



REQUEST FOR PROPOSAL

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

MPOX Vaccines

FOR DELIVERY DURING THE PERIOD 2024 – 2025

RFP-DAN-2024-503748

29th August 2024

PROPOSALS must be sent to the email supplybid@unicef.org up to **16.00 hours** (Copenhagen time) on

6 September 2024 for phase 1

11 September 2024 for phase 2

18 September 2024 for phase 3

Upon meeting the regulatory milestone (EUL)

Reference to RFP-DAN-2024-503748 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. Chinara Israilova, Contracts Specialist

Approved by:

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

Ms Katinka Rosenbom
Chief, Contracting Centre
Supply Division, UNICEF

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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 The overall purpose and intent with the tender is to establish a collaborative procurement framework uniting buyers, funders, and strategic technical leadership to secure access to mpox vaccines for Low- and Middle-Income Countries (LMICs). This joint framework will streamline interactions with vaccine suppliers, prevent competition among buyers and facilitate need-based allocations under one allocation framework, to optimize use of initially limited supply of mpox vaccines across procured and donated doses in support of programmatic objectives.

UNICEF in collaboration with Africa CDC, WHO, Gavi, the Vaccine Alliance (Gavi), and PAHO is seeking comprehensive proposals from manufacturers for the supply of mpox vaccines of assured quality to address the immediate short term demand to respond to the ongoing outbreak of mpox caused by the monkeypox virus (MPXV). This request for proposals follows the Africa CDC Declaration of mpox as a Public Health Emergency of Continental Security (PHECS) on the 13th of August; and the declaration of mpox as a Public Health Emergency of International Concern (PHEIC) under the International Health Regulations (2005) (IHR) on the 14th of August by WHO's Director-General. Considering the

complexity of the crisis and the increased impact on children and pregnant women, UNICEF Executive Director has approved the recommendation to activate UNICEF's Level 3 (L3) Corporate Emergency Activation Procedure (CEAP) to scale-up mpox preparedness and response in countries with active transmission of mpox variants Clade 1b and/or Clade 1. UNICEF's response to the mpox outbreak is comprehensive, prioritizing children, pregnant women and underserved communities, focusing on the disease transmission interruption, and monitoring and addressing the secondary impacts on children and communities, such as child protection and school closures. UNICEF is working closely with Africa CDC to provide direct emergency support to the mpox response in key areas as immunization; nutrition; primary prevention including behaviour change communication and related support to address stigma; research and science on the unknowns of mpox transmission in children.

1.5 The overall objectives of this solicitation are to:

- Secure access to mpox vaccines of assured quality for immediate use to implement vaccination strategies aligned with National Plans, Continental/Regional Plans, and the Mpox Global Strategic Preparedness and Response Plan (MG-SPRP);
- To ensure access to prices that allows to maximise outbreak response, and are affordable to countries and donors;
- Secure access to near term production capacity in 2024-2025 to meet evolving supply requirements in anticipation of the future establishment of a global stockpile;
- Diversify the supplier base including manufacturing in Africa.

The tender may be extended for 12 months, however, it is anticipated that a subsequent tender may be issued in Q2 2025 to secure supply for a global stockpile in line with the decision by the Gavi Alliance Board in June 2024, contingent on outcomes of regulatory and technical review processes as well as meeting certain financial assumptions.

1.6 The purpose of this Request for Proposal (RFP) is to meet the above objectives through the establishment of Long-Term Arrangements (LTAs) for the supply of mpox vaccines meeting requirements for the period 2024 to 2025 for countries procuring through UNICEF based on funding from Gavi or other donors as well as domestic resources. Purchase Orders for delivery of mpox vaccine throughout the period will be placed against the LTA(s) resulting from this RFP. To the extent possible, UNICEF aims to establish an access framework that would enable Africa CDC, WHO and PAHO to access vaccines on similar terms; with the understanding that mpox vaccines will be allocated under a global or regional allocation mechanism to optimise programmatic needs.

2. BACKGROUND

a) Disease and programmatic background.

Mpox is an infectious disease caused by the monkeypox virus (MPXV) of the Orthopoxvirus genus. The MPXV is closely related to the variola virus responsible for smallpox, and vaccines that are available to address the current outbreak of mpox were initially developed and continue to be in production as part of updates of bioterror stockpiles in a number of high income countries. Since 1970, cases of mpox have been reported across several countries in the African region where the disease is endemic, with occasional export of cases historically. Transmission is through contact with infected animals or through human-to-human contacts¹. Two different Clades of mpox exist: Clade I and Clade II; the 2022-2023 global outbreak was caused by clade IIb, with cases reported in 117 countries between January 2022

¹ [WER9934-eng-fre.pdf \(who.int\)](#)

through to April 2024. Unlike previous outbreaks which have been more local, linked to zoonotic transmission and self-limiting, the 2022-2023 outbreak was primarily driven by human-to-human transmission. In response, the WHO declared mpox a PHEIC in July 2022, with the PHEIC being lifted in May 2023 following a 90% drop in cases.

In the DRC, where mpox is endemic, a new Clade Ib has been identified, and cases continue to rise. As of week 24, in 2024, there have been 9,192 suspected cases and 419 deaths, resulting in a case fatality rate (CFR) of 4.7%² with cases reported in 20 out of 26 provinces. In 2023 a total of 14,626 suspected cases and 654 deaths (CFR of 4.6%) were reported, tripling the numbers from 2022. Data from 2024 shows that children under 15 are most affected in DRC, accounting for 66% of suspected cases and 84% of deaths. In 2023, approximately 70% of reported suspected mpox cases and 85% of deaths occurred among children under 15 years of age. Notably, children under 1 year are four times more likely to die compared to those over 15 years³.

The recent emergence and rapid spread of the Clade Ib mpox virus strain in the DRC, particularly through sexual networks, and its detection in neighbouring countries, as well as spread to children is especially concerning and contributed to the declaration of a PHEIC again in August. Over the past month, more than 100 laboratory-confirmed Clade Ib cases have been reported in Burundi, Kenya, Rwanda, and Uganda—countries that had not previously reported mpox.

b) Product description

Proposals are sought for mpox vaccines that i) aim to meet the WHO Target Product Profile (TPP) for mpox vaccine (which is currently in development)⁴; ii) from Bidders that have expressed an interest to submit a dossier for emergency evaluation of their mpox vaccine to WHO with the intent to ultimately pursue WHO prequalification; and iii) for products and product presentations that are acceptable to implementing countries. Supply is required for delivery in 2024 to address the acute phase of the pandemic and through 2025 based on funding from Gavi, Africa CDC, or other funding sources. A global stockpile of mpox vaccines will be established in the future based on funding from Gavi.

For Bidders that are yet in early stages of development of an mpox vaccine, UNICEF would also encourage to submit a Proposal, with the understanding that at this point in time only mpox vaccines that achieve WHO Emergency Use Listing may be considered for awards. Mandatory Technical Requirements are included in Annex B.

c) Product allocations

As vaccines are anticipated to be in limited supply, allocation processes and principles are currently in development between UNICEF, Africa CDC, WHO, and Gavi with the purpose and intent to ensure timely and sufficient distribution initially to hotspot areas. The immediate priority is to vaccinate those at highest risk of infection in areas with ongoing transmission, thereby helping to halt the outbreak. As a second target, immunization efforts will focus on expanding protection to reduce the number of susceptible individuals and eventually as vaccine supplies allow increase population immunity in regions at risk of future outbreaks. Only in the scenario that these priorities have been fully met, would supply potentially be available to countries that would want to establish stockpiles of mpox vaccines as part of their pandemic preparedness and response. It is the intent that an agreed allocation process and principles will apply across all sources of supply and across all buyers.

² Draft vaccination plan for DRC, dated 28 June 2024

³ WHO update to the Global mpox partnership 22nd May 2024

⁴ [Microsoft Word - TPP for vaccines MPox_16082024_clean for publication.docx \(who.int\)](#)

d) Historical context of the solicitation

UNICEF has not procured mpox prior to the issuance of this tender in the absence of funded demand during the 2022-2023 PHEIC. UNICEF anticipates that a next tender will be issued in Q2 2025 following additional modelling activities to project the right sizing of a future stockpile, to be established after the ongoing transmission chains have been interrupted and as supply would allow. The development of a Roadmap by Gavi partners as per standard processes were initiated prior to the current outbreak, with the purpose to explore market shaping activities that would lead to long term sustainable supply markets. In absence of WHO approved vaccines and funding, the current sourcing strategy relies on vaccine donations which are sporadic and unpredictable, and which has proven during the Covid pandemic to be suboptimal because of the inability to appropriately manage, control and plan for incoming vaccine supply across multiple supply streams, as well as providing product presentations that were not always acceptable or appropriate to recipient countries; therefore this tender is intended to ensure better visibility on supply options, facilitate better supply planning and ensuring timely supply.

e) Market Analysis

Because vaccines were initially developed for stockpiling for use against a deliberate or accidental release of smallpox, there is limited production of vaccines and a need to plan production around replenishment of stockpiles. Following the PHEIC and the fact that there are certain target groups in high income countries for which vaccination is recommended, mpox vaccines are available in a few countries in commercial markets. Currently there are two vaccines with varying product characteristics recommended for mpox vaccination: MVA-BN⁵ (manufactured by Bavarian Nordic, Denmark) and LC16m8 (manufactured by KM Biologics, Japan). Both vaccines are recommended by WHO's Strategic Advisory Group of Experts (SAGE) on Immunization. The MVA-BN is approved by a number of WHO-listed national regulatory authorities; the LC16m8 is approved by the Japanese National Regulatory Authority PMDA. Furthermore, the MVA-BN has been granted emergency use authorisation (EUA) in the Democratic Republic of Congo (DRC) and Nigeria, with the LC16m8 having received EUA in DRC. There are other vaccines at different stages of development and approvals e.g. ACAM2000 (manufactured by Emergent BioSolutions, USA) is recommended for smallpox, and is under consideration by USFDA to expanded indication to include immunization against mpox virus.

On 9 August WHO issued an invitation for manufacturers of mpox vaccines to submit Expression of Interest for Emergency Use Listing following the WHO Director-General announcement on 7th August that he had triggered the process of EUL of mpox vaccines given trend of the disease spread⁶. The first outcome of the process is expected to be shared in the week starting 16th September following the convening of a Technical Advisory Group based on the technical review by the WHO Prequalification Team. Provided that the first mpox vaccines are granted EUL as an outcome of the review, confirming quality, safety and efficacy, this step will allow UNICEF to procure and Gavi to fund mpox vaccines.

f) Demand Forecast / RFP demand quantification

The accurate projection of demand is not available at the moment, however, there is an urgent need to secure access to available products that are acceptable and suitable for use; and to secure production capacity of suitable products that can be used to curb the current outbreak. Demand quantification is currently ongoing on the African continent with the expectation that a continental mapping will be available in the coming weeks. Based on WHO estimates of addressing requirements in hotspots under the current stage of the outbreak, the immediate target population in high risk areas is estimated to around 1 million based on the current epidemiology. Requirements for further expansion to cover target

⁵ [JYNNEOS | FDA](#); [Imvanex | European Medicines Agency \(EMA\) \(europa.eu\)](#); [\[Product Monograph Template - Standard\] \(hres.ca\)](#)

⁶ [WHO invites mpox vaccine manufacturers to submit dossiers for emergency evaluation](#)

populations in phases two and three of WHO's response plan are yet to be developed with estimates expected to be available to be shared with Bidders week of 2nd September. Based on extrapolation of vaccine requirements from two countries, the immediate requirement could be up to 12 million people in need of vaccination; doses through UNICEF. Multiple requests have been received by UNICEF including from countries outside of the African Continent, from regional agencies, including for stockpiling as part of country pandemic preparedness.

Therefore, demand figures will be continuously assessed, both based on updated demand forecasts as well as information about donations and available vaccines for supply. UNICEF will update Bidders when new information becomes available.

g) 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.

h) Tender Period

The tender period will cover September 2024 for supplies to pick up as soon as possible to 31st December 2025, with an option to extend for an additional 12 months.

i) Minimum Quantity Guarantees, Firm Contracting and other Risk Sharing Terms

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 as part of Bidders' Proposals, provided they help achieve the objectives of this solicitation process. Such approaches may include any obligations regarding production of drug substance, joint planning of rolling production capacity for fill and finish on a monthly or quarterly basis, including a right of first refusal to such production capacity, to maximise flexibility and risk sharing of both the Bidder and UNICEF and partners in the context of the current outbreak.

Subject to funding availability, such a commitment would be conditional upon a reciprocal commitment from an awarded Supplier and any such commitments 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.

2.2 Procurement Reference Group

Considering the emergency and urgency of the procurement to be undertaken and the partnership of the solicitation, a Procurement Reference Group (PRG) comprised of independent and partner experts, will be established to provide advice with regards to the award approach and procurement allocations between Bidders. This PRG 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 The proposed LTA(s) will be valid for an initial period starting as soon as possible through to 31st December 2025.
- 4.2 The duration of the LTA may be extended for an additional period of twelve (12) months, 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)
- UNICEF Guidelines for Vaccine Barcode Specifications
- 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 Phased receipt of bids and awards

Given the objectives of the tender to secure access to immediately available supply and to maximize access to production capacity in 2024 to respond to the ongoing emergency, UNICEF will accept Proposals by either 6th September, 11th September or 18th September. Bidders are also encouraged to submit proposals beyond these deadlines upon meeting the regulatory milestone (EUL) in accordance with instructions provided on the front page of this document.

3.2 Acknowledgement of receipt of RFP.

Bidders are requested to inform UNICEF as soon as possible by email to Chinara Israilova, Contracts Specialist, at cisrailova@unicef.org with copy to Bette Hjulmand, Procurement Associate at bhjulmand@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 Chinara Israilova, Contracts Specialist at cisrailova@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 Bid conference. A bid conference will be held one week after the issuance of the RFP. Detailed information will be shared with interested Bidders and announced on the UNGM website.

3.6 Samples

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

Each Proposal must include for each vaccine offered, the following:

- Pictures of vaccine primary container including closure and electronic file of label
- Pictures of vaccine diluent/buffer primary container, if applicable
- Mock up of inner box and vaccine insert, including pictures or designs of barcodes on secondary pack and higher pack levels, including human readable information (HRI)

If the sample materials provided are different from those submitted to WHO for EUL, the differences should be explained.

If at the time of submission of a Proposal the Bidder is not able to provide the sample materials as stated above, the Bidder should provide explanation and an indication of when the sample materials could be provided. For products in development, where packaging material has not yet been developed, Bidders are requested to provide sample materials for UNICEF's record as soon as available.

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

3.7 Proposal submission schedule

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

3.8 Proposal opening

Proposals received prior to the stated closing times and dates will be kept unopened. The Officer of the Bid Section will open/print the Proposals when the specified time has arrived. Proposals received thereafter will be considered at the next closing times and dates. 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 31st December 2025. 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 DATES, 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 reserves the right to disclose information regarding the proposals received against this RFP with the Gavi Secretariat; and on a confidential basis with members of the Procurement Reference Group as described in Part I, Section 2.
- UNICEF will make details of each award public as described in Part IV, Section 2.9.

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 disproportionally high compared to past years' annual production quantity, the Bidder will demonstrate, that it is able to supply the quantity being proposed by it to UNICEF during the quoted timeframe. The Bidder will also advise UNICEF of the current annual production quantity. WHO'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. Proposals for local production or technology transfer may be submitted as part of the Proposal, which will be shared with Africa CDC; as a minimum Bidders are requested to provide information about their plans, if any, to initiate production on the African Continent.
- 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), Barcoding/Serialization, 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.
- 3.5 Traceability and Verification System (TRVST): UNICEF requests all Suppliers to make product master, batch and serialization data of vaccines available via a digital interface to TRVST to enable (future) use of barcode scanning by countries. Suppliers are required to report on their plans of establishment an interface to TRVST.

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 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. In the context of the current PHEIC, UNICEF encourages Bidders to offer not-for-profit pricing. The Bidder is requested to provide information on factors that influence the pricing offered to UNICEF including, the basis for any quantity-based pricing.
- 6.2 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.
- 6.3 Most Favoured Customer. The Bidder confirms that the prices with respect to the goods specified in the Proposal for supply to Gavi supported countries and Low Income Countries as defined in accordance with the World Bank classification based on domestic funding 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.
- 6.4 Tiered Pricing. In accordance with its Vaccine Procurement Principles, UNICEF provides Bidders the option to quote tiered pricing based on the World Bank classification of countries by income level for countries. For Middle Income Countries, the Bidder represents to UNICEF that, in respect of the Goods purchased under this LTA/Purchase Order, UNICEF is not being charged more than other clients for similar vaccines in similar quantities, in a similar product presentation and in similar circumstances. In the event that UNICEF is charged more than other clients in the circumstance referred to in the proceeding sentence, the Bidder shall thereafter offer the same price to UNICEF for all Goods to be supplied un the remaining term of this Purchase Order/LTA.
- 6.5 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 [NEAREST INTERNATIONAL AIRPORT]; or
DAP - Delivered-at-Place [PLACE OF DESTINATION]**

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

- 6.6 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.
- 6.7 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), if applicable.
- 6.8 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.
- 6.9 Discounts. Bidders are requested to advise as to:
- (a) Quantity / volume discounts, in form of large quantity / volume discounts and staircase pricing (i.e. varying prices according to different quantities procured);
 - (b) Cumulative quantity / volume discount levels, i.e. discounts that increase as the cumulative order value/volume increases throughout the validity of the LTA;
 - (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.
- 6.10 Alternative Proposals. UNICEF welcomes alternative Proposals, including Proposals which may include special contracting terms or where pricing is conditional upon firm UNICEF commitment to defined quantities, or subject to pre-payment or 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).
- 6.11 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 currently recommended under the WHO Prequalification program (Prequalified or EUL), 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 approved by WHO under Prequalification or EUL. For products offered that are not currently recommended under the WHO EUL, but for which an expression of interest has been submitted to WHO, Bidders are requested to include in their response a detailed plan on the timeline to obtain WHO EUL and subsequently Prequalification. The timeline will include information regarding the product and plans for development, manufacturing and licensing.
- Awards will be determined based on the following criteria:
 - Contribution to meeting the procurement objectives
 - Products meeting the technical specifications, including WHO approval (Prequalification or EUL)

- List of countries where product is registered
- Timing of product availability
- FCA Price nearest international airport/DAP Place of destination
- Proven past performance (if applicable)
- Products meeting countries' preferred product presentation

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

Tender Objective	Evaluation criteria
ACCESS Ensure secured access to the mpox vaccines of assured quality for immediate deployment	<ul style="list-style-type: none"> • WHO Emergency Use Listing/Prequalification • Product offered • Vial size, presentation offered • Shelf life • Quantity offered, conditions of quantity offered; demonstration of capacity to provide quantities offered • Delivery preparation lead time for quantities offered • Realistic lead time offered • Willingness to offer access on similar terms and conditions to UNICEF procurement partners through establishment of term sheets
PRICE To ensure access to prices that allows to maximise outbreak response, and are affordable to countries and donors	<ul style="list-style-type: none"> • FCA price nearest international airport/DAP place of destination • Price conditions offered - Alternative offers providing additional beneficial affordability/prices/commercial terms • Factors that influence the pricing offered to UNICEF • Reciprocity in any special contracting terms • Payment terms • Validity of the proposal
SUPPLY SECURITY Ensure availability and security of the mpox vaccine production in 2024 – 2025; in anticipation of the future establishment of a global stockpile	<ul style="list-style-type: none"> • Weight and volume, cold chain requirements • Medium and 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 (including buffer stock) • Conditions of offer and acceptance of UNICEF General Terms of Conditions • Registration in countries (planned, pending, actual, expiry, intend to maintain) • 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) <p>Supplier performance (existing)</p> <p>Proven capacity to supply offered and forecasted quantities</p> <ul style="list-style-type: none"> ○ Timeliness of PO acknowledgment

	<ul style="list-style-type: none"> ○ Timeliness of Notification of Goods Readiness (NGR) ○ Timeliness of delivery ● For pipeline Suppliers: <ul style="list-style-type: none"> ○ Establishing milestones to WHO PQ/ EUL and supply to UNICEF: ○ Dates for clinical trials yet to be completed (Phase I, II and III) ○ Dates for planned submission and expected national licensure in country of production, plans for parallel review of national regulatory authority and EMA under Article 58 ○ Date of submission to WHO PQ/EUL ○ Expected date of WHO PQ/EUL ○ 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, timely communication ○ Willingness to include a Vaccine Arrival Report as part of shipping documents ○ Environmental and social sustainability: Collaboration on sustainability, e.g. via consultations, information sharing on environmental and social sustainability topics; and (future) performance monitoring. ● Adherence to packing and shipping requirements, including temperature monitoring devices ● Compliance to mandatory bar coding requirements ● Adherence to preferred bar coding requirements (serialization, aggregation), plans to establish an interface to TRVST
Diversifying the supplier based including manufacturing in Africa	<ul style="list-style-type: none"> ● Proposals or plans for production or technology transfer to manufacturers in Africa, alternatively, indications of plans or intent towards this

- 1.3 The award strategy under this tender will include considerations regarding the known country preference split at the time as well as funded demand.
- 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 Proposals, taking into consideration the actual market situation for each vaccine including available donations, the forecasted quantities under any scenario as it firms up may be awarded to Bidders in accordance with the objectives of this RFP.
- 2.2 Acceptance by Destination Country. Final award is subject to explicit acceptance of both the product and manufacturer by the destination country.
- 2.3 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.
- 2.4 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 interest of UNICEF.
- 2.5 Negotiation. UNICEF reserves the right to negotiate with the Bidder(s) in support of achieving the procurement objectives of the RFP.
- 2.6 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.
- 2.7 Award Debrief. Bidder(s) that has/have been awarded an LTA will be invited to a formal debriefing and award initiation meeting. Bidder(s) that do not receive an award may request a formal debriefing. During a debriefing, the strengths and weaknesses of the Proposal may be discussed. Details concerning the evaluation results of other Proposals will not be divulged, except in accordance with Section 2.8 below.
- 2.8 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.

- 2.9 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 for UNICEF to consider any risks and risk mitigations including any reciprocity required.

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 assess 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, 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:	Select date
RFP reference:	RFP-DAN-2024-503748		

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 ⁷ have not been found guilty pursuant to a final judgment or a final administrative decision of any of the following:		
	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"/>
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) (<i>being a shell company</i>)	<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

⁷ "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

and Conditions set out or specified in this **RFP-DAN-2024-503748** 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?	<div><input type="checkbox"/> Yes [insert UNGM vendor number]</div> <div><input type="checkbox"/> No*</div> <div><p>*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</p><p>Please note that while Basic level registration is sufficient for evaluation purposes, Proposers are highly encouraged to register at least at Level 1.</p></div>
Are you a UNICEF vendor?	<div><input type="checkbox"/> Yes <input type="checkbox"/> No</div>
Have you provided audited financial statements to UNICEF in the past 12 months	<div><input type="checkbox"/> Yes <input type="checkbox"/> No*</div> <div><p>* If not, please proceed as per Part II, Section 1.2 of this Request for Proposal.</p></div>

COMMERCIAL PROPOSAL SHEET

A. Quantitative Proposal

Name of Proposer:	[Insert Name of Proposer]]	Date:	Select date
RFP reference:	RFP-DAN-2024-503748		

1. mpox Vaccine, vial of ____ doses, in _____ formulation (specify e.g. lyophilized, with diluent, etc.)

Quantities per year in vials and doses:
2024: vials (..... doses)
2025: vials (..... 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]]	Price in USD*/vial, DAP [Insert nearest International Airport]]	Price in EUR*/vial DAP [Insert nearest International Airport]]	Conditions/Discounts**	Total Amount (USD)
September 2024								
October 2024								
November 2024								
Total for 2024								
Q1 2025								
Q2 2025								
Q3 2025								
Q4 2025								

* 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.

** 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).

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]]	Price in USD*/vial, DAP [Insert nearest International Airport]]	Price in EUR*/vial DAP [Insert nearest International Airport]]	Conditions/ Discounts**	Total Amount (USD)
2024								
2025								

* 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>Proposers 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>Proposers 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), Barcoding/Serialization, 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>Proposers 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>Proposers 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>), maximum number of doses per day, minimum order quantities and ability to prepare products for emergencies within 48 to 72 hours: <u>Proposers 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. 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>Proposers 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 vaccines. In addition, please indicate whether facilities for bulk production and fill and finish are dedicated,

	<p>multipurpose and/or shared facilities.</p> <p><u>Proposers response:</u></p>
10	<p>Please advise what is your company's maximum annual capacity for mpox vaccine bulk production and finished product.</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. Kindly confirm your cold chain capacity to store finished product in number of doses by month.</p> <p><u>Proposers response:</u></p>
12	<p>Please provide your company's 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>
13	<p>Please provide your company's plans and status on establishment of digital interface to TRVST. Please confirm contact persons and their e-mail addresses with whom UNICEF can engage on questions connected to progress on onboarding to TRVST.</p>

MONTHLY OFFERED QUANTITIES (DOSES)

Vaccine offered: _____

2024-2025 (in DOSES)	
September 2024	
October 2024	
November 2024	
December 2024	
TOTAL 2024	
January 2025	
February 2025	
March 2025	
Q2 2025	
Q3 2025	
Q4 2025	
Total 2025	

VACCINE REGISTRATION STATUS SHEET

Please list the completed registrations for each vaccine and each presentation included in the Proposal. Rows may be added to the table as necessary. (Part III, Section 1)

Product	Presentation	Country	NRA name	Date of registration	Date of expiry	Registration reference	Intention to renew	For use in private market or national program

Please provide any additional information on planned and pending registrations. (Part III, Section 2):



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-2024-503748		
Vaccine description			
Qty offered, in doses and vials:	<p>[2024]: doses/vials</p> <p>[2025]: doses/vials</p>		
WHO pre-qualified product/EUL	<p><input type="checkbox"/> Yes <input type="checkbox"/> No*</p> <p>*If no, please include information requested as per Section IV, 15: Proposals of Vaccines not yet WHO Pre-Qualified.</p>		
Language on label/package insert	<p>Label:</p> <p>Package insert:</p>		
Samples	<p><input type="checkbox"/> Yes</p> <p>If sample materials provided are different from those submitted to WHO for pre-qualification, the differences should be explained:</p> <p><input type="checkbox"/> No</p> <p>Please provide justification as per Section 3.5 of Part II:</p>		
Vaccine Vials Monitor (VVM)	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, which type:</p> <p>If no, please indicate feasibility to include VVM in the future, including timeline:</p>		
Barcodes	<p>A GS1- barcode with GTIN, Expiry Date and Batch number on secondary pack and higher levels is a mandatory requirement. Please indicate your barcode implementation:</p> <p>At secondary packing level, in accordance with Annex C: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>At tertiary packing level, in accordance with Annex C: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Please advise the type of barcode which is included (i.e. GS1 barcode, 2D Data Matrix barcode) and at which level of packing:</p> <p>Where a diluent is packed separately, please provide information on bar code inclusion on secondary and tertiary packing level for diluent:</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not relevant (no diluent supplied in separate secondary pack)</p>		

<p>Barcodes serialization and aggregation</p>	<p><u>Preferred barcoding requirement :</u> Serialisation and aggregation of barcodes is a preferred requirement. Please advise if serialisation and aggregation is already implemented for the offered product and if not, whether you are working towards implementation thereof, including the timeline for implementation.</p> <p>Serialization at secondary packing level, in accordance with Annex C: <input type="checkbox"/> Yes <input type="checkbox"/> No*</p> <p>Serialization at tertiary packing level, in accordance with Annex C: <input type="checkbox"/> Yes <input type="checkbox"/> No*</p> <p>Aggregation in place, in accordance with Annex C: <input type="checkbox"/> Yes <input type="checkbox"/> No*</p> <p>Where the diluent is packed separately, please provide information on serialized bar code inclusion on secondary and tertiary packing level for diluents: <input type="checkbox"/> Yes <input type="checkbox"/> No* <input type="checkbox"/> Not relevant (no diluent supplied in separate secondary pack)</p> <p>Please advise type of barcode which is included (i.e. 2D Data Matrix barcode, GS1 barcode) and at which level of packing:</p> <p>*Indicate whether you are working towards such implementation and provide timeline for implementation:</p>
<p>Data upload to TRVST / TRVST onboarding</p>	<p>Upload of barcode encoded data to TRVST is a preferred requirement and would require onboarding to TRVST to make data available for subsequent use cases.</p> <p>For those Suppliers that have an established interface to TRVST, including automatic data upload for the respective GTIN(s) (GTIN/vaccine product(s) offered via this tender), tick the following box: <input type="checkbox"/> <i>TRVST interface fully operational for offered product</i> and skip the remainder of this TRVST onboarding section.</p> <p>For Suppliers that have not yet established or initiated the interface connection to TRVST (in accordance with Annex C), please indicate whether you are working towards such implementation and provide timeline for implementation for the offered product:</p>
<p>Continuous quality assurance</p>	<p>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.</p>
<p>Total annual production capacity</p>	<p>Bulk:</p> <p>Final filled product of the offered vaccine:</p> <p>Source of bulk, if acquired externally, documentation for access to meet offered quantities:</p> <p>If fill and finish outsourced to contract manufacturer, documentation for access to meet offered quantities:</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>
<p>Batch size</p>	<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: 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 Proposal for local production or technology transfer to manufacturers on the African continent; as a minimum information about plans, if any, to initiate production on the African Continent <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>Proposers response:</u>
Country of Origin:	<u>Proposers response:</u>
National Regulatory Authority (NRA) of record:	<u>Proposers response:</u>
Variations/changes to licensure	<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>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>Proposers response:</u></p>

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	<div><input type="checkbox"/> Ice packs</div> <div><input type="checkbox"/> Dry Ice*</div> <div>*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.</div>
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		