

**Rapporteur's**  
~~<Preliminary>~~ ~~<Final>~~ Public Assessment Report  
for paediatric studies submitted in accordance  
with Article 45 of Regulation (EC) No1901/2006, as  
amended

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

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

<b>Rapporteur:</b>	
<del><b>Start of the procedure (day 0):</b></del>	
<del><b>Date of this report:</b></del>	
<del><b>Deadline for Rapporteur's preliminary paediatric assessment report (PPdAR) (day 70):</b></del>	
<del><b>Deadline for CMS's comments (day 85):</b></del>	
<del><b>Date re-start procedure (day 90):</b></del>	
<del><b>Deadline for CMS's comments (day 115):</b></del>	
<b>Finalisation procedure (day 120):</b>	
<del><b>Date of finalisation of PAR</b></del>	

## ADMINISTRATIVE INFORMATION

Invented name of the medicinal product(s):	See section VI†
INN (or common name) of the active substance(s):	
MAH (s):	See section VI†
Pharmaco-therapeutic group (ATC Code):	
Pharmaceutical form(s) and strength(s):	
<del>Rapporteur's contact person:</del>	<p>_____</p> <p><b>Name</b> _____</p> <p>Tel: _____</p> <p>Email: _____</p> <p>_____</p>
<del>Name of the assessor(s)</del>	<p><b>Name:</b> _____</p> <p>Tel: _____</p> <p>Email: _____</p>

## I. EXECUTIVE SUMMARY

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

## II. RECOMMENDATION<sup>1</sup>

## III. INTRODUCTION

Several MAHs submitted < number'X' > completed paediatric study(ies) for <active substance>, in accordance with Article 45 of the Regulation (EC)No 1901/2006, 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>>

In addition, the following documentation has been included as per the procedural guidance:

- A line listing
- <An annex including SmPC wording of sections 4.1 and 4.2 related to the paediatric use of the medicinal product>

## IV. SCIENTIFIC DISCUSSION

### IV.1 Information on the pharmaceutical formulation used in the clinical 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 < Non-clinical aspects>

#### 1. Introduction

*Note: A list of all the non-clinical studies submitted with a brief description for each study should be included (see line-listing provided by the MAH)*

<sup>1</sup> The recommendation from section V can be copied in this section.

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

- <study number and title>;
- <study number and title>;

The MAH submitted <an> extended synopsis for:

- <study number and title>;
- <study number and title>;

## 2. Non clinical study(ies)

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

### **<NON CLINICAL STUDY NUMBER and TITLE >**

#### ➤ **Description**

#### ➤ **Methods**

- Study design
- Species/strain/age
- Dose

#### ➤ **Results**

## 3. Discussion on non clinical aspects

### IV.3 <Clinical aspects>

#### 1. Introduction

*Note: A list of all the clinical studies submitted with a brief description for each study should be included (see line-listing provided by the MAH)*

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

- <study number and title>;
- <study number and title>;

The MAH submitted <an> extended synopsis for:

- <study number and title>;
- <study number and title>;

## 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 #IB variation is recommended, please specify the texts proposed for inclusion in the relevant SmPC sections.*

➤ **Overall conclusion**

➤ **Recommendation**

<No further action required>

<Type **H|B** 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><sup>2</sup> as part of this worksharing procedure. (see section IV "Request for supplementary information")~~

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

<Not applicable>

Or

<

List of ~~questions~~:

**VII.VI. LIST OF MEDICINAL MEDICINAL PRODUCTS AND  
MARKETING AUTHORISATION HOLDERS INVOLVED**

*The list can be taken from the spreadsheet compiled from the EMA*

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<sup>2</sup>—Directly linked to the study(ies) submitted