EMA/430892/2017

European Medicines Agency decision

P/0212/2017

of 9 August 2017

on the acceptance of a modification of an agreed paediatric investigation plan for zanamivir (Relenza), (EMEA-001318-PIP01-12-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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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/0097/2013 issued on 29 April 2013 and the decision P/0094/2015 issued on 8 May 2015,

Having regard to the application submitted by GlaxoSmithKline Trading Services Limited on 24 March 2017 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 23 June 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 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 zanamivir (Relenza), inhalation powder, pre-dispensed, solution for infusion, inhalation use, 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 GlaxoSmithKline Trading Services Limited, Currabinny, Carrigaline, County Cork, Ireland.

EMA/PDCO/241591/2017
London, 23 June 2017

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

EMEA-001318-PIP01-12-M02

Scope of the application

Active substance(s):

Zanamivir

Invented name:

Relenza

Condition(s):

Prevention of influenza

Treatment of influenza

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Inhalation powder, pre-dispensed

Solution for infusion

Route(s) of administration:

Inhalation use

Intravenous use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Trading Services Limited

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited submitted to the European Medicines Agency on 24 March 2017 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/0097/2013 issued on 29 April 2013 and the decision P/0094/2015 issued on 8 May 2015.

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

The procedure started on 25 April 2017.

A meeting with the Paediatric Committee took place on 21 June 2017.

Scope of the modification

Some 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 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 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

1.1. Condition:

Treatment of influenza

The waiver applies to:

- all subsets of the paediatric population from birth to less than 5 years of age;
- inhalation powder, pre-dispensed, inhalation use;
- on the grounds that the specific medicinal product is likely to be ineffective.

And to:

- all subsets of the paediatric population from 5 to less than 18 years of age;
- inhalation powder, pre-dispensed, inhalation 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 paediatric population.

1.2. Condition:

Prevention of influenza

The waiver applies to:

- all subsets of the paediatric population from birth to less than 5 years of age;
- inhalation powder, pre-dispensed, inhalation use;
- on the grounds that the specific medicinal product is likely to be ineffective.

And to:

- all subsets of the paediatric population from 5 to less than 18 years of age;
- inhalation powder, pre-dispensed, inhalation 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 paediatric population.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of influenza

2.1.1. Indication(s) targeted by the PIP

Treatment of influenza A and B virus infection

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

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	**Study 1** Open-label, single-arm study to evaluate PK, safety and tolerability of zanamivir in hospitalized children from 6 months to less than 18 years of age with confirmed influenza virus infection **Study 2** Open-label, single-arm study to evaluate PK, safety and tolerability of zanamivir in hospitalized children from birth to less than 6 months of age with confirmed influenza virus infection
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.2. Condition:

Prevention of influenza

2.2.1. Indication(s) targeted by the PIP

Prevention of influenza A and B virus infection

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

From birth to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Solution for infusion

2.2.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	**Study 3** Extrapolation of efficacy and safety zanamivir IV for the prevention of influenza infection from adult data for prevention (challenge study) and from the treatment of influenza program in children
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 issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2023
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 influenza infection

   Authorised indication(s):

- Relenza is indicated for treatment of both influenza A and B in adults and children (≥ 5 years) who present with symptoms typical of influenza when influenza is circulating in the community.

2. Prevention of influenza infection

   Authorised indication(s):

- Relenza is indicated for post-exposure prophylaxis of influenza A and B in adults and children (≥ 5 years) following contact with a clinically diagnosed case in a household. In exceptional circumstances, Relenza may be considered for seasonal prophylaxis of influenza A and B during a community outbreak (e.g. in case of a mismatch between circulating and vaccine strains and a pandemic situation).

Authorised pharmaceutical form(s):

Inhalation powder, pre-dispensed

Authorised route(s) of administration:

Inhalation use