

RFP-DAN-2020-503278



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## REQUEST FOR PROPOSAL

UNITED NATIONS CHILDREN'S FUND (UNICEF)  
wishes to receive proposals for

### ROTAVIRUS VACCINE (RV)

FOR DELIVERY DURING THE PERIOD 2022 THROUGH 2026

RFP-DAN-2020-503278

18 December 2020

#### UNITED NATIONS CHILDREN'S FUND (UNICEF)

Attention: BID SECTION RFP-DAN-2020-503245  
Oceanvej 10-12  
2150 Nordhavn, Copenhagen  
Denmark  
Tel +45 4533 5500

**EMAILED PROPOSALS must be sent to the email [supplybid@unicef.org](mailto:supplybid@unicef.org) up to 16h00 Hours. (Copenhagen time) on 29 January 2021. 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**

Prepared by Edouard Kamangaza,  
Contracts Manager 22-12-2020

Approved by:

Mr. Hans Christiansen,  
Contracts Manager,  
f/OIC, Vaccine Centre,  
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22-12-2020

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## PART I – PURPOSE OF THE REQUEST FOR PROPOSAL

### 1. PURPOSE

- 1.1 UNICEF promotes the rights and wellbeing of every child in everything we do. Together with our partners, we work in 190 countries and territories to translate that commitment into practical action, focusing special effort on reaching the most vulnerable and excluded children, to the benefit of all children, everywhere. The fundamental mission of UNICEF is to promote the rights of every child, everywhere, in everything the organization does — in programs, in advocacy and in operations. The equity strategy, emphasizing the most disadvantaged and excluded children and families, translates this commitment to children's rights into action. For UNICEF, equity means that all children have an opportunity to survive, develop and reach their full potential, without discrimination, bias or favouritism. To the degree that any child has an unequal chance in life — in its social, political, economic, civic and cultural dimensions — her or his rights are violated. There is growing evidence that investing in the health, education and protection of a society's most disadvantaged citizens — addressing inequity — not only will give all children the opportunity to fulfil their potential but also will lead to sustained growth and stability of countries. This is why the focus on equity is so vital. It accelerates progress towards realizing the human rights of all children, which is the universal mandate of UNICEF, as outlined by the Convention on the Rights of the Child, while also supporting the equitable development of nations.
- 1.2 UNICEF vaccine procurement is guided by the principle of vaccine security: the sustained, uninterrupted supply of affordable vaccines of assured quality.
- 1.3 UNICEF is seeking comprehensive and innovative proposals from the manufacturer for the sustained and uninterrupted supply of affordable Rotavirus Vaccine (RV) to Gavi 64 countries and Middle-Income Countries (MICs).
- 1.4 The overall objectives of this solicitation are to:
  - Achieve security of supply to meet demand
    - Ensure sufficient supply of products that accommodate country preferences, including new programmatically improved presentations.
    - Manage uncertainties due to potential switches to other products or new presentations
  - Maintain a long-term competition in the Rota market
    - Ensure three viable suppliers remain in the market
    - Improve the weighted average price (WAP) per child to fully vaccinate with RV to an appropriate and sustainable level.
  - Gather knowledge about appropriate and innovative products
- 1.5 The purpose of this Request for Proposal (RFP) is to establish non-exclusive Long-Term Arrangements (LTAs) for the procurement and supply of Rotavirus Vaccines for the period of 2022 to 2026 to meet demand for routine immunization programmes in Gavi-eligible countries. The maximum quantity requested of Rotavirus Vaccine for this period is 294.8 million courses considering quantities already requested by countries through applications to Gavi and Middle-Income Countries demand.
- 1.6 As a result of this RFP, UNICEF will work with selected manufacturers to establish LTAs that best meet the needs of both parties for ensuring that the procurement objectives are met. The number of LTAs, duration (up to five years) and quantities to be awarded will be decided in order:
  - to establish a low, sustainable vaccine price,
  - to ensure an adequate supply base, and
  - to ensure appropriate products in quantities to meet country needs.

These Long-Term Arrangements will provide the basis on which Purchase Orders will be made for specific vaccine deliveries throughout the period

- 1.7 As UNICEF moves towards implementation of the Sustainable Development Goals (SDGs), UNICEF is keenly interested in the efforts made by suppliers towards sustainable initiatives and will use this Request for Proposal to collect information about such initiatives (PART VII – Environmental Suitability Sheet).

## 2. BACKGROUND

### 2.1 ACCESS TO ROTAVIRUS VACCINES

In June 2019, the Gavi Board approved a new five-year strategy ('Gavi 5.0') with a vision to 'leave no-one behind with immunisation' and a mission to save lives and protect people's health by increasing equitable and sustainable use of vaccine.

The 2022-2025 strategy has four goals, each supporting Gavi's overall mission: "to save children's lives and protect people's health by increasing equitable use of vaccines in lower-income countries":

1. The vaccine goal: Introduction and scaling-up coverage of high-impact vaccines in eligible countries will continue to be at the heart of the Gavi strategy;
2. The equity goal: Strengthen health systems to increase equity in immunisation;
3. The sustainability goal: Improve Sustainability of Immunisation Programmes;
4. The healthy markets goal: Ensure healthy markets for vaccines and related products.

Since 2009, the WHO SAGE recommended the inclusion of rotavirus vaccines into the national immunisation programme of all countries as part of a comprehensive diarrhoea disease control strategy, complementing improved water, sanitation, hygiene, and treatment that includes the use of low-osmolarity oral rehydration salts (ORS), and zinc supplementation, particularly in countries with high rotavirus gastroenteritis associated fatality rates. Yet, in over ten years, as of 2018, WHO estimates the global immunisation coverage for the rotavirus vaccine RV to have only reached 35 per cent, against a global WHO vaccination target coverage rate of 90 per cent nationally, and 80 per cent in every district. It is estimated that over the period 2018–2027, the Rotavirus vaccination has the potential to prevent nearly 600,000 deaths in Gavi countries. Averted outpatient visits and hospitalisations could lead to treatment savings of approximately USD 484 million from the government perspective and USD 878 million from a societal standpoint.

UNICEF procured 172 million RV courses over 2011-2019. Most of this volume was for countries supported by Gavi, the Vaccine Alliance (Gavi), with only one per cent supplied to Middle-Income Countries not supported by Gavi. UNICEF's procurement steadily increased over the past eight years from 900,000 courses in 2011, to reach 38.7 million courses in 2019 on behalf of 52 countries at a value of USD 134.7 million.

Accelerating access to rotavirus vaccines, which protect against the most severe and deadly form of diarrhoea in young children, in countries where they are needed most, is one of the cornerstone objectives of Gavi, the Vaccine Alliance. Gavi opened window of support for rotavirus vaccination to all Gavi-supported countries in 2009.

Following the previous, UNICEF on behalf of countries began procurement of RV in 2011. This has enabled 48 countries to introduce RV into their routine immunization programmes.

This procurement aims to achieve prices that are more affordable to both the poorest countries and the donors supporting the procurement and supply of vaccines, as well as to self-financing countries, while allowing for the development and maintenance of a healthy vaccine market that meets countries' needs.

With the experience gained after the previous solicitation and with the permanent and long term engagement of stakeholders in the development of Rotavirus Vaccines together with manufacturers as well as third party analyses of the supply market including cost of goods assessments, it is considered appropriate and achievable that vaccine prices to Gavi-eligible countries should be considerably below the currently offered prices.

Therefore, suppliers are encouraged to provide in the proposal pricing and contracting alternatives and/or innovative options, which will allow access the lowest possible prices. These options may include, but are not limited to, volume-based discounts and firm commitments.

Special financing mechanisms/contracting terms: UNICEF will welcome alternative proposals from suppliers which may include special contracting terms (such as for firm commitments or prepayments). If proposals in that sense are received from bidders, such proposals will be evaluated against their utility in reaching the specific objectives of the tender and must be accompanied by a separate valid proposal which fully conforms to the instructions and terms of the tender.

UNICEF may request additional information on costing as well as substantiation of offered prices.

## **2.2 New 2021-2025 high level strategy to leave no-one behind with immunisation approved by Gavi Board.<sup>1</sup>**

Equitable and sustainable use of vaccines, support for health systems and healthier markets to drive Gavi's work: In June 2019 – The Gavi Board today approved a new strategy to guide the Vaccine Alliance's work over the 2021-2025 period, prioritising reaching communities with immunisation that are currently missed, such as those in urban slums, remote areas and conflict settings. The new strategy, which is the culmination of 18 months of consultations with stakeholders, analysis and discussion, will be anchored in the Sustainable Development Goals, echoing its driving mission to leave no one behind. To do this it will target four goals to save lives and protect people's health by increasing the equitable and sustainable use of vaccines:

1. To introduce and scale-up vaccines  
Since 2000, Gavi has supported countries to conduct more than 400 introductions of new and under-used vaccines. In Gavi's first phase the Alliance began by supporting vaccines that protect against six infectious diseases. By 2025 this will have increased to at least 18, including the inactivated polio vaccine (IPV) and new vaccines like rabies, hepatitis B birth dose and multivalent meningococcal. Gavi will also support vaccines, like those for Ebola, cholera and typhoid, that tackle outbreaks, fight antimicrobial resistance and boost global health security. Given the increasing number of Gavi-supported vaccines, the Alliance will help countries to prioritise vaccines based on local epidemiology, national capacity and sustainability considerations.
2. Strengthen health systems to increase equity in immunisation  
Gavi-supported countries reached a record 64 million children with a full course of basic vaccines in 2017, up from 41 million in 2000. Yet still as many as one in ten children in Gavi-supported countries receive no routine vaccines. To reach these missing millions Gavi will bring a much stronger focus on reaching those most marginalised, by strengthening primary healthcare systems, building and sustaining community demand, and using innovation to ensure that immunisation services reach these children. It will also bring a greater focus and enhanced approach to tackle gender-related barriers that stand in the way of reaching every child.
3. Improve sustainability of immunisation programmes  
Gavi actively works with supported countries so they co-finance and gradually take over the financing of their vaccines as they get wealthier. In this regard, countries transition out of Gavi support over time, with the Alliance supporting them so their immunisation programmes remain strong. From 2011 to 2018, countries have increased the amount they themselves spend on Gavi-supported vaccines from US\$ 36 million to US\$ 475 million, and 19 countries are expected to have transitioned out of Gavi support completely by 2020. Gavi will continue its work building political support and

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<sup>1</sup> <https://www.gavi.org/news/media-room/new-2021-2025-high-level-strategy-leave-no-one-behind-immunisation-approved-gavi>

increasing domestic public resources for immunisation and primary health care, as well as supporting countries as they move away from Gavi funding to self-finance their vaccine programmes.

#### 4. Ensure healthy markets for vaccines and related products

Since Gavi was founded in 2000, its market shaping work has helped increase the number of vaccine manufacturers supplying Gavi-eligible countries has expanded from 5 to 17 and prices have reduced dramatically. In recent years the Alliance has widened the focus of its market shaping work towards building healthy markets for each of its vaccines, as well as related products like cold-chain equipment. Gavi will continue to work on balancing all the elements necessary to ensure healthy market dynamics for vaccines and immunisation-related products, focusing on reliable, consistent and affordable supply as an overarching objective. It will also bring a more purposeful approach to driving innovation for immunisation-related products and services.

### 2.3 Product Description

The product for which Proposals are sought is the WHO pre-qualified Rotavirus vaccine, with Vaccine Vial Monitor (VVM) affixed onto each individual vial.

### 2.4 Demand forecast 2022-2028

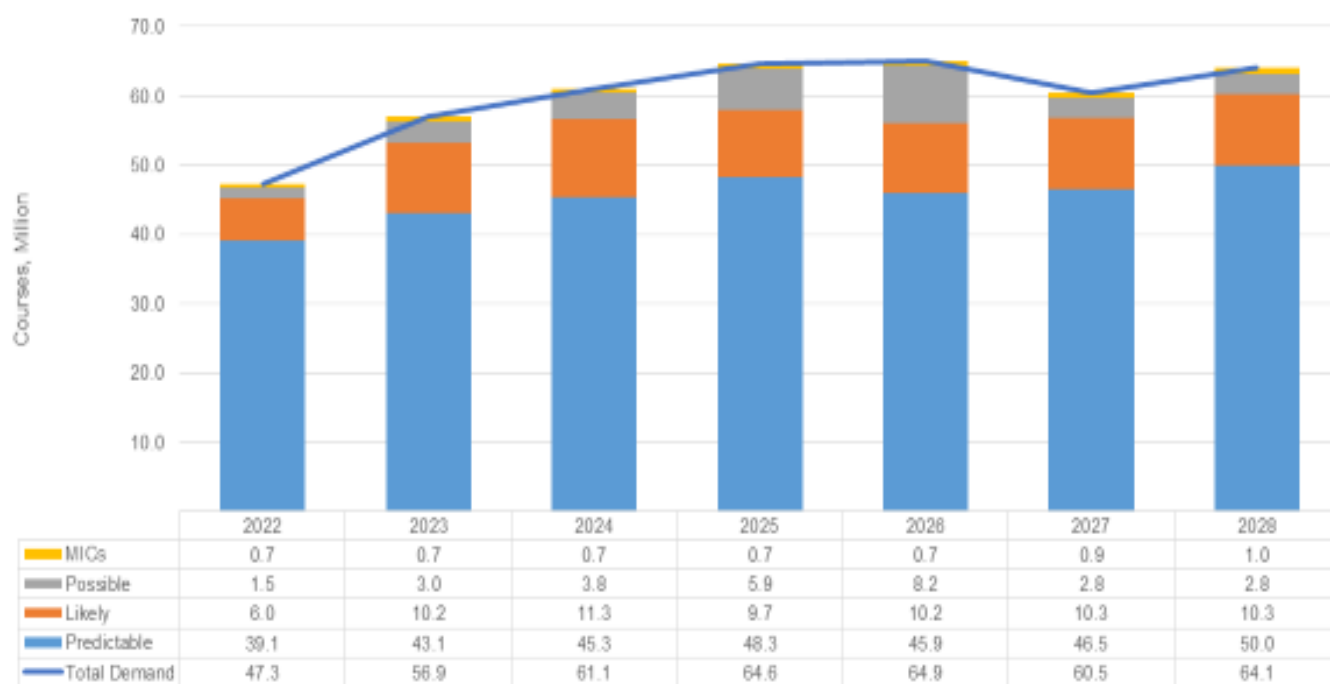
For the purpose of this tender:

- The tender forecast has been based on the short-term demand forecast (UNICEF – Gavi Secretariat), Strategic Demand Scenarios -SDS and demand forecast for the Middle-Income Countries.
- The plans of introductions by countries, have been carefully analyzed based on experience with similar new vaccine introductions.
- It has been considered that the preference for vaccine presentation at this point in time will remain unchanged throughout the tender period. Should countries subsequently indicate preferences for a different vaccine formulation or presentation (to what they currently receive) then the Supply would have to be adapted accordingly. Country switches may be influenced by prices as a result of this tender and innovative vaccines that reduce the cold chain requirements on a per course basis.

The demand from the Gavi 64 countries that are expected to procure through UNICEF is categorized depending on the likelihood that the vaccine will be procured for on-going programmes and also introduced in new countries during the period:

- “Predictable” for countries having introduced and still receiving Gavi support for RV.
- “Likely” for countries:
  - which have been approved but pending introduction,
  - that have already applied, and
  - that have indicated they will submit applications.
- “Possible” Gavi eligible but that have not manifested clear intentions to apply.
- Middle-Income countries demand Eswatini, Namibia, State of Palestine, Congo Brazzaville, Albania, Turkmenistan and PICs; all these countries have already introduced Rotavirus vaccines.

## Demand forecast - Next tender 2022-2028



The above forecast is based on when deliveries are expected to be required by countries. It is nevertheless to be noted that:

- Pending Gavi issuance of authorizations for the on-going programmes, and
- Should any country already authorised be ready to introduce the Rotavirus Vaccine as of 1 January 2022.

UNICEF will aim to award quantities to meet the procurement objectives including to ensure adequate supply to meet demand. Given the uncertainties related to the actual development of demand, in particular with regards to timing of introduction of any new vaccine e.g. in large countries, funding availability, UNICEF may opt not to award the maximum requirement of 294.8 million courses during 2022-2026.

### 2.5 Suppliers' Forecast to UNICEF

It is important that the supply forecasts made by each Bidder to UNICEF and included in the Proposals are accurate and realistic. Ensuring the supply of vaccines to immunization programmes depends to a great extent upon the actual quantities offered by the Bidders in their Proposals and the need stated at country level. Inaccurate and unrealistic forecasts jeopardize supply security and may have a negative impact on immunization programs.

### 2.6 Tender Period

The tender period will cover the years 2022 to 2026. However, the same RFP reference may be used for awarding contracts for additional two (2027-2028) as well as any other middle-income country subject to agreement by both parties.

### 3. LONG TERM ARRANGEMENT(S)

- 3.1 UNICEF wishes to enter into non-exclusive Long-Term Arrangement(s) ("LTA") for the procurement of the vaccines described in Section 2 above, as required from time to time during the term of the LTA. It will be a provision of the LTA that UNICEF will not be committed to purchase any minimum quantity of these vaccines, unless UNICEF specifically agrees to do so in the LTA. UNICEF will not be liable for any cost in the event that no purchases are made under any resulting LTA(s).
- 3.2 Purchases will be made against Purchase Orders to be issued by UNICEF 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.
- 3.3 Any quantities outlined in this RFP, are an estimated forecast of the total requirement for the duration of the LTA or, if so specified, an estimated forecast for the annual requirement. Any estimates are provided in good faith and will not in any way be deemed to be a commitment on the part of UNICEF regarding any quantity for future purchases.

### 4. DURATION

- 4.1 The resulting LTA(s) will be valid for an initial period of Sixty (60) months from 1 January 2022 until 31 December 2026.
- 4.2 The duration of the LTA may be extended for an additional period of Twenty-four (24) months at UNICEF sole discretion and upon mutual agreement between UNICEF and each awarded manufacturer.

### 5. RFP DOCUMENTS

- 5.1 This RFP is comprised of the following:
  - This document
  - The UNICEF General Terms and Conditions of Contract (Goods)
  - Answer Sheets
- 5.2. This RFP is not an offer capable of being accepted or as creating any contractual or other legal rights. Nothing in, or in connection with, this RFP will give rise to any liability on the part of UNICEF.

## PART II – PROPOSAL SUBMISSION PROCESS

### 1. PROPOSAL SUBMISSION SCHEDULE

#### 1.1 Acknowledgement of receipt of RFP.

Bidders are requested to inform UNICEF as soon as possible by e-mail to the Contracts Manager, Mr. Edouard Kamangaza at [ekamangaza@unicef.org](mailto:ekamangaza@unicef.org), with copy (CC) to the Procurement Assistant Mr. Hans Christian Pedersen at [hcpedersen@unicef.org](mailto:hcpedersen@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.**

#### 1.2 Questions from Bidders.

Bidders are required to submit any questions in respect of this RFP by email to the Contracts Manager, Mr. Edouard Kamangaza at [ekamangaza@unicef.org](mailto:ekamangaza@unicef.org), with copy (CC) to the Procurement Assistant Mr. Hans Christian Pedersen at [hcpedersen@unicef.org](mailto:hcpedersen@unicef.org). The deadline for receipt of any questions is seven (7) days before the Proposal Submission Deadline.



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

Bidders 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 Bidders and/or post these on the UNICEF website and/or respond to the question at a bid conference. After any such bid conference, a Questions and Answers document may be prepared and posted on the UNGM website. Information provided orally will not be considered in any way as a change in the RFP.

- 1.3 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 Bidders. Bidders 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. Bidders will not benefit from such ambiguities, errors, omissions, discrepancies, inconsistencies or other faults.
- 1.4 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 Bidders that have received the RFP directly from UNICEF will be notified in writing of all amendments to the RFP. In order to afford prospective Bidders reasonable time in which to take the amendment into account in preparing their Proposals, UNICEF may, at its sole discretion, extend the Submission Deadline.
- 1.5 Samples. Sample packaging materials are required for this solicitation process for technical review. However, if the Bidder has provided samples of the vaccine to UNICEF at any time in the three years preceding the Proposal Submission Deadline, and there has been no change to the packaging materials since last submission, it is not required to comply with this requirement. In this case, the Bidder is required to provide a reference to the solicitation process under which the samples were provided.

Each Proposal must include, with regard to each vaccine offered in the Proposal, three (3) samples of each of the following:

- Vaccine primary container including closure and label
- Vaccine diluent/buffer primary container, if applicable
- Vaccine dropper or any other device and material to be provided in the secondary packaging, if applicable
- Vaccine insert
- Inner box

Samples must be sent to UNICEF at the following address (please note that samples can be sent at room temperature):

UNICEF Supply Division  
 Oceanvej 10-12  
 DK – 2150 Copenhagen  
 Denmark  
 Attention: Vaccine Center, Contracts Manager, Edouard Kamangaza

If the samples provided are different from those submitted to WHO for pre-qualification, the differences should be explained.

Samples should be marked with the RFP number (stated on the front page of this document) and mailed to the address above, arriving at UNICEF's address above no later than the deadline for submitting Proposals.

Failure to provide samples in accordance with the instructions requested under this Section 1.5 may result in invalidation of the Proposal.

- 1.6 Submission Deadline. The deadline for submission of Proposals is as indicated on the front page of this document.

Any Proposals received by UNICEF after the Submission Deadline will be rejected.

- 1.7 Proposal opening. Emailed Proposals received prior to the stated closing time and date will be kept unopened. The Officer of the Bid Section will print the Proposals when the specified time has arrived, and no Proposal received thereafter will be considered. UNICEF will accept no responsibility for the premature opening of a Proposal which is not properly addressed or identified. Due to the nature of this RFP, there will be no public opening of Proposals.

## **2. PROPOSAL AND ANSWERING SHEETS**

- 2.1 Bidders 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 FORM in original. ANSWERING SHEETS have been provided to assist in the organization of the Proposal.

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

- PROPOSAL FORM
- TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET
- QUALITATIVE PROPOSAL SHEET
- QUANTITATIVE PROPOSAL SHEET(S)
- PACKING DETAILS SHEET(S)
- COMMERCIAL TERMS SHEET
- VACCINE REGISTRATION IN COUNTRIES
- ENVIRONMENTAL SUSTAINABILITY SHEET

- 2.5 The Proposal should, at a minimum:

- Include the statement of acceptance of the RFP and resulting LTA terms and conditions and certify the date of validity of the Proposal (PROPOSAL FORM).
- 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.
- Contain qualitative information on account management, proven experience and past performance (QUALITATIVE PROPOSAL SHEET). Guidance on completing this answering is included with the answering sheet.

- Define the proposed vaccine (QUANTITATIVE PROPOSAL SHEET), including the proposed shelf life, quantities offered, calendar of projected availability and price in accordance with the technical requirements.
- Contain packing details for each vaccine presentation offered (PACKING DETAILS SHEET).
- Provide explanations to any requirements or request for exceptions or clarification on the COMMERCIAL TERMS SHEET.
- Provide details on vaccine registration status in countries (Vaccine Registration Sheet) Bidders should complete the sheet in MS Word or excel and convert it into PDF. Handwritten or scanned documents shall be rejected.

2.6 Bidders are invited to offer alternative products and presentations in response to this RFP. An additional blank ALTERNATIVE PROPOSAL SHEET is available for Bidders who wish to offer alternative vaccine presentation(s). It can be submitted in several copies if multiple alternatives will be offered. For each alternative Proposal sheet, information requested under 2.5 is required to be provided.

### 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. Bidders must indicate the validity period of their Proposal. Proposals should be valid for a period through to 31 December 2026. 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 Bidders who decline to extend the validity of their Proposal will 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. 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, faxed or written request received by UNICEF's Bid Section from the Bidder prior to Submission Deadline. 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 companies 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 VI of this RFP-DAN-2020- 503278, including the representations on ethical standards and conflicts of interest.

5.2 Registration as a UNICEF Supplier. UNICEF is part of the United Nations Global Marketplace (UNGM). All Bidders must be registered as a UNICEF supplier 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 Bidders that are not registered in this way. Bidders must include their UNGM registration number in the *Technical and Financial Mandatory Requirements Answering Sheet*.

Simultaneously with application to UNGM, Bidders 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 Bidders to provide information as complete as possible, as awards will only be made to suppliers which meet UNICEF'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 Bidders 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-G, 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-G with UNICEF.
- (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.
- (c) If a joint venture's Proposal is selected for award, UNICEF will award the LTA-G to the joint venture, in the name of its designated lead entity. The lead entity will sign the LTA-G for and on behalf of all other member entities.

### 5.4 Proposals from Government Organizations. The eligibility of Bidders 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 Bidders to inform themselves in preparing their Proposal. In this regard, the Bidders must:

- Examine all terms, requirements and formal submission instructions included in the RFP (including the Instruction to Bidders 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 (and also publicly available on the UNICEF Supply website: [http://www.unicef.org/supply/index\\_procurement\\_policies.html](http://www.unicef.org/supply/index_procurement_policies.html));
- Review the UNICEF policies publicly available on the UNICEF Supply website: [http://www.unicef.org/supply/index\\_procurement\\_policies.html](http://www.unicef.org/supply/index_procurement_policies.html). In particular, Bidders 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 UNICEF's stated requirements. 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. Proposals must be sent to the email to: **supplybid@unicef.org not later than the specified date and time on the cover page of this proposal.** Proposals sent to any other email or sent after the deadline, 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 twenty-five (25) Megabytes) 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 to UNICEF, will be considered the property of UNICEF and will not be returned to the Bidders.
- 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 may share such information on a confidential basis with members of the Procurement Reference Group.
  - UNICEF will make details of each award public as described in Section 2.9 of Part III below.

## 8. MULTIPLE PROPOSALS AND PROPOSALS FROM RELATED ORGANIZATIONS; JOINT VENTURES

### Multiple Proposals not Permitted

- 8.1 Except for alternative Proposals submitted in accordance with Section 2.6 of this Part II, Bidders will not submit more than one Proposal as part of this solicitation process.
- 8.2 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.

## 9. EXPERIENCE AND PAST PERFORMANCE; PROPOSED QUANTITIES

*All information in response to this Section 9 should be provided in the Qualitative Proposal Answering Sheet.*

- 9.1 Experience in Vaccines Supply and Delivery. The Bidder will demonstrate proven experience and qualification in the supply and delivery of the vaccines being proposed. The Bidder should provide the following information:

- Number of years of production and delivery by vaccine (quantities).
- Customer reference list by vaccine. This should include customer contact names and communication information (phone/e-mail/fax) (applicable to all Bidders with less than 3 years' experience as a UNICEF supplier); and
- Names of regulatory bodies where products are registered, and date of original registration. (As per Vaccine Registration Status Sheet).

The Bidder may also supply other information as it considers appropriate in order to demonstrate proven experience and qualification in the supply and delivery of the vaccines being proposed.

- 9.2 Past Performance Record. Bidders that have not previously supplied to UNICEF must demonstrate that they have been able to provide on-time deliveries and maintained production schedules; they must also specify the time period over which the on-time delivery performance has been measured. UNICEF will also review past performance of former and current suppliers to UNICEF by reference to criteria set out in Part III, Section 1. All Bidders are expected to advise UNICEF of their annual production quantity.

- 9.3 Past Performance Record of Joint Ventures. Where a joint venture is presenting its track record and experience in a similar undertaking as those required in this RFP, it should present such information in the following manner:

- (a) Those that were undertaken together by the joint venture; and
- (b) Those that were undertaken by the individual entities of the joint venture expected to be involved in the performance of the activities defined in this RFP.

## 10. PRODUCT DETAILS, QUANTITIES AND PLANS

*All information in response to this Section 10 should be provided in the Qualitative Proposal Answering Sheet.*

- 10.1 Reasonable Proposed Quantity. If the proposed quantity is disproportionally high compared to past years' annual production quantity, the Bidder will demonstrate, that it is able to supply the quantity being proposed by it to UNICEF during the quoted timeframe. The Bidder will also advise UNICEF of the current annual production quantity. WHO/PQT may evaluate the capacity of the Bidder to supply the proposed quantity as part of the technical evaluation of the Proposal.

- 10.2 Medium- and Long-Term Plans. Bidders are requested to provide information on their medium- and long-term plans for production of the vaccine(s) being offered, or of vaccines that may be offered in the future, including an overview of business factors affecting the decision to produce the vaccine at the quantities offered.
- 10.3 National Regulatory Licensure Requirements by the Importing Governments. Bidders are expected to undertake all reasonable efforts to ensure products are registered in the countries that require registration prior to use and to keep UNICEF informed of the progress and development of same. In addition to the information on existing registrations required under Section 9.1, Bidders are requested to provide information on planned and pending registrations and intent to maintain existing registrations upon expiry. (Please refer to VACCINE REGISTRATION STATUS SHEET).
- 10.4 Country of Origin. Bidders shall advise of country of origin of Vaccines offered, including that for Vaccines produced in countries other than that of the Bidder must be indicated, stating the country of origin. Bidders may be required to submit a Certificate of Origin of Goods issued by the Chamber of Commerce or other equivalent authority.
- 10.5 Sub-contractors. Bidders must identify in their Proposal any products which may be offered by themselves but originate from another supplier and/or country. All sub-contracting arrangements will be reviewed by UNICEF as part of its evaluation of the Proposal. In addition, all Bidders not producing the vaccine offered or their own vaccine bulk concentrate must indicate the source(s) for the vaccine quantity offered. Bidders will provide evidence of the contractual agreements for the quantities being offered. Furthermore, the Bidder must confirm that the quantities offered do not violate any contractual commitments made between the Bidder and the vaccine or bulk concentrate manufacturer.
- 10.5 Catalogues. Bidders, who have not already done so, are kindly requested to include a copy of their current catalogue or list of products offering in their Proposal.

## 11. ACCOUNT MANAGEMENT

*All information in response to this Section 11 should be provided in the Qualitative Proposal Answering Sheet.*

- 11.1 The Bidder will provide UNICEF with 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.
- 11.2 UNICEF expects the primary contact person(s) to be able to execute the appropriate account management which includes: accurate and reliable planning and forecasting, efficient order processing, accurate and complete documentation, close production follow up, facilitate timely submission to NRA for release and follow-up of the same, shipping and logistics as well as any other related issues including fast response time to inquiries. Communication and documentation shall be in English. The communication is seen as an important prerequisite for successful account management and needs to be frequent, timely and accurate.
- 11.3 Suppliers are not expected to have direct contact with recipient country Governments.

## PART III – EVALUATION OF PROPOSALS; AWARDS

### 1. EVALUATION OF PROPOSALS

#### 1.1 Evaluation.

The evaluation is carried out by UNICEF in accordance with UNICEF's regulations, rules and practices and all determinations are made in UNICEF's sole discretion.

After opening the Proposals, the Proposals will be evaluated as follows:

**1.1.1 General:**

The merits of each Proposal will be evaluated to assess its ability to support the objectives of this RFP as set out in Part I. UNICEF will evaluate each Proposal to determine whether the products offered are acceptable commercially and technically and are of the required quality.

**1.1.2 Review of Compliance with Mandatory Requirements**

Each Proposal will be evaluated for compliance with the mandatory requirements of this RFP. Compliance with the Mandatory Technical Requirements will be evaluated by WHO. Compliance with all other mandatory requirements will be evaluated by UNICEF. 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. If the Proposal is deemed interesting in its potential ability to support the objectives of this tender and meets the Mandatory Technical Requirements, except that the product is not WHO pre-qualified, UNICEF will proceed as outlined in Part IV Section 15.

**1.1.3 Evaluation of Quantitative and Qualitative Content:**

All the quantitative and qualitative information requested, and the related evaluation criteria are provided in the table below. During this evaluation, the nature of the commercial proposal will be studied and compared to the evaluation criteria. In order to determine to what extent a Proposal is found satisfactory, all quantitative data will be evaluated together with the qualitative data to determine how the factors presented in each Proposal will support the RFP objectives set out in Part I.

**1.1.4 Awards will be determined based on the following criteria:**

1. Contribution to meeting the tender objectives
2. Products meeting the technical specifications, including WHO pre-qualification
3. Timing of product availability from 2022 to 2026
4. FCA Price

The detailed evaluation criteria to be used to assess the proposals are shown in the below table.

Overview of Quantitative Information	
Objective	Evaluation criteria
Maintain a long-term competition in the Rota market <ul style="list-style-type: none"> <li>▪ Ensure three viable suppliers remain in the market</li> <li>▪ Improve the weighted average price (WAP) per child to fully vaccinate with RV to an appropriate and sustainable level.</li> </ul>	<ul style="list-style-type: none"> <li>• FCA price nearest international airport, including VVM and cold chain monitors</li> <li>• Product offered</li> <li>• Quantity offered; conditions of quantity offered; demonstration of capacity to provide quantities offered</li> <li>• Total production capacity</li> <li>• Lead times for quantities within forecast</li> <li>• Product shelf-life and shelf life at time of delivery</li> <li>• Vial size, presentation and formulation offered</li> <li>• Agreement to store vaccines on a need basis as well as under what circumstances</li> <li>• Cold chain requirement of offered products</li> <li>• Payment terms</li> <li>• Validity of offer</li> </ul>
Overview of Qualitative Information	
Objective	Evaluation Criteria
Achieve security of supply to meet demand. <ul style="list-style-type: none"> <li>▪ Ensure sufficient supply of products that accommodate</li> </ul>	<ul style="list-style-type: none"> <li>• WHO prequalified vaccine</li> <li>• Registrations in importing countries (planned, pending, actual, expiry, intend to maintain)</li> <li>• Access to necessary bulk capacity</li> </ul>



<p>country preferences, including new programmatically improved presentations.</p> <ul style="list-style-type: none"> <li>▪ Manage uncertainties due to potential switches to other products or new presentations</li> </ul> <p>Gather knowledge about appropriate and innovative products.</p>	<ul style="list-style-type: none"> <li>• Supplier performance (existing supplier) <ul style="list-style-type: none"> <li>○ Proven capacity to supply offered and forecasted quantities</li> <li>○ Reliable and firm forecasted supply</li> <li>○ Realistic quantity offered</li> <li>○ Timeliness of purchase order acknowledgement</li> <li>○ Timeliness of notification of goods readiness</li> <li>○ Timeliness of delivery</li> </ul> </li> <li>• Medium and long-term plans for production of the vaccine being offered.</li> <li>• Account management resources (organization charts with names) and customer service capabilities including accurate and reliable planning and forecasting; willingness to include a Vaccine Arrival Report as part of the shipping documents.</li> <li>• Experience in vaccine supply and delivery (number of years of production and delivery (quantity))</li> <li>• Adherence to packing and shipping requirements, including temperature monitoring devices.</li> <li>• Acceptance of inclusion of additional demand as and when new demand is confirmed by countries.</li> <li>• Indicate factors that influence the price setting</li> <li>• Reciprocity in any special contracting terms</li> <li>• Agreement to publication of awarded prices and quantities</li> </ul>
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## 1.2 Minimum Order Quantity:

Bidders must declare in their Proposals if there will be any minimum order quantity(ies) for the vaccine(s) detailed in the schedule to this RFP. Any such minimum order quantities will be considered as part of the evaluation process.

## 1.3 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.

## 1.4 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.

## 1.5 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, the forecasted quantities will be awarded to Bidders in accordance with the objectives of this RFP.

### 2.2 Limited Award:

If a Bidder has not been a supplier to UNICEF previously, UNICEF reserves the right to introduce the supplier incrementally during the award period and assess the performance closely.

### 2.3 Award Period:

UNICEF reserves the right to make an award for a shorter period of time than announced in this RFP if, in UNICEF's opinion, this would better meet the procurement objectives of this RFP or be in the best interested of UNICEF.

## **2.4 Negotiation**

UNICEF reserves the right to negotiate with the Bidder(s) in support of achieving the procurement objectives of the RFP.

## **2.5 Award Notification**

UNICEF will notify the Bidder(s) that has/have been awarded the LTA-G(s) resulting from this solicitation process. UNICEF will also notify the other Bidders of the outcome of this solicitation process.

## **2.6 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 2.8 below.

## **2.7 Award Publication**

UNICEF will make each award public by publishing the following information on the UNICEF website: the supplier name, vaccine(s), duration of award, and total award value. UNICEF reserves the right to disclose the price and quantity information relating to any LTA(s) and related Purchased Orders resulting from this RFP. UNICEF may also make public the annual awarded Weighted Average Prices (WAPs) for each vaccine presentation.

## **2.8 Bidder Acknowledgement**

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

## **3. The LTA 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 LTA and linked Purchase Orders awarded in connection with this RFP.

3.2 By signing the Bid Form, each Bidder is deemed to have confirmed its acceptance of the LTA and the UNICEF General Terms and Conditions (Goods).

## **4. RIGHTS OF UNICEF**

4.1 UNICEF reserves the following rights:

(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 Bidder 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.

4.2 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 4.1 above.

4.3 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, 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. 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 – MANDATORY TECHNICAL REQUIREMENTS

### 1. COMPLIANCE WITH TECHNICAL SPECIFICATIONS AND WHO REQUIREMENTS

1.1 The vaccines offered must meet all the World Health Organization (WHO) requirements currently in force. It should be understood that if WHO requirements are changed during the period of validity of the LTA(s) resulting from this RFP, the corresponding supplier(s) will be required to implement such changes per agreed upon timeline.

1.2 UNICEF reserves the right to reject any vaccine which does not conform to the required specifications, as per the terms contained in “Delivery not Acceptance: Consequences of Delayed Delivery and Non-Conforming Goods” under the UNICEF General Terms and Conditions (GTC) which are annexed to and constitute an integral part of the present RFP and any resulting LTA(s) and Purchase Order(s)

### 2. WHO PRE-QUALIFICATION

Only vaccines which are pre-qualified by WHO will be procured by UNICEF.

### 3. PRODUCTION AND TESTING

3.1 The vaccines offered will be produced and tested in conformity with the requirements of national legislation and the following recommendations established by the World Health Organization (WHO), or any subsequent revisions.

- (a) Good Manufacturing Practices for pharmaceutical products: main principles (WHO\_TRS\_986\_annex 2 GMP main principles)
- (b) Good manufacturing practices for sterile pharmaceutical products (WHO Technical Report Series No.961, 2011. Annex, 6)
- (c) Good Manufacturing Practices for Biological Products (WHO Technical Report Series No. 999, Annex 2, 2016)
- (d) Good Manufacturing Practices. Water for pharmaceutical use (WHO Technical Report Series No. 970, annex 2 (2012)
- (e) WHO good practices for pharmaceutical quality control laboratories (WHO Technical Report Series No. 957 Annex 1)

- (f) WHO good practices for pharmaceutical microbiology laboratories. WHO Technical Report Series, No. 961), Annex 2
- (g) Guidance on good data and record management practices (WHO Technical Report Series, No. 996, Annex 5 (2016))
- (h) WHO guidelines on quality risk management. WHO Technical Report Series, No. 981), Annex 2
- (i) Good Manufacturing Practices: Requirements for sampling of starting materials (WHO Technical Report Series No. 929, 2005. Annex 2)
- (j) Supplementary guidelines on good manufacturing practices: validation. WHO Technical Report Series, No. 937), Annex 4
- (k) WHO guidelines for drafting a site master file. (WHO Technical Report Series, No. 961), Annex 14
- (l) Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Technical Report Series, No. 961), Annex 9
- (m) General Requirements for the Sterility of Biological Substances (WHO Technical Report Series No. 530, Annex 4, 1973), Amendment 1995 (WHO Technical Report Series No. 872, Annex 3, 1998)
- (n) Recommendations for the evaluation of animal cell cultures as substrates for the manufacture of biological medicinal products and for the characterization of cell banks (WHO Technical Report Series No. 978, annex 3, 2013)
- (o) WHO Guidelines on Nonclinical Evaluation of Vaccines (WHO Technical Report Series No. 927, Annex 1, 2005)
- (p) Guidelines on the nonclinical evaluation of vaccine adjuvants and adjuvanted vaccines (WHO Technical Report Series No. 987, annex 2, 2014)
- (q) Guidelines on Clinical Evaluation of Vaccines: Regulatory Expectations (WHO Technical Report Series No. TRS 1004, Annex 9, 2017)
- (r) Guidelines on stability evaluation of vaccines (WHO Technical Report Series No. 962, Annex 3, 2011)
- (s) Guidelines on the stability evaluation of vaccines for use under extended controlled temperature conditions (WHO Technical Report Series No. 999, Annex 5, 2016)
- (t) Guidelines on procedures and data requirements for changes to approved vaccines (WHO Technical Report Series No. 993, Annex 4, 2015)
- (u) Guidance on Variations to a Prequalified Vaccine  
[http://www.who.int/immunization\\_standards/vaccine\\_quality/PQ\\_VXA\\_Variations\\_V7.pdf?ua=1](http://www.who.int/immunization_standards/vaccine_quality/PQ_VXA_Variations_V7.pdf?ua=1)
- (v) Report of a WHO Consultation on Medicinal and other Products in relation to Human and Animal Transmissible Spongiform Encephalopathies (WHO/BLG/97.2)
- (w) WHO Guidelines on Transmissible Spongiform Encephalopathies in relation to Biological and Pharmaceutical Product <http://www.who.int/biologicals/publications/en/whotse2003.pdf?ua=1>

#### 4. VACCINES

The offered vaccines must meet all the WHO requirements and recommendations currently in force.

- Guidelines to assure the quality, safety and efficacy of Recombinant Rotavirus Virus-Like Particle Vaccines (WHO/BS/06.2050)

#### 5. NATIONAL REQUIREMENTS

- 5.1 It is recognized that, because of the special needs for vaccines for the developing countries, the specifications prepared for UNICEF by WHO may be more detailed than those given in the WHO Requirements, although they are not in conflict with them.
- 5.2 In those aspects where WHO GMP requirements are not detailed enough, other international guidelines will be followed by the manufacturer – e.g. those of the European Union (EU), PDA (Parenteral Drug Association), and United States Pharmacopoeia (USP) – and appropriate justification for the choice will be provided. In such cases WHO will assess against the standard used.

## 6. PROGRAMMATICALLY PREFERRED VACCINE CHARACTERISTICS

Some vaccine characteristics have been identified as programmatic preferences, although they are not currently mandatory for acceptance for prequalification evaluation. These characteristics are described in WHO's guideline "Assessing the programmatic suitability of vaccines considered for WHO prequalification" (WHO/IVB/14.10). The below preferred characteristics will in particular be considered by UNICEF:

- 6.1 Labelling and bar coding: Labelling and bar coding are included in WHO's guideline "Assessing the programmatic suitability of vaccines considered for WHO prequalification" as preferred vaccine characteristics. Programmatic preference for Labels and Barcodes are:
- Labelling: Primary and secondary containers should be labelled according to the principles set out in TRS 996, Annex 2.
  - Bar Coding: With implementation latest 31st December 2021, bar codes are required on all packaging levels used by manufacturers for supply to UNICEF, with the exception of primary packaging. Bar codes shall conform to GS1 standards, allowing through a unique company prefix to identify vaccines available in the global supply chain from each manufacturer. The bar codes shall include Global Trade Item Number (GTIN), lot number and expiry date.
- 6.2 Thermostable vaccines: Programmatic preference for thermostable vaccines allowing application of the Controlled Temperature Chain - keeping vaccines at temperatures outside of +2° to 8° for a limited period of time under monitored and controlled conditions as appropriate to the stability of the antigen:
- Vaccines and diluents that can be stored for extended periods at temperatures above +8°
  - Vaccines with data and licensing allowing for higher temperature storage. If feasible, use 40° as the current threshold target.

## 7. CHANGES IN FORMULATION, METHODS OR PROCESSES

- 7.1 For WHO prequalified vaccines, changes introduced in formulation, in methods of manufacturing in facilities or in any other aspects of production which might result in a change of safety and/or efficacy of the vaccines, or which change the licensing agreement between the manufacturer and the National Regulatory Authority should be notified to the WHO Department of Essential Medicines and Health Products, WHO's Prequalification Team (hereafter WHO PQT) in accordance with the WHO agreed timeframe. If the regulations of the country of manufacture do not require approval of the changes by the NRA, then the WHO Department of Essential Medicines and Health Products (WHO PQT) in Geneva should be consulted in a timely manner before the changes are introduced.
- 7.2 Such changes may require additional activities by WHO to assure continued compliance with WHO requirements.

## 8. LABELS AND PACKAGE INSERTS

- 8.1 The labels on vaccine primary containers will be those approved by WHO and will be affixed with water-resistant adhesive so that the labels do not become loose or fall off. Labels should state the name of vaccine, name of manufacturer, lot number, dose and mode of administration, expiry date, storage temperature, and number of doses per primary container. Expiry date and lot number will be printed on each primary container in indelible ink. Adsorbed vaccines will have the warning "DO NOT FREEZE".
- 8.2 The package insert will be that approved by WHO during prequalification or as revised and approved by WHO and will be printed at least in English, French, Portuguese and Russian. Spanish and Arabic are optional. Separate inserts in the language appropriate for the country of destination will be welcome. In all inserts the following should be inserted under "Description of vaccines". "The vaccine fulfils WHO requirements for Rotavirus Vaccine".

## 9. OVER LABELLING

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9.1 Over labelling will only be accepted if the following criteria are met:

- (a) The over labelling of the vaccine has been approved by the National Regulatory Authority of the country of manufacture (released by NRA).
- (b) UNICEF Supply Division is consulted prior to delivery.
- (c) The receiving country agrees to receive the vaccine and communicates this fact to the UNICEF Supply Division.

## 10. CLOSURES

Vaccines in vial presentations will be fitted with closures that conform to ISO standards 8362 (parts 2 through 7, as applicable). The container/closure system must be the same as submitted for prequalification.

## 11. VACCINE VIAL MONITORS (VVM)

UNICEF requests vaccines with Vaccine Vial Monitors.

Vaccine vials should be fitted with Vaccine Vial Monitors (VVMs). VVMs should comply with WHO PQS Performance Specification (WHO/PQS/E06/IN05.1) or such updated version and in the PQS independent type-testing protocol (WHO/PQS/E06/IN05.VP.1). More information about VVM can be found here:

[http://www.who.int/immunization\\_standards/vaccine\\_quality/vvm\\_10years\\_index/en/](http://www.who.int/immunization_standards/vaccine_quality/vvm_10years_index/en/)

## 12. RELEASE CERTIFICATION

Final acceptance of vaccines will be subject to lot release by the National Regulatory Authority (NRA) of the country of manufacture or the NRA of Record agreed to with WHO during review for prequalification. Lot release certificates must be based as a minimum on review of the lot summary protocols.

The lot release certificate issued by the NRA of Record stating that the vaccine lots supplied meet the relevant national and WHO requirements, should accompany each shipment. Copies should be provided, upon request, to WHO PQT. Lot release certificates and Production and Control Summary Lot Protocols (according to WHO guidelines) will be provided, upon request, to consignees, UNICEF or WHO.

## 13. RETENTION OF SAMPLES AND TESTING

Samples of each batch of vaccine supplied under the LTA(s) and purchase orders resulting from this RFP will be retained by the corresponding supplier until their expiry date. The number of samples to be retained for each type of vaccine is specified in the table below.

Vaccine	Number of vials of finished vaccine required (and appropriate diluent when needed)
Rotavirus Vaccine	Twenty (20) vials

These samples will be provided, upon request, to WHO PQT for testing.

## 14. SHELF LIFE

The vaccines supplied under the LTA(s) and purchase orders resulting from this RFP will be supplied with the maximum shelf life possible consistent with current vaccine production technology and stability data. Unless

separately authorized by UNICEF, the remaining shelf life at the time of dispatch will not be less than the ones stated below:

<b>Vaccine</b>	<b>Remaining shelf life at the time of dispatch</b>
Rotavirus Vaccine	Eighteen (18) months

## **15. PROPOSALS OF VACCINES NOT YET WHO PRE-QUALIFIED**

If the bidder offers a vaccine that is not WHO pre-qualified, the proposal must include a detailed plan on the timeline to obtain WHO pre-qualification. The timeline should include information regarding the vaccine and plans for manufacturing and licensing:

- Vaccine Development: Status and plans, including source of bulk antigens to be used;
- Clinical Trials: Trials conducted so far and planned, with timelines;
- National Regulatory Registration: Status and plans for registration, including NRA that would be responsible for release of the finished vaccine and planned vaccine presentations; and
- File submission to WHO: Status and plans.

If the bidder's proposal was deemed of interest to UNICEF, UNICEF will advise the bidder of such and will request that UNICEF be kept informed about the progress of the submitted timeline.

If the offered vaccine obtains WHO pre-qualification during the award period and upon confirmation that the mandatory requirements of this RFP are met, UNICEF would consider awarding a quantity to the bidder under one or more of the following conditions:

- UNICEF is facing a monopoly situation or a near monopoly situation;
- Lack of performance of current supplier(s);
- Insufficient supply from current supplier(s);
- If it meets the specific objectives of the tender; or
- To meet unallocated demand quantities.

The quantities considered for award would be those not met under established contracts or quantities that could be reallocated from existing LTA(s) after negotiation with the corresponding suppliers.

## **16. ADVERSE EVENTS AND RECALLS**

In the execution of LTA(s) and purchase orders resulting from this RFP, the corresponding supplier shall in case of:

### **16.1 Adverse Events**

- The Supplier shall comply with all applicable laws, regulations and requirements. This includes monitoring, reporting and any consequent modification of product information regarding vaccine safety required under national laws and regulations in the country of manufacture, in any other country in which the vaccine receives marketing authorisation and also as required to fulfil the conditions of WHO prequalification. The terms used surrounding adverse experiences shall have the meanings set forth in the International Conference on Harmonization (ICH) of Technical Requirements of Pharmaceuticals for Human Use E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting and the WHO Global Manual on Surveillance of Adverse Events Following Immunization.

- The Supplier shall promptly inform WHO/PQT and UNICEF of serious issues (actual or alleged) regarding vaccine safety and shall provide them with information sufficient to consider such issues. UNICEF shall promptly notify the Supplier of serious adverse events involving the Supplier's vaccine of which they become aware.

#### 16.2 Quality complaints and recalls

- The Supplier shall notify UNICEF of any quality complaints that it becomes aware of related to the vaccine delivered to UNICEF. If any circumstance or event may require or make reasonably appropriate any recall or withdrawal of the vaccine or any field alert regarding the vaccine, the supplier shall immediately notify WHO/PQT and UNICEF and other appropriate entities. When a recall, withdrawal or field alert is required or appropriate, the supplier shall take all appropriate actions and shall bear all associated expenses.

### 17. **PACKING AND SHIPPING**

Packaging/Shipping arrangements will be in accordance with the WHO "Guidelines on the International Packaging and Shipping of Vaccines", (WHO/IVB/05.23, [http://apps.who.int/iris/bitstream/10665/69368/1/WHO\\_IVB\\_05.23\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/69368/1/WHO_IVB_05.23_eng.pdf)) or any subsequent revisions. Detailed instructions regarding shipping and requirements for invoice and shipping documents will be provided to the awarded Supplier as part of each Purchase Order.

Bidders should be informed that WHO is currently revising the "Guidelines on the International Packaging and Shipment of Vaccines". The revision is being conducted by WHO in consultation with industry. Any changes in requirements in the Guidelines will be implemented within a reasonable timeline.

All containers, invoices and shipping documents are to bear the expiry dates of the vaccine and appropriate storage temperatures.

### 18. **PACKING OF DILUENT FOR RECONSTITUTED VACCINES**

The packed quantity per box of the diluent vials of a vaccine should be equal to the packed quantity per box of the vaccine vials.

### 19. **PACKING, PACKAGING, PACKING LIST, LABELLING AND DANGEROUS GOODS INSTRUCTIONS**

- 19.1 Under the LTA-G, the supplier will be required to comply with the requirements (as updated from time to time) for packing, packaging, packing list, and labelling goods set out in the "Guidelines on the International Packaging and Shipping of Vaccines", (WHO/IVB/05.23) (or any subsequent revisions to such Guidelines) and the additional requirements (if any) for packing, packaging, packing list, and labelling goods set out in the specifications for the Goods in the Mandatory Technical Requirements and the relevant Purchase Order. This includes those requirements that apply to dangerous goods. The classification of goods (including packaging) as "dangerous goods" is a supplier responsibility and must be communicated to UNICEF when submitting the Proposal. For any goods (including packaging) classified as dangerous goods, Bidders must submit all relevant Material Safety Data Sheets indicating accurate classification for transport purposes, storage, labeling and shipping requirements when submitting the Proposal.
- 19.2 The supplier will also be required to comply with the instructions for markings of the Goods set out in the specifications for such Goods [and the relevant Purchase Order].
- 19.3 The supplier's costs of complying with the requirements of this Section 19 will be the sole responsibility of the supplier.

### 20. **GROSS WEIGHT AND VOLUME**

Bidders are required to state the total estimated gross weight and volume of the vaccines offered as part of the PACKING DETAILS SHEET.



**21. TRANSPORT AND STORAGE**

All shipments of vaccines on behalf of UNICEF will be arranged through UNICEF designated freight forwarders, unless otherwise specified. The awarded Supplier will contact and provide assistance and all documents to the UNICEF designated freight forwarder well in advance of the scheduled delivery date. Any expected delay in delivery of the shipment will be communicated to UNICEF and the UNICEF designated freight forwarder without delay.

**22. STANDARD DOCUMENTS**

In the execution of LTA(s) and PO(s) resulting from this RFP, the Supplier will submit to the UNICEF Freight Forwarder the following documentation:

- a) Invoice;
- b) Packing list; the Packing List must clearly indicate the Purchase Order item number(s) contained in each package, a description of the Goods, their value, quantity, gross weight, volume in cubic meters, dimensions and markings, expiry date of vaccine, and appropriate storage temperature;
- c) Release certificate issued by the National Regulatory Authority of the country of manufacture for each lot of vaccine supplied;
- d) If applicable, hazardous Goods documents, such as in the case of use of dry ice;
- e) Any other documents as specified in each Purchase Order.

**23. TIME TEMPERATURE MONITORING DEVICE**

In order to monitor the cold-chain during international transit to Government central stores of vaccines manufacturers are requested to include WHO PQS prequalified electronic shipping indicators (E006 category) in each and every shipping carton. These devices meeting WHO requirements for international shipments can be found at the following site:

[http://www.who.int/immunization\\_standards/vaccine\\_quality/pqs\\_e6\\_temp\\_monitoring/en/](http://www.who.int/immunization_standards/vaccine_quality/pqs_e6_temp_monitoring/en/)

**24. VACCINE ARRIVAL REPORT (VAR)**

Manufacturers will include a Vaccine Arrival Report together with the other shipping documentation in shipping box number one. The current VAR will be provided by UNICEF upon award. An example VAR is included in the Guidelines on the International Packaging and Shipping of Vaccines, WHO/IVB/05.23.

[http://apps.who.int/iris/bitstream/10665/69368/1/WHO\\_IVB\\_05.23\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/69368/1/WHO_IVB_05.23_eng.pdf)

**25. DELIVERY PREPARATION LEAD-TIME**

Bidders will indicate, as part of the QUANTITATIVE PROPOSAL SHEET, the delivery preparation lead-time for each vaccine and presentation after receipt of an order. Delivery preparation lead-time includes time to complete administrative arrangements, including documentation, packing and marking. The maximum lead time should not exceed 30 days.

**PART V – 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 Most Favoured Customer. The Bidder confirms that the prices with respect to the Goods specified in the Proposal are the most favourable prices available to any customer of the Bidder (or any of the Bidder's affiliates). If the Bidder offers to sell the same Goods at a price lower than the price effective under the LTA-G, the Bidder will offer the same price to UNICEF for the remaining validity period of the LTA-G.

- 1.2 Pricing based on Delivery Term. Bidders are requested to provide unit pricing in accordance with the following RFP-DAN-2020-

delivery terms (INCOTERMS 2020):

**FCA – FCA named airport [SPECIFY NAME OF AIRPORT]**

Failure to quote in accordance with the requested INCOTERMS may, in UNICEF's discretion, result in invalidation of the Proposal.

- 1.3 Currency. The currency of the proposal shall be either 1) US Dollars or 2) US Dollars and EURO. Bidders 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.
- 1.4 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. Bidders 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.
- 1.5 Affordability of Pricing. UNICEF believes in paying a price that is affordable to Governments and donors and a price that reasonably covers manufacturers' minimum requirements. The Bidder is requested to provide information on factors that influence the pricing offered to UNICEF including, the basis for any quantity-based pricing. Any price increase over previous years' pricing should be explained in the *Qualitative Proposal Answering Sheet*.
- 1.6 Maximum Pricing. Prices offered by Bidders, 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.
- 1.7 Taxes. Article II, Section 7, of the Convention on the Privileges and Immunities provides, inter alia, that the United Nations, including UNICEF 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.
- 1.8 Tiered Pricing. In accordance with its Vaccine Procurement Principles, UNICEF gives suppliers the option to quote tiered pricing in accordance with the World Bank classification of countries by income level for countries not supported by Gavi.
- 1.9 Discounts. Bidders are requested to advise as to:
  - (a) Quantity / volume discounts, in form of large quantity / volume discounts and staircase pricing (i.e. varying prices according to different quantities procured);
  - (b) Cumulative quantity / volume discount levels i.e. discounts that increase as the cumulative order value/volume increases throughout the validity of the LTA-G;
  - (c) Early payment discounts, i.e. payment within a specified period of time faster than UNICEF's standard payment term of 30 days net;
  - (d) Any other unconditional discounts.

Any discount offered in the successful Proposal will be reflected in the awarded LTA and will be applied in the affected Purchase Orders issued under such LTA.

- 1.10 Alternative Proposals. UNICEF welcomes alternative Proposals, including Proposals which may include special contracting terms or where pricing is conditional upon firm UNICEF commitment to defined quantities, or subject to

pre-payment or advanced payments. Such Proposals will be evaluated against their utility in reaching the specific objective(s) of the RFP. Any firm commitment by UNICEF would be subject to funding availability as well as other agreed upon conditions, including reciprocity clauses (e.g. liquidated damages).

- 1.11 **Payment Terms.** Unless an alternative Proposal has been awarded that includes pre-payment or advanced payment, invoices may be issued to UNICEF only after the delivery terms of the Purchase Order (as issued in accordance with the provisions of the LTA-G) have been fulfilled. The standard terms of payment are net 30 days, after receipt of invoice and required supporting documentation. Payment will be effected by bank transfer in the currency of the Purchase Order.

## **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 LTA 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 minimum delivery lead-time specified in the LTA. Bidders 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 of delay in delivery of Goods, as well as the consequences of delay, and UNICEF's rights and remedies in respect of any such delay, are governed by the UNICEF General Terms and Conditions of Contract (Goods).
- 2.4 The LTA also specifies that, without prejudice to any of the other rights and remedies of UNICEF, if the supplier fails to deliver the Goods under any Purchase Order in accordance with the stated time for delivery, or if UNICEF exercises its right to reject Goods that do not conform to the requirements in the LTA and the relevant Purchase Order, UNICEF may claim liquidated damages from the supplier and, at UNICEF's option, the supplier will pay such liquidated damages to UNICEF or UNICEF 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 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 or the relevant Consignee. The supplier will not be responsible for the costs of such pre-delivery

inspection.

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

(c) The supplier will advise UNICEF of the location of the manufacturing facility/facilities. UNICEF 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 as soon as possible and at least three (3) working days prior to the Goods readiness date.

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

3.2 The Supplier acknowledges that any inspection of the Goods by UNICEF 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 carries out such pre-delivery inspection of the Goods.

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

#### **4. TEMPORARY STORAGE**

4.1 Under the LTA, the supplier will be required to properly store, from time to time and at no cost to UNICEF, finished products of vaccines for delivery at a later date. Storage of vaccines will be under controlled environmental conditions to facilitate the conservation of the vaccines. The storage facilities will comply with all national regulations for the storage of vaccines in force in the country where the storage facility is located.

#### **5. INSPECTION OF FACILITIES**

5.1 Under the LTA, the supplier will be expected to permit UNICEF 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.

#### **6. MONTHLY ALLOCATION REPORTING**

6.1 Under the LTA, the supplier will be required to provide UNICEF with a monthly allocation report, listing the following for each vaccine presentation:

- the total quantities forecasted for delivery during the next six-month period;
- total quantity in stock with NRA release;
- total quantity in stock pending NRA release for UNICEF;
- the total quantities in production for UNICEF; and
- any additional relevant information the Parties agree to include

#### **7. NATIONAL REGULATORY LICENSURE REQUIREMENTS BY THE IMPORTING GOVERNMENTS**

Under the LTA, the supplier is expected to continuously update UNICEF 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 [(or

withdrawal of registrations)] in any countries.

## 8. WARRANTY

8.1 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 and 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 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;
- (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.

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

8.3 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, at UNICEF'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.

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

## 9. PERFORMANCE MONITORING

9.1 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.

9.2 The UNICEF General Terms and Conditions of Contract (Goods) specify that UNICEF will monitor the supplier's performance under the LTA 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.

- 9.3 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	Less than or equal to 5 working days after Purchase Order placement
	Timeliness of Notification of Goods Readiness	Notification of Goods' Readiness parameter (Greater than or equal to 3 working days before potential delivery)
	Timeliness of Delivery	Less than or equal to 5 working days after Purchase Order delivery date

## PART VI – 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 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 will refrain from any action which may adversely affect UNICEF 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, 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 requires that all Bidders 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 regard 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 against fraud, in the solicitation process and in the performance of any resulting LTA-G 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](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.unqgm.org](http://www.unqgm.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 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 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.

## PART VII – ANSWERING SHEETS

### PROPOSAL FORM

The Undersigned, having read the Instructions to Proposers of this Request for Proposal **RFP-DAN-2020- 503278** and all related documents hereby offers to supply the goods and contributions to meet the overall objectives sought in



accordance with any specifications stated 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 and any other terms and conditions specified in this RFP.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Name & Title: \_\_\_\_\_

Company: \_\_\_\_\_

Postal Address: \_\_\_\_\_

Tel No: \_\_\_\_\_

Fax No: \_\_\_\_\_

E-mail : \_\_\_\_\_

Validity of Offer: \_\_\_\_\_

## TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET

**Please include a response to the following.**

1. Does the product offered have WHO pre-qualification?
2. If the answer to the above is "No", then please provide information on your timeline to obtain WHO pre-qualification.
3. If the answer to question 1. above is "No", please also provide the following information:
  - a) Name of the NRA in the country of origin.
  - b) Name of the NRA taking responsibility for the regulatory oversight of the vaccine, including issuing lot release certificates.
  - c) List the countries where the offered product is licensed:

4. 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.

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

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

## QUALITATIVE PROPOSAL SHEET

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

1. Please provide full description of product being offered:
  - a. Name \_\_\_\_\_.
  - b. Presentation \_\_\_\_\_.
2. Advise the number of years that your company has production and delivery of the offered product(s).
3. Provide a list of the names of regulatory bodies in MICs where your products are planned for or pending registration, already registered as well as original date of registration, expiry date of registration as applicable and intent to maintain registration (Complete the vaccine registration status Sheet below in word and share a PDF copy).
4. Given that UNICEF has requested prices that are affordable to country governments and donors, please indicate factors influencing your price setting.
5. Please indicate your willingness to include additional middle-income countries into this offer, with the flexibility of country specific prices and other terms and conditions.
6. Please indicate your acceptance of additional awards, that may be offered later in response to this RFP for the outer years as well as other middle-income countries subject to agreement by both parties.
7. Please include in your Proposal 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 any other aspect of the production process (formulation, fill and finish) is not undertaken by the proposer, please indicate the source and provide evidence of contractual agreements for the quantities being offered. Proposer should also confirm that the quantities offered do not violate any contractual commitments made between the Proposer and the vaccine or bulk concentrate manufacturer.
8. Please include in your Proposal timelines for bulk production (from start of the production process until bulk is ready for formulation and filling) and timelines for formulation, filling and having the product released both internally and by the relevant NRA.
9. Please provide information on your medium and long terms plans for production of the vaccine being offered, including an overview of business factors effecting the decision to produce the vaccine at the quantities offered to UNICEF.
10. Please advise whether the production of the vaccine offered effects the production, or potential production, of any other vaccine being supplied to UNICEF by your company.
11. Please indicate the capacity and willingness to include bar codes which conform to GS1 standards on all packaging levels for supply to UNICEF, with the exception of primary packaging by 31st December 2021.
12. Please indicate the capacity and willingness to store vaccines on a need basis indicating any conditions that may apply.
13. Please indicate if there will be any minimum award and/or order quantity(ies) for the vaccine(s) detailed in the schedule to this RFP.

14. In the past, how has your company been able to maintain the quality level for the supplied products? If your company has faced quality problems, please provide frequency and explanations as well as measurements taken for improvement.
15. For any Proposer planning to increase capacity (bulk and/or filling), please provide the following information:
  - 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 National Regulatory Authority
  - c. Timelines for WHO approval as applicable
  - d. Expected timeline for release and availability to UNICEF of first product from new capacity
16. Any other information deemed relevant for the evaluation of the proposal.

**QUANTITATIVE PROPOSAL SHEET****Rotavirus (RV) 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:

Rotavirus (RV) Vaccine..... dose vial			
<b>Comments:</b> The quantity requested represents the estimated maximum demand. <b>Please include multiple Proposal Sheets, as required, for alternative presentations.</b>			
Year	Annual quantity Vials	Unit Price per vial FCA International USD	Total Amount USD
2022			
2023			
2024			
2025			
2026			
2027			
2028			

**INCOTERMS (2020) FCA Nearest International Airport (Name Airport):**

**Type of Vaccine Vial Monitor:**

**Total annual production capacity:**

**Normal shelf life at time of shipment:**

**Vaccination schedule:**

**Number of doses required per course:**

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

**Country of Origin:**

**WHO pre-qualified product:** Yes:\_\_\_\_ No:\_\_\_\_

**Additional comments, including any alternative offers on price and vaccine costs, such as firm contracting provisions, minimum procurement guarantees, payment terms etc.:**

**PACKING DETAILS SHEET**  
**Rotavirus Vaccine**

The Proposer is requested to provide UNICEF with packing details for each vaccine product/presentation offered using this SHEET.

- a. Name of Vaccine:**
- b. Please advise if this vaccine is packed using ice packs or dry ice. If the vaccine is packed using dry ice, please advise of any plans to change to packing with ice packs. Also, please advise of any effect this would have on quantity, weight and dimension.**
- c. Please specify type of temperature monitoring device:** \_\_\_\_\_
- d. Please specify price adder of temperature monitoring device as added cost per shipping box:** \_\_\_\_\_
- e. Standard EXPORT Packing Dimensions and Weight\*:**

	Vaccine
Total No. of Doses per EXPORT Packing:	_____
Total no. of vials per EXPORT Packing:	_____
Dimensions: Length:	_____
Width:	_____
Height:	_____
Gross Weight:	_____
Net Weight:	_____
Number of inner cartons per EXPORT Packing:	_____

\*In case the supplier has agreed with WHO to supply additional information material together with the vaccine in the Shipping boxes, please ensure that such additional weight is included.

**f. Standard INNER CARTON Packing Dimensions and Weight:**

	Vaccine
Total No. of Doses per inner carton:	_____
Total no. of vials per inner carton:	_____
Dimensions: Length:	_____
Width:	_____
Height:	_____
Gross Weight:	_____
Net Weight:	_____

**COMMERCIAL TERMS SHEET**

In compliance with the Instructions to Proposers of this Request for Proposal and all sections hereto, the undersigned offers the supply of the vaccine under the conditions and in quantities, at prices and within the number of days as indicated in the QUALITATIVE PROPOSAL SHEET AND QUANTITATIVE PROPOSAL SHEET; and the undersigned accepts in full the TERMS and CONDITIONS.

Signature:\_\_\_\_\_

Date:\_\_\_\_\_

Name & Title:\_\_\_\_\_

Company:\_\_\_\_\_

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 commercial terms:**

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

## VACCINE REGISTRATION STATUS SHEET

(add more rows if needed)

[illegible]



## ENVIRONMENTAL SUSTAINABILITY SHEET

As UNICEF moves towards the implementation of the Sustainable Developmental Goals, we are keenly interested in the efforts made by the manufacturers and suppliers towards sustainable initiatives and would like to collect information about such initiatives. Herewith you are kindly requested to read and answer below questions and return the filled questionnaire along with your submission in response to UNICEF's **RFP-DAN-2020- 503278**

However, if the Bidder has provided completed the environmental sustainability sheet in the previous 12 months and there has been no changes since the last submission, it is not required to comply with this requirement. In this case, the Bidder is required to provide a reference to the solicitation process under which the answer sheet was completed.

Important: The questionnaire is not a part of the tender mandatory requirements. Your answers to the questionnaire will not be used in the evaluation of the offers.

1. Does your company have a formal Environmental policy? If yes, please include the copy.
2. Does your company have an Environmental Management System in place e.g. ISO 14 001 or equivalent? If yes, please include the copy.
3. Does your company have an Energy Management System in place comparable to e.g. ISO 50 001 or equivalent? If yes, please include the copy.
4. Please indicate the percentage of your company's power consumption from non-renewable energy sources and provide information on any plans to convert to renewable energy sources. (your original question)
5. Does your company monitor CO2 emission from its operations, including production, travel and transport of goods?
6. Please list the 3-main negative Environmental impacts of your manufacturing facility, and explain how you are working to reduce/prevent those impacts as well as highlight any specific results achieved so far.
7. Does your company have a recycling plan for the waste generated in vaccine production?
8. Does your company have a formal plan to reduce waste generated in vaccine production?
9. Please indicate how your company handles Pharmaceutical waste, and attach certificates issued by local authorities or any subcontracted company handling the pharmaceutical waste.
10. Please indicate the percentage of any recycled material used in production?
11. Does your company use any recyclable material for packaging and/or labelling of vaccines, or tries to reduce the environmental impact of packaging of goods?