European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 14 August 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for human normal immunoglobulin (Gammagen) (EMEA-000415-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 Orfagen on 7 November 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 June 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines has given an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver,

(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,

(4) It is therefore appropriate to adopt a Decision granting a 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

A Paediatric Investigation Plan for human normal immunoglobulin (Gammagen), 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 (Gammagen), 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

A waiver for human normal immunoglobulin (Gammagen), 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 4

This decision is addressed to Orfagen, Parc Technologique du Canal, 4 rue Marie Curie, BP 22132, 31521 Ramonville Saint Agne, France.

Done at London, 14 August 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/359588/2009
EMEA-000415-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

Scope of the application

Active substance(s):
Human normal immunoglobulin

(Invented) name:
Gammagen

Condition(s):
Dermatopolymyositis

Pharmaceutical form(s):
Solution for infusion

Route(s) of administration:
Intravenous use

Name/corporate name of the PIP applicant:
Orfagen

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 16 of Regulation (EC) No 1901/2006 as amended, Orfagen submitted for agreement to the EMEA on 7 November 2008 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 11 December 2008.

Supplementary information was provided by the applicant on 17 April 2009

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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,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Articles 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

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

2. 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 are set out in the Annex I.

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

London, 26 June 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

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

A. CONDITION(S)

Dermatopolymyositis

B. WAIVER

- **Condition**

Dermatopolymyositis

The waiver applies to:

- Paediatric population from birth to less than 2 years of age
- for 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).

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Dermatopolymyositis

- **Proposed PIP indication**

Treatment of Juvenile Dermatomyositis (JDM), Polymyositis in children and Overlap Myositis in children

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 2 to less than 18 years

- **Formulation(s)**

Solution for infusion for intravenous use

- **Studies**

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	1	Efficacy and safety of a human normal immunoglobulin product for intravenous administration (IVIg) in the treatment of juvenile dermatomyositis (JDM), juvenile polymyositis (PM) and juvenile overlap myositis: prospective, randomised, double-blind, comparative, two-parallel group, multicentric study in children from 2 to less than 18 years of age.

Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By September 2014**
Deferral for some or all studies contained in the paediatric investigation plan:	**No**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

Invented Name	Strength	Pharmaceutical Form	Route Administration
Ig VENA	50 g/l solution for infusion 20 ml	Solution for infusion	Intravenous use
Ig VENA	50 g/l solution for infusion 50 ml	Solution for infusion	Intravenous use
Ig VENA	50 g/l solution for infusion 100 ml	Solution for infusion	Intravenous use
Ig VENA	50 g/l solution for infusion 200 ml	Solution for infusion	Intravenous use