EMA/335570/2010

European Medicines Agency decision

P/98/2010

of 4 June 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral for fidaxomicin (EMEA-000636-PIP01-09) 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 agreement of a paediatric investigation plan and on the granting of a deferral for fidaxomicin (EMEA-000636-PIP01-09) 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 FGK Representative Service GmbH on 18 June 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 April 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 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,

(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.

[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 fidaxomicin, tablet, powder for oral use, 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 fidaxomicin, tablet, powder for oral use, 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

This decision is addressed to FGK Representative Service GmbH, Heimeranstrasse 35, 80339 Munich, Germany.

Done at London, 4 June 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

EMA/PDCO/227240/2010

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

EMEA-000636-PIP01-09

Scope of the application

Active substance(s):

Fidaxomicin

Condition(s):

Enterocolitis caused by Clostridium difficile

Pharmaceutical form(s):

Tablet

Powder for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

FGK Representative Service GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, FGK Representative Service GmbH submitted for agreement to the European Medicines Agency on 18 June 2009 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 23 July 2009.

Supplementary information was provided by the applicant and the waiver application was withdrawn on 5 February 2010.

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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.

   The Icelandic and the Norwegian Paediatric Committee member(s) agree(s) with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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(es) and appendix.

London, 16 April 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

The measures and timelines of the agreed Paediatric Investigation Plan

1. Condition(s)

Enterocolitis caused by Clostridium difficile

2. Waiver

Not applicable

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Enterocolitis caused by Clostridium difficile

3.1.1. Indication targeted by the PIP

Treatment of enterocolitis caused by Clostridium difficile

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

From birth to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Powder for oral suspension

Tablet

3.1.4. Studies

Area	Number of studies	Description
Quality	1	1. Development of an age-appropriate oral suspension formulation for use in children from birth to less than 18 years
Non-clinical	3	2. Pharmacokinetic evaluation of fidaxomicin oral suspension as compared to fidaxomicin oral tablets in adult beagle dogs 3. Dose range-finding study for the evaluation of toxicokinetics and tolerability of fidaxomicin oral suspension in young beagle dogs 4. Study for the evaluation of toxicity and toxicokinetics and effect on the developing gastrointestinal tract of fidaxomicin oral suspension in young beagle dogs
Clinical	5	5. Multi-centre, open-label study to determine the safety and pharmacokinetics of fidaxomicin oral suspension and tablets taken q12h for ten days in paediatric patients aged 2 to less than 18 years with Clostridium difficile Associated Disease (CDAD) 6. Multi-centre, open label, randomized, parallel-group study to

Area	Number of studies	Description
		compare the safety and efficacy of fidaxomicin oral suspension and tablets taken q12h, with vancomycin oral suspension and capsules taken q6h, for ten days in paediatric patients aged 2 to less than 18 years with Clostridium difficile Associated Disease (CDAD) 7. Multi-centre, open label, randomized, parallel-group study to compare the safety and efficacy of fidaxomicin oral suspension taken q12h, with vancomycin oral suspension taken q6h, for ten days in paediatric patients aged 1 to less than 24 months with Clostridium difficile Associated Disease (CDAD) 8. Study to determine the role of Clostridium difficile in the pathogenesis of disease observed in neonates and to investigate the feasibility of a study to evaluate safety, efficacy and pharmacokinetics of fidaxomicin oral suspension in neonates with Clostridium difficile Associated Disease (CDAD) 9. Study to evaluate safety, efficacy and pharmacokinetics of fidaxomicin oral suspension in neonates with Clostridium difficile Associated Disease (CDAD)

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues and/or efficacy in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes