EMA/169115/2014

European Medicines Agency decision

P/0098/2014

of 10 April 2014

on the acceptance of a modification of an agreed paediatric investigation plan for atazanavir (sulphate) (Reyataz), (EMEA-000804-PIP01-09-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/226/2010 issued on 27 October 2010, and the decision P/0009/2013 issued on 22 January 2013,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG on 19 December 2013 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 March 2014, 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 atazanavir (sulphate) (Reyataz), capsule, hard, oral powder, oral 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 Bristol-Myers Squibb Pharma EEIG, Uxbridge Bussiness Park, Sanderson Road, UB8 1DH – Uxbridge, United Kingdom.

Done at London, 10 April 2014

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

EMA/PDCO/19647/2014

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

EMEA-000804-PIP01-09-M02

Scope of the application

Active substance(s):

Atazanavir (sulphate)

Invented name:

Reyataz

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Capsule, hard

Oral powder

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Bristol-Myers Squibb Pharma EEIG

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, Bristol-Myers Squibb Pharma EEIG submitted to the European Medicines Agency on 19 December 2013 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/226/2010 issued on 27 October 2010, the decision P/0009/2013 issued on 22 January 2013.

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

The procedure started on 21 January 2014.

Scope of the modification

Amendment of some clinical key elements.

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 Icelandic and the Norwegian Paediatric Committee members agree 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.

London, 21 March 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 human immunodeficiency virus (HIV-1) infection

The waiver applies to:

- oral powder, oral use;
- the paediatric population from birth to less than 3 months;
- on the grounds that the specific medicinal product is likely to be unsafe.

And to:

- the paediatric population from 11 years to less than 18 years;
- on the grounds that the specific medicinal product is likely to be ineffective.

The waiver applies to:

- capsules, hard, oral use;
- the paediatric population from birth to less than 6 years;
- on the grounds that the specific medicinal product is likely to be unsafe.

And to:

- the paediatric population from 6 years to less than 18 years;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

2. Paediatric Investigation Plan

2.1. Condition: treatment of human immunodeficiency virus (HIV-1) infection

2.1.1. Indication(s) targeted by the PIP

Treatment of human immunodeficiency virus (HIV-1) infection.

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

From 3 months to less than 11 years of age.

2.1.3. Pharmaceutical form(s)

Oral powder (50 mg/sachet).

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	1	**Study 1:** Development of the oral powder (50 mg/sachet)
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 2:** Single arm, open-label, multicentre study to evaluate the safety, efficacy and pharmacokinetics of atazanavir powder boosted with ritonavir with an optimised nucleoside reverse transcriptase inhibitor background therapy, in HIV infected paediatric patients from 3 months to less than 6 years of age. **Study 3:** Single arm, open-label, multicentre study to evaluate the safety, efficacy and pharmacokinetics of atazanavir powder boosted with ritonavir with an optimised nucleoside reverse transcriptase inhibitor background therapy, in HIV infected, antiretroviral naïve and experienced paediatric patients from 3 months to less than 11 years of age.
Extrapolation, modelling& 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:	Yes
Date of completion of the paediatric investigation plan:	By July 2015
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of human immunodeficiency virus (HIV-1) infection

Authorised indication(s):

- Reyataz capsules, co-administered with low dose ritonavir, are indicated for the treatment of HIV-1 infected adults and paediatric patients 6 years of age and older in combination with other antiretroviral medicinal products.

  Based on available virological and clinical data from adult patients, no benefit is expected in patients with strains resistant to multiple protease inhibitors (≥ 4 PI mutations). There are very limited data available from children aged 6 to less than 18 years (see sections 4.4 and 5.1).

  The choice of Reyataz in treatment experienced adult and paediatric patients should be based on individual viral resistance testing and the patient's treatment history (see sections 4.4 and 5.1).

Authorised pharmaceutical form(s):

Capsules, hard

Authorised route(s) of administration:

Oral use