EMA/493103/2017

European Medicines Agency decision

P/0258/2017

of 4 September 2017

on the acceptance of a modification of an agreed paediatric investigation plan for human fibrinogen (EMEA-001208-PIP01-11-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.

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on the acceptance of a modification of an agreed paediatric investigation plan for human fibrinogen (EMEA-001208-PIP01-11-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/0200/2012 issued on 24 August 2012, the decision P/0334/2014 issued on 22 December 2014 and the decision P/0119/2015 issued on 5 June 2015,

Having regard to the application submitted by Octapharma Pharmazeutika Produktionsges. m. b. H on 2 May 2017 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 July 2017, 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 human fibrinogen, powder and solvent for solution for infusion, intravenous 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 Octapharma Pharmazeutika Produktionsges. m. b. H, Oberlaaer Strasse 235, 1100 – Vienna, Austria.

EMA/PDCO/286002/2017
London, 21 July 2017

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

EMEA-001208-PIP01-11-M03

Scope of the application

Active substance(s):

Human fibrinogen

Condition(s):

Treatment of congenital fibrinogen deficiency

Pharmaceutical form(s):

Powder and solvent for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Octapharma Pharmazeutika Produktionsges. m. b. H

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Octapharma Pharmazeutika Produktionsges. m. b. H submitted to the European Medicines Agency on 2 May 2017 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0200/2012 issued on 24 August 2012, the decision P/0334/2014 issued on 22 December 2014 and the decision P/0119/2015 issued on 5 June 2015.

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

The procedure started on 24 May 2017.

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 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 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition

Treatment of congenital fibrinogen deficiency

2.1.1. Indication(s) targeted by the PIP

Treatment of congenital fibrinogen deficiency

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)

Powder and solvent for solution for infusion

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	0	**Study 1** Deleted during procedure EMEA-001208-PIP01-M03.
Non-clinical studies	0	Not applicable.
Clinical studies	3	**Study 2** A prospective, controlled, randomised, cross-over study investigating the pharmacokinetic properties, surrogate efficacy and safety of Human fibrinogen compared to Haemocomplettan P/ RiaSTAP in paediatric (12 to less than 18 years of age) and adult patients with congenital fibrinogen deficiency. **Study 3** Prospective, open-label, uncontrolled study to assess the efficacy and safety of Human fibrinogen for on-demand treatment of acute bleeding and perisurgical prophylaxis in paediatric (12 to less than 18 years of age) and adult patients with congenital fibrinogen deficiency.

		Study 4 Prospective, open-label, uncontrolled study to assess the pharmacokinetic properties, efficacy and safety of Human fibrinogen for on-demand treatment of acute bleeding and perisurgical prophylaxis in paediatric patients with congenital fibrinogen deficiency below 12 years of age.
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 December 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes