INFORMATION TO BE PROVIDED BY APPLICANT FOR DEVELOPMENT OF A WHO PUBLIC ASSESSMENT REPORT FOR A PREQUALIFIED FINISHED PHARMACEUTICAL PRODUCT									
				Source of information for innovator or multisource generic product, approved by a stringent regulatory authority (SRA)		**Source of information for multisource generic product**			
Part	**Title**	**Drafted by**	**Type and /or format of information**	**…for which a public assessment report is available**	**…for which NO public assessment report is available (if a confidential report is available the applicant may enclose it with the submission or WHO can request it from the SRA concerned)**	**…for which acceptable comparator / reference product available**		**…for which NO acceptable comparator/reference product available (e.g. new combinations of existing products, such as fixed-dose combinations (FDCs) or traditionally-used multisource product such as an artemisinine**	
1	Abstract	WHO	Overview of key information						
2a	All Accepted Presentations	WHO	Description of all accepted presentations and dosages, as given in WHO List of Prequalified Medicinal Products						
2b	Appearance of Product	WHO	Photograph of formulation (solid forms) or other product characteristics (liquid forms)						
3	Product Information for the User (in English)	Applicant	Practical, easily understandable information for the user of the product and that the user can act upon directly, if necessary	As approved by national medicines regulatory authority (NMRA) of an ICH member or associated country[1] (in English, or as authorized English translation Link to relevant (section of) public assessment report on the SRA website	As approved by NMRA of an ICH member or associated country[1] (in English, or as authorized English translation	In English See guidance: 2, 3, 4, 5	The text should reflect the information available for the innovator / comparator product. The comparator product must be one that is acceptable to WHO. In particular, the indication and safety profile should be the same as for the approved comparator / reference product(s). However, special reference may be made by the WHO Prequalification Team to WHO treatment guidelines, which may result in deviations from the reference product's information.	In English See guidance: 2, 3, 4, 5	A bibliographic submission must be submitted if e.g. no (acceptable) comparator / reference product exists (such as products containing a new combination of active ingredients or a new dose / dose ratio or traditionally/used multisource products such as artemisinins). It should include: • information on safety and efficacy as would be requested by an SRA • a clinical overview written by a qualified person (the CV of whom is included in the submission) that: ○ summarizes all relevant scientific literature, including, in the case of new FDCs (for which the combined use of the single actives has not been established according to WHO treatment guidelines), including evidence relating to the safety and efficacy of the equivalent combination of the single active pharmaceutical ingredients ○ references original clinical research (if carried out) ○ references relevant treatment guidelines, particularly those issued by WHO • references other relevant documentation (listing all references and to be made available upon request by WHO) that supports the information that are or will be included in Parts 3, 4 and 6 of a WHOPAR).
4	Information for the Health Care Provider (in English)	Applicant (WHO)	All practical and essential medical (background) information on the product for health care providers	Summary of Product Characteristics (SmPC) as approved by NMRA of an ICH member or associated country[1], in English, or as authorized English translation Link to relevant section of public assessment report on NMRA website	SmPC approved by NMRA of an ICH member or associated country,[1] in English, or as authorized English translation	SmPC, in English See guidance: 5, 6, 7, 8		In English See guidance: 5, 6, 7, 8	
5	Labelling (in English)	Applicant (WHO)	All text for packaging (primary and secondary)	As approved by NMRA of an ICH member or associated country,[1] in English, or as authorized English translation Link to relevant (section of) public assessment report on SRA website	As approved by NMRA of an ICH member or associated country,[1] in English, or as authorized English translation See guidance: 9	In English See guidance: 5, 9, 10, 11		In English See: 5, 9, 10 11	

6	Scientific Discussion	WHO, based on • assessment reports on quality	Outcome of quality and bioequivalence evaluation and, if required, the overview of current product safety and efficacy				
		• bioequivalence study and/or summary of product safety and efficacy		Summary of product safety and efficacy can be submitted *voluntarily* or link provided to relevant section of public assessment report on NMRA website of an ICH member or associated country[1] See guidance: 12	Summary of product safety and efficacy, as contribution to Part 6, can be submitted *voluntarily* See guidance: 12	Note: Not required since relevant information on safety and efficacy is generally available for this type of product	Comprehensive summary of product safety and efficacy of the FPP See guidance: 12
7	Steps taken for prequalification	WHO	Chronological description of main steps of assessment of product, by whom Information on international licensing status, including on countries and licensing numbers				
8	Steps taken following prequalification	WHO	Chronological description of main steps of assessment of product, by whom				

[1] International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The current ICH members are Canada, the European Union, Japan, Switzerland and the USA. Other countries associated with ICH (through legally binding mutual recognition agreements) include Australia, Norway, Iceland and Liechtenstein. See: www.ich.org
[2] *Patient Information Leaflet (PIL) (or Package Leaflet) template*
[3] *Annotated Patient Information Leaflet (PIL) template*
[4] *Section Guidance for Part 3 of a WHO Public Assessment Report — Product Information for the User*
[5] *Ensuring Consistency Between Product Information Documents*
[6] *Summary of Product Characteristics (SmPC) Template*
[7] *Annotated Summary of Product Characteristics (SmPC) Template*
[8] *Section Guidance for Part 4 of a WHO Public Assessment Report — Information for the Health Care Provider*
[9] *Section Guidance for Part 5 of a WHO Public Assessment Report — Labelling*
[10] *Labelling Template*
[11] *Annotated Labelling Template*
[12] *Guidance for Part 6 of a WHO Public Assessment Report — Scientific Discussion*