EMA/193657/2011

European Medicines Agency decision

P/69/2011

of 15 March 2011

on the acceptance of a modification of an agreed paediatric investigation plan for saxagliptin (Onglyza) (EMEA-000200-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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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/176/2009 issued on 7 September 2009 and the decision P/16/2010 issued on 4 February 2010,

Having regard to the application submitted by Bristol Myers Squibb/AstraZeneca EEIG on 6 December 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 February 2011, 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 saxagliptin (Onglyza), film-coated tablets, 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/AstraZeneca EEIG, Bristol-Myers House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, United-Kingdom.

Done at London, 15 March 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/835215/2010

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

EMEA-000200-PIP01-08-M02

Scope of the application

Active substance(s):

Saxagliptin

Invented name:

Onglyza

Condition(s):

Treatment of type 2 diabetes mellitus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablets

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Bristol Myers Squibb/AstraZeneca 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/AstraZeneca EEIG submitted to the European Medicines Agency on 6 December 2010 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/176/2009 issued on 7 September 2009 and the decision P/16/2010 issued on 4 February 2010.
The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 22 December 2010.

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 the 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 annex(es) and appendix.

London, 18 February 2011

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 type 2 diabetes mellitus

The waiver applies to:

- Children from birth to less than 10 years,
- for film-coated tablets, oral use,
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of type 2 diabetes mellitus

2.1.1. Indication(s) targeted by the PIP

Treatment of type 2 diabetes mellitus.

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

From 10 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Film-coated tablets.

2.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	2	Study 1: Randomised, double-blind, placebo-controlled study to evaluate the efficacy, safety, tolerability and pharmacokinetics of saxagliptin in children and adolescents with type 2 diabetes from 10 years to less than 18 years of age. Study 2: Randomised, double-blind, placebo-controlled study to evaluate the efficacy, safety and tolerability of saxagliptin in combination with metformin IR or metformin XR in children and adolescents, from 10 years to less than 18 years of age, with type 2 diabetes with inadequate glycaemic control on metformin alone.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By April 2015
Deferral for one or more studies contained in the paediatric investigation plan:	No

3.1. Refusal of deferral

A deferral was not granted by the PDCO, since the marketing authorisation application was submitted before the entry into force of Article 7 of Regulation (EC) No 1901/2006 i.e. 26 July 2008. Therefore to extend the approved use in adults to the paediatric population in the above mentioned condition, the paediatric results will need to be collected in compliance with this plan, hence a deferral is not required.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Type 2 diabetes mellitus

   Authorised indications:

   Onglyza is indicated in adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control:

- in combination with metformin, when metformin alone, with diet and exercise, does not provide adequate glycaemic control;
- in combination with a sulphonylurea, when the sulphonylurea alone, with diet and exercise, does not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate;
- in combination with a thiazolidinedione, when the thiazolidinedione alone with diet and exercise, does not provide adequate glycaemic control in patients for whom use of a thiazolidinedione is considered appropriate.

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Package size
EU/1/09/545/	Onglyza	5 mg	Film-coated tablet	Oral use	Non-perforated blister (Alu/Alu)	14 tablets
EU/1/09/545/	Onglyza	5 mg	Film-coated tablet	Oral use	Non-perforated blister (Alu/Alu)	28 tablets
EU/1/09/545/	Onglyza	5 mg	Film-coated tablet	Oral use	Non-perforated blister (Alu/Alu)	56 tablets
EU/1/09/545/	Onglyza	5 mg	Film-coated tablet	Oral use	Non-perforated blister (Alu/Alu)	98 tablets
EU/1/09/545/	Onglyza	5 mg	Film-coated tablet	Oral use	Non-perforated calendar blister (Alu/Alu)	14 tablets
EU/1/09/545/	Onglyza	5 mg	Film-coated tablet	Oral use	Non-perforated calendar blister (Alu/Alu)	28 tablets
EU/1/09/545/	Onglyza	5 mg	Film-coated tablet	Oral use	Non-perforated calendar blister (Alu/Alu)	56 tablets
EU/1/09/545/	Onglyza	5 mg	Film-coated tablet	Oral use	Non-perforated calendar blister (Alu/Alu)	98 tablets
EU/1/09/545/	Onglyza	5 mg	Film-coated tablet	Oral use	Perforated blister (Alu/Alu)	30 x 1 tablets
EU/1/09/545/	Onglyza	5 mg	Film-coated tablet	Oral use	Perforated blister (Alu/Alu)	90 x 1 tablets