Alternative Performance Evaluation Pathway

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Before we start

All participants' microphones are on "mute"

Questions will be taken at the end of the presentation; please use the chat button
WebEx objective

- Present the new alternative performance evaluation to stakeholders, particularly manufacturers
- Provide key information on the new process and requirements
- Provide the opportunity to manufacturers to seek for further information

- Interested laboratories can contact the Prequalification Team and schedule a meeting to discuss further
WebEx content

1. Background for the new alternative performance evaluations pathway
2. Network of partner laboratories
3. New process
4. WHO PQDx evaluating laboratories
5. Questions
Background for introducing the alternative performance evaluations pathway
Prequalification of in vitro diagnostics programme

- Includes three components:
  - Review of a product dossier;
  - Performance evaluation, including operational characteristics; and
  - Manufacturing site(s) inspection.

- Looks into *quality, safety and performance* through dossier review, performance evaluation and inspection
  - Dossier: safety and performance
  - Performance evaluation: performance
  - Inspections: quality
The current process: Full VS abbreviated assessment

**Full prequalification assessment**
- Pre-submission form
  - Priority product: Yes
    - Dossier screening
      - Dossier incomplete
        - Dossier review
        - Site inspection
        - Laboratory evaluation
      - Dossier complete
        - Prequalification decision
  - Priority product: No
    - Dossier screening
      - Dossier incomplete
        - Prequalification decision

**Abbreviated prequalification assessment**
- Pre-submission form
  - Priority product: Yes
    - Full PQ assessment
      - Abbreviated site inspection
      - Laboratory evaluation
      - Prequalification decision
  - Priority product: No
    - Decision on abbreviated PQ assessment
      - Abbreviated site inspection
      - Laboratory evaluation
      - Prequalification decision
PQDx streamlining

Streamlined process:
- Focus on active applications, minimize effort into immature applications, assess more products, expanded programme scope
  - Defined number of steps and timelines
  - Intensified communications with Mx
  - Developing several guidance documents and sample dossiers
PQDx streamlining cont'd

Expanded network for performance evaluations:

- Less burden for CCs, wider utilisation of PQ outcomes through USG
  - Established collaboration with USAID/CDC
  - Broader network of labs - NHLS
  - Leveraging PQ outcomes through common WHO/USAID QA mechanism
PQDx streamlining cont'd: Potential improvements to the process

Where are the current hurdles?

- Sequential activities still occur
- Mx requesting additional time affect overall schedule
- Coordination of 3 activities is complex (5 entities involved)
- Some performance evaluations are challenging and take long

How to further gain efficiency?

- Potential process improvements by shifting evaluations earlier in the process
- Further expand laboratories network
Expanded network of partner laboratories
Key principles

- Manufacturers can approach WHO-assessed laboratories before submitting to PQ
- A list of WHO-assessed laboratories will be made publicly available, manufacturers can approach these labs at a time point of their choice
- The study will be performed using the established WHO protocol
- The laboratory will have an ascertained QMS in place
- Manufacturers will have more control over timelines and lab selection
Expected added value

- More flexibility
  - Manufacturers have the choice between following usual PQ pathway where WHO mandates the evaluation OR mandating a WHO-assessed lab to evaluate the product
- Save time where dossier screening is smooth
- Lighten WHO coordination
- Bring evaluations closer to countries of use
- Broader network of laboratories; expanded network of partner organisations for better coordination of efforts
  - Reduce (avoid) overlapping and duplication of activities
Revised PQDx process
Key principles

• Bring evaluations into earlier PQ stage (pre-assessment)
• Perform evaluations in parallel with dossier compilation
• Avoid sequential action and enhance parallel activities
• Avoid inspection where evaluation data is unsatisfactory
• Ensure sufficient time for challenging evaluations
• Ensure a more timely assessment phase with easier control of timelines
Revised process

- **Pre-submission form**
- **Priority product**
  - **Option 2: Performance evaluation scheduled by Mx and conducted by WHO listed site.**
  - **Dossier incomplete**
  - **Dossier complete**
  - **Dossier review**
  - **Site inspection**
- **Option 1: Performance evaluation scheduled by WHO and conducted by WHO listed site.**
- **Dossier screening**
- **Prequalification decision**

Lab evaluation
2 performance evaluations pathways

Option 1: Performance evaluation coordinated by WHO at an earlier stage of the prequalification process

- The performance evaluation will be scheduled by WHO as soon as the product is designated as meeting WHO prioritization criteria
- Evaluation facilitated by WHO
- Expected to shorten overall assessment timelines
Option 2: Performance evaluation commissioned by the manufacturer and carried out at a Prequalification Evaluating Laboratory listed by WHO

- The manufacturer selects a laboratory from the list of Prequalification Evaluating Laboratories
- The manufacturer will bear the cost of the evaluation and be responsible for coordinating it directly with the laboratory
- The selected evaluating laboratory will inform PQ as soon as an evaluation has been commissioned by a manufacturer
### 2 performance evaluations pathways: comparison

<table>
<thead>
<tr>
<th>Option 1: evaluation coordinated by WHO</th>
<th>Option 2: evaluation coordinated by the manufacturer</th>
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</thead>
<tbody>
<tr>
<td>As per WHO evaluation protocol</td>
<td>As per WHO evaluation protocol</td>
</tr>
<tr>
<td>Performed by PQ evaluating laboratory</td>
<td>Performed by PQ evaluating laboratory</td>
</tr>
<tr>
<td>Scheduled and facilitated by WHO</td>
<td>Scheduled and coordinated by the manufacturer</td>
</tr>
<tr>
<td>Cost covered by WHO</td>
<td>Cost covered by the manufacturer</td>
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New pre-assessment phase

• The PQ process will continue to be initiated by the receipt of the pre-submission form from the manufacturer
  • A revised version of the PSF will contain information on the option selected by the manufacturer for the performance evaluation.
• **Option 1**: If the product meets PQ prioritization criteria and option 1 is requested, the manufacturer will receive a prioritization letter defining the type of assessment that the product will have to undergo (either an abbreviated or a full assessment)
• **Option 2**: The manufacturer will receive a prioritization letter defining the type of assessment **AND** instructions on how the data generated from the performance evaluation need to be submitted
WHO Prequalification Evaluating Laboratories
List 1 and List 2

Two separate lists of WHO Prequalification Evaluating Laboratories will exist

- **List 1** will include laboratories that will work directly with WHO and will participate in option 1
- **List 2** will be more extensive than list 1 and will include additional laboratories that will not be included in List 1
- Manufacturers will be able to coordinate evaluations with laboratories from list 2
Invitation to submit an EOI

- WHO issued an invitation to submit an EOI for laboratories to indicate their interest in being listed for WHO PQ performance evaluations; List 1 only, List 2 only or both
- Laboratories with experience in conducting independent performance evaluations of IVDs which assist in the diagnosis and/or monitoring of infection with HIV-1/HIV-2, syphilis, hepatitis B, hepatitis C, Human Papillomavirus (HPV) and G6PD
- The invitation scope will progressively expand
Invitation to submit an EOI cont'd

- Process to assess the suitability of candidate laboratories having submitted an EOI to conduct performance evaluations of IVDs for WHO PQ purposes
- The assessment of the candidate laboratories by WHO consists of the following:
  - Receipt of an EOI;
  - Stage 1 audit- Assessment of EOI and specific QMS documentation;
  - Stage 2 audit- On-site audit of the laboratory to assess compliance with WHO requirements; and
  - Listing of successful laboratories as WHO Prequalification Evaluating Laboratories
Invitation to submit an EOI cont'd

• The invitation contains a list of criteria and requirements that will need to be met in order for laboratories to be considered.
• Criteria for selection of laboratories are based on international best practice, in particular on ISO standards ISO 17025:2005 General requirements for the competence of testing and calibration laboratories, ISO 15189:2012 Medical laboratories -- Requirements for quality and competence or equivalent.
• Laboratories will be audited by WHO in order to verify compliance with WHO requirements.
Timelines

- The new approach will follow a phased implementation through 2016
- All current laboratories will be assessed in 2016, with new partner laboratories coming into the pipeline in 2017
- A pilot is taking place with 2 audits scheduled in August 2016
- Progressively, the scope of products undergoing this approach will be expanded – progressive shift from the current system to the new mechanism to avoid disruption
- For malaria RDTs the current system will be kept throughout 2016 and 2017
Questions:

please use the chat button