

**REQUIREMENTS ON ELECTRONIC SUBMISSIONS  
RENEWALS AND VARIATIONS WITHIN MRP, DCP OR NATIONAL PROCEDURES**

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December 2008  
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For general information, see tables for Electronic submissions for New applications within MRP, DCP or National procedure in NtA 2A chapter 7 section 3.3. For PSUR document requirements, please refer to EudraLex Volume 9A Annex 6.

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.

**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<br>BfArM | DE<br>PEI | EE               | EL | ES                     | FI | FR             | HU             | IE | IT                  | LV | LT | LU               | MT             | NL              | PL | PT  | RO | SE             | SK                 | SI              | UK<br>9,11,13  | IS | NO              |
|--|----------------|------------------------|----------------|----|----------------|----|-------------|-----------|------------------|----|------------------------|----|----------------|----------------|----|---------------------|----|----|------------------|----------------|-----------------|----|---|----|----------------|--------------------|-----------------|----------------|----|-----------------|
| Notifications, art. 61(3)                        | 1 <sup>5</sup> | 1 <sup>3,9,10,13</sup> | 1              | -  | 1 <sup>9</sup> | -  | -           | -         | -                | -  | 1 <sup>8,9,13,18</sup> | -  | -              | -              | -  | 1 <sup>5,7,18</sup> | -  | -  | -                | 1 <sup>7</sup> | 1 <sup>13</sup> | -  | -   | -  | 1 <sup>9</sup> | 2 <sup>5,8,9</sup> | 1 <sup>16</sup> | 1              | 1  | 1 <sup>15</sup> |
| Variations type IA                               | 1 <sup>5</sup> | 1 <sup>3,9,10,13</sup> | -              | -  | 1 <sup>9</sup> | -  | -           | -         | -                | -  | 1 <sup>8,9,13,18</sup> | -  | -              | -              | 1  | 1 <sup>5,7,18</sup> | -  | -  | 1 <sup>2+5</sup> | 1 <sup>7</sup> | 1 <sup>13</sup> | -  | 1 <sup>12</sup>                                     | -  | 1 <sup>9</sup> | 2 <sup>5,8,9</sup> | 1 <sup>16</sup> | 1              | 1  | 1 <sup>15</sup> |
| Variations type IB                               | 1 <sup>5</sup> | 1 <sup>3,9,10,13</sup> | -              | -  | 1 <sup>9</sup> | -  | -           | -         | -                | -  | 1 <sup>8,9,13,18</sup> | -  | -              | -              | 1  | 1 <sup>5,7,18</sup> | -  | -  | 1 <sup>2+5</sup> | 1 <sup>7</sup> | 1 <sup>13</sup> | -  | 1 <sup>12</sup>                                     | -  | 1 <sup>9</sup> | 2 <sup>5,8,9</sup> | 1 <sup>16</sup> | 1              | 1  | 1 <sup>15</sup> |
| Variations type II                               | 1 <sup>5</sup> | 1 <sup>3,9,10,14</sup> | -              | -  | 1 <sup>9</sup> | -  | -           | -         | -                | -  | 1 <sup>8,9,13,18</sup> | -  | 1 <sup>9</sup> | -              | -  | 2 <sup>5,7,18</sup> | -  | -  | -                | 1 <sup>7</sup> | 1 <sup>13</sup> | -  | 1 <sup>6,7,9</sup>                                  | -  | 1 <sup>9</sup> | 2 <sup>5,8,9</sup> | 1 <sup>16</sup> | 1              | 1  | 1 <sup>15</sup> |
| Other national variations                        | 1 <sup>5</sup> | 1 <sup>3,9,10,13</sup> | -              | -  | 1 <sup>9</sup> | -  | -           | -         | -                | -  | 1 <sup>8,9,13,18</sup> | -  | -              | -              | -  | 1 <sup>5,7,18</sup> | -  | -  | -                | 1 <sup>7</sup> | 1 <sup>13</sup> | -  | -   | -  | 1 <sup>9</sup> | 2 <sup>5,8,9</sup> | 1 <sup>16</sup> | 1              | 1  | 1 <sup>15</sup> |
| Variation Response/<br>Supplementary information | 1 <sup>5</sup> | 1 <sup>3,9,13</sup>    | 1 <sup>3</sup> | -  | 1 <sup>9</sup> | -  | -           | -         | 1 <sup>3,7</sup> | -  | 1 <sup>8,9,13,18</sup> | -  | -              | 1 <sup>1</sup> | -  | 2 <sup>5,7,18</sup> | -  | -  | 1 <sup>2+5</sup> | 1 <sup>7</sup> | 1 <sup>13</sup> | -  | IB:<br>1 <sup>12</sup><br>II:<br>1 <sup>6,7,9</sup> | -  | 1 <sup>9</sup> | 2 <sup>5,8,9</sup> | 1               | 1 <sup>3</sup> | 1  | 1 <sup>15</sup> |
| Renewals   | 1 <sup>5</sup> | 1 <sup>3,9,10,13</sup> | -              | -  | 1 <sup>9</sup> | -  | -           | -         | -                | -  | 1 <sup>8,9,13,18</sup> | -  | -              | 1 <sup>9</sup> | -  | 1 <sup>5,7,18</sup> | -  | -  | -                | 1 <sup>7</sup> | 1 <sup>13</sup> | -  | 1 <sup>6,7,9</sup>                                  | -  | 1 <sup>9</sup> | 2 <sup>5,8,9</sup> | 1 <sup>16</sup> | 1              | 1  | 1 <sup>15</sup> |
| Renewal Response/<br>Supplementary information   | 1 <sup>5</sup> | 1 <sup>3,9,10,13</sup> | 1 <sup>3</sup> | -  | 1 <sup>9</sup> | -  | -           | -         | 1 <sup>3,7</sup> | -  | 1 <sup>8,9,13,18</sup> | -  | -              | 1 <sup>9</sup> | -  | 1 <sup>5,7,18</sup> | -  | -  | 1 <sup>2+5</sup> | 1 <sup>7</sup> | 1 <sup>13</sup> | -  | 1 <sup>2,6,7,9</sup>                                | -  | 1 <sup>9</sup> | 2 <sup>5,8,9</sup> | 1               | 1 <sup>3</sup> | 1  | 1 <sup>15</sup> |

**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<br>BfArM     | DE<br>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 <sup>14</sup> | -  | 1  | 2               | 2              | 1 <sup>14</sup>   | -                | -  | 1  | -  | 1 <sup>8,9</sup> | -                  | 1 <sub>6</sub> | 1  | -              | 1 <sup>2+16</sup> | 2 <sup>6</sup> | -  | 1              | -  | 1 <sup>4</sup>    | 1   | -  | -  | -  | -  | -  |
| Variations type IA   | -  | -  | 1              | 1 <sup>14</sup> | -  | 1  | 2 <sup>11</sup> | 2              | 1 <sup>14</sup>   | 3 <sup>8,9</sup> | -  | 1  | -  | 1 <sup>8,9</sup> | -                  | 1 <sub>6</sub> | 1  | -              | -                 | 2 <sup>6</sup> | -  | 1              | -  | 1 <sup>4</sup>    | 1   | -  | -  | -  | -  | -  |
| Variations type IB   | -  | -  | 1              | 1 <sup>14</sup> | -  | 1  | 2 <sup>11</sup> | 2              | 1 <sup>14</sup>   | 3 <sup>8,9</sup> | -  | 1  | -  | 1 <sup>8,9</sup> | -                  | 1 <sub>6</sub> | 1  | -              | -                 | 2 <sup>6</sup> | -  | 1              | -  | 1 <sup>4</sup>    | 1   | -  | -  | -  | -  | -  |
| Variations type II   | -  | -  | 1              | 1 <sup>14</sup> | -  | 1  | 2 <sup>11</sup> | 2              | 1 <sup>14</sup>   | 3 <sup>8,9</sup> | -  | 2  | -  | 1 <sup>8,9</sup> | 1 <sup>11,17</sup> | 1 <sub>6</sub> | 1  | -              | 1 <sup>2+16</sup> | 2 <sup>6</sup> | -  | 1              | -  | 1 <sup>4,14</sup> | 1   | -  | -  | -  | -  | -  |
| Other national variations                                  | -  | -  | 1              | 1 <sup>14</sup> | -  | 1  | 1 <sup>11</sup> | 2              | 1 <sup>14</sup>   | 3 <sup>8,9</sup> | -  | 2  | -  | 1 <sup>8,9</sup> | -                  | 1 <sub>6</sub> | 1  | -              | 1 <sup>2+16</sup> | 2 <sup>6</sup> | -  | 1              | -  | 1 <sup>4</sup>    | N/A | -  | -  | -  | -  | -  |
| Variation Response documents/<br>Supplementary information | -  | -  | -              | 1 <sup>14</sup> | -  | 1  | 2 <sup>2</sup>  | 2              | 1 <sup>6,14</sup> | 1 <sup>1</sup>   | -  | 2  | -  | -                | -                  | 1 <sub>6</sub> | 1  | -              | -                 | 2 <sup>6</sup> | -  | 1 <sup>2</sup> | -  | 1 <sup>4</sup>    | 1   | -  | -  | -  | -  | -  |
| Proposed product information<br>in word format (RTF/doc)   | -  | -  | 1              | 1 <sup>14</sup> | -  | 1  | 1 <sup>9</sup>  | 1 <sup>9</sup> | 1                 | 1 <sup>2</sup>   | -  | 2  | -  | 1 <sup>13</sup>  | -                  | 1 <sub>6</sub> | 1  | 1 <sup>3</sup> | 1 <sup>2+16</sup> | 2 <sup>6</sup> | -  | 1              | -  | 1 <sup>4</sup>    | 1   | -  | -  | -  | -  | -  |
| Renewals   | -  | -  | 1 <sup>8</sup> | 1 <sup>14</sup> | -  | 1  | 2               | 2              | 1 <sup>14</sup>   | 3 <sup>8,9</sup> | -  | 2  | -  | -                | -                  | 1 <sub>6</sub> | 1  | -              | 1 <sup>2+16</sup> | 2 <sup>6</sup> | -  | 1              | -  | 1 <sup>4</sup>    | 1   | -  | -  | -  | -  | -  |
| Renewal Response documents/<br>Supplementary Information   | -  | -  | -              | 1 <sup>14</sup> | -  | 1  | 1 <sup>2</sup>  | 2              | 1 <sup>6,14</sup> | 1 <sup>1</sup>   | -  | 2  | -  | -                | -                  | 1 <sub>6</sub> | 1  | -              | -                 | 2 <sup>6</sup> | -  | 1 <sup>2</sup> | -  | 1 <sup>4</sup>    | 1   | -  | -  | -  | -  | -  |
| Proposed product information<br>in word format (RTF/.doc)  | -  | -  | 1              | 1 <sup>14</sup> | -  | 1  | 1 <sup>9</sup>  | 1 <sup>9</sup> | 1                 | 1 <sup>1</sup>   | -  | 2  | -  | -                | -                  | 1 <sub>6</sub> | 1  | 1 <sup>3</sup> | 1 <sup>2+16</sup> | 2 <sup>6</sup> | -  | 1              | -  | 1 <sup>4</sup>    | 1   | -  | -  | -  | -  | -  |

*\*For numbers of paper copies requested, please refer to Notice to Application volume 2A chapter 7, section 3.1 and 3.2.  
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 (up to 20MB) with no additional paper (also the cover letter and application form electronic only)
- 2) Should additionally to the CD/DVD also be sent by e-mail/EudraLink
- 3) Could be sent by e-mail/EudraLink instead of sending CD/DVD
- 4) DVD is not accepted
- 5) A paper copy should be available on request (see table for paper requirements)
- 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 stated in NtA volume 2A Chapter 7
- 9) For specific format requirements on the electronic submission, see NCA's website
- 10) The application form is *not* required in paper format
- 11) Applications could or should be made through the NCA's website or portal (see NCA's website)
- 12) Applications within the national procedure should be made through the NCA's website or portal (see NCA's website)
- 13) Electronic format (eCTD or NeeS) is mandatory.
- 14) Module 4 and 5 in electronic format only (Module 1-3 additionally required in paper format)
- 15) Module 1-5 electronically (Module 1-2 additionally required in paper format)
- 16) Module 1-5 electronically (Module 1 additionally required in paper format)
- 17) Paper copy required for Type II National variations only within 10 days of the online submission.
- 18) Proof of payment should be sent in paper original