

# Reference documents in Prequalification of vaccines

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WHO PREQUALIFICATION PROGRAMME

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# General documents

Vaccines against	TRS Number	Link	Comments
PQ procedure	TRS 978, Annex 6 (2012)	<a href="http://www.who.int/entity/immunization_standards/vaccine_quality/TRS_978_61st_report_Annex_6_PQ_vaccine_procedure.pdf">http://www.who.int/entity/immunization_standards/vaccine_quality/TRS_978_61st_report_Annex_6_PQ_vaccine_procedure.pdf</a>	---
GCP	TRS 850 (1995)	<a href="http://apps.who.int/prequal/info_general/documents/TRS850/WHO_TRS_850-Annex3.pdf">http://apps.who.int/prequal/info_general/documents/TRS850/WHO_TRS_850-Annex3.pdf</a>	---
Non-clinical evaluation of vaccines	TRS 927 (2005)	<a href="http://who.int/biologicals/vaccines/nonclinical_evaluation_of_vaccines/en/">http://who.int/biologicals/vaccines/nonclinical_evaluation_of_vaccines/en/</a>	---
Clinical evaluation of vaccines	TRS 924 (2004)	<a href="http://who.int/entity/biologicals/vaccines/clinical_evaluation/en/index.htm">http://who.int/entity/biologicals/vaccines/clinical_evaluation/en/index.htm</a>	---
Important clinical considerations	---	<a href="http://www.who.int/immunization_standards/vaccine_quality/pq_vaccine_evaluation/en/">http://www.who.int/immunization_standards/vaccine_quality/pq_vaccine_evaluation/en/</a>	Not a TRS but summarizes key requirements



# Specific documents 1

Vaccine against	TRS Number	Link	Comments
Tuberculosis	TRS 979 (2013)	<a href="http://www.who.int/biologicals/areas/vaccines/TRS_979_Annex_3.pdf?ua=1">http://www.who.int/biologicals/areas/vaccines/TRS_979_Annex_3.pdf?ua=1</a>	No correlate of protection. Efficacy study required with BCG as comparator
Cholera	----	----	No correlate of protection. Efficacy study is required with PQ vaccine as comparator
DT based Combined Vaccines	TRS 980 (2014)	<a href="http://www.who.int/biologicals/vaccines/Combined_Vaccines_TRS_980_Annex_6.pdf?ua=1">http://www.who.int/biologicals/vaccines/Combined_Vaccines_TRS_980_Annex_6.pdf?ua=1</a>	Correlate of protections except for pertussis, the magnitude of response is compared between the responses to test and control (non-inf – 95% upper CI GMC or GMT ratio usually less 1.5 or 2.0 or as agreed with NRA)
Dengue	TRS 979 (2013)	<a href="http://www.who.int/biologicals/areas/vaccines/TRS_979_Annex_2.pdf?ua=1">http://www.who.int/biologicals/areas/vaccines/TRS_979_Annex_2.pdf?ua=1</a>	Efficacy study required



# Specific documents 2

Vaccines against	TRS Number	Link	Comments
Hepatitis A	---	<a href="http://www.who.int/wer/2012/wer8728_29.pdf?ua=1">http://www.who.int/wer/2012/wer8728_29.pdf?ua=1</a>  (WER, No. 28-29, 2012, 87, 261–276)	Correlates of protection proposed but a positive (qualitative) test for total anti-HAV antibodies is considered to signify immunity to hepatitis A
Hepatitis B	---	<a href="http://www.who.int/wer/2009/wer8440.pdf?ua=1">http://www.who.int/wer/2009/wer8440.pdf?ua=1</a>  (WER, No. 40, 2009, 84, 405–420)	Correlate of protection
HPV	TRS 962 (2011)  An update is awaited	<a href="http://www.who.int/biologicals/vaccines/hpv/Annex_1_WHO_TRS_962-2.pdf?ua=1">http://www.who.int/biologicals/vaccines/hpv/Annex_1_WHO_TRS_962-2.pdf?ua=1</a>	Based on rates of CIN2/3 and AIS associated with vaccine HPV types after three vaccine doses on schedule.
Influenza	---	<a href="http://www.who.int/wer/2012/wer8747.pdf?ua=1">http://www.who.int/wer/2012/wer8747.pdf?ua=1</a>	Correlate of protection



# Specific documents 3

Vaccines against	TRS Number	Link	Comments
Japanese Encephalitis Vaccine	TRS 963 (2011)	<a href="http://www.who.int/biologicals/vaccines/japanese_encephalitis/en/">http://www.who.int/biologicals/vaccines/japanese_encephalitis/en/</a>	Correlates of protection exist
	TRS 980 (2014)	<a href="http://www.who.int/biologicals/vaccines/JE-Recommendations_TRS_980_Annex_7.pdf?ua=1">http://www.who.int/biologicals/vaccines/JE-Recommendations_TRS_980_Annex_7.pdf?ua=1</a>	
Measles	TRS 840 (1994)	<a href="http://www.who.int/biologicals/publications/trs/areas/vaccines/mmr/WHO_TRS_840_A3.pdf?ua=1">http://www.who.int/biologicals/publications/trs/areas/vaccines/mmr/WHO_TRS_840_A3.pdf?ua=1</a>	Correlates of protection exist
Meningococcal Vaccine	TRS 962 (2011) (also 924, 926, 963)	<a href="http://www.who.int/biologicals/vaccines/Annex_2_WHO_TRS_962.pdf?ua=1">http://www.who.int/biologicals/vaccines/Annex_2_WHO_TRS_962.pdf?ua=1</a>	Correlates of protection exist
Pneumococcal Vaccine	TRS 977 (2013)	<a href="http://www.who.int/biologicals/vaccines/TRS_977_Annex_3.pdf?ua=1">http://www.who.int/biologicals/vaccines/TRS_977_Annex_3.pdf?ua=1</a>	Correlates of protection exist



# Specific documents 4

Vaccine	TRS Number	Link	Comments
Polio	TRS 926 (2004)	<a href="http://www.who.int/biologicals/publications/trs/areas/vaccines/polio/Annex%20%20(65-89)TRS926Polio2003.pdf?ua=1">http://www.who.int/biologicals/publications/trs/areas/vaccines/polio/Annex%20%20(65-89)TRS926Polio2003.pdf?ua=1</a>	Correlates of protection exist
	TRS 993 (2015)	<a href="http://www.who.int/biologicals/vaccines/Annex3_IPV_Recommendations_eng.pdf?ua=1">http://www.who.int/biologicals/vaccines/Annex3_IPV_Recommendations_eng.pdf?ua=1</a>	
Rota virus	TRS 941 (2007)	<a href="http://www.who.int/biologicals/publications/trs/areas/vaccines/rotavirus/Annex%20%20rotavirus%20vaccines.pdf?ua=1">http://www.who.int/biologicals/publications/trs/areas/vaccines/rotavirus/Annex%20%20rotavirus%20vaccines.pdf?ua=1</a>	Efficacy study needed
Typhoid	TRS 987 (2014)	<a href="http://www.who.int/biologicals/areas/vaccines/TRS_987_Annex3.pdf?ua=1">http://www.who.int/biologicals/areas/vaccines/TRS_987_Annex3.pdf?ua=1</a>	<p>In age group 2 years and older, group the pre-licensure assessment of the likely protective efficacy of conjugated Vi vaccines could be based on appropriate studies of comparative immunogenicity using validated assays (supported by challenge studies)</p> <p>In less than 2 years, efficacy study needed (NRA could depending on burden of disease decide on appropriate immunogenicity study followed by post approval effectiveness)</p>
Yellow Fever	TRS 978 (2013)	<a href="http://www.who.int/biologicals/areas/vaccines/TRS_978_Annex_5.pdf?ua=1">http://www.who.int/biologicals/areas/vaccines/TRS_978_Annex_5.pdf?ua=1</a>	Efficacy study not needed



# Notice

It is crucial to be very conversant with the guidelines related to each vaccine and ask question if necessary



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