

**UNITED NATIONS CHILDREN'S FUND (UNICEF) and GAVI, THE VACCINE
ALLIANCE
REQUEST FOR EXPRESSION OF INTEREST (EOI)
COVID-19 VACCINES
Reference EOI-VC-2020-01**

1. Purpose

The purpose of this Expression of Interest (EOI) is for UNICEF and Gavi to collect information from manufacturers'/developers' on their plans to supply COVID-19 vaccines to protect against the SARS-CoV-2 virus. The information will help inform the design of the COVID-19 Vaccine Global Access (COVAX) Facility and Gavi COVAX Advance Market Commitment (AMC), procurement, budgeting, and timelines. Feedback will contribute to the understanding of the potential availability of bulk and final product, and commercialisation issues of the COVID-19 vaccine. The information will also help UNICEF, Gavi and other stakeholders understand the support needed by developers/manufacturers to bring their COVID-19 vaccines to market.

UNICEF and Gavi expect to initiate procurement of COVID-19 vaccines in 2020 or as soon as one or more vaccine candidate(s) demonstrate efficacy and safety. Developers/manufacturers are therefore urged to provide a response to this request if they are currently developing or producing a COVID-19 vaccine and consider it likely that they could offer such to the ACT Accelerator COVAX Facility.

Information received will be treated as confidential. In an aggregated level, key findings will be summarised and shared with key partners of the ACT Accelerator.

2. Background

The world urgently needs safe and efficacious COVID-19 vaccines to protect the most vulnerable people, stop transmission and prevent resurgence of COVID-19. Vaccination is considered the linchpin intervention to sustainably restore health and societal stability. Through vaccination, we can mitigate the need for repeated rounds of distancing measures and associated negative social and economic impacts, which would be significant.

It is critical that there is sufficient supply of the most suitable (safe, efficacious, quality assured and appropriate) COVID-19 vaccines to be available the moment a vaccine candidate successfully emerges from clinical development and ensure global health security as allocation would be based on public health needs to control the pandemic. This includes facilitating access to vaccines for developing countries, who would otherwise face a disproportionate health, economic and social burden. To help achieve this ambition, within the overarching Access to COVID-19 Tools (ACT) Accelerator, a COVAX Facility is being established as a part of the ACT Vaccines Pillar.

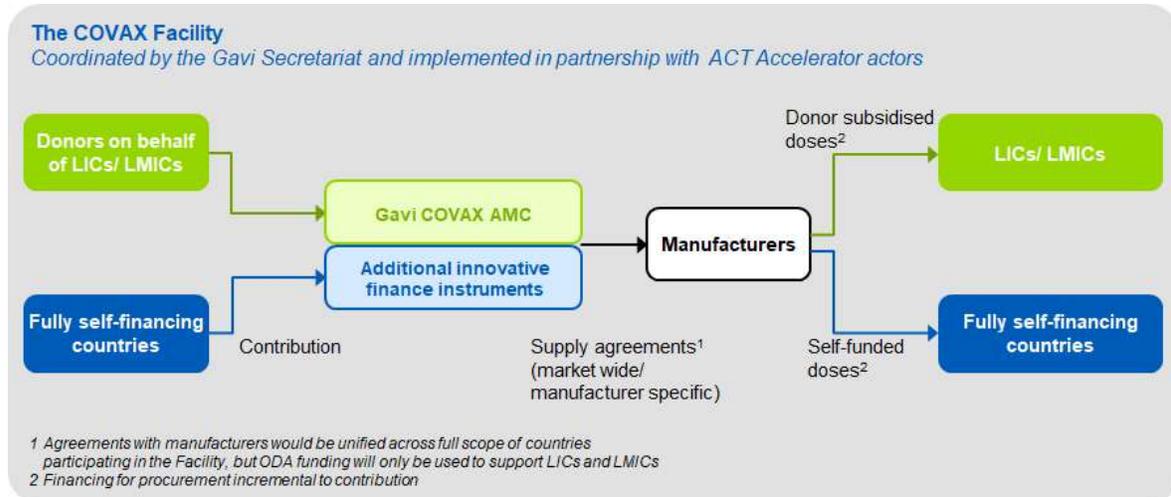
The COVAX Facility is the umbrella mechanism through which demand and resources will be pooled to support procurement of and equitable access to COVID-19 vaccines. All countries are invited to participate in the Facility and all participating countries would benefit by securing affordable access to vaccine supply through the Facility. Countries with less purchasing power as well as fewer resources and capacities to enter into their own agreements with manufacturers would benefit by entering into a joint pool for securing and procuring vaccine doses. Even those countries who do have the resources to enter into bilateral agreements with manufacturers, or have already done so, would benefit as the Facility provides access to a portfolio of vaccine candidates, insuring against the risk that the candidates they have invested in are unsuccessful.

Within the COVAX Facility, an innovative financing instrument – the COVAX Advance Market Commitment (AMC) – will be utilised to secure access to timely and sufficient supply of vaccines. The COVAX AMC will utilise two types of pull mechanisms. Gavi/UNICEF will enter into manufacturer-specific volume contingent volume guarantees to procure vaccines that meet the agreed WHO Target Product Profile (TPP), so as to de-risk and incentivize timely investment in expansion of manufacturing capacity. The COVAX AMC will also rely on a market-wide demand guarantee, which could provide continued incentives and assurances to manufacturers to expand production capacity and to bring products to market meeting the TPP. These guarantees would be secured by future financial commitments from countries. 'Push' funding (i.e., direct financial support to facilitate expansion of manufacturing capacity) is being led by ACT Accelerator partners (the Coalition for Epidemic Preparedness (CEPI), the Bill and Melinda Gates Foundation (BMGF) and other stakeholders) outside the COVAX Facility. The effectiveness of the Facility 'pull' instruments will rely on close collaboration and sharing of information with those financing 'push' investments, which will be achieved through collaboration within the ACT Accelerator Vaccines Pillar.

Vaccine pricing will be negotiated under the expectation that manufacturers seek minimal returns in the near term for supply to vaccinate priority populations and control the pandemic, and will take into consideration any other direct financial support received by manufacturers. For the short-term period, depending on the manufacturer proposals received, there could be a flat price from manufacturers with a cross-subsidization mechanism to establish differential pricing for countries to account for varying ability to pay. The Facility may accommodate manufacturer requests for tiered pricing if the price levels offered for each tier are considered appropriate. Beyond the near term, pricing would evolve to a traditional tiered pricing approach. Upon availability of doses, vaccines will be procured via existing procurement mechanisms (e.g., UNICEF Supply Division, PAHO Revolving Fund, EC, individual country procurement mechanisms).

To ensure participation in the Facility – and access to the vaccines secured through it – is possible for all countries, it is envisaged that some participating countries will receive financial support, where needed, for predictable and timely financing. This is likely to include support from Gavi to low and lower middle-income countries (LICs/LMICs) through Official Development Assistance (ODA) funding. These countries could potentially receive support, for example, for contributions to the Facility, vaccine procurement, delivery and technical assistance. There is also the potential for Multilateral Development Banks (MDBs) to provide support for other countries.

Given the previous successful experiences with similar advance purchase and market commitments, the Gavi Secretariat would coordinate the activities of the COVAX Facility and implement the Gavi COVAX AMC, working closely with other ACT Accelerator partners. Roles and responsibilities, the financing structure and legal agreements for the COVAX Facility will be further defined. The figure below provides a simplified schematic description of the participation of countries in the COVAX Facility, including both LICs/LMICs supported by ODA and other participating countries (UMICs and HICs), and the COVAX AMC as the initial innovative financing instrument for LICs and LMICs. <https://www.gavi.org/news/media-room/gavi-launches-innovative-financing-mechanism-access-COVID-19-vaccines>



3. Request for Expression of Interest

This document is a request for an EOI and sharing of information only. It is neither a request for quotation or proposal nor an invitation to bid. Although it is important that information on planned strategies is as realistic as possible, the indications made by each developer/manufacturer will not be considered by UNICEF or Gavi to be in any way binding. Each reply or proposal will hereafter be referred to as 'Indication'.

It is expected that a significant portion of the information provided in the Indication would be considered to be strategic, confidential and/or proprietary. Please refer to Section 6 on the details of how confidentiality will be handled.

As this document is not requesting a firm commercial proposal, the standard UNICEF terms and conditions are not attached, but they are available from the UNICEF website. For Manufacturers not familiar with how UNICEF does business, it is important to read the information on the website¹.

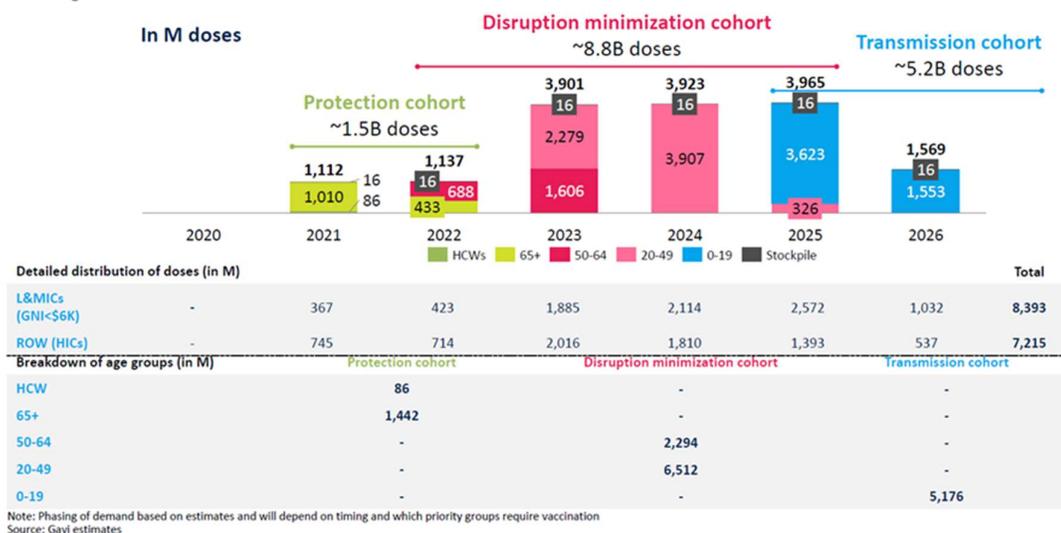
Through this EOI, UNICEF and Gavi are soliciting industry input with the objective to obtain indications of the development and supply of COVID-19 vaccines. Information provided will guide strategic decisions, design and funding of the COVAX Facility and AMC, future procurement and support needed.

In order to provide context, below is a demand quantification scenario. The demand to date is uncertain and the below provides a scenario that the COVAX Facility could potentially be called on to supply in the short term.

¹ http://www.unicef.org/supply/index_procurement_policies.html

View as of 1 May: Estimates subject to change as additional information becomes available

Overview of global vaccine need across all cohorts and age groups



Potential target population includes essential health care workers, people over the age of 65 and productive workforce. In addition, a global stockpile of 16 million doses will be constituted at all times.

- 2021: 1.112 billion doses
- 2022: 1.137 billion doses
- 2023: 3.901 billion doses
- 2024: 3.923 billion doses
- 2025: 3.965 billion doses
- 2026: 1.569 billion doses

4. COVID-19 vaccine supply factors – Pricing, Financing and Other factors

Please provide the following information. Refer to the Indication Sheets to provide the feedback.

A. Pricing for countries participating in the Facility mechanism:

- Please indicate if you have a preferred pricing policy. For example, a tiered pricing schedule based on ability to pay (e.g., as assessed via GNI), or a single price, or a single price for the short-term period followed by a price that follows a tiered pricing schedule.
- Please provide indicative price ranges per dose of vaccine. This may include indicative price ranges based on country tiers (ie. LIC/LMIC, UMIC, HIC) and indications based on volumes.
- Provide any factors that influence pricing decisions. Including duration of contract, volume guarantees, or other terms.

For information, UNICEF procures vaccines under Incoterm FCA-closest international airport and airfreight is contracted and paid for by UNICEF, not by the manufacturer.

B. Funding support: Please provide information on “push and /or pull” funding received from national or other public-private entities. Including whether bulk or production volumes are committed and if bulk or final dose pricing has been agreed.

C. Other factors: Please share any ideas for innovative solutions which could ensure rapid availability, large volumes and/or affordable prices, as well as what would be needed from UNICEF and Gavi and other stakeholders to help this materialise.

D. Support: Please indicate any support needed from UNICEF, Gavi, WHO or via the COVAX Facility that would help the development of your product and bringing it to market. I.e., advice on production/presentation decisions, over and above existing TPP, etc.

5. COVID-19 vaccine supply factors – Product and Manufacturing

Please provide the following information. Refer to the Indication Sheets to provide the feedback.

E. Timelines: For vaccines currently in development, please provide information on clinical trials that are underway or planned. Including: location of the trial, population, whether children or pregnant women are included, data on inter and intra effect with other routine immunization vaccines (coadministration), and starting and endpoint dates.

F. Product Profile:

- Vaccine type (technological platform)
- Information about any studies that may help inform the product profile that are relevant, e.g. thermo-stability
- Pharmaceutical form (e.g. liquid, lyophilised)
- Preservative (if applicable)
- Product presentation (e.g. prefilled syringe, vial, number of doses per vial)
- Administration (e.g. injected intramuscularly, oral, etc.)
- Cold chain requirements (if any) for vaccine conservation as well as volume per dose and per primary packaging)
- Shelf- life; and shelf-life at different temperature ranges
- Dosage (expected number of courses and dose volume)
- Packaging
- VVM

G. Manufacturing technology:

- Chosen manufacturing technology/platform
- Number of marketed products and/or products under advanced development (beyond the COVID-19 vaccine candidate) which are using the same manufacturing technology/platform
- Targeted date for start of manufacturing scale-up
- Targeted date for entry at full scale steady-state production.

H. Bulk production volumes: Quantities of bulk planned to be available by 2020, by June 2021, by end of year 2021, in 2022, in 2023.

I. Pre-licensure, Emergency Use production volumes:

- Planned quantities to be available in 2020 and 2021.
- Manufacturer(s) of quantities, if other than submitter.

J. Licensed Production volumes/capacities:

- Planned production volumes at full capacity and lead-time for full capacity to be available by end of 2020, by June 2021, by end of year 2021, in 2022, in 2023.
- Quantities, or percentage of full capacity, to be available for COVAX Facility to be available by end of 2020, by June 2021, by end of year 2021, in 2022, in 2023.

- Manufacturer(s) of quantities
- Key factors that would affect availability of such volumes.

K. Regulatory authority(ies) for bulk and final product, including timelines for WHO pre-qualification. Including if different based on final production location.

6. Confidential Environment

It is understood that the majority of the information being requested is considered to be strategic, confidential and/or proprietary to each Developer/Manufacturer. An understanding of these sensitive issues will help optimize budgeting, planning and future procurement activities in a way that is mutually beneficial to industry and countries.

UNICEF and Gavi reserve the right to make information received in response to this EOI publicly available at aggregate level. Manufacturer specific information will be only shared with key parties on a need to know basis and under confidentiality agreements.

WHO will have access to the technical parts of the Indications in order to undertake review and assessment of vaccine development and plans for capacity expansion, including timelines.

7. Procedure and instructions to participating developers/manufacturers

Invitee list

This request for EOI has been sent electronically to developers/manufacturers known by UNICEF and Gavi of having candidate COVID-19 vaccines in the clinical trial phase, and vaccine manufacturers with a candidate COVID-19 vaccine, and developer/manufacturers that have received public-sector push funding to develop and manufacture a COVID-19 vaccine. Furthermore, the EOI has been published on the UNICEF website and can be responded to by any developer or manufacturer. The target invitees are developers or manufacturers and not agents/trade representatives.

Submission deadline

Indications should be received via email to Yalda Momeni, Contracts Manager, UNICEF at ymomeni@unicef.org. The subject line of the email should be marked with the EOI number **EOI-VC-2020-01** and should be received no later than **22 June 2020** at 12h00pm Copenhagen time.

Request for information

Please submit any queries on this EOI via e-mail Yalda Momeni, Contracts Manager, UNICEF ymomeni@unicef.org. Inquiries received less than twenty-four (24) hours prior to closing date of this EOI cannot be guaranteed any response. Only written inquiries will be entertained.

Response format

The indication format may correspond to the format and numbering system used in the body of this EOI. Other formats are also acceptable.

Review of Indications

UNICEF, or its designee, and Gavi may arrange individual meetings or telephone conferences with each developer/manufacturer for further clarification of any aspect of the Indication.

UNICEF and Gavi

Please follow these links for more information on [UNICEF immunisation programmes](#), [UNICEF procurement of vaccines](#) and [Gavi, the Vaccine Alliance](#).

INDICATION SHEET

PLEASE USE THE ATTACHED EXCEL SHEET TO PROVIDE INPUT

EOI-VC-2020-01

GENERAL INFORMATION

Full company name:	
Developer/Manufacturer:	
Address:	
Country:	
Contact Person	Name: Title:
E-mail address:	
Tel:	

COVID-19 VACCINE SUPPLY FACTORS

A. Pricing:

- Please indicate if you have a preferred pricing policy for countries. For example, a tiered pricing schedule based on ability to pay (e.g., as assessed via GNI), or a single price, or a single price for the short-term period followed by a price that follows a tiered pricing schedule.
- Please provide indicative price ranges per dose of vaccine. This may include indicative price ranges based on country tiers (ie. LIC/LMIC, UMIC, HIC) and indications based on volumes.
- Provide any factors that influence pricing decisions. Including duration of contract, volume guarantees, or other terms.

B. Funding support: Please provide information on push and / or pull funding received from national or other public-private entities. Including whether bulk or production volumes are committed and if bulk or final dose pricing has been agreed.

C. Other factors: Please share any ideas for innovative solutions which could ensure rapid availability, large volumes, affordable prices as well as what would be needed from UNICEF and Gavi and other stake holders to help this materialise.

D. Support: Please indicate any support needed from UNICEF, Gavi, WHO or via the COVAX facility that would help the development of your product and bringing it to market. I.e., advice on production/presentation decisions, over and above existing TPP, etc.

E. Timelines: For vaccines currently in development, please provide information on clinical trials that are underway or planned. Including: location of the trial, population, whether children or pregnant women are included, data on inter and intra effect with other routine immunization vaccines (coadministration) and starting and endpoint dates.

F. Product Profile:

- Vaccine type (technological platform)
- Information about any studies that may help inform the product profile that are relevant, e.g. thermo-stability
- Pharmaceutical form (e.g. liquid, lyophilised...)
- Preservative (if applicable)
- Product presentation (e.g. prefilled syringe, vial, number of doses per vial)
- Administration (e.g. injected intramuscularly, oral, etc.)
- Cold chain requirements (if any) for vaccine conservation as well as volume per dose and per primary packaging)
- Shelf- life; and shelf-life at different temperature ranges
- Dosage (expected number of courses and dose volume)
- Packaging
- VVM

G. Manufacturing technology:

- Chosen manufacturing technology/platform
- Number of marketed products and/or products under advanced development (beyond the COVID-19 vaccine candidate) which are using the same manufacturing technology/platform
- Targeted date for start of manufacturing scale-up
- Targeted date for entry at full scale steady-state production.

H. Bulk production volumes:

- Quantities of bulk planned to be available by end of 2020:
- by June 2021:
- by end of year 2021:
- 2022:
- 2023:

I. Pre-licensure, Emergency Use production volumes:

- Planned quantities to be available in 2020 and 2021:
- Manufacturer(s) of quantities, if other than submitter:

J. Licensed Production volumes/capacities:

- Planned production volumes at full capacity and lead-time for full capacity:
- Quantities, or percentage of full capacity, to be available for COVAX facility:
- Manufacturer(s) of quantities:
- Key factors that would affect availability of such volumes:

K. Regulatory authority(ies) for bulk and final product. Including if different based on final production location.

SIGNATURE
EOI-VC-2020-01

Signature (electronic is acceptable):

Date: _____

Name & Title: _____

Company: _____