EMA/201171/2013

European Medicines Agency decision

P/0097/2013

of 29 April 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for zanamivir (Relenza), (EMEA-001318-PIP01-12) 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 application submitted by GlaxoSmithKline Research and Development Limited on 28 June 2012 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 March 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 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 and on the granting of a waiver.

(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.

(4) It is therefore appropriate to adopt a decision granting a waiver.

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

Has adopted this decision:

Article 1

A paediatric investigation plan for zanamivir (Relenza), inhalation powder, pre-dispensed, solution for infusion, inhalation use, intravenous 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 zanamivir (Relenza), inhalation powder, pre-dispensed, solution for infusion, inhalation use, intravenous 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

A waiver for zanamivir (Relenza), inhalation powder, pre-dispensed, solution for infusion, inhalation use, intravenous 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 4

This decision is addressed to GlaxoSmithKline Research and Development Limited, 980 Great West Road, TW89GS - Brentford, Middlesex, United Kingdom.

Done at London, 29 April 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/201171/2013 Corr.

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

EMEA-001318-PIP01-12

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 Research and Development

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Research and Development submitted for agreement to the European Medicines Agency on 28 June 2012 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 9 August 2012.

Supplementary information was provided by the applicant on 15 December 2012. 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 the paediatric investigation plan in accordance with Article 18 of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population and to Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

2. The measures and timelines of the agreed 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(es) and appendix.

London, 15 March 2013

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

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
- for 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
- for Inhalation powder, pre-dispensed, inhalation use
- On the grounds that clinical studies 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
- for 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
- for Inhalation powder, pre-dispensed, inhalation use
- On the grounds that clinical studies 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

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

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 March 2019.
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 (see section 5.1 for children aged 5-11 years). 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