**Decentralised Procedure**

**The applicant’s** **<joint>/****<Quality>/****<Non-Clinical>/****<Clinical>/****<Module 1>response**

**Responses to the questions raised by RMS and CMSs**

**<Invented Name>**

**<(Active Substance)>**

**AB/H/{nnnn} /{nnn}/DC**

**Applicant:**

Tick boxes:

 [ ]  This is a draft D106 joint response document

 [ ]  This is a D106 joint response document

 [ ]  This is a D160 joint response document

[ ]  This is a D196 to 209 joint response document

[ ]  Confirmation that all questions from the RMS and from the CMSs comments have been transferred into this template without any amendments

 [ ]  Confirmation that word document and pdf document are identical

# Responses to Questions of RMS and CMS

The applicant loads the joint response template from <https://www.hma.eu/127.html>.

The applicant prepares the responses to RMS’s D70 and CMSs’ D100 questions as they have been introduced, by compiling them verbatim into the joint response template by D106. Similarly, the responses in further steps of the procedure are filled in.

All sections (i.e. question, the applicant’s response, assessment of the applicant’s response, and overall summary and conclusion) should be replicated as many times as questions under each relevant topic (i.e. DP, DS; pharmacology, PK, toxicology; PK, PD, efficacy, safety, PhV; module 1). ASMF related questions are answered separately from joint response template. The applicant may choose whether one joint response document or several separate response documents are prepared. Adequate title on the front page is picked up.

The questions should follow the same order as included in the overview LoQ. Each question should be clearly identified and responded, identifying whether they were raised by RMS or CMS. Questions are not allowed to be combined.

In case the RMS requests the draft D106 responses, the (joint) response document is to be sent according to the RMS requirements.

Applicant’s responses to clinical, nonclinical, quality and Module 1 issues should be provided in one joint document or as separate documents per Module. The response document(s) should be provided both in pdf format in Module 1 and in current Word format in the working doc folder, with a confirmation on the cover page that both versions are identical. This document will not be used for supporting technical documentation which will be included in the relevant Modules. Moreover, the applicant should provide PI documents (SmPC, PL, labelling text) in a tabulated format according to the CMDh guideline “*Applicant’s response document in Mutual Recognition and Decentralised procedures for Marketing Authorisation Applications*”.

The applicant should use this template for each response prepared throughout the procedure.

## Quality aspects

NB: This document should only address responses to questions not related to the ASMF.

*Responses to questions on the Applicant’s Part and Restricted Part of the ASMF can be found in a separate document*

**Major Objections (RMS) / Potential Serious Risks to Public Health (CMS)**

**Drug substance (related to additional data provided by applicant only)**

Question

The applicant prefills the RMS and CMSs questions (D70/100; D120/145; D180/195) as they have been introduced, i.e. verbatim. Numbering of the questions must be according to the overview. Each question should be followed by the initials of the Member State who raised the question.

The applicant’s response:

The applicant prefills their complete responses concerning each question. It is not acceptable to just refer to annexes. However, annexes may be used and referred to if large data packages, new data, space consuming tables or pictures need to be included to support the responses. Annexes referred to should be easily identified into the response.

Assessment of the applicant’s response:

Overall summary and conclusion:

These sections are to be filled by the RMS, only, the fields may not be deleted by the applicant.

**Drug product**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Other concerns**

**Drug substance (related to additional data provided by applicant only)**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Drug product**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

## Non-clinical aspects

**Major Objections (RMS) / Potential Serious Risks to Public Health (CMS)**

**Pharmacology**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Pharmacokinetics**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Toxicology**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Other concerns**

**Pharmacology**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Pharmacokinetics**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Toxicology**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

## Clinical aspects

**Major Objections (RMS) / Potential Serious Risks to Public Health (CMS)**

**Pharmacokinetics**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Pharmacodynamics**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Clinical Efficacy**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Clinical Safety**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Pharmacovigilance**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Other Concerns**

**Pharmacokinetics**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Pharmacodynamics**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Clinical Efficacy**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Clinical Safety**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Pharmacovigilance**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

## Module 1 aspects

**Major Objections (RMS) / Potential Serious Risks to Public Health (CMS)**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Other concerns**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

## Additional remarks from the applicant:

The changes proposed by the Applicant should be listed here, e.g. change of MAH, addition/deletion of manufacturing sites etc. either at day 106/160, change of names, change of authorised persons, etc.

## Manufacturing chain – GMP documents overview:

This section is included to keep the RMS informed about the changes proposed by the Applicant in the manufacturing chain and/or in the submitted GMP documents, including the submission of more recent versions during the further steps of the procedure. The Applicant will either confirm no changes are made or fill the tables below. The numbers of the GMP documents currently provided in the Module 1 should be listed. The column “Current” will be filled in case of change of the GMP document number compared to the day 0.

[ ]  The Applicant confirms that no changes are made to the GMP documents already submitted in this procedure.

[ ]  The Applicant confirms that all GMP documents are valid.

*Active substance manufacturing sites (QP declaration)*

|  |  |  |
| --- | --- | --- |
| **Name and address of the manufacturing site** | **Auditing body** | **Date of audit** |
| Original submission | Current  |
|  |  |  |  |

*Finished product manufacturing, batch control and batch release sites*

|  |  |  |
| --- | --- | --- |
| **Name and address of the manufacturing site** | **MIA No. (for EU)** | **GMP No.** |
| Original submission | Current | Original submission | Current |
|  |  |  |  |  |