



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/525486/2010

European Medicines Agency decision P/154/2010

of 27 August 2010

on the acceptance of a modification of an agreed paediatric investigation plan for boceprevir,
(EMA-000583-PIP01-09-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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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 European Medicines Agency's decision P/97/2010 issued on 4 June 2010,

Having regard to the application submitted by Merck Sharp & Dohme Ltd on 28 June 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 August 2010, 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 boceprevir, granules, hard capsules, oral use, including changes to a 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 Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon EN11 9BU, United-Kingdom.

Done at London, 27 August 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/483452/2010

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000583-PIP01-09-M01

Scope of the application

Active substance(s):

Boceprevir

Condition(s):

Chronic Hepatitis C

Pharmaceutical form(s):

Granules

Hard capsules

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Merck Sharp & Dohme Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme Ltd submitted to the European Medicines Agency on 28 June 2010 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/97/2010 issued on 4 June 2010.

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

The procedure started on 15 July 2010.



Scope of the modification

Some timelines of the original Opinion have been modified.

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 on changes to the paediatric investigation plan and to the deferral.

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

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

London, 6 August 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 and the subset(s) of the paediatric population and condition(s) covered by the waiver

1. Condition(s)

Chronic Hepatitis C

2. Waiver

2.1. Condition(s)

The waiver applies to:

- The paediatric population from birth to less than 3 years of age.
- for hard capsule, granules, oral use
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Chronic Hepatitis C

3.1.1. Indication(s) targeted by the PIP

Treatment of children and adolescents from 3 years to less than 18 years of age with genotype 1 chronic HCV infection and without liver decompensation.

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

From 3 to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Hard capsule for oral use

Age-appropriate granules for oral use

3.1.4. Studies

Area	Number of studies	Description
Quality	1	Development of the granule formulation, including palatability testing, formulation selection and manufacture, bioavailability testing, and formulation development scale-up.
Non-clinical	2	One-month thyroid hormone evaluation study of boceprevir in juvenile rats Testicular toxicity and toxicokinetic study of oral (gavage) boceprevir in

		male neonatal rats
Clinical	1	PK, efficacy, and safety study of boceprevir in combination to peginterferon + ribavirin versus peginterferon + ribavirin in children and adolescents 3 to less than 18 years of age with chronic hepatitis C genotype 1

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues, efficacy in relation to paediatric use:	Yes/No
Date of completion of the paediatric investigation plan:	By Oct 2016
Deferral for one or more studies contained in the paediatric investigation plan:	Yes