[insert only for PRAC endorsed reports; insert also EMA header and footer]

<insert full date>

<insert Doc.Ref.>

Pharmacovigilance Risk Assessment Committee (PRAC)

PRAC <Rapporteur> Risk Management Plan (RMP) Assessment Report

[Please delete the guidance text in green as well as the optional sentences that do not apply when circulating the report]

<Invented name>

<(Active substance)>

EMEA/H/C/<xxx>

Applicant:

| PRAC Rapporteur: |  |
| --- | --- |
| EMA PM: |  |
| EMA RMS: |  |
| Start of the procedure: |  |
| Date of this report: |  |
| Deadline for comments: |  |
| RMP Version number: |  |

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Administrative information

|  |  |
| --- | --- |
| **Name of the PRAC Rapporteur**  **EMA Procedure Manager:**  **EMA Risk Management Specialist:** | **Name**  Email:  **Name**  Email:  **Name**  Email: |
| **PRAC Rapporteur contact person:** | **Name:**  Tel:  Email: |
| **Names of the PRAC Rapporteur’s assessors** | **Name**  Email:  **Name**  Email:  **Name**  Email: |

Declarations

The assessor confirms that proprietary information on, or reference to, third parties (e.g. ASMF holder) or products are not included in this assessment, unless there are previous contracts and/or agreements with the third party(ies).

The assessor confirms that reference to ongoing assessments or development plans for other products is not included in this assessment report.

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

List of abbreviations

1. Product overview

|  |  |
| --- | --- |
| **Brief description of the product**  [chemical class  summary of mode of action  important information about its composition (e.g. origin of active substance of biological, relevant adjuvants or residues for vaccines] |  |
| **Applied Indication(s)** |  |
| **Dosage** |  |
| **Pharmaceutical form(s) and strengths** |  |
| **Is the product subject to additional monitoring in the EU?** | Yes  No |
|  |  |

1. PRAC Rapporteur overall conclusion and recommendations

[Please copy and paste the overall conclusion here and please select the appropriate option to reflect what stage the procedure is at]

<The RMP Part III-VI is acceptable.>

or

<The RMP Part III-VI is acceptable with minor revisions required for the next update.>

or

<The RMP Part III-VI could be acceptable provided an updated RMP and satisfactory responses to the list of questions (section 3):

or

<The RMP Part III-VI is not acceptable.>

[For generics}

<The Applicant has provided a RMP in support of its application for a generic product, which <is no different from the reference product <name of reference product> in terms of dose, formulation or indication that would have any implications for safety.>

Or

<differs from the reference product <name of the reference product> in terms of <dose/formulation/indication> with implications for safety, as follows: [specify]>.

1. <CHMP Rapporteur conclusion on Safety Specification and Safety Concerns>

[This section of the AR is only for background purposes**.]**

[Copy and paste the table from RMP module SVIII.]

Table SVIII.1: Summary of safety concerns

| **Summary of safety concerns** | |
| --- | --- |
| Important identified risks | <List> |
| Important potential risks | <List> |
| Missing information | <List> |

[Add here the recommendations as presented in section 3.4.2 and 3.4.3 of the CHMP Rapporteur’s D80 overview and any additional comments from the Co-Rapporteur].

[Comments on the Safety Specification should be sent directly to the CHMP during the commenting phase, and should not be included here.]

1. Pharmacovigilance plan

[Within this section, the PRAC rapporteur should comment on whether the applicant has discussed how the safety concerns from Module SVIII are proposed to be addressed within the pharmacovigilance plan and whether all areas requiring further investigation have been identified.]

* 1. <Summary of planned additional PhV activities from RMP>

Table Part III.3.1: On-going and planned additional pharmacovigilance activities

| Study *(study short name, and title)*  Status *(planned/on-going)* | | Summary of objectives | Safety concerns addressed | Milestones  *(required by regulators)* | Due dates |
| --- | --- | --- | --- | --- | --- |
| **Category 1** - Imposed mandatory additional pharmacovigilance activities which are conditions of the marketing authorisation *(key to benefit risk)* | | | | | |
|  |  | |  |  |  |
| **Category 2** – Imposed mandatory additional pharmacovigilance activities which are Specific Obligations in the context of a conditional marketing authorisation or a marketing authorisation under exceptional circumstances *(key to benefit risk)* | | | | | |
|  |  | |  |  |  |
| **Category 3** - Required additional pharmacovigilance activities *(by the competent authority)* | | | | | |
|  | |  |  |  |  |

[Please make sure all on-going and planned categories 1-3 safety studies included in the Pharmacovigilance Plan are listed above.

Comment on the usefulness of the study/activity to address the safety concern for category 1, 2 and 3 studies only.

The applicant should provide information on the study population, clear milestones and due dates, submission of interim results or other intermediate milestones, if requested.

If a study aims to evaluate the effectiveness of risk minimisation measures, this needs to be made explicit in the study summary of objectives.

Comment on the appropriateness of milestones and due dates for category 1, 2 and 3 studies only.]

* **Category 1 studies,** i.e. those that are considered key for the benefit–risk balance, should also be included as conditions of the MA (Annex II). These are studies where confirmation or identification of a safety concern could lead to major regulatory action including suspension or revocation of the MA.
* **Category 2 studies** are those imposed as specific obligations in the context of a conditional MA or MA under exceptional conditions (Annex II).
* **Category 3 studies**: These activities may include trials or studies which are already on-going (e.g. from clinical trials where the activity would be to provide a report) or be planned where the activity is to conduct the study. Category 3 studies/activities would include studies or activities requested by another Regulatory authority where the results are expected to provide information relevant to existing areas of uncertainty. Studies which have been specifically requested by the CHMP/PRAC (which are not conditions of the MA) or which may be suggested by the applicant to investigate a safety concern should also be included here. Studies to measure the effectiveness of risk minimisation measures would also normally fall into this category.]
  1. Overall conclusions on the PhV Plan

[The PRAC rapporteur should consider the following points when writing the overall conclusions on the PhV plan:

* For all safety concerns identified in the safety specification, is routine PhV sufficient?
* Are additional PhV activities required for any safety concern? If yes, are the additional PhV activities proposed by the Applicant appropriate, clearly defined and described and suitable for further identifying or characterising risks or providing missing information? Are there additional activities proposed by the PRAC rapporteur?
* Do the objectives of the activities align with the identified / potential risks / missing information requiring confirmation or further investigation? ]

The PRAC Rapporteur, having considered the data submitted, is of the opinion that <routine pharmacovigilance is sufficient to identify and characterise the risks of the product.>< the proposed post-authorisation PhV development plan is sufficient to identify and characterise the risks of the product.>< the proposed post-authorisation PhV development plan is not sufficient to identify and characterise the risks of the product and the applicant should propose PhV studies.>

Or if nothing has been proposed

For new product

<the <applicant> should propose a post-authorisation PhV development plan.>

The PRAC Rapporteur also considered that <routine PhV remains sufficient to monitor the effectiveness of the risk minimisation measures.> or < the study(ies) in the post-authorisation development plan <is><are>sufficient to monitor the effectiveness of the risk minimisation measures.> or <Applicant> should propose a study to monitor the effectiveness of [state which additional risk minimisation measures should be studied and include question in section 3].

For generics

<in line with the reference product><the Applicant should propose a post-authorisation PhV development plan>

[or, in exceptional circumstances use:]

<Due to the differences between the generic product and the reference product, a post-authorisation safety study will be necessary to collect further data on x [specify].>

The <PRAC Rapporteur><assessor> also considered that

[Choose one of the following]

< routine PhV <is><remains> sufficient to monitor the effectiveness of the risk minimisation measures>or < the study(ies) in the post-authorisation development plan <is><are><remain<s>> sufficient to monitor the effectiveness of the risk minimisation measures > or <the Applicant should propose a study to monitor the effectiveness of <> [state which additional risk minimisation measures should be studied]

1. <Plans for post-authorisation efficacy studies >
   1. <Summary of Post authorisation efficacy development plan>

Table Part IV.1: Planned and on-going post-authorisation efficacy studies that are conditions of the marketing authorisation or that are specific obligations.

| **Study** *(study short name and title),*  **Status** *(planned, on-going)* | **Summary of objectives** | | **Efficacy uncertainties addressed** | | **Milestones** | **Due Date** |
| --- | --- | --- | --- | --- | --- | --- |
| Efficacy studies which are conditions of the marketing authorisation | | | | | | |
|  |  | |  | |  |  |
| Efficacy studies which are Specific Obligations in the context of a conditional marketing authorisation or a marketing authorisation under exceptional circumstances | | | | | | |
|  | |  | |  |  |  |

[Comment if needed. The need of PAES will be raised by the CHMP. No in-depth assessment is expected from the PRAC Rapporteur.

Please consider that text from the table below will be included verbatim in the RMP public summary.]

1. Risk minimisation measures
   1. Routine Risk Minimisation Measures

[The RMP may cover more than one medicinal product. In some circumstances risk minimisation measures may be specified per product, or certain risks may not be relevant to all products.]

Table Part V.1: Description of routine risk minimisation measures by safety concern

|  |  |
| --- | --- |
| **Safety concern** | **Routine risk minimisation activities**  *Please provide the following information, as applicable:* |
| <Safety concern 1> | <Routine risk communication:>  *Provide only reference to SmPC/PL section(s) (do not copy the complete SmPC/PL wording):*  *e.g. <SmPC section 4.8.>*  *e.g. <PL section 4>*  <Routine risk minimisation activities recommending specific clinical measures to address the risk:>  *Include the specific clinical measures/monitoring information for healthcare professionals in SmPC or patients in PL:*  *e.g. <recommendation for liver function monitoring are included in SmPC sections 4.4>*  *e.g. <how to detect early signs and symptoms of serious infections in PL sections 2 and 3>*  <Other routine risk minimisation measures beyond the Product Information:>  <Pack size:>  *e.g. when the amount of medicine in a pack helps ensuring that the medicinal product is used correctly.*  <Legal status:>  *e.g. restricted medical prescription, special medical prescription, categorisation at member states level etc.* |

[Please make sure all safety concerns from Part II: Module SVIII are listed above.]

[Comment if needed]

* 1. <Additional risk minimisation measures>

[State which additional risk minimisation measures are proposed by the Applicant, whether they are needed and which safety concerns they address. Are there additional activities proposed by the PRAC rapporteur? Additional risk minimisation measures should only be included in the RMP if the proposed measures are necessary for the safe and effective use of the product. Request the applicant to remove any items which do not meet this criterion.

This section may not be applicable for initial marketing authorisation applications for generic, hybrid medicinal products and fixed combination medicinal product with no new active substance, where the originator medicinal product does not have additional risk minimisation activities.]

* 1. Overall conclusions on risk minimisation measures

For new products or generics

The PRAC Rapporteur having considered the data submitted was of the opinion that:

[Choose one of the following:]

<In line with the reference product><the proposed risk minimisation measures are sufficient to minimise the risks of the product in the proposed indication(s).>

[Or if some other risk minimisation measures (either routine or additional) need to be added]

<In line with the reference product><the proposed risk minimisation measures are not sufficient to minimise the risks of the product> and supplementary risk minimisation measures are required relating to: *[List safety concerns and ensure questions added to List of Questions.]*

[Or when the risks cannot be brought to a satisfactory level]

<the proposed risk minimisation measures are not sufficient to minimise the risks of the product in the proposed indication(s).>

1. Part VI Summary of the risk management plan

This section should not be assessed during the first round i.e. before adopting the Day 120 List of Questions (except for accelerated assessment procedures).

The Applicant should update this section throughout the procedure, and assessment is expected earliest within Day 150.

1. < Protected Personal Data (PPD) and Commercially Confidential Information (CCI) considerations for the RMP >

[Complete this section for application including a new active substance]

<The rapporteur identified the following PPD/CCI in the RMP parts other than the Safety Specification, which should be removed/anonymised in the updated RMP:>

[List sections of the RMP where PPD/CCI information is located and the type of information that requires deletion/anonymisation.]

<The rapporteur did not identify PPD/CCI in the RMP parts other than Safety Specification.>

<The Applicant is reminded that in case of a Positive Opinion, the body of the RMP and Annexes 4 and 6 (as applicable) will be published on the EMA website at the time of the EPAR publication, so considerations should be given on the retention/removal of Protected Personal Data (PPD) and identification of Commercially Confidential Information (CCI) in the updated RMP submitted with the responses.>

1. <PRAC outcome>

To be filled only in case there is an early PRAC discussion at the first round. Depending on the outcome, section 2 and 3 could be updated accordingly.

1. List of questions to be addressed by the applicant

<Not applicable>

Or

<The applicant should provide an updated RMP answering the following questions and points:>

**Major objections**

Risk management plan

* Pharmacovigilance plan
* Risk minimisation measures

**Other concerns**

Risk management plan

* Pharmacovigilance plan
* Risk minimisation measures