1st Invitation to manufacturers of In vitro diagnostic (IVD) medical devices used for the qualitative detection of Mycobacterium tuberculosis complex DNA and mutations associated with drug-resistant tuberculosis to apply for WHO prequalification assessment as of 22 September 2022

1. Background

To support the global effort to end the TB epidemic, through the provision of guidance to interested United Nations (UN) and other agencies and WHO Member States in their procurement decisions, **WHO hereby invites manufacturers of In vitro diagnostic (IVD) medical devices used for the qualitative detection of Mycobacterium tuberculosis complex DNA and mutations associated with drug-resistant tuberculosis to apply for WHO prequalification assessment as of 22 September 2022.**

The Prequalification Unit (PQT) works in close collaboration with the WHO Global TB Programme (GTB); the GTB leads and guides the global effort to end the TB epidemic through universal access to people-centered prevention and care, multisectoral action and innovation while PQT assesses IVDs for compliance with quality, safety and performance standards.

2. Prequalification assessment

WHO prequalification of IVDs is a comprehensive quality assessment of individual products through a standardized procedure aimed at determining whether an IVD meets WHO prequalification requirements. The assessment is coordinated through the WHO Prequalification Unit and its focus is placed on IVDs for priority diseases and their suitability for use in resource-limited settings.

Before engaging in the prequalification assessment manufacturers should carefully review the information available on the WHO website. In particular, manufacturers should familiarize themselves with the assessment overview document and other relevant guidance referenced under point 5 below.

3. Scope of this invitation

The objective of this invitation is to expand the current eligibility criteria for WHO prequalification of IVDs to encompass products used for the qualitative detection of Mycobacterium tuberculosis complex DNA and mutations associated with drug-resistant tuberculosis and invite applications from manufacturers of such products. The eligibility expansion will become effective on 22 September 2022.

WHO PQT reserves the right to prioritize specific applications based on public health needs, in consultation with the WHO GTB.

4. Submission modalities

Manufacturers of IVDs used for the qualitative detection of Mycobacterium tuberculosis complex DNA and mutations associated with drug-resistant tuberculosis are invited to submit a pre-submission form to the PQT – In Vitro Diagnostics Assessment Team by sending an email to diagnostics@who.int

WHO will inform all applicants on the acceptability of their submission and will provide instructions on the assessment steps.

5. Assessment process following receipt of the pre-submission form

- WHO PQT will start accepting applications for IVDs used for the qualitative detection of Mycobacterium tuberculosis complex DNA and mutations associated with drug-resistant tuberculosis on 22 September 2022.
- The process begins when the manufacturer sends a pre-submission form to the IVD Assessment Team of the PQT. Instructions for the completion of the pre-submission form are available to assist manufacturers with this step. Applicants who are applying for prequalification assessment for the first time should contact the IVD Assessment Team at diagnostics@who.int to schedule a mandatory pre-submission call. The objective of this call is to explain the prequalification process and requirements and answer any questions from the manufacturer.
- WHO will invite manufacturers of products accepted for assessment to submit a product dossier and pay an assessment fee. A comprehensive overview of the structure and content of the dossier submission is available in the dedicated guidance document and a product dossier checklist assists applicants with preparing their submission according to WHO requirements.
- The product will undergo either a full or an abridged assessment, depending on the evidence of a prior stringent regulatory review. In addition, the technical specifications provide manufacturers with detailed information on the specific technical requirements that will be considered during the assessment process.
- Product dossiers received by WHO PQT first undergo a screening for completeness. Any missing information will be requested from the applicant. Complete dossiers will undergo review and WHO will inform the manufacturers of the review outcome. In addition, the manufacturer will undergo a site inspection to assess the quality management system and the product will be assessed for performance and operational characteristics through an independent performance evaluation. For this purpose, the manufacturer will receive an evaluation protocol and will be provided with instructions on the evaluation implementation.
- WHO will strive to complete the prequalification assessment within target assessment timelines. The outcomes of the product dossier review, performance evaluation and site inspection will be considered for the final prequalification decision. For products meeting the requirements across all assessment components a labelling review will be performed by WHO prior to the compilation of a Public Report and prequalification listing. The manufacturer will have to comply with post-listing obligations communicated by WHO.
- Products listed as WHO prequalified will become eligible or continue their eligibility under the new process for procurement by United Nations (UN) agencies and other agencies relying on prequalification listing.

6. Next steps

Manufacturers interested in applying for PQ assessment of IVDs used for the qualitative detection of Mycobacterium tuberculosis complex DNA and mutations associated with drug-resistant tuberculosis are invited to attend a **workshop intended at introducing the PQ technical specifications.** The virtual workshop will take place on **21 September 2022 12:00 – 13:30 (UTC+2).**

Register in advance for this WHO PQ-IVD Workshop using the link below:
https://who.zoom.us/webinar/register/WN_Im4vSUC5SN24YQDPH1EgEQ

Applicants can submit their application as of 22 September, once they have compiled a product dossier as per the WHO instructions and requirements referenced above.

To facilitate assessment planning and optimize assessment resources, WHO invites manufacturers interested in applying for prequalification assessment to inform the PQT of their intention to submit a product for assessment and provide a tentative timeline (month and year) for submission at diagnostics@who.int

7. Further information

Manufacturers interested in the prequalification assessment can find additional information on the WHO website. Any queries can be directed to the IVD Assessment Team at diagnostics@who.int