EMA/356070/2011

European Medicines Agency decision

P/134/2011

of 8 June 2011

on the acceptance of a modification of an agreed paediatric investigation plan for sitagliptin (phosphate monohydrate) (Januvia), (EMEA-000470-PIP01-08-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.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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on the acceptance of a modification of an agreed paediatric investigation plan for sitagliptin (phosphate monohydrate) (Januvia), (EMEA-000470-PIP01-08-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/61/2009 issued on 27 March 2009, the decision P/211/2009 issued on 30 October 2009, the decision P/171/2010 issued on 6 September 2010 and the decision P/19/2011 issued on 25 January 2011,

Having regard to the application submitted by Merck Sharp and Dohme (Europe), Inc. on 7 February 2011 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 20 April 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 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 sitagliptin (phosphate monohydrate) (Januvia), film-coated tablet, oral 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 Merck Sharp and Dohme (Europe), Inc., 5 Clos du Lynx, 1200 Brussels, Belgium.

Done at London, 8 June 2011

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

EMA/PDCO/243324/2011

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

EMEA-000470-PIP01-08-M04

Scope of the application

Active substance(s):

Sitagliptin (phosphate monohydrate)

Invented name:

Januvia

Condition(s):

Treatment of type 2 diabetes mellitus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Merck Sharp and Dohme (Europe), Inc.

Information about the authorised medicinal product:

See Annex II

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Merck Sharp and Dohme (Europe), Inc. submitted to the European Medicines Agency on 7 February 2011 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/61/2009 issued on 27 March 2009, the decision P/211/2009 issued on 30 October 2009, the decision P/171/2010 issued on 6 September 2010 and the decision P/19/2011 issued on 25 January 2011.

The applicant proposed modifications to the paediatric investigation plan.

The procedure started on 23 February 2011.

Scope of the modification

Some measures and timelines of the original Opinion 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 of the paediatric population and conditions 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, 20 April 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:

- The paediatric population 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 subsets.

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 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablets, oral use, 25 mg, 50 mg and 100 mg

2.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable
Non-clinical		Not applicable
Clinical	2	1. Randomized, double-blind, placebo-controlled, single-dose trial to evaluate the pharmacokinetics of sitagliptin in children from 10 to less and 18 years of age, with type 2 diabetes mellitus. 2. Multicenter, double-blind, randomized, placebo- and metformin-controlled trial to evaluate the safety and efficacy of sitagliptin in children from 10 to less than 18 years of age, with type 2 diabetes mellitus with inadequate glycaemic control.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By October 2018
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:

- In adults for the treatment of type 2 diabetes mellitus as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.
- In adults for the treatment of type 2 diabetes mellitus as dual oral therapy in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control.
- In adults for the treatment of type 2 diabetes mellitus as dual oral therapy in combination a sulphonylurea when diet and exercise plus maximal tolerated dose of a sulphonylurea alone do not provide adequate glycaemic control and when metformin is inappropriate due to contraindications or intolerance.
- In adults for the treatment of type 2 diabetes mellitus as dual therapy in combination a peroxisome proliferator-activated receptor gamma (PPARγ) agonist (i.e. a thiazolidinedione) when use of a PPARγ agonist is appropriate and when diet and exercise plus the PPARγ agonist alone do not provide adequate glycaemic control.
- In adults for the treatment of type 2 diabetes mellitus as triple oral therapy in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these agents do not provide adequate glycaemic control.
- In adults for the treatment of type 2 diabetes mellitus as triple oral therapy in combination with a PPARγ agonist and metformin when use of a PPARγ agonist is appropriate and when diet and exercise plus dual therapy with these agents do not provide adequate glycaemic control.
- In adults for the treatment of type 2 diabetes mellitus as add-on to insulin (with or without metformin) when diet and exercise plus stable dose of insulin do not provide adequate glycaemic control.

EU Number	(Invented) name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Package size
EU/1/07/383/001	Januvia	25 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVDC/alu)	14
EU/1/07/383/002	Januvia	25 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVDC/alu)	28
EU/1/07/383/003	Januvia	25 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVDC/alu)	56
EU/1/07/383/004	Januvia	25 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVDC/alu)	84
EU/1/07/383/005	Januvia	25 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVDC/alu)	98
EU/1/07/383/006	Januvia	25 mg	Film-coated tablet	Oral use	perforated unit dose blister (PVC/PE/PVDC/alu)	50 x 1
EU/1/07/383/007	Januvia	50 mg	Film-coated	Oral use	blister	14

			tablet		(PVC/PE/PVDC/alu)	
EU/1/07/383/008	Januvia	50 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVDC/alu)	28
EU/1/07/383/009	Januvia	50 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVDC/alu)	56
EU/1/07/383/010	Januvia	50 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVDC/alu)	84
EU/1/07/383/011	Januvia	50 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVDC/alu)	98
EU/1/07/383/012	Januvia	50 mg	Film-coated tablet	Oral use	perforated unit dose blister (PVC/PE/PVDC/alu)	50 x 1
EU/1/07/383/013	Januvia	100 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVDC/alu)	14
EU/1/07/383/014	Januvia	100 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVDC/alu)	28
EU/1/07/383/015	Januvia	100 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVDC/alu)	56
EU/1/07/383/016	Januvia	100 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVDC/alu)	84
EU/1/07/383/017	Januvia	100 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVDC/alu)	98
EU/1/07/383/018	Januvia	100 mg	Film-coated tablet	Oral use	perforated unit dose blister (PVC/PE/PVDC/alu)	50 x 1