European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 24 June 2008

on the application for agreement of a Paediatric Investigation Plan for tifacogin EMEA-000027-PIP01-07 in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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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 Novartis Europharm Limited on 26 July 2007 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 8 May 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, 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 Agency has given a positive opinion,

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting a waiver.

(4) 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 tifacogin, 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 waiver for tifacogin, solution for infusion, intravenous use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A deferral for tifacogin, solution for infusion, intravenous use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Novartis Europharm Limited, Wimblehurst Road, Horsham, RH12 5AB.

Done at London, 24 June 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

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

EMEA/PDCO/222202/2008
EMEA-000027-PIP01-07

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR

Scope of the application

Active substance:
Tifacogin

Condition(s):
Septicaemia

Pharmaceutical form(s):
Solution for infusion

Route(s) of administration:
Intravenous use

Name/corporate name of the PIP applicant:
Novartis Europharm Limited

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted for agreement to the EMEA on 26 July 2007 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 30 August 2007.

Supplementary information was provided by the applicant on 6 March 2008.

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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 Regulation (EC) No 1901/2006 as amended,
- to grant a deferral in accordance with Article 21 of Regulation (EC) No 1901/2006 as amended
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended and concluded in accordance with Article 11(1)(a) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population

The Icelandic and the Norwegian Paediatric Committee members agree 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 annex(es) and appendix(ces).

London, 8 May 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

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) / DISEASE(S)

Septicaemia

B. WAIVER

Condition

Septicaemia

Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered
The waiver applies to neonates and infants from 0 to less than 4 months of age for the solution for infusion

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Septicaemia

- **Proposed PIP indication**

Adjunctive treatment of children with severe sepsis with coagulopathy, including but not limited to children with severe community acquired pneumonia.

- **Subset(s) covered**

Children from 4 months to less than 18 years

- **Formulation(s)**

Solution for infusion

- **Studies / Measures**

Area	Subarea	Number	Description
Clinical	Pharmacokinetic	1	Phase 1 ascending dose pharmacokinetic/pharmacodynamic study in paediatric population aged from 4 months to less than 18 years of age admitted with a febrile illness suspected or proven to be secondary to infection
	Efficacy and safety	1	Multicenter, double-blind, randomised, placebo-controlled study to assess efficacy and safety of tifacogin in pediatric population with severe sepsis with coagulopathy aged from 4 months to less than 18 years.

Need for paediatric measures in a EU-Risk Management Plan: To be rediscussed with the PDCO

Date of completion of the paediatric investigation plan: by 30 September 2013

A deferral has been granted: Yes