Prequalification Team – Medicines (PQTm)

Update

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Time to prequalification of medicines (FPPs, median, full assessment)

WHO times have been consistently below the target 270 days (median) since 2013.

- around 200 days since 2013
WHO and company time to prequalification of FPPs (days)
PQ measures to reduce manufacturer time, and total time to prequalification

- PQ can provide advice at any stage before, or after submission (F2F-meetings, TC, e-mails, specific pre-submission meetings) – PQ is accessible. You should use this opportunity!
- PQ tries to provide timely responses to questions, or requests for clarifications (esp. via e-mail).
- PQ develops product-specific guidances, on an ongoing basis, eg BE study design, or Q&As (zinc, magnesium, RH products etc).
- PQ reviews final draft BE study protocols, before study start.
- PQ does an in-depth screening of dossiers, to ensure that dossiers are complete before start of full assessment. This feedback is provided to the applicant. The screening checklist is on the PQ website.
- PQ needs to frequently review its assessment pipeline, to make sure all dossiers are live. Reminders to companies may be needed. Dossier withdrawals/cancellations may also be necessary.
- Model dossier in CTD format to guide applicants (2016)
A specific, and recent, measure to reduce the impact of data integrity and GMP issues on time to prequalification of medicines

- Intensified interaction between PQ assessments, PQ inspections and the applicant, for dossiers that are close to prequalification
  - to ensure prompt submission of replacement data or risk assessment/CAPAs by the applicant;
  - to ensure priority review of these data, performance of re-inspections as needed, and final decisions regarding inspection issues by WHO

- Of the 27 products prequalified by mid-2017, half would otherwise have taken longer to be prequalified.

- Only possible if the applicant provides timely and complete responses.

- Prequalification of medicines is a collaboration between PQ and the applicant.

- It is also in WHO’s interest that your products become prequalified - because the medicines are needed, and PQ, being entirely donor-funded, obviously needs to perform.
Additional measures to reduce time to prequalification?

- Limiting the number of rounds of assessment, or imposing strict due dates for response submission?
  - PQ medicines does not do this, since this may discourage new submissions, or discourage progress of existing applications, especially if the manufacturer is less experienced. Of course, the time needed for the company to address an issue, also depends on the nature of the issue.
  - PQ does send reminders however, and could do so more frequently.
- Increased provision of technical assistance, through external providers (outside of PQ) could help.

Fast track to prequalification = Good quality dossier at submission + prompt, complete, good-quality responses to PQ’s questions, throughout the process.