

# New Dossier Format for Vaccine Prequalification



World Health  
Organization



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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](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](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](http://www.who.int/immunization_standards/vaccine_quality/VaccinePQ-dossier-V3-2017.pdf?ua=1)
- ICH guidelines for Modules 2,3,4 and 5 <http://www.ich.org/products/ctd.html>

# Thank you



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