EMA/249385/2016

European Medicines Agency decision

P/0119/2016

of 28 April 2016

on the acceptance of a modification of an agreed paediatric investigation plan for solithromycin (EMEA-001581-PIP01-13-M02) 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

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on the acceptance of a modification of an agreed paediatric investigation plan for solithromycin (EMEA-001581-PIP01-13-M02) 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/0254/2014 issued on 30 September 2014,

Having regard to the application submitted by Triskel EU Services, Ltd on 4 January 2016 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 1 April 2016, 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 deferral 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 deferral and 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 solithromycin, capsule, hard, powder for concentrate for solution for infusion, powder for oral suspension, oral use, intravenous use, including changes to the deferral and 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 Triskel EU Services, Ltd, c/o CODDAN CPM Ltd., 120 Baker Street, W1U 6TY – London, United Kingdom.

Done at London, 28 April 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/18305/2016
London, 1 April 2016

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

EMEA-001581-PIP01-13-M02

Scope of the application

Active substance(s):

Solithromycin

Condition(s):

Treatment of bacterial pneumonia

Treatment of tularaemia

Treatment of anthrax

Pharmaceutical form(s):

Capsule, hard

Powder for concentrate for solution for infusion

Powder for oral suspension

Route(s) of administration:

Oral use

Intravenous use

Name/corporate name of the PIP applicant:

Triskel EU Services, Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Triskel EU Services, Ltd submitted to the European Medicines Agency on 4 January 2016 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0254/2014 issued on 30 September 2014.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
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The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and to the waiver.

The procedure started on 2 February 2016.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Amendment of the scope of the Paediatric Investigation Plan - changes in the conditions and the waiver.

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 deferral and to the waiver in the scope set out in the Annex I of this opinion.

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

2. The measures and timelines of the paediatric investigation plan 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 annex and appendix.

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

Not applicable

2. Paediatric investigation plan

2.1. Condition

Treatment of bacterial pneumonia

2.1.1. Indication(s) targeted by the PIP

Treatment of bacterial pneumonia

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Capsule, hard

Powder for concentrate for solution for infusion

Powder for oral suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1) Development of powder for oral suspension Same study as study 1 in the PIP EMEA-001581-PIP02-16 and subsequent modifications.
Non-clinical studies	1	Study 2) 1410-010 Reprotox study of pre- and postnatal development to evaluate adverse effects of the test article on the pregnant/lactating female and on the development of the conceptus and the offspring. Same study as study 2 in the PIP EMEA-001581-PIP02-16 and subsequent modifications.
Clinical studies	3	Study 3) Open-label, multi-centre study to evaluate the PK and safety of a 5-day oral dosing regimen of solithromycin as add-on therapy

		to antimicrobial agent administered to patients (from 12 to less than 18 years of age) with a suspected or confirmed infection Same study as study 3 in the PIP EMEA-001581-PIP02-16 and subsequent modifications. Study 4) Open-label, multi-centre study to evaluate the PK and safety of solithromycin (IV or oral) as add-on therapy to antimicrobial agent administered to patients (from birth to less than 18 years of age) with a suspected or confirmed infection Same study as study 4 in the PIP EMEA-001581-PIP02-16 and subsequent modifications. Study 5) Randomised, investigator blinded, multi-centre, comparative study to determine the safety and activity of solithromycin (intravenous and oral) in patients from 2 months to less than 18 years of age with suspected or confirmed community acquired bacterial pneumonia (CABP) Same study as study 5 in the PIP EMEA-001581-PIP02-16 and subsequent modifications. Study 6) Removed during modification of an agreed PIP EMEA-001581-PIP01-13-M02.
Extrapolation, modelling and simulation studies	1	Study 7) Analysis of existing in house data on solithromycin
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.2. Condition

Treatment of tularaemia

2.2.1. Indication(s) targeted by the PIP

Treatment of inhalation tularaemia following exposure to Francisella tularaensis

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

From birth to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Capsule, hard

Powder for concentrate for solution for infusion

Powder for oral suspension

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1) 1386099617462 Same as for bacterial pneumonia
Non-clinical studies	1	Study 2) 1410-010 Same as for bacterial pneumonia Study 8) FY14-020 Exploratory toxicity/efficacy study
Clinical studies	0	Not applicable.
Extrapolation, modelling and simulation studies	1	Study 7) Same as for bacterial pneumonia
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.3. Condition

Treatment of anthrax

2.3.1. Indication(s) targeted by the PIP

Treatment of inhalation anthrax following exposure to *Bacillus anthracis*

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

From birth to less than 18 years of age.

2.3.3. Pharmaceutical form(s)

Capsule, hard

Powder for concentrate for solution for infusion

Powder for oral suspension

2.3.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1) 1386099617462 Same as for bacterial pneumonia
Non-clinical studies	0	Study 2) 1410-010 Same as for bacterial pneumonia Study 9) 3169-100047701 Exploratory toxicity/efficacy study
Clinical studies	0	Not applicable.
Extrapolation, modelling and simulation studies	1	Study 7) Same as for bacterial pneumonia
Other studies	0	Not applicable.
Other measures	0	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 February 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes