EMA/779669/2014

European Medicines Agency decision

P/0019/2015

of 30 January 2015

on the acceptance of a modification of an agreed paediatric investigation plan for surotomycin (EMEA-001226-PIP01-11-M01) 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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on the acceptance of a modification of an agreed paediatric investigation plan for surotomycin (EMEA-001226-PIP01-11-M01) 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/0096/2013 issued on 29 April 2013,

Having regard to the application submitted by Cubist (UK) Ltd. on 19 September 2014 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 December 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 and to the deferral.

(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.

[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 surotomycin, tablet, age-appropriate oral solid formulation, oral use, including changes to the deferral, 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 Cubist (UK) Ltd., 2nd Floor, Waverley House, 7-12 Noel Street, W1F8GQ – London, United Kingdom.

Done at London, 30 January 2015

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

EMA/PDCO/582106/2014

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

EMEA-001226-PIP01-11-M01

Scope of the application

Active substance(s):

Surotomycin

Condition(s):

Treatment of clostridia infections

Pharmaceutical form(s):

Tablet

Age-appropriate oral solid formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Cubist (UK) Ltd.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Cubist (UK) Ltd. submitted to the European Medicines Agency on 19 September 2014 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0096/2013 issued on 29 April 2013.

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

The procedure started on 14 October 2014.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

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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 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 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, 12 December 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

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of clostridia infections

2.1.1. Indication(s) targeted by the PIP

Treatment of *Clostridium difficile* associated diarrhoea

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)

Tablet

Age-appropriate oral solid formulation

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate oral solid formulation that can be dispersed or dissolved.
Non-clinical studies	3	**Study 2** Single-dose subcutaneous pharmacokinetic study in juvenile dogs. **Study 3** 14-day subcutaneous dose ranging study including toxicokinetics in juvenile dogs. **Study 4** 1-month subcutaneous toxicity study in juvenile dogs.
Clinical studies	2	**Study 5** Open-label, multiple dose trial to evaluate safety and pharmacokinetics of surotomycin in children from birth to less than 18 years of age with *C. difficile* infection.

Area	Number of measures	Description
		Study 6 Evaluator-blinded, randomised, multiple dose, active controlled trial to evaluate safety and tolerability of surotomycin in children from birth to less than 18 years of age with *C. difficile* infection.
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 December 2021
Deferral for one or more measures contained in the paediatric investigation plan:	Yes