

RFP-DAN-2020-503209

Covid-19 Vaccines of Assured Quality for Use
against the Pandemic Caused by SARS-CoV2 virus

Pre-Bid Conference

UNICEF Supply Division
PAHO Revolving Fund
18 November 2020



Introduction and objectives of the session

Objectives

- Information-sharing with vaccine manufacturers to support delivery of 2 billion doses of COVID-19 vaccine in 2021
- During the session, UNICEF and PAHO as procurement agencies of the COVAX Facility will provide vaccine manufacturers with an overview of the ongoing RFP-DAN-2020-503209

Expected outcomes

- To have clear understanding of the requirements of the Request for Proposal (RFP)
- To provide high level clarifications to the questions received so far from proposers

Housekeeping

Please stay on mute with video off, while not speaking to preserve the livestream quality

Please state your name and your company before sharing a comment or question

Please write your question in the chat function as much as possible

Please save questions until after the presentation where there will be an opportunity to raise questions through raising your hand functionality on your screen

Session materials and additional questions

All material from the session will be made available on the UNGM RFP link by November 20th

Written responses to questions raised to date including during this session will be included

All technical questions related to regulatory aspects will be responded to in writing and posted in UNGM

Additional questions to be raised in the future will be responded to in line with the RFP, in advance of deadlines for submission of Proposals and posted on the same site

Request for Proposal to secure access to at least 2 billion doses of vaccine to be delivered by end 2021

APPROACH A pooled tender has been issued *jointly by UNICEF and PAHO*

Purpose	<p>Gavi, as COVAX Facility Secretariat, can establish advance purchase commitments - APCs</p> <p>UNICEF and PAHO can establish procurement and supply arrangements based on the APCs</p> <p>UNICEF, as COVAX Procurement Coordinator, establishes key basic terms that COVAX self-financing self-procuring participants reference in their supply agreements with manufacturers.</p>
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Objectives	<ol style="list-style-type: none">1. Speed Expedite access to Covid-19 vaccines by building on push and pull contracts (established by BMGF, CEPI and Gavi) for the COVAX participating economies2. Volumes ACT-A target is to secure at least 2bn doses by end 20213. Price Drawing on the financing and de-risking provided by the push and pull contracts and the pooled COVAX volumes, COVAX targets to achieve the lowest price on the market4. Balanced Portfolio Balanced geographically diverse portfolio across multiple vaccine platforms
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COVAX demand

2

billion

The initial target of COVAX is to deliver at least 2 billion doses of Covid-19 vaccine by the end of 2021

preliminarily split

92 AMC economies (estimated 950 million doses, with potential additional doses subject to financing initiatives)

At least 94 self-financing economies (estimated range from 550-950 million doses)

Buffer for humanitarian use (100 million doses)

As country participation in the COVAX Facility is firmed up, these demand forecasts will continue to be refined and the latest estimates will be communicated in due course

Tender Invitees

Open to all manufacturers.
Emphasis on delivery in 2021

Current Status

RFP has been issued on November 11th.
Published on UNGM at following link
<https://www.ungm.org/public/Notice/117711>

Modality

Rolling tender with evaluation and awards being made in phases

Timelines

- Phase 1: Submission deadline is 25th November, by **16:00 hours (Copenhagen time)**
Mainly targeting Manufacturers **with Gavi APC, MOUs, and SOIs.**
- Phase 2: Submission deadline 9th December, by **16:00 hours (Copenhagen time)**
Mainly targeting Manufacturers that plan to have **vaccine availability during the first half of 2021.**
- Phase 3: Submission deadline is 23rd December, by **16:00 hours (Copenhagen time)**
Mainly targeting Manufacturers that plan to have **vaccine availability from the second half of 2021**
MANUFACTURERS ARE ENCOURAGED TO SUBMIT PROPOSALS EARLIER THAN THE DATES

EMAILED PROPOSALS should be sent to: supplybid@unicef.org

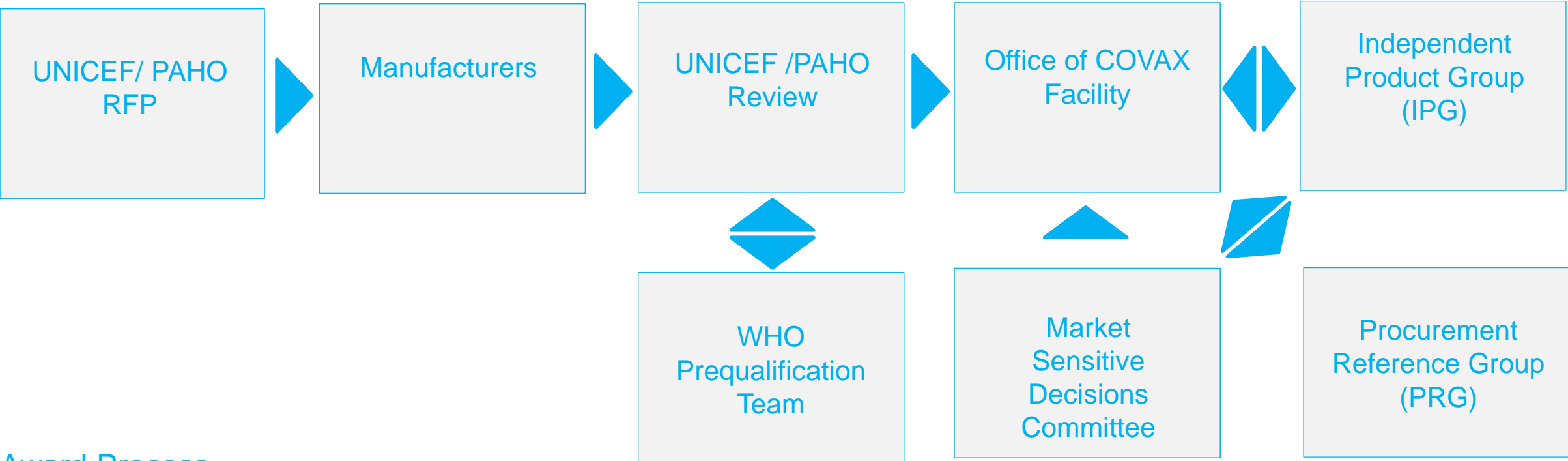
Proposal and Answering sheets (Part IV)

Only the forms and answering sheets provided in the RFP document should be used however, supplementary information can be provided on each of the answering sheets:

- PROPOSAL AND COMMERCIAL TERMS SHEET (RFP, p31)
- TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET (RFP , p32)
- PRODUCT PROFILE SHEET (RFP, p33)
- QUALITATIVE PROPOSAL SHEET (RFP, p38)
- QUANTITATIVE PROPOSAL SHEET (RFP, p40)

In order to facilitate the evaluation, Proposers are requested to send each of the above as a separate file, when submitting the Proposal, clearly marking each file with the manufacturer, name, product identification and section.

High level summary of joint UNICEF/PAHO Tender Review and Evaluation process (PART III-RFP, p16-19)



Award Process

1. Office of COVAX Facility
APC

2. UNICEF /PAHO
LTAS

Manufacturers

Minimum IPG Requirement to start a Technical Evaluation of proposal (RFP, p33-37)

In case an incomplete offer submitted, the following are the minimum requirements to facilitate the work of Independent Product Group (IPG) to begin a review of the technical proposal)

1. An overview of the vaccine development plan, including timeline and information on studies completed to date
2. An overview of the vaccine product profile and delivery attributes
3. A section on manufacturing, supply, and market considerations

The information may be provided in a **Power Point presentation** (preferred) or as a report:

Please respond as fully and completely as possible, based on recent available information. If responses cannot be provided at this stage please indicate whether information is not yet available or is not expected to be available.

For Vaccines not yet approved under the WHO EUL or Prequalification procedure (Annex D)

- The Proposal must include a detailed plan on the timeline to obtain WHO prequalification.
- UNICEF and PAHO may, as an exceptional measure, consider procuring licensed vaccines which comply with certain criteria such as marketing authorization granted and oversight by a Stringent Regulatory Authority.
- Should UNICEF and PAHO decide to procure such vaccines, procurement will be subject to specific contracting terms as explained in RFP document; including acceptance by receiving country.

Prices and Discounts (Part IV - Other Mandatory Requirements. RFP, p20)

- Proposers requested to provide unit pricing in accordance with the offered delivery terms (INCOTERMS 2020).
- Prices shall be inclusive of packaging, packing and all the temperature monitoring devices and must be net of any direct taxes and any other taxes and duties, unless otherwise specified in the RFP.
- Currency of the offer shall be in US Dollars or US Dollars and EURO. Proposers who wish to offer in EURO are requested to offer one price in US Dollars and one price in EURO
- Prices offered by Proposers, will constitute maximum ceiling prices and cannot be increased for the duration of the tender period and during the validity of Proposal. Prices may be reduced at any time.
- Proposers shall confirm that the offered prices are the most favorable prices available to any customer of the Proposer (or any of the Proposer's affiliates).

High Level Purchase Order Process Flow for AMC92 and Self Financing Participants procuring through UNICEF

One purchase order per consignee per allocation
82 AMC countries will receive their supply through UNICEF

All shipments of vaccines procured through UNICEF will be shipped directly from manufacturers to consignee, using the UNICEF appointed freight forwarders

Manufacturer receives Purchase Orders from UNICEF or PAHO against LTA for AMC92/Self Financing Participants procuring through UNICEF/PAHO as Procurement Agencies

There is NO PLAN to establish a logistic hub to be managed by UNICEF/PAHO



PAHO's International Logistics for Vaccines and Pharmaceuticals



PAHO's High Level Steps

- Purchase Order sent to Supplier & Consignee
- PO Supplier's acknowledgement must be received 5 days after receipt of PO.

1

- Supplier is responsible for the delivery up to airport of destination (**DPU Incoterm 2020**)
- Insurance of **110% Total PO value** by supplier

2

- Supplier sends complete shipping details and documents to PAHO and consignee at least **5 days** prior delivery date
- Some countries may require pre-clearance before shipment.

3

- Shipment execution & arrival
- “WHO’s Guidelines International Packaging and Shipping of Vaccines”, and any related update for COVID-19

4

Supply Forecasts and Proposals validity

- It is important that the supply forecasts made by each Proposer in response to RFP and included in the Proposals are as accurate and realistic as possible.
- It is understood that forecasts for products in development may need further iterations (and/or confirmations) later in time.
- Proposals shall be valid through 31 December 2021.

Clarifications based on Questions received

Clarification

Do Manufacturers with APCs, MOUs, SOI or on-going negotiations with Gavi/COVAX including Independent Product Group, submit a Proposal?

Answer

All manufacturers need to respond to the tender in order to be considered for COVAX supply in 2021, regardless of the stage of discussions with the COVAX Facility (including COVAX bodies such as the IPG) on Advance Purchase Commitments (APCs).

Clarification

How should a manufacturer with an MOU refer to the terms agreed upon with Gavi in the MOU for this tender submission?

Answer

There MUST be alignment with the terms offered to Gavi for an APC, 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 Terms & Conditions or requirements of this RFP.

Clarifications based on Questions received

Clarification

To what extent will the Key Basic Terms be binding for Self-Financing Countries (SFCs) wanting to procure via UNICEF and PAHO?

Answer

The Key Basic Terms will apply to 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 the UNICEF/PAHO LTAs

Clarification

Does COVAX have a minimum supply quantity requirement for each supplier?

Answer

COVAX does not have a minimum supply quantity requirement. 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

Clarification

Has COVAX Facility given price suggestions and guidance for different vaccine candidates? If not, is there a unified proposed price?

Answer

The COVAX Facility does not have a unified proposed price. Drawing on the push and pull investments as well as the pooled demand, COVAX is expecting to achieve the lowest price on the market given its principle of fair and equitable access to COVID-19 vaccines.

Clarifications based on Questions received

Clarification

Labels?
Packaging materials?

Answer

WHO working position on model packaging
<https://www.who.int/teams/regulation-prequalification/eul/covid-19/covid-19-model-packaging>

Clarification

Use of Emergency Use Listing
procedure for vaccines against
COVID-19

Answer

(<https://www.who.int/teams/regulation-prequalification/eul>)

<https://www.who.int/teams/regulation-prequalification/eul/covid-19>

<https://www.who.int/news-room/q-a-detail/coronavirus-disease-use-of-emergency-use-listing-procedure-forvaccines-against-covid-19>

Manufacturers will need to commit to prequalification

Clarifications based on questions received

Clarification

Insurance related to transportation

Answer

UNICEF INCO Terms is FCA

UNICEF cargo insurance will cover from FCA, Named Place until handover to the consignee (usually arrival airport).

PAHO INCO Terms is DPU

Seller to deliver the goods at the disposal of the buyer after they've been unloaded from the arriving means of transport.

The supplier should include insurance for 110% of their DPU value.

Clarifications based on questions received

Clarification

Country Readiness

Answer

Two tools have been released:

- The Vaccine Readiness Assessment Tool (VIRAT)
It provides a roadmap for countries to plan introduction and a framework to self-monitor readiness progress against key milestones
- National Deployment and Vaccination Planning (NDVP) intended to help countries develop their plan for COVID-19 vaccine introduction

Additional guidance documents will be released

Clarification

Questions around minimum order quantities

Answer

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 regulatory approvals

Follow Up Questions

Any questions in respect of the RFP shall be sent by email to
Ms. Dorcas Noertoft at dnoertoft@unicef.org
with copy to
Mr. Andisheh Ghazieh at aghazieh@unicef.org.

All Questions and Responses will be shared with all Proposers

PROPOSALS ARE NOT TO BE SENT TO THE INDIVIDUAL STATED ABOVE – ANY PROPOSALS SENT TO THE ABOVE-NAMED INDIVIDUAL WILL BE DISQUALIFIED.

THANK YOU

