EMA/501714/2014

European Medicines Agency decision

P/0225/2014

of 5 September 2014

on the refusal of a modification of an agreed paediatric investigation plan for telaprevir (Incivo), (EMEA-000196-PIP01-08-M03) 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
Contact EMA www.ema.europa.eu/contact

European Medicines Agency decision

P/0225/2014

of 5 September 2014

on the refusal of a modification of an agreed paediatric investigation plan for telaprevir (Incivo), (EMEA-000196-PIP01-08-M03) 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/127/2008 issued on 23 December 2008, the decision P/0008/2012 issued on 24 January 2012, and the decision P/0034/2014 issued on 5 March 2014,

Having regard to the application submitted by Janssen Infectious Diseases BVBA on 18 April 2014 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 18 July 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 refusal of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the refusal of changes to the agreed paediatric investigation plan, including changes to the deferral and the waiver.

[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 telaprevir (Incivo), film-coated tablet, chewable tablet, oral use, including changes to the deferral and the waiver, 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, are hereby refused.

Article 2

This decision is addressed to Janssen Infectious Diseases BVBA, Turnhoutseweg 30, 2340 – Beerse, Belgium.

Done at London, 5 September 2014

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

EMA/PDCO/280410/2014

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

EMEA-000196-PIP01-08-M03

Scope of the application

Active substance(s):

Telaprevir

Invented name:

Incivo

Condition(s):

Treatment of chronic hepatitis C

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Chewable tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Janssen Infectious Diseases BVBA

Information about the authorised medicinal product:

See Annex II

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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 18 April 2014 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/127/2008 issued on 23 December 2008, the decision P/0008/2012 issued on 24 January 2012, and the decision P/0034/2014 issued on 5 March 2014.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral. Supplementary information was provided by the applicant on 14 July 2014. The applicant proposed changes to the agreed paediatric investigation plan and to the waiver.

The procedure started on 21 May 2014.

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 refuse the changes proposed by the applicant regarding the paediatric investigation plan and the deferral and the scope of the waiver;

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. 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 remain unchanged and are set out in the Annex I.

3. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

London, 18 July 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman

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

1.1. Condition:

Treatment of Chronic Hepatitis C

The waiver applies to:

- all subsets of the paediatric population from birth to less than 3 years of age;
- for film coated tablets and chewable tablets, 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.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of chronic hepatitis C

2.1.1. Indication(s) targeted by the PIP

Telaprevir in combination with peginterferon alfa and ribavirin is indicated for the treatment of children and adolescents with genotype 1 chronic hepatitis C virus infection.

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

From 3 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Chewable tablets

Film-coated tablets

2.1.4. Studies

Area	Number of studies	Description
Quality	1	**Study 1:** Development of chewable tablet formulation, in 100 and 250 mg strength.
Non-clinical	0	Not applicable.
Clinical	2	**Study 2:** Single-dose, randomized, two-way crossover study in adults to evaluate the relative bioavailability of the chewable tablet formulation to the adult tablet formulation. **Study 3:** Two-phase, safety and pharmacokinetics study of telaprevir in association with peginterferon and ribavirin in children and adolescents.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2016
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of chronic hepatitis C

Authorised indication(s):

INCIVO, in combination with peginterferon alfa and ribavirin, is indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis):

- who are treatment naïve;
- who have previously been treated with interferon alfa (pegylated or non pegylated) alone or in combination with ribavirin, including relapsers, partial responders and null responders.

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use