

## Requirements on electronic submissions and paper documentation for Variations and renewals within MRP, DCP or National procedures

Most NCAs are now ready to receive electronic only submission and this document is published to guide applicants what formats that are acceptable by different NCAs in the EEA.

Electronic submissions should preferably be submitted in VNeS format (the only acceptable electronic format accepted by some NCAs as shown by footnotes in the tables) in accordance with the guidance document and the validation criteria published by the Telematics Implementation Group for electronic submissions (TIGes) on the [EMA eSubmission website](#) (veterinary). There is also a free validation tool to use for the technical validation before sending an electronic submission to the authorities.

Please, also seek advice at different NCA's websites where referred to by footnotes.

Website addresses to each NCA can be found at the [Heads of Medicines Agencies website](#) and in [Notice to Application](#) volume 6A chapter 7.

The Product Information should always be in QRD/CMDv template, (see the CMDv Annotated QRD template for MR/DC procedures at the [Heads of Medicines Agencies website](#)) and be included in the application. If word copies are provided together with a VNeS, these should always be placed in a folder called "additional information".

**The electronic submission should always be provided on CD or DVD unless stated by the use of footnotes that e-mail/EudraLink could be used for some NCAs.**

The application form and cover letter should always be submitted in signed paper original, also for electronic only submissions, unless stated by the use of footnotes that it is not needed by some NCAs. There could also be other signed paper originals required by some NCAs in addition to the electronic submission, which is then indicated by a footnote referring to the NCA's webpage.

Even if electronic-only applications are accepted by most NCAs (as specified in the green marked table 1), a few agencies still require some part of the application to be submitted in paper together with the full electronic submission which is specified in the yellow marked table 2. The requirement for an NCA could also differ depending on the role of that NCA in an MRP/DCP (RMS or CMS) and also for national procedures (see footnotes used for details on this).

All veterinary agencies also accept full paper applications, if the applicant for some reason cannot submit in a full electronic format. The paper requirements for these cases are specified in table 3.

**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 NCAs that accept electronic only submissions, but still requires one or more parts in paper beside the full electronic dossier (i.e. "yellow" NCAs)

**Table 3** refers to full paper submissions to be used where the applicant cannot provide an acceptable electronic-only submission. *An electronic copy of the submission is anyhow appreciated.*

**Table 1. Electronic-only submissions (the full application). Number of required CD/DVD.**

Documentation	AT	BE	BG	CY	CZ	DK	DE, PEI	DE, BVL	EE	ES	FI	FR	IE	IT	LV	LT	LU	MT	NL	PT	SE	SK	SI	UK	IS	NO
Variations type IA and IA <sub>IN</sub>	1	1 <sup>5</sup>	*	1	2 <sup>5</sup>	1 <sup>2,5,7</sup>	1	2	1	1 <sup>2,5</sup>	2 <sup>2</sup>	1	1 <sup>7</sup>	*	*	1	*	*	1	1 <sup>8</sup>	1 <sup>2,8</sup>	2 <sup>11</sup>	1 <sup>2</sup>	1 <sup>2,6</sup>	1	1 <sup>2</sup>
Variations type IB	1	1 <sup>5</sup>	*	1	2 <sup>5</sup>	1 <sup>2,5,7</sup>	1	2	1	1 <sup>2,5</sup>	2 <sup>2</sup>	1/2 <sup>9</sup>	1 <sup>7</sup>	*	*	1	*	*	1	2	1 <sup>2,8</sup>	2 <sup>11</sup>	1 <sup>2</sup>	1 <sup>2,6</sup>	1	1 <sup>2</sup>
Variations type II	1	1 <sup>5</sup>	*	1	2 <sup>5</sup>	1 <sup>2,5,7</sup>	1	2	1	1 <sup>2,5</sup>	2 <sup>2</sup>	1/2 <sup>9</sup>	1 <sup>7</sup>	*	*	1	*	*	1	2	1 <sup>2,8</sup>	2 <sup>11</sup>	1 <sup>2</sup>	1 <sup>2,6</sup>	1	1 <sup>2</sup>
Other national variations	1	1 <sup>5</sup>	*	1	2 <sup>5</sup>	1 <sup>2,5,7</sup>	1	2	1	1 <sup>2,5</sup>	2 <sup>2</sup>	-	1 <sup>7</sup>	*	*	1	*	*	1	2	1 <sup>2,8</sup>	2 <sup>11</sup>	1 <sup>2</sup>	1 <sup>2,6</sup>	1	1 <sup>2</sup>
Renewals	1	1 <sup>5</sup>	*	1	2 <sup>5</sup>	1 <sup>2,5,7</sup>	1	2	1	1 <sup>2</sup>	2 <sup>2</sup>	1	1 <sup>7</sup>	*	*	1	*	*	1	1	1 <sup>2,8</sup>	2 <sup>11</sup>	1 <sup>2</sup>	1 <sup>2,6</sup>	1	1 <sup>2</sup>
Responses	1 <sup>8</sup>	1 <sup>5</sup>	*	1	2 <sup>5</sup>	1	1 <sup>8</sup>	1 <sup>8</sup>	1	1 <sup>2</sup>	2	1/2 <sup>9</sup>	1	*	*	1	*	*	1	2 <sup>8</sup>	1 <sup>8</sup>	2 <sup>11</sup>	1 <sup>2</sup>	1 <sup>2,6</sup>	1	1 <sup>2</sup>
Electronic copy of the proposed Product Information in word format with tracked changes	1	1	*	1	1	1	1	1	1 <sup>3</sup>	-	1 <sup>3</sup>	1	1	*	*	1	*	*	1	1 <sup>1</sup>	1	2 <sup>11</sup>	1	1	1	1

**Table 2. Electronic submissions (the full application) together with paper copies (one or more parts). Number of required CD/DVD and paper copies.**

Documentation	EL	HU	PL	RO
Variations type IA and IA <sub>IN</sub> , electronic	1	1 <sup>4</sup>	2	1
Variations type IB, electronic	1	1 <sup>4</sup>	2	1
Variations type II, electronic	1	1 <sup>4</sup>	2	1
Other national variations, electronic	1	1 <sup>4</sup>	2	1
Renewals, electronic	1	1 <sup>4</sup>	2	1
Additional paper of Part I	1	1 <sup>4</sup>	1	1 <sup>3</sup>
Additional paper of Part II	1	-	-	1 <sup>3</sup>
Additional paper of Part III	-	-	-	1 <sup>3</sup>
Additional paper of Part IV	-	-	-	1 <sup>3</sup>
Responses in electronic format	1	1	2 <sup>8</sup>	1
Paper copies of Responses	-	1	-	1 <sup>3</sup>
Electronic copy of the proposed Product Information in word format with tracked changes	1	1	1	1 <sup>3</sup>

**Table 3. Paper submission requirement for “green” or “yellow” NCAs : Only when the applicant is not able to provide an electronic-only application in accordance with table 1 or 2.**

Documentation	AT	BE	BG	CY	CZ	DK	DE, PEI	DE, BVL	EE	EL	ES	FI	FR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	RO	SE	SK	SI	UK	IS	NO
Variations type IA	1	1	*	1	1	1	1 <sup>10</sup>	1 <sup>10</sup>	*	1	3	1 <sup>7</sup>	1	1 <sup>4</sup>	1	*	*	1	*	*	1	2	1	1	1	1	1	1	1	1
Variations type IB	1	1	*	1	1	1	1 <sup>10</sup>	1 <sup>10</sup>	*	1	3	1 <sup>7</sup>	1/2 <sup>9</sup>	1 <sup>4</sup>	1	*	*	1	*	*	1	2	2	1	1	1	1	1	1	1
Variations type II	1	1	*	1	1	1	1 <sup>10</sup>	1 <sup>10</sup>	*	1	3	1 <sup>7</sup>	1/2 <sup>9</sup>	1 <sup>4</sup>	1	*	*	1	*	*	1	2	2	1	1	1	1	1	1	1
Renewals	1	1	*	1	1	1	1 <sup>10</sup>	3	*	1	3	1 <sup>7</sup>	1	1 <sup>4</sup>	2	*	*	1	*	*	1	2	1	1	1	1	1	1	1	1
Responses in electronic format	1 <sup>8</sup>	1	*	1	1	1	1 <sup>8</sup>	2 <sup>8</sup>	*	1	-	2	1	1	1	*	*	1	*	*	1	2 <sup>8</sup>	2 <sup>8</sup>	1	1	1	1	1	1	1
Paper copies of Responses	1	1	*	1	2	1	1 <sup>10</sup>	3	*	-	3	1	1/2 <sup>9</sup>	1	1	*	*	1	*	*	1	2	2	1	1		1	1	1	1
Electronic copy of the proposed Product Information in word format with tracked changes	1	1	*	1	1	1	1	1	*	1	-	1 <sup>7</sup>	1	1	1	*	*	1	*	*	1	1	1 <sup>1</sup>	1 <sup>3</sup>	1	1	1	1	1	1

- 1) Should only be sent by e-mail/EudraLink (if < 10 MB / < 80 MB)
  - 2) Only VNeS format is accepted for electronic submissions
  - 3) For national applications and applications where the member state acts as RMS
  - 4) Additional signed paper originals in accordance with National requirements are required, see NCA’s website
  - 5) For specific requirements on the electronic submission (e.g. on format, required templates, electronic signatures), see NCA’s website
  - 6) The application form and the cover letter are *not* required in paper format
  - 7) The application form is *not* required in paper format
  - 8) Could be sent either on CD/DVD or by e-mail/Eudralink (if < 10 MB / < 80 MB)
  - 9) For immunological products
  - 10) Further paper copies should be available on request.
  - 11) Should be sent both by e-mail/EudraLink and on CD/DVD
  - 12) Electronic-only applications are *not* accepted for paper based MA dossiers
- \*) No information available