EMA/640003/2014

European Medicines Agency decision

P/0292/2014

of 24 October 2014

on the acceptance of a modification of an agreed paediatric investigation plan for tigecycline (Tygacil), (EMEA-000120-PIP01-07-M05) 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

An agency of the European Union

European Medicines Agency decision

P/0292/2014

of 24 October 2014

on the acceptance of a modification of an agreed paediatric investigation plan for tigecycline (Tygacil), (EMEA-000120-PIP01-07-M05) 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, the decision P/85/2009 issued on 18 May 2009, and the decision P/0002/2013 issued on 18 January 2013,

Having regard to the application submitted by Pfizer Limited on 21 July 2014 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 10 October 2014, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the 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, 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, CT13 9NJ – Sandwich, United Kingdom.

Done at London, 24 October 2014

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

EMA/PDCO/459228/2014

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

EMEA-000120-PIP01-07-M05

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

An agency of the European Union

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Limited submitted to the European Medicines Agency on 21 July 2014 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, the decision P/85/2009 issued on 18 May 2009, and the decision P/0002/2013 issued on 18 January 2013.

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

The procedure started on 13 August 2014.

Scope of the modification

Some measures and 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 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, 10 October 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 (PIP)

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.

1.1. 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 with limited treatment options.

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. Measures

Area	Number of studies	Description
Quality-related studies		Not applicable.
Non-clinical studies		Not applicable.

Area	Number of studies	Description
Clinical studies	1	Study 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.
Extrapolation, modelling and simulation studies	2	Study 2: Modelling and simulation study to define the dose for use of tigecycline in children from 8 years to less than 18 years of age with complicated skin and soft tissue infections and complicated intra-abdominal infections. Study 3 Extrapolation study to evaluate the use of tigecycline in children from 8 years to less than 18 years of age with complicated skin and soft tissue infections complicated intra-abdominal infections.
Other studies	1	Study 4 A systematic review of all in-house and published literature data on use of tigecycline in the paediatric population together with an analysis of available preclinical and microbiological data.
Other measures		Not applicable.

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 with limited treatment options.

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. Measures

Area	Number of studies	Description
Quality-related studies		Not applicable.
Non-clinical studies		Not applicable.
Clinical studies	1	Study 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.
Extrapolation, modelling and simulation studies	2	Study 2 Same study as for condition “treatment of complicated skin and soft tissue infections”: Modelling and simulation study to define the dose for use of tigecycline in children from 8 years to less than 18 years of age with complicated skin and soft tissue infections and complicated intra-abdominal infections. Study 3 Same study as for condition “treatment of complicated skin and soft tissue infections”: Extrapolation study to evaluate the use of tigecycline in children from 8 years to less than 18 years of age with complicated skin and soft tissue infections and complicated intra-abdominal infections.
Other studies	1	Study 4 Same study as for condition “treatment of complicated skin and soft tissue infections”: A systematic review of all in-house and published literature data on use of tigecycline in the paediatric population together with an analysis of available preclinical and microbiological data.
Other measures		Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2010
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.

Tygacil should be used only in situations where it is known or suspected that other alternatives are not suitable.

Authorised pharmaceutical formulation(s):

Powder for solution for infusion

Authorised route(s) of administration:

Intravenous use