<Date>

Responses to <D90><D120><D180> <list of questions><list of outstanding issues> - <quality<-ASMF>> <nonclinical> <clinical>

\* more granular documents e.g. Efficacy, Safety, Product Information can be submitted, but at minimum, 1 response document for each module (i.e. quality, nonclinical and clinical). Please make sure the title of the document is very clear as regards the contents. Please ensure that the header matches this title.

<Product name>

International non-proprietary name or common name: <INN> or <Common name\*\*>

\*\*eg for vaccines and some ATMPs

<Pharmaceutical form and strength>

Procedure No. <EMEA/H/C/XXXX/0000><IRIS procedure number>

Applicant:

Tick boxes:

The applicant confirms that all questions have been transferred into this document without any amendments

The applicant confirms that the word document in the *Working Documents* folder and the pdf document in Module 1 are identical

**Instructions to Applicants**

The applicant is expected to respond to all the questions directly in this document and submit both PDF and MS Word versions with their official responses in eCTD.

The questions should be copied/pasted verbatim and must not be combined or amended. After each question, copy/paste the title for the Applicant’s response as well as the box for (Co)-Rapporteur’s assessment. The questions should follow the same order and numbering as included in the list adopted by the committee.

All sections (i.e., question, applicant’s response and assessment of the applicant’s response) should be replicated as many times as needed and questions placed under each relevant topic (i.e., drug product; drug substance; pharmacology, toxicology; pharmacokinetics; pharmacodynamics; clinical efficacy; clinical safety; pharmacovigilance; orphan similarity and derogations; new active substance (NAS) status; additional data exclusivity/marketing protection, etc.). Questions on the closed part of the active substance master file (ASMF) are to be answered separately by the ASMF holder.

If any sections are not applicable (e.g., if there are no major objections for a particular topic), please state “not applicable”. The headings <Orphan similarity and derogations>, <New active substance status>, <Additional data exclusivity/Marketing protection> can be deleted if not relevant.

The Applicant is expected to prepare - at minimum - separate response documents for quality, nonclinical and clinical aspects as well as a separate document on aspects on product information. In addition, the Applicant may choose to further separate the responses into more granular response documents, e.g., clinical pharmacology, clinical safety, clinical efficacy. In the case of multiple response documents, an informative title should be added on the front page. Applicants should not create one response document per question. The submission should have a maximum of 15 response documents.

The Applicant adds their complete responses concerning each question. It is not acceptable to just refer to appendices. However, appendices may be used and referred to if space-consuming tables or pictures need to be included to support the responses. Cross links are encouraged to ease the assessment. Study reports or similar should not be included as appendices but placed in the correct section of the eCTD and cross-referenced. Appendices referred to should be easily identified in the response. There should not be unnecessary repetition between the response body and the appendices.

Prior to the submission of the responses, the Applicant should delete all the blue guidance text in this document[[1]](#footnote-3).

**Instructions to Assessors**

Please use the assessment boxes to complete the assessment of the applicant’s responses. Don’t forget to update the Overview and propose relevant updates to SmPC and/or RMP as needed for each issue.

Prior to the circulation of the assessment of the responses, the assessor should delete all the green guidance text in this document.

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1. Declarations

To be completed by the assessment teams:

|  |
| --- |
| This response document includes an Active Substance Master File (ASMF):  Yes  No  **(Co)-Rapporteur**  The assessment team should tick one or other of the 2 boxes below:  The (Co)-Rapporteur and/or the Assessor confirm(s) that this assessment **does not** include non‑public proprietary information (with the exception of data provided by the applicant), including commercially confidential information provided by a third party (e.g. ASMF, information shared by other competent authorities or organisations, reference to on-going assessments, development plans etc), irrespective from which entity was received\*.  \* If the entity from which non-public information originates has consented to its further disclosure, the box should be ticked and there would be no need to add details.  The (C0)-Rapporteur and/or the Assessor confirm(s) that this report **does** include non-public information (as described above), but all relevant paragraphs containing confidential information have been **highlighted in blue,** so that they can be removed before sharing the document with the applicant or other parties. |

1. Abbreviations

Please add any abbreviations used in the document.

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1. Quality aspects

NB: in relation to the ASMF, this document should only address responses to questions pertaining to the open part of the ASMF.

Major Objections

Drug substance

If there are no major objections for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Drug product

If there are no major objections for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Other concerns

Drug substance

If there are no other concerns for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Drug product

If there are no other concerns for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

1. Non-clinical aspects

Major Objections

Pharmacology

If there are no major objections for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Pharmacokinetics

If there are no major objections for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Toxicology

If there are no major objections for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Other concerns

Pharmacology

If there are no other concerns for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Pharmacokinetics

If there are no other concerns for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Toxicology

If there are no other concerns for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

1. Clinical aspects

Major Objections

Pharmacokinetics

If there are no major objections for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Pharmacodynamics

If there are no major objections for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Clinical Efficacy

If there are no major objections for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Clinical Safety

If there are no major objections for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Risk management plan

If there are no major objections for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Pharmacovigilance

If there are no major objections for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Other Concerns

Pharmacokinetics

If there are no other concerns for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Pharmacodynamics

If there are no other concerns for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Clinical Efficacy

If there are no other concerns for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Clinical Safety

If there are no other concerns for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Risk management plan

If there are no other concerns for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Pharmacovigilance

If there are no other concerns for this section, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

1. Multidisciplinary questions

Major Objections

If there are no multidisciplinary major objections, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

Other Concerns

If there are no multidisciplinary other concerns, just state “None” and delete the question and response headings below as well as the box.

<None>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

1. Other

Depending on what other questions are raised by the Rapporteurs, please delete any sections that don’t apply and only leave the Major Objections and/or Other Concerns raised.

<Orphan similarity and derogations>

<Major Objections>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

<Other Concerns>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

<New active substance status>

<Major Objections>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

<Other Concerns>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

<Additional data exclusivity /Marketing protection>

<Major Objections>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

<Other Concerns>

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

<Product information>

There are a number of different ways to address questions on the product information. Any questions, even if related to product information, included in the quality, non-clinical or clinical lists of questions by the Rapporteurs should be addressed in that context and not copied here.

If the Rapporteurs have provided comments and questions on the product information directly on the annexes with comments and/or track changes, the applicant may choose to respond to those also directly in the annexes.

The following section, unlike the previous, is not structured in Major Objections or Other concerns, rather it provides an option for responding to comments on the annexes.

Clean and track-changes versions of the annexes must be provided in eCTD module 1.3.1. in any case.

Question <number>

<Question text>

* + - 1. Applicant’s response:

<Response text>

|  |
| --- |
| <Co->Rapporteur’s assessment of applicant’s response:  <Text>  Conclusion:  <Issue <not> considered resolved><Issue not resolved but no follow-up questions as no further impact on Overview/CHMP AR, B/R, SmPC or RMP>  <Text>  Additional resulting questions:  <None><Text>  Updated documentation:  Overview/CHMP AR;  B/R conclusions;  SmPC;  RMP. |

1. References

Any references cited in the responses should be available in the eCTD sequence for the response.

<Text>

1. To quickly delete all the blue guidance text, use the following instructions: Click on Ctrl-Alt-Shift-S to view the “styles” window. Select “guidance notes for applicant” and click on the drop-down menu icon on the right, chose “Select all XXX instances”, press the “Delete” key on the keyboard. [↑](#footnote-ref-3)
2. Applicants can also add a table of contents for tables and a table of figures if they want. [↑](#footnote-ref-4)