

**Requirements on Electronic submissions (NeeS and eCTD) and paper documentation
for Variations and Renewals within MRP or National procedures**

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Electronic submissions should generally be submitted in eCTD format (highly recommended) or in NeeS format (Non-eCTD electronic submission). Please, refer to the [Notice to Application volume 2B](#) for the eCTD EU Module 1 Specification and to the [EMA eSubmission website](#) for the ICH eCTD documents and specifications and also for the eCTD guidance document, the NeeS guidance document and Validation criteria published by the EU Telematics Implementation Group for electronic submissions (TIGes).

Please, also refer to the [CMDh BPG for eCTD in MRP and DCP](#) and seek advice at different NCA's websites if specific requirements are stated by a footnote in the table below. Website addresses to each NCA can be found at the [Heads of Medicines Agencies website](#) and in [Notice to Application](#) volume 2A chapter 7. Relevant e-mail addresses for electronic response documents in MRP and DCP can also be found at the [Heads of Medicines Agencies website](#).

The electronic submission should be provided on CD or DVD unless otherwise stated by the use of footnotes. The application form and cover letter should always be submitted in signed paper original together with the full electronic submission, unless otherwise stated by the use of footnotes. There could also be other signed paper originals required by some NCAs, which is then indicated by use of a footnote referring to national requirements.

For variations submitted as a Worksharing and Grouping procedure, the requirements in the tables below refer to the highest variation type included.

The Product Information should always be in QRD/CMDh template, (see the CMDh Annotated QRD template for MR/DC procedures at the [Heads of Medicines Agencies website](#) and be included in the dossier. If the Product Information is also required in word format, these copies should not be included in the eCTD or NeeS structure, but be provided on the same CD/DVD unless otherwise stated by the use of footnotes.

Response documents submitted during the MR procedure should comply with the CMDh recommendations "[Applicant's response document in MR and DC Procedures Recommended CTD Format](#)" and for eCTDs also with the current EU Module 1 Specification (see [Notice to Application volume 2B](#)).

Most NCAs are now ready to receive electronic-only applications and applicants are therefore strongly encouraged to submit in electronic format (eCTD or NeeS) to these NCAs, even if many still also accept paper applications.

A few NCAs require some modules in paper beside the full electronic dossier. The requirement for an NCA could differ depending on the role (RMS or CMS) of that NCA in an MRP and also for national procedures. It could also differ if the first MA dossier for the product was in paper format.

To give as clear information as possible for these different situations, the dossier requirements are given in three different tables:

Table 1 refers only to NCAs that accept electronic only submissions (i.e. "green" NCAs)

Table 2 refers to electronic submissions where the NCA still requires some modules in paper beside the full electronic dossier (i.e. "yellow" NCAs).

Table 3 is used for NCAs that prefer electronic-only submissions (with or without some paper modules), but that still *accept* a full paper dossier if the applicant is not able to provide an electronic-only application. This table should only be used in these specific cases and all applicants are expected to move to eCTD or NeeS as soon as possible.

Table 1. Electronic-only submissions. Number of required CD/DVD.

Documentation	AT	BE	BG	CY	CZ	DK	DE-BIaFm	DE-PEI	EE	EL	ES	FI	FR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	RO	SE	SK	SI	UK	IS	NO
Notifications, art 61(3)	1	1 ^{3,9,11,12}	1	1	1	1		1 ⁸	1 ¹²	2	1 ^{8,9,12}	-	1 ^{9,17}	1 ⁸	1	1	1 ¹³	1		1 ⁹	1 ¹²	2	1	1	1 ^{3,9,11}	-	-	1	1	1
Variations type IA and IA _{IN}	1	1 ^{3,9,11,12}	1	1	1	1		1 ⁸	1 ¹²	2	1 ^{8,9,12}	-	1 ^{9,17}	1 ⁸	1	1 ^{14,8}	1 ¹³	1 ⁸		1 ⁹	1 ¹²	2	1 ¹⁶	1	1 ^{3,9,11}	-	-	1	1	1
Variations type IB	1	1 ^{3,9,11,12}	1	1	1	1		1 ⁸	1 ¹²	2	1 ^{8,9,12}	-	1 ^{9,17}	1 ⁸	1	1 ^{14,8}	1 ¹³	1 ⁸		1 ⁹	1 ¹²	2	1 ¹⁶	1	1 ^{3,9,11}	-	-	1	1	1
Variations type II	1	1 ^{3,9,11,12}	1	1	1	1		1 ⁸	1 ¹²	3	1 ^{8,9,12}	-	1 ^{9,17}	1 ⁸	1	1 ⁸	1 ¹³	1 ⁸		1 ⁹	1 ¹²	2	2 ^{6,7,9}	1	1 ^{9,11}	-	-	1	1	1
Response/Supplementary information for variations	1	1 ^{3,9,11,12}	1 ²	1	1 ³	1		1	1 ^{3,12}	1	1 ^{8,9,12}	-	1 ^{9,17}	1 ¹	1	1 ^{3,8}	1 ¹³	1 ²		1 ⁹	1 ¹²	2	-	1 ^{3,6}	1 ^{3,9}	-	-	1	1	1
Renewals	1	1 ^{3,9,11,12}	2	1	1	1		1 ⁸	1 ¹²	3	1 ^{8,9,12}	-	1 ^{9,17}	1 ⁸	1 ^{11,15}	1 ^{14,8}	1 ¹³	1 ^{8,12}		1 ⁹	1 ¹²	2	IB 1 ¹⁶ II 2 ^{6,7,9}	1 ^{8,6}	1 ^{9,11}	-	-	1	1	1
Response/Supplementary information for Renewals	1	1 ^{3,9,11,12}	1 ²	1	1 ³	1		1	1 ^{3,12}	1	1 ^{8,9,12}	-	1 ^{9,17}	1 ¹	1 ^{11,15}	1	1 ¹³	1 ²		1 ⁹	1 ¹²	2	3 ^{6,9} 1 ^{7,9}	1 ^{2,8,6}	1 ^{3,9}	-	-	1	1	1
Electronic copy of the proposed Product Information in word format (no tracked changes)	1	1 ^{3,9,11,12}	-	1	1 ³	-		1 ^{2,8}	1 ⁶	1	1 ^{8,9,12}	-	1 ^{9,17}	1 ⁸	1 ^{11,15}	1	1	1 ^{2,9}		1 ⁹	1 ¹²	2	1	1	-	-	-	1	1	1
Electronic copy of the proposed Product Information in word format with tracked changes	1	1 ^{3,9,11,12}	1	1	1 ³	1		1 ^{2,8}	1 ⁶	1	1 ^{8,9,12}	-	1 ^{9,17}	1 ⁸	1 ^{11,15}	1	1	1 ^{2,9}		1 ⁹	1 ¹²	2	1	1	1 ^{3,9}	-	-	1	1	1

Table 2. Electronic submissions with part of the dossier also required in paper. Number of required paper copies of each module as well as number of CD/DVD.

Documentation	AT	BE	BG	CY	CZ	DK	DE-BIaFm	DE-PEI	EE	EL	ES	FI	FR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	RO	SE	SK	SI	UK	IS	NO
Notifications, art 61(3)	-	-	-	-	-	-		-	-	-	-	2	-	-	-	-	-	-		-	-	-	-	-	-	1 ^{5,14}	1	-	-	-
Variations type IA and IA _{IN}	-	-	-	-	-	-		-	-	-	-	2	-	-	-	-	-	-		-	-	-	-	-	-	1 ^{5,14}	1	-	-	-
Variations type IB	-	-	-	-	-	-		-	-	-	-	2	-	-	-	-	-	-		-	-	-	-	-	-	1 ^{5,14}	1	-	-	-
Variations type II	-	-	-	-	-	-		-	-	-	-	2	-	-	-	-	-	-		-	-	-	-	-	-	1 ^{5,14}	1	-	-	-
Additional paper copies of the full variation application	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-	-	1 ⁸	-	-	-	-
Additional paper copy of module 1	-	-	-	-	-	-		-	-	-	-	1	-	-	-	-	-	-		-	-	-	-	-	-	1	1	-	-	-
Additional paper copy of module 2	-	-	-	-	-	-		-	-	-	-	1	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-
Additional paper copy of module 3	-	-	-	-	-	-		-	-	-	-	1	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-
Response/Supplementary information for variations, electronic format	-	-	-	-	-	-		-	-	-	-	2 ²	-	-	-	-	-	-		-	-	-	-	-	-	1	1	-	-	-
Additional paper copies of Response/Supplementary information for variations	-	-	-	-	-	-		-	-	-	-	1	-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-

Renewals, electronic format	-	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-	1 ^{5,14}	1	-	-	-
Additional paper copy of module 1	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	1 ⁸	1	-	-	-
Additional paper copy of module 2	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Additional paper copy of module 3	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Response/Supplementary information for Renewals, electronic format	-	-	-	-	-	-	-	-	-	-	-	2 ²	-	-	-	-	-	-	-	-	-	-	-	-	1	1	-	-	-
Additional paper copies of Response/Supplementary information for renewals	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Electronic copy of the proposed Product Information in word format (no tracked changes)	-	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-	1	1	-	-	-
Electronic copy of the proposed Product Information in word format with tracked changes	-	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-	1	1	-	-	-

Table 3. Paper submission requirement if the applicant is not able to provide an electronic-only application in accordance with table 1 or 2. Number of required paper copies.

Documentation	AT	BE	BG	CY*	CZ	DK*	DE* BfArM	DE* PEI	EE*	EL	ES	FI	FR*	HU	IE	IT	LV	LT	LU	MT	NL	PL*	PT	RO	SE*	SK	SI	UK	IS	NO
Notifications, art 61(3)	1	-	1	1	-	1		2	1	1	-	1	3	1	-	1	1	1		1	-	2	-	1	1	-	1	-	1	1
Variations type IA	1	-	1 ⁸	1	-	1		2	1	1	-	1	3	1	-	1	1	1 ⁸		1	-	2	-	1	1	-	1	-	1	1
Variations type IB	1	-	1 ⁸	1	-	1		2	1	1	-	1	3	1	-	1	1	1 ⁸		1	-	2	-	1	1	-	1	-	1	1
Variations type II	1	-	1 ⁸	1	-	1		2	1	1	-	1	3	1	-	1	1	1 ⁸		1	-	2	-	1	1	-	1	-	1	1
Response/Supplementary information for variations	1	-	1	1	-	1		2	1	1	-	1	4	1	-	1	1	1 ²		1	-	2	-	1 ^{3,6}	1	-	1	-	1	1
Renewals	1	-	1 ⁸	1	-	1		2	1	1	-	1	4	1	1	1	1	1 ^{8,12}		1	-	2	-	1 ^{8,6}	1	-	1	-	1	1
Response/Supplementary information for Renewals	1	-	1	1	-	1		2	1	1	-	1	4	1	1	1	1	1 ²		1	-	2	-	1 ⁸	1	-	1	-	1	1
Electronic copy of the proposed Product Information in word format (no tracked changes)	1	-	-	1	-	-		1 ²	1	1	-	2	1	1	1	1	1	1 ^{2,9}		1	-	2	-	1	-	-	1	-	1	1
Electronic copy of the proposed Product Information in word format with tracked changes	1	-	1	1	-	1		1 ²	1	1	-	2	1	1	1	1	1	1 ^{2,9}		1	-	2	-	1	1	-	1	-	1	1

*) Paper submissions are still accepted but should only be use when a valid eCTD or NeeS submission cannot be provided by the applicant. An electronic copy of the paper dossier is anyhow appreciated, even if not validated, to facilitate the assessment. Applicants are then strongly encouraged to move to eCTD or NeeS in accordance with current guidance as soon as possible.

- 1) Should only be sent by e-mail/EudraLink
- 2) Should be sent both by e-mail/EudraLink and on CD/DVD
- 3) *Could* be sent by e-mail/EudraLink instead of sending CD/DVD (applicant's choice)
- 4) DVD is not accepted
- 5) A paper copy should be available on request within 28 days

- 6) For national applications and applications where the member state acts as RMS
- 7) For applications where the member state acts as CMS
- 8) Additional signed paper original in accordance with National requirements, see the NCA's website
- 9) For specific requirements on the electronic submission (e.g. on format, required templates, electronic signatures), see the NCA's website
- 10) The application form and the cover letter are not required in paper format
- 11) The application form is not required in paper format
- 12) Electronic format (eCTD or NeeS) is mandatory
- 13) Only eCTD format accepted for electronic-only submissions
- 14) Applications should be made through the NCA's website or portal (see the NCA's website)
- 15) Applications *could* be made through the NCA's website or portal (applicant's choice; see the NCA's website)
- 16) Applications within the national procedure should be made through the NCA's website or portal (see the NCA's website)
- 17) Electronic-only applications are *not* accepted for paper based MA dossiers