EMA/757737/2010

European Medicines Agency decision

P/306/2010

of 22 December 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for human normal immunoglobulin / recombinant human hyaluronidase (EMEA-000872-PIP01-10) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Baxter Innovations GmbH on 4 March 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 November 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 13 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for human normal immunoglobulin / recombinant human hyaluronidase, solution for infusion, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for human normal immunoglobulin / recombinant human hyaluronidase, solution for infusion, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for human normal immunoglobulin / recombinant human hyaluronidase, solution for infusion, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Baxter Innovations GmbH, Industriestrasse 67, 1221 Vienna, Austria.

Done at London, 22 December 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/551201/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-000872-PIP01-10

Scope of the application

Active substance(s):

Human normal immunoglobulin / recombinant human hyaluronidase

Condition(s):

Treatment of Primary immunodeficiency (PID)

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Baxter Innovations GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Baxter Innovations GmbH submitted for agreement to the European Medicines Agency on 4 March 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 15 April 2010.

Supplementary information was provided by the applicant on 26 August 2010.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation,
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex(es) and appendix.

London, 12 November 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan.

1. Waiver

1.1. Condition: Treatment of Primary immunodeficiency (PID)as model for replacement therapy

Primary immunodeficiency (PID)

This covers

- Primary immunodeficiency
- Myeloma
- Chronic lymphocytic leukaemia
- AIDS

The waiver applies to:

- All subsets of the paediatric population from birth to less than 24 months of age
- for solution for infusion for subcutaneous use
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of Primary immunodeficiency (PID) as model for replacement therapy

2.1.1. Subset(s) of the paediatric population concerned by the paediatric development

From 24 months to less than 18 years of age.

2.1.2. Pharmaceutical form(s)

Solution for infusion for subcutaneous use

2.1.3. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	3	Study 1) (160601) Open-label, multi-centre study to evaluate the tolerability and pharmacokinetics of 10% immune globulin administered intravenously or subcutaneously in patients with primary immunodeficiency disease Study 2) (160603)

		Open-label, multi-centre study to evaluate efficacy, tolerability and pharmacokinetics of 10% immune globulin (IGIV, 10%) administered intravenously compared to IGIV, 10% administered subcutaneously following administration of recombinant human hyaluronidase (rHuPH20) in patients with primary immunodeficiency disease Study 3) (160902) Open-label study to evaluate the tolerability and safety of subcutaneous immune globulin solution administered following administration of recombinant human hyaluronidase (rHuPH20) in subjects with Primary Immunodeficiency Diseases (PID)

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By April 2012
Deferral for one or more studies contained in the paediatric investigation plan:	Yes