Optimizing and Streamlining WHO Diagnostics Prequalification

Diagnostics are critical to the prevention, diagnosis, and treatment of high-burden diseases, such as HIV/AIDS, hepatitis, malaria, and tuberculosis. WHO prequalification of diagnostics (PQ Dx) became operational in 2010 and promotes and facilitates access to safe and appropriate diagnostic technologies of assured quality in an equitable manner. As such, it complements WHO prequalification of medicines and vaccines. It also plays an important role in providing independent technical information and advice to WHO Member States, UN agencies, and other partners on the quality of currently available test kits and technologies for high-burden diseases\(^1\), and their suitability for use in resource-limited settings. The WHO List of Prequalified Diagnostic Products\(^2\) guides many international and national procurement agencies.

Based on the experience it has acquired during the past four years in prequalifying diagnostics, and valuable input received from its stakeholders, WHO wishes to respond to a number of challenges in order to ensure efficient and timely prequalification of quality-assured diagnostics for both existing and innovative technologies. In the coming months, stakeholders can expect a number of improvements to be made to the operation of PQ Dx. In addition, a new, complementary mechanism — the Expert Review Panel for Diagnostics (ERPD) — will be introduced, to facilitate time-limited access to diagnostic products that have not yet been prequalified or stringently approved, but that are urgently needed by public health programmes (See Table 1). These improvements follow on from the consolidation earlier in 2013 of the three prequalification programmes for diagnostics, medicines and vaccines into a single structural unit (Prequalification Team), which is serving to streamline procedures, and facilitate communication and consistency in practice.

Table 1: Planned improvements to WHO diagnostics prequalification

<table>
<thead>
<tr>
<th>WHEN</th>
<th>WHAT</th>
<th>HOW</th>
</tr>
</thead>
</table>
| 1st QUARTER 2014 | Faster market access to priority products | • Establish an Expert Review Panel for Diagnostics (ERPD), similar to the ERP for medicines, and identify highest priority products for ERPD assessment  
  o to facilitate earlier, time-limited market access through use of a risk-based approach to product assessment  
  o in anticipation of completion of the PQ Dx process for priority products |
| Improved efficiency of the PQ process for diagnostics | • Regularly consult with WHO disease programmes and procurement organizations to establish consensus regarding PQ Dx prioritization criteria  
  • Identify successful assessment and administrative procedures and criteria from prequalification of medicines, and vaccines  
  • Update pre-submission criteria for acceptance of |
products for PQ assessment, to speed up the PQ process

- Establish and publicly communicate clear timelines and goals for all parts of the PQ Dx process
- Maximize use of the fast-track procedure for products previously approved by stringent regulatory authorities, to minimize duplication of dossier assessment
- Accept recent manufacturing site inspection reports issued by appropriate bodies, under the fast-track procedure

**Greater transparency**

- Establish procedures to ensure clear, timely communication with manufacturers about and during the PQ process

**Improved consistency**

- Advocate for harmonized product quality assurance policies for procurement

**Technical support to increase readiness for PQ**

- Create a dedicated team to advise manufacturers on:
  - product specifications and desirable characteristics appropriate for resource-limited settings
  - quality management systems and the compilation of technical documentation on the product (its design, manufacture, and performance)
- Develop tools to support manufacturers seeking prequalification
  - publish an example of a product dossier

| 2nd QUARTER 2014 | Faster market access to priority products | • Pilot the ERPD for one of the highest-priority product categories
| | | • Evaluate the pilot ERPD programme and modify as required
| | Improved efficiency of the PQ process | • Implement the updated assessment and administrative procedures and criteria
| | | • Coordinate relevant PQ activities, such as laboratory evaluation, with external bodies
| | | • Implement updated pre-submission criteria to accept products for PQ assessment
| | Greater transparency | • Implement updated instructions on product dossier submissions and manufacturing site inspections
| | | • Make clearer reference to international global standards used in the PQ Dx process
| | Improved consistency | • Update standard operating procedures for all PQ processes
| | Technical support to increase readiness for PQ | • Scale up dedicated technical information sessions for manufacturers
| | | • Scale up pre-submission meetings and advisory visits with individual manufacturers to assess the readiness of their products for PQ
| | | • Generate priority product-specific guidance to assist manufacturers in preparing for PQ Dx
<table>
<thead>
<tr>
<th>3rd QUARTER 2014</th>
<th>Faster market access to priority products</th>
<th>Conduct ERPD review for additional identified highest priority products</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Improved efficiency of the PQ process</strong></td>
<td>• Build a robust data system to facilitate tracking and to generate data for progress reports for key aspects of the PQ Dx process</td>
</tr>
<tr>
<td></td>
<td><strong>Greater transparency</strong></td>
<td>• Publish periodic PQ Dx reports that track whether or not WHO PQ Dx timeline goals are being met</td>
</tr>
</tbody>
</table>

| 4th QUARTER 2014 | Improved efficiency of the PQ process | Evaluate changes made to PQ Dx to determine the level of improvement they have made (if any) to the efficiency of the PQ Dx process |
|                  | Improved consistency                     | • Participate in the piloting of the International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program[^3] as it develops |

WHO welcomes your feedback on these proposed changes to improve PQ Dx and bring needed quality-assured products forward. Please provide comments to diagnostics@who.int.