



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/52893/2014

European Medicines Agency decision

P/0075/2014

of 2 April 2014

on the acceptance of a modification of an agreed paediatric investigation plan for human normal immunoglobulin (EMA-000775-PIP01-09-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 (EMA-000775-PIP01-09-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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/120/2010 issued on 9 July 2010,

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

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,

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

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, intravenous 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

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

Done at London, 2 April 2014

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

EMA/PDCO/746833/2013

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

EMA-000775-PIP01-09-M01

Scope of the application

Active substance(s):

Human normal immunoglobulin

Condition(s):

Treatment of Idiopathic thrombocytopenic purpura (ITP)

Treatment of 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 22 of Regulation (EC) No 1901/2006 as amended, Kedrion S.p.A. submitted to the European Medicines Agency on 22 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/120/2010 issued on 9 July 2010.

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

The procedure started on 18 December 2013.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified and a study has been added.

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.

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 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.

1.2. Condition treatment of 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.

2. Paediatric Investigation Plan

2.1. Condition treatment of Primary Immunodeficiency (PID)

2.1.1. 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.

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 infusion for intravenous use 100 g/L.

2.1.4. Studies

Area	Number of studies	Description
Quality related studies		Not applicable.
Non-clinical studies		Not applicable.
Clinical studies	2	Study 1 (KB052) Open-Label Multicentre Study to Evaluate the Pharmacokinetics, Safety and Tolerability of Intravenous Immunoglobulin Preparation in Patients with Primary Immunodeficiency (PID) Study 2 (KB060) Open-Label Multicentre Study to Evaluate the Pharmacokinetics, Safety and Tolerability of Intravenous Immunoglobulin Preparation in Patients with Primary Immunodeficiency (PID)

3. 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 December 2016
Deferral for one or more studies contained in the paediatric investigation plan:	No