



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/761386/2015

European Medicines Agency decision

P/0313/2015

of 21 December 2015

on the acceptance of a modification of an agreed paediatric investigation plan for elbasvir (EMA-001603-PIP01-13-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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on the acceptance of a modification of an agreed paediatric investigation plan for elbasvir (EMA-001603-PIP01-13-M01) 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 726/2004¹,

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/0023/2015 issued on 30 January 2015,

Having regard to the application submitted by Merck Sharp & Dohme (Europe), Inc. on 21 August 2015 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 13 November 2015, 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.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

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 elbasvir, film-coated tablet, granules, oral use, 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 (Europe), Inc., 5 Clos du Lynx / Lynx Binnenhof 5, B-1200 – Brussels, Belgium

Done at London, 21 December 2015

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

EMA/PDCO/601685/2015
London, 13 November 2015

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

EMA-001603-PIP01-13-M01

Scope of the application

Active substance(s):

Elbasvir

Condition(s):

Treatment of chronic hepatitis C

Pharmaceutical form(s):

Film-coated tablet

Granules

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Merck Sharp & Dohme (Europe), Inc.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe), Inc. submitted to the European Medicines Agency on 21 August 2015 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/0023/2015 issued on 30 January 2015.

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

The procedure started on 15 September 2015.

Scope of the modification

Some measures 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 in the scope set out in the Annex I of this opinion.

The Norwegian Paediatric Committee member agrees 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.

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:

- the paediatric population from birth to less than 3 years of age;
- film-coated tablet, granules, oral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Treatment of chronic hepatitis C

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic hepatitis C genotype 1, 4 and 6 infection in combination with other medicinal products in children and adolescents from 3 years to less than 18 years of age.

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)

Film-coated tablet

Granules

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1: Development of granules for oral use
Non-clinical studies	0	Not applicable.

Area	Number of measures	Description
Clinical studies	2	Study 2: Open-label, randomised, crossover, single-dose trial in healthy adults to evaluate relative bioavailability and safety of the age-appropriate oral solid dosage forms of grazoprevir and elbasvir versus the adult formulation <i>This study is the same as study 2 of the grazoprevir PIP EMEA-001602-PIP01-13 and subsequent modifications thereof and the grazoprevir/elbasvir PIP EMEA-001604-PIP01-13 and subsequent modifications thereof</i> Study 3: Open-label, single arm trial to evaluate pharmacokinetics, safety, antiviral activity and acceptability/palatability of grazoprevir in combination with elbasvir in children from 3 to less than 18 years of age with chronic hepatitis C genotype 1, 4 or 6 infection. <i>This study is the same as study 3 of the grazoprevir PIP EMEA-001602-PIP01-13 and subsequent modifications thereof and the grazoprevir/elbasvir PIP EMEA-001604-PIP01-13 and subsequent modifications thereof</i>
Extrapolation, modelling and simulation studies	0	Not applicable.
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:	Yes
Date of completion of the paediatric investigation plan:	By March 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes