REQUEST FOR PROPOSAL (RFP)

UNITED NATIONS CHILDREN'S FUND (UNICEF)
wishes to receive proposals in support of the COVAX Facility for

COVID-19 Vaccines of assured quality for use against the pandemic caused by SARS-CoV-2 virus

From January to December 2021

RFP-DAN-2020-503209 **12 November 2020**

EMAILED PROPOSALS must be sent to the email supplybid@unicef.org by 16:00 hours (Copenhagen time) on

25 November 2020 for Phase 1
9 December for Phase 2
23 December for Phase 3

Proposals sent to a different email will be INVALIDATED, even if received before the stipulated deadline.

PROPOSALS RECEIVED IN ANY OTHER MANNER WILL BE INVALIDATED

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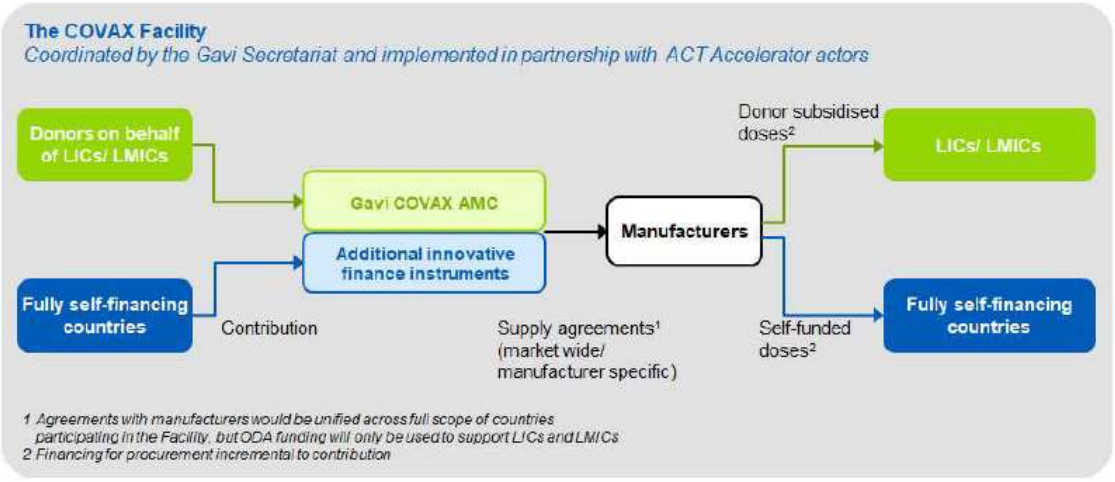
PART I – PURPOSE OF THIS REQUEST FOR PROPOSALS

1. Purpose

The world is experiencing an unprecedented moment with the global coronavirus pandemic. This is driving an unprecedented rapid pursuit for the discovery, development and scale-up of a Covid-19 vaccine. The efforts by vaccine developers and manufacturers across the world, are reducing the time to bring a vaccine to the market from 10-20 years to likely 1-3 years. Even so, in -2021 it is unlikely that volumes will be able to meet global demand and there will be large variances between product characteristics. A ground-breaking global multilateral mechanism – the Access to COVID-19 Tools Accelerator (ACT-A) - was created in April 2020 to accelerate the development, production, and equitable access to Covid-19 diagnostics, therapeutics and vaccines. Co-led by Gavi, the Vaccine Alliance (Gavi), the World Health Organization (WHO) and the Coalition for Epidemic Preparedness Innovations (CEPI), the COVID-19 Vaccine Global Access (COVAX) Facility is the part of ACT-A that has the aim that all economies have fair and equitable access to Covid-19 vaccines.

The COVAX Facility1 is drawing on existing public health infrastructure and Gavi is serving as the COVAX Facility Secretariat. In August, 172 countries expressed interest to be a part of the COVAX Facility. At its Board meeting on July 30th, Gavi was approved to support 92 lower income economies through Gavi's COVAX Advance Market Commitment (AMC)2, which forms part of the COVAX Facility. At the 29-30 September Gavi Board meeting, a cost sharing policy was approved for the 92 AMC economies to promote country ownership, global solidarity and unlock new funding from sources such as development banks3. All other economies will be self-financing their vaccine and making down/upfront payments to help fund the COVAX Facility to engage in advance purchase commitments to scale up and secure production capacity and early production prior to licensure to accelerate access. As of 26 October, in addition to the 92 AMC economies there are 92 participants in the COVAX Facility4, hereafter jointly referred to as COVAX Participants.

[1] https://www.gavi.org/covax-facility
[2] https://www.gavi.org/news/media-room/gavi-launches-innovative-financing-mechanism-access-covid-19-vaccines
[3] https://www.gavi.org/news/media-room/gavi-provide-us-150-million-support-low-and-middle-income-countries-readiness
[4] https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_23-09.pdf



The initial target of COVAX Facility is to deliver at least 2 billion doses of Covid-19 vaccine by the end of 2021. The main strategy to achieve this is to establish access to a diverse portfolio of vaccines, including with push and pull contracts by COVAX partners – CEPI, the Bill & Melinda Gates Foundation (BMGF) and Gavi - and drawing on these contracts as candidate vaccines become qualified for supply to COVAX participants.

UNICEF and the Pan American Health Organization (PAHO) are co-leading procurement efforts on behalf of the COVAX Facility, with PAHO responsible for participating economies in Latin America and the Caribbean. UNICEF and PAHO will be the Procurement Agencies for the 92 COVAX AMC economies. Self-financing economies will have the option to self-procure or procure via UNICEF or PAHO. Throughout this document, when referring to UNICEF in its capacity as procurement agency, reference is implicitly including PAHO, with UNICEF managing the tender from an administrative perspective through to receipt of proposals.

This Request for Proposals (RFP) is issued by UNICEF on behalf of UNICEF5 and PAHO6 in order to secure access in 2021 to Covid-19 vaccines and for the objectives specified in Section 2, below. UNICEF will receive offers on behalf of UNICEF and PAHO, and for the purpose of assessments, all documents, bids, and/or information provided to UNICEF under this RFP will be shared equally with PAHO, whereas all relevant information, subsets, extracts or summaries needed will be shared on a confidential basis with the established advisory groups to the COVAX Facility, the Independent Product Group (IPG), the Procurement Reference Group (PRG) and Gavi; the COVAX Secretariat.

2. Procurement Objective

2.1 The overall objective of the procurement is to accelerate access to sufficient volumes in 2021 of Covid-19 vaccines of assured quality for COVAX participating economies by providing a pooled bid from which:

[5] https://www.unicef.org/what-we-do
[6] https://www.paho.org/en/who-we-are

i) Gavi, as COVAX Facility Secretariat, establishes pull contracts (advance purchase commitments - APCs[7]), including that draw on push contracts (from CEPI and BMGF).
ii) UNICEF and PAHO establishes procurement and supply arrangements.
iii) UNICEF, as COVAX Procurement Coordinator, establishes key basic terms that COVAX self-financing self-procuring economies can reference in their supply arrangements with Proposers.

2.2 In order to meet the overall objective stated above, this procurement aims to achieve the following:

i) **Speed**
Expedite access to Covid-19 vaccines by building on push and pull contracts (established by BMGF, CEPI and Gavi) for the COVAX Participants.

ii) Volumes
The target of the ACT-A is to secure access to at least 2 billion doses by end 2021. To protect against anticipated candidate vaccine failure, the COVAX Facility aims to enter into agreements with manufacturers for 4 billion doses, assuming a 50% success rate of vaccines becoming technically acceptable and produced in sufficient quantities in that timeframe.

iii) Price
Drawing on the financing and de-risking provided by the push and pull contracts, indemnity and liability provisions, and the pooled COVAX volumes, COVAX expects to achieve the lowest price on the market. Manufacturers should provide access to the lowest price during the pandemic phase for all COVAX Participants.

iv) Balanced portfolio
- Which vaccines will be successful will not be known at the time of contracting, therefore the more diverse portfolio of vaccines under contract, the greater likelihood of accessing a successful Covid-19 vaccine.
- To help mitigate risks including dependency on a particular vaccine platform or exporting regulatory authority, pull contracts (APCs) and procurement arrangements will aim to result in a balanced geographically diverse portfolio across multiple vaccine platforms.

2.3 This procurement is guided by the principle of Vaccine Security: the sustained, uninterrupted supply of affordable vaccines of assured quality.

2.4 Informed by the pooled bid made up of Proposals from this RFP, Gavi aims to enter into APCs, based on technical advice from the IPG, PRG and WHO. UNICEF and PAHO will establish individual long-term arrangements (LTAs) coherent and informed by the APCs that will set the framework for subsequent Purchase Orders (POs). LTAs will be aligned to respective terms & conditions of UNICEF and PAHO. POs will be issued for specific vaccine deliveries throughout the period following allocations provided by the WHO Allocation Framework as products meet the Target Product Profile (TPP) and quality assurance guidance by WHO.

[7] In certain instances prior to entering into an APC, Gavi will enter into a Memorandum of Understanding or a Statement of Intent which are non-binding agreements aimed to facilitate APC negotiations in good faith between Gavi and manufacturers, while a number of aspects of the COVAX Facility including final country participation, and funding resources are being finalised

2.5 In addition, Key Basic Terms of the APCs and LTAs will be made available by UNICEF, as the COVAX Procurement Coordinator, to the self-procuring COVAX participating economies that chose to procure their allocated volume (by WHO) from the manufacturer directly. Key basic terms may include pricing, volume, priority for access, unrestricted access, delivery lead-time, regulatory compliance, product profile, and other terms as relevant.

3. COVAX Procurement Coordinator

UNICEF, as the COVAX Procurement Coordinator, has the following key responsibilities:

- Monitor supply and demand based on allocation prioritization decisions and in line with the terms of the APCs;
- Monitor usage / draw down of APCs; and
- Provide support to and alignment between COVAX self-procuring participants on Key Basic Terms and supporting consistency towards manufacturers.

In order to support the above, manufacturers with APCs and LTAs shall provide reporting to the COVAX Procurement Coordinator, as defined in Part III, section 6 of this RFP.

4. Product Description

Proposals are sought for candidate Covid-19 vaccines that aim to meet the WHO Target Product Profile (TPP)[8] for a Covid-19 vaccine with availability in 2021.

Mandatory Technical Requirements are described in Annex D.

5. Long Term Arrangement(s)

5.1. UNICEF and PAHO wish to enter into non-exclusive, time-bound LTAs for the procurement of the vaccines described in section 4 above, as required from time to time during the term of the LTA. UNICEF and PAHO will not be liable for any cost in the event that no purchases are made under any resulting LTA(s).

5.2. The LTAs will be conditional until the candidate vaccine i) meets the WHO TPP, as confirmed by the WHO Prequalification Team ii) receives Emergency Use Listing or pre-qualification by WHO, or on an exceptional basis, licensure or authorization by a Stringent Regulatory Authority (SRA)[9] , as confirmed by WHO. In addition, manufacturers are required to send supplemental information to UNICEF, as indicated in Annex F and Annex G and Part II, section 2.8 below.

5.3. Following approval of the candidate Covid-19 vaccine, as defined in section5.2 above purchases will be made against Purchase Orders to be issued by UNICEF and PAHO in accordance with the terms and conditions of any resulting LTA(s). Actual quantities to be purchased will vary from Purchase Order to Purchase Order.

5.4. Any quantities outlined in this RFP are an estimated forecast of the total requirement for the

[8] https://www.who.int/blueprint/priority-diseases/key-action/WHO_Target_Product_Profiles_for_COVID-19_web.pdf
[9] https://www.who.int/medicines/regulation/sras/en/

duration of the LTA. Any estimates are provided in good faith and will not in any way be deemed to be a commitment regarding any quantity for future purchases.

5.5. The resulting LTA(s) will be valid from signing (estimated December 2020) through December 2021. The duration of the LTA may be extended for an additional period of twelve (12) months at the discretion of UNICEF and PAHO, and upon mutual agreement with each awarded manufacturer.

6. Demand Forecast and Allocation Framework

6.1 The target of the ACT-A is to deliver 2 billion doses by end 2021, which may require 4 billion doses on contract, assuming a 50% success rate.
The COVAX Facility is aiming to deliver 2 billion doses by the end of 2021 to satisfy initial global demand for Covid-19 vaccines under the COVAX Facility. This will be preliminarily split as follows:

- 92 AMC economies (estimated 950 million doses, with potential additional doses subject to funding and financing initiatives)
- At least 92 Self-Financing economies (estimated range from 550-950 million doses)
- Humanitarian Buffer (100 million doses)

To support the participation of AMC economies in the Facility, the COVAX AMC has fundraised almost $1.8 billion of its initial seed funding target of $2 billion by end-2020.

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

6.2 The COVAX Facility is basing its 2021 demand volumes on the WHO Allocation Framework[10] as follows:

i) starting by delivering all COVAX Participants 3% of their population (in doses)
ii) then by delivering all COVAX Participants up to an additional 17%, for a total of up to 20%, of their population, depending on the volume committed by each self-financing country (in doses)
iii) then, once all COVAX Participants have received 20% of their population, additional volumes will be delivered to self-financing economies, per their commitment, anticipated for an additional 30% up to 50% of the population. This may also apply to AMC economies deciding to self-finance.

6.3 Purchases of allocated doses for the AMC countries will be done by UNICEF and PAHO. Self-financing countries may purchase their allocated doses through UNICEF or PAHO or directly with manufacturers per the Key Basic Terms.

Additionally, allocations of the humanitarian buffer could be purchased by UN agencies, NGOs or other entities per the Key Basic Terms.

[10] https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility

TA list of COVAX Participants by procurement channel is included in Annex F.

7. RFP Documents

7.1 This RFP is comprised of the following:

- This document, including its Annexes
- UNICEF General Terms and Conditions of Contract (Goods)
- PAHO General Terms and Conditions
- PAHO Packaging, Labelling, and Shipping
- Answer Sheets

PART II – PROPOSAL SUBMISSION PROCESS

1. Proposal Submission Schedule

1.1 Phased receipt of bids and awards

Given the objectives of the procurement and the unprecedented development of the Covid-19 vaccine market, there will be a phasing of bids and awards, so as to maximize the number of bids received to provide visibility on the pipeline while moving quickly with manufacturers that already have APCs in place and those that plan to have Covid-19 vaccine available in 2021.

The phases will be applied as follows:

- Phase 1 25 November: Manufacturers **with Gavi APC, MOUs, and SOIs in place** will be invited to submit their bids first. This deadline would be referred to as Phase 1.
- Phase 2 9 December: 2 weeks later, manufacturers that plan to have **vaccine availability during the first half of 2021** need to submit their bid by the Phase 2 deadline.
- Phase 3. 23 December: 4 weeks later, manufacturers that plan to have **vaccine availability from the second half of 2021** need to submit their bid by the Phase 3 deadline.

In case manufacturers are able to provide a proposal including the required information under this RFP during an earlier phase than what would be determined by the anticipated timing of vaccine availability, such a bid may be accepted for review, however, the Procurement Agencies reserve the right to assess the bids in a manner that best supports the overall objectives of the tender. While it is understood that all information required under this tender may not be available at the time of submission of the proposal, manufacturers are encouraged to respond to the tender, including an indicative timeline for when additional information would be expected to be available for submission.

1.2 Acknowledgement of receipt of RFP

Proposers are requested to inform UNICEF as soon as possible by e-mail to the Senior Contract Manager Ms. Dorcas Noertoft at dnoertoft@unicef.org with copy to Andisheh Ghazieh at aghazieh@unicef.org that they have received this RFP.

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

1.3 Questions from Proposers

Proposers are required to submit any questions in respect of this RFP by email to the Senior Contracts Manager, Ms. Dorcas Noertoft at dnoertoft@unicef.org with copy to Andisheh Ghazieh at aghazieh@unicef.org. The deadline for receipt of any questions is 7 days before the Proposal Submission Deadline for Phase 1 and 10 days before the Proposal Submission Deadline (by Phase 2 and 3).

Proposers are required to submit questions in writing and to keep all questions as clear and concise as possible.

UNICEF will compile the questions received. UNICEF may, at its discretion, at once copy any anonymized question and its reply to all other invited Proposers and/or post these on the UNICEF website and/or respond to the question at **a pre-bid conference on 18 November 2020**. After any such bid conference, a Questions and Answers document may be prepared and posted on the United Nations Global Market Place www.ungm.org. Information provided orally will not be considered in any way as a change in the RFP.

1.4 Errors or Ambiguities in the RFP. Each Bidder acknowledges that UNICEF, its directors, employees and agents make no representations or warranties (express or implied) as to the accuracy or completeness of this RFP or any other information provided to the Proposers. Proposers are expected to immediately notify UNICEF in writing of any ambiguities, errors, omissions, discrepancies, inconsistencies or other faults in any part of the RFP, providing full details. Proposers will not benefit from such ambiguities, errors, omissions, discrepancies, inconsistencies or other faults.

1.5 Amendments to RFP. At any time prior to the Submission Deadline, UNICEF may, for any reason, whether at its own initiative or in response to a clarification requested by a prospective Bidder, modify the RFP by amendment. If the RFP was available publicly online, amendments will also be posted publicly online. Further, all prospective Proposers that have received the RFP directly from UNICEF will be notified in writing of all amendments to the RFP. In order to afford prospective Proposers reasonable time in which to take the amendment into account in preparing their Proposals, UNICEF may, at its sole discretion, extend the Submission Deadline of a given Phase. Should a Bidder already have submitted its bid prior to the amendment in accordance with the Phased approach, UNICEF will consult with the Proposers to understand any impact that the amendment may have on the submitted bid.

1.6 Submission Deadlines. The deadlines for submission of Proposals (by Phase) are as indicated on the front page of this document.

1.7 Proposal opening. Due to the nature of this RFP, there will be no public opening of Proposals. Proposals will be received and recorded by UNICEF's Bid Section within each Phase and handed over to the evaluation teams on a running basis.

2. Proposal and Answering Sheets

2.1 Proposers are invited to develop a proposal (the "Proposal") that is responsive to the requirements listed in this RFP and provides a comprehensive explanation of the offer being made. The Proposal must include a signed PROPOSAL AND COMMERCIAL TERMS SHEET. ANSWERING SHEETS have been provided to assist in the organization of the Proposal.

2.2 Proposers are expected to fully utilize the opportunity of an RFP to include all relevant information in the Proposal including procurement and contracting methodologies which allows the Bidder to best contribute to achieving the procurement objectives.

2.3 The Bidder must provide sufficient information in the Proposal to address each area of evaluation to ensure that a fair assessment of the Proposal can be conducted.

2.4 It is important that the supply forecasts made by each Bidder to UNICEF and included in the Proposals are as accurate and realistic as possible. Inaccurate and unrealistic forecasts will jeopardize the Procurers' ability to meet the objectives of the tender and may have a negative impact on the ability to respond to Covid-19 pandemic or other requirements.

For the avoidance of doubt, UNICEF is encouraging Proposals from Proposers with products in development and acknowledges that supply forecasts for such products may need further iterations (and/or confirmations) later in time.

2.5 Only the forms and answering sheets provided in Part VI should be used to present the various aspects of the Proposal. Supplementary information can be provided on each of the answering sheets:

- PROPOSAL AND COMMERCIAL TERMS SHEET
- TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET
- PRODUCT PROFILE SHEET
- QUALITATIVE PROPOSAL SHEET
- QUANTITATIVE PROPOSAL SHEET

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, product identification and section.

2.6 The Proposal should, at a minimum:

- Include the statement of acceptance of the RFP and certify the date of validity of the Proposal. Provide explanations to any requirements or request for exceptions or clarification to the terms and conditions of this RFP (PROPOSAL AND COMMERICAL TERMS SHEET).

- Contain all the requested information on mandatory requirements for offered products (TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET). Guidance on completing this answering is included with the answering sheet.

- Provide details related to the product(s) offered and the extent to which they meet, or plan to meet, the TPP (PRODUCT PROFILE SHEET). Guidance on completing this answering is included with the answering sheet.

- Contain qualitative information on experience, volumes proposed, account management, etc (QUALITATIVE PROPOSAL SHEET). Guidance on completing this answering is included with the answering sheet.

- Define the proposed vaccine (QUANTITATIVE PROPOSAL SHEET) to the extent possible at this stage of development, including the, quantities offered, projected availability and price in accordance with the technical requirements. Proposers must declare in their Quantitative Proposals if there will be any minimum purchase order delivery quantity(ies) for the vaccine(s) detailed in the schedule to this RFP and provide explanations to any requirements impacting price or volumes.

2.7 Proposers are invited to offer alternative products and presentations in response to this RFP.

2.8 Additional information to be submitted in order to activate an LTA:

LTAs are conditional until a candidate Covid-19 vaccine meets the requirements stated in Part I, section 5.2 above. In order to start procurement and delivery under an LTA, the manufacturer shall submit additional information to UNICEF and/or PAHO as defined in Annex F and Annex G.

3. Language

3.1 The Proposal prepared by the Bidder and all correspondence and documents relating to the Proposal exchanged by the Bidder and UNICEF, will be written in English. Supporting documents and printed literature provided by the Bidder should also be provided in English.

4. Validity of Proposals; Modification and Clarifications; Withdrawal

4.1 Validity Period. Proposers must indicate the validity period of their Proposal. Proposals should be valid for a period through to December 2021. UNICEF may request the validity period to be extended. A Proposal valid for a shorter period of time may not be further considered. UNICEF may request the Bidder to extend the validity period. The Proposal of Proposers who decline to extend the validity of their Proposal may become disqualified as no longer valid.

4.2 Corrections and Other Changes to the Proposal. All corrections or other changes to a Proposal must be received by UNICEF prior to the Submission Deadline (by Phase). The Bidder must clearly indicate that the revised Proposal is a modification and supersedes the earlier version of their Proposal and clearly state and explain the changes from the original Proposal. Erasures or other corrections in the Proposal must be explained and the signature of the Bidder shown alongside.

4.3 Withdrawal of Proposal. A Proposal may be withdrawn by the Bidder on e-mailed, request received by UNICEF's Bid Section from the Bidder prior to Submission Deadline (by Phase). Negligence on the part of the Bidder confers no right for the withdrawal of the Proposal after it has been opened.

5. Eligibility; Bidder Information

5.1 Bidder. The term "Bidder" refers to those manufacturers that submit a Proposal pursuant to this RFP and "Proposal" refers to all the documents provided by the Bidder in its response to this RFP. A Bidder will only be eligible for consideration if it complies with the representations set out in Part V of this **RFP-DAN-2020-503209**, including the representations on ethical standards and conflicts of interest.

5.2 Registration as a UNICEF/PAHO Supplier. UNICEF and PAHO are part of the United Nations Global Marketplace (UNGM). All Proposers must be registered through the UNGM prior to submitting a Proposal in response to this RFP. This must be done via the UNGM website at http://www.ungm.org. UNICEF will not accept Proposals from Proposers that are not registered

in this way. Proposers must include their UNGM registration number in the *Technical and Financial Mandatory Requirements Answering Sheet*.

Simultaneously with application to UNGM, Proposers must submit their most recent Audited Financial Statement and Quality System Certificate to the UNICEF Quality Assurance Supplier Evaluation Unit, UNICEF Supply Division, Oceanvej 10-12, 2150, Copenhagen, Denmark. This information will be used by UNICEF for evaluation and approval purposes before making an award. It is in the interest of the Proposers to provide information as complete as possible, as awards will only be made to Proposers which meet this RFP's supplier selection criteria (see the *TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS ANSWERING SHEET*).

UNICEF reserves the right at any time to require updated information from Proposers that have previously registered with UNGM.

5.3 Joint Venture, Consortium or Association.

(a) If the Bidder is a group of legal entities that will form or have formed a joint venture, consortium or association at the time of the submission of the Proposal, each such legal entity will confirm in their joint Proposal that:

(i) they have designated one party to act as a lead entity, duly vested with authority to legally bind the members of the joint venture jointly and severally, and this will be evidenced by a Joint Venture Agreement among the legal entities, which will be submitted along with the Proposal; and

(ii) if they are awarded the LTA, the designated lead entity, who will be acting for and on behalf of all the member entities comprising the joint venture, will enter into the LTA with UNICEF or PAHO.

(b) After the Proposal has been submitted to UNICEF, the lead entity identified to represent the joint venture will not be altered without the prior written consent of UNICEF and/or PAHO, depending on signatories to the LTA.

(c) If a joint venture's Proposal is selected for award, UNICEF or PAHO will award the LTA to the joint venture, in the name of its designated lead entity. The lead entity will sign the LTA for and on behalf of all other member entities.

5.4 Proposals from Government Organizations. The eligibility of Proposers that are wholly or partly owned by the Government may be subject to UNICEF's further evaluation and review of various factors such as being registered as an independent entity, the extent of Government ownership/share, receipt of subsidies, mandate, access to information in relation to this RFP, and other factors.

6. Preparation of Proposal

6.1 It is the responsibility of Proposers to inform themselves in preparing their Proposal. In this regard, the Proposers must:

- Examine all terms, requirements and formal submission instructions included in the RFP (including the Instruction to Proposers section);
- Review the RFP to ensure that they have a complete copy of all documents;
- Examine all of the Mandatory Technical Requirements and Other Mandatory Requirements;
- Review the UNICEF General Terms and Conditions of Contract (Goods) for the supply of Goods attached to this RFP as Annex A (and also publicly available on the UNICEF Supply website: http://www.unicef.org/supply/index_procurement_policies.html;
- Review the PAHO Terms and Conditions attached to this RFP as Annex B
- Review the UNICEF policies publicly available on the UNICEF Supply website: http://www.unicef.org/supply/index_procurement_policies.html. In particular, Proposers should familiarize themselves with the obligations imposed on suppliers and their personnel and sub-contractors under the UNICEF Policy Prohibiting and Combatting Fraud and Corruption and the UNICEF Policy on Conduct Promoting the Protection and Safeguarding of Children;
- Fully inform and satisfy themselves as to requirements of any relevant authorities and laws that apply, or may in the future apply, to the supply of the goods.

6.2 Failure to meet all requirements and instructions in the RFP or to provide all requested information will be at the Bidder's own risk and may result in rejection of the Bidder's Proposal.

6.3 The Proposal must be organized to follow the format of this RFP. Each Bidder must respond to the stated requests or requirements and indicate that the Bidder understands and confirms acceptance of the stated requirements in this RFP. The Bidder should identify any substantive assumption made in preparing its Proposal. The deferral of a response to a question or issue to any contract negotiation stage (if any) is not acceptable. Any item not specifically addressed in the Proposal will be deemed as accepted by the Bidder. Incomplete or inadequate responses, lack of response or misrepresentation in responding to any questions will affect the evaluation of the Proposal.

6.4 Proposals must be clearly marked with the RFP number. Failure to do so may result in the Proposal being invalidated.

6.5 Answer sheets must be completed in full by the Bidder.

6.6 The completed and signed Proposal Form must be submitted together with the Proposal. The Bid Form must be signed by a duly authorized representative of the Organization/Company.

EMAILED PROPOSALS should be sent to: **supplybid@unicef.org clearly indicating the Phase of the procurement.** Proposals sent to any other email, will be invalidated.

EMAILED PROPOSALS instructions:

All e-mail communication in relation to the Proposal must clearly indicate the reference RFP number and the company name in the "Subject" line of the e-mail.

The Proposal Form is sent as a scanned copy of an original signed form in PDF format.

Ensure the "acknowledge receipt" of your Proposal is received after the e-mail submission. The subject line of an "acknowledge receipt" will show "UNICEF Supply Division - Bid

confirmation. Ref: "Name of Company X".

Attachments must be maximum ten (10) megabytes per email and submitted in PDF format. Larger attachments and attachments other than PDF format will not be accepted.

No other recipient should be "cc" or "bcc" in the email submission.

6.7 Each Bidder acknowledges that its participation in any stage of the solicitation process for this RFP is at its own risk and cost. The Bidder is responsible for, and UNICEF is not responsible for, the costs of preparing its Proposal or response to this RFP, submission of any samples, attendance at any bid conference, site visit, meetings or oral presentations, regardless of the conduct or outcome of the solicitation process.

7. Proposal Documents; Confidentiality

7.1 This RFP, together with all Proposal documents provided by the Bidder in response to this RFP, will be considered the property of UNICEF and will not be returned to the Proposers.

7.2 Information contained in the Proposal documents, or otherwise provided by the Bidder in connection with the Proposal, will be treated as confidential unless otherwise noted by the Proposer, except that:

- UNICEF will receive offers on behalf of UNICEF and PAHO, and for the purpose of assessments, all documents, bids, and/or information provided to UNICEF under this RFP will be shared equally with PAHO, whereas all relevant information, subsets, extracts or summaries needed will be shared on a confidential basis with the established advisory groups to the COVAX Facility, the Independent Product Group (IPG), the Procurement Reference Group (PRG) and Gavi; the COVAX Secretariat. UNICEF, PAHO and Gavi will make details of each award public as described in Section 2.5 of Part III below.

8. Multiple Proposals and Proposals from Related Organizations; Joint Ventures

8.1 Multiple Proposals not Permitted. If the Bidder is a group of legal entities that will form or have formed a joint venture, consortium or association at the time of the submission of the Proposal then neither the lead entity nor the member entities of the joint venture may submit another Proposal, either in its own capacity or as a lead entity or a member entity for another joint venture submitting another Proposal.

PART III – EVALUATION OF PROPOSALS; AWARDS

1. Use and Evaluation of PROPOSALS

1.1 General. The merits of each Proposal will be evaluated to assess its ability to support the Procurement Objective and intended outcomes of this RFP as set out in Part I.

1.2 Compilation of Proposals. UNICEF, with input from WHO, will compile the Bids after each Phase. The compilation will include a screening by UNICEF and PAHO for compliance to mandatory terms, sufficiency of information and a technical assessment by WHO.

1.3 Evaluation. Evaluation of Compliance with Mandatory Requirements. Each Proposal will be evaluated for compliance with the mandatory requirements of this RFP. Proposals deemed not to meet all of the mandatory requirements will be considered non-compliant and rejected at this stage without further consideration. Failure to comply with any of the terms and conditions contained in this RFP, including, but not limited to, failure to provide all required information, may result in a Proposal being disqualified from further consideration.

UNICEF, with input from PAHO, will provide the COVAX Secretariat with a compilation of Commercial, Technical and Quality information provided in each Phase.

COVAX Secretariat will share the Technical and Quality compilations with the IPG to inform the advice they provide that will inform Gavi's decision on which products should be considered for an APC. For manufacturers already having an APC in place the information will be used to assess progress, and the Bid will be assessed for establishment of LTAs.

COVAX Secretariat will share the advice from the IPG and the Commercial compilations with the PRG to inform the advice the PRG provides Gavi with respect to which manufacturers should be considered for an APC as well as the amount and terms.

- APC will be determined by, among others, the following criteria:
    - Contribution to meeting the procurement objective as described Part I
    - Products meeting the technical specifications
    - Timing of product availability through 2021
    - Price and delivery terms
- APCs will include volumes (some of which may be guaranteed), timing of volumes, pricing and other key basic terms for other Self-Financing Participants.

1.4 UNICEF and PAHO will use the Proposal information for negotiating and awarding LTAs to support the Procurement objectives. The resulting LTAs will be time-bound, good faith, non-binding and will contain the information and terms needed for a standard procurement and supply agreement to facilitate purchase and deliveries to be made once the product has been authorized by WHO.

As noted in Part II section 2.8, supplementary information needs to be provided to UNICEF and PAHO as it becomes available and prior to any Purchase Orders being issued.

1.5 Clarifications Requested by UNICEF. During the evaluation of Proposals, UNICEF may, in its sole discretion, seek clarifications from any Bidder in order for UNICEF to fully understand the Bidder's Proposal and assist in the examination, evaluation and comparison of Proposals. UNICEF may seek such clarifications through written communications or may request an interview with any Bidder.

1.6 Interpretation of Errors. UNICEF may seek clarification of any errors identified by it in a Proposal. Absent satisfactory clarification, such errors will be interpreted by UNICEF in its sole discretion. In the case of errors in the extension price that are not clarified to UNICEF's satisfaction, unit price will govern.

1.7 References. UNICEF reserves the right to contact any or all references supplied by the Bidder(s) and to seek references from other sources as UNICEF deems appropriate.

2. Award

2.1 Objectives of this RFP. Upon evaluation of all Proposals, taking into consideration the actual market situation for each vaccine, awards will be made to Proposers in accordance with the objectives of this RFP.

2.2 Negotiation. The Procurers reserve the right to negotiate with the Bidder(s) in support of achieving the procurement objectives of the RFP.

2.3 Award Notification. UNICEF and PAHO will each notify the Bidder(s) that has/have been awarded an LTA(s) resulting from this solicitation process. UNICEF will also notify the other Proposers of the outcome of this solicitation process after the Phase for which they have submitted a Proposal has been concluded.

2.4 Award Debrief. Bidder(s) that has/have been awarded an LTA will be invited to a formal debriefing and award initiation meeting. Bidder(s) that do not receive an award may request a formal debriefing. During a debriefing, the strengths and weaknesses of the Proposal may be discussed. Details concerning the evaluation results of other Proposals will not be divulged, except in accordance with Section 2.7 below.

2.5 Award Publication. 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.

2.6 Bidder Acknowledgement. The Bidder acknowledges and accepts the decision of the Procurers as to whether its Proposal meets the minimum requirements in this RFP and the Procurers' and evaluation of the Proposal.

3. The LTAs and UNICEF's General Terms and Conditions Of Contract Goods

3.1 UNICEF's General Terms and Conditions of Contract (Goods) which are attached at Annex A to this RFP will apply to any LTAs signed by UNICEF and linked Purchase Orders awarded in connection with the LTA.

3.2 By signing the UNICEF Commercial Terms Sheet without requested exceptions, each Bidder is deemed to have confirmed its acceptance of the UNICEF General Terms and Conditions of Goods.

4. The LTAs and PAHO's General Terms and Conditions

4.1 PAHO's General Terms and Conditions which are attached at Annex B to this RFP will apply to any LTAs signed by PAHO and linked Purchase Orders awarded in connection with the LTA.

4.2 By signing the PAHO Commercial Terms Sheet without requested exceptions, each Bidder is deemed to have confirmed its acceptance of the PAHO General Terms and Conditions.

5. Rights of UNICEF

5.1 UNICEF reserve the following rights which will be executed in consultation with PAHO:

(a) to accept any Proposal, in whole or in part; to reject any or all Proposals; or to cancel this solicitation process in its entirety and re-tender if it so chooses;

(b) to request additional information from the Bidder and to verify any information contained in Bidder's response (and the Bidder will provide UNICEF with its reasonable cooperation with such verification);

(c) to invalidate any Proposal received from a Bidder that, in UNICEF's sole opinion has previously failed to perform satisfactorily or complete contracts or Purchase Orders on time, or UNICEF believes is not in a position to perform the LTA provided however that UNICEF's failure to invalidate a Proposal does not constitute an acceptance that the Proposer is in a position to perform any LTA issued as a result of this RFP or any Purchase Order issued under such LTA;

(d) to invalidate any Proposal that, in UNICEF's sole opinion, fails to meet the requirements and instructions stated in this RFP;

(e) to suspend negotiations or withdraw an award to a Bidder at any time up until an LTA has been signed with such Bidder. UNICEF is not required to provide any justification but will give notice prior to any such suspension of negotiations or withdrawal of award.

(f) to retender should the result of the tender be deemed nonresponsive by UNICEF.

5.2 UNICEF is not liable to any Bidder for any costs, expense or loss incurred or suffered by such Bidder in connection with this RFP or solicitation process, including, but not limited to, any costs, expense or loss incurred as result of UNICEF exercising any of its rights in paragraph 5.1

above.

5.3 Each Bidder will permit UNICEF, either itself or through a designated representative entity, to have access to the facilities where the products offered are manufactured and stored, at all reasonable times during the tender period to inspect the manufacturing site and processes for the production, quality control, quality assurance and packing of the products as well as storage facility. The Bidder will provide reasonable assistance to the representatives for such appraisal, including copies of any documentation (including, but not limited to, test results or quality control reports) as may be necessary. The inspection may be carried out in conjunction with the appropriate national authority. Failure to do so may result in the rejection of the Proposal.

PART IV – OTHER MANDATORY REQUIREMENTS

1. Prices and Discounts

Except as otherwise stated in this Section, all pricing information must be included in the Quantitative Proposal Sheet.

1.1 Pricing based on Delivery Term. Proposers are requested to provide unit pricing in accordance with the offered delivery terms (INCOTERMS 2020.

1.2 Currency. The currency of the proposal shall be either 1) US Dollars or 2) US Dollars and EURO. Proposers wishing to offer in EURO are requested to offer one price in US Dollars and one price in EURO, leaving it to UNICEF's sole discretion to determine which price to accept and consider for award. For evaluation purposes, the EURO price will be converted to US Dollars using the United Nations currency exchange rate on the deadline date for receipt of proposals.

1.3 Inclusive Pricing. Pricing should include the cost of packaging and packing the Goods and all temperature monitoring devices in accordance with the packaging and packing requirements set out in the Mandatory Technical Requirements. Proposers are requested to specify the price implications of temperature monitoring devices in the *Packing Details Answering Sheet*. Unit pricing must include the price of VVM if offered.

1.4 Maximum Pricing. 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.

1.5 Price - Most Favoured Customer. The Proposer confirms that the prices with respect to the Goods specified in the Proposal are the most favorable prices available to any customer of the Proposer (or any of the Proposer's affiliates). If the Proposer offers to sell the same Goods under similar circumstances at a price lower than the price effective under the LTA, the Proposer will offer the same price to UNICEF and/or PAHO for the remaining validity period of the LTA.

1.6 Taxes. Article II, Section 7, of the Convention on the Privileges and Immunities provides, inter alia, that the United Nations, including UNICEF and PAHO as a subsidiary organ, is exempt from all direct taxes, except charges for public utility services, and is exempt from customs restrictions, duties, and charges of a similar nature in respect of articles imported or exported for its official use. All prices quoted in the Proposal must be net of any direct taxes and any other taxes and duties, unless otherwise specified in this RFP.

1.7 Pricing and Payments Proposers are requested to advise as to:

(a) Early payment discounts, i.e. payment within a specified period of time faster than UNICEF's standard payment term of 30 days net;

(b) Any other unconditional discounts.

Any discount offered in the successful Proposal will be reflected in the awarded LTA and will be applied in the subsequent Purchase Orders.

Volume guarantees or other financial commitments in a Gavi APC will be reduced by payments made for Purchase Orders by any COVAX Participant (including self-procuring economies) accordingly.

Purchase Order Payment Terms. Unless otherwise agreed in the APC and reflected in the LTA, invoices may be issued to UNICEF and PAHO respectively only after the delivery terms of the Purchase Order to a specific country (as issued in accordance with the provisions of the LTAs) have been fulfilled. The standard terms of payment are net 30 days, after receipt of invoice and required supporting documentation. Payment will be affected by bank transfer in the currency of the Purchase Order. The per dose cost of the vaccine invoiced should be net of any recoverable down payment made by COVAX in accordance with the terms of the APC.

2. Delivery Terms and Delivery Lead Time; Liquidated Damages

Except as otherwise stated in this Section, all information required in this Section must be included in the Quantitative Proposal Sheet.

2.1 The LTAs requires that the Supplier comply with the applicable INCOTERM and all other delivery terms and instructions stated in the LTA and the relevant Purchase Order. With respect to the definition of "INCOTERMS" in the UNICEF General Terms and Conditions of Contract (Goods), the applicable version of the "INCOTERMS" will be the most-recently issued version of the INCOTERMS at the start date of the LTA; provided however that if a new version of the INCOTERMS is issued after the effective date of the LTA, the Parties will in good faith consult with each other on the implications for the LTA with a view to adopting such new version.

2.2 The Supplier will be expected to comply with the maximum Purchase Order delivery lead-time specified in the LTA. Proposers should therefore indicate the realistic lead-time for delivery for each vaccine offered (subject to quantities). "Delivery lead-time" is the period from the date of receipt of a Purchase Order by the Supplier to the date of delivery of the Goods in accordance with the applicable delivery term and instructions specified in the relevant Purchase Order (as issued in accordance with the provisions of the LTA) and includes the period for packing the products, delivery in accordance with the specified delivery term and provision of all documentation required in connection with such delivery. UNICEF will monitor and measure the performance of the Supplier, including by measuring performance against the lead-time indicated in its Proposal and reflected in the LTA.

2.3 The Supplier's obligations in respect of delay in delivery of Goods, including (but not limited to) obligations to notify UNICEF or PAHO respectively of delay in delivery of Goods, as well as the consequences of delay. UNICEF's rights and remedies in respect of any such delay, are governed by the UNICEF General Terms and Conditions of Contract (Goods). PAHO's rights and remedies in respect of any such delay, are governed by the PAHO General Terms and Conditions.

2.4 The LTA also specifies that, without prejudice to any of the other rights and remedies of UNICEF or PAHO, if the Supplier fails to deliver the Goods under any Purchase Order in accordance with the stated time for delivery, or if UNICEF or PAHO exercises its right to reject Goods that do not conform to the requirements in the LTA and the relevant Purchase Order, UNICEF or PAHO

may claim liquidated damages from the Supplier and, at UNICEF's and PAHO's option respectively, the Supplier will pay such liquidated damages to UNICEF or PAHO, or UNICEF or PAHO will deduct such liquidated damages from the Supplier's invoice(s). Such liquidated damages will be calculated as follows: one half of one per cent (0.5%) of the price of such Goods for each day of delay, until delivery of conforming Goods, up to a maximum of ten per cent (10%) of the value of the relevant Purchase Order. The payment or deduction of such liquidated damages will not relieve the Supplier from any of its other obligations or liabilities pursuant to the LTA and the relevant Purchase Order.

3. Pre-Delivery Inspection

3.1 In the exceptional situation where the requirements of a country of destination specify pre-delivery inspection, then UNICEF or PAHO may stipulate in a Purchase Order that the Goods to be supplied under that Purchase Order (as the case may be), are subject to pre-delivery inspection and the following provisions will apply:

(a) Pre-delivery inspection will be conducted by an independent inspection agency selected by UNICEF, PAHO, or the relevant Consignee. The Supplier will not be responsible for the costs of such pre-delivery inspection.

(b) At UNICEF's or PAHO's request, the Supplier will provide its reasonable cooperation to UNICEF or PAHO and its designated inspection agency, at no additional cost to UNICEF or PAHO.

(c) The Supplier will advise UNICEF or PAHO of the location of the manufacturing facility/facilities. UNICEF or PAHO will advise the Supplier of the name of the designated inspection agency.

(d) Notice of the readiness of each consignment of Goods, in the form attached to the Purchase Order, must be provided by the Supplier to UNICEF or PAHO as soon as possible and at the latest 24 hours after Purchase Order placement.

(e) UNICEF or PAHO will notify the Supplier promptly of its decision whether or not to release the Goods for shipment. If UNICEF or PAHO notifies the Supplier that the Goods are non-conforming, then Article 2.6 of the UNICEF General Terms and Conditions of Contract (Goods) or Article 5.7 of the PAHO Terms and Conditions will apply.

3.2 The Supplier acknowledges that any inspection of the Goods by UNICEF, PAHO, or its designated inspection agents does not constitute a determination whether the specifications for the Goods (including Mandatory Technical Requirements) have been met. The Supplier will be required to comply with its warranty and other contractual obligations whether or not UNICEF or PAHO carries out such pre-delivery inspection of the Goods.

3.3 The pre-delivery inspection of the Goods undertaken by UNICEF, PAHO, or its designated inspection agents will not substitute for the inspection of the Goods upon delivery to Consignee.

4. Inspection of Facilities

4.1 Under the LTA, the Supplier will be expected to permit UNICEF, PAHO and WHO, or their

representatives as may be designated under notice to the Supplier, to have access to its manufacturing and warehouse facilities at all reasonable times to assess (or periodically reassess) the production and capacity, testing, packaging and storage of the Goods, and will provide reasonable assistance for such assessment including the provision of copies of manufacturing protocols, lot production records, test results or quality control reports.

5. **Monthly Delivery Reporting and Planning**

5.1 Under the LTA, the Supplier will be required to provide UNICEF and PAHO respectively with a monthly delivery report, listing the following for each vaccine presentation:

- The total quantities forecasted for delivery against Purchase Orders
- Any additional relevant information the Parties agree to include

6. Reporting to the COVAX Procurement Coordinator

6.1 Under the APC and LTA with UNICEF, the Supplier will be required to provide regular reporting to UNICEF, as the COVAX Procurement Coordinator, including:

- Monthly updates of progress towards meeting clinical and regulatory milestones, production progress and supply availability:
  - total quantity in stock with NRA release for COVAX;
  - total quantity in stock pending NRA release for COVAX;
  - the total quantities in production and status for COVAX;
- Weekly release plans for supply availability for pick up (rolling 3-month basis) to support the Allocation Framework

- Actual deliveries in doses (to all COVAX Participants) for monitoring APA utilization
- Actual invoice amounts (to all COVAX Participants) for monitoring relevant APA financial obligations

7. National Regulatory Licensure Requirements by the Importing Governments

Under the LTA, the Supplier is expected to continuously update UNICEF or PAHO respectively of any changes in status of any existing registrations (including, but not limited to, any decision not to renew or to withdraw) and any new registrations in any countries.

In order to help efficient registration in country, the manufacturers may be requested to provide a standard set of documentation to facilitate the process.

8. Warranty

7.1 Warranty. Under the LTA, the Supplier is required to warrant that the Goods (including packaging) offered by it will meet each of the following minimum criteria:

(a) The Goods conform to the quality, quantity and specifications for the Goods stated in the LTA and linked Purchase Order (including, in the case of perishable or pharmaceutical products, the shelf life specified in the LTA or agreed to in the linked Purchase Order);

(b) The Goods conform in all respects to the technical documentation provided by the Supplier in respect of such Goods and, if samples were provided to UNICEF or PAHO prior to entering into the LTA, the Goods are equal and comparable in all respects to such samples;

(c) The Goods are new and factory-packed;

(d) The Goods are fit for the purposes for which such Goods are ordinarily used and any purposes expressly made known to the Supplier by UNICEF or PAHO;

(e) The Goods are free from defects in design, manufacture, workmanship and materials;

(f) The Goods are free from all liens, encumbrances or other third-party claims;

(g) The Goods are contained or packaged in accordance with the standards of export packaging for the type and quantities of the Goods specified in the LTA and linked Purchase Order, and for the modes of transport of the Goods specified in the LTA and linked Purchase Order (including but not limited to, in a manner adequate to protect them in such modes of transport), and marked in a proper manner in accordance with the instructions stipulated in the LTA and linked Purchase Order and applicable law.

7.2 Warranty Period. Under the LTA, the period of validity of the warranty will be no less than the shelf life of the Goods.

7.3 Assignment of Manufacturer Warranties. If the Supplier is not the original manufacturer of the Goods or any part of the Goods, under the LTA, the Supplier will be expected to assign to UNICEF or PAHO (or, at UNICEF's or PAHO's instructions, the Government or other entity that receives the Goods) all manufacturers' warranties in addition to any other warranties specified in the LTA and linked Purchase Order.

7.4 Extension of Warranty to Partners. The Bidder should note that, under the LTA, the warranties are expected to be made to UNICEF or PAHO and to extend to (a) each entity that makes a direct financial contribution to UNICEF or PAHO for the purchase of Goods; and (b) each Government or other entity that receives the Goods.

8. Performance Monitoring

8.1 As part of UNICEF's continuous strive to improve our ability to provide products of the appropriate standards to UNICEF programs and partners and in a timely manner, monitoring of Suppliers' performance will continue to be strengthened.

8.2 The UNICEF General Terms and Conditions of Contract (Goods) specify that UNICEF will monitor the Supplier's performance under the LTAs and linked Purchase Orders. The Supplier is required to provide its full cooperation with such performance monitoring, at no additional cost or expense to UNICEF, and provide relevant information as reasonably requested by UNICEF.

8.3 UNICEF has identified generic criteria that will be applied for evaluating and monitoring Supplier performance against their contractual obligations as an outcome of this procurement

process.

Key Categories	Performance Metrics	Performance Baseline
Time	Timeliness of Purchase Order Acknowledgement	
	Timeliness of Notification of Goods Readiness	
	Timeliness of Delivery	

PART V – BIDDER REPRESENTATIONS

1. General Representations

By submitting its Proposal in response to this RFP, the Bidder confirms to UNICEF as at the Submission Deadline and throughout the validity period of the Proposal:

1.1 The Bidder has (a) the full authority and power to submit the Proposal and to enter into any resulting LTA and linked Purchase Order(s), and (b) all rights, licenses, authority and resources necessary, as applicable, to develop, source, manufacture and supply the Goods and to perform its other obligations under any resulting LTA and linked Purchase Order(s). The Bidder has not and will not enter into any agreement or arrangement that restrains or restricts any person's rights to use, sell, dispose of or otherwise deal with the goods.

1.2 All of the information it has provided to UNICEF concerning the Goods and the Bidder is true, correct, accurate and not misleading.

1.3 The Bidder is financially solvent and is able to supply the Goods to UNICEF and PAHO in accordance with the requirements described in this RFP.

1.4 The use or supply of the Goods does not and will not infringe any patent, design, trade-name or trade-mark.

1.5 The development, manufacture and supply of the Goods has complied, does comply, and will comply with all applicable laws, rules and regulations.

1.6 The Bidder will fulfill its commitments with the fullest regard to the interests of UNICEF and PAHO and will refrain from any action which may adversely affect UNICEF, PAHO, or the United Nations.

1.7 It has the personnel, experience, qualifications, facilities, financial resources and all other skills and resources to perform its obligations under any resulting LTA and linked Purchase Order(s).

1.8 The Bidder agrees to be bound by the decisions of UNICEF and PAHO, including but not limited to, decisions as to whether the Bidder's Proposal meets the requirements and instructions stated in this RFP and the results of the evaluation process.

2. Ethical Standards

UNICEF require that all Proposers observe the highest standard of ethics during the entire solicitation process, as well as the duration of any LTA that may be awarded as a result of this solicitation process. UNICEF also actively promotes the adoption by its suppliers of robust policies for the protection and safeguarding of children and the prevention and prohibiting of sexual exploitation and sexual abuse.

By submitting its Proposal in response to this RFP, the Bidder makes the following representations and warranties to UNICEF as at the Submission Deadline and throughout the

validity period of the Proposal:

2.1 In respect of all aspects of the solicitation process the Bidder has disclosed to UNICEF any situation that may constitute an actual or potential conflict of interest or could reasonably be perceived as a conflict of interest. In particular, the Bidder has disclosed to UNICEF if it or any of its affiliates is, or has been in the past, engaged by UNICEF to provide services for the preparation of the design, specifications, cost analysis/estimation, and other documents to be used for the procurement of the goods requested under this RFP; or if it or any of its affiliates has been involved in the preparation and/or design of the programme/project related to the Goods requested under this RFP.

2.2 The Bidder has not unduly obtained, or attempted to obtain, any confidential information in connection with the solicitation process and any LTA and linked Purchase Order(s) that may be awarded as a result of this solicitation process.

2.3 No official of UNICEF or of any United Nations System organisation has received from or on behalf of the Bidder, or will be offered by or on behalf of the Bidder, any direct or indirect benefit in connection with this RFP including the award of the LTA and linked Purchase Order(s) to the Bidder. Such direct or indirect benefit includes, but is not limited to, any gifts, favours or hospitality.

2.4 The following requirements with regards to former UNICEF officials have been complied with and will be complied with:

(a) During the one (1) year period after an official has separated from UNICEF, the Bidder may not make a direct or indirect offer of employment to that former UNICEF official if that former UNICEF official was, during the three years prior to separating from UNICEF, involved in any aspect of a UNICEF procurement process in which the Bidder has participated.

(b) During the two (2) year period after an official has separated from UNICEF, that former official may not, directly or indirectly on behalf of the Bidder, communicate with UNICEF, or present to UNICEF, about any matters that were within such former official's responsibilities while at UNICEF.

2.5 Neither the Bidder nor any of its affiliates, or personnel or directors, is subject to any sanction or temporary suspension imposed by any United Nations System organisation or other international inter-governmental organisation. The Bidder will immediately disclose to UNICEF if it or any of its affiliates, or personnel or directors, becomes subject to any such sanction or temporary suspension. If the Bidder or any of its affiliates, or personnel or directors becomes subject to any such sanction or temporary suspension during the validity of the Proposal, UNICEF will be entitled to invalidate the Proposal.

2.6 The Bidder will (a) observe the highest standard of ethics; (b) use its best efforts to protect UNICEF and PAHO against fraud, in the solicitation process and in the performance of any resulting LTA and linked Purchase Order(s); and (c) comply with the applicable provisions of UNICEF's Policy Prohibiting and Combatting Fraud and Corruption which can be accessed on the UNICEF website at http://www.unicef.org/supply/index_procurement_policies.html. In particular, the Bidder will not engage, and will ensure that its personnel, agents and sub-

contractors do not engage, in any corrupt, fraudulent, coercive, collusive or obstructive conduct as such terms are defined in UNICEF's Policy Prohibiting and Combatting Fraud and Corruption.

2.7 The Bidder will comply with all laws, ordinances, rules and regulations bearing upon its participation in this solicitation and the UN Supplier Code of Conduct (available at the United Nations Global Marketplace website - www.ungm.org).

2.8 Neither the Bidder nor any of its affiliates, is engaged, directly or indirectly, (a) in any practice inconsistent with the rights set forth in the Convention on the Rights of the Child, including Article 32, or the International Labour Organisation's Convention Concerning the Prohibition and Immediate Action for the Elimination of the Worst Forms of Child Labour, No. 182 (1999); or (b) in the manufacture, sale, distribution, or use of anti-personnel mines or components utilised in the manufacture of anti-personnel mines.

2.9 The Bidder has taken and will take all appropriate measures to prevent sexual exploitation or abuse of anyone by its personnel including its employees or any persons engaged by the Bidder to perform any services in the Bidder's participation in this solicitation. For these purposes, sexual activity with any person less than eighteen years of age, regardless of any laws relating to consent, will constitute the sexual exploitation and abuse of such person. The Bidder has taken and will take all appropriate measures to prohibit its personnel including its employees or other persons engaged by the Bidder, from exchanging any money, goods, services, or other things of value, for sexual favours or activities or from engaging in any sexual activities that are exploitive or degrading to any person.

2.10 The Bidder confirms that it has read UNICEF's Policy on Conduct Promoting the Protection and Safeguarding of Children. The Bidder will ensure that its Personnel understand the notification requirements expected of them and will establish and maintain appropriate measures to promote compliance with such requirements. The Bidder will further cooperate with UNICEF's implementation of this Policy.

2.11 The Bidder will inform UNICEF as soon as it becomes aware of any incident or report that is inconsistent with the undertakings and confirmations provided in this Section 2.

2.12 Each of the provisions in Section 2 of this Part V constitutes an essential condition of participation in this solicitation process. In the event of a breach of any of these provisions, UNICEF is entitled to disqualify the Bidder from this solicitation process and/or any other solicitation process, and to terminate any LTA and linked Purchase Order(s) that may have been awarded as a result of this solicitation process, immediately upon notice to the Bidder, without any liability for termination charges or any liability of any kind. In addition, the Bidder may be precluded from doing business with UNICEF and any other entity of the United Nations System in the future.

3. Audit

3.1 From time to time, UNICEF or PAHO may conduct audits or investigations relating to any aspect of an LTA and/or linked Purchase Order awarded in relation to this RFP, including but not limited to the award of the LTA and/or linked Purchase Order and the Bidder's compliance with the provisions of Section 2 above. The Bidder will provide its full and timely cooperation with

any such audits or investigations, including (but not limited to) making its personnel and any relevant data and documentation available for the purposes of such audits or investigations, at reasonable times and on reasonable conditions, and granting UNICEF or PAHO and those undertaking such audits or investigations access to the Bidder's premises at reasonable times and on reasonable conditions in connection with making its personnel and any relevant data and documentation available. The Bidder will require its sub-contractors and its agents to provide reasonable cooperation with any audits or investigations carried out by UNICEF or PAHO.

4. Indemnity and liability for claims arising from covid-19 vaccines under COVAX Facility or their administration

4.1 In view of the exceptional circumstances which characterize the rapid development, scale-up, and deployment of COVID-19 vaccines procured or distributed under COVAX ("Vaccines"), the COVAX Facility is developing a system pursuant to which manufacturers of Vaccines, donors (of funds for vaccine procurement and/or Vaccines) to the COVAX Facility and other related stakeholders including UNICEF, WHO, PAHO, vaccine administrators and distributors (collectively, "Indemnified Persons") will be indemnified by countries participating in the COVAX Facility against losses they incur (as determined pursuant to final legal awards) arising out of or in connection with any vaccine recipient claim or relevant third party claim associated with the use of a COVID-19 vaccine or its administration under the COVAX Facility. It is expected that there will be some limitations to this indemnification requirement, including that it will not apply to:

a. losses incurred by Indemnified Persons arising out of or in connection with: (a) the Vaccine manufacturers' failure to comply with good manufacturing practices, the terms of any applicable marketing authorization or emergency use authorization or (b) the Indemnified Persons' failure to comply with state of the art policies, procedures, instructions or specifications with respect to the manufacture, storage and delivery of the Vaccine; (c) the willful misconduct or gross negligence of an Indemnified Person or third parties collaborating with such an Indemnified Person, or
b. losses arising out of claims that are either: (a) time-barred under the law of the receiving country; or (b) associated with a Vaccine put into circulation in the receiving country after the point at which it is deemed by the COVAX Facility that either adequate insurance is available to the manufacturer in the market, or the manufacturer can self-insure, but in any event no later than 30 June 2022, which date may be extended by the COVAX Facility based on periodic reviews.

4.2 Discussions are currently ongoing to require that each country receiving COVID-19 vaccines through the COVAX Facility does indemnify the Indemnified Persons, in accordance with the general principles described above. The outcome of the discussions and the resulting model indemnity clause will be shared with all prospective Proposers as soon as they have been finalized (currently expected November). Each country is expected to sign an indemnity agreement with the manufacturer whose Vaccine the country will be receiving.
Manufacturers and/or suppliers of Vaccines will still be expected, as envisaged in the UNICEF and PAHO General Terms and Conditions, to indemnify, hold harmless and defend UNICEF and

PAHO for product liability claims and other third-party claims arising out of their acts and omissions in breach or violation of the manufacturers'/suppliers' respective supply agreements with UNICEF and PAHO. UNICEF and PAHO, pursuant to their respective supply agreements, will notify the manufacturer of any third party claims for which such indemnification is sought, and the manufacturer will be expected to take over the claim and conduct any negotiations and litigation in settlement of the claim, provided however that no such settlement shall prejudice any privileges and/or immunities enjoyed by UNICEF or PAHO or be entered into on the basis of an admission of fault or liability by UNICEF or PAHO.

PART VI – ANSWERING SHEETS

PROPOSAL AND COMMERICAL TERMS SHEET

The Undersigned, having read the Instructions to Proposers of this Request for Proposal **RFP-DAN-2020-503209** and all related documents, hereby offers to supply the Goods and contributions to meet the overall objectives sought in accordance with any specifications stated, under the conditions and in quantities, at prices and within the number of days as indicated in the PRODUCT PROFILE, QUALITATIVE AND QUANTITATIVE PROPOSAL SHEETS, and subject to all Terms and Conditions set out or specified in this RFP and accepting that any Long Term Arrangement(s) – resulting from this RFP shall contain the UNICEF General Terms and Conditions or the PAHO General Terms and Conditions and any other terms and conditions specified in this RFP.

Signature: _____

Date: _____

Name & Title: _____

Company: _____

Postal Address: _____

Tel No.: _____

Email: _____

Validity of Offer: _____

Any requested EXCEPTIONS or CLARIFICATIONS are to be defined below (additional pages may be attached):

TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET

Please include a response to the following.

1. Please provide your United Nations Global Marketplace (UNGM) registration number_____

   If your company has not yet registered through the UNGM, please submit an application through the UNGM website at http://www.ungm.org under http://www.ungm.org/Registration/RegisterSupplier.aspx.

   Instructions are provided on the site.

2. Have you provided audited financial statements to UNICEF in the past 12 months?

   If not, please proceed as per Part II, Section 5.2.

PRODUCT PROFILE SHEET

Referring to the WHO Target Product Profile (TPP) for Covid-19 vaccines, please provide the below information for your products offered. Please include all components mentioned in the TPP. If the preferred TPP characteristic will not be offered initially, please indicate when it will be. Please also indicated minimal or critical characteristics until the preferred is available.

Please include multiple Proposal Sheets, as required, for alternative presentations.

WHO TPP Vaccine Characteristics	Preferred and Timing (month/year)	Minimal or Critical
Indication for use		
Contraindication		
Target Population		
Safety/Reactogenicity		
Measures of Efficacy		
Dose Regimen		
Durability of protection		
Route of Administration		
Product Stability and Storage (please include type of VVM to be used)		
Co-administration with other vaccines		
Presentation		
Registration and Prequalification		
Accessibility		

Additionally, please provide the following information required to inform work of the IPG

The Independent Product Group (IPG) is established to make recommendations to the Office of the COVAX Facility on the inclusion of vaccines in the COVAX Facility; regularly review the COVAX Facility portfolio for balance; review updates on timing and availability of doses; and consider any implications for the COVAX Facility portfolio.

The IPG is primarily advisory, and the aim of the IPG review process is to make a recommendation to the Office of the COVAX Facility on vaccine candidate prioritisation and portfolio balance. Once the Office of the COVAX Facility has negotiated the ensuing deal terms, taking into consideration independent technical advice from the Procurement Reference Group (PRG), the deal would then be considered by the Gavi Market Sensitive Decisions Committee.

Please include the following information in a slide presentation (preferred) or report which addresses the following areas, as detailed below:

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*

Please respond to this 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.

Data types

1. **Vaccine development**

a. Overview of the plan and timeline for vaccine development, including status of studies conducted, started or planned, key milestones, end points (deliverables) and risks

b. Overview of preclinical studies, including the following information:
   i. Description and results of relevant in vitro studies
   ii. Description of animal studies (i.e. type of animal, description of challenge, safety and toxicity, immune response measured, immune response assays, level of immunogenicity)
   iii. Please summarise any other findings or data of relevance for developmental and reproductive toxicity

c. Overview of safety and dose-finding studies, including information on the following, if available:
   i. Data on populations of interest (for completed planned studies; whether information be collected through surveillance and follow up; populations of interest might include, but are not limited to: pregnant & lactating women, children, older adults and specific co-morbidity risk groups)
   ii. Description of dose-finding studies and justification
   iii. Description of safety follow up and availability of data to support safety follow up (including size of safety database)
   iv. Frequency and nature of mild and severe adverse events, including any unexpected findings that require further investigation

d. Overview of relevant data and findings on immunogenicity, including information addressing the following areas, if available:
   i. Onset of immune response after the primary dose; immune response after the second dose, if applicable (measured as concentrations/titres of antibodies or

seroconversion rates vs pre-vaccination values or, if a correlate is established, seroprotection rates).
   ii. Virus neutralization data and/or other relevant immunological correlates
   iii. Evidence concerning T-cell responses
   iv. Persistence of protective antibodies over time and any other measures of durability of immune response
   v. Description of variation by different subgroups

e. Overview of efficacy (Phase IIb/ III) studies, including the following information:
   i. Timelines and status of planned or ongoing studies, including expected timing of availability of interim and final data (please include range of scenarios, if available)
   ii. Study design including confirmation of dose selection; relevant case definitions and endpoints; use of placebo/ control; summary of statistical considerations related to vaccine efficacy; whether the protocol is publicly available; inclusion in multi-arm trial (e.g. WHO Solidarity; ACTIV)
   iii. Geographic location, population of interest, inclusion of sub-groups of interest (older adults, pregnant and lactating women, specific co-morbidity risk groups, children), exclusion criteria; difference in efficacy by different subgroups
   iv. Any known or anticipated special requirements or operational considerations that may have implications for future delivery of licensed or authorised vaccines
   v. Proposed future studies (including plans for immunobridging and post-implementation studies). If known, please indicate any studies which you would envisage doing after resolution of the pandemic, e.g. booster studies and long term follow up, including reference to specific subpopulations.

f. Regulatory pathway
   i. Summarise any regulatory guidance received on considerations such as nonclinical testing requirement/ vaccine efficacy requirements, and by which authority
   ii. Is the vaccine development undertaken with the oversight of a functional NRA?
   iii. Which NRA of Record will be requested to undertake batch releases?
   iv. Please provide a summary of engagement with WHO Prequalification and expected timelines for regulatory review

2. Vaccine product profile and delivery attributes

(*Purpose: to provide overview of product and implications for future vaccine programmes, including feasibility and delivery requirements. This information may be a combination of known and Target Product characteristics, based on profile of similar products. Respondents should indicate whether the relevant characteristic is confirmed or targetted*)

In case this information is not available at time of submission of the proposal, the proposer is expected to submit new information related to the items below as these become available.

a. Description of the vaccine candidate and underlying technology

b. Description of the indicative vaccination strategy, including age group(s) and target population(s)

c. Dosing and product presentation
    i. Anticipated dose schedule (number of doses required to achieve protection, and interval between doses)
    ii. Adjuvant yes/no
    (if yes, please include the response to the following questions: has it been used previously in vaccines licensed by stringent regulatory authorities/ WHO prequalified; if provided by third party, is supply secured and, if known, please provide an indication of how much adjuvant is available relative to the supply of antigen; and whether it anticipated that the antigen and adjuvant will be combined in a single container or mixing/reconstitution required before administration)
    iii. Volume per dose
    iv. Vials (Number of vials per dose/secondary package(?); type of VVM; single and/or multi-dose – 2, 5, 10, 50 doses per vial; 1 or 2 vials per dose)
    v. Formulation and use of preservative, suitability for OCC, applicability of MDVP
    vi. Expected availability of a range of presentations
    vii. Barcodes on secondary packaging

d. Information on administration, including the following:

    i. Route of administration
    ii. Recommended device (if relevant)
    iii. Co-administration and interchangeability of vaccines with two or more doses

e. Information on storage and cold chain requirements, including the following:
    i. cold chain requirements (if any) for vaccine storage and transportation (temperature indication)
    ii. Volume per dose in primary and secondary packaging
    iii. Duration of shelf-life at different temperature ranges
    iv. Are there plans to further optimise stability and temperature requirements and/or optimise stability? If yes, when will data arrive?

3. Manufacturing, supply and market considerations

a. Information on the manufacturing platform, including the following:
    i. Description of technology
    ii. Number of marketed products and/or products under advanced development (beyond the COVID-19 vaccine candidate) which use the same manufacturing technology/platform

b. Description of manufacturing considerations, including the following:
    i. Targeted date for start of manufacturing scale-up
    ii. When is it projected that full scale steady-state production will be reached?
    iii. Narrative on key scientific, operational and financial risks or considerations
    iv. Narrative on any expected impact on or implications for manufacturing/ supply of other vaccines

c. Volume and supply timelines, including the following:

i. Pre-licensure/post licensure: Production lead time for bulk vaccine, and projected availability of released bulk volumes in finished dose equivalent per month in 2020, June 2021, end 2021, 2022, 2023, by manufacturing site
ii. Lead time for conversion of bulk into finished product
iii. Target date for licensure and WHO prequalification
iv. Projected availability of licensed product released by NRA of Record by month in 2021
v. If subcontractors are used for parts of the process, please confirm the physical location, provide documentation for authority to produce from country of production, and a copy of the contract between manufacturer and subcontractor to document contractual arrangement
vi. Please provide a narrative on critical factors that could affect availability of such volumes
vii. Please confirm that your company will be the marketing holder, and clarify any restrictions on your rights to supply to any COVAX Facility participating economies
viii. Please provide a narrative on any proposed technology transfer – outsourcing or in-licensing - and likely arrangements, including timing, location and contractual status

d. Description of R&D funding (amounts), including the following:
   i. External contributions received and source
   ii. Type of funding and associated commitments
   iii. Please provide a brief narrative on any funding gaps

e. Description of manufacturing investments, including the following:
   i. Push or pull funding received from national or other public-private entities (e.g. support to tech transfer, scale-up or scale out, reservation fees, inventory build or Advance Purchase Agreements)

f. Outline of committed bulk or production volumes and agreement on bulk or final dose pricing

g. Outline of pre-existing access agreements, including associated conditions (prioritisation of supply, volumes, etc.)

QUALITATIVE PROPOSAL SHEET

Please provide response to the following in your Proposal together with any other information deemed relevant.

1. Experience. Demonstrate proven experience in development, production and delivery of vaccines and/or biologicals, or similar.

2. Volumes offered.

    a) Proposed Quantity. Explain the key determinants for the proposed quantity to be available during the quoted timeframe, as well as any key risks. WHO/PQT may evaluate the capacity of the Bidder to supply the proposed quantity as part of the technical evaluation of the Proposal.
    b) Include your total annual production capacities for bulk and final filled product for each offered vaccine. If the vaccine bulk is not produced by the Proposer, please advise source of bulk, and evidence of contractual access to bulk. If the fill and finish is not performed by the Proposer, please advise source of fill and finish capacity, and evidence of contractual access to such capacity.
    c) If a tech transfer is required for bulk or fill and finish, please share timelines as well as any limitations or restrictions in market access.
    d) Provide the minimum and maximum batch size for bulk production; as well as the minimum and maximum batch size (throughput) for fill and finish.
    e) Please provide the maximum capacity by day/week for warehouse capacity for packaging of goods for pick up by freight forwarder, including any bottlenecks (e.g. access to dry ice)
    f) Please also confirm any pre-existing commitments for supply of the offered vaccine

3. Please provide the following information regarding production scale-up:
    a. Milestones and timelines related to any scale up in production capacity, including if required, any new facilities
    b. Milestones and timelines for anticipated approval by the NRA
    c. Timelines for submission of WHO application, and anticipated approval as applicable
    d. Expected timeline for release by the NRA of Record and the manufacturer for availability (for shipment) to UNICEF of first product from new capacity

4. Please advise whether the production of the vaccine offered affects the production, or potential production, of any other vaccine being supplied to UNICEF or PAHO by your company. In addition, indicate whether facilities for bulk production and fill and finish are dedicated, multipurpose and/or shared facilities.

5. Medium- and Long-Term Plans. Provide information on their medium- and long-term plans for production of the vaccine(s) being offered.

6. Account Management. Provide organizational charts and names of the responsible persons within each of the following departments: Production, Quality Assurance, Governmental Affairs, Shipping/Logistics, Sales and Marketing, specifying the name(s) of the person(s) who will be the primary contact for UNICEF, PAHO and Gavi.

7. Any other information deemed relevant for the evaluation of the proposal.

QUANTITATIVE PROPOSAL SHEET

COVID-19 Vaccine Presentation(s)……

In compliance with terms and conditions of this Request for Proposal and all sections hereto, the undersigned offers the supply of the vaccine in quantities, at prices and within the number of days indicated below:

Annual quantity in doses	Unit price per dose (FCA – Closest International Airport or FCA, Supplier Premises)

Delivery preparation lead time required for preparation of delivery (administration of order, packing, markings, etc.) for any order within above-mentioned schedule: _____ days.

INCOTERMS (2020) FCA, Nearest International Airport (Name Airport)/ **FCA, Supplier Premises**: _____

Vaccine Vial Monitor? Yes:____ No:___If yes, which type:
In the current pandemic phase, VVMs for Covid-19 vaccines are preferred characteristics but not mandatory, in line with the Target Product Profile[11]

Barcodes at secondary packaging level in accordance with specifications in Annex E (including serialization): Yes:_____ No:_____

Barcodes at tertiary packaging level in accordance with specifications in Annex E:
Yes:_____No:_____

Ability and willingness to store data for availability on request for at least the shelf life of product:
Yes:_____ No:_____
In the current pandemic phase, barcodes are preferred characteristics but not mandatory.

Minimum purchase order delivery quantity:

Please indicate which of the following terms of payment are offered under this Proposal:

10 days 3.0% _____ 15 days 2.5% _____ 20 days 2.0% _____

30 days net _____ Other_____

Please indicate any additional special terms:

Please indicate any additional terms and conditions that would be specific to Self-Financing Self-Procuring Participants of the COVAX Facility i.e. buyers not procuring through UNICEF and/or PAHO.

[11] https://www.who.int/publications/m/item/who-target-product-profiles-for-covid-19-vaccines

MONTHLY OFFERED QUANTITIES (DOSES)

Vaccine offered: _____

2020 (in DOSES)	
November 2020	
December 2020	
TOTAL 2020	
2021 (in DOSES)	
January 2021	
February 2021	
March 2021	
April 2021	
May 2021	
June 2021	
July 2021	
August 2021	
September 2021	
October 2021	
November 2021	
December 2021	
TOTAL 2021	
H1 2022	
H2 2022	
Total 2022	
H1 2023	
H2 2023	
Total 2023	