<Preliminary> <Updated> <Final>- Assessment Report for the Post-Authorisation Measure <number>

<Invented name>

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

Product No. EMEA/H/C/<XXX>

Marketing authorisation holder:

[Additional steps may need to be added manually, e.g. GMP inspection, discussion at a working party…]

| **Status of this report and steps taken for the assessment** |
| --- |
| PAM number |
| **Current step¹** | **Description** | **Planned date** | **Actual Date** | Need for discussion² |
| [ ]  | Submission |  |  | [ ]  |
| [ ]  | Start of procedure |  |  | [ ]  |
| **[ ]**  | Rapporteur’s preliminary Assessment Report |  |  | **[ ]**  |
| [ ]  | <PRAC> Members comments |  |  | [ ]  |
| [ ]  | Updated Rapporteur’s Assessment Report |  |  | [ ]  |
| [ ]  | <PRAC adoption of conclusions:> |  |  | [ ]  |
| [ ]  | <CAT Members comments:> |  |  | [ ]  |
| [ ]  | <CAT adoption of conclusions:>  |  |  | [ ]  |
| [ ]  | CHMP Members comments: |  |  | [ ]  |
| [ ]  | CHMP adoption of conclusions:  |  |  | [ ]  |
| Additional rows only in case of request for supplementary information assessed as part of a follow-up PAM |
| **PAM number:** |
| [ ]  | Submission |  |  | [ ]  |
| [ ]  | Re-start of procedure |  |  | [ ]  |
| [ ]  | Rapporteur’s preliminary Assessment Report |  |  | [ ]  |
| [ ]  | <PRAC> Members comments |  |  | [ ]  |
| [ ]  | Updated Rapporteur’s Assessment Report |  |  | [ ]  |
| [ ]  | <PRAC adoption of conclusions:>  |  |  | [ ]  |
| [ ]  | <CAT Members comments:> |  |  | [ ]  |
| [ ]  | <CAT adoption of conclusions:>  |  |  | [ ]  |
| [ ]  | CHMP Members comments: |  |  | [ ]  |
| [ ]  | CHMP adoption of conclusions: |  |  | [ ]  |

¹ Tick the box corresponding to the applicable step – do not delete any of the steps. If not applicable, add n/a instead of the date.

² Criteria for plenary discussion: substantial disagreement between the Rapporteur and other CHMP members and/or at the request of the Rapporteur or the Chair

Note to the Rapporteurs, Co-Rapporteurs: Assessment reports and comments should be circulated to EMA via **EUDRALINK**.

[Please note there are specific templates available for the assessment of P46 studies, signals and imposed PASS protocols/results. See [templates for Assessors section](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000338.jsp&mid=WC0b01ac058046aa58) on the EMA website.]

Administrative information

|  |  |
| --- | --- |
| **<CHMP> <CAT> <PRAC> Rapporteur** | **Name** |
| **<CHMP> <CAT> <PRAC> Rapporteur contact person** | **Name:**Email: |
| **<CHMP> <CAT> <PRAC> Rapporteur’s assessors**  | **Name**Email:**Name**Email:**Name**Email: |
| **Product Lead/Risk management specialist/ Quality Specialist** | **Name**Email:Tel: |
|  |  |

 Declarations

This application includes an Active Substance Master File (ASMF):

[ ]  Yes

[ ]  No

[ ]  The assessor confirms that this assessment does **not** include non-public information, including commercially confidential information (e.g. ASMF, information shared by other competent authorities or organisations, reference to on-going assessments or 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 below.*

Whenever the above box is un-ticked please indicate section and page where confidential information is located here:

Table of contents

Important: Do not edit this table. The TOC-field is to be updated automatically (place the cursor in the TOC-field and press F9 for 'update Field').

[1. Introduction 4](#_Toc411253456)

[1.1. Steps taken for the assessment 4](#_Toc411253459)

[2. Summary of data submitted 4](#_Toc411253460)

[3. Scientific discussion 4](#_Toc411253461)

[4. Overall conclusion 5](#_Toc411253462)

List of abbreviations

Provide a list of relevant abbreviations used throughout the assessment report.

1. Introduction

This report covers the following post-authorisation commitments undertaken by the MAH:

[Full text/description of the PAM]

[In case of submission of a final study report, the application should be resubmitted as a variation. Please inform the product lead accordingly.]

1. Summary of data submitted

This section should summarise the MAH’s data.

1. Scientific discussion

[Include here a critical review of the data provided. In terms of structure it should, in principle, follow the flow of the presentation of data described above.

Be as clear and concise as possible, identifying the most important findings and deficiencies described above (do not repeat data: summarise evidence for each conclusion, discuss if the data submitted fulfil the requirements (legal, guidelines, scientific advice)) and describe the major issues raised and how they were addressed.

Incorporate comments received in the discussion or overall conclusion. Ensure that the discussion does not contain references to individual CHMP/CAT/PRAC Member States comments.]

1. Overall conclusion

[Provide a brief and clear overall conclusion on the assessment of the data, an outcome (PAM fulfilled/not fulfilled) and further actions if required for each PAM.]

[For Quality PAMs only, if applicable:]

<With respect to on-going stability programs and in accordance with EU GMP guidelines (6.32 of Vol. 4 Part I of the Rules Governing Medicinal Products in the European Union), any confirmed out of specification result, or significant negative trend, should be reported to the Rapporteur and the EMA.>

[Tick the appropriate box for the outcome of the assessment.]

[ ]  **PAM fulfilled**

<No regulatory action required.>

To be ticked if **all** commitments are fulfilled.

[ ]  **PAM not fulfilled - - further action required:**

PAMs requiring periodic updates/further submissions (e.g. annual registry updates or protocol review but the final report is still outstanding, etc…) should be ticked as not fulfilled until the last submission.]**.**

* <Request for supplementary information required by <date/within 60 days>> *[please add a specific deadline or use the default 60 days deadline]*
1. [List further data required to be submitted].
* <Next interim report should be submitted by <date>>

[In cases where the Rapporteur has identified the need for a PI update based on data that is already available, the following sentence should be used:]

<In addition, in view of the available data regarding [….] the MAH should submit a variation in accordance with Articles 16 and 17 of Regulation (EC) No 726/2004 or provide a justification for not doing so. This should be provided ***no later than 60 days after the receipt*** of the final assessment report.>

[In cases where the Rapporteur has identified the potential need for a PI update which needs to be further investigated or confirmed by the MAH before submitting a Type II variation, the following sentence should be used:]

<The impact of the available data regarding […] on the product information should be further considered. >

[In case of safety-related requests by the Rapporteur (e.g. cumulative safety review to be submitted, or assessment of a measure that is reflected in the RMP), the following sentence should be used:]

<The following safety data shall be ***submitted within <X months/>/<the next PSUR>***:

In case of inspection-related requests for follow-up by the Rapporteur, the following sentence should be used:

<The MAH is requested to submit the following Corrective Action/Preventive Action (CAPA) related data by <date>.

1. <Evaluation of the MAH responses to the Request for supplementary information (RSI)>

[MAH responses are evaluated under a new PAM number**. Update the Steps taken for the assessment in Section 1.1]**

Responses to the RSI are evaluated in <procedure number>.

[Include here the assessment of the clarifications provided]

1. <Overall conclusion>

[Provide a brief and clear overall conclusion on the assessment of the data, an outcome (PAM fulfilled/not fulfilled) and further actions if required for each PAM.]

[For Quality PAMs only, if applicable:]

<With respect to on-going stability programs and in accordance with EU GMP guidelines (6.32 of Vol. 4 Part I of the Rules Governing Medicinal Products in the European Union), any confirmed out of specification result, or significant negative trend, should be reported to the Rapporteur and the EMA.>

[Tick the appropriate box for the outcome of the assessment.]

[ ]  **PAM fulfilled**

<No regulatory action required.>

To be ticked if **all** commitments are fulfilled.

[ ]  **PAM not fulfilled - further action required:**

Please note that PAMs requiring periodic updates/further submissions (e.g. annual registry updates or protocol review but the final report is still outstanding, etc…) should be ticked as not fulfilled until the last submission.]**.**

* <Request for supplementary information required by <date>>
1. [List further data required].
* <Next interim report should be submitted by <date>>

[In cases where the Rapporteur has identified the need for a PI update based on data that is already available the following sentence should be used:]

<In addition, in view of the available data regarding [….] the MAH should submit a variation in accordance with Articles 16 and 17 of Regulation (EC) No 726/2004 or provide a justification for not doing so. This should be provided ***no later than 60 days after the receipt*** of the final assessment report.>

[In cases where the Rapporteur has identified the potential need for a PI update which needs to be further investigated or confirmed by the MAH before submitting a Type II variation the following sentence should be used:]

<The impact of the available data regarding […] on the product information should be further considered. >

[In case of safety-related requests by the Rapporteur (e.g. cumulative safety review to be submitted, or assessment of a measure that is reflected in the RMP), the following sentence should be used:]

<The following safety data shall be ***submitted within <X months/>/<the next PSUR>***:

In case of inspection-related requests for follow-up by the Rapporteur, the following sentence should be used:

<The MAH is requested to submit the following Corrective Action/Preventive Action (CAPA) related data by <date>.