EMA/585444/2016

European Medicines Agency decision

P/0259/2016

of 5 October 2016

on the acceptance of a modification of an agreed paediatric investigation plan for selepressin (EMEA-000506-PIP01-08-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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on the acceptance of a modification of an agreed paediatric investigation plan for selepressin (EMEA-000506-PIP01-08-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/183/2010 issued on 24 September 2010 and the decision P/0013/2016 issued on 29 January 2016,

Having regard to the application submitted by Ferring Pharmaceuticals A/S on 27 May 2016 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 19 August 2016, 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 selepressin, concentrate for solution for infusion, intravenous 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 Ferring Pharmaceuticals A/S, Kay Fiskers Plads 11, 2300 - Copenhagen S, Denmark.

EMA/PDCO/389737/2016
London, 19 August 2016

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

EMEA-000506-PIP01-08-M02

Scope of the application

Active substance(s):

Selepressin

Condition(s):

Treatment of septic shock

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Ferring Pharmaceuticals A/S

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Ferring Pharmaceuticals A/S submitted to the European Medicines Agency on 27 May 2016 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/183/2010 issued on 24 September 2010 and the decision P/0013/2016 issued on 29 January 2016.

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

The procedure started on 21 June 2016.

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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 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 to be investigated

Treatment of septic shock

2.1.1. Indication(s) targeted by the PIP

Treatment of septic shock in paediatric patients in need of vasopressor support

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)

Concentrate for solution for infusion

2.1.4. Studies

Area	Number of studies	Description
Quality	2	**Study 1** Development of a concentrate for solution for infusion suitable for use in neonates and infants and avoiding the need for multiple manipulation/dilution steps. **Study 2** Study of potential interactions/compatibility issues of FE 202158 with the most commonly co-administered IV medications and infusions used in the paediatric population
Non-clinical	4	**Study 3** Dose-range finding in juvenile (8-10 weeks old) dogs **Study 4** Main 4-week toxicity study in juvenile (8-10 weeks old) dogs **Study 5** Main 4-week toxicity study in juvenile (Postnatal day 4) dogs **Study 6** Deleted during Modification of the agreed PIP EMEA-000506-PIP01-08-M02

		Study 10 Dose-range finding in juvenile (postnatal day 4) dogs
Clinical	3	**Study 7** Pharmacokinetic study of FE 202158 in children aged 1 – 12 years with warm septic shock **Study 8** Safety, tolerability and efficacy study evaluating two doses of FE 202158 for vasopressor support in children aged 1 – 18 years with warm septic shock **Study 9** Safety, tolerability and efficacy study of ascending doses of FE 202158 for vasopressor support in children aged 0 – 1 year including pre-terms with warm septic shock

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By May 2026
Deferral for one or more studies contained in the paediatric investigation plan:	Yes