EMA/239204/2023 Corr[1]

European Medicines Agency decision

P/0228/2023

of 14 June 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral for fosmanogepix, (EMEA-003280-PIP01-22) 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.

[1] 28 February 2024

European Medicines Agency decision

P/0228/2023

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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[2],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[3],

Having regard to the application submitted by Pfizer Europe MA EEIG on 4 July 2022 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 April 2023, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

[2] OJ L 378, 27.12.2006, p.1, as amended.
[3] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for fosmanogepix, solution for infusion, age-appropriate parenteral formulation, tablet, age-appropriate oral formulation, intravenous use, oral use, 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, is hereby agreed.

Article 2

A deferral for fosmanogepix, solution for infusion, age-appropriate parenteral formulation, tablet, age-appropriate oral formulation, intravenous use, oral use, 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, is hereby granted.

Article 3

This decision is addressed to Pfizer Europe MA EEIG, 17 Boulevard de la Plaine, 1050 – Brussels, Belgium.

EMA/PDCO/54761/2023 Corr[1]
Amsterdam, 26 April 2023

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-003280-PIP01-22

Scope of the application

Active substance(s):

Fosmanogepix

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of invasive fungal infections

Pharmaceutical form(s):

Solution for infusion

Age-appropriate parenteral formulation

Tablet

Age-appropriate oral formulation

Route(s) of administration:

Intravenous use

Oral use

Name/corporate name of the PIP applicant:

Pfizer Europe MA EEIG

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Pfizer Europe MA EEIG submitted for agreement to the European Medicines Agency on 4 July 2022 an application for a

[1] 8 June 2023

paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation

The procedure started on 16 August 2022.

Supplementary information was provided by the applicant on 20 January 2023. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree with the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

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

2. The measures and timelines of the agreed 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 annexes 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 invasive fungal infections

2.1.1. Indication(s) targeted by the PIP

- Treatment of invasive candidiasis (IC)
- Treatment of invasive aspergillosis (IA) and other invasive rare mould infections (IMI)

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)

- Solution for infusion
- Age-appropriate parenteral formulation
- Tablet
- Age-appropriate oral formulation

2.1.4. Measures

Area	Description
Quality-related studies	Study 1: Development of age-appropriate oral formulation Study 2: Development of age-appropriate parenteral formulation
Non-clinical studies	Study 3: Toxicity study in juvenile rats to investigate potential effects on the central nervous system (CNS)
Clinical studies	Study 4: Open-label, single-arm study to evaluate pharmacokinetics, safety and tolerability of single-dose (SD) and multiple-dose (MD) fosmanogepix in paediatric patients from birth to less than 18 years of age who have an indication for antifungal prophylaxis.

	Study 5: Open-label, single arm study to evaluate safety, tolerability, and pharmacokinetics of fosmanogepix in paediatric patients from birth to less than 18 years of age with possible, proven or probable invasive fungal infections.
Modelling and simulation studies	Study 6: Modelling and simulation study to determine the initial doses (both IV and PO) for Study 4 and Study 5 and to confirm the paediatric doses.
Other studies	Not applicable
Extrapolation plan	Studies 4 and 5 are part of an extrapolation plan covering the paediatric population from birth to less than 18 years of age, as agreed by the PDCO.

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 2035
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.