INFORMATION TO BE PROVIDED BY APPLICANT FOR DEVELOPMENT OF FOOD AND DRUGS AUTHORITY PUBLIC ASSESSMENT REPORT (FAPAR) FOR A FINISHED MEDICINAL PRODUCT						
Part	**Title**	**Drafted by**	**Type and /or format of information**	**Source of information for innovator or generic product, approved by WHO listed reference Authorities**		**Source of information for generic product**
				…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 FDA can request it from the reference authority concerned)**	**…for which acceptable comparator / reference product is available**
1	Abstract	FDA	Overview of key information			
2a	All Accepted Presentations	FDA	Description of all accepted presentations and dosages, as given in the product dossier			
2b	Appearance of Product	FDA	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 the reference authority (in English, or as authorized English translation	As approved by reference authority (in English, or as authorized English translation	The text should reflect the information available for the innovator / comparator product. The comparator product must be one that is acceptable to the FDA. 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 FAPAR committee to National treatment guidelines, which may result in deviations
4	Information for the Health Care Provider (in English)	Applicant (FDA)	All practical and essential medical (background) information on the product for health care providers	Summary of Product Characteristics (SmPC) as approved by reference authority, in English, or as authorized English translation	SmPC approved by reference authority, in English, or as authorized English translation	

[1] 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 FAPAR— Product Information for the User*
[5] *Readability guideline*
[6] *Summary of Product Characteristics (SmPC) Template*
[7] *Annotated Summary of Product Characteristics (SmPC) Template*
[8] *Section Guidance for Part 4 FAPAR — Information for the Health Care Provider*
[9] *Section Guidance for Part 5 of FAPAR— Labelling*
[10] *Labelling Template*
[11] *Annotated Labelling Template*
[12] *Guidance for Part 6 of FDA Public Assessment Report — Scientific Discussion*

5	Labelling (in English)	Applicant (FDA)	All text for packaging (primary and secondary)	As approved by reference authority, in English, or as authorized English translation	As approved by reference authority, in English, or as authorized English translation See guidance: 9	from the reference product's information.
6	Scientific Discussion	FDA, based on • assessment reports on quality	Outcome of quality and bioequivalence evaluation (where applicable) and, if required, the overview of current product safety and efficacy			
		• bioequivalence (where applicable) 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 website of a reference authority 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
7	Steps taken for registration	FDA	Chronological description of main steps of assessment of product			
8	Steps taken following registration	FDA	Chronological description of main steps after registration of product			

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