EMA/795743/2012

European Medicines Agency decision

P/0002/2013

of 18 January 2013

on the acceptance of a modification of an agreed paediatric investigation plan for tigecycline (Tygacil), (EMEA-000120-PIP01-07-M03) 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 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Medicines Agency decision

P/0002/2013

of 18 January 2013

on the acceptance of a modification of an agreed paediatric investigation plan for tigecycline (Tygacil), (EMEA-000120-PIP01-07-M03) 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/113/2008 issued on 1 December 2008, and the decision P/85/2009 issued on 18 May 2009,

Having regard to the application submitted by Pfizer Limited on 14 September 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 7 December 2012, 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 tigecycline (Tygacil), powder for solution for infusion, intravenous 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 Pfizer Limited, Ramsgate Road, Sandwich - CT13 9NJ, United Kingdom.

Done at London, 18 January 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/615153/2012

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000120-PIP01-07-M03

Scope of the application

Active substance(s):

Tigecycline

Invented name:

Tygacil

Condition(s):

Treatment of complicated skin and soft tissue infections

Treatment of complicated intra-abdominal infections

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Pfizer Limited

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 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Limited submitted to the European Medicines Agency on 14 September 2012 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/113/2008 issued on 1 December 2008, and the decision P/85/2009 issued on 18 May 2009.

The application for modification proposed changes to the agreed paediatric investigation plan and to the waiver.

The procedure started on 10 October 2012.

Scope of the modification

Amendment of the scope of the Paediatric Investigation Plan to exclude a condition. Some timelines of the Paediatric Investigation Plan have been modified.

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 changes to the paediatric investigation plan and to the waiver in the scope set out in the Annex I of this opinion.

   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 European Medicines Agency, together with its annexes and appendix.

London, 7 December 2012

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

1.1. Condition: treatment of complicated skin and soft tissue infections

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.

1.2. Condition: treatment of complicated intra-abdominal infections

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.

2. Paediatric Investigation Plan

2.1. Condition: treatment of complicated skin and soft tissue infections

2.1.1. Indication(s) targeted by the PIP

Treatment of patients aged 8 to less than 18 years with complicated skin and soft tissue infections.

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 8 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for solution for infusion

2.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	2	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. 2. 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 complicated skin and soft tissue infections (cSSTI) including those caused by MRSA.

2.2. Condition: treatment of complicated intra-abdominal infections

2.2.1. Indication(s) targeted by the PIP

Treatment of patients aged 8 to less than 18 years with complicated intra-abdominal infections.

2.2.2. Subset(s) of the paediatric population concerned by the paediatric development

From 8 years to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Powder for Solution for Infusion

2.2.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	2	1. Same study as for condition "treatment of complicated skin and soft tissue infections": 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. 3. A randomized double-blind (third-party unblinded), multi-center, active-comparator, safety study in 8-17 years old patients with complicated intra-abdominal infections (cIAI) or community acquired pneumonia (CAP).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By November 2015
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of complicated skin and soft tissue infections

   Authorised indication:

   - Tygacil is indicated in adults for the treatment of complicated skin and soft tissue infections, excluding diabetic foot infections.

2. Treatment of complicated intra-abdominal infections

   Authorised indication:

   - Tygacil is indicated in adults for the treatment of complicated intra-abdominal infections.

Authorised pharmaceutical formulation(s):

Powder for solution for infusion

Authorised route(s) of administration:

Intravenous use