Annex 2: Documentation abridged authorisation procedure

Proposed documentation for the abridged authorization procedure for reference institution (RI)-approved medicinal products

All documents requested in the following adapted Module 1 MUST be submitted as original and translated in English (notarised), if original is not in English

Adapted Module 1

	Documentation to be provided	**Comments**
1.0 Letter of application		
Attachments to the letter:		
Annex III (permission of data sharing) of the abridged authorisation procedure		
1.1 Comprehensive table of contents (TOC)	Comprehensive TOC including Module 1 information	
Quality information summary (QIS-RI-FPP (Annex IVa) and QIS-RI-BTP (Annex IVb))	Any differences in the dossier submitted to the RI should be explained, including differences in product information.	
1.3 Product information		
1.3.1 Summary of product characteristics	Product information for the healthcare professional as applicable for the region where the application will be submitted	
1.3.2 Patient information leaflet or package insert	Mock-ups	
1.3.3 Labelling	Mock-ups	Language and information to reflect national requirements
1.4 Marketing authorisation from reference institution		
1.4.1 Marketing authorisation from reference institution	Yes	

	Documentation to be provided	Comments
1.4.2 Assessment report from reference institution (Access to the full assessment report from the reference institution, if available)	Agreement from the manufacturer to allow reference institution to share the report with NMRAs. Prior to sharing, the reference institution 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 Centralised Procedure. Public reports are preferred as they already contain all useful information, except those considered to give a competitive advantage.
1.5 Good manufacturing practices (GMP) certification		
1.5.1 Copy of the GMP certificate of the active pharmaceutical ingredient (API)/drug substance (DS) supplier, if available	Yes	Currently, this is not always available. If not available, statement signed by qualified person (QP) from FPP/DP manufacturing site to be provided or at least CoA
1.5.2 Copy of the GMP certificate of the finished pharmaceutical product (FPP)/drug product (DP) manufacturer(s)	Yes	
1.5.3 GMP inspection report of the manufacturing site(s) (FPP) from any reference institution	Agreement from the manufacturer to allow the reference institution to share the report with the NRA. Prior to sharing, the reference institution 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.
1.6 Other documentation		

	Documentation to be provided	**Comments**
If generic dossier: – full GCP inspection report of the bioequivalence study from any reference institution, if any; – bridging report (where applicable) especially for innovative medicines (Section 6.3 in the Guideline on Reliance); – information on national representatives or distributor.	Agreement from the manufacturer to allow reference institution to share the report with NMRA. Prior to sharing, the RI 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.
1.7 Others -Samples	Statement that samples have been submitted or, exceptionally, commitment letter for sample submission	If, for a specific reason, samples cannot be submitted with the application, these should be submitted within two weeks after receipt of the submission.