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In reply please
refer to: 2026_RFQ_PQT_AMD_001

Your reference: PQT/AMD/dh

1 April 2026

Request for Quotation: Agreement of Performance of Work (APW) for WHO's Medical Device Prequalification Assessment

The World Health Organization (WHO) prequalification programme aims to ensure that key health products meet global standards of quality, safety and efficacy, in order to optimize use of health resources and improve health outcomes.

The prequalification process is carried out for the following product streams: immunization devices, in vitro diagnostic medical devices, medicines, vaccines, vector control products and inspection services and consists of a transparent, scientifically sound assessment, which may include dossier review, product testing, performance evaluation, and inspection of manufacturing sites contract research organizations. Prequalification outputs — including the lists of prequalified products, the list of prequalified quality control laboratories, and WHO Public Assessment and Inspection Reports — are used by UN and other procurement agencies to inform their purchasing decisions regarding health products. In 2026 the Assessment of Medical Devices team in Prequalification Unit plans to expand activities to include prequalification assessment of medical devices, commencing with a pilot assessment of (1) computer aided detection software for tuberculosis screening, (2) male latex condoms, female condoms and copper-bearing intrauterine devices and (3) male circumcision devices.

To this end, WHO is seeking requests for quotations (RFQs) from interested companies to assist in technical documentation review activities for medical devices which has been submitted for WHO's Prequalification Assessment and support the Assessment of Medical Devices Team of the Prequalification Unit. This RFQ is open to companies with proven experience in medical device regulatory affairs, quality assurance, development and/or manufacturing of medical devices. The company is expected to have human resources with sufficient capacity and knowledge for the following areas: experience of regulatory requirements (FDA, EU MDR, ISO standards and other global regulatory requirements and quality standards); dossier submission and life cycle management for medical devices, and the ability to comprehend principles of engineering, physiology, and medical device use. WHO pays utmost attention to the level of qualification and experience of the individuals involved, and to continuity in the services. The profiles (no individual names required) of the personnel proposed for these services should be included in the technical quotation.

WHO is a public international organization, consisting of 194 Member States, and a Specialized Agency of the United Nations with the mandate to act as the directing and coordinating authority on international health work. As such, WHO is dependent on the budgetary and extra-budgetary contributions it receives for the implementation of its activities. Bidders are therefore requested to propose the best and most cost-effective solution to meet WHO requirements, while ensuring a high level of service.

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WHO requires the successful bidder, the provider, to carry out the work as stated in the attached Terms of Reference. Activities will be carried in normal working hours of the bidder's local time zone.

Bidders should follow the instructions set forth below in the submission of their quotation to WHO. The quotation and all correspondence and documents relating thereto shall be prepared and submitted in the English language. The technical offer should be concisely presented and structured to include the following information:

- Proposed solution: The bidder shall describe the services they can offer.
- Approach/Methodology: The bidder shall demonstrate their capacity and capability to fulfil the requirements of the Terms of Reference, and indicate their previous relevant experience (clients, period and types of activities undertaken).
- Proposed time line:
- Financial quotation: Bidders are requested to submit the financial propose indicating daily rates for the work for each deliverable.
- Complete and sign the Acceptance form for this RFQ.

Any information which the bidder considers confidential, if any, should be clearly marked as such. The bidder shall submit the complete quotation to WHO in writing no later than **15 May 2026 at 17.00 hours UTC + 1 hour/Geneva time** ("the closing date"), **by email at the following address: healyd@who.int copy to largadov@who.int.**

Requests for clarification from bidders will not be accepted any later than **6 May 2026**. Responses to request for clarification will be communicated via email to **healyd@who.int copy to largadov@who.int** by **7 May 2026**.

Each quotation shall be marked Ref: **2026_RFQ_PQT_AMD_001** and be signed by a person or persons duly authorized to represent the bidder, to submit a quotation and to bind the bidder to the terms of this RFQ.

WHO may, at its own discretion, extend the closing date for the submission of quotation by notifying all bidders thereof in writing.

Any bid received by WHO after the closing date for submission of quotations may be rejected.

The offer outlined in the quotation must be valid for a minimum period of 180 calendar days after the closing date. A quotation valid for a shorter period may be rejected by WHO. In exceptional circumstances, WHO may solicit the bidder's consent to an extension of the period of validity. The request and the responses thereto shall be made in writing. Any bidder granting such an extension will not, however, be permitted to otherwise modify its quotation.

The bidder may withdraw its quotation any time after the quotation's submission and before the above mentioned closing date, provided that written notice of the withdrawal is received by WHO via email: **healyd@who.int**, as provided above, before the closing date.

No quotations may be modified after its submission, unless WHO has issued an amendment to the RFQ allowing such modifications.

No quotation may be withdrawn in the interval between the closing date and the expiration of the period of quotation validity specified by the bidder in the quotation (subject always to the minimum period of validity referred to above).

WHO may, at any time before the closing date, for any reason, whether on its own initiative or in response to a clarification requested by a (prospective) bidder, modify the RFQ by written

amendment. Amendments could, *inter alia*, include modification of the project scope or requirements, the project timeline expectations and/or extension of the closing date for submission.

All prospective bidders that have received the RFQ will be notified in writing of all amendments to the RFQ and will, where applicable, be invited to amend their quotation accordingly.

Before conducting the technical and financial evaluation of the quotation it has received, WHO will perform a preliminary examination of these quotations to determine whether they are complete, whether any computational errors have been made, whether the documents have been properly signed, and whether the quotations are generally in order. Quotations which are not in order as aforesaid may be rejected.

Please note that WHO is not bound to select any bidder and may reject all quotations. Furthermore, since a contract would be awarded in respect of the quotation which is considered most responsive to the needs of the project concerned, due consideration being given to WHO's general principles, including economy and efficiency, WHO does not bind itself in any way to select the bidder offering the lowest price.

WHO may, at its discretion, ask any bidder for clarification of any part of its quotation. The request for clarification and the response shall be in writing. No change in price or substance of the quotation shall be sought, offered or permitted during this exchange.

WHO reserves the right to:

- a) Award the contract to a bidder of its choice, even if its bid is not the lowest;
- b) Award separate contracts for parts of the work, components or items, to one or more bidders of its choice, even if their bids are not the lowest;
- c) Accept or reject any quotation, and to annul the solicitation process and reject all quotations at any time prior to award of contract, without thereby incurring any liability to the affected bidder or bidders and without any obligation to inform the affected bidder or bidders of the grounds for WHO's action;
- d) Award the contract on the basis of the Organization's particular objectives to a bidder whose quotation is considered to be the most responsive to the needs of the Organization and the activity concerned;
- e) Not award any contract at all.

WHO has the right to eliminate bids for technical or other reasons throughout the evaluation/selection process. WHO shall not in any way be obliged to reveal, or discuss with any bidder, how a quotation was assessed, or to provide any other information relative to the evaluation/selection process or to state the reasons for elimination to any bidder.

NOTE: WHO is acting in good faith by issuing this RFQ. However, this document does not oblige WHO to contract for the performance of any work, nor for the supply of any products or services.

At any time during the evaluation/selection process, WHO reserves the right to modify the scope of the work, services and/or goods called for under this RFQ. WHO shall notify the change to only those bidders who have not been officially eliminated due to technical reasons at that point in time.

WHO reserves the right at the time of award of contract to extend, reduce or otherwise revise the scope of the work, services and/or goods called for under this RFQ without any change in the base price or other terms and conditions offered by the selected bidder.

WHO also reserves the right to enter into negotiations with one or more bidders of its choice, including but not limited to negotiation of the terms of the quotation(s), the price quoted in such

quotation(s) and/or the deletion of certain parts of the work, components or items called for under this RFQ.

Within 30 days of receipt of the contract, the successful bidder shall sign and date the contract provided to it by WHO, and return it to WHO according to the instructions provided at that time. If the bidder does not accept the contract terms without changes, then WHO has the right not to proceed with the selected bidder and instead contract with another bidder of its choice.

Any and all of the contractor's (general and/or special) conditions of contract are hereby explicitly excluded from the contract, i.e., regardless of whether such conditions are included in the contractor's offer, or printed or referred to on the contractor's letterhead, invoices and/or other material, documentation or communications.

We look forward to receiving your response to this RFQ.

Yours sincerely,



Ms Irena Prat
Team Lead
Assessment of Medical Devices Team
Prequalification Unit
Regulation and Prequalification Department