EMA/553360/2011

European Medicines Agency decision

P/195/2011

of 29 July 2011

on the acceptance of a modification of an agreed paediatric investigation plan for human normal immunoglobulin (EMEA-000167-PIP01-07-M02) 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-000167-PIP01-07-M02) 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/115/2008 issued on 1 December 2008 and the decision P/77/2010 issued on 7 May 2010,

Having regard to the application submitted by LFB Biotechnologies on 2 May 2011 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 15 July 2011, 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 LFB Biotechnologies, 3, avenue des Tropiques B.P. 50052 - Les Ulis, 91942 Courtaboeuf, France.

Done at London, 29 July 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/364595/2011

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

EMEA-000167-PIP01-07-M02

Scope of the application

Active substance(s):

Human normal immunoglobulin

Condition(s):

Primary immunodeficiency (PID)

Idiopathic thrombocytopenic purpura (ITP)

Neonatal haemolytic disease (ABO - Rh-incompatability)

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

LFB Biotechnologies

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, LFB Biotechnologies submitted to the European Medicines Agency on 2 May 2011 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/115/2008 issued on 1 December 2008 and the decision P/77/2010 issued on 7 May 2010.

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

The procedure started on 18 May 2011.

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Scope of the modification

Some measures 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 changes to the paediatric investigation plan.

   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(es) and appendix.

London, 15 July 2011

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. Condition(s)

Primary immunodeficiency (PID);

Idiopathic thrombocytopenic purpura (ITP);

Neonatal haemolytic disease (ABO - Rh-incompatibility).

2. Waiver

2.1. Condition

1. 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 18 years of age for the solution for infusion for intravenous use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit.

2. Idiopathic thrombocytopenic purpura (ITP) as model for immunomodulation.
This covers:

- Idiopathic thrombocytopenic purpura, in children or adults at high risk of bleeding prior to surgery to correct the platelet count;
- 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 the solution for infusion for intravenous use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit.

3. Neonatal haemolytic disease (ABO - Rh-incompatability).
The waiver applies to:

- Infants and toddlers (from 28 days to less than 24 months), Children (from 2 to less than 12 years), Adolescents (from 12 to less than 18 years);
- for the solution for infusion for intravenous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Neonatal haemolytic disease (ABO - Rh-incompatability).

3.1.1. Indication targeted by the PIP

Treatment of neonatal haemolytic disease (ABO - Rh-incompatability).

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

From birth to less than 28 days of age.

3.1.3. Pharmaceutical form(s)

Human normal immunoglobulin Solution for infusion for intravenous use 5g/100 ml (5%).

3.1.4. Studies

Area	**Number of studies**	**Description**
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	1	Study 1) Systematic review of the literature and perform a meta-analysis of all existing trials focusing on the efficacy and safety.

4. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By November 2009
Deferral for one or more studies contained in the paediatric investigation plan:	No