

REQUEST FOR PROPOSAL

UNITED NATIONS CHILDREN'S FUND (UNICEF)

Wishes to receive Proposals from Manufacturers

For the period January 2021 until December 2025

Monovalent (Sabin) Oral Polio Vaccine type 2 in Bulk Form, potential Conversion into Finished Product and Delivery, including the Services for Storage, Management, and Maintenance in a Global Stockpile

RFP-DAN-2020-503251

19th November 2020

EMAILED PROPOSALS must be sent to the email supplybid@unicef.org by 16h00 hours (Copenhagen time) on 15th January 2021

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

Prepared by: Ian Lewis
Contracts Specialist

Approved by:

Ann Ottosen

19-11-2020
Ann Ottosen
f/Chief
Vaccine Center
UNICEF Supply Division

Katinka Rosenbom

19-11-2020
Katinka Rosenbom
Chief
Contracting Center
UNICEF Supply Division



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1. PURPOSE

In its capacity as procurement agency for the Global Polio Eradication Initiative (GPEI) and upon request from WHO, UNICEF wishes to enter into a Contract for Products and Services for the supply of one billion doses of monovalent Oral Polio Vaccine type 2 (mOPV2) in bulk form, and the storage, management and maintenance of the same with the Supplier. Should there be a requirement for delivery of a finished product, the Supplier shall convert part or all of the bulk into finished product, store, manage and maintain the finished product, and eventually deliver a WHO prequalified mOPV2 vaccine.

The mOPV2 bulk vaccine is intended to become part of the Global Bulk Stockpile to be stored with the Supplier for potential release by UNICEF for processing into finished product mOPV2.

In case the expiry date of the bulk is beyond the duration of the Request for Proposal (RFP), or any mOPV2 in finished product converted upon request by UNICEF on behalf of WHO, UNICEF may request the Supplier to extend any resulting Contract.

1.1 OUTLINE OF THE PROCESS FOR PRODUCTS AND SERVICES

1.1.1 Award: Upon the conclusion of the tender, and following a request from WHO on behalf of GPEI, UNICEF may issue an award letter to the Supplier stating the total number of mOPV2 bulk doses required to be included in the Global Bulk Stockpile for storage with the Supplier.

1.1.2 Acceptance of mOPV2 bulk vaccine: The Supplier shall provide i) a copy of the release certificate issued by the National Regulatory Authority (NRA) of Record for each batch of the mOPV2 bulk vaccine; and ii) written confirmation from Supplier's Qualified Person confirming the available mOPV2 bulk vaccine volume, the equivalent number of bulk doses, and the corresponding number of finished product of mOPV2, which the Supplier would expect to be able to deliver to UNICEF if requested to convert such bulk doses into finished product mOPV2 in a formulation which complies with the requirements to apply the Vaccine Vial Monitor type 2 (VVM2). UNICEF will share the documents with WHO's Prequalification Team (WHO/PQT) for review to ensure that the mOPV2 bulk offered meets the mandatory technical requirements of the RFP and to verify the calculation of the number of doses. Upon WHO/PQT's confirmation that the mOPV2 meets the requirements the bulk will be accepted into the Global Bulk Stockpile, to be kept at the Supplier's premises.

1.1.3 Fee: Upon acceptance of the bulk into the Global Bulk Stockpile by WHO and UNICEF, the Supplier will submit the invoice to UNICEF for the product as well as services to be provided for the storage, management and maintenance of the mOPV2 bulk. UNICEF will pay the invoice in line with the agreed payment terms.

1.1.4 Acceptance of mOPV2 finished product: Upon conclusion of production and release of the mOPV2 by the NRA of Record and the Supplier's Qualified Person, the Supplier shall provide i) a copy of the lot release certificate issued by the NRA of Record; ii) Lot release certificate and Lot Summary Protocol for each batch issued by the Supplier, iii) an overview of the Supplier's records to confirm quantities by batch, certified by the Qualified Person; and iv) a mock-up of the external packaging of a box and vial label. UNICEF will share the documents with WHO's Prequalification Team (WHO/PQT) for review to ensure that the production services has been completed and the mOPV2 finished product meets the mandatory technical requirements of the RFP. UNICEF further requires that the finished product is Prequalified by WHO, or as a minimum, listed by WHO under the Emergency Use Listing before accepting the product for stockpile purposes. Upon WHO/PQT's confirmation that the mOPV2 meets the

requirement including Prequalification the vaccine will be accepted into the global stockpile, to be kept at the Supplier's premises.

1.1.5 Fee: Upon acceptance of the vaccine into the Global Stockpile of Finished Product by WHO and UNICEF, the Supplier will submit the invoice to UNICEF for the services provided covering the conversion of mOPV2 bulk available in the Global Bulk Stockpile into mOPV2 finished product, storage, management and maintenance and potential delivery to the nearest international airport to the Supplier's production site on FCA terms. UNICEF will pay the invoice in line with the agreed payment terms.

1.1.6 Issuance of Purchase Order for Finished Product: Following a technical review of a country request for release of mOPV2 from the Global Stockpile of Finished Product, the WHO Director-General may notify UNICEF that mOPV2 can be released from the Global Stockpile in a specified quantity to an outbreak affected country. UNICEF will issue a ZERO Dollar (\$0.00) Purchase Order to the Supplier confirming the number of doses to be delivered, the consignee details, the FCA delivery point and stating that the Purchase Order is prepaid.

1.1.7 Goods Readiness/Delivery: Given the urgency of the outbreak situation and the obligation for countries to undertake an outbreak response within 14 days, the Supplier is requested to have the Goods packed and ready for shipment within 3 working days of receipt of a Purchase Order. To facilitate this timeline, UNICEF will notify the Supplier of a possible required delivery as soon as UNICEF is aware of a possible request (usually 2 to 3 days in advance of issuing the Purchase Order). The Supplier is responsible for obtaining any required authorisations from the relevant authorities in the country of manufacture to allow for exportation of the mOPV2 finished product.

1.2 SPECIAL CONSIDERATIONS FOR THE STOCKPILE

1.2.1 mOPV2 Bulk Product: Ownership of the mOPV2 bulk will remain with the Supplier upon acceptance of the mOPV2 bulk vaccine into the Global Bulk Stockpile. During the contract period, the Supplier shall grant to UNICEF and WHO an irrevocable exclusive lien over the mOPV2 Global Bulk Stockpile to reflect UNICEF's and WHO's exclusive rights to use and dispose of the Stockpile, including issuance of requests for conversion of some or all of the mOPV2 bulk available in the Stockpile into finished product.

1.2.2 Production, storage, management and maintenance of bulk: As part of the services, the Supplier will be required to produce and store the mOPV2 bulk vaccine at its facility under the appropriate storage conditions relevant to mOPV2 bulk, including containment requirements as defined by the National Authority of Containment. Storage, management and maintenance will be required until such time that the mOPV2 bulk is either i) converted into finished product upon issuance of an Award Letter from UNICEF; or ii) has reached the expiry date, at which time the Supplier will be expected to dispose of the bulk vaccine at its own cost in line with the national guidelines, as applicable, provided that such destruction has been confirmed in writing by UNICEF.

1.2.3 Ownership of mOPV2 in finished product: Upon acceptance of the finished product into the Global Stockpile of Finished Product and upon UNICEF's payment of the fee to the Supplier, it is the intent that ownership of the mOPV2 finished product will transition to WHO. The WHO Director-General has the sole authority to approve release of vaccines from the Global Stockpile of Finished Product. Any representations, warranties and indemnification granted to UNICEF under the Contract shall be extended to WHO, which will be a third party beneficiary to the Contract.

1.2.4 Production, storage, management and maintenance of finished product: As part of the services, the Supplier will be required to store the finished product produced under the Contract at its facility under the appropriate conditions relevant to mOPV2. Storage, management and maintenance will be required until such time that the mOPV2

vaccine doses have either been delivered against Purchase Orders or have reached their expiry date, at which time the Supplier will be expected to dispose of the vaccines at its own cost in line with the national guidelines, as applicable, provided that such destruction has been confirmed in writing by UNICEF.

2. BACKGROUND

2.1 PROGRAMMATIC UPDATE

Global production of Oral Polio Vaccine (OPV) Type 2 in bulk form discontinued prior to April 2016 when the type 2 component of the tOPV was withdrawn from the global market in a synchronised manner across 155 countries and territories. In preparation for the global cessation of use of type 2 containing vaccines, in 2009, UNICEF on behalf of the GPEI issued a tender to establish a global stockpile of type 2 bulk vaccine, with the purpose to ensure bulk vaccine to respond to an anticipated limited number of outbreaks after cessation. Based on offers received from three manufacturers that were producing type 2 bulk vaccine to meet global requirements and on WHO's technical guidance, UNICEF established a Global Bulk Stockpile with two of these manufacturers, totalling 519 million doses of mOPV2 bulk. At the time of discontinued use of type 2 containing vaccines, in addition to the bulk secured for the stockpile, all three bidders had residual volumes in stocks of which most have subsequently been included in the Global Bulk Stockpile and converted to finished product.

Due to the number and expanding spread of outbreaks of circulating Vaccine Derived Polio Virus type 2 (cVDPV2) and the need to respond to these with mOPV2 (and now tOPV) the bulk stockpile is almost depleted. While a novel mOPV2 has concluded phase II clinical development in a limited number of subjects and is expected to become available shortly under WHO's Emergency Use Listing, in case of failure or any significant delays the GPEI, as a risk mitigation, is requesting an additional 1 billion doses of mOPV2 bulk to be made available. This ask will require the restart of type 2 bulk production.

2.2 PRODUCTS AND SERVICES REQUESTED

The products, services and deliverables requested under this RFP is for the supply of **mOPV2 vaccine in bulk form to be available with the Supplier**, and the storage, management and maintenance of **the same** to become part of the Global Bulk Stockpile. Should there be a need, UNICEF will request the Supplier to convert the bulk in part or in total into finished mOPV2 product.

2.3 OBJECTIVE OF THE TENDER

The main objective of the tender is to:

- i) secure 1 billion doses of mOPV2 bulk vaccine, including the storage, management and maintenance in a global stockpile; and
- ii) ensure capacity to convert some or all of the bulk into a WHO Prequalified finished product of mOPV2 if required.

A secondary objective is to diversify risks and avoid dependency on a single source of supplies. Therefore, the objective would be to award two bulk suppliers which are able to produce substantial quantities (greater than 500 million doses of type 2 bulk annually and with a fill and finish capacity to produce a minimum of 200 million doses in finished product), in compliance with production requirements as determined by the NAC. As the procurement of mOPV2 bulk vaccine for the Global Bulk Stockpile is to operate as a risk mitigation strategy in case of nOPV2 failure, the bulk should be available as soon as possible, with the aim that finished product could be available in case of need preferably from early 2022.

While currently the GPEI is envisaging that the risk mitigation should secure additional capacity of mOPV2 in bulk and/or finished product based on need, UNICEF would take the opportunity of this tender to understand the ability and capacity of Bidders to deliver a trivalent OPV, should the requirements change. UNICEF would therefore be interested

in understanding the capacity and ability to also produce, supply and deliver mOPV1 and mOPV3 in case of need.

Offers for all quantities are welcomed.

3. INSTRUCTIONS TO PROPOSER

3.1 RFP TERMS

This RFP, along with any Proposal made in response to this RFP, shall be considered the property of UNICEF. Proposals will not be returned.

In submitting the Proposal, the Proposer:

- agrees to accept the decision of UNICEF as to whether the Proposal meets the minimum requirements stated in this RFP; and the UNICEF evaluation of the Proposal
- offers to supply the products and services to meet the overall objectives sought in accordance with any specifications stated and subject to UNICEF's General Terms and Conditions (Goods) (attached in Annex A), UNICEF's General Terms and Conditions (Services) (attached in Annex B) and any other mandatory requirements and terms and conditions specified in this RFP, and warrants that these have been considered in the elaboration of the Proposal
- accepts that any subsequent Product and Service Agreement resulting from this RFP shall contain the UNICEF General Terms and Conditions (Goods). UNICEF's General Terms and Conditions (Services) and any other terms and conditions specified in this RFP
- declares having examined all Schedules / Forms and all Instructions pertaining to the Proposal included in this RFP

Information provided in the Proposal will be treated as confidential unless otherwise noted by the Proposer. However, the Proposer's attention is brought to Section 3.9 PUBLIC POSTING, DISCLOSURE OF PRICES AND QUANTITIES, of this RFP.

The Proposal must be made in accordance with the instructions contained in this RFP.

UNICEF shall not pay any costs incurred in the preparation or submission of Proposal.

3.2 RFP IN ELECTRONIC FORMAT

The RFP will be provided in an electronic format and Proposal must also be returned to UNICEF as an electronic format, as defined on the Front Page and in Section 3.5.5.

3.3 MANDATORY REQUIREMENTS

"Mandatory requirements" identify the minimum requirements for the Proposals to be considered. Mandatory requirements will be indicated throughout this RFP by the words "mandatory", "shall", "must", or "will" in regard to obligations on the part of the Proposer. Proposals that do not meet the mandatory requirements will not be eligible for award.

3.4. SUPPLIER REGISTRATION

UNICEF is part of the United Nations Global Marketplace (UNGM). Accordingly, Proposer is requested to register to become a UNICEF vendor by creating a vendor profile and submitting their national incorporation license/certificate at the Level 1 stage of vendor registration process in the UNGM website: www.ungm.org

Please note that UNGM registration, including provision of national incorporation license/certificate, should be submitted as soon as possible and is a mandatory

requirement for any eventual award.

The United Nations Global Marketplace (UNGM) registration number is to be provided in the TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET (see Section 3.5).

Simultaneously with application to UNGM, and unless this information has already been provided to UNICEF within the previous twelve (12) months, Proposer shall submit a copy of their most recent Audited Financial Statement and a Quality System Certificate to the UNICEF Quality Assurance Supplier Evaluation Unit, UNICEF Supply Division, Oleanvej 10-12, 2150, Copenhagen, Denmark. This information will be used by UNICEF for evaluation and approval purposes before making an award. It is in the interest of the Proposer to provide information as complete as possible, as awards will only be made to suppliers who meet UNICEF's supplier selection criteria (see the TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET)

3.5 TENDER PROCESS – RESPONSES TO THE REQUEST FOR PROPOSALS

3.5.1 CONTENT AND FORMAT

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

Proposers are expected to fully utilise the opportunity of the RFP to include all relevant information in the offer, including procurement and contracting methodologies which allows the Proposer to best possibly contribute to achieving the procurement objectives.

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

Only the forms and answering sheets provided in Section 5 should be used to present the various aspects of the Proposal. Supplementary information can be provided on each of the answering sheets:

- PROPOSAL FORM
- TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET
- QUALITATIVE PROPOSAL SHEET
- QUANTITATIVE PROPOSAL SHEET(S)
- COMMERCIAL TERMS SHEET

The Proposal should, as a minimum:

- Include the statement of acceptance of the RFP and resulting product and services contract terms and conditions and certify the date of validity of the offer (PROPOSAL FORM)
- Contain all the requested information on mandatory requirements for offered products (TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET). Guiding questions associated with the technical and financial aspects of the Proposer's offer are included in this Technical and Financial mandatory requirements sheets.
- Contain qualitative information on account management, proven experience and past performance (QUALITATIVE PROPOSAL SHEET). Guiding questions associated with the qualitative aspects of the Proposer's proposal are included in this Qualitative Proposal sheet.
- Define the proposed bulk vaccine (QUANTITATIVE PROPOSAL SHEET), including the proposed shelf life of such bulk, volume in litres, concentration, equivalent in bulk doses; and equivalent in finished product doses offered, calendar of availability and price or fee in accordance with the technical requirements

- Provide explanations to any requirements or request for exceptions or clarification on the COMMERCIAL TERMS SHEET.

3.5.2 REQUESTING INFORMATION FROM UNICEF DURING THE TENDER PROCESS

Any request for information should be forwarded to the Contracts Specialist preparing the RFP, and NOT to the Bid Section (see front page). Please send any request for information to Ian Lewis at e-mail: ilewis@unicef.org with copy (CC) to Ann Ottosen at e-mail aottosen@unicef.org with specific reference to this RFP in the subject of the e-mail so that the query may be answered in the normal course of business.

3.5.3 ERROR IN PROPOSAL

The Proposers are expected to examine all Schedules and all Instructions pertaining to the RFP. Failure to do so will be at Proposer's own risk.

3.5.4 CORRECTIONS

Erasures or other corrections in the Proposal must be explained and the signature of the Proposer shown alongside.

3.5.5 SUBMISSION OF ELECTRONIC PROPOSALS

EMAILED PROPOSALS should be sent to:

supplybid@unicef.org

no later than the specified date and time on the cover page of this proposal.

Proposals sent to any other email or sent after the deadline, will be invalidated. Proposals received without the RFP number will be invalidated.

EMAILED PROPOSALS instructions:

All e-mail communication in relation to the Proposal must clearly indicate the reference Bid number and the company name (e.g. Company Name xxx for RFP-DAN-2020-503251) in the "Subject" line of the e-mail.

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

Ensure the "acknowledge receipt" of the Bid is received after the e-mail submission. The subject line of an "acknowledge receipt" will show "UNICEF Supply Division - Bid confirmation. Ref: "Name of Company xxx".

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

No other recipient should be "cc" or "bcc" in the e-mail submission.

3.5.6 TIME FOR RECEIVING PROPOSALS

Emailed Proposals received prior to the stated closing time and date will be kept unread. The Officer of the Bid Section will read the Proposals when the specified time has arrived and no Proposal received thereafter will be considered.

UNICEF will accept no responsibility for the premature opening of a Proposal which is not properly addressed or identified.

3.5.7 MODIFICATION AND WITHDRAWAL

A Proposer may make changes to its Proposal after it has been received by UNICEF, on the following conditions: a new set of Proposal documents must be submitted; the revised Proposal documents must clearly state that it is a revised Proposal and supersedes and replaces the Proposal already submitted by the Proposer; and the revised Proposal must be received by UNICEF prior to the deadline for submitting Proposals.

A Proposer may withdraw its Proposal at any time prior to the deadline for submitting proposals by giving UNICEF written notice (by email or other, sent to the BID SECTION). Negligence on the part of the Proposer confers no right for the withdrawal of the Proposal after it has been opened.

Modifications to and possible withdrawals of proposals must only be sent to the Bid Sections e-mail (supplybid@unicef.org).

3.5.8 OPENING OF PROPOSAL

Due to the nature of the RFP, there will be no public opening of Proposals.

3.6 EVALUATION OF PROPOSALS AND BASIS FOR AWARD

3.6.1 PROPOSAL EVALUATION METHOD and EVALUATION CRITERIA

Proposals will be evaluated upon receipt based on qualitative and quantitative criteria. Upon evaluation of the Proposal, awards will be made to the Proposer considering the evaluation criteria against the objectives of the tender.

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

Overview of Quantitative Information	
Objective	Evaluation criteria
Secure 1 billion doses of mOPV2 bulk vaccine, including the storage, management and maintenance in a global stockpile	<ul style="list-style-type: none"> Product offered Quantity offered; conditions of quantity offered Demonstration of capacity to provide quantities offered; possible effects of quantities offered on other vaccine presentations including OPV. Agreement to store bulk until expiration in case of none conversion into finished product Agreement to destroy bulk upon expiry at no additional costs Fee for the bulk product and the service of storing, management and maintenance Price conditions offered - Alternative offers providing additional beneficial affordability/prices/commercial terms
Ensure capacity to convert some or all of the bulk into a finished product if required.	<ul style="list-style-type: none"> Annual/monthly capacity to covert bulk into finished product Price of the conversion fee Indicate factors that influence the price setting Reciprocity in any special contracting terms
Overview of Qualitative Information	
Objective	Evaluation Criteria

<p>Secure 1 billion doses of mOPV2 bulk vaccine, including the storage, management and maintenance in a global stockpile</p>	<ul style="list-style-type: none"> • Ability to meet WHO GAPIII containment requirements as recommended by the Containment Advisory Group • Facility must currently be entered in the Containment Certification Scheme (CCS) and holding approved documentation from GCC • Agreement with the National Authority of Containment to manufacture OPV type 2 bulk • Supplier performance (existing supplies) • Proven capacity to supply offered and forecasted quantities • Reliable and firm forecasted supply; accurate monthly forecasting for current suppliers: <ul style="list-style-type: none"> ◦ Realistic quantity offered ◦ Timeliness of purchase order Acknowledgement ◦ Timeliness of Notification of Goods readiness ◦ Timeliness of delivery • Account management resources (organizational charts with names) and customer service capabilities including: • Experience in vaccine supply and delivery: <ul style="list-style-type: none"> ◦ Number of years of production and delivery (quantity)
<p>Ensure capacity to convert some or all of the bulk into a finished product if required.</p>	<ul style="list-style-type: none"> • Product offered should be with VVM2 • Finished product should be licensed in the country of manufacture • Product should be WHO prequalified and the manufactures agrees to maintain the prequalification of the product until all the bulk is convert or the parts agree. • The production/storage of finished product must meet requirements of the National Authority for containment and GAPIII requirements as recommended by CAG • Facility must currently be entered in the Containment Certification Scheme (CCS) and holding approved documentation from GCC • Shelf life of the product should be minimum 24 months but longer is preferable • Duration the manufacturer will maintain the capacity to convert the bulk into finished product • Willingness to maintain national licensure of mOPV2 finished product • Willingness to maintain WHO pre-qualification of mOPV2 finished product

3.6.2 EVALUATION METHODOLOGY:

The evaluation consists of two main reviews:

- 1) Review of compliance with Mandatory Requirements, and
- 2) Evaluation of Quantitative and Qualitative Content of the Proposal.

3.6.3 REVIEW OF MANDATORY REQUIREMENTS

Technical Mandatory Requirements will be evaluated by WHO/PQT and WHO containment team. All other Mandatory Requirements will be evaluated by UNICEF. For a Proposal to be eligible for an award, all Mandatory Requirements must be met.

3.6.4 EVALUATION OF QUANTITATIVE AND QUALITATIVE CONTENT

During this evaluation, the nature of the commercial Proposal will be studied and compared to the evaluation criteria.

In order to obtain to what extent a Proposal is found satisfactory, all quantitative data will be evaluated together with the qualitative data to determine how the factors presented in each proposal will support the tender objectives as per Section 2.

3.6.5 BASIS FOR AWARD

The basis for the award will be assessed on how the Proposal meets the objectives of this tender.

Awards will only be considered for Proposal meeting the Technical Requirements of Section 4.

Awards will be determined based on the following criteria:

- Ability to meet the tender objectives
- Products meeting the technical specifications
- Timing of product availability
- Price for the products and services

3.7 RIGHTS OF UNICEF

3.7.1 UNICEF reserves the right (a) to INVALIDATE any Proposal for reasons stated in this RFP, and, (b) unless otherwise specified by UNICEF or by the Proposer, to accept any item offered in the Proposal.

3.7.2 UNICEF reserves the right to INVALIDATE any Proposal received from a Proposer which, in the opinion of UNICEF, is not in a position to perform any Service Contract issued as a result of this RFP; 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 Service Contract issued as a result of this RFP or any Purchase Order issued.

3.7.3 UNICEF reserves the right to request additional or supplementary information from the Proposer.

3.7.4 UNICEF reserves the right to retender should the result of the tender be deemed nonresponsive by UNICEF.

3.7.5 UNICEF reserves the right to negotiate with the Proposer

3.8 AWARD NOTIFICATION

Proposer will receive a written notification stating whether it has been awarded a Product and Service Contract under this RFP or not.

3.9 PUBLIC POSTING, DISCLOSURE OF PRICES AND QUANTITIES

3.9.1 UNICEF will make each award public by publishing the following information on the UNICEF website: The supplier name, vaccine(s), duration of award, total award value.

3.9.2 UNICEF reserves the right to disclose price and quantity information relevant to the product and services contract resulting from this tender.

3.10 DEBRIEFING

Proposer receiving an award will be invited to a formal debriefing and award initiation meeting. Proposer not receiving an award may request a formal debriefing. During a debriefing, the strengths and weaknesses of the Proposal may be discussed.

3.11 PRODUCT AND SERVICES CONTRACT

3.11.1 The UNICEF General Terms and Conditions of Contract (Goods) attached to this RFP (Annex A), UNICEF's General Terms and Conditions (Services) (attached in Annex B), the technical mandatory requirements and any other terms and conditions specified in this RFP shall also apply to the resulting Product and Services Contract. The UNICEF General Terms and Conditions of Contract (Goods), attached as Annex A and UNICEF's General Terms and Conditions of Contract (Services) (attached in Annex B) will apply to the Product and Services Contract to be entered into between the parties upon acceptance of the award letter by the Supplier. In the case of any inconsistencies, the following order of precedence shall prevail:

- (a) The Product and Services Contract;
- (b) The RFP

3.11.2 The UNICEF's General Terms and Conditions of Contract (Goods) and UNICEF's General Terms and Conditions of Contract (Services) will apply to the Product and Service contract(s) awarded in connection with this RFP. By signing the Request for Proposal for Products and Services Form, the Proposer is deemed to have confirmed its acceptance of the UNICEF General Terms and Conditions of Contract (Goods) Annex A and UNICEF's General Terms and Conditions of Contract (Services) (attached in Annex B). The Proposer understands that if it proposes any amendments or additional terms to the UNICEF General Terms and Conditions of Contract (Goods) and/or UNICEF's General Terms and Conditions of Contract (Services), these must be clearly detailed in the Proposal and may negatively affect the evaluation of the Proposal.

3.12 ETHICAL STANDARDS

UNICEF requires that Proposers observe the highest standard of ethics during the entire solicitation process, as well as the duration of any contract 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 prohibition of sexual exploitation and sexual abuse.

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

3.12.1 In respect of all aspects of the solicitation process the Proposer 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 Proposer 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 services requested under this RFPS; or if it or any of its affiliates has been involved in the preparation and/or design of the programme/project related to the services requested under this RFP.

3.12.2 The Proposer has not unduly obtained, or attempted to unduly obtain, any confidential information in connection with the solicitation process and any contract that may be awarded as a result of this solicitation process.

3.12.3 No official of UNICEF or of any United Nations System organisation has received from or on behalf of the Proposer, or will be offered by or on behalf of the Proposer, any direct or indirect benefit in connection with this RFP including the award

of the contract to the Proposer. Such direct or indirect benefit includes, but is not limited to, any gifts, favours or hospitality.

3.12.4 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 Proposer 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 Proposer 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 Proposer, communicate with UNICEF, or present to UNICEF, about any matters that were within such former official's responsibilities while at UNICEF.

3.12.5 Neither the Proposer 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 Proposer 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 during the term of the contract. If the Proposer or any of its affiliates, or personnel or directors becomes subject to any such sanction or temporary suspension during the term of any resulting contract, UNICEF will be entitled to suspend the contract for a period of time up to thirty (30) days or terminate the contract, at its sole choice, with immediate effect upon delivery of a written notice of suspension or termination, as the case may be, to the Proposer. If UNICEF chooses to suspend the contract it will be entitled to terminate the contract at the end of the thirty (30) days' suspension at UNICEF's sole choice.

3.12.6 The Proposer 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 contract; and (c) comply with the applicable provisions of UNICEF's Policy Prohibiting and Combatting Fraud and Corruption which can be accessed on the UNICEF website at http://www.unicef.org/supply/index_procurement_policies.html. In particular, the Proposer 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.

3.12.7 The Proposer 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).

3.12.8 Neither the Proposer 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.

3.12.9 The Proposer 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 Proposer to perform any services in the Proposer'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 Proposer has taken

and will take all appropriate measures to prohibit its personnel including its employees or other persons engaged by the Proposer, 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.

3.12.10 The Proposer confirms that it has read UNICEF's Policy on Conduct Promoting the Protection and Safeguarding of Children. The Proposer 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 Proposer will further cooperate with UNICEF's implementation of this Policy.

3.12.11 The Proposer 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 Article 3.

3.12.12 Each of the provisions in this Article 3.12 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 Proposer from this solicitation process and/or any other solicitation process, and to terminate any contract that may have been awarded as a result of this solicitation process, immediately upon notice to the Proposer, without any liability for termination charges or any liability of any kind. In addition, the Proposer may be precluded from doing business with UNICEF and any other entity of the United Nations System in the future.

4. RFP TERMS AND CONDITIONS

4.1 FORECAST REQUIREMENTS

4.1.1 PRODUCTS AND SERVICES DESCRIPTION

UNICEF is requesting offers for up to **one billion doses of mOPV2**, to be added to the Global Bulk Stockpile under WHO's control. In addition, UNICEF is requesting an offer for the services for the management, storage and maintenance of the same mOPV2 in bulk form, at the Supplier's facility.

Should there be a requirement for mOPV2 in fished product, UNICEF will request for part or all of the bulk to be converted, and for the storage, management, maintenance of mOPV2 in finished product to be Prequalified by WHO. The service fee for conversion should include the costs related to management, storage and maintenance of the same mOPV2 finished product, at the Supplier's facility, and its potential delivery FCA nearest international airport (INCOTERMS 2020).

Offers for all quantities are welcomed.

4.2 MANDATORY TECHNICAL REQUIREMENTS

4.2.1 COMPLIANCE WITH TECHNICAL SPECIFICATIONS AND WHO REQUIREMENTS

The mOPV2 bulk and finished product offered must meet all the WHO recommended requirements stipulated in Annex C.

UNICEF reserves the right to reject any bulk or finished product 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 of Contract (Goods) which are included as Annex A and constitute an integral part of the present RFP and any resulting Purchase Order(s)

4.2.2 WHO PREQUALIFICATION

The manufacturer must agree to obtain or maintain national licensure and WHO prequalification of the finished mOPV2 product as soon as possible and throughout the duration of the contract.

4.3 INSPECTION RIGHTS

The Supplier shall permit UNICEF/WHO or their representatives, as may be designated under notice to the Supplier, to have access to the manufacturing and/or storage facilities at all reasonable times, and shall provide reasonable assistance to the representatives in such inspection, including providing copies of manufacturing protocols, batch production records, test results or quality control reports as may be requested.

4.4 FINANCIAL AND COMMERCIAL REQUIREMENTS

4.4.1 PROPOSER'S REPRESENTATION

In submitting the Proposal, the Proposer:

- agrees to acceptance of the decision of UNICEF as to whether the Proposal meets the minimum requirements stated in this RFP; and the related evaluation
- offers to supply the services and deliverables to meet the overall objectives sought in accordance with any specifications stated and subject to UNICEF General Terms and Conditions of Contract (Goods) and UNICEF's General Terms and Conditions of Contract (Services) as annexed to this RFP and any other mandatory requirements

and terms and conditions specified in this RFP and warrants that these have been considered in the elaboration of the Proposal

- accepts that any Product and Services Contract resulting from this RFP shall contain the UNICEF General Terms and Conditions of Contract (Goods), UNICEF's General Terms and Conditions of Contract (Services) and any other terms and conditions specified in this RFP, and
- declares having examined all Schedules / Forms and all Instructions pertaining to the Proposal included in this RFP

Furthermore, the Proposer represents and warrants that it has the personnel, experience, qualifications, facilities and all other skills and resources necessary to perform its obligations as described in this RFP under any Service contract resulting from this RFP.

4.4.2 VALIDITY OF PROPOSAL

Proposal shall be valid for a period up to 31st December 2025 (PROPOSAL FORM). UNICEF may request the validity period to be extended.

4.4.3 UNIT PRICING

Unit pricing should include the total cost of the product and the services for the management, storage and maintenance of the type 2 monovalent bulk; and the conversion, management, storage and maintenance and potential delivery of the mOPV2 in finished product.

4.4.4 CURRENCY OF PROPOSAL

The currency of the Proposal shall be US Dollars.

Failure to quote in the currency stated in this RFP document will invalidate the Proposal.

4.4.5 AFFORDABILITY OF PRICES OFFERED

UNICEF believes in paying a fee that is affordable to Governments and Donors and a fee that reasonably covers Supplier' minimum requirements.

The Proposer is requested to provide information on factors that influence the fee offered to UNICEF including, the basis for any quantity-based fees in the QUALITATIVE PROPOSAL SHEET.

4.4.6 ACCOUNT MANAGEMENT

The Proposer shall provide UNICEF with organizational charts and names of the responsible persons within each of the following departments: Production, Quality, Governmental Affairs, Shipping/Logistics, Sales and Marketing, specifying the name(s) of the person(s) who will be the primary contact for UNICEF (QUALITATIVE PROPOSAL SHEET).

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 are expected to be in English. The communication is seen as an important prerequisite for successful account management and needs to be frequent, timely and accurate.

4.4.7 INTERRUPTION IN PRODUCTION, RELEASE PROCESSES AND/OR STORAGE

Any issues arising which may result in problems with production, quality control and/or release of vaccine should be communicated in a timely manner to UNICEF and WHO/PQT.

5. ANSWERING SHEETS

PROPOSAL FORM

The Undersigned, having read the Instructions to Proposer of this Request for Proposal **RFP-DAN-2020-503251** and all related documents hereby offers to supply the Products and Services to meet the overall objectives sought in accordance with any specifications stated and subject to all Terms and Conditions set out or specified in this RFP and accepting that any Products and Services Contract resulting from this RFP shall contain the UNICEF General Terms and Conditions of Contract (Goods) UNICEF's General Terms and Conditions of Contract (Services) and any other terms and conditions specified in this RFP.

Signature:_____

Date: _____

Name & Title:_____

Company:_____

Postal Address:_____

Tel No:_____

Fax No:_____

E-mail:_____

Validity of Offer:_____

TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET

Please include a response to the following.

1. Does the finished product based on the mOPV2 bulk vaccine offered have licensure by the NRA or Record and WHO pre-qualification?
2. If the answer to the above is "No", then please provide an overview of timelines and milestones to obtain WHO pre-qualification of the mOVP2 in finished product.
3. If the answer to question 1. above is "No", please also provide the following information:
 - a) Name of the NRA in the country of origin.
 - b) Name of the NRA taking responsibility for the regulatory oversight of the vaccine, including issuing lot release certificates.
4. Please provide your United Nations Global Marketplace (UNGM) registration number_____

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

Instructions are provided on the site.

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

If not, please proceed as per Section 3.4.

QUALITATIVE PROPOSAL SHEET

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

1. Provide organizational charts and names of the responsible persons within each of the following departments: Production, Quality, Governmental Affairs, Shipping/Logistics, Sales and Marketing, specifying the name(s) of the person(s) who will be the primary contact for UNICEF.
2. Given that UNICEF has requested fees that are affordable to the poorest country governments and donors, please indicate factors influencing your fee levels for the volume offered.
3. Please include in your Proposal your total annual production capacities for bulk and final filled product for each offered vaccine.
4. In your proposal please include the following time lines:
 - a. What would be the lead time between receiving the request to start bulk production until the bulk is released and ready to be filled?
 - b. What would be the estimated number of doses per batch of mOPV2 bulk in finished product equivalent suitable for VVM2?
 - c. Is the bulk production facility dedicated to mOPV2, or is it shared for production of other bulk vaccines? If yes, which antigen(s)? Based on existing commitments for other antigens, what would be the number of batches of mOPV2 bulk that could be produced on an annual basis?
 - d. What would be the production lead time between receipt of confirmation to convert the released bulk into finished product?
 - e. What is the annual filling capacity for mOPV2 in a 20 dose vial?
 - f. Would your company be willing and able to deliver tOPV, should such need materialise in the future?
5. When would you need confirmation from UNICEF of an award to start the bulk production to meet the availability schedule provide in the Quantitative Proposal Sheets.
6. What is the expected shelf life of the mOPV2 bulk? Please provide information on stability programs to extend shelf life, and willingness of Supplier to commit to extend it and the target shelf life of such extension?
7. What is the expected shelf life of the finished product? Please provide information on stability programs to extend the shelf life of the finished product, and willingness of the Supplier to commit to extend such shelf life and the target shelf life?
8. If there is any limitations to the storage capacity of the bulk being offered?
9. Please confirm the total cold chain capacity for finished OPV products required to be stored at -20°C, and any plans and ongoing activities to expand such capacity?
10. In the past, how has your company been able to maintain the quality level for the supplied products? If your company has faced quality problems, please provide frequency and explanations as well as measurements taken for improvement.
11. Any other information deemed relevant for the evaluation of the proposal.

12. Would the production, management, maintenance and storage impact the production of other supply commitments to UNICEF?

QUANTITATIVE PROPOSAL SHEET

For the supply of, storage, management and maintenance of Oral Polio Vaccine type 2 in Bulk form

In compliance with terms and conditions of this Request for Proposal and all sections hereto, the undersigned offers to i) provide the products and services for the storage, management and maintenance of the bulk in quantities, at fees indicated below:

Year	Quantity per batch (litres)	Equivalent in finished product (doses)	Total offered doses in finished product equivalent	Equivalent finished product fee per dose (USD)	Total Amount USD
2021					
2022					
2023					

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

PACKING DETAILS SHEET

mOPV2 Vaccine Bulk

The Proposer is requested to provide UNICEF with packing details for nOPV2 bulk vaccine offered using this SHEET.

a. Name of Bulk:

b. Please advise the storage condition under which the bulk is kept.

QUANTITATIVE PROPOSAL SHEET

For the conversion, storage, management and maintenance and delivery of Monovalent Oral Polio Vaccine type 2 (mOPV2) in finished product – 20 dose vial

In compliance with terms and conditions of this Request for Proposal and all sections hereto, the undersigned offers to i) provide the services and deliverables for the conversion, storage, management and maintenance of the vaccine in quantities, at the below fees, which reflects contributions already made by third parties, if any; and ii) the eventual delivery of vaccines at FCA nearest international airport from the WHO owned Global Stockpile of finished product in quantities and to receiving countries as instructed by UNICEF in case of need within 72 hours:

Type 2 Monovalent Oral Polio Vaccine (mOPV2) – 20 dose vial			
Please include multiple Proposal Sheets, as required, for alternative presentations.			
Year	Annual quantity Vials	Fee per vial USD	Total Amount USD
2021			
2022			
2023			
2024			
2025			

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

Type of Vaccine Vial Monitor: _____

Total annual capacity for fill and finish: _____

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

WHO pre-qualified product: Yes:_____ No:_____

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

PACKING DETAILS SHEET
mOPV2 Vaccine

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

a. Name of Vaccine:

b. Please advise if this vaccine is packed using ice packs or dry ice. If the vaccine is packed using dry ice, please advise of any plans to change to packing with ice packs. Also please advise of any effect this would have on quantity, weight and dimension.

c. Please specify type of temperature monitoring device: _____

d. Please specify price adder of temperature monitoring device as added cost per shipping box: _____

e. Standard EXPORT Packing Dimensions and Weight:

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

f. Standard INNER CARTON Packing Dimensions and Weight:

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

QUANTITATIVE PROPOSAL SHEET

For the conversion, storage, management and maintenance and delivery of trivalent Oral Polio Vaccine (tOPV) in finished product – 20 dose vial

In compliance with terms and conditions of this Request for Proposal and all sections hereto, the undersigned offers to i) provide the services and deliverables for the conversion, storage, management and maintenance of the vaccine in quantities, at the below fees, which reflects contributions already made by third parties, if any; and ii) the eventual delivery of vaccines at FCA nearest international airport from the WHO owned Global Stockpile of finished product in quantities and to receiving countries as instructed by UNICEF in case of need within 72 hours:

trivalent Oral Polio Vaccine (tOPV) – 20 dose vial			
Please include multiple Proposal Sheets, as required, for alternative presentations.			
Year	Annual quantity Vials	Fee per vial USD	Total Amount USD
2021			
2022			
2023			
2024			
2025			

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

Type of Vaccine Vial Monitor: _____

Total annual capacity for fill and finish: _____

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

WHO pre-qualified product: Yes:_____ No:_____

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

PACKING DETAILS SHEET
tOPV Vaccine

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

a. Name of Vaccine:

b. Please advise if this vaccine is packed using ice packs or dry ice. If the vaccine is packed using dry ice, please advise of any plans to change to packing with ice packs. Also please advise of any effect this would have on quantity, weight and dimension.

c. Please specify type of temperature monitoring device: _____

d. Please specify price adder of temperature monitoring device as added cost per shipping box: _____

e. Standard EXPORT Packing Dimensions and Weight:

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

f. Standard INNER CARTON Packing Dimensions and Weight:

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

COMMERCIAL TERMS SHEET

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

Signature:_____

Date:_____

Name & Title:_____

Company:_____

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

10 days 3.0% _____ **15 days 2.5%** _____ **20 days 2.0%** _____
30 days net _____ **Other**_____

Please indicate any additional special commercial terms:

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