

**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 do not request additional data

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Additional DATA requested	BE	BG	CY	CZ	DE	EL	ES	FI	FR	HU	IT	LV	LT	PL	RO	SI	SK
Statement for the MA transfer to local subsidiary (SK originally signed)	-	-	-	-	-	X	-	X	-	-	-	-	X	-	-	-	X
A <i>certified</i> copy of the marketing authorisation granted by the RMS	-	-	-	-	-	-	-	-	-	-	-	-	X	-	-	-	-
An <i>original or certified</i> copy of the Contract between MAH and responsible of batch release / manufacturer / importer/legal representative	-	-	-	-	-	-	X	-	-	-	-	-	X	-	-	-	-
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	-	-	X	-	-	X	-	-	-	-	-	-	-	-	-	-	-
Copy of proof of establishment of the applicant in the EEA (updated extract from the register of entrepreneurs).Polish or English translation/Slovak or English translation	-	-	-	-	-	-	-	-	-	-	-	-	-	X	-	-	X
Original updated extract from the register of entrepreneurs for proposed MAH for Poland / Slovakia (point 2.4.1 of the applicant form) Polish or English translation. (original) / Slovak or English translation (original or copy signed by Notary Public)	-	-	-	-	-	-	-	-	-	-	-	-	-	X	-	-	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. (original)	-	-	-	-	-	-	-	-	-	-	-	-	-	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). SK: Signed by person listed in the extract from the register of entrepreneurs	-	X	-	X	-	-	-	-	-	X	-	-	-	X	X	-	X
Confirmation of the identical dossier with an original signature	-	X*	-	X*	-	-	-	-	-	X*	-	X*	-	-	X*	-	-
Declaration of patent and data exclusivity	-	-	-	-	-	-	-	-	-	X	-	-	-	-	-	-	-
Cover letter has to be submitted in Slovene language	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	X	-
Cover letter, similar to a standard one, in the Slovak language	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	X
For medicinal products treated with ionising radiation, a separate application form is to be filled in. Information given on the national competent authorities website	-	-	-	-	✘	-	-	-	-	-	-	-	-	-	-	-	-
National Data Base should be completed	-	-	-	-	-	-	X	-	-	-	-	-	-	-	-	-	-
Application form, Annex 5.22 with original signature	-	X	-	-	-	-	-	-	-	X	-	-	-	X	X	-	-
Greek authorities require the Trade mark of the product to be submitted with the new application	-	-	-	-	-	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 when Italy acts as RMS	-	-	-	-	-	-	-	-	-	-	X	-	-	-	-	-	-
Declaration of conformity for national translations of the SmPC, PL and labelling	X	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

* If not mentioned in the signed cover letter