EMA/266752/2016

European Medicines Agency decision

P/0120/2016

of 28 April 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for solithromycin (EMEA-001581-PIP02-16) 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

European Medicines Agency decision

P/0120/2016

of 28 April 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for solithromycin (EMEA-001581-PIP02-16) 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 application submitted by Triskel EU Services, Ltd. on 25 January 2016 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 1 April 2016, in accordance with Article 18 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 agreement of a paediatric investigation plan.

(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 for concentrate for solution for infusion, 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 agreed.

Article 2

A deferral for solithromycin, capsule, hard, powder for concentrate for solution for infusion, 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 for concentrate for solution for infusion, 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, 120 Baker Street, c/o Coddan CPM Ltd, 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/147607/2016
London, 1 April 2016

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

EMEA-001581-PIP02-16

Scope of the application

Active substance(s):

Solithromycin

Condition(s):

Treatment of gonococcal infection

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 16(1) of Regulation (EC) No 1901/2006 as amended, Triskel EU Services, Ltd. submitted for agreement to the European Medicines Agency on 25 January 2016 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 1 March 2016.

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.

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 gonococcal infection

2.1.1. Indication(s) targeted by the PIP

Treatment of gonococcal infection

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

From 12 years 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-PIP01-13 and subsequent modifications.

Non-clinical studies	1	Study 2) 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-PIP01-13 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-PIP01-13 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-PIP01-13 and subsequent modifications. Study 5) 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 August 2016
Deferral for one or more measures contained in the paediatric investigation plan:	Yes