



REQUEST FOR PROPOSAL

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

Oral Cholera Vaccines

FOR DELIVERY DURING THE PERIOD 2024 – 2028

RFP-DAN-2023-503563

26th May 2023

PROPOSALS must be sent to the email supplybid@unicef.org up to
23:59 hours (Copenhagen time) 7th July 2023

Reference to RFP-DAN-2023-503563 should be made in the subject line of the email.
Proposals sent to a different email will be **INVALIDATED**, even if received before the
stipulated deadline.

**PROPOSALS RECEIVED IN ANY OTHER MANNER AND PROPOSALS RECEIVED
AFTER THE STIPULATED DATE AND TIME WILL BE INVALIDATED**

Prepared by: Mrs. Antonia Naydenov, Contracts Specialist

Approved by:

A handwritten signature in black ink, appearing to be "A. Jones".

Mr Andrew Jones
Principal Adviser, Vaccine Centre
Supply Division, UNICEF

A handwritten signature in black ink, appearing to be "K. Rosenbom".

Ms Katinka Rosenbom
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TABLE OF CONTENTS

Section	Section Title	Page
TITLE PAGE	REQUEST FOR PROPOSAL DAN-2023-503563	1
PART I	PURPOSE OF THIS REQUEST FOR PROPOSAL	3
PART II	ELIGIBILITY AND PROPOSAL SUBMISSION PROCESS	8
PART III	COMMERCIAL REQUIREMENTS	16
PART IV	EVALUATION OF PROPOSALS; AWARDS	23
PART V	BIDDER REPRESENTATIONS	29
PART VI	ANSWER SHEETS	33

Annex	Annex Title
A.	UNICEF General Terms and Conditions of Contract (Goods)
B.	Mandatory Technical Requirements
C.	UNICEF Guidelines for Vaccine Barcode Specifications

PART I – PURPOSE OF THIS 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 favoritism. 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 one of the largest procurers of supplies and services in the United Nations. These supplies and services have a wide-ranging impact on children, their environment, health, learning, protection and inclusion. Given the scale of UNICEF’s vaccine procurement and the importance of ‘leading by example’, how UNICEF pursues procurement is important in its own right but also in relation to the Sustainable Development Goals (SDGs), particularly Goal 12 – “Ensure Sustainable Consumption and Production Patterns” and its target 12.7 – “promote public procurement practices that are sustainable, in accordance with national policies and priorities. UNICEF’s vision is to become a leading practitioner and contributor to the UN sustainable procurement. Sustainable procurement, guided by the principle of environmental, social and economic sustainability, is critical to UNICEF’s supply and logistics operations.
- 1.4 UNICEF is seeking comprehensive and innovative proposals from manufacturers for the sustained and uninterrupted supply of affordable Oral Cholera Vaccine (OCV) of assured quality, starting from January 2024 through December 2028.
- 1.5 The overall objectives of this solicitation are to:
 - To secure access to available supply of quality assured OCV to meet projected demand for planned campaigns and outbreak response activities
 - To enhance short-, medium- and long-term availability to UNICEF
 - To expand supplier base to improve market health
- 1.6 As a result of this RFP, UNICEF will work with selected manufacturers to establish long-term arrangements that best meet the requirements of both parties for ensuring that the demand for

countries and vaccine security objectives are met. These arrangements will provide the basis on which Purchase Orders (POs) are made for specific vaccine deliveries throughout the period.

2. BACKGROUND

Cholera is a global threat to public health. During 19th century, six cholera pandemics were recorded, which killed millions of people across all continents. The current pandemic started in South Asia in 1961, reached Africa in 1970 and the Americas in 1991. To date, cholera remains endemic in many countries, sickening and killing the poorest, most vulnerable, and marginalized populations. The number of cholera cases and deaths occurring globally is under-reported but in 2015¹ it has been estimated at 1.3 – 4 million cases, and 21,000 - 143,000 deaths per year worldwide with a disproportionate burden in Africa and South Asia. Since 2021, there has been an increase in cholera cases and their geographical distribution globally. In 2021, 23 countries reported cholera outbreaks, mainly in the WHO Regions of Africa and the Eastern Mediterranean. This trend has continued into 2022 with over 29 countries reporting cholera cases or outbreaks.

Since 1991, a Global Task Force on Cholera Control (GTFCC), chaired by the WHO, has aimed to reduce mortality and morbidity associated with cholera, and to address the social and economic consequences of the disease. The GTFCC contributed to planning and implementation of various projects and plans relevant to cholera control. However, both the GTFCC and cholera efforts in general were chronically under-resourced, both in terms of human and financial resources. In 2017, the Global Task Force on Cholera Control (GTFCC) launched “Ending Cholera: A Global Roadmap to 2030” (GTFCC Ending cholera, a global roadmap to 2030), a strategy to reduce global cholera deaths by 90 per cent and eliminate the disease as a threat for public health by 2030 in at least 20 of 47 countries endemic for cholera identified, in the global roadmap to 2030, as GTFCC target countries.

2.1 OCV Stockpile

UNICEF is managing the global stockpile of OCV since 2016. OCV stockpile has two components – emergency and non-emergency reserve. Emergency and Non-emergency reserve are managed as one stockpile (with different urgencies when deploying). The OCV stockpile is funded by Gavi. Decisions related to deployment of OCV responding to cholera outbreaks/emergencies is managed by International Coordination Group (ICG) which comprises of four decision making partners (the International Federation of Red Cross and Red Crescent Societies (IFRC), Médecins Sans Frontières (MSF), United Nations Children's Fund (UNICEF) and WHO). Based on recommendations put forward by ICG, 5 million doses of OCV are required to be available for emergency use at all times. The non-emergency reserve is used for preventive vaccination activities. Until end of 2022, The Global Task Force on Cholera Control (GTFCC), a global network of organizations involved in the fight against cholera across all sectors was responsible for reviewing and approving applications from countries for preventive support.

¹ Ali M, Nelson AR, Lopez AL, Sack D. (2015). Updated Global Burden of Cholera in Endemic Countries. *PLoS Negl Trop Dis* 9(6): e0003832. doi:10.1371/journal.pntd.0003832.

Since the beginning of 2023, this process has transitioned to Gavi and countries will be able to apply for multi-year campaign support through Gavi processes.

2.2 Demand forecast

There are currently two streams of demand for OCV through UNICEF: demand for preventive campaigns and demand for outbreak response activities. Though demand for OCV has been steadily increasing, supply availability remains the primary limiting factor in the OCV market. The unpredictable nature of outbreaks is confounded by the limited supply availability to mitigate risk in endemic areas, making OCV demand forecasting challenging. Excluding the 2019 to 2020 drop, global demand for OCV has steadily increased since 2013. Until 2021 approximately 50% of annual availability was allocated for preventive use, after all emergency vaccine needs were met. In 2022, due to increased numbers of Cholera cases reported worldwide, available supply of OCV has been prioritised for emergency response over preventative campaigns.

The Gavi secretariat, in collaboration with partners developed Strategic Demand Scenarios (SDS), which provide potential ranges in demand based on certain assumptions including campaign targets, scope of countries introducing, timing of introductions and frequency of revaccinations. The SDS depicts potential range in demand that is supply unconstrained. The high scenario assumes wider campaign targets, larger scope of countries introducing and more frequent revaccination. Based on the SDS, annual demand over the next 10 years is expected to range from 20M doses to over 200M doses, with the average demand in the medium scenario approximately 87M doses annually between 2025 and 2028, assuming no supply constraints, including demand for outbreak response of approximately 10-15M doses annually and excluding India. The medium scenarios consider moderate and conservative implementation of preventative campaigns resulting in a reduction in emergency response vaccination needs post 2030.

Table 1 below presents the OCV demand forecast based on Gavi SDS, for the two medium unconstrained demand scenarios for both the preventative programme and emergency response.

Table 1: Oral Cholera Vaccine Strategic Demand Scenarios, including outbreak

GAVI SDS, Medium Scenarios A and B - in millions of doses										
	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Medium A	88	91	77	87	92	84	69	60	55	47
Medium B	88	91	77	87	92	88	76	71	70	65

Balancing the limited available vaccine supply against the demand, ensuring that counties have access to uninterrupted supply for ongoing and planned preventive activities, while fostering an environment that encourages increasing availability of Oral Cholera Vaccines is one of the key objectives of this solicitation process.

Through this solicitation process, UNICEF seeks to ensure timely access to available supply of quality assured Oral Cholera Vaccine and therefore all developers of Oral Cholera Vaccines anticipating entering the Cholera Vaccine market during the tender period up to 2028, are encouraged to submit their comprehensive proposals.

Proposers are requested to submit proposal for maximum available annual quantities of their Cholera Vaccine that can be offered for supply through UNICEF.

2.3 Bidders forecasts 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. UNICEF is encouraging Proposals from Bidders with products in development and acknowledges that supply forecasts for such products may need further iterations and/or confirmations later in time.

2.4 Tender Period

The tender period will cover supply from 1st January 2024 to 31st December 2028.

2.5 Minimum Quantity Guarantees and Firm Contracting

To meet the objectives of the RFP, UNICEF is open to consider contracting terms that consider Suppliers' risks by providing the opportunity to present a comprehensive proposal through the RFP process. Therefore, UNICEF will consider innovative approaches to contracting, such as volume-based commitments as part of Bidders' Proposals, provided they help achieve the objectives of this solicitation process.

Subject to funding availability, such a commitment would be conditional upon a reciprocal commitment from an awarded Supplier to a defined quantity over a defined time period. In addition, any such commitment would be conditional to the Supplier's acceptance of clearly defined performance terms. Alternative contracting terms may be presented by all Bidders as part of the Proposal submitted in response to this RFP.

Where alternative contracting terms are presented by the Bidder, baseline offer without special contracting terms should also be included in the proposal, to enable UNICEF to examine the nature of the Proposal and seek the contracting modality that best meets the objectives of this tender.

2.6 Procurement Reference Group

Considering the strategic nature of the procurement to be undertaken, an advisory group – Procurement Reference Group (PRG) comprised of independent and partner experts, is established to provide advice with regards to objectives and procurement strategy, award approach and procurement allocations and this group will continuously provide input and advice to UNICEF. UNICEF will share summary information related to the proposal(s) and recommended award(s) with the PRG under strict confidentiality.

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 (Goods) described in Section 2 above, with the specifications outlined in the schedules contained in this RFP, 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 LTA(s) duration will be subject to suppliers' interest in expanding production capacity and will be valid for a minimum period of 3 years (1st January 2024 to 31st December 2026) and a maximum period of 5 years (1st January 2024 to 31st December 2028).

4.2 The duration of the LTA may be extended for an additional period at UNICEF sole discretion and subject to agreement with the awarded Supplier on the terms of such extension and/or if required to ensure the uninterrupted supply of vaccines to the relevant programme.

5. RFP DOCUMENTS

5.1 This RFP is comprised of the following:

- This document
- UNICEF General Terms and Conditions of Contract (Goods)
- Answer Sheets:
 - Commercial Proposal
 - Proposal Form
 - Proposer Information Sheet
 - Commercial Proposal Sheet (Qualitative & Quantitative)
 - Vaccine Registration Status Sheet
 - Technical Proposal
 - Technical Proposal Sheet
 - Packing Details Sheet

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 – ELIGIBILITY AND PROPOSAL SUBMISSION PROCESS

1. ELIGIBILITY; BIDDER INFORMATION

- 1.1 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 V of this RFP, including the representations on ethical standards and conflicts of interest.
- 1.2 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 *Proposer Information Sheet*.

Simultaneously with application to UNGM, Bidders must submit their most recent Audited Financial Statement and Incorporation Certificate to the UNICEF Quality Assurance Supplier Evaluation Unit, UNICEF Supply Division, Oceanvej 10-12, 2150, Copenhagen, Denmark. For more information on registration as UNICEF Supplier, Bidders can consult UNICEF’s website: <https://www.unicef.org/supply/suppliers-and-service-providers>.

Bidders registered with UNGM, which did not provide audited financial statements to UNICEF in the past 12 months must also submit these as per above. 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.

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

- 1.3 Joint Venture, Consortium or Association.
- (a) If the Bidder is a group of legal entities that will form or have formed a joint venture, consortium or association at the time of the submission of the Proposal, each such legal entity will confirm in their joint Proposal that:
- (i) they have designated one party to act as a lead entity, duly vested with authority to legally bind the members of the joint venture jointly and severally, and this will be evidenced by a Joint Venture Agreement among the legal entities, which will be submitted along with the Proposal; and
 - (ii) if they are awarded the LTA, the designated lead entity, who will be acting for and on behalf of all the member entities comprising the joint venture, will enter into the LTA with UNICEF.
- (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 to the joint venture, in the name of its designated lead entity. The lead entity will sign the LTA for and on behalf of all other member entities.

1.4 The description of the organization of the joint venture, consortium or association must clearly define the expected role of each of the entities in the joint venture, consortium or association in delivering the requirements of this RFP, both in the Proposal and the joint venture, consortium or association agreement. All entities that comprise the joint venture, consortium or association will be subject to the eligibility and qualification assessment by UNICEF.

1.5 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.

2. MULTIPLE PROPOSALS AND PROPOSALS FROM RELATED ORGANIZATIONS; JOINT VENTURES

Multiple Proposals not Permitted

2.1 Except for alternative Proposals submitted in accordance with Part II, Section 4.6, Bidders will not submit more than one Proposal as part of this solicitation process.

2.2 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.

2.3 UNICEF reserves the right to reject separate Proposals submitted by two or more Bidders if the Bidders are related organizations and are found to have any of the following:

- (a) they have at least one controlling partner, director or shareholder in common; or
- (b) any one of them receive or have received any direct or indirect subsidy from the other(s); or
- (c) they have a relationship with each other, that gives one or more Bidders access to confidential information about, or influence over, the other Proposal(s); or
- (d) they are subcontractors to each other's Proposal, or a subcontractor to one Proposal also submits another Proposal under its name as lead Bidder; or
- (e) an expert proposed to be in the team of one Bidder participates in more than one Proposal received for this solicitation process.

3. PROPOSAL SUBMISSION SCHEDULE

3.1 Acknowledgement of receipt of RFP.

Bidders are requested to inform UNICEF as soon as possible by email to **Mrs. Antonia Naydenov, Contracts Specialist** at anaydenov@unicef.org that they have received this RFP.

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

3.2 Questions from Bidders.

Bidders are required to submit any questions in respect of this RFP by email to **Mrs. Anna Larsson**, Procurement Associate at alarsson@unicef.org with copy to **Mrs. Antonia Naydenov**, Contracts Specialist at anaydenov@unicef.org. The deadline for receipt of any questions is seven (7) calendar days before the Proposal Submission Deadline.

IMPORTANT: PROPOSALS ARE NOT TO BE SENT TO THE INDIVIDUAL(S) STATED ABOVE – ANY PROPOSALS SENT TO THE ABOVE NAMED INDIVIDUAL(S) 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 UNGM website and/or respond to the question at a bid conference. After any such bid conference, a Questions and Answers document will be prepared and posted on the UNGM website. Information provided orally will not be considered in any way as a change to the RFP.

3.3 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.

3.4 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. For RFPs 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.

3.5 Samples

Sample packaging materials are required for this solicitation process for technical review.

- **In electronic format:** Each Proposal must include, with regard to each vaccine offered in the Proposal, samples of each of the following in electronic format:
 - High-quality photo of vaccine primary container including closure and label

- Electronic copy of primary container label
- High-quality photo of vaccine diluent/buffer primary container, if applicable
- High-quality photo of vaccine dropper or any other device and material to be provided in the secondary packaging, if applicable
- Electronic copy of vaccine insert
- High-quality photo of inner box

In physical format: 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:

UNICEF Supply Division
 Oceanvej 10-12
 DK – 2150 Copenhagen
 Denmark
 Attention: Vaccine Center, Mrs. Antonia Naydenov, Contracts Specialist

Please note that samples shall be sent at room temperature and please do not send the shipping box/tertiary packaging.

If the samples provided are different from those submitted to WHO for pre-qualification, the differences should be explained. In case the Bidder has agreed with WHO that any supplementary material be provided together with the vaccine, UNICEF requests to receive samples of such material as well. Any impact on weight and volume of such material should be specified in Part VI, Technical Proposal, Packaging Details Sheet.

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.

If at the time of submission of a Proposal the Bidder is not able to provide the samples as stated above, the Bidder should provide explanation and an indication of when the samples could be provided. For products in development, where packaging material has not yet been developed, bidders are requested to provide soft copy of mock-up of the artwork for UNICEF’s record as soon as available.

Failure to provide samples in accordance with the instructions requested under this Section 3.5 may result in invalidation of the Proposal.

3.6 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.

3.7 Proposal opening

Proposals received prior to the stated closing time and date will be kept unopened. The Officer of the Bid Section will open/print the Proposal 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.

4. PROPOSAL AND ANSWERING SHEETS

4.1 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.

The ANSWERING SHEETS have been provided to assist in the organization of the Proposal into COMMERCIAL PROPOSAL and TECHNICAL PROPOSAL. No price information should be contained in the TECHNICAL PROPOSAL. Apart from the PROPOSAL FORM, UNICEF encourages the proposers to submit The ANSWERING SHEETS in MS Word format, if possible.

4.2 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.

4.3 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.

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

COMMERCIAL PROPOSAL:

- PROPOSAL FORM
- PROPOSER INFORMATION SHEET
- COMMERCIAL PROPOSAL SHEET (QUANTITATIVE AND QUALITATIVE)
- VACCINE REGISTRATION STATUS SHEET

TECHNICAL PROPOSAL:

- TECHNICAL PROPOSAL SHEET
- PACKING DETAIL SHEET

4.5 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 confirming Bidder’s eligibility in PROPOSER INFORMATION SHEET.

- Define the commercial Proposal through both, qualitative information on Bidder's past performance and organizational structure as well as information on price and quantities in the COMMERCIAL PROPOSAL SHEET which consists of QUALITATIVE and QUANTITATIVE Proposals.
- Contain information required for technical evaluation of proposals, including TECHNICAL PROPOSAL SHEET and PACKING DETAILS SHEET.
- The COMMERCIAL and TECHNICAL Proposals can be submitted in one e-mail, it is NOT a requirement to submit COMMERCIAL and TECHNICAL Proposals through separate e-mails.

4.6 Bidders are invited to offer alternative products and presentations in response to this RFP. COMMERCIAL PROPOSAL SHEET includes an option for ALTERNATIVE PROPOSAL for Bidders who wish to offer alternative vaccine presentation(s). It can be submitted in several copies if multiple alternatives will be offered.

5. LANGUAGE

5.1 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.

6. VALIDITY OF PROPOSALS; MODIFICATION AND CLARIFICATIONS; WITHDRAWAL

6.1 Validity Period. Bidders must indicate the validity period of their Proposal. Proposals should be valid for a period through to 31 December 2028. 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.

6.2 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.

6.3 Withdrawal of Proposal. A Proposal may be withdrawn by the Bidder on emailed, 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.

7. PREPARATION OF PROPOSAL

7.1 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 (e.g. regarding form and timing of submission, marking of envelopes, as applicable) 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: <https://www.unicef.org/supply/documents/general-terms-and-conditions-contract>);
- Review the UNICEF policies publicly available on the UNICEF Supply website: <https://www.unicef.org/supply/resources/procurement-policies>. 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.

7.2 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.

7.3 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.

7.4 Submission of Proposals

Bidders must make clear reference to the RFP NUMBER in the subject field of email submitted to supplybid@unicef.org. Email submission shall not exceed 25 MB, including the size of the cover email. If the Proposal consists of large electronic files, it is recommended to send these files separately before CLOSING TIME AND DATE, indicating the order of emails (email 1, email 2, etc.) after the RFP NUMBER in the subject line of each email.

Bidders are expected to ensure the "acknowledge receipt" of the Proposal is received after the email submission. The subject line of an "acknowledge receipt" will show "UNICEF Supply Division - Bid confirmation".

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

Proposals sent to any other email, or without RFP NUMBER included in the subject field of email or Proposals sent after the CLOSING TIME AND DATE will be INVALIDATED.

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

7.6 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.

8. PROPOSAL DOCUMENTS; CONFIDENTIALITY

- 8.1 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.
- 8.2 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 Bidder, except that:
- UNICEF may share such information on a confidential basis with members of the Procurement Reference Group/Advisory Group as described in Part I, Section 2.
 - UNICEF will make details of each award public as described in Part IV, Section 2.9.

UNICEF reserves the right to disclose information regarding the proposals received against this RFP with the Gavi Secretariat and International Coordinating Group (ICG) on Vaccine Provision.

PART III – COMMERCIAL REQUIREMENTS

This section provides background information for completion of the Commercial Proposal. It also provides information on UNICEF's commercial requirements for awarded Suppliers under an eventual LTA and Purchase Order.

1. EXPERIENCE AND PAST PERFORMANCE; PROPOSED QUANTITIES

1.1 Experience in Vaccines and/or Biologicals Supply and Delivery. The Bidder will demonstrate proven experience and qualification in development, supply and delivery of the vaccines and/or biologicals including the offered product(s). The Bidder should provide the following information:

- Number of years of production and delivery by vaccine and/or biologicals (quantities).
- Applicable to all Bidders with less than 3 years of experience as a vaccine Supplier to UNICEF: Customer reference list by vaccine and/or biological. This should include customer contact names and communication information (phone/email/fax). Delivery report and delivery performance report for minimum period of the past 3 years, including reasons for delays in deliveries and frequency, and measures taken to resolve the delays. Information on total annual quantities supplied to other customers.
- Names of regulatory bodies where products are registered, and date of original registration.

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.

Bidders should be prepared to substantiate the claimed experience by presenting copies of relevant documents and references if so requested by UNICEF.

1.2 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 IV, Section 1.2.

1.3 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.

2. PRODUCT DETAILS, QUANTITIES AND PLANS

- 2.1 Reasonable Proposed Quantity. If the proposed quantity is disproportionately 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's Prequalification Team – WHO/PQT - may evaluate the capacity of the Bidder to supply the proposed quantity as part of the technical evaluation of the Proposal.
- 2.2 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 to UNICEF.
- 2.3 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 1.1, Bidders are requested to provide information on planned and pending registrations and intent to renew existing registrations upon expiry.
- 2.4 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. (*Information shall be provided as part of Technical Proposal Sheet*).
- 2.5 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. (*Information shall be provided as part of Technical Proposal Sheet*).
- 2.6 Catalogues. Bidders, who have not already done so, are kindly requested to include a copy of their current catalogue or list of product offering in their Proposal.

3. ACCOUNT MANAGEMENT

- 3.1 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, and Environmental, Social and Governance (ESG), specifying the name(s) of the person(s) who will be the primary contact for

UNICEF.

- 3.2 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.

- 3.3 The communication on all elements connected to execution of an eventual LTA and subsequent Purchase Orders should be solely between UNICEF and the awarded Supplier. Suppliers are not expected to have direct contact with recipient country Governments.
- 3.4 ESG Reporting: All Suppliers awarded LTAs with UNICEF will be required to provide one annual report, with timing of such reporting to be agreed, on ESG using a UNICEF's questionnaire format which will be provided to the Supplier.

4. PERFORMANCE MONITORING

As part of UNICEF's continuous strive to improve the 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.

- 4.1 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. As part of execution of eventual LTA, the awarded Supplier will be 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.
- 4.2 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

5. MONTHLY ALLOCATION REPORTING

5.1 Under the LTA, the awarded 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.

6. PRICES AND DISCOUNTS

6.1 Pricing based on Delivery Term. Bidders are requested to provide unit pricing in accordance with the following 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.

6.2 Currency of Proposals. The currency of the proposal will 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 official United Nations rate of exchange in effect on the submission deadline date.

6.3 Inclusive Pricing. Pricing should include the cost of packaging and packing the goods and all temperature monitoring devices in accordance with the packaging and packing requirements set out in the Mandatory Technical Requirements. 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 Vaccine Vial Monitor (VVM).

6.4 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.

6.5 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 *Commercial Proposal*.

6.6 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.

6.7 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, the Bidder will offer the same price to UNICEF for the remaining validity period of the LTA.

6.8 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;
- (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) Trade discounts;
- (e) 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.

6.9 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 advance 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).

6.10 Payment Terms. Unless an alternative Proposal has been awarded that includes pre-payment or advance 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) 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.

7 DELIVERY TERMS AND DELIVERY LEAD TIME; LIQUIDATED DAMAGES

7.1 Under the LTA, the awarded Supplier will be required to 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.

7.2 The awarded 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.

- 7.3 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).
- 7.4 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.

8. PRE-DELIVERY INSPECTION

- 8.1 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 and the designated inspection agency 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 issues a release notice, the Supplier will immediately expedite shipment of the released consignment. 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.
- 8.2 The awarded 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) as set out in eventual LTA or any Purchase Order have been met. The awarded 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.

- 8.3 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.

9. TEMPORARY STORAGE

- 9.1 Under an eventual LTA, the awarded 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.

10. WARRANTY

- 10.1 Warranty. Under an eventual LTA, the awarded Supplier will be 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.
- 10.2 Warranty Period. Under the LTA, the period of validity of the warranty will be no less than the shelf life of the Goods.
- 10.3 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.

- 10.4 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.

PART IV – EVALUATION OF PROPOSALS; AWARDS

1. EVALUATION

- 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:

- 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.
- Review of Compliance with Eligibility, Commercial and Technical Mandatory Requirements. Each Proposal will be evaluated for compliance with the requirements of this RFP.
- Technical evaluation will be based on information provided by Bidders as part of their Technical Proposal and evaluation will take place in accordance with the Mandatory Technical Requirements assessed in collaboration with WHO. Compliance with all other requirements will be evaluated by UNICEF.
- Proposals deemed not to meet all of the 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 Section below.
- Commercial evaluation. During the evaluation, the nature of Commercial Proposal will be studied and compared to the evaluation criteria. In order to determine to what extent a Proposal is found satisfactory, all information included in both, the Commercial and Technical Proposal will be evaluated together to determine how the factors presented in each Proposal will support the RFP objectives set out in Part I.
- Products not yet WHO pre-qualified. For products offered that are not WHO pre-qualified, Bidders are requested to include in their response a detailed plan on the timeline to obtain WHO pre-qualification. The timeline will include information regarding the product and

plans for manufacturing and licensing. In case the total offered quantity of WHO pre-qualified vaccine is insufficient to meet the total requirement at the specified time, UNICEF may, as an exceptional measure, consider procurement of non-WHO pre-qualified vaccines. Any procurement of non-WHO pre-qualified vaccine will be subject to specific and additional contracting terms. In such case the following additional evaluation criteria will be the basis for determining a potential award:

(a) The vaccine shall be licensed by the national authority in the Country of Manufacture, and this NRA must be considered functional (as assessed by WHO Regulatory Systems Strengthening) and take responsibility for the regulatory oversight of the vaccine including issuing lot release certificates for UNICEF supplied vaccines, under the guidance of WHO.

(b) Vaccines registered for sale in well-regulated countries (such as EU countries, Japan or USA) will be preferred.

(c) Manufacturers that have obtained WHO pre-qualification for at least one (1) vaccine product will be preferred.

- Awards will be determined based on the following criteria:
 - Contribution to meeting the procurement objectives
 - Products meeting the technical specifications, including WHO pre-qualification
 - Timing of product availability
 - FCA Price nearest international airport
 - Proven past performance

1.2 The detailed evaluation criteria to be used to assess the Proposals are shown in the below table:

QUANTITATIVE INFORMATION	
Objective	Evaluation criteria
Securing access to available supply of quality assured OCV for planned campaigns and outbreak response activities	<ul style="list-style-type: none"> • Price FCA nearest international airport, including VVM and cold chain monitors • Validity of proposal • Payment terms • Price conditions offered – alternative offers providing additional benefits in terms of affordability/prices/commercial terms • Product offered • Vial size • Shelf life • Presentation offered • Quantity offered against demand forecast • Conditions of offer • Demonstrated capacity to provide the offered quantities • Possible effects of offered quantities on other vaccine presentations • Lead-time

	<ul style="list-style-type: none"> • Total production capacity • Gross weight and volume
QUALITATIVE INFORMATION	
Objective	Evaluation Criteria
<p>Securing access to available supply of quality assured OCV for planned campaigns and outbreak response activities</p> <p>Expanding supplier base to improve market health</p>	<ul style="list-style-type: none"> • WHO prequalification • Pricing compared to other offers • Factors that influence the pricing offered to UNICEF. • Reciprocity in any special contracting terms. • Registration in key countries (planned, pending, actual, expiry, intend to maintain) • Supplier performance (existing suppliers): <ul style="list-style-type: none"> - Maintained quality level per WHO requirements - Proven capacity to supply offered and forecasted quantities - Reliable and firm forecasted supply - Accurate monthly allocation reporting - Flexibility for supplying unforecasted quantities (timing, quantities) - Timeliness of PO acknowledgment - Timeliness of Notification of Goods Readiness (NGR) - Timeliness of delivery - Problem solving willingness and capacity • For pipeline suppliers: <ul style="list-style-type: none"> - Dates for clinical trials yet to be completed (Phase I, II and III) - Dates for national licensure in country of production - Date of submission to WHO PQ - Expected date of WHO PQ - Expected date of first supply to UNICEF • Realistic quantity offered • Account management resources (organizational chart with names) and customer service capabilities including: <ul style="list-style-type: none"> - Accurate and reliable planning and monitoring of NRA release, efficient order processing, accurate and complete documentation, close production follow-up) - Environmental and social sustainability: Collaboration on sustainability; e.g. via consultations, information sharing on environmental and social sustainability topics; and (future) performance monitoring. - Willingness to include Vaccine Arrival Report as part of shipping documents • Experience in vaccine supply and delivery: <ul style="list-style-type: none"> - Number of years of production and delivered quantities. - Customer reference list (applicable to all suppliers with less than 3 years' experience as a UNICEF supplier supplying against long-term agreement)

	<ul style="list-style-type: none"> • Realistic lead-time offered • Long-term plans for production of the offered vaccine, including overview of business factors affecting the decision to produce the vaccine at the offered quantities. • Agreement and conditions for storing vaccines on a need basis (buffer stock/emergency stockpile) • Agreement to outbreak response conditions and timelines for a quantity requested in bidding documents • Confirmation of adherence to packing and shipping requirements, including temperature monitoring devices • VVM implementation/timelines for implementation
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- 1.3 The award strategy under this tender will include considerations regarding the overall development towards healthy market.
- 1.4 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.
- 1.5 Clarifications Requested by UNICEF. During the evaluation of Proposals, UNICEF may, in its sole discretion, seek clarifications from any Bidder in order for UNICEF to fully understand the Bidder’s Proposal and assist in the examination, evaluation and comparison of Proposals. UNICEF may seek such clarifications through written communications or may request an interview with any Bidder.
- 1.6 Interpretation of Errors. UNICEF may seek clarification of any errors identified by it in a Proposal. Absent satisfactory clarification, such errors will be interpreted by UNICEF in its sole discretion. In the case of errors in the extension price that are not clarified to UNICEF’s satisfaction, unit price will govern.
- 1.7 References. UNICEF reserves the right to contact any or all references supplied by the Bidder(s) and to seek references from other sources as UNICEF deems appropriate.

2. AWARD

- 2.1 Objectives of this RFP. Upon evaluation of all Proposals, taking into consideration the actual market situation for each vaccine, 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.

- 2.6 Negotiation. UNICEF reserves the right to negotiate with the Bidder(s) in support of achieving the procurement objectives of the RFP.
- 2.7 Award Notification. UNICEF will notify the Bidder(s) that has/have been awarded the LTA(s) resulting from this solicitation process. UNICEF will also notify the other Bidders of the outcome of this solicitation process.
- 2.8 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 2.9 below.
- 2.9 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.
- 2.10 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 The terms set out in UNICEF's standard LTA for vaccines will apply to any LTA awarded in connection with this RFP and any linked Purchase Orders issued under such LTA.
- 3.2 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.
- 3.3 By signing the Proposal Form, each Bidder is deemed to have confirmed its acceptance of the UNICEF General Terms and Conditions (Goods). The Bidder understands that if it proposes any amendments or additional terms to the LTA or the UNICEF General Terms and Conditions (Goods), these must be clearly detailed in the Proposal and may negatively affect the evaluation of the Proposal.

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 Proposer is in a position to perform any LTA issued as a result of this RFP or any Purchase Order issued under such LTA;

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

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

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

- 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. Failure to do so may result in the rejection of the Proposal. The inspection may be carried out in conjunction with the appropriate national authority.

PART V – BIDDER REPRESENTATIONS

1. GENERAL REPRESENTATIONS

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

- 1.1 The Bidder has (a) the full authority and power to submit the Proposal and to enter into any resulting LTA and linked Purchase Order(s), and (b) all rights, licenses, authority and resources necessary, as applicable, to develop, source, manufacture and supply the goods and to perform its other obligations under any resulting LTA and linked Purchase Order(s). The Bidder has not and will not enter into any agreement or arrangement that restrains or restricts any person's rights to use, sell, dispose of or otherwise deal with the goods.
- 1.2 All of the information it has provided to UNICEF concerning the Goods and the Bidder is true, correct, accurate and not misleading.
- 1.3 The Bidder is financially solvent and is able to supply the Goods to UNICEF 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 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 <https://www.unicef.org/supply/resources/procurement-policies>. In particular, the Bidder will not engage, and will ensure that its personnel, agents and sub-contractors do not engage, in any corrupt, fraudulent, coercive, collusive or obstructive conduct as such terms are defined in UNICEF's Policy Prohibiting and Combatting Fraud and Corruption.
- 2.7 The Bidder will comply with all laws, ordinances, rules and regulations bearing upon its participation in this solicitation and the UN Supplier Code of Conduct (available at the United Nations Global Marketplace website - www.ungm.org).
- 2.8 Neither the Bidder nor any of its affiliates, is engaged, directly or indirectly, (a) in any practice inconsistent with the rights set forth in the Convention on the Rights of the Child, including Article 32, or the International Labour Organisation's Convention Concerning the Prohibition and Immediate Action for the Elimination of the Worst Forms of Child Labour, No. 182 (1999); or (b) in the manufacture, sale, distribution, or use of anti-personnel mines or components utilised in the manufacture of anti-personnel mines.
- 2.9 The Bidder has taken and will take all appropriate measures to prevent sexual exploitation or abuse of anyone by its personnel including its employees or any persons engaged by the Bidder to perform any services in the Bidder's participation in this solicitation. For these purposes, sexual activity with any person less than eighteen years of age, regardless of any laws relating to consent, will constitute the sexual exploitation and abuse of such person. The Bidder has taken and will take all appropriate measures to prohibit its personnel including its employees or other persons engaged by the Bidder, from exchanging any money, goods, services, or other things of value, for sexual favours or activities or from engaging in any sexual activities that are exploitive or degrading to any person.
- 2.10 The Bidder confirms that it has read UNICEF's Policy on Conduct Promoting the Protection and Safeguarding of Children. The Bidder will ensure that its Personnel understand the notification requirements expected of them and will establish and maintain appropriate measures to promote compliance with such requirements. The Bidder will further cooperate with UNICEF's implementation of this Policy.
- 2.11 The Bidder will inform UNICEF as soon as it becomes aware of any incident or report that is inconsistent with the undertakings and confirmations provided in this Section 2.
- 2.12 Each of the provisions in Section 2 of this Part V constitutes an essential condition of participation in this solicitation process. In the event of a breach of any of these provisions, UNICEF is entitled to disqualify the Bidder from this solicitation process and/or any other solicitation process, and to terminate any LTA and linked Purchase Order(s) that may have been awarded as a result of this solicitation process, immediately upon notice to the Bidder, without any liability for termination charges or any liability of any kind. In addition, the Bidder may be precluded from doing business with UNICEF and any other entity of the United Nations System in the future.

3. AUDIT

- 3.1 From time to time, UNICEF 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 VI: ANSWER SHEETS

Answer Sheets / Checklist

This form serves as a checklist for preparation of your Proposal. Please complete the Answer Sheets in accordance with the instructions in the RFP document and return them as part of your Proposal submission. No alteration to format of sheets shall be permitted.

As indicated in the Part II, Section 4 of the RFP document, the Proposal must include a signed PROPOSAL FORM in original. The ANSWERING SHEETS, apart from the PORPOSAL FORM, can be submitted in MS Word format, if possible.

Commercial Proposal

▪ Proposal Form	<input type="checkbox"/>
▪ Proposer Information Sheet	<input type="checkbox"/>
▪ Commercial Proposal Sheet (Quantitative & Qualitative)	<input type="checkbox"/>
▪ Vaccine Registration Status Sheet	<input type="checkbox"/>

Technical Proposal

▪ Technical Proposal Sheet	<input type="checkbox"/>
▪ Packing Details Sheet	<input type="checkbox"/>

COMMERCIAL PROPOSAL

PROPOSAL FORM

Important: The company identified as Proposer will be the party to which UNICEF will issue its LTA(s)/PO(s) in case of award resulting from this solicitation process.

Name of Proposer:	[INSERT NAME OF PROPOSER]]	Date:	<input type="text" value="Select date"/>
RFP reference:	RFP-DAN-2023-503563		

Part 1: Declaration

The undersigned, being a duly authorized representative of the Company, represents and declares that:

		YES	NO
1	The Company and its Management ² have not been found guilty pursuant to a final judgment or a final administrative decision of any of the following:	YES	NO
	a. Fraud;	<input type="checkbox"/>	<input type="checkbox"/>
	b. Corruption;	<input type="checkbox"/>	<input type="checkbox"/>
	c. Conduct related to a criminal organisation;	<input type="checkbox"/>	<input type="checkbox"/>
	d. Money laundering or terrorist financing;	<input type="checkbox"/>	<input type="checkbox"/>
	e. Terrorist offences or offences linked to terrorist activities;	<input type="checkbox"/>	<input type="checkbox"/>
	f. Sexual exploitation and abuse;	<input type="checkbox"/>	<input type="checkbox"/>
	g. Child labour, forced labour, human trafficking; or	<input type="checkbox"/>	<input type="checkbox"/>
	h. Irregularity (non-compliance with any legal or regulatory requirement applicable to the Company or its Management).	<input type="checkbox"/>	<input type="checkbox"/>
2	The Company and its Management have not been found guilty pursuant to a final judgment or a final administrative decision of grave professional misconduct.	<input type="checkbox"/>	<input type="checkbox"/>
3	The Company and its Management are not: bankrupt, subject to insolvency or winding-up procedures, subject to the administration of assets by a liquidator or a court, in an arrangement with creditors, subject to a legal suspension of business activities, or in any analogous situation arising from a similar procedure provided for under applicable national law.	<input type="checkbox"/>	<input type="checkbox"/>
4	The Company and its Management have not been the subject of a final judgment or a final administrative decision finding them in breach of their obligations relating to the payment of taxes or social security contributions.	<input type="checkbox"/>	<input type="checkbox"/>

² “Management” means any person having powers of representation, decision-making or control over the Organization. This may include, for example, executive management and all other persons holding downstream managerial authority, anyone on the board of directors, and controlling shareholders

5	The Company and its Management have not been the subject of a final judgment or a final administrative decision which found they created an entity in a different jurisdiction with the intent to circumvent fiscal, social or any other legal obligations in the jurisdiction of its registered office, central administration, or principal place of business (creating a shell company).	<input type="checkbox"/>	<input type="checkbox"/>
	The Company and its Management have not been the subject of a final judgment or a final administrative decision which found the Company was created with the intent referred to in point (5) (being a shell company)	<input type="checkbox"/>	<input type="checkbox"/>

The UNICEF reserves the right to disqualify the Company suspend or terminate any contract or other arrangement between the UNICEF and the Company, with immediate effect and without liability, in the event of any misrepresentation made by the Company in this Declaration. It is the responsibility of the Company to immediately inform the UNICEF of any changes in the situations declared. This Declaration is in addition to, and does not replace or cancel, or operate as a waiver of, any terms of contractual arrangements between the UNICEF and the Company.

Part 2: Confirmation of Proposal

The Undersigned, having read the Instructions to Proposers of this Request for Proposal and all related documents hereby offers to supply the Goods to meet the overall objectives sought in accordance with any specifications stated, under the conditions and in quantities, at prices and within the number of days as indicated in your Proposal, and subject to all Terms and Conditions set out or specified in this **RFP-DAN-2023-503563** 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.

I, the undersigned, certify that I am duly authorized by [INSERT NAME OF PROPOSER]] to sign this Proposal.

Signature: _____
Date: _____
Name: _____
Title: _____
Company as per the certificate of incorporation: _____
Postal Address: _____
Tel No.: _____
Email: _____
Validity of Offer: _____

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 _____

Any requested EXCEPTIONS or CLARIFICATIONS to the requirements defined by UNICEF in this Request for Proposal and all related documents, including UNICEF’s General Terms and Conditions are to be described by the Proposer below. Additional pages may be attached. Request for EXCEPTIONS after an AWARD has been made may result in invalidation of the Proposal:

[Stamp with official stamp of the proposer]

PROPOSER INFORMATION SHEET

Are you a UNGM registered vendor?	<input type="checkbox"/> Yes [insert UGNM vendor number] <input type="checkbox"/> No* *If your company has not yet registered through the UNGM, please submit an application through the UNGM website at http://www.ungm.org/Account/Registration Please note that while Basic level registration is sufficient for evaluation purposes, Proposers are highly encouraged to register at least at Level 1.
Are you a UNICEF vendor?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Have you provided audited financial statements to UNICEF in the past 12 months	<input type="checkbox"/> Yes <input type="checkbox"/> No* * If not, please proceed as per Part II, Section 1.2 of this Request for Proposal.

COMMERCIAL PROPOSAL SHEET

A. Quantitative Proposal

Name of Proposer:	[Insert Name of Proposer]]	Date:	Select date
RFP reference:	RFP-DAN-2023-503563		

1. Oral Cholera Vaccine, 1-dose vial, with VVM						
Quantities per year in vials and doses: 2024: 88,000,000 vials (88,000,000 doses) 2025: 91,000,000 vials (91,000,000 doses) 2026: 77,000,000 vials (77,000,000 doses) 2027: 87,000,000 vials (87,000,000 doses) 2028: 92,000,000 vials (92,000,000 doses) The forecast represents the estimated needs for routine vaccination and supplementary immunisation activities in countries.						
Period	Quantity offered (doses)	Quantity offered (vials)	Price in USD*/vial, FCA [Insert nearest International Airport]]	Price in EUR*/vial FCA [Insert nearest International Airport]]	Conditions/ Discounts**	Total Amount (USD)
2024						
2025						
2026						
2027						
2028						

ALTERNATIVE PROPOSAL						
Vaccine: Description: Vial size:						
Quantities per year in vials and doses:						
Period	Quantity offered (doses)	Quantity offered (vials)	Price in USD*/vial, FCA [Insert nearest International Airport]]	Price in EUR*/vial FCA [Insert nearest International Airport]]	Conditions/ Discounts**	Total Amount (USD)
2024						
2025						
2026						

2027						
2028						

* Offers can be in USD only (in which case only the USD column needs to be completed). If offer is provided in EURO please ensure that both USD & EURO prices are given. Please refer to Part III, Section 6.2, CURRENCY OF PROPOSALS for further information. Offers expressed only in EURO will be invalidated.

** Please indicate in the column “conditions/discounts” with check mark if there are any conditions/discounts associated with the price offered in your Proposal. Please outline the details of the conditions/discounts below (Please refer to Part III, Section 6.8).

B. Qualitative Proposal

Experience and past performance. Account management.	
1	Demonstrate proven experience and qualification in development, supply and delivery of vaccines and/or biologicals, including the offered product(s). Advise number of years of experience in production and delivery of the offered product. <i>(Part III, Section 1)</i> <u>Proposer's response:</u>
2	For Proposers with less than 3 years of experience as a vaccine supplier to UNICEF, please provide a full customer reference list, delivery report and delivery performance report for the minimum period of the past 3 years. Advise of the reasons for delays in deliveries and frequency, as well as measures taken to resolve the delays. Please also advise the total annual quantities supplied to other customers. <i>(Part III, Section 1)</i> Proposers should be prepared to substantiate the claimed experience by presenting copies of relevant documents and references if so requested by UNICEF. <u>Proposer's response:</u>
3	Provide organizational charts and names of the responsible persons within each following department: Production, Quality Assurance, Governmental Affairs, Shipping/Logistics, Sales and Marketing, Environmental Social and Governance (ESG) specifying the name(s) of the person(s) who will be the primary contact for UNICEF. <i>(Part III, Section 3)</i> <u>Proposers response:</u>
Pricing	
4	Given that UNICEF has requested prices that are affordable to the poorest country governments and donors please indicate factors influencing your price setting. Please also provide explanation of any price increase over previous years' pricing (if applicable). <i>(Part III, Section 6)</i> . <u>Proposer's response:</u>
Volumes offered, timelines	
5	Proposed Quantity: Explain the key determinants for the proposed quantity to be available during the proposed timeframe, as well as any key risks. <u>Proposer's response:</u>
6	Delivery preparation lead time (administration of UNICEF's Purchase Order, packing, markings etc.) for any order within above mentioned schedule, in number of days <i>(Part III, Section 7)</i> : <u>Proposer's response:</u>
7	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, labelling, and having the product released both internally and by the relevant NRA. <u>Proposer's response:</u> Bulk production: Formulation: Filling: Labelling and Internal release process: NRA release:
8	Please provide information on your medium and long-term plans for production of the vaccine(s) being offered, or of vaccines that may be offered in the future, including overview of business factors affecting the decision to produce the vaccine at the quantities offered to UNICEF. <i>(Part III, Section 2)</i> <u>Proposer's response:</u>
9	Please advise whether the production of any of the vaccines offered affects the production, or potential production, of another vaccine being offered or supplied by your company. If yes, please advise which

	<p>vaccines. In addition, please indicate whether facilities for bulk production and fill and finish are dedicated, multipurpose and/or shared facilities.</p> <p><u>Proposer's response:</u></p>
10	<p>Please advise if the company will be able to supply quantities above the forecast and indicate the lead times for each product offered as part of your Proposal, for quantities above forecast.</p> <p><u>Proposer's response:</u></p>
Other	
11	<p>Storage of vaccines shall be under controlled environmental conditions to facilitate the conservation of the vaccines. Vaccines will be kept at the manufacturers' premises until these are either supplied through UNICEF Purchase Order(s) or reach expiry date. Please confirm that your company will bear the responsibility and cost of destruction should the vaccines, by any event, reach expiry date when stored at your warehouse.</p> <p><u>Proposer's response:</u></p>
12	<p>Outbreak response: Please explicitly confirm that your company is able to prepare an order for up to 1 million doses of Oral Cholera vaccine within 48 hours from receipt of a UNICEF purchase order without any impact on other forecasted requirements from UNICEF.</p> <p><u>Proposer's response:</u></p>
13	<p>Please provide your company's Environmental Social Governance (ESG) policy (or equivalent) and confirm contact persons and their e-mail addresses with whom UNICEF can engage on questions connected to progress on environmental and social sustainability implementation operations.</p> <p><u>Proposer's response:</u></p>

QUARTERLY OFFERED QUANTITIES IN DOSES (2024 to 2028)

Please provide the offered quarterly quantity in doses for each vaccine included in your Proposal.

Vaccine (quantity in doses)	1 st Quarter	2 nd Quarter	3 rd Quarter	4 th Quarter	Annual Total
2024					
2025					
2026					
2027					
2028					

For Proposers offering more than one product presentation please provide separate quarterly offered sheets for each presentation.

TECHNICAL PROPOSAL SHEET

Proposers are requested to submit one technical proposal form for each vaccine product/presentation offered:

Name of Proposer:	[Insert Name of Proposer]]	Date:	Select date
RFP reference:	RFP-DAN-2023-503563		
Vaccine description			
Qty offered, in doses and vials:	2024: _____ doses/vials 2025: _____doses/vials 2026: _____doses/vials 2027: _____doses/vials 2028: _____ doses/vials		
WHO pre-qualified product	<input type="checkbox"/> Yes <input type="checkbox"/> No* *If no, please include information requested as per Section IV, 15: Proposals of Vaccines not yet WHO Pre-Qualified.		
Language on label/package insert	Label: Package insert:		
Samples	<input type="checkbox"/> Yes If samples provided are different from those submitted to WHO for pre-qualification, the differences should be explained: <input type="checkbox"/> No Please provide justification as per Section 3.5 of Part II:		
Vaccine Vials Monitor (VVM)	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, which type: If no, please indicate feasibility to include VVM in the future, including timeline:		
Bar codes	At secondary packing level, in accordance with Annex C: <input type="checkbox"/> Yes <input type="checkbox"/> No At tertiary packing level, in accordance with Annex C: <input type="checkbox"/> Yes <input type="checkbox"/> No Please advice type of barcode which is included (i.e. GSCC barcode, 2D Data Matrix barcode) and at which level of packing: Please provide information on bar code inclusion on secondary and tertiary packing level for diluents or adjuvants: <u>For UNICEF's information only, but not part of evaluation:</u> Serialisation: Please advise if serialisation is already implemented and if not, whether you are working towards including serialisation, including the timeline for implementation. <i>Note:</i> Serialisation is not required however, specifications for such are also included as part of Annex C.		

Continuous quality assurance	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 measures taken for improvement.
Total annual production capacity	<p>Bulk:</p> <p>Final filled product for the offered vaccine:</p> <p>Source of bulk:</p> <p>Source of fill and finish:</p> <p>If you are not bulk producer, or you do not perform the fill and finish for the product offered, please include evidence of contractual access to bulk/fill and finish capacity.</p>
Batch size	<p>Please provide minimum and maximum batch size for bulk production:</p> <p>Please provide minimum and maximum batch size (throughput) for fill and finish:</p>
Storage capacity	<p>Please indicate cold storage capacity for bulk and finished product, indicating the maximum storage capacity in number of doses at any time.</p> <p>Bulk:</p> <p>Finished product:</p>
Capacity Expansion	<p>In case of plans to scale-up production, please provide information on:</p> <ol style="list-style-type: none"> Milestones and timelines related to any scale up in production capacity, including if required, any new facilities Milestones and timelines for anticipated approval by the NRA Timelines for WHO approval as applicable Expected timeline for release and availability to UNICEF of first product from new capacity <p><u>Proposers response:</u></p>
Shelf life	<p>Remaining minimum shelf life at the time of shipment:</p> <p>Total shelf life of the vaccine offered:</p> <p>Please provide information on any plans to increase the current total shelf life of the vaccine including the timelines related to anticipated approval by the NRA and WHO, as applicable.</p>
Vaccination schedule:	<u>Proposer's response:</u>
Country of Origin:	<u>Proposer's response:</u>
National Regulatory Authority (NRA) of record:	<u>Proposer's response:</u>

<p>Variations/changes to licensure and WHO prequalification dossier</p>	<p>Are there any variations currently pending for review and approval by:</p> <p>NRA of record <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>WHO PQT <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If you answered “yes” to any of the above, please provide information on the nature of the variation, what is the anticipated timeline for endorsement and whether the variation will require updates for licensure by NRAs in other countries.</p> <p><u>Proposer’s response:</u></p>
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PACKING DETAILS SHEET

Proposers are requested to provide UNICEF with packing details for each vaccine product offered using this form:

Vaccine description	
Type of coolant	<input type="checkbox"/> Ice packs <input type="checkbox"/> 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.
Type of time temperature monitoring device	

PACKING

Standard EXPORT Packing Dimensions and Weight	Vaccine	Diluent
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		

Standard INNER CARTON Packing Dimensions and Weight	Vaccine	Diluent
Total no. of Doses per INNER carton		
Total no. of Vials per INNER carton		
Dimensions: Length Width Height		
Gross Weight		
Net Weight		



ANNEX A – UNICEF GENERAL TERMS AND CONDITIONS OF CONTRACT (GOODS)

Please refer to the attached Annex A.

ANNEX B – 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 Long Term Agreement(s) (LTA) resulting from this Request For Proposal (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 (but not limited to) established by the World Health Organization (WHO), or any subsequent revisions: [https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/vaccine-standardization /](https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/vaccine-standardization/).
 - a) Good Manufacturing Practices for pharmaceutical products: main principles (WHO Technical Reports Series No. 986 Annex 2, 2014)
 - 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) Guidance on good data and record management practices (WHO Technical Report Series, No. 996, Annex 5 (2016))
 - g) WHO guidelines on quality risk management. WHO Technical Report Series, No. 981), Annex 2, 2013
 - h) Good Manufacturing Practices: Requirements for sampling of starting materials (WHO Technical Report Series No. 929, 2005. Annex 2)
 - i) Supplementary guidelines on good manufacturing practices: validation. WHO Technical Report Series, No. 937), Annex 4, 2006

- j) 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)
- k) 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)
- l) WHO Guidelines on Nonclinical Evaluation of Vaccines (WHO Technical Report Series No. 927, Annex 1, 2005)
- m) Guidelines on the nonclinical evaluation of vaccine adjuvants and adjuvanted vaccines (WHO Technical Report Series No. 987, annex 2, 2014)
- n) Guidelines on Clinical Evaluation of Vaccines: Regulatory Expectations (WHO Technical Report Series No. TRS 1004, Annex 9, 2017)
- o) Guidelines on stability evaluation of vaccines (WHO Technical Report Series No. 962, Annex 3, 2011)
- p) Guidelines on procedures and data requirements for changes to approved vaccines (WHO Technical Report Series No. 993, Annex 4, 2015)
- q) Guidance on Variations to a Prequalified Vaccine, July 2015
https://extranet.who.int/pqweb/sites/default/files/documents/PQ_VXA_Variations_V7.pdf
- r) Report of a WHO Consultation on Medicinal and other Products in relation to Human and Animal Transmissible Spongiform Encephalopathies (WHO/BLG/97.2), Geneva, March 1997
- s) WHO Guidelines on Transmissible Spongiform Encephalopathies in relation to Biological and Pharmaceutical Products, Geneva, 2003
- t) WHO good practices for pharmaceutical microbiology laboratories. WHO Technical Report Series, No. 961), Annex 2
- u) WHO guidelines for drafting a site master file. (WHO Technical Report Series, No. 961), Annex 14, 2011
- v) Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Technical Report Series, No. 961), Annex 9
- w) WHO Guidelines for independent lot release of vaccines by regulatory authorities. WHO TRS 978, Annex 2.
- x) Guidelines on the stability evaluation of vaccines for use under extended controlled temperature conditions (WHO Technical Report Series No. 999, Annex 5, 2016)
- y) WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. WHO/CDS/CSR/APH/2000.3. Geneva March 1999
- z) WHO Guidelines on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies. WHO, 2006.
<https://apps.who.int/iris/bitstream/handle/10665/43498/9789241547017-eng.pdf>
- aa) Assessing the programmatic suitability of vaccine candidates for WHO prequalification. [WHO/IVB/14.10. WHO 2014.](#)
- bb) [Guidelines on the quality, safety and efficacy of plasmid DNA vaccines, Annex 2, TRS No 1028 Replacement of Annex 1 of WHO Technical Report Series No. 941 10 March 2021: https://www.who.int/publications/m/item/plasmid-dna-vaccines-annex-2-trs-no-1028](#)
- cc) [Guidelines on the quality, safety and efficacy of biotherapeutic protein products prepared by recombinant DNA technology. WHO TRS No. 987 Annex 4, 2014](#)
- dd) WHO Recommendations, Guidelines and other documents related to the manufacture and quality control of biological substances used in medicine. WHO TRS No. 999 Annex 1, 2016
- ee) Regulatory assessment of approved rDNA-derived biotherapeutics. WHO TRS No. 999 Annex 3, 2016

ff) Evaluation of the quality, safety and efficacy of messenger RNA vaccines for the prevention of infectious diseases: regulatory considerations (WHO/BS/2021.2402 under final review)

4. VACCINES

- 4.1. The offered vaccines must meet all the WHO requirements and recommendations currently in force: Guidelines for the production and control of inactivated oral cholera vaccine, Annex 3, Technical Report Series 924, 2004 (<https://www.who.int/publications/m/item/annex-3-trs924-cholera-vax>)
- 4.2. In case the Supplier has agreed with WHO that any supplementary material is to be provided together with the vaccine, UNICEF requests to receive samples of such material as well and they should also be available to be supplied to WHO on request.

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 ([EudraLex – Volume 4](#)), United States FDA ([21 CFR](#)) and International Council for Harmonisation ([ICH Q7](#)) – 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

- 6.1.1 Labelling is included in WHO's guideline "Assessing the programmatic suitability of vaccines considered for WHO prequalification" as preferred vaccine characteristics.
- 6.1.2 Programmatic preference for Labels are:
 - Primary and secondary containers should be labelled according to the principles set out in TRS 996, Annex 2 and Annex 3.

6.2 Thermostable Vaccines

Programmatic preference for thermostable vaccines allowing application of the Controlled Temperature Chain or Extended Controlled Temperature Conditions - 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 can be stored for extended periods at temperatures above +8° C.
- 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 Regulation and Prequalification Department (RPQ), 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 RPQ Department (WHO PQT) in Geneva should be consulted in a timely manner before the changes are introduced. Refer to WHO Guidance on Variations to a Prequalified Vaccine July 2015: https://extranet.who.int/pgweb/sites/default/files/documents/PQ_VXA_Variations_V7.pdf
- 7.2 Such changes may require additional activities by WHO to assure continued compliance with WHO requirements.

8. ACCESS TO FACILITIES

- 8.1 Under an eventual LTA, the awarded 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 access to information necessary for review of manufacturing protocols, lot production records, test results or quality control reports.

9. LABELS AND PACKAGE INSERTS

- 9.1 The labels on vaccine primary containers will be those approved by WHO as part of the prequalification process 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 as well as others known to be freeze sensitive will have the warning "DO NOT FREEZE".
- 9.2 The package insert will be that approved by WHO during prequalification or as revised and accepted by WHO, in correspondence with WHO recommendations (e.g. position papers if available) 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 desirable. In all inserts the following should be inserted under "Description of vaccines". "The vaccine fulfils WHO requirements for..... (Name of vaccine)".

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 that

submitted to or assessed by the WHO-Prequalification Team.

11. VACCINE VIAL MONITORS (VVM)

- 11.1. UNICEF requests vaccines with Vaccine Vial Monitors.
- 11.2. Vaccine vials should be fitted with Vaccine Vial Monitors (VVMs). VVMs should comply with WHO PQS Performance Specification (WHO/PQS/E006/IN05.3) or such updated version and in the PQS independent type-testing protocol (WHO/PQS/E006/IN05.VP.3). More information about VVM can be found here:
https://extranet.who.int/pqweb/sites/default/files/documents/WHO_PQS_E006_IN05.3_May%202018.pdf

12. RELEASE CERTIFICATION

- 12.1. 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.
- 12.2. 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.
- 12.3. 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

- 13.1 Samples of each batch of vaccine supplied under the LTA(s) resulting from this RFP will be retained by the corresponding Supplier until their expiry date, in line with the post-prequalification requirements set out in the “Procedure for assessing the acceptability, in principle, of vaccine for purchase by United Nations agencies” ([WHO TRS 978 annex 6](#)) and further specified in the conditions of the WHO prequalification decision letter, as well as per GMP requirements ([WHO TRS 999 annex 2](#)). These samples will be provided, upon request, to WHO PQT for testing.

14. SHELF LIFE

- 14.1 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:

Vaccine	Remaining shelf life at the time of dispatch
Oral Cholera Vaccine	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 RPQ 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/RPQ 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, Sixth Edition: <https://apps.who.int/iris/bitstream/handle/10665/338012/9789240015432-eng.pdf?sequence=1&isAllowed=y> or any subsequent revisions.

This Sixth Edition of the Guidelines, in effect since January 2021, has replaced previous version which has been in effect since 2005.

Detailed instructions regarding shipping and requirements for invoice and shipping documents will be provided to the awarded Supplier as part of each Purchase Order.

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

18. PACKING, PACKAGING, PACKING LIST, LABELLING AND DANGEROUS GOODS INSTRUCTIONS

- 18.1 Under the LTA, 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 WHO Guidelines on the International Packaging and Shipping of Vaccines, Sixth Edition, (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, 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.
- 18.2 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.
- 18.3 The Supplier’s costs of complying with the requirements of this Section 18 will be the sole responsibility of the Supplier.

19. BAR CODES

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. Please refer to “Annex C - UNICEF Guidelines for Vaccine Barcode Specifications” for further information.

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 in their TECHNICAL PROPOSAL.

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. Manufacturer's Summary Lot Protocol and 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. These devices should, at a minimum, meet the specifications outlined in PQS performance specification for electronic shipping indicators, E006/TR07.3 or any updated version of the same specification, in each and every shipping carton. These devices meeting WHO requirements for international shipments can be found at the following site:

<https://extranet.who.int/pqweb/sites/default/files/documents/WHO-PQS-E006-TR07%203-final.pdf>

Use of temperature monitoring devices powered by lithium batteries other than coin cells should be avoided (IATA 2017 Lithium Battery Guidance Document) as this would require shipments to be labelled as Dangerous Goods.

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, Sixth Edition.

<https://apps.who.int/iris/bitstream/handle/10665/338012/9789240015432-eng.pdf?sequence=1&isAllowed=y>

25. DELIVERY PREPARATION LEAD-TIME

Bidders will indicate, as part of their COMMERCIAL PROPOSAL, 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 for orders aimed for preventative vaccination campaigns.

26. OUTBREAK RESPONSE

The LTA(s) for Oral Cholera Vaccine (OCV) will include a requirement for outbreak buffer stock of up to 5 million doses of (OCV) in 1-dose vial presentation.

Outbreak response orders are to be prepared within **48 hours** from receipt of a UNICEF Purchase Order. In the COMMERCIAL PROPOSAL, Bidders are requested to confirm their ability to do so without a negative impact on other forecasted demand from UNICEF.

ANNEX C - UNICEF GUIDELINES FOR VACCINE BARCODE SPECIFICATIONS

UNICEF is supporting the general efforts to improve traceability of vaccines in the receiving countries. Barcodes on different packaging levels bear options to support supply chains and improve traceability of vaccines.

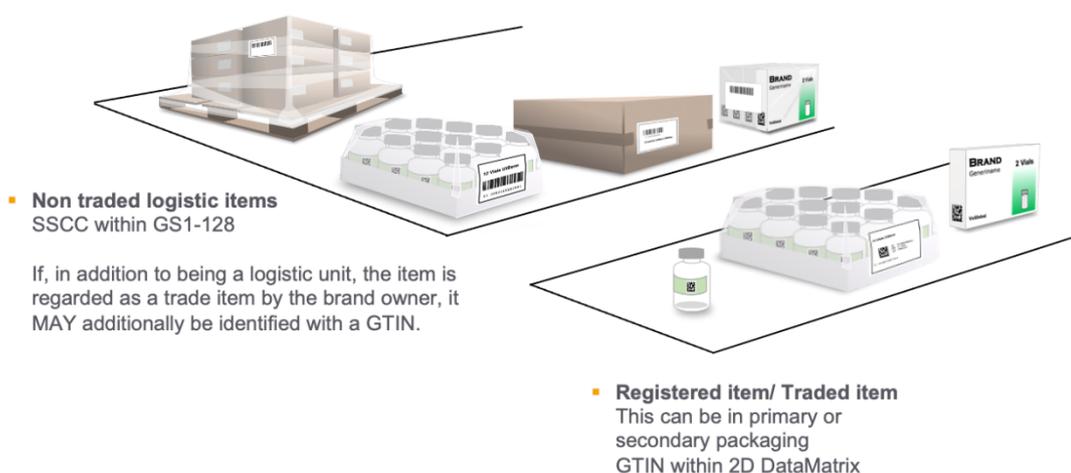
For UNICEF tenders issued after 1 October 2019, the application of barcodes on secondary packaging and higher levels is mandatory for the supply of vaccines from 1 January 2022 and onwards.

Whereas the application of GS1-barcodes on secondary packaging and higher level is considered as the minimum and **mandatory** requirement, GS1-serialised barcodes are considered a **preferred** characteristic.

The application of barcodes should not replace any information on the packaging or labels as currently required in accordance with the WHO guidelines for labelling.

A. GS1-Coding Specifications³ to comply with mandatory characteristics

The illustration provides an overview of the mandatory coding specifications which are covered in detail through this document under section A.



A.1 Registered item/ Traded Item

Data Carrier Symbol: Data Matrix ISO version ECC 200

³ At the time of writing version 20 of the GS1 General Specifications were published at <https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications> and form the basis of all references within this document

Data encoding: Data should be encoded using the GS1 system element strings and will utilize ASCII encoding according to ISO 16022.

Data:

Three data elements that are **required:**

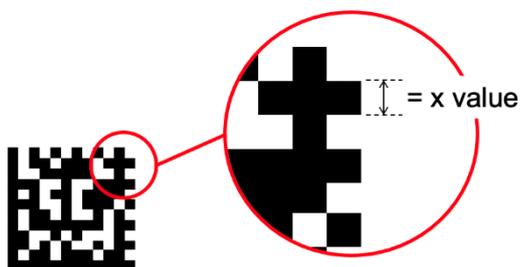
Data element	Application Identifier	Example
Global Trade Item Number	01	01234567890123
Expiry date	17	210131
Batch/ Lot	10	abc123

There is no guidance for the order in which the data elements should be encoded in the Data Matrix; however, it is more efficient to encode the fixed length fields first i.e., GTIN and Expiry date, followed by the variable length fields.

For full details of GS1 elements strings and application identifiers please refer to section 3 of the GS1 General Specifications.

Additional element strings: These may be included in the Data Matrix. An example of an additional element string could be a National Healthcare Reimbursement Number, used where GTIN alone does not meet the needs of the national systems.

Size and shape: There are no preferences regarding the use of square or rectangular symbols. The x dimension of each module should comply with recommendations made by GS1 for healthcare items, namely a minimum x value of 0.255mm and a maximum of 0.615mm.



Negative and positive symbols: The Data Matrix symbol may be produced either dark on a light background or light on a dark background, both are acceptable, as long as they meet the data carrier quality requirement.

Data Carrier Quality: The quality of the Data Matrix code printing/ marking should be 1.5 (C) or better in accordance with ISO/TEC 15415:2011.

Overprint headings: This tender does not specify the overprint headings to be used or the physical location of these, as these are typically defined within national labelling regulations/ requirements and may include local language variations. In GS1 terms this text is referred to a non-HRI (human readable information).

It is however generally good practice to display this information adjacent to the Data Matrix, taking into consideration the quiet zone around the symbol. The following is for illustration purposes only and does not form part of the specifications of the tender (the 2D Data Matrix will not scan).



PC 01234567890123
EXP 11.2020
Lot 7654321D

In addition to the overprint headings human readable interpretation (HRI) may be applied, subject to physical and technical constraints. For further information on HRI please see section 4.15.1 of the GS1 General Specifications.

A.2 Non-traded logistic items (also referred to a tertiary packaging)

This an item established for the purposes of transport and storage and therefore needs to be managed through the supply chain.

Data Carrier Symbol and encoding: GS1-128 linear barcode symbology.

Full details and specifications for the GS1-128 can be found in section 5.4 of the GS1 General Specifications document.

Data: Serial Shipping Container Code (SSCC).

Human readable interpretation: Should the GS1-128 barcode fail to scan for example, through the result of damage, it is necessary that the SSCC is still available to be captured. The use of HRI (Human readable interpretation) is included on the packaging. For HRI rules refer to section 4.15.1 of the GS1 General Specifications.

The following is an example of a GS1-128 shown with HRI, it is not reproduced to size.



Additional element strings: These may be included within the GS1-128.

Data Carrier Quality: 128 linear barcode symbols must be evaluated in accordance with ISO/IEC 15416 which defines a standardized methodology for measuring and grading barcodes.

B. GS1-Coding Specifications⁴ to comply with preferred characteristics

The illustration provides an overview of the preferred coding specifications which are covered in detail through this document under section B.

⁴ At the time of writing version 20 of the GS1 General Specifications were published at <https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications> and form the basis of all references within this document



B.1 Registered item/ Traded Item

Data Carrier Symbol: Data Matrix ISO version ECC 200

Data encoding: Data should be encoded using the GS1 system element strings and will utilize ASCII encoding according to ISO 16022.

Data:

The data elements for the preferred barcode specifications/characteristics:

Data element	Application Identifier	Example
Global Trade Item Number	01	01234567890123
Expiry date	17	210131
Batch/ Lot	10	abc123
Serial number	21	a1b2c3000987654

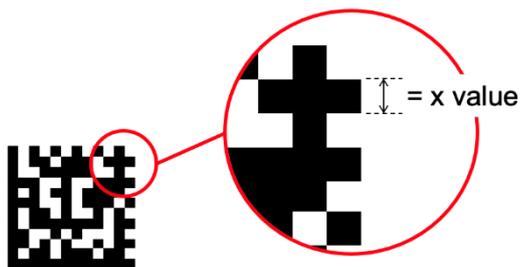
There is no guidance for the order in which the data elements should be encoded in the Data Matrix, however it is more efficient to encode the fixed length fields first i.e. GTIN and Expiry date, followed by the variable length fields.

For full details of GS1 elements strings and application identifiers please refer to section 3 of the GS1 General Specifications.

Additional element strings: These may be included in the Data Matrix. An example of an additional element string could be a National Healthcare Reimbursement Number, used where GTIN alone does not meet the needs of the national systems.

Serial number randomization: The serial number, if included, must be randomized to reduce the ability to guess the next serial number in a sequence. The probability of guessing a valid serial number must be less than 1 in 10,000. Consideration must also be given for large sets of serial numbers and the use of fixed patterns or algorithms which can be worked out given a set of serial numbers.

Size and shape: There are no preferences regarding the use of square or rectangular symbols. The x dimension of each module should comply with recommendations made by GS1 for healthcare items, namely a minimum x value of 0.255mm and a maximum of 0.615mm.

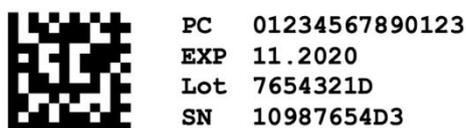


Negative and positive symbols: The Data Matrix symbol may be produced either dark on a light background or light on a dark background, both are acceptable, as long as they meet the data carrier quality requirement.

Data Carrier Quality: The quality of the Data Matrix code printing/ marking should be 1.5 (C) or better in accordance with ISO/TEC 15415:2011.

Overprint headings: This tender does not specify the overprint headings to be used or the physical location of these, as these are typically defined within national labelling regulations/ requirements and may include local language variations. In GS1 terms this text is referred to a non-HRI (human readable information).

It is however generally good practice to display this information adjacent to the Data Matrix, taking into consideration the quiet zone around the symbol. The following is for illustration purposes only and does not form part of the specifications of the tender (the 2D data Matrix will not scan).



In addition to the overprint headings human readable interpretation (HRI) may be applied, subject to physical and technical constraints. For further information on HRI please see section 4.15.1 of the GS1 General Specifications.

Tamper Sealed: To prevent the contents being separated from the stock keeping unit/serialized registered item, it is preferred that a tamper seal should be applied. The primary function is to ensure the integrity of the pack is maintained.

B.2 Non-traded logistic items (also referred to a tertiary packaging)

This an item established for the purposes of transport and storage and therefore needs to be managed through the supply chain.

Data Carrier Symbol and encoding: GS1-128 linear barcode symbology.

Full details and specifications for the GS1-128 can be found in section 5.4 of the GS1 General Specifications document.

Data: Serial Shipping Container Code (SSCC).

Human readable interpretation: Should the GS1-128 barcode fail to scan for example, through the result of damage, it is necessary that the SSCC is still available to be captured. The use of HRI (Human readable interpretation) is included on the packaging. For HRI rules refer to section 4.15.1 of the GS1 General Specifications.

The following is an example of a GS1-128 shown with HRI, it is not reproduced to size.



Additional element strings: These may be included within the GS1-128.

Data Carrier Quality: 128 linear barcode symbols must be evaluated in accordance with ISO/IEC 15416 which defines a standardized methodology for measuring and grading barcodes.

B.3 Serialization and Batch data

Although there is no traceability system currently in place to upload the serialization and batch data, the data must be stored and made available for upload on request for at least the shelf life of the product.

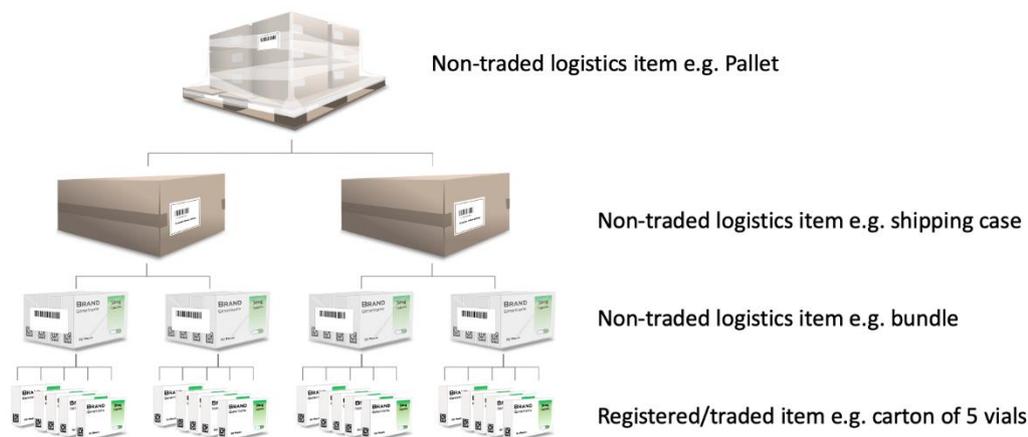
The following is a list of the data for the preferred barcode specification:

- GTIN
- Batch/ Lot
- Expiry date
- **Date of manufacture**
- **Serial numbers**

Aggregation

For the purposes of this preferred tender requirement on serialization, aggregation is determined to be a relationship created between two items, one which is packed inside the other.

An example would be 10 cartons packed in a shipping case, a relationship is made between the individual serial numbers on the 10 cartons and the SSCC on the shipping case. By capturing aggregation data and storing this, it is possible to scan the SSCC and then look up the specific serial numbers on the cartons contained inside, without opening up the shipping case.



To facilitate the potential future tracing of physical products through the supply chain, aggregation should be implemented where possible.

Aggregation relationships need to be made between the highest level of packaging e.g. the pallet, all the way down to the stock keeping unit. If a bundle is produced but is not handled as a logistics item (it has no label and SSCC), then it can be excluded from the aggregation.

When aggregation relationships have been made this data must be stored and made available for upload on request, for at least the shelf life of the product.

The manufacturer must keep a record of which batches have aggregation applied and which have not and be able to produce this information on request.

Master Data

The following master data items must be made available on request for each stock keeping unit.

GTIN, Product name, MAH Name

There are no master data requirements for the SSCC.

UNICEF is supporting the general efforts to improve traceability of vaccines in the receiving countries. For this tender the application of barcodes is considered a preferred characteristic. The application of barcodes should not replace any information on the packaging or labels as currently required in accordance with the WHO guidelines for labelling.

Coding Specifications⁵ to comply with preferred characteristics

The illustration provides an overview of the coding specifications which are covered in detail through this document.

⁵ At the time of writing version 20 of the GS1 General Specifications were published at <https://www.gs1.org/standards/barcodes-epc/fid-id-keys/gs1-general-specifications> and form the basis of all references within this document



Registered item/ stock keeping unit

Data Carrier Symbol: Data Matrix ISO version ECC 200

Data encoding: Data should be encoded using the GS1 system element strings and will utilise ASCII encoding according to ISO 16022.

Data: Four data elements are preferred.

Data element	Application Identifier	Example
Global Trade Item Number	01	01234567890123
Expiry date	17	210131
Batch/ Lot	10	abc123
Serial number	21	a1b2c3000987654

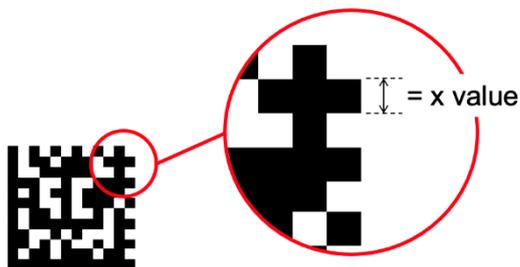
There is no guidance for the order in which these should be encoded in the Data Matrix, however it is more efficient to encode the fixed length fields first i.e. GTIN and Expiry date, followed by the variable length fields.

For full details of GS1 elements strings and application identifiers please refer to section 3 of the GS1 General Specifications.

Additional element strings: These may be included in the Data Matrix. An example of an additional element string could be a National Healthcare Reimbursement Number, used where GTIN alone does not meet the needs of the national systems.

Serial number randomisation: The serial number must be randomised to reduce the ability to guess the next serial number in a sequence. The probability of guessing a valid serial number must be less than 1 in 10,000. Consideration must also be given for large sets of serial numbers and the use of fixed patterns or algorithms which can be worked out given a set of serial numbers.

Size and shape: There are no preferences regarding the use of square or rectangular symbols. The x dimension of each module should comply with recommendations made by GS1 for healthcare items, namely a minimum x value of 0.255mm and a maximum of 0.615mm.

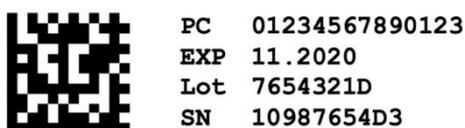


Negative and positive symbols: The Data Matrix symbol may be produced either dark on a light background or light on a dark background, both are acceptable, as long as they meet the data carrier quality requirement.

Data Carrier Quality: The quality of the Data Matrix code printing/ marking should be 1.5 (C) or better in accordance with ISO/TEC 15415:2011.

Overprint headings: This tender does not specify the overprint headings to be used or the physical location of these, as these are typically defined within national labelling regulations/ requirements and may include local language variations. In GS1 terms this text is referred to a non-HRI (human readable information).

It is however generally good practice to display this information adjacent to the Data Matrix, taking into consideration the quiet zone around the symbol. The following is for illustration purposes only and does not form part of the specifications of the tender (the 2D data Matrix will not scan).



In addition to the overprint headings human readable interpretation (HRI) may be applied, subject to physical and technical constraints. For further information on HRI please see section 4.15.1 of the GS1 General Specifications.

Tamper Sealed: To prevent the contents being separated from the serialised registered item/ stock keeping unit, it is preferred that a tamper seal should be applied. The primary function is to ensure the integrity of the pack is maintained.

Non-traded logistic items (also referred to a tertiary packaging)

This an item established for the purposes of transport and storage and therefore needs to be managed through the supply chain.

Data Carrier Symbol and encoding: GS1-128 linear barcode symbology.

Full details and specifications for the GS1-128 can be found in section 5.4 of the GS1 General Specifications document.

Data: Serial Shipping Container Code (SSCC).

Human readable interpretation: Should the GS1-128 barcode fail to scan for example, through the result of damage, it is necessary that the SSCC is still available to be captured. The use of HRI (Human readable interpretation) is included on the packaging. For HRI rules refer to section 4.15.1 of the GS1 General Specifications.

The following is an example of a GS1-128 shown with HRI, it is not reproduced to size.



Additional element strings: These may be included within the GS1-128.

Data Carrier Quality: 128 linear barcode symbols must be evaluated in accordance with ISO/IEC 15416 which defines a standardised methodology for measuring and grading barcodes.

Batch and serialisation data

Although there is no traceability system currently in place to upload the batch and serialisation data, the data must be stored and made available for upload on request for at least the shelf life of the product.

The following is a list of the preferred data:

- GTIN
- Batch/ Lot
- Expiry date
- Date of manufacture (please refer to Annex D as this is under consideration by WHO)
- Serial numbers

Aggregation

For the purposes of this tender, aggregation is determined to be a relationship created between two items, one which is packed inside the other.

An example would be 10 cartons packed in a shipping case, a relationship is made between the individual serial numbers on the 10 cartons and the SSCC on the shipping case. By capturing aggregation data and storing this, it is possible to scan the SSCC and then look up the specific serial numbers on the cartons contained inside, without opening up the shipping case.



To facilitate the potential future tracing of physical products through the supply chain, aggregation should be implemented where possible.

Aggregation relationships need to be made between the highest level of packaging e.g. the pallet, all the way down to the stock keeping unit. If a bundle is produced but is not handled as a logistics item (it has no label and SSCC), then it can be excluded from the aggregation.

When aggregation relationships have been made this data must be stored and made available for upload on request, for at least the shelf life of the product.

The manufacturer must keep a record of which batches have aggregation applied and which have not and be able to produce this information on request.

Master Data

The following master data items must be made available on request for each stock keeping unit.

GTIN, Product name, MAH Name

There are no master data requirements for the SSCC.

Electronic leaflets

There is no specific requirement however, it is possible to utilise the GS1 Digital Link standards to link the data in the 2D DataMatrix with online leaflets and other digital information.