New Dossier Format for Vaccine Prequalification

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New format of Vaccine Prequalification dossier proposed

- The current format of the dossier (Product Summary File) [PSF] to be submitted for prequalification of vaccines is specified in TRS 978, Annex 6

- The PSF format requirements (effective from 2012) had only changed marginally from the previous process revision (2005) but did allow for the PSF to be supplemented by cross-referenced CTD dossier
New format of Vaccine Prequalification dossier - Why change?

- The global use of CTD format has increased significantly since the last revision of the vaccine prequalification procedure.
- Most manufacturers have a prepared dossier in CTD format that they have used to register the product in one or more countries.
- Some PSF format dossier sections already in Site Master Files (required for submission before inspection).
- Reduces manufacturers’ regulatory burden for maintaining and updating dossiers in multiple formats.
- Many countries that import prequalified products require submission of a CTD format dossier for registration.
- CTD dossier format is used for WHO prequalification submissions for pharmaceuticals.
New format of Vaccine Prequalification dossier - Content and timeframe for adoption

• Modules 2-5 of CTD format are common wherever the dossier is submitted
• Module 1 of CTD format is used for specific information depending on the agency to which the dossier is submitted
• WHO website indicates proposed content of Module 1 for WHO PQ submission
• Comment on the content was invited from interested parties before finalisation
• Received comments are currently under review
• Timeframe has not yet been set for adoption of new format, including duration of a transitional period in which current format dossiers will be accepted
New format of Vaccine Prequalification dossier - Some feedback to date

• Regional differences in CTD

• Concern about transition period because companies have commenced preparation of PSF format dossiers

• For vaccines that have been nationally registered for a long time, concern about lack of data for some CTD sections
References

• Current WHO Prequalification procedure
  http://www.who.int/entity/immunization_standards/vaccine_quality/TRS_978_61st_report_Annex_6_PQ_vaccine_procedure.pdf?ua=1

• Web notification of proposed change to CTD dossier format
  http://www.who.int/entity/immunization_standards/vaccine_quality/TRS_978_61st_report_Annex_6_PQ_vaccine_procedure.pdf?ua=1

• Content proposed for comment of WHO PQ CTD dossier – Module 1
  http://www.who.int/immunization_standards/vaccine_quality/VaccinePQ-dossier-V3-2017.pdf?ua=1

• ICH guidelines for Modules 2, 3, 4 and 5
Thank you

WHO

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