

Dossier languages:

to be used for marketing authorisation applications, variations and renewals in the national, mutual recognition and decentralised procedures

Instructions applicable to all MS:

- For national marketing authorisation applications (MAA), texts for product information /mock ups should be submitted in national language already at the start of procedure.
- For MRP/DCP MAA, variations and renewals, English is sufficient at the beginning of the procedure. However, texts for product information /mock ups should be submitted in national language at end of the procedure, if applicable (type IB/II variation). For type IA variations concerning product information, national translations should be submitted with the application.

For paper submissions Part IB should be provided electronically (Word or rtf format).

The following Member States will require translations to the national language of the following parts for MAA, variation and renewal:

	BE	ES	IT	PL
MAA				
Part IA – Format		ES	IT ¹	PL ¹
Part IB – SPC				
Part IB – Package insert & labels				
Part IC – Expert reports			IT	
Part II				
Part III				
Part IV				
Written responses				
Variations				
Application form			IT ¹	PL ¹
Type I A/B – documentation				
Type II – Documentation				
Written responses				
Renewal				
Application form			IT ¹	PL ¹
SPC				
Package insert & labels				
Annexes				
End of the procedure				
Product Information	FR & NL & DE			

1. purely national applications : cover letter in Italian

BG	Bulgarian	ET	Estonian	LT	Lithuanian	RO	Romanian
CS	Czech	FI	Finnish	LV	Latvian	SK	Slovakian
DA	Danish	FR	French	MT	Maltese	SL	Slovenian
DE	German	HR	Croatia	NL	Dutch	SV	Swedish
EL	Greek	HU	Hungarian	NO	Norwegian		
EN	English	IS	Icelandic	PL	Polish		
ES	Spanish	IT	Italian	PT	Portuguese		