

Example Coverage

EU Module 1 Section		Examples			
		01-CPv1.0	02-Nv1.0	03-DCPv1.0	04-MRPv1.0
	Country	emea	be	common	it – es, fr
	Language	en	fr, nl, de	en	it – es, fr
	Envelope				
	Application Number	1	1	1	1
	Agency Name	1	1	1	2
	ATC	1	1	1	1
	Procedure Type	CP	NP	DCP	MRP
	Invented Name	1	3	1	1
	INN	1	1	1	1
	Related Sequence	-	-	-	-
1.0	Cover Letter	1	1	1	2
1.2	Application Form	1	1	1	2
1.3	Product Information				
1.3.1	SPC, Labelling and Package Leaflet	1 pim	9 pdf	3 pdf	3 pdf
1.3.2	Mock-up	1	1	1	1
1.3.3	Specimen	-	-	1	1
1.3.4	Consultation with Target Patient Groups	1	1	1	1
1.3.5	Product Information already approved in the Member States	-	-	-	1
1.3.6	Braille	1	1	1	1
1.4	Information about the Experts				
1.4.1	Quality	1	1	1	1
1.4.2	Non-Clinical	1	1	1	1
1.4.3	Clinical	1	1	1	1

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1.5	Specific Requirements for Different Types of Applications				
1.5.1	Information for Bibliographical Applications	-	-	-	-
1.5.2	Information for Generic, 'Hybrid' or Bio-similar	-	1 generic	1 hybrid	1 hybrid
1.5.3	(Extended) Data/Market Exclusivity	-	-	-	1
1.5.4	Exceptional Circumstances	1	-	1	-
1.5.5	Conditional Marketing Authorisation	-	-		-
1.6	Environmental Risk Assessment				
1.6.1	Non-GMO	1 non-gmo	-	-	-
1.6.2	GMO	-	-	-	-
1.7	Information relating to Orphan Market Exclusivity				
1.7.1	Similarity	1	-	1	-
1.7.2	Market Exclusivity	1	-	1	-
1.8	Information relating to Pharmacovigilance				
1.8.1	Pharmacovigilance System	1	1	1	1
1.8.2	Risk-management System	1	1	1	1
1.9	Information relating to Clinical Trials	1	1	1	1
	Responses to Questions	-	-	-	-
	Additional Data	-	1	1	2