EMA/773326/2015

European Medicines Agency decision

P/0295/2015

of 3 December 2015

on the acceptance of a modification of an agreed paediatric investigation plan for human normal immunoglobulin (Gammaplex), (EMEA-000830-PIP02-10-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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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/121/2011 issued on 7 June 2011 and the decision P/0172/2013 issued on 30 July 2013,

Having regard to the application submitted by Bio Products Laboratory Limited on 18 August 2015 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 November 2015, 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 (Gammaplex), 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 Bio Products Laboratory Limited, Dagger Lane, WD6 3BX - Elstree, Herts, United Kingdom.

Done at London, 3 December 2015

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/561185/2015
London, 13 November 2015

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

EMEA-000830-PIP02-10-M02

Scope of the application

Active substance(s):

Human normal immunoglobulin

Invented name:

Gammaplex

Condition(s):

Treatment of primary immunodeficiency as model for replacement therapy

Treatment of idiopathic thrombocytopenic purpura as model for immunomodulation

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Bio Products Laboratory Limited

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bio Products Laboratory Limited submitted to the European Medicines Agency on 18 August 2015 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/121/2011 issued on 7 June 2011 and the decision P/0172/2013 issued on 30 July 2013.

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

The procedure started on 15 September 2015.

Scope of the modification

Some measures of the Paediatric Investigation Plan 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 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 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 annexes and appendix.

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 (PIP)

1. Waiver

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition: treatment of primary immunodeficiency (PID) as model for replacement therapy.

2.1.1. Indication(s) targeted by the PIP

Treatment of PID as a model for replacement therapy in:

- primary immunodeficiency syndromes;
- myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections;
- children with congenital AIDS and recurrent infections.

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for infusion for intravenous use.

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Study 1: GMX04 Multicentre, open-label study to evaluate the efficacy, safety and pharmacokinetics of Gammaplex in primary immunodeficiency diseases (PID) in children and adolescents.

2.2. Condition: treatment of idiopathic thrombocytopenic purpura as model for immunomodulation.

2.2.1. Indication(s) targeted by the PIP

Treatment of idiopathic thrombocytopenic purpura as model for immunomodulation, to include:

- idiopathic thrombocytopenic purpura, in children or adults at high risk of bleeding or prior to surgery to correct the platelet count;
- Guillain Barré syndrome;
- Kawasaki disease.

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

From birth to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Solution for infusion for intravenous use.

2.2.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Study 1: GMX04 Multicentre, open-label study to evaluate the efficacy, safety and pharmacokinetics of Gammaplex in primary immunodeficiency diseases (PID) in children and adolescents.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use.	No
Date of completion of the paediatric investigation plan:	By August 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of primary immunodeficiency as model for replacement therapy.

Authorised indication:

Replacement therapy in adults, children and adolescents (0-18years):

- Primary immunodeficiency syndromes such as:
  - congenital agammaglobulinaemia and hypogammaglobulinaemia;
  - common variable immunodeficiency;
  - severe combined immunodeficiency;
  - Wiskott Aldrich syndrome.
- Myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections.
- Children with congenital AIDS and recurrent infections.

Authorised pharmaceutical form(s):

Sterile liquid for intravenous administration

Authorised route(s) of administration:

Intravenous use