

EMA/711355/2014

European Medicines Agency decision

P/0340/2014

of 22 December 2014

on the agreement of a paediatric investigation plan and on the granting of a deferral for *Clostridium difficile* toxin B human monoclonal antibody (EMEA-001645-PIP01-14) 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 Merck Sharp & Dohme (Europe), Inc. on 8 August 2014 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 14 November 2014, 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 *Clostridium difficile* toxin B human monoclonal antibody, concentrate for solution for infusion, 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 *Clostridium difficile* toxin B human monoclonal antibody, concentrate for solution for infusion, 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 granted.

Article 3

This decision is addressed to Merck Sharp & Dohme (Europe), Inc., Clos du Lynx, 5, B-1200 – Brussels, Belgium.

Done at London, 22 December 2014

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/622030/2014

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

EMA-001645-PIP01-14

Scope of the application

Active substance(s):

Clostridium difficile toxin B human monoclonal antibody

Condition(s):

Treatment of *Clostridium difficile* infection

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name / corporate name of the PIP applicant:

Merck Sharp & Dohme (Europe), Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe), Inc. submitted for agreement to the European Medicines Agency on 8 August 2014 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 16 September 2014.



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 members agree 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 and appendix.

London, 14 November 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 *Clostridium difficile* infection

2.1.1. Indication(s) targeted by the PIP

Prevention of recurrence of *Clostridium difficile* infection related diarrhoea in adults and paediatric patients

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)

Concentrate for solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1: Development of a vial containing max. 25 mL of 25 mg/ml concentrate for solution for infusion of <i>Clostridium difficile</i> toxin B human monoclonal antibody.
Non-clinical studies	0	Not applicable.
Clinical studies	2	Study 2: Randomised, double-blind, single dose, placebo controlled trial to evaluate efficacy, safety, and pharmacokinetics of <i>Clostridium difficile</i> toxin B human monoclonal antibody (MK-6072) as add-on to standard of care antibiotic treatment in children from 2 to less than 18 years of age with <i>Clostridium difficile</i> infection (CDI). Study 3: Open label, single dose trial to evaluate safety, tolerability, and pharmacokinetics of <i>Clostridium difficile</i> toxin B human monoclonal antibody (MK-6072) in children from birth to less than 2 years of age with suspected or documented <i>Clostridium difficile</i> Infection (CDI), or at risk for developing CDI.

Area	Number of measures	Description
Extrapolation, modelling and simulation studies	1	Study 4 Modelling and simulation study to evaluate the use of <i>Clostridium difficile</i> toxin B human monoclonal antibody (MK-6072) in children from birth to less than 18 years of age with <i>Clostridium difficile</i> Infection (CDI).
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:	No
Date of completion of the paediatric investigation plan:	By November 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes