EMA/355119/2011

European Medicines Agency decision

P/121/2011

of 7 June 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral for human normal immunoglobulin (Gammaplex), (EMEA-000830-PIP02-10) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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 application submitted by Bio Products Laboratory on 7 October 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 20 April 2011, in accordance with Article 18 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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting 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

A paediatric investigation plan for human normal immunoglobulin (Gammaplex), solution for infusion, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for human normal immunoglobulin (Gammaplex), solution for infusion, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Bio Products Laboratory, Dagger Lane, WD6 3BX, Elstree, Herts, United Kingdom.

Done at London, 7 June 2011

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

EMA/PDCO/101647/2011

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-000830-PIP02-10

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

Information about the authorised medicinal product:

See Annex II

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Bio Products Laboratory submitted for agreement to the European Medicines Agency on 7 October 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 18 November 2010.

Supplementary information was provided by the applicant on 2 February 2011. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation.

   The Icelandic Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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.

London, 20 April 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. 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 March 2013
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):

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.

EU Number	Invented name	Strength	Pharmaceu-tical form	Route of administration	Packaging	Content (concentration)	Package size
PL08801/0053	Gamma-plex	5g/100ml /	Sterile liquid for intravenous administra-tion	Intra-venous use	Type II glass bottle sealed with a halobutyl rubber stopper and aluminium overseal	5%	2.5 g 5 g 10 g