Suggested template for harmonization/ alignment of Module 1

Section	Suggested Documentation Included in the Section
1.0 Cover letter	Cover Letter
1.1 Comprehensive table of content	TOC
1.2 Application Form (Administrative data)	Application Form Administrative Information Patent Information Legal and Statutory Documents
1.3 Product Information	Labelling Mock-ups Packaging Inserts Summary of Product Characteristics Description and Composition PIL
1.4 Information about experts	Information about Quality and Clinical experts
1.5 Specific Requirements for Procedures - Applications	Specific Requirements for different types of applications Information on the application/submission type Literature Based Documents Information for Generic, 'Hybrid' or Bio-similar Applications Co-marketed or Combination medicines information Conditional Marketing Orphan Drug Status/Information/Exclusivity Brief profile of the manufacturer's research activity Exclusivity (Market or data) Pricing (list, certificates) Foreign Regulatory Information Invoices Other related documents
1.6 Correspondence	Response to Questions Meeting Request, Minutes, Correspondence Scientific Advice Additional data agreed upon to be provided Life-cycle management tracking Information Amendments (not part of Mod 2-5)
1.7 Environmental Risk Assessment	Environmental Risk Assessment Genetically Modified Organism (GMO) Status
1.8 Information relating to Pharmacovigilance	Pharmacovigilance (PV) Risk Management Plan (RMP) Protocols for PV plans
1.9 Clinical/ Bioequivalence *Where data is not already included in the NRA submission in modules 2-5*	Information relating to clinical trials (Synopsis, ongoing trials, study reports, post-marketing studies, etc.) Bioequivalence Biopharmaceutic studies Clinical information

1.10 Regulatory Certification	GMP, CPP, Manufacturing License Technical Contract (Open part) in case of contract manufacturing (If Applicable) Health authority approval of the latest Plasma master file
1.11 Manufacturer declarations and Certificates	Certificates of Suitability Letters of Access (Master files, etc.) Declaration letter from the manufacturer company for name and address of Man., MAH, Invoice, Export, and Release
1.12 Lot / Batch information	(CoA, Lot release certificate, SLP)
1.13+ Country additional data	Data requirements that do not fit in the above categories