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Justification table template – Module 2.5 (Clinical Overview)

**Justification Table: Invented Product Name (INN) – procedure number**

< **Module 2.5** (Clinical Overview) > - <Name of the document as per naming convention> - <Name of the Applicant/MAH>

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| **By submitting this justification table, you confirm that you have checked that the information you wish to redact is NOT in the public** **domain. Please ensure that the proposed redactions are in line with Annex 3 of POLICY/0070 and the Guidance on identification and redaction of commercially confidential information in clinical reports submitted to the European Medicines Agency for the purpose of publication.** |

| Page number(s) | Title of Section(s) | Text proposed for redaction by the Applicant/MAH | Applicant/MAH to provide justification of CCI (Please explain how the release of this information will damage your company’s commercial interest or competitive position) | Agency Assessment of the proposed redaction:  Rejected/ Partially Accepted/ Accepted | Agency's rationale/redaction code |
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Justification table template – Module 2.7.1 (Summary of Biopharmaceutical Studies and Associated Analytical Methods)

**Justification Table: Invented Product Name (INN) – procedure number**

< **Module 2.7.1** (Summary of Biopharmaceutical Studies and Associated Analytical Methods) > <Name of the document as per naming convention> - <Name of the Applicant/MAH>

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| **By submitting this justification table, you confirm that you have checked that the information you wish to redact is NOT in the public domain. Please ensure that the proposed redactions are in line with Annex 3 of POLICY/0070 and the Guidance on identification and redaction of commercially confidential information in clinical reports submitted to the European Medicines Agency for the purpose of publication.** |

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Justification table template – Module 2.7.2 (Summary of Clinical Pharmacology Studies)

**Justification Table: Invented Product Name (INN) – procedure number**

< **Module 2.7.2** (Summary of Clinical Pharmacology Studies) > - <Name of the document as per naming convention> - <Name of the Applicant/MAH>

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| **By submitting this justification table, you confirm that you have checked that the information you wish to redact is NOT in the public domain. Please ensure that the proposed redactions are in line with Annex 3 of POLICY/0070 and the Guidance on identification and redaction of commercially confidential information in clinical reports submitted to the European Medicines Agency for the purpose of publication.** |

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Justification table template – Module 2.7.3 (Summary of Clinical Efficacy)

**Justification Table: Invented Product Name (INN) – procedure number**

< **Module 2.7.3** (Summary of Clinical Efficacy) > - <Name of the document as per naming convention> - <Name of the Applicant/MAH>

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| **By submitting this justification table, you confirm that you have checked that the information you wish to redact is NOT in the public domain. Please ensure that the proposed redactions are in line with Annex 3 of POLICY/0070 and the Guidance on identification and redaction of commercially confidential information in clinical reports submitted to the European Medicines Agency for the purpose of publication.** |

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Justification table template – Module 2.7.4 (Summary of Clinical Safety)

**Justification Table: Invented Product Name (INN) – procedure number**

< **Module** **2.7.4** (Summary of Clinical Safety) > - <Name of the document as per naming convention> - <Name of the Applicant/MAH>

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Justification table template – Module 5.3.x.x – CSR BODY

**Justification Table: Invented Product Name (INN) – procedure number**

<**Module 5.3.x.x - CSR BODY**> - <Name of the document as per naming convention><Name of the Applicant/MAH >

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Justification table template – Module 5.3.x.x – CSR Appendices 16.1.x

**Justification Table: Invented Product Name (INN) – procedure number**

<**Module 5.3.x.x - CSR Appendices 16.1.x**> - <Name of the document as per naming convention> - <Name of the Applicant/MAH>

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| **By submitting this justification table, you confirm that you have checked that the information you wish to redact is NOT in the public domain. Please ensure that the proposed redactions are in line with Annex 3 of POLICY/0070 and the Guidance on identification and redaction of commercially confidential information in clinical reports submitted to the European Medicines Agency for the purpose of publication.** |

***Table section to be completed for CSR Appendices 16.1.x.***

| Page number(s) | Title of Section(s) | Text proposed for redaction by the Applicant/MAH | Applicant/MAH to provide justification of CCI (Please explain how the release of this information will damage your company’s commercial interest or competitive position) | Agency Assessment of the proposed redaction:  Rejected/ Partially Rejected/ Accepted | Agency's rationale/redaction code |
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Justification table template – Module 5.3.x.x – CSR BODY and Appendices

**Justification Table: Invented Product Name (INN) – procedure number**

<**Module 5.3.x.x - CSR BODY and Appendices** > - <Name of the document as per naming convention> - <Name of the Applicant/MAH >

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| **By submitting this justification table, you confirm that you have checked that the information you wish to redact is NOT in the public domain. Please ensure that the proposed redactions are in line with Annex 3 of POLICY/0070 and the Guidance on identification and redaction of commercially confidential information in clinical reports submitted to the European Medicines Agency for the purpose of publication.** |

***Table section to be completed for CSR BODY***

| Page number(s) | Title of Section(s) | Text proposed for redaction by the Applicant/MAH | Applicant/MAH to provide justification of CCI (Please explain how the release of this information will damage your company’s commercial interest or competitive position) | Agency Assessment of the proposed redaction:  Rejected/ Partially Accepted/ Accepted | Agency's rationale/redaction code |
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***Table section to be completed for CSR Appendices 16.1.2.***

| Page number(s) | Title of Section(s) | Text proposed for redaction by the Applicant/MAH | Applicant/MAH to provide justification of CCI (Please explain how the release of this information will damage your company’s commercial interest or competitive position) | Agency Assessment of the proposed redaction:  Rejected/ Partially Accepted/ Accepted | Agency's rationale/redaction code |
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***Table section to be completed for CSR Appendices 16.1.9.***

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