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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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| **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 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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| **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 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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