

Rapporteur's
~~←Preliminary→~~ ~~←Final→~~ Public Assessment Report
 for paediatric studies submitted in accordance
 with Article 46 of Regulation (EC) No1901/2006, as
 amended

<Product name(s)>
 <(Active Substance)>

XX/W/{nnnn}/pdWS/{nnn}

Marketing Authorisation Holder:

Rapporteur:	
Start of the procedure (day 0):	
Date of this report:	
Deadline for Rapporteur's preliminary paediatric assessment report (PPdAR)(day 70):	
Deadline for CMS's comments:	
Date re-start of procedure (day 90)	
Deadline CMS's comments (day 115)	
Finalisation procedure (day 120):	
<u>Date of finalisation of PAR</u>	

ADMINISTRATIVE INFORMATION

Invented name of the medicinal product:	
INN (or common name) of the active substance(s):	
MAH:	
Currently approved Indication(s)	
Pharmaco-therapeutic group (ATC Code):	
Pharmaceutical form(s) and strength(s):	
Rapporteur's contact person:	Name: Tel: _____ Email: _____
Name of the Assessor:	Name: _____ Tel: _____ Email: _____

I. EXECUTIVE SUMMARY

<SmPC and PL changes are proposed in sections xxxx and xxxx.>
<No SmPC and PL changes are proposed.>

II. RECOMMENDATION¹

III. INTRODUCTION

On < date>, the MAH submitted <a> completed paediatric study(ies) for<name of the medicinal product>, in accordance with Article 46 of Regulation (EC) No1901/2006, as amended, on medicinal products for paediatric use.

A short critical expert overview has also been provided.

The MAH stated that the submitted paediatric study(ies) <do(es) not> influence the benefit risk for<name of the medicinal product> and that there is <no> <a> consequential regulatory action.

<The MAH proposed the following regulatory action: <description of proposed amendments to the sections of the product information>>

IV. SCIENTIFIC DISCUSSION

IV.1 Information on the pharmaceutical formulation used in the study(ies)

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

IV.2 Clinical aspects

1. Introduction

Note: 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 The recommendation from section V can be copied in this section

2. Clinical study(ies)

Note: For each clinical study, the following structure is recommended. Assessors should consider if safety results should be discussed in the context of post-marketing safety data, liaising with pharmacovigilance colleagues if necessary.

<CLINICAL STUDY NUMBER AND TITLE>

➤ Description

➤ Methods

- Objective(s)
- Study design
- Study population /Sample size
- Treatments
- Outcomes/endpoints
- Statistical Methods

➤ Results

- Recruitment/ Number analysed
- Baseline data
- Efficacy results
- Safety results

3. Discussion on clinical aspects

Note: If relevant any relevant Pharmacovigilance information related to the active substance should be mentioned and discussed in this section.

V. **RAPPORTEUR'S MEMBER STATES OVERALL CONCLUSION AND RECOMMENDATION**

*Note: Please ensure that the **final** conclusion does not contain references to individual Member States. "If a type **HIB** variation is recommended, please specify the texts proposed for inclusion in the relevant SmPC sections.*

➤ **Overall conclusion**

➤ **Recommendation**

<No further action required>

<Type **HIB** variation to be requested from the MAH by <date> >

~~<Based on the data submitted, the MAH should provide <description of the additional clarifications requested per study>² as part of this worksharing procedure (see section IV “Request for Supplementary Information”)>~~

~~**VI. REQUEST FOR SUPPLEMENTARY INFORMATION**~~

~~<Not applicable>~~

~~Or~~

~~<List of questions>~~

² ~~Directly linked to the study(ies) submitted~~