Amsterdam, <insert full date>

<insert Doc.Ref.>

Committee for Medicinal Products for Human Use (CHMP)

<Preliminary> <Updated> <Final> assessment report for paediatric studies submitted in accordance with article 46 of regulation (EC) No 1901/2006, as amended

<Invented name>

International non-proprietary name: <INN>

Procedure no.: EMA/H/C/<XXX>/P46

Marketing authorisation holder (MAH):

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

**Guidance text** is in green italics. You may print a copy of this template with the drafting note, then delete them all in one go:

Click on Ctrl-Alt-Shift-S to view the “styles” window. Select “Drafting notes (Agency)” and click on the icon on the right, chose “Select all XXX instances”, press the “Delete” key on the keyboard.

Do not change or delete the titles and the numbering style. (Add “Not applicable” if necessary)

Suggested font: Verdana 9.

Paragraph tab: alignment left, outline level: body text, indentation: 0, spacing before: 0pt and after: 7pt; line spacing: at least, at: 14pt.

| **Status of this report and steps taken for the assessment** | | | | |
| --- | --- | --- | --- | --- |
| **Current step¹** | **Description** | **Planned date** | **Actual Date** | Need for discussion² |
|  | Start of procedure |  |  |  |
|  | CHMP Rapporteur Assessment Report |  |  |  |
|  | CHMP members comments |  |  |  |
|  | Updated CHMP Rapporteur Assessment Report |  |  |  |
|  | CHMP adoption of conclusions: |  |  |  |
| Additional rows only in case of request for supplementary information | | | | |
|  | Submission |  |  |  |
|  | Re-start |  |  |  |
|  | CHMP Rapporteur Assessment Report |  |  |  |
|  | CHMP members comments |  |  |  |
|  | Updated CHMP Rapporteur Assessment Report |  |  |  |
|  | 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 CHMP plenary discussion: substantial disagreement between the Rapporteur and other CHMP members and/or at the request of the Rapporteur or the Chair

Administrative information

|  |  |
| --- | --- |
| **Procedure resources** | |
| **Rapporteur:** | **Name:**  Tel:  Email: |
| **Contact person Rapporteur**  **Assessor Rapporteur** | **Name:**  Tel:  Email:  **Name:**  Tel:  Email:  **Name:**  Tel:  Email: |
| **EMA Product Lead**  **Procedure Assistant** | **Name:**  Tel:  Email:  **Name:**  Tel:  Email: |

Declarations

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:

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1. Introduction

On <XXX>, the MAH submitted <a> completed paediatric stud<y><ies> for <XXX>, in accordance with Article 46 of Regulation (EC) No1901/2006, as amended.

<These data are also submitted as part of the <post-authorisation measure(s) <specific obligation(s)>

A short critical expert overview has also been provided.

1. Scientific discussion
   1. Information on the development program

<The MAH stated that < study title(s) and number(s)> <is> <are> <a> stand alone stud<y><ies>.>

<The MAH stated that < study title(s) and number(s)> <is> <are> part of a clinical development program. The <variation><extension> application consisting of the full relevant data package (i.e containing several studies) is expected to be submitted by <MM/YY>. A line listing of all the concerned studies is annexed.>

* 1. Information on the pharmaceutical formulation used in the study<ies>

[Information on the pharmaceutical formulation used in the study(ies), the existence of a suitable paediatric formulation, or conditions for extemporaneous formulations if applicable, should be mentioned here]

* 1. Clinical aspects
     1. Introduction

[If several studies are submitted, a list of all the clinical studies should be included with a brief description for each study.]

The MAH submitted <a> final report(s) for:

• <study number and title>;

• <study number and title>;

* + 1. Clinical study<ies>

Note: For each clinical study, the following structure is recommended

<Clinical study number and title>

Description

Methods

Study participants

Treatments

Objective(s)

Outcomes/endpoints

Sample size

Randomisation and blinding (masking)

Statistical Methods

Results

Participant flow

Recruitment

Baseline data

Number analysed

Efficacy results

Safety results

* + 1. Discussion on clinical aspects

1. <Rapporteur’s><CHMP> overall conclusion and recommendation

[Provide a brief and clear overall conclusion on the assessment of the data, an outcome and further actions if required. Incorporate, in the conclusion or outcome, comments received from individual members. Please ensure that the final conclusion does not contain references to individual CHMP Members or Member States. In addition, tick the appropriate box for the outcome of the assessment.]

Fulfilled:

<No regulatory action required.>

[The following option is only applicable if the study(ies) is/are not part of a PAM/SO and provided that the variation/extension is expected within 18 months following receipt of the first submitted study(ies) of the full relevant data package.]

<No further action required, however further data are expected in the context of a <variation> <extension> prior any conclusion on product information amendments is made. The MAH <should commit> to submit this <variation> <extension> application by <date>.

[If requesting a variation, please provide recommendation on SmPC and PL wordings as precise as possible.]

<In view of the available data regarding [….] the MAH should either 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 without any delay and <***no later than 60 days after the receipt*** of these conclusions.> or <by date>.

[For additional data not directly linked to the submitted study(ies)choose the following sentence:]

<Based on the data submitted, the MAH should provide <description of a new post-authorisation measure> by <date> as a separate post-authorisation commitment. >

Not fulfilled:

[For additional data directly linked to the submitted study(ies, choose the following sentence:]

<Based on the data submitted, the MAH should provide <description of the additional clarifications requested per study>as part of this procedure. (see section “Request for supplementary information”)

1. <Request for supplementary information>

Based on the data submitted, the MAH should address the following questions as part of this procedure:

The timetable is <a 30 day response timetable without clock stop.>< a 30 day response timetable with clock stop.>

MAH responses to Request for supplementary information

[Include here assessment of the clarifications provided and update the scientific discussion and/or overall conclusion’s section accordingly]

<Annex. Line listing of all the studies included in the development program>

The studies should be listed by chronological date of completion:

<Non clinical studies>

Product Name: Active substance:

|  |  |  |  |
| --- | --- | --- | --- |
| Study title | Study number | Date of completion | Date of submission of final study report |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

<Clinical studies>

Product Name: Active substance:

|  |  |  |  |
| --- | --- | --- | --- |
| Study title | Study number | Date of completion | Date of submission of final study report |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |