



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/261595/2010

European Medicines Agency decision

P/73/2010

of 5 May 2010

on the acceptance of a modification of an agreed paediatric investigation plan for human normal immunoglobulin (EMEA-000454-PIP01-08-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-000454-PIP01-08-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/187/2009 issued on 8 September 2009,

Having regard to the application submitted by Kedrion S.p.A. on 24 December 2009 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 March 2010, 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 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

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

Done at London, 5 May 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/151465/2010

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

EMA-000454-PIP01-08-M01

Scope of the application

Active substance(s):

Human normal immunoglobulin

Condition(s):

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 24 December 2009 an application for modification of the agreed paediatric investigation plan and a waiver as set out in the European Medicines Agency's decision P/187/2009 of 8 September 2009. The application for modification proposed changes.

The procedure started on 21 January 2010.

Scope of the modification

The timelines of the original opinion 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 the changes proposed by the applicant regarding the timelines of the paediatric investigation plan.

The Norwegian Paediatric Committee member(s) agree(s) 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, 19 March 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)

Primary immunodeficiency (PID)

2. Waiver

2.1. Condition

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.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Primary immunodeficiency (PID) as model for replacement therapy

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 18 years.

3.1.3. Pharmaceutical form(s)

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

3.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical		Open-Label Study to Evaluate the Pharmacokinetics, Safety and Tolerability Subcutaneous Immunoglobulin Preparation in the Treatment of Hypo- or Agammaglobulinaemic patients.

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 December 2012
Deferral for some or all studies contained in the paediatric investigation plan:	No