EMA/489362/2012

European Medicines Agency decision

P/0172/2012

of 27 July 2012

on the acceptance of a modification of an agreed paediatric investigation plan for human normal immunoglobulin (EMEA-000872-PIP01-10-M01) 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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on the acceptance of a modification of an agreed paediatric investigation plan for human normal immunoglobulin (EMEA-000872-PIP01-10-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 European Medicines Agency's decision P/306/2010 issued on 22 December 2010,

Having regard to the application submitted by Baxter Innovations GmbH on 22 March 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 June 2012, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for human normal immunoglobulin, solution for infusion, subcutaneous use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

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

Done at London, 27 July 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/298219/2012

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000872-PIP01-10-M01

Scope of the application

Active substance(s):

Human normal immunoglobulin

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

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Baxter Innovations GmbH submitted to the European Medicines Agency on 22 March 2012 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/306/2010 issued on 22 December 2010.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 16 April 2012.

Scope of the modification

Some timelines and the description of the medicinal product have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

   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 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, 8 June 2012

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% human normal immunoglobulin (IGIV, 10%) 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

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By October 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes