EMA/103190/2014

European Medicines Agency decision

P/0085/2014

of 4 April 2014

on the acceptance of a modification of an agreed paediatric investigation plan for human normal immunoglobulin (EMEA-000454-PIP01-08-M04) 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-000454-PIP01-08-M04) 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/187/2009 issued on 8 September 2009, the decision P/73/2010 issued on 5 May 2010, the decision P/0275/2012 issued on 21 November 2012, and the decision P/0290/2013 issued on 29 November 2013,

Having regard to the application submitted by Kedrion S.p.A. on 21 November 2013 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver and proposing a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 February 2014, in accordance with Article 22 of Regulation (EC) No 1901/2006, and Article 21 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 acceptance of changes to the agreed paediatric investigation plan and on the granting of a deferral.

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

(3) It is therefore appropriate to adopt a decision on the granting of a 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 injection, subcutaneous use, 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

A deferral for human normal immunoglobulin, solution for injection, subcutaneous use, the details of which are set out in the opinion of the Paediatric Committee 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, 55051 - Castelvecchio Pascoli - Barga (Lucca), Italy.

Done at London, 4 April 2014

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

EMA/PDCO/748496/2013

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

EMEA-000454-PIP01-08-M04

Scope of the application

Active substance(s):

Human normal immunoglobulin

Condition(s):

Treatment of Primary Immunodeficiency (PID)

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Kedrion S.p.A.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Kedrion S.p.A. submitted to the European Medicines Agency on 21 November 2013 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/187/2009 issued on 8 September 2009, the decision P/73/2010 issued on 5 May 2010, the decision P/0275/2012 issued on 21 November 2012, and the decision P/0290/2013 issued on 29 November 2013.

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

The procedure started on 18 December 2013.

Scope of the modification

A deferral for the Paediatric Investigation Plan has been added.

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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 in the scope set out in the Annex I of this opinion;
   - to grant a deferral, the details of which are set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees 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 and appendix.

London, 14 February 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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)

Primary immunodeficiency (PID) as model for replacement therapy.

This covers replacement therapy in:

- Primary immunodeficiency syndromes;
- Myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinemia and recurrent infections;
- Children with congenital AIDS and recurrent infections.

The waiver applies to:

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

2. Paediatric Investigation Plan

2.1. Condition: treatment of primary immunodeficiency (PID)

2.1.1. Indication(s) 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

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

From 24 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Human normal immunoglobulin Solution for injection for subcutaneous use 160 g/L.

2.1.4. Measures

Area	Number of measures	Description
Quality related studies		Not applicable.
Non-clinical studies		Not applicable.

Area	Number of measures	Description
Clinical studies	1	**Study 1:** Open-Label Study to Evaluate the Pharmacokinetics, Safety and Tolerability Subcutaneous Immunoglobulin Preparation in the treatment of Hypo- or Agammaglobulinaemic patients.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By April 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes