

**Requirements on Electronic submissions (NeeS and eCTD) and paper documentation
for New Applications within MRP, DCP or National procedures**

Doc. Ref.: CMDh/085/2008/Rev8
July 2011

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 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, by use of footnotes in the tables, the Product Information or Module 2 documentation is required in word format, these copies should not be included in the eCTD or NeeS structure.

Response documents submitted during the MR/DC 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](#)).

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, also for electronic only submissions, 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.

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.

No NCA requires a full paper dossier anymore; however, a few NCAs require some modules in paper beside the full electronic dossier. The requirement for an NCA could also differ depending on the role (RMS or CMS) of that NCA in an MRP/DCP and for national procedures.

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-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
Module 1-5 electronic only (No additional paper)	1	1 ¹²	2 ^{7,12}	1	1 ^{7,8,12,13}	1 ^{8,10}	2 ⁷	1 ⁷	1 ¹²	3 ⁷	1 ^{7,8,11,12}	-	1 ^{7,8,10}	1 ^{7,8}	1 ⁸	1 ⁷	1 ^{7,8,13}	-	1	1 ⁸	1 ^{8,12}	2 ^{7,8}	4 ¹²	2 ⁷	1 ¹⁰	-	-	1 ^{8,9,11}	1	1 ^{6/3} ⁵
Electronic Response Documents	1	1 ¹²	2 ^{7,12}	1	1 ^{12,13}	1 ¹	2	1	1 ¹²	3 ²	1 ^{7,8,11,12}	-	1 ^{7,8,10}	1 ^{7,8}	1 ⁸	1	1 ^{7,8,13}	-	1	1 ⁸	1 ^{1,8,12}	2 ^{7,8}	4 ¹²	1 ^{2,7}	1	-	-	1 ¹	1	1
Electronic copy of Product Information in word format	1	-	-	1	1	1	1 ²	1	1 ⁵	1	-	-	1 ⁸	1	1 ⁸	1	-	-	-	1 ⁸	1 ⁸	1	1 ¹²	1	1	-	-	-	1	1
Electronic copy of Module 2 in word format	-	-	-	-	-	-	1 ²	1	-	1	-	-	-	1 ⁵	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-

Table 2. Paper submissions (whole dossier or part of dossier). Number of required paper copies of each module as well as number of CD/DVD.

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	
Module 1-5 in electronic format	-	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-	1 ^{7,8}	-	-	-	-	-	-	-	-	2 ^{4,8}	1	-	-	-
Electronic Response Documents	-	-	-	-	-	-	-	-	-	-	-	2 ²	-	-	-	-	-	1 ²	-	-	-	-	-	-	-	1	1	-	-	-	
Electronic copy of Product Information in word format	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	1	-	-	-	
Electronic copy of Module 2 in word format	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Additional paper for Module 1	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	1 ⁵	-	-	-	-	-	-	-	1	1	-	-	-	
Additional paper for Module 2	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	1 ⁵	-	-	-	-	-	-	-	-	-	-	-	-	
Additional paper for Module 3	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	1 ⁵	-	-	-	-	-	-	-	-	-	-	-	-	
Additional paper for Module 4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Additional paper for Module 5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Response Documents in paper for module 1, 2 and 3	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	1 ⁵	-	-	-	-	-	-	-	-	-	-	-	-	

- 1) Should only be sent by e-mail/EudraLink
- 2) Should be sent both by e-mail/EudraLink and on CD/DVD
- 3) DVD is not accepted
- 4) A paper copy should be available on request within 14 days
- 5) For national applications and applications where the member state acts as RMS
- 6) For applications where the member state acts as CMS
- 7) Additional signed paper original in accordance with National requirements (as stated on the CMDh website)
- 8) For specific requirements on the electronic submission (e.g. on format, required templates, electronic signatures), see NCA's website
- 9) The application form and the cover letter are *not* required in paper format
- 10) The application form is *not* required in paper format
- 11) Applications should be made through the NCA's website or portal
- 12) Electronic format is mandatory
- 13) Only eCTD format accepted for electronic only submissions

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
Module 1	1	-	-	1	-	1	2	2	-	2	-	1	20	1	1	1	1	1	1	1	-	1	-	1 ⁷	1	1	1	-	1	1
Module 2	1	-	-	1	-	1	2	2	-	2	-	1	20	1	1	1	1	1	-	1	-	1	-	1	1	1	1	-	1	1
Module 3	1	-	-	1	-	1	2	2	-	1	-	1	5	1	1	1	1	1	-	1	-	1	-	1	1	1	1	-	1	1
Module 4	1	-	-	1	-	1	2	2	-	1	-	1	3	1	1	-	1	1	-	1	-	1	-	1	1	1	1	-	1	1
Module 5	1	-	-	1	-	1	2	2	-	1	-	1	3	1	1	-	1	1	-	1	-	1	-	1	1	1	1	-	1	1
Response Documents	1	-	-	1	-	2	2 ²	2	-	2 ¹	-	1	4	-	1	-	1	1	-	1	-	1	-	1	1	1	1	-	1	1
Electronic copy of Product Information in word format	1	-	-	1	-	1	1 ^{2,8}	1 ²	-	1	-	1	1 ⁸	-	1	-	-	1	-	1	-	1	-	1	1	-	1	-	1	1
Electronic copy of Module 2 in word format	1	-	-	1	-	-	1 ^{2,8}	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-

*) Paper submissions are still accepted but should only be used 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) DVD is not accepted
- 4) A paper copy should be available on request within 28 days
- 5) For national applications and applications where the member state acts as RMS
- 6) For applications where the member state acts as CMS
- 7) Additional signed paper original in accordance with National requirements (as stated on the CMDh website)
- 8) For specific requirements on the electronic submission (e.g. on format, required templates, electronic signatures), see NCA's website
- 9) The application form and the cover letter are not required in paper format
- 10) The application form is not required in paper format
- 11) Applications should be made through the NCA's website or portal
- 12) Electronic format is mandatory
- 13) Only eCTD format accepted for electronic submissions