August~~May~~ 2024
CMDh/043/2007, Rev.20~~19~~

Data requested for New Applications in the MRP/DCP which are not stated in the current EU legislation and/or in Volume 2B, Presentation and format of the dossier Common Technical Document (CTD) and/or in the EEA approved Guidelines/Recommendation papers

Member States who are not mentioned in the table below do not request additional data.
For number and format requirements on submissions for New Applications within MRP, DCP and National Procedures, including requirements for signed paper copies of eAF and cover letter, please refer to the published document "Requirements on submissions (number and format) for New MA Applications within MRP, DCP or National procedures" at the CMDh website (eSubmissions).

Additional data requested	**BE**	**BG**	**CY**	**EL**	**ES**	**FR**	**HR**	**HU**	**IT**	**~~LV~~**	**PL**	**PT**	**RO**	**SK**
Application form signed by the MAH of the medicinal product in the RMS									X					
The person responsible for placing the product on the market in France (so called "exploitant" in French) should be specified, knowing that this "exploitant" should be a pharmaceutical site						X								
Pharmacovigilance responsible in National Territory. This is not a validation issue, which stops the start of a procedure.		X			X	X						X		
Pharmacovigilance responsible in National Territory. This is not a validation issue, which stops the start of a procedure. Proof that the future MAH has responsible person for Pharmacovigilance seated in Croatia authorised by the Agency or proof that application for his/her approval has been submitted to the Agency.							X							
Contact person for pharmacovigilance and scientific services living in Cyprus or a declaration letter committing that a contact person responsible for those activities will be appointed before MA is granted (validation issue which stops the start of a procedure).			X											
Pharmacovigilance responsible in National Territory. This is not a validation issue, which stops the start of a procedure. It is notified together with the MA but not blocking the licensing.	X													
Pharmacovigilance responsible in National Territory. This is not a validation issue, which stops the start of a procedure. Written commitment must be provided within the validation responses.				X										
Annex 5.3 Updated extract from the register of entrepreneurs for proposed MAH for Poland (document should contain list of people authorized to sign on behalf of the company). Electronic versions of the register of entrepreneurs from national commercial registers are accepted, which can be verified by URPL on these websites. If this is not possible, the document should be provided in original with handwritten signature authorised person or in electronic version with qualified electronic signature compliant with the eIDAS regulation.											X			
It has to be proved that the applicant and proposed MAH in Poland are taken as one entity according to commission communication 98/C 229/03 (in original with handwritten signature authorised person or in electronic version with qualified electronic signature compliant with the eIDAS regulation).											X			
Annex 5.4 Letter of authorisation for communication on behalf of the applicant/MAH (the signatures must be officially authenticated by a notary or Administrative official).		X											X	
Annex 5.4 Letter of authorisation for person/company residing in the Slovak Republic authorized by the MAH to represent and act in the name of the MAH (signed by person listed in the extract from the register of entrepreneurs) should be submitted in the national phase at the latest (the signatures must be officially authenticated by a notary or Administrative official). This is not a validation issue, which stops the start of a procedure. The original PoA and LoA for each procedure is only necessary in case SUKL does not have the original version of general PoA and LoA of acting parties.														X
Annex 5.4 Letter of authorisation for communication on behalf of the applicant/MAH (the signatures must be officially authenticated by a notary or Administrative official). Power of attorney-local agent for service of process.								X						
Annex 5.4 Letter of authorisation for communication on behalf of the applicant/MAH (in original with handwritten signature authorised person or in electronic version with qualified electronic signature compliant with the eIDAS regulation).											X			
Confirmation of the identical dossier with an original signature if not mentioned in the signed cover letter		X						X		~~X~~	X		X	
Declaration of patent and data exclusivity								X						
National Data Base should be completed												X		
Annex 5.22 with original signature		X									X		X	
The Trade mark of the product must be submitted with the new application. This is not a validation issue, which stops the start of a procedure.				X										
All Annexes to the Application Form and Statements must be submitted in original or as legalised copy. This requirement applies for national procedures and for MRP's and DCP's where the MS acts as RMS									X					

Additional data requested	BE	BG	CY	EL	ES	FR	HR	HU	IT	~~LV~~	PL	PT	RO	SK
Required annexes to the Application Form and Statements must be submitted in original or as legalised copy (with handwritten signature authorised person or in electronic version with qualified electronic signature compliant with the eIDAS regulation). This requirement applies for national procedures and for MRP's and DCP's where the MS acts as RMS.											X			
Written statement by the future MAH (if not seated in Croatia) naming its local representative seated in Croatia with the contact details							X							
Declaration of conformity for national translations of the SmPC, PL and labelling. This is not a validation issue, which stops the start of a procedure.	X													
Letter of Access to the ASMF in original (with handwritten signature authorised person or in electronic version with qualified electronic signature compliant with the eIDAS regulation).											X			
Cover letter, identical to the one submitted in eCTD, with wet signature should be sent to EOF or the cover letter included in eCTD should contain a proper digital signature.				X										
Annex 5.4 Power of attorney from the proposed MAH in Greece to the applicant				X										
Signed declaration from the proposed MAH in Greece is required, that they do not own another MA in EU for the same product (Same Active substance/ Pharmaceutical form/Strength) as the new product				X										