

Languages to be used for Marketing Authorisation Applications (MAAs), Variations and Renewals - National, Mutual Recognition and Decentralised applications

Instructions applicable to all MS:

For national applications, texts for product information /mock ups should be submitted in national language.

For MRP/DCP MAA and type II variations, if applicable, texts for product information /mock ups should be submitted in national language at end of the procedure. For type IA/IB variations concerning product information national translation should be submitted with the application.

CTD	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IS	IT	LI	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK (NI)
MAAs																															
Module 1.0 cover letter	DE/EN	EN/FR-NL ¹	BG/EN	EL/EN	CS/EN	DE/EN	DA/EN	ET/EN	EL/EN	ES/EN	FI/EN/SV	FR/EN	HR/EN	HU/EN	EN	IS/EN	IT/EN	DE/EN	LT/EN	EN	LV/EN	EN	NL/EN	NO/EN	PL/EN	PT/EN ³	RO/EN	SV/EN	SL/EN	SK/EN	EN
Module 1.1 Comprehensive table of content	DE/EN	EN/FR-NL	BG/EN	EL/EN	CS/EN	DE/EN	DA/EN	ET/EN	EL/EN	EN/ES	FI/EN/SV	FR/EN	HR/EN	HU/EN	EN	IS/EN	IT/EN	DE/EN	LT/EN	EN	LV/EN	EN	NL/EN	NO/EN	PL/EN	PT/EN	RO/EN	SV/EN	SL/EN	SK/EN	EN
Module 1.2 Application form	DE/EN	EN/FR-NL	BG/EN	EL/EN	CS/EN	DE/EN	DA/EN	ET/EN	EL/EN	ES	EN	FR/EN	HR/EN	HU/EN	EN	IS/EN	IT/EN	DE/EN	LT/EN	EN	LV/EN	EN	NL/EN	NO/EN	PL/EN ³	PT/EN ³	RO/EN	SV/EN	SL/EN	SK/EN ⁴	EN
Module 1.2 - Annexes	DE/EN	EN/FR-NL	BG/EN	EL/EN	CS/EN	DE/EN	DA/EN	ET/EN	EL/EN	ES/EN	FI/EN/SV	FR/EN	HR/EN	HU/EN	EN	IS/EN	IT/EN	DE/EN	LT/EN	EN	LV/EN	EN	NL/EN	NO/EN	PL/EN	PT/EN	RO/EN	SV/EN	SL/EN	SK/EN	EN
Module 1.3.1 Summary of Product Characteristics, Package Leaflet and Labelling	DE/EN	FR-NL	BG/EN	EL/EN	CS/EN	DE/EN	DA/EN	ET/EN	EL/EN	ES/EN	EN	FR/EN	HR/EN	HU/EN	EN	IS/EN	IT/EN	DE/EN	LT/EN	EN/FR/DE ²	LV/EN	EN	NL/EN	NO/EN	PL/EN	PT/EN	RO/EN	SV/EN	SL/EN	SK/EN	EN
Module 1.3.2 – 1.3.6	DE/EN	EN/FR-NL	BG/EN	EL/EN	CS/EN	DE/EN	DA/EN	ET/EN	EL/EN	ES/EN	EN	FR/EN	HR/EN	HU/EN	EN	IS/EN	IT/EN	DE/EN	LT/EN	EN	LV/EN	EN	NL/EN	NO/EN	PL/EN	PT/EN	RO/EN	SV/EN	SL/EN	SK/EN	EN
Module 1.4 Information about the Experts	DE/EN	EN/FR-NL	BG/EN	EL/EN	CS/EN	DE/EN	DA/EN	ET/EN	EL/EN	ES/EN	EN	FR/EN	HR/EN	HU/EN	EN	IS/EN	IT/EN	DE/EN	LT/EN	EN	LV/EN	EN	NL/EN	NO/EN	PL/EN	PT/EN	RO/EN	SV/EN	SL/EN	SK/EN	EN
Module 1.5 Specific Requirements for different types of applications	DE/EN	EN/FR-NL	BG/EN	EL/EN	CS/EN	DE/EN	DA/EN	ET/EN	EL/EN	ES/EN	EN	FR/EN	HR/EN	HU/EN	EN	IS/EN	IT/EN	DE/EN	LT/EN	EN	LV/EN	EN	NL/EN	NO/EN	PL/EN	PT/EN	RO/EN	SV/EN	SL/EN	SK/EN	EN
All remaining Module 1 documents	DE/EN	EN/FR-NL	BG/EN	EL/EN	CS/EN	DE/EN	DA/EN	ET/EN	EL/EN	ES/EN	EN	FR/EN	HR/EN	HU/EN	EN	IS/EN	IT/EN	DE/EN	LT/EN	EN	LV/EN	EN	NL/EN	NO/EN	PL/EN	PT/EN	RO/EN	SV/EN	SL/EN	SK/EN	EN
Written responses	DE/EN	EN/FR-NL	BG/EN	EL/EN	CS/EN	DE/EN	DA/EN	ET/EN	EL/EN	ES/EN	EN	FR/EN	HR/EN	HU/EN	EN	IS/EN	IT/EN	DE/EN	LT/EN	EN	LV/EN	EN	NL/EN	NO/EN	PL/EN	PT/EN	RO/EN	SV/EN	SL/EN	SK/EN	EN
Module 2	DE/EN	EN/FR-NL	BG/EN	EL/EN	CS/EN	DE/EN	DA/EN	ET/EN	EL/EN	ES/EN	EN	FR/EN	HR/EN	HU/EN	EN	IS/EN	IT/EN	DE/EN	LT/EN	EN	LV/EN	EN	NL/EN	NO/EN	PL/EN	PT/EN	RO/EN	SV/EN	SL/EN	SK/EN	EN
Modules 3, 4 and 5	DE/EN	EN/FR-NL	BG/EN	EL/EN	CS/EN	DE/EN	DA/EN	ET/EN	EL/EN	ES/EN	EN	FR/EN	HR/EN	HU/EN	EN	IS/EN	IT/EN	DE/EN	LT/EN	EN	LV/EN	EN	NL/EN	NO/EN	PL/EN	PT/EN	RO/EN	SV/EN	SL/EN	SK/EN	EN
Variations and renewals																															
Application form	DE/EN	EN/FR-NL	BG/EN	EL/EN	CS/EN	DE/EN	DA/EN	ET/EN	EL/EN	ES	EN	FR/EN	HR/EN	HU/EN	EN	IS/EN	IT/EN	DE/EN	LT/EN	EN	LV/EN	EN	NL/EN	NO/EN	PL/EN ³	PT/EN	RO/EN	SV/EN	SL/EN	SK/EN ⁴	EN

Documentation	DE/EN	EN/FR- NL	BG/EN	EL/EN	CS/EN	DE/EN	DA/EN	ET/EN	EL/EN	ES/EN	EN	FR/EN	HR/EN	HU/EN	EN	IS/EN	IT/EN	DE/EN	LT/EN	EN	LV/EN	EN	NL/EN	NO/EN	PL/EN	PT/EN	RO/EN	SV/EN	SL/EN	SK/EN	EN
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1. In Belgium for national procedure the language to be used is depending on the linguistic role of the MAH. The linguistic role depends on the specific region if the MAH is situated in Belgium. If it is outside Belgium the MAH can choose his linguistic role. However one MAH can only correspond to one linguistic role.
2. Product information /mock ups should be submitted in French and/or German at end of procedure.
3. For national procedure the documents should be submitted in national language.
4. Special cover letter for the application filled in the Slovak language must be submitted (cover letters are published at: http://www.sukl.sk/sk/registracia-humannych-liekov/tlaciva?page_id=2508)

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	Croatian	NL	Dutch	SV	Swedish
EL	Greek	HU	Hungarian	NO	Norwegian		
EN	English	IS	Icelandic	PL	Polish		
ES	Spanish	IT	Italian	PT	Portuguese		