EMA/639654/2016

European Medicines Agency decision

P/0286/2016

of 4 November 2016

on the acceptance of a modification of an agreed paediatric investigation plan for human normal immunoglobulin (NAXIGLO and associated names), (EMEA-000454-PIP01-08-M07) 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 (NAXIGLO and associated names), (EMEA-000454-PIP01-08-M07) 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/187/2009 issued on 8 September 2009, the decision P/73/2010 issued on 5 May 2010, the decision P/0275/2012 issued on 21 November 2012, the decision P/0290/2013 issued on 29 November 2013, the decision P/0085/2014 issued on 4 April 2014, the decision P/0319/2014 issued on 19 December 2014, and the decision P/0113/2015 issued on 5 June 2015,

Having regard to the application submitted by Kedrion S.p.A. on 27 June 2016 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 September 2016, 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 and to the waiver.

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

[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 (NAXIGLO and associated names), solution for subcutaneous infusion, subcutaneous use, including changes to the waiver, 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.

EMA/PDCO/501386/2016
London, 16 September 2016

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-000454-PIP01-08-M07

Scope of the application

Active substance(s):

Human normal immunoglobulin

Invented name:

NAXIGLO and associated names

Condition(s):

Treatment of Primary Immunodeficiency (PID)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for subcutaneous infusion

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Kedrion S.p.A.

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, Kedrion S.p.A. submitted to the European Medicines Agency on 27 June 2016 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/187/2009 issued on 8 September 2009, the decision P/73/2010 issued on 5 May 2010, the decision P/0275/2012 issued on 21 November 2012, the decision P/0290/2013 issued on 29 November 2013, the decision P/0085/2014 issued on 4 April 2014, the decision P/0319/2014 issued on 19 December 2014, and the decision P/0113/2015 issued on 5 June 2015.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and changes to the waiver to cover the remaining subsets of the paediatric population.

The procedure started on 19 July 2016.

Scope of the modification

The waiver has been extended to cover all subsets of the paediatric population.

Opinion

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 and to amend the scope of the waiver in the scope set out in the Annex I of this opinion in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition

Treatment of Primary Immunodeficiency (PID)

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- solution for subcutaneous infusion, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

1. Treatment of immunodeficiencies

Authorised indication(s):

- Replacement therapy in adults in case of:
  - Primary immunodeficiency syndromes with impaired antibody production (see section 4.4).
  - Hypogammaglobulinaemia and recurrent bacterial infections in patients with chronic lymphocytic leukaemia (CLL), in whom prophylactic antibiotics have failed or are contra-indicated.
  - Hypogammaglobulinaemia and recurrent bacterial infections in multiple myeloma (MM) patients.
  - Hypogammaglobulinaemia in patients pre- and post- allogeneic haematopoietic stem cell transplantation (HSCT).

Authorised pharmaceutical form(s)

Solution for subcutaneous infusion

Authorised route(s) of administration

Subcutaneous use