

RFP-DAN-2024-503748

Mpox Vaccines for Delivery 2024-2025

Emergency Procurement

Pre-bid meeting - RFP-DAN-2024-503748

UNICEF Supply Division

5 September 2024



Mpox vaccine – UNICEF | for every child
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Introduction and objectives of the session

Objectives

- For UNICEF to provide potential Bidders with an overview of the ongoing RFP-DAN-2024-503748
- Share information and provide a platform for any required clarifications with potential Bidders to facilitate delivery of mpox vaccines in the short to medium term

Expected outcomes

- For potential Bidders to have a clear understanding of the requirements of the Request for Proposal (RFP)
- To provide high level clarifications to questions received so far (if any)

Housekeeping

Please stay on mute with video off, while not speaking to preserve the live-stream quality

Please state your name and company before sharing a comment or a question

Please write the question in the chat function as much as possible

Please save questions until after the presentation where there will be an opportunity to raise questions through raising your hand functionality on your screen

Session materials and additional questions

All material from the session will be made available on the UNGM weblink by Friday 6th

Written responses to questions raised to date including during this session will be included

All technical questions related to regulatory aspects will be responded to in writing and posted on the UNGM

Additional questions to be raised in the future will be responded to in line with the RFP, in advance of deadlines for submission of Proposals and posted on the same site

Request for Proposal for Mpox Vaccines for Delivery During the Period 2024-2025

Trigger events

- Africa Centres for Disease Control and Prevention (CDC) announces Public Health Emergency of Continental Security 13th Aug
- WHO announces Public Health Emergency of International Concerns 14th Aug
- Gavi, the Vaccine Alliance confirms that its First Response Fund of \$500 million can be accessed to address the mpox outbreak 17th Aug
- UNICEF Executive Director activates Level 3 Corporate Emergency Activation procedure 21st August
- Offers for donations are expected to be insufficient to meet demand

Overall Purpose of Tender	Procurement Objectives
<p>To establish a collaborative procurement framework uniting buyers, funders and strategic technical leadership to secure access to mpox vaccine of assured quality to address the ongoing outbreak; prevent competition between buyers and streamline interactions with suppliers through clear, efficient and transparent processes</p> <p>UNICEF is collaborating with Africa CDC; WHO; Gavi, the Vaccine Alliance; and PAHO</p>	<p>1. Access</p> <p>Secure access to mpox vaccines of assured quality for vaccination strategies aligned with with National Plans, Continental/Regional Plans, and the WHO Mpox Global Strategic Preparedness and Response Plan (MG-SPRP)</p>
	<p>2. Prices</p> <p>To ensure access to prices that allows to maximise outbreak response, and are affordable to countries and donors</p>
	<p>3. Production capacity</p> <p>Secure access to near term production capacity 2024/2025 to meet evolving supply requirements [in anticipation of the future establishment of a global stockpile]</p>
	<p>4. Supplier diversification</p> <p>Diversify the supplier base including manufacturing in Africa</p>

Expected outcomes

1. Establishment of Long-Term Agreements for supply of mpox vaccines available for immediate use during the acute phase of the PHEIC; as well as production capacity 2024 to 2025 to meet evolving demand; with the option to extend for 12 months if required
2. To establish a low price that will allow to maximise mpox outbreak response
3. To potentially establish an access framework/term sheet with key basic terms that would enable Africa CDC, WHO and PAHO to access vaccines on similar terms, should they desire to procure
4. To potentially secure proposals for local production or technology transfer to be shared with Africa CDC; or as a minimum to secure information about plans, if any, to initiate production on the African Continent

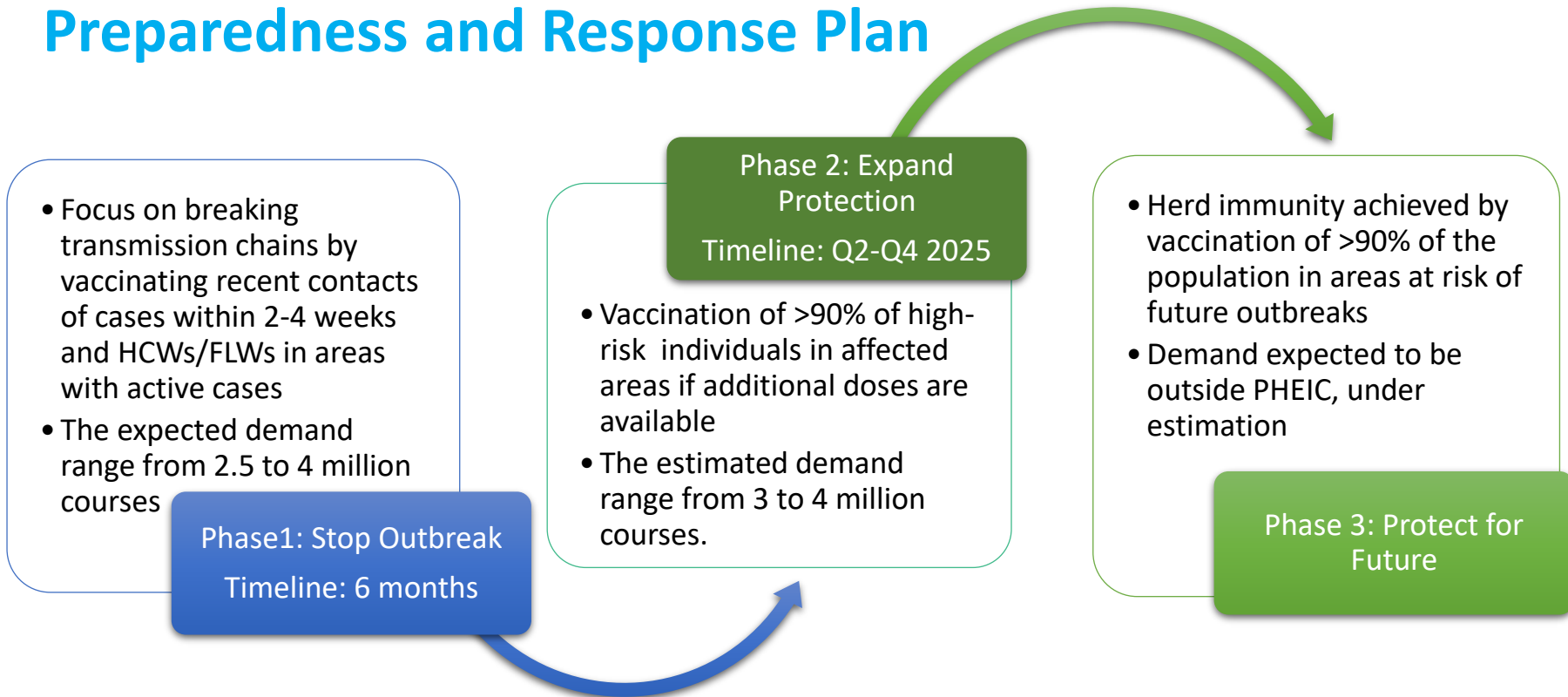
Product Description

Proposals are sought for mpox vaccines that

- Aim to meet the WHO Target Product Profile*) for mpox vaccine (which is currently in development)
- Vaccine from Bidders that have expressed an interest to submit a dossier for emergency evaluation of their mpox vaccine to WHO with the intent to pursue WHO prequalification
- Vaccine presentations that are acceptable to implementing countries
- The offered vaccines should meet all the WHO requirements and recommendations currently in force: [Recommendations for the production and quality control of smallpox vaccines, TRS 926, Annex 1](#)

*) [Microsoft Word - TPP_for_vaccines_MPox_16082024_clean for publication.docx \(who.int\)](#)

Demand estimate approach WHO's Global Strategic Preparedness and Response Plan



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.

Tender approach

- **Type of tender document** - Request for Proposal which will allow the Bidders to present comprehensive offers and options which can be assessed against the tender objectives
- **Tender invitees** – Open to all Bidders, including Bidders with products in development, intending to submit to WHO for EUL/Prequalification
- **Modality** - Rolling tender with evaluation and awards being made in phases
- **Duration of the LTAs** – September 2024 - 31st December 2025 (with option of 12 months extension)
- **Timelines** – Closing dates 16.00 hours Copenhagen time on 6th, 11th, 18th September, and upon achieving WHO EUL/Prequalification
- **Scope of countries and needs** - Demand for countries that would be procuring through UNICEF, Africa CDC, WHO or PAHO irrespective of funding source [with first priority to address current outbreak response over establishment of stockpiles to address future outbreaks]

Proposal and Answer Sheets

Only the forms and answering sheets provided in the RFP document should be used however, supplementary information can be provided on each of the answering sheets:

COMMERCIAL PROPOSAL

- PROPOSAL FORM (RFP, p. 35-36)
- PROPOSER INFORMATION SHEET (RFP, p. 37)
- COMMERCIAL PROPOSAL SHEET (QUANTITATIVE AND QUALITATIVE) (RFP, p. 38-42)
- VACCINE REGISTRATION STATUS SHEET (RFP, p. 43)

TECHNICAL PROPOSAL

- TECHNICAL PROPOSAL SHEET (RFP, p. 44-46)
- PACKING DETAIL SHEET (RFP, p. 47)

In order to facilitate the evaluation, Bidders are requested to send each of the above as separate files, when submitting the Proposal, clearly marking each file with the manufacturer, name product identification and section.

Ask of Bidders in RFP (1/2)

Regulatory aspects

- Manufacturers need to commit to engage in EUL with the purpose and intent to secure prequalification
- Manufacturers to work with WHO to support recipient countries in authorizing vaccines for importation and use

Product liability

- Standard product liability and other warranties to be provided

Additional information

- List of countries where product is registered
- Total production capacity/production lead time/immediate available stocks and lead time
- If readily available, a proposal for production or technology transfer to manufacturers in Africa, alternatively, indications of plans or intent towards this outcome

Ask of Bidders in RFP (2/2)

Prices and discounts

- **Affordability of prices** – Paying a price that is affordable to Governments and donors and a price that reasonably covers manufacturers' minimum requirements; recommending Bidders to offer not-for-profit pricing in context of base costs covered by High Income Countries
- **Most favorite nation pricing** - For Gavi supported and Low Income Countries procuring based on domestic funding
- **Maximum prices** – 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 the Proposal. Prices may be reduced at any point in time.

Contracting

Standard contracting modalities

- Value or time bound, non – exclusive Long-Term Agreements with multiple Manufacturers
- Good faith supply agreements with high utilisation

Alternative proposals

- Special Contracting, Minimum Quantity Guarantees, Firm Contracting and other Risk Sharing Terms
- Innovative contracting approach to achieve the RFP objectives;

Will be conditional to better achieving the tender objectives; funding availability and other agreed upon conditions, including reciprocity clauses and performance terms on Manufacturers' side

Evaluation of the Proposals

Review of Compliance with Eligibility, Commercial and Technical Mandatory Requirements

Proposal will be evaluated for compliance with the requirements of this RFP



Technical evaluation

Assessment of Technical Proposal and Mandatory Technical Requirements, conducted in collaboration with WHO



Commercial evaluation

Assessment of the Commercial proposal and review of the information provided both in Technical and Commercial proposals to assess factors supporting the RFP objectives set out in Part 1.

Evaluation of the Proposals

Products not yet approved under WHO EUL or PQ

- Bidders requested to provide estimated timelines and plan to obtain EUL and subsequently Prequalification

Clarifications

- UNICEF may seek clarifications from Bidder in order to fully understand Bidder's proposal
- Clarifications might be in writing or interview request with Bidder with written notes endorsed by both parties

Interpretation of Errors

- UNICEF may seek clarification of any errors identified in a Proposal. Should there be no satisfactory clarifications the errors will be interpreted by UNICEF in its sole discretion
- Should this error be related to price that is not clarified to UNICEF's satisfaction, unit price will prevail

Negotiations

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

Engagement with a Procurement Reference Group

UNICEF, Africa CDC, WHO and Gavi is convening a Procurement Reference Group as for procurement of other strategic vaccines

The Procurement Reference Group will be comprised of independent and partner experts with expertise in areas such as epidemiology; demand; implementation; vaccine production and supply; and contracting

The Procurement Reference Group will provide input and advice on award considerations, based on a summary of the proposal(s) and recommended award(s) prepared by UNICEF that will be shared with the PRG under strict confidentiality.

Awards Strategy

Awards

Considering the uncertainty around the demand, UNICEF is considering a two-pronged award strategy

- **Initial awards:** Upon clarification of offers, technical assessment, negotiations – if possible, prior to EUL determination, as conditional; address the immediate needs while respecting manufacturing timelines and country product preferences
- **Subsequent awards:** i) as demand and funding materializes for the upcoming requirements; ii) to secure productions throughout 2025

Procurement timeline

Activity	Timeline
Tender Issuance	29 August 2024
Closing of Tender	6 + 11+18 September 2024 and upon EUL
Technical and commercial evaluation of proposals	9-23 September 2024 and upon EUL
First convening of Procurement Reference Group meeting	12 September 2024
Negotiations and partner consultation	September 2024
Award notification to Suppliers starting from and ongoing*	September 2024
Establishment of LTAs starting from and ongoing	September 2024

* An award notification could be issued following due diligence review on process and endorsement by UNICEF's director, with such award potentially conditional to WHO Emergency Use Listing

Questions???



For additional information and
questions, please reach out in
writing to Chinara Israilova
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Thank You



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