates which will be no exempt to supply to UNICEF. This criteria would be	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)

	conflicting to the principle of emergency use time, the actual supply time is likely to be postponed to a very late time, which needs to be reconsidered by UNICEF;	
	35. According to the quantity of global supply mentioned in the RFP, it is speculated that the supplying capacity of all qualified manufacturers may still not achieve to the goal of quantity requirements, and the clinical differences of products developed by different technical platform will be very large. In view of this, one proposal is that the RFP reconsiders the evaluation mode apart from the traditional procurement, that is, if the product is proved to be safe and effective, meets most of the WHO TPP	To respond to the global pandemic, the evaluation criteria for vaccines to be supplied and delivered under this RFP have been developed and outlined in Part III Page 16 or 41 of the RFP while the Mandatory Technical Requirements have similarly been developed and are outlined in Annex D.

	benchmarks, and the manufacturer also meets the corresponding WHO GMP conditions (the specific evaluation criteria can be coordinated by COVAX), it can be considered to being shortlisted;	
	36. The clinical trial of our candidate products is still under ongoing, and there is no official package form as approving in our Country, therefore, some of requirements of packaging in the RFP would not be satisfied in this moment. Those are like as: - Ice bag / dry ice transportation plan (the finished products will be considered in detail when the time of marketing application, and the final information cannot be provided for the time being) - Standard export packing & inner	For questions related to packing, Proposers are requested to follow the guidance set out in WHO working position on model packaging https://www.who.int/teams/regulation-prequalification/eul/covid-19/covid-19-model-packaging Other questions related to product inserts as requested in Annex D should be discussed with the WHO Prequalification team. It is acknowledged that due to the early stages of product development, manufacturers may not be able to provide all required information with the bid submission. Provided that it is considered feasible that a product will be available, meeting the quality, safety and efficacy requirements for delivery in 2021, we still encourage that a proposal is submitted.

	packing size and weight (not available for the time being, still in trial process) In the meanwhile, many contents required in the product information part, such as population, contraindications, etc., those still depend on clinical results. In view of the above situation, it seems that many requirements in the RFP may not reflect the real situations of the manufacturer; we propose that UNICEF have further work on systematic arrangements on those.	
	37. Price and quantity. Does COVAX have a minimum supply quantity requirement for each supplier? If so, how much volume is it? For the supply price, the production costs of different technical platform will be varying, has	COVAX does not have a minimum supply quantity requirement by manufacturer. Each candidate will be evaluated for the value it brings to the COVAX portfolio based on a number of factors, including the overall mix of candidates, supply delivery timelines, volumes, pricing, other commercial terms, etc. COVAX does not have a unified proposed price. COVAX is aiming to achieve the lowest price on the market given its principle of fair and equitable access to COVID-19 vaccines.

	COVAX given prices suggestions and guidance for different candidates? If not, is there a unified proposed price?	
	38. Transportation. In case of damage and loss during transportation and distribution, will UNICEF require the manufacturer to complement the corresponding quantity again? We wonder if the above losses shall be borne by the manufacturer.	PAHO's purchases will be under Delivery Place Unloaded (DPU Incoterm) that requires the seller to deliver the goods at the disposal of the buyer after they've been unloaded from the arriving means of transport sellers is responsible. Additionally, the supplier should include insurance for 110% of their DPU value. In case of any damage or loss during transportation, the supplier should be the liaison between the insurance company and the consignee (country or territory). A replacement shipment may be requested before the insurance company determines how to proceed. For UNICEF Shipments: Any loss or damage to the supplies prior to delivery INCOTERM FCA have to be covered by the supplier. After delivery and handover has taken place UNICEF will make sure the supplies are covered by a cargo insurance covering physical loss or damage. The policy will provide coverage until the consignee is in receipt of the supplies, normally the point of entry to the arriving country.
	39. Supplying period. A proposal is that in case of any quantities of special increasing or decreasing during the supplying period determined in advance, UNICEF is better to communicate with the manufacturer at least 2-3 months in advance to reduce the	Noted. Please include any such requests for notification in your proposal.

	waste of producing cost;	