[Choose appropriate title depending on evaluation stage]

Rapporteurs Day <106\*><150> Joint Assessment Report of the responses to the list of questions - Clinical

Rapporteurs Day<136\*><195> Joint Assessment Report of the responses to the list of outstanding issues - Clinical

\*in case of accelerated assessment

<Invented name>

<(Active substance)>

EMEA/H/C/<xxx>

For EU-M4all, procedure number is EMEA/H/W/xx

Applicant:

|  |  |
| --- | --- |
| CHMP/CAT Rapporteur: |  |
| CHMP/CAT Co-rapporteur: |  |
| CHMP coordinator(s) *to be included only for CAT procedures* |  |
| PRAC Rapporteur: |  |
| EMA PL: |  |
| Date of this report: |  |
| Deadline for comments: |  |

*Note to the (Co)[Rapporteurs](https://www.ema.europa.eu/en/glossary/rapporteur" \o "One of the two members of a committee or working party who leads the evaluation of an application." \t "_blank): Assessment reports and comments should be circulated VIA EUDRALINK.* *Product Shared Mailbox: product.name-xxxx@ema.europa.eu and product initial MAA dedicated mailbox: MAAxxxx@ema.europa.eu (xxxx refers to the product number EMA/H/C/xxxx) should always be copied*.

Declarations

The assessor confirms that this assessment does **not** include non-public information, including commercially confidential information (eg. 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:

List of abbreviations

1. Assessment of the responses to the <CHMP> <CAT> List of <questions><outstanding issues> - Clinical aspects
   1. Major objections
      1. Pharmacokinetics

Question

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

* + 1. Pharmacodynamics

Question

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

* + 1. Clinical Efficacy

Question

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

* + 1. Clinical Safety

Question

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

* + 1. Risk Management plan

[Please complete appendix 1 below after assessing the responses to the LOQ.]

Question on <safety specification> < Pharmacovigilance plan> < Risk minimisation measures>

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

* + 1. Pharmacovigilance system

Question

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

* 1. Other concerns
     1. Pharmacokinetics

Question

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

* + 1. Pharmacodynamics

Question

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

* + 1. Clinical Efficacy

Question

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

* + 1. Clinical Safety

Question

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

* + 1. Risk Management plan

[Please complete appendix 1 after assessing the responses to the LOQ.]

Question on <safety specification> < Pharmacovigilance plan> < Risk minimisation measures>

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

* + 1. Pharmacovigilance system

Question

Summary of the Applicant’s Response

Assessment of the Applicant’s Response

Conclusion

1. Overall summary and conclusions on the Applicant’s responses
   1. Unresolved Issues
2. Appendix 1: [this appendix is optional]

PRAC Rapporteur’s advice on conditions or restrictions with regard to the safe and effective use of the medicinal product

<The PRAC Rapporteur does not advise any changes to the current conditions of the Marketing Authorisation.>

[or]

<The PRAC Rapporteur considers that changes to the conditions of the Marketing Authorisation are necessary and advises that the following changes should be made to the conditions of the Marketing Authorisation.>

[If you chose the second sentence, please fill in below sections]

* 1. Additional risk minimisation measures

<No additional risk minimisation measures are necessary.>

*or*

<The PRAC Rapporteur considers that the following additional risk minimisation measures are necessary for the safe and effective use of the product:

*[If this option above is chosen, select below all that apply and please explain why.]*

<A DHPC addressing <points to be addressed>>

<An educational material for healthcare professionals to address the risk(s) of*>*

*[list safety concerns to be addressed]*

<An educational material for <patients><and/or carers> to address the risk(s) of>

*[list safety concerns to be addressed]*

<A pregnancy prevention plan to address the risk(s) of>

*[list safety concerns to be addressed]*

<A patient alert card to address the risk(s) of>

*[list safety concerns to be addressed]*

<A patient monitoring card to address the risk(s) of>

[list safety concerns to be addressed]

[For Post authorisation only (e.g. line extension)]

<The PRAC Rapporteur considers that <the following> conditions or restrictions are no longer necessary for the safe and effective use of the medicinal product:>

[Specify any measures no longer considered necessary.]

* 1. Obligation to conduct post-authorisation measures

[This relates to imposed studies (Annex II conditions for CAPs).]

<No conditions are necessary.>

[Or if new PhV studies or activities are needed, for EACH new study/activity which should be an Annex II condition and please explain why.]

<The PRAC Rapporteur recommends that a <study><activity> to investigate <name safety concern(s)> should be a condition of the MA.>

[Optional statement]

<The PRAC Rapporteur recommends that this should take the form of:>