European Medicines Agency

Doc. Ref. EMEA/272680/2009
P/85/2009

EUROPEAN MEDICINES AGENCY DECISION

of 18 May 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for tigecycline (Tygacil), (EMEA-000120-PIP01-07-M01) 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 decision P/113/2008 of the European Medicines Agency on 1 December 2008,

Having regard to the application submitted by Wyeth Europa Limited on 24 December 2008 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 3 April 2009, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

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 an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an 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 tigecycline (Tygacil), powder for 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, are hereby accepted.

Article 2

This decision, that supersedes previous decision of the European Medicines Agency P/113/2008, is addressed to Wyeth Europa Limited, Huntercombe Lane South, Taplow, Maidenhead, SL6 0PH, United Kingdom.

Done at London, 18 May 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/113770/2009
EMEA-000120-PIP01-07-M01

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance(s):
Tigecycline

(Invented) name:
Tygacil

Condition(s):
Complicated skin and soft tissue infections
Complicated intra-abdominal infections
Diabetic Foot Infections

Pharmaceutical form(s):
Powder for solution for infusion

Route(s) of administration:
Intravenous use

Name/corporate name of the PIP applicant:
Wyeth Europa Limited

Information about the authorised medicinal product:
See Annex II.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Wyeth Europa Limited submitted to the EMEA on 24 December 2008 an application for modification of the agreed paediatric investigation plan and a waiver, as set out in the EMEA decision P/113/2008 of 1 December 2008, proposing changes.

The procedure started on 5 February 2009.

Scope of the modification

The applicant proposed modifications to the agreed PIP to clarify and revise some of the agreed measures and timelines.

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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 the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan

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 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, 3 April 2009

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)

Complicated skin and soft tissue infections (cSSTI)
Complicated intra-abdominal infections (cIAI)
Diabetic Foot Infections

B. WAIVER

- **Condition**

Complicated skin and soft tissue infections

- **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to children aged 0 to less than 8 years of age for powder for solution for infusion, intravenous use, on the grounds that the specific medicinal product is likely to be unsafe.

- **Condition**

Complicated intra-abdominal infections

- **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration Covered**

The waiver applies to children aged 0 to less than 8 years of age, for powder for solution for infusion, intravenous use, on the grounds that the specific medicinal product is likely to be unsafe.

- **Condition**

Diabetic Foot Infections with/without osteomyelitis

- **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to all paediatric subsets for powder for solution for infusion, intravenous use, on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

C. PAEDIATRIC INVESTIGATION PLAN

- **Conditions to be investigated**
  C.1
  Complicated skin and soft tissue infections

  C.2
  Complicated intra-abdominal infections

- **Proposed PIP indication**
  Treatment of patients aged 8 to less than 18 years with
  - complicated skin and soft tissue infections
  - complicated intra-abdominal infections

- **Subset(s) covered**
  Children aged 8 to less than 18 years

- **Formulation(s)**
  Powder for Solution for Infusion

- **Studies**

Area	Subarea	Number	Description
Clinical	PK, safety and tolerability	**1**	An open-label, multiple ascending dose pharmacokinetic, safety and tolerability study in patients (8-11 years old) with selected serious infections who require intravenous antibiotic therapy.
	Safety and Efficacy	**1**	A randomized double-blind (third-party unblinded), multi-center, active-comparator, non-inferiority study of the safety and efficacy of tigecycline in 8-17 years old patients with cSSTI including those caused by MRSA.
	Safety	**1**	A randomized double-blind (third-party unblinded), multi-center, active-comparator, safety study in 8-17 years old patients with complicated intra-abdominal infections or community acquired pneumonia.

Measures to address long term follow-up on potential safety issues in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**by November 2012**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name	Strength	Pharmaceutical Form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/06/336/001	Tygacil	50 mg	Powder for solution for infusion	Intravenous use	Vial (glass)	5 ml	10 vials