A new streamlined assessment approach for WHO Prequalification of Diagnostics

- Industry briefing -

15/16 May 2014
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Role of WHO prequalification

- Facilitate access to safe, appropriate priority diagnostics, medicines & vaccines
- Support two of WHO's six core functions
  - setting norms & standard/promoting their implementation
  - providing technical support, catalyzing change & building institutional capacity
- Contribute to achieving four of WHO's impact goals
  - reduce under-five mortality
  - reduce maternal mortality
  - reduce the number of people dying from AIDS, tuberculosis and malaria
  - eradicate polio
EMP reorganization: single PQ programme for further impact & restructured regulatory units

- Consolidated prequalification team aiming at
  - Enhanced management & operations
    - e.g. quality management system
    - e.g. administrative efficiencies, incl. financial management
  - Better relationship with stakeholders
    - e.g. single voice when dealing with national regulatory authorities
    - e.g. increased transparency around processes and outcomes
  - Cross-product stream learning
    - e.g. extension of ERP process to new product categories
    - e.g. bigger pool of external experts and testing laboratories
    - e.g. PQDx benefit from medicines and vaccines experience to improve efficiency
Department of Essential Medicines & Health Products: structure

- Essential Medicines and Health Product [EMP]
  - Policy, Access and Use [PAU]
    - Technologies Standards and Norms [TSN]
  - Regulation of Medicines and other Health Technologies [RHT]
    - Regulatory Systems Strengthening [RSS]
  - Public Health, Innovation and Intellectual Property [PHI]
    - Prequalification Team [PQT]
    - Safety and Vigilance [SAV]
Review of PQDx experience and analysis of gaps and challenges

PQDx weaknesses

- Timelines
- Transparency (pass/fail criteria, fast tracking, post-PQ)
- Guidance and specific information to Mx
- Communications with stakeholders
- Overloaded pipeline

Way forward

- Increase efficiency (proactive, responsive, define and follow timelines)
- Improve transparency (communicate expectations, provide further guidance)
- Strengthen support to Mx (guidance, updates, training, advisory visits)
- Improve communications (meet commitments, have regular updates, send clear simple messages)
- Clean pipeline with active applications
What is streamlining?

- Objectives:
  - Increase efficiency (timelines for WHO work)
  - Improve transparency (requirements, process)
  - Strengthen work with key partners (manufacturers, procurement and other agencies, NRAs)
  - Strengthen communications

- Focus on active applications
Review and optimization of WHO PQDx process

- Rethink PQ pathway
  - what has worked and what needs to be redefined

- Define timelines for WHO and Mx
  - WHO internal and Mx target timelines

- Number of rounds for dossier and inspections aspects

- Decision-making for each PQ component and communicating decisions
Review and optimization of WHO PQDx process cont'd

- Termination/rejection of applications

- Avoid unnecessary steps
  - Letter of Agreement can be captured in the dossier submission

- Pre-acceptance criteria for full PQ assessment
  - what and when

- When to request a PQ fee
  - First fee for screening and second fee for assessment
Pre-dossier assessment phase

Pre-submission form and dossier submission & screening

- Application form renamed and amended to better reflect needs
  - Pre-submission form
    - Information needed for prioritization

- Prioritization criteria: review current criteria, discuss with donors and WHO disease programmes

- Pre-acceptance criteria
  - Following successful screening: application accepted for assessment (dossier, inspection and evaluation)
  - Application accepted for assessment/inspection/laboratory evaluation
Streamlining product dossier review

- Definition of screening, assessment and post-assessment phases
- Specify number of screening amendments, decision points, post-assessment phase
- Improve current instructions and provide better guidance to manufacturers
Streamlining product dossier review cont'd

- Define minimum requirements
  - Define critical dossier sections with high impact on product quality, safety and performance
  - Grading of non-conformities
  - Additional sections needed/redundant sections
  - Define post-assessment phase: expectations, number of rounds, decision points

- Abbreviated assessment waives requirement for dossier submission and review
Streamlining inspections

- Rethink the process
  - Planning activities
  - Defining the duration needed
  - Number of action plans for review
  - Timelines
  - Stage 1 inspection / stage 2 inspection / follow up / re-inspection
  - Acceptance/rejection
  - Abbreviated assessment

- International harmonization: IMDRF, and particularly the Medical device single audit program (MDSAP)
Streamlining laboratory evaluations

- Work with partners
  - Which partner is doing what – which areas are less well covered
  - Types of evaluations carried out by partners: objectives and relevance for PQ
  - Protocols harmonization and reliance on partners' work where objectives are aligned

- Addressing priority areas not covered by partners

- Avoid duplication of efforts on the same products
Abbreviated prequalification assessment

- Terminology
  - fast tracking → abbreviated assessment

- Re-adjust the system to avoid duplication

- Which aspects deserve WHO's attention?
  - where does PQDx bring added value to Member States

- Non-stringently assessed diagnostics where a stringently assessed version exists
Results of streamlined WHO PQDx assessment

- Efficient and timely prequalification of quality-assured diagnostics
  - Fewer steps
  - Defined timelines
  - Defined number of rounds
  - Improved scheduling

- More interactions with manufacturers including more teleconferences at critical steps
Expected impact of new PQDx process

- Increased transparency and efficiency
- Clean pipeline
  - Better focus on active applications
- Division between PQDx assessment and assistance to Mx
  - Transparent PQDx assessment process in place
  - Additional guidance to assist Mx, WebEx briefings, sample dossiers, training plan for priority topics
  - Robust capacity building programme in place through TA group:
    - advisory visits to tackle specific gaps and
    - training programme to address most common PQ issues