EMA/413296/2010

European Medicines Agency decision

P/120/2010

of 9 July 2010

on the agreement of a paediatric investigation plan and on the granting of a waiver for human normal immunoglobulin (EMEA-000775-PIP01-09) 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 agreement of a paediatric investigation plan and on the granting of a waiver for human normal immunoglobulin (EMEA-000775-PIP01-09) 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 application submitted by Kedrion S.p.A. on 16 November 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 May 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 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 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, solution for infusion, intravenous 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 waiver for human normal immunoglobulin, solution for infusion, intravenous 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

This decision is addressed to Kedrion S.p.A., Loc. Ai Conti, Castelvecchio Pascoli, 55051 Barga – Lucca, Italy.

Done at London, 9 July 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/280636/2010

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

EMEA-000775-PIP01-09

Scope of the application

Active substance(s):

Human normal immunoglobulin

Condition(s):

Idiopathic thrombocytopenic purpura (ITP)

Primary Immunodeficiency (PID)

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Kedrion S.p.A.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Kedrion S.p.A. submitted for agreement to the European Medicines Agency on 16 November 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 23 December 2009.

Supplementary information was provided by the applicant on 1 March 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 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 Norwegian Paediatric Committee member(s) agree(s) 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, 21 May 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

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

1. Condition(s)

Idiopathic thrombocytopenic purpura (ITP)

Primary immunodeficiency (PID)

2. Waiver

2.1. Condition

Idiopathic thrombocytopenic purpura (ITP)

This covers

- Idiopathic thrombocytopenic purpura
- Guillain Barré syndrome
- Kawasaki disease
- Allogeneic bone marrow transplantation.

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age
- for solution for infusion for intravenous 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.

2.2. Condition

Primary immunodeficiency (PID)

This covers

- Primary immunodeficiency
- Myeloma
- Chronic lymphocytic leukaemia
- AIDS

The waiver applies to:

- Neonates and infants from birth to less than 24 months of age
- for solution for infusion for intravenous 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.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Primary immunodeficiency (PID)

3.1.1. Indication targeted by the PIP

Replacement therapy in primary immunodeficiency syndrome (PID) as a model for replacement therapy in primary immunodeficiency syndrome (PID), in myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinemia and recurrent infections and in children with congenital AIDS and recurrent infections.

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

From 24 months to less than 18ears of age.

3.1.3. Pharmaceutical form(s)

Human normal immunoglobulin solution for infusion for intravenous use 100 g/L

3.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	1	Study 1) Open-Label Multicentre Study to Evaluate the Pharmacokinetics, Safety and Tolerability of Intravenous Immunoglobulin Preparation in Patients with Primary Immunodeficiency (PID)

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 2013
Deferral for one or more studies contained in the paediatric investigation plan:	No