Appendix 5

Proposed documentation for collaborative procedure for reference SRA-approved pharmaceutical products and vaccines

Notes:
The format of the documentation corresponds to common technical document (CTD) in accordance with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) format/content. For practical reasons nonclinical (Module IV) and clinical data (Module V) are replaced by summaries included in Module II. Should there be a need for more extensive data from Module IV and Module V, these are available on request.

Confidentiality of submitted data and non-disclosure to a third party is – in addition to relevant national legislation and organizational measures applied by national regulatory authorities (NRAs) participating in the Procedure – assured by a commitment on confidentiality that represents an integral part of the Procedure[1] (Appendix 1), is signed by representatives of participating NRAs and archived by WHO.

Adapted Module 1

		Documentation to be provided	Comments
1.0	Letter of application		Cover letter in English, French, or as applicable to the region
	Attachments to the letter:		
	Appendix 3A of the reference stringent regulatory authority (SRA) Procedure		

[1] Collaborative procedure in assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities, facilitated by WHO.

Table *continued*

		Documentation to be provided	Comments
	Appendix 3B of the reference SRA Procedure		
	Appendix 4	Includes information as specified in Commitment letter 1 (additional administrative data) and Commitment letter 2 (additional stability data for climatic zones). Any differences in the dossier submitted to the reference SRA should be explained, including differences in product information.	Submitted in English or French as applicable to the region
1.1	Comprehensive table of contents (TOC)	Comprehensive TOC including Module 1 information	
1.2	Quality information summary (QIS-SRA)	This will be included instead of a country-specific application form	Refer to Appendix 9 for the QIS-SRA template To be included in the adapted Module 1
1.3	**Product information**		
1.3.1	Package insert or summary of product characteristics	Product information as applicable for the region where the application will be submitted	Submitted in English or French as applicable to the region
1.3.2	Patient information leaflet or package leaflet	Mock-ups	Submitted in English or French as applicable to the region
1.3.3	Labelling	Mock-ups	Language and information to reflect national requirements

Table *continued*

		Documentation to be provided	Comments
1.4	**Marketing authorization from reference SRA**		
1.4.1	Marketing authorization from reference SRA	Yes	
1.4.2	Assessment report from reference SRA (Access to the full assessment report from the reference SRA, if available)	Agreement from the manufacturer to allow reference SRA to share the report with WHO and national regulatory authorities (NRAs). Prior to sharing, the reference SRA and manufacturer should agree on the content of the document that is shared. If fully justified, sentences referring to highly confidential information and/or highly sensitive data and/or not related to the product assessment data could be masked.	Note that this type of document is available only for products registered in Europe, via the Centralized Procedure. Public reports are preferred as they already contain all useful information, except those considered to give a competitive advantage. The sharing process is facilitated by WHO, between reference SRA and NRAs.
1.5	**Good manufacturing practices (GMP) certification**		
1.5.1	Copy of the GMP certificate of the active pharmaceutical ingredient (API) supplier, if available	Yes If not available, statement signed by qualified person (QP) from the finished pharmaceutical product manufacturing site to be provided	Currently, this is not always available. No legalization is required.
1.5.2	Copy of the GMP certificate of the finished pharmaceutical product (FPP) manufacturer(s)	Yes	No legalization is required.

Table *continued*

		Documentation to be provided	Comments
1.5.3	GMP inspection report of the manufacturing site(s) (FPP) from any reference SRA	Agreement from the manufacturer to allow the reference SRA to share the report with WHO and NRAs. Prior to sharing, the reference SRA and manufacturer should agree on the content of the document that is shared. If fully justified, sentences referring to highly confidential information and/or highly sensitive data and/or not related to the product assessment data could be masked.	Public reports are preferred as they already contain all useful information, except those considered to give a competitive advantage. The sharing process is facilitated by WHO, between the reference SRA and NRAs.
1.6	**Other documentation**		
	If generic dossier: – full GCP inspection report of the bioequivalence study from any reference SRA, if any; – bridging report (where applicable) especially for innovative medicines (Appendix 6); – information on local representatives or distributor.	Agreement from the manufacturer to allow reference SRA to share the report with WHO and NRAs. Prior to sharing, the reference SRA and manufacturer should agree on the content of the document that is shared. If fully justified, sentences referring to highly confidential information and/or highly sensitive data and/or not related to the product assessment data could be masked.	Public reports are preferred as they already contain all useful information, except those considered to give a competitive advantage. The sharing process is facilitated by WHO, between the reference SRA and NRAs.

Module 2 summaries

Module 2 should be complete as submitted to the reference SRA.

Note: In the case of generic medicines for which a Clinical summary is not available, the Clinical overview (Module 2.5) should be included.

Module 3 Quality documentation

Complete Module 3 as submitted to the reference SRA, except corresponding open part of the active pharmaceutical ingredient master file (APIMF) is submitted, unless indicated otherwise according to the requirements of the participating NRA. If climatic zone III–IV stability data are not available, the commitment and protocol should be provided for stability studies under the appropriate climatic conditions for the receiving country. Any preliminary data under the required climatic conditions for the participating NRA should be provided. The stability data should be assessed by the reference SRA, where applicable or possible.

Additional region-specific information for Module 3 should be provided, where applicable.

Module 4 non-clinical documentation

Data to be provided only if required by the participating NRAs according to their national requirements, otherwise, these data are on request.

Module 5 clinical documentation

For innovative medicines, data to be provided only if required by the participating NRAs according to their national requirements, otherwise, these data are available on request. For generic products, complete documentation on bioequivalence studies should be provided in the submission in-line with WHO Guidelines on registration requirements to establish interchangeability[2] and applicable national regulatory requirements for participating NRAs.

[2] WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-first report. Geneva: World Health Organization; 2017: (WHO Technical Report Series, No. 1003, Annex 6), 181-236.