



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/528092/2014

European Medicines Agency decision

P/0254/2014

of 30 September 2014

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for solithromycin (EMA-001581-PIP01-13) 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.



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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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Triskel EU Services, Ltd on 13 December 2013 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 August 2014, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation, and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.
- (4) It is therefore appropriate to adopt a decision granting a 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

A paediatric investigation plan for solithromycin, capsule, hard, powder and solvent for solution for injection, powder for oral suspension, oral use, 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 deferral for solithromycin, capsule, hard, powder and solvent for solution for injection, powder for oral suspension, oral 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 granted.

Article 3

A waiver for solithromycin, capsule, hard, powder and solvent for solution for injection, powder for oral suspension, oral 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 granted.

Article 4

This decision is addressed to Triskel EU Services, Ltd, 124 Baker Street, W1U 6TY – London, United Kingdom.

Done at London, 30 September 2014

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/338024/2014

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA-001581-PIP01-13

Scope of the application

Active substance(s):

Solithromycin

Condition(s):

Treatment of bacterial pneumonia

Treatment of gonococcal infection

Pharmaceutical form(s):

Capsule, hard

Powder and solvent for solution for injection

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 16(1) of Regulation (EC) No 1901/2006 as amended, Triskel EU Services, Ltd submitted for agreement to the European Medicines Agency on 13 December 2013 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 21 January 2014.



Supplementary information was provided by the applicant on 26 May 2014. The applicant proposed modifications to the paediatric investigation plan.

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 said Regulation;
- to grant a deferral in accordance with Article 21 of said Regulation;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Norwegian Paediatric Committee member agrees 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 European Medicines Agency, together with its annex and appendix.

London, 15 August 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 gonococcal infection

The waiver applies to:

- the paediatric population from birth to less than 12 years;
- capsule, hard; oral use, and powder and solvent for solution for injection; intravenous use, and powder for oral suspension; oral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

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 and solvent for solution for injection

Powder for oral suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1) 1386099617462 Development of powder for oral suspension
Non-clinical studies	1	Study 2) 1410-010, PIP study number 1386182902762 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

Area	Number of measures	Description
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 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 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)
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.2. Condition:

Treatment of gonococcal infection

2.2.1. Indication(s) targeted by the PIP

Treatment of gonococcal infection

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

From 12 to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Capsule, hard

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1) 1386099617462 See "Treatment of bacterial pneumonia"
Non-clinical studies	1	Study 2) 1410-010, PIP study number 1386182902762 See "Treatment of bacterial pneumonia"
Clinical studies	3	Study 3) See "Treatment of bacterial pneumonia" Study 4) See "Treatment of bacterial pneumonia" Study 6) Open-label, randomized, multi-centre study to evaluate the efficacy and safety of a single-dose of oral solithromycin compared to single-dose intramuscular ceftriaxone plus single-dose oral azithromycin in patients with uncomplicated urogenital gonorrhoea
Extrapolation, modelling and simulation studies	0	Not applicable.
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 2018
Deferral for one or more measures contained in the paediatric investigation plan:	Yes