WHO Diagnostics Prequalification

Potential areas for improvement

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Objectives

- Share my early thoughts on role of PQ
- Review few areas of work
  - What is the program already in the process of addressing?
  - What additional questions/ideas might the program consider to improve its work?
- Present potential ideas for how we all can help
Role of WHO Prequalification

- Quality assurance is one of many elements necessary to achieve the ultimate goal of health impact
- GH will be most successful if quality assurance mechanisms shape activities to optimize toward the following results:
  - Fast launch
  - Quality product
  - Appropriate product
  - Affordable product
  - Sustainable supply
- Success in achieving these results depends upon other factors (strong organizations – manufacturers, country actors, implementers, etc.; supportive processes; financing; laboratories; etc.)
- For GH diagnostics, existing regulatory agencies are not financed to review diagnostics with an eye toward achieving the results above. WHO’s program may help fill this gap.
The What vs. The How

What (service design)
- Provide desired product specifications
- Provide technical guidance
- Prioritize areas of focus
- Review submissions
- Capacity building
- Manage communications
- Mobilize funding
- Etc.

How (service delivery)
- Impartial
- Transparent
- Scientifically sound
- Efficiently
- Expedient
- Customer focused orientation*
- Etc.

Fast launch
Quality product
Appropriate product
Affordable product
Sustained supply

* Customers = patients, practitioners, developing country governments, procurement agencies, manufacturers, donors
Activity Review: Prioritization criteria for review of applications

What is in process…

- Prioritizing based upon initial criteria (e.g. need, appropriateness, requests from WHO member states, performance capabilities, gap)
- Organizing process to review criteria with broader community to update

Questions to consider…

- What about other criteria?
  - Influence on market dynamics
  - SRAs not likely to evaluate product category and may be complex for many member state NRAs
  - Transformational vs. marginal improvement in health impact given new technology characteristics
  - Cost savings for lower cost product
## Activity Review: Product review process

<table>
<thead>
<tr>
<th>What is in process…</th>
<th>Questions to consider…</th>
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<tbody>
<tr>
<td>• Building processes with FDA to reduce duplicative assessments</td>
<td>• Given how frequently diagnostic technologies change, what should be the target review timeline to keep pace with the changing market? Does this vary by technology? How might PQ alter its approach to meet this desired time target?</td>
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<td>• Setting and tracking time targets for different phases of work</td>
<td>• When a gap of prequalified products exists, how can WHO provide assistance to procurers to select suppliers with minimal risk? e.g. mimic medicine ERP process, provide links to technologies reviewed by other SRAs</td>
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<td>• Setting deadlines for deliverables from WHO Collaborating Centers</td>
<td>• Should you add a FAQ on website to respond to question about why WHO does not add products reviewed by other SRAs to its PQ list?</td>
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<td>• Closing inactive applications to increase efficient use of resources</td>
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Activity Review: Customer orientation (“how”)

**What is in process…**

- Improving website
  - Process overview
  - Status of applications
- Quarterly newsletter
- Survey and consultations with manufacturers

**Questions to consider…**

- Providing data on average time for different review steps (WHO clock time vs. manufacturer clock time)
- Easy “Contact Us” link for procurement agencies who need advice
- Easy “Contact Us” link for manufacturers enquiring about application
How we all can help…

- Support analyses to document benefits of prequalification (health impact, cost savings) to compare to overall costs
- Encourage agencies to standardize procurement policies to promote procurement of quality products
- Encourage regulatory authorities to second staff to support inspections
- Identify creative sources for flexible financial resources to allows WHO PQ to finance according to need not donor preferences
- Allow program to run a few more turns to demonstrate its ability against the “what” and the “how” before bringing it into the pit for a fix-up