September 2022

CMDh/443/2022, Rev. 0

**MAH’s response document on variation<s>**

**<Invented Name>**

**<(Active Substance)>**

**<AB/H/{nnnn}/II/{nnn}>**

**<AB/H/{nnnn}/II/{nnn}/G>**

**<AB/H/xxxx/WS/{nnn}>**

**Marketing Authorisation Holder:**

**Date:**

*This template is for MAH’s responses to the questions in the Preliminary Variation Assessment Report and CMS comments, if applicable.*

*It is strongly recommended to use this template. The MAH loads the joint response template from* [*https://www.hma.eu/human-medicines/cmdh/templates/variations.html*](https://www.hma.eu/human-medicines/cmdh/templates/variations.html)

*The applicant prepares the responses to all RMS’s PVAR (day 15/40/70) and CMSs’ questions (day 20/55/80) by compiling them verbatim into this response template. All sections (i.e. question, the MAH’s response and assessment of the MAH’s responses box) should be replicated as many times as questions under each relevant topic (i.e. quality, nonclinical or clinical). ASMF related questions are answered separately from joint response template. Each question should be clearly identified and responded by relevant module and by MO/OC; questions are not allowed to be combined.*

*The response document should be provided both in pdf format in Module 1 and in current Word format (docx) in the working doc folder, with a confirmation on the cover page that both versions are identical.*

Tick boxes:

☐ 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 the Member State(s) Request for supplementary information

## <Quality> <Non-clinical> <Clinical> <Product information related> aspects

<III.1. **Major objections**>

Question

The MAH prefills the RMS and CMSs questions as they have been introduced, i.e. verbatim. Numbering of the questions must be according to PVAR. Each question should be followed by the initials of the Member State who raised the question.

MAH’s response:

The MAH 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 MAH’s response:  These sections are to be filled by the RMS, only. The fields may not be deleted by the applicant. |

<III.1.2 Other concerns>

<Text> <N/A>

Question

MAH’s response:

|  |
| --- |
| Assessment of the MAH’s response: |

<Text> <N/A>

Question

MAH’s response:

|  |
| --- |
| Assessment of the MAH’s response: |