EMA/476175/2013

European Medicines Agency decision

P/0217/2013

of 6 September 2013

on the acceptance of a modification of an agreed paediatric investigation plan for exenatide (Byetta, Bydureon) (EMEA-000689-PIP01-09-M04) 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/237/09 issued on 30 November 2009, the decision P/12/2010 issued on 20 January 2010, the decision P/21/2011 issued on 25 January 2011, and the decision P/224/2011 issued on 27 September 2011,

Having regard to the application submitted by Bristol-Myers Squibb / AstraZeneca EEIG on 29 April 2013 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 19 July 2013, 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 exenatide (Byetta, Bydureon), solution for injection in pre-filled pen, powder and solvent for prolonged-release suspension for injection, subcutaneous 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 Bristol-Myers Squibb / AstraZeneca EEIG, Sanderson Road, UB8 1DH - Uxbridge, United Kingdom.

Done at London, 6 September 2013

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

EMA/PDCO/272217/2013

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

EMEA-000689-PIP01-09-M04

Scope of the application

Active substance(s):

Exenatide

Invented name:

Byetta

Bydureon

Condition(s):

Treatment of type 2 diabetes mellitus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection in pre-filled pen

Powder and solvent for prolonged-release suspension for injection

Route(s) of administration:

Subcutaneous 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 29 April 2013 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/237/09 issued on 30 November 2009, the decision P/12/2010 issued on 20 January 2010, the decision P/21/2011 issued on 25 January 2011, and the decision P/224/2011 issued on 27 September 2011.

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

The procedure started on 22 May 2013.

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 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.

London, 19 July 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(s): Treatment of Type 2 diabetes mellitus

Indication:

Treatment of type 2 diabetes mellitus as monotherapy.

The waiver applies to:

- children from birth to less than 10 years;
- for exenatide, solution for injection, prefilled pen and powder and solvent for prolonged-release suspension for injection, subcutaneous 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.

Indication:

Treatment of type 2 diabetes mellitus in combination with metformin, and/or sulphonylureas in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.

The waiver applies to:

- children from birth to less than 10 years;
- for exenatide, solution for injection, prefilled pen and powder and solvent for prolonged-release suspension for injection, subcutaneous 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.

Indication:

Treatment of type 2 diabetes mellitus in combination with thiazolidinediones and with metformin with a thiazolidinedione.

The waiver applies to:

- children from birth to less than 10 years;
- for exenatide, solution for injection, prefilled pen and powder and solvent for prolonged-release suspension for injection, subcutaneous 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.

The waiver applies to:

- children from 10 to less than 18 years;
- for exenatide, solution for injection, prefilled pen and powder and solvent for prolonged-release suspension for injection, subcutaneous use;
- on the grounds that the combination of medicinal products is likely to be unsafe in the paediatric population.

Indication

Treatment of type 2 diabetes mellitus in combination with insulin with or without other oral antidiabetic agents.

This waiver applies to:

- children from birth to less than 10 years;
- for exenatide, solution for injection, prefilled pen and powder and solvent for prolonged-release suspension for injection, subcutaneous 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.

The waiver applies to:

- children from 10 to less than 18 years;
- for exenatide, solution for injection, prefilled pen and powder and solvent for prolonged-release suspension for injection, subcutaneous 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 as monotherapy or in combination with metformin, and/or sulphonylureas in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.

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

From 10 to less than 18 years.

2.1.3. Pharmaceutical form(s)

Solution for injection (prefilled pen)

Powder and solvent for prolonged-release suspension for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.

Area	Number of studies	Description
Clinical	2	Double-blind, placebo-controlled, randomized, multi-center parallel study of the safety and efficacy of exenatide twice daily (as monotherapy and adjunctive therapy to oral antidiabetic agents) in children and adolescents with type 2 diabetes mellitus (H8O-MC-GWBQ). Double-blind, placebo-controlled, randomized, multi-center parallel study of the safety and efficacy of exenatide once weekly (as monotherapy and adjunctive therapy to oral antidiabetic agents) in children and adolescents with type 2 diabetes mellitus (BCB 114).

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 August 2016
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 Type 2 Diabetes Mellitus

Authorised indications:

- Treatment of Type 2 Diabetes Mellitus in adult patients, in combination with metformin in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.
- Treatment of Type 2 Diabetes Mellitus in adult patients, in combination with sulphonylureas in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.
- Treatment of Type 2 Diabetes Mellitus in adult patients, in combination with thiazolidinediones in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.
- Treatment of Type 2 Diabetes Mellitus in adult patients, in combination with metformin and a sulphonylurea in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.
- Treatment of Type 2 Diabetes Mellitus in adult patients, in combination with metformin and a thiazolidinedione in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.

Authorised pharmaceutical form(s):

Solution for injection.

Authorised route(s) of administration:

Subcutaneous use.