EMA/10917/2014

European Medicines Agency decision

P/0012/2014

of 22 January 2014

on the acceptance of a modification of an agreed paediatric investigation plan for simeprevir (EMEA-000625-PIP01-09-M02) 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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An agency of the European Union

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on the acceptance of a modification of an agreed paediatric investigation plan for simeprevir (EMEA-000625-PIP01-09-M02) 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/55/2010 issued on 7 April 2010 and the decision P/0276/2012 issued on 21 November 2012,

Having regard to the application submitted by Janssen Infectious Diseases BVBA on 16 September 2013 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 December 2013, 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 simeprevir, capsule, hard, age-appropriate oral 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 Janssen Infectious Diseases BVBA, Turnhoutseweg 30, 2340 – Beerse, Belgium.

Done at London, 22 January 2014

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/578172/2013 corr

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

EMEA-000625-PIP01-09-M02

Scope of the application

Active substance(s):

Simeprevir

Condition(s):

Treatment of chronic viral hepatitis C

Pharmaceutical form(s):

Capsule, hard

Age-appropriate oral formulation

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Janssen Infectious Diseases BVBA

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Janssen Infectious Diseases BVBA submitted to the European Medicines Agency on 16 September 2013 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/55/2010 issued on 7 April 2010 and the decision P/0276/2012 issued on 21 November 2012.

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

The procedure started on 10 October 2013.

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Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan 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 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 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.

London, 6 December 2013

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

1. Waiver

1.1. Condition: Treatment of chronic viral hepatitis C

The waiver applies to:

- the paediatric population from birth to less than 3 years of age;
- for the capsule, hard, for oral use and for the age-appropriate oral formulation;
- 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.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of chronic viral hepatitis C

2.1.1. Indication(s) targeted by the PIP

- Treatment of children and adolescents from 3 years to less than 18 years of age with genotype 1 or genotype 4 chronic HCV infection and who are treatment-naïve or treatment-experienced with simeprevir, in combination with one or more direct-acting anti-viral medicine(s)

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

From 3 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

- Capsule, hard, for oral use.
- Age-appropriate oral formulation.

2.1.4. Measures

Area	Number of studies	Description
Quality	1	Measure 1: Development of age-appropriate oral formulation.
Non-clinical	0	Not applicable.
Clinical	3	Measure 2: Trial to investigate pharmacokinetics of the potential age-appropriate paediatric formulation(s) of simeprevir compared with capsule, hard, for oral use in adults. Measure 4: Single-arm, multi-centre trial to evaluate pharmacokinetics, tolerability, safety, acceptability and anti-viral activity of simeprevir in combination with one or more direct-acting anti-viral in treatment-naïve and in treatment-experienced children with chronic viral hepatitis C from 3 years to less than 18 years of age.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2022
Deferral for one or more studies contained in the paediatric investigation plan:	Yes