

Requirements on Electronic submissions for New Applications within MRP, DCP or National procedures

Note: The information in these tables will soon be updated as more NCAs now do accept electronic only applications

Doc. Ref.: CMDh/085/2008/Rev5
February 2010

The table below refers to number of electronic copies requested by each National Competent Authority for new applications for approval for Marketing Authorisation. If for some reason the requirements cannot be fulfilled, the applicant should contact the relevant NCA before submission.

Website addresses to each National Competent Authority can be found at the Heads of Medicines Agencies website (<http://www.hma.eu/>) 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 (<http://www.hma.eu/> – CMDh – Contact points).

For all electronic submissions, the eCTD format is highly recommended. However, in general, the Non-eCTD electronic submission format (NeeS) is also accepted. Please, refer to the Notice to Application volume 2B for the eCTD specifications and otherwise to the document “Guidance for Industry on Providing Regulatory Information in Electronic Format: Non-eCTD electronic Submissions (NeeS)” – to be endorsed and published by the EU Telematic Implementation Group for electronic submissions (TIGes) at the EMEA website (<http://www.emea.europa.eu/>). Please, also seek advice at different NCA’s websites if specific format requirements are stated by footnotes in the table below.

The electronic submission should be provided on CD (or preferably on DVD if not fitted into one CD) unless otherwise stated by the use of footnotes in the table below. The application form and cover letter should always be submitted in signed paper original, unless otherwise stated by the use of footnotes in the table below.

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 (<http://www.hma.eu/126.html>)). 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” see http://www.hma.eu/uploads/media/response_ctd.pdf and for eCTDs also with the EU Module 1 Specification V1.2.1 (see <http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm#2b>).

Table 1: Electronic submission strongly recommended instead of paper or with only some modules additionally in paper (Number of electronic copies asked for)*

Documentation	AT	BE	BG	CY	CZ	DK	DE	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 ^{8,10,14}	-	-	-	1 ^{7,8,11,13}	-	1 ^{7,8}	1 ^{7,8}	1	-	-	-	-	1 ⁸	-	-	-	1 ^{8,10}	-	-	1 ^{8,9,11}	1	1 ^{6/3} ⁵	
Module 1-5 electronic with additional paper for Module 1 *	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	4 ¹⁰	-	-	2 ^{4,8}	1 ^{4,7}	-	-	-
Module 1-5 electronic with additional paper for Module 1-2*	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1 ^{4,6}	1 ⁶	-	2 ⁶	-	-	-	7 ^{3,6,7}	-	-	-	-	-	-
Module 1-5 electronic with additional paper for Module 1-3 *	-	-	-	1	1 ^{6,12}	-	-	-	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	
Response Documents electronic only (No additional paper)	-	1	-	-	-	1 ⁸	-	1 ⁶	1 ¹	1 ^{7,8,13}	-	1 ^{7,8}	1 ^{7,8}	-	-	1 ⁶	-	-	1 ⁶	1 ^{1,8}	-	4 ¹⁰	6 ³	1 ^{8,10}	-	-	1	1	-

Table 2: Electronic submission strongly recommended together with the required paper original (Number of electronic copies asked for)*

Documentation	AT	BE	BG	CY	CZ	DK	DE	EE	EL	ES	FI	FR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	RO	SE	SK	SI	UK	IS	NO
Electronic copy of Module 1-5*	-	-	1	-	1 ⁵	-	2	1	-	-	2	-	-	-	1 ⁸	1 ⁵	1 ⁵	-	2 ⁵	-	4 ³	-	1 ^{3,5,7}	1 ⁸	-	-	-	-	-
Electronic copy of Product Information in word format	-	-	-	-	1	1	1 ^{2,8}	1	1	-	1	1	-	1	-	-	-	-	1	-	1 ³	-	1 ⁵	1 ⁸	-	-	-	1	-
Electronic copy of Module 2 in word format	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1 ⁸	-	-	-	-	-
Electronic copy of Response Documents	-	-	1	1	-	-	2 ²	1 ⁵	-	-	1 ¹	-	1	-	-	1 ⁵	-	-	1 ⁵	-	4 ³	-	1 ⁵	1 ⁸	-	-	-	1	-

**For numbers of paper copies requested, please refer to Notice to Application volume 2A chapter 7, section 3.1. Please note that some NCAs may require a reduced number of paper copies if electronic copies are provided.*

- 1) Should only be sent by e-mail/EudraLink.
- 2) Should additionally be sent by e-mail/EudraLink.
- 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.
- 8) For specific requirements on the electronic submission, 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) A signed commitment should be provided stating that a paper copy of specified parts of Modules 4 and/or 5 should be submitted within 48 hours upon request and, if necessary, a full paper version of Modules 4 and/or 5 within 1 week.
- 13) Electronic format (eCTD or NeeS) is mandatory