European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 1 December 2008

on the application for agreement of a Paediatric Investigation Plan for sitagliptin phosphate monohydrate, metformin hydrochloride (Janumet) EMEA-000165-PIP01-07 in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 Merck Sharp and Dohme (Europe) on 8 February 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 October 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency, has given a negative opinion,

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan,

(3) 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 sitagliptin phosphate monohydrate, metformin hydrochloride (Janumet), film-coated tablet, oral 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 not agreed.

Article 2

A waiver for sitagliptin phosphate monohydrate, metformin hydrochloride (Janumet), film-coated tablet, oral use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Merck Sharp and Dohme (Europe), Inc., 5 Clos du Lynx, Binnenhof, 1200 – Brussels, Belgium.

Done at London, 1 December 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

EMEA/PDCO/518495/2008
EMEA-000165-PIP01-07

NEGATIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR

Scope of the application

Active substance:
Sitagliptin phosphate monohydrate, metformin hydrochloride

Invented name:
Janumet

Condition(s):
Type 2 Diabetes Mellitus

Pharmaceutical form(s):
Film-coated tablet

Route(s) of administration:
Oral use

Information about the authorised medicinal product: see Annex I.

Basis for opinion
Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Merck Sharp and Dohme (Europe), Inc. submitted for agreement to the EMEA on 8 February 2008 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 13 March 2008.

Supplementary information was provided by the applicant on 14 August 2008.

A meeting with the Paediatric Committee took place on 15 October 2008.

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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 refuse the paediatric investigation plan in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and pursuant to Article 12 of Regulation (EC) 1901/2006 as amended, to grant a waiver for all subsets of the paediatric population and all above-mentioned conditions in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The scientific conclusions and the grounds for refusal of the paediatric investigation plan are set out in the summary report appended to this opinion.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex and appendix.

London, 17 October 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU number	Invented name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
EU/1/08/455/001	Janumet	50 mg/850 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	14 tablets
EU/1/08/455/002	Janumet	50 mg/850 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	28 tablets
EU/1/08/455/003	Janumet	50 mg/850 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	56 tablets
EU/1/08/455/004	Janumet	50 mg/850 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	112 tablets
EU/1/08/455/005	Janumet	50 mg/850 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	168 tablets
EU/1/08/455/006	Janumet	50 mg/850 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	196 tablets
EU/1/08/455/007	Janumet	50 mg/850 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	50x1 tablets
EU/1/08/455/008	Janumet	50 mg/1000 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	14 tablets
EU/1/08/455/009	Janumet	50 mg/1000 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	28 tablets
EU/1/08/455/010	Janumet	50 mg/1000 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	56 tablets
EU/1/08/455/011	Janumet	50 mg/1000 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	112 tablets
EU/1/08/455/012	Janumet	50 mg/1000 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	168 tablets
EU/1/08/455/013	Janumet	50 mg/1000 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	196 tablets
EU/1/08/455/014	Janumet	50 mg/1000 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	50x1 tablets