Public announcement to TB in vitro diagnostics manufacturers, procurement agencies and national TB programmes on inclusion of WHO Prequalification for TB in vitro diagnostics

The World Health Organization (WHO), through its Prequalification Unit and Global Tuberculosis Programme, would like to announce future changes to the WHO procedure to determine procurement eligibility for tuberculosis (TB) in vitro diagnostics (IVDs).

The WHO Global TB Programme (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. As part of its policy development work, WHO GTB has been assessing emerging evidence on TB IVDs and producing recommendations on the use of TB IVDs based on the patient important outcomes, diagnostic accuracy, economic evidence, feasibility, accessibility and equity aspects of specific diagnostic technologies.

Established in 2008, WHO Prequalification (PQ) of IVDs is used across the UN agencies, other partner donor agencies and Member States to determine procurement eligibility of HIV, Hepatitis B and C, malaria, HPV, G6PD, Cholera and Syphilis tests. In the future WHO PQ will also become the determinant of procurement eligibility of TB IVDs. WHO plans to launch prequalification assessments of TB assays; the timelines for specific types of assays will be communicated in due course. The PQ technical specifications for each class of the TB diagnostic tests, recommended by GTB, will be developed and published before prequalification assessments commence.

The current TB diagnostic assessment process for TB IVDs will evolve into a mechanism which focuses on the evaluation of classes of TB diagnostic technologies for WHO recommendation through WHO GTB while the WHO PQ will evaluate each specific product brand for quality, safety and performance within the product intended use.

WHO evaluation of classes of TB diagnostic technologies will be conducted by GTB through one of the following two pathways:

- Pathway A - for all first-in-class technologies. This evaluation will follow the existing WHO guideline development process, based on the WHO adopted Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. All products included in this assessment will automatically be eligible for PQ assessment.

- Pathway B - for all products that are not first-in-class technologies and had not been already assessed through Pathway A. This evaluation will consist in a rapid assessment to determine whether a product belongs to a class of diagnostics already endorsed by GTB and could be referred to PQ. If it does not belong to an existing class of diagnostics an assessment for first-in-class technologies through Pathway A will be performed.

Once a product is confirmed by GTB to belong to a product class covered by an existing WHO recommendation an application to PQ will then need to be submitted to undergo a PQ assessment of the product's quality, safety and performance. This will include a product dossier review, manufacturing site(s) inspection and an independent performance evaluation. The prequalification decision will be taken based on the outcomes of the PQ assessment and listing of prequalified IVDs will trigger WHO procurement eligibility.

The WHO/PQ and WHO/GTB are working together on a smooth transition from the current procurement eligibility mechanism to prequalification listing based WHO procurement eligibility. Table 1 provides summary information on the assessments undertaken by GTB and PQ.

Table 1: Comparison of GTB and PQ assessments

	GTB evidence assessment	PQ assessment
Triggered by	Identified public health needs/new products developed	Diagnostic classes covered by a WHO recommendation and identified as eligible for PQ assessment, including: • GTB diagnostic class listing • previously WHO endorsed products
Scope	Diagnostic classes	Specific product brands
Focus	Systematic review of evidence on patient important outcomes, diagnostic accuracy, economic evidence, feasibility, accessibility and equity aspects of technologies within a diagnostic class in specific patient populations against an appropriate comparator.	Assessment of quality, safety and performance through dossier review, site inspection and performance evaluation
Outcome	WHO recommendations for diagnostic classes (Pathway A). Referral to PQ for products in existing class (Pathway B)	PQ listing of specific product brands

Until 31 December 2022 WHO procurement eligibility remains valid based on the current WHO endorsement mechanism. However, to remain eligible for WHO procurement after this date, the PQ process should be completed for all previously WHO recommended diagnostic products by 31 December 2022 or within 2 years from the date of WHO recommendations. After 31 December 2022 all products will have to be covered by a WHO recommendation and Prequalified to be eligible for procurement by WHO and other UN/International Procurement Agencies.

TB IVDs procurers and National TB Programmes are encouraged to review their procurement policies for TB IVDs and prepare a transition plan in order to align with these revised WHO recommendations. Manufacturers are encouraged to keep informed on new PQ Technical Specification Series to best prepare for PQ assessments.