EMA/691227/2011

European Medicines Agency decision

P/177/2011

of 26 August 2011

on the granting of a product specific waiver for vildagliptin (Galvus), (EMEA-000700-PIP02-10) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by Novartis Europharm Limited on 9 May 2011 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 August 2011 in accordance with Article 13 of Regulation (EC) No 1901/2006,

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

Whereas:

(1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.

(2) 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 waiver for vildagliptin (Galvus), 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 granted.

Article 2

This decision is addressed to Novartis Europharm Limited, Wimblehurst Road, RH12 5AB - Horsham, United Kingdom.

Done at London, 26 August 2011

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

EMA/PDCO/613831/2011

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMEA-000700-PIP02-10

Scope of the application

Active substance(s):

Vildagliptin

Invented name:

Galvus

Condition(s):

Treatment of Type 2 Diabetes Mellitus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the European Medicines Agency on 9 May 2011 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

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The procedure started on 15 June 2011.

Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report :

   - to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population, Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

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

2. The grounds for the granting of the waiver are set out in Annex I.

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

London, 12 August 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of Type 2 Diabetes Mellitus

The waiver applies to:

- children from birth to less than 10 years of age;
- for tablet, 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(s).

The waiver applies to:

- children and adolescents from 10 to less than 18 years;
- for tablet, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

Treatment of Type 2 Diabetes Mellitus

Authorised indication:

Vildagliptin is indicated in the treatment of type 2 diabetes mellitus:

As dual oral therapy in combination with

- metformin, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin;
- a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance;
- a thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate.

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Package size
EU/1/07/414/001	Galvus	50 mg	Tablet	Oral use	Blister (PA/Al/PVC//Al)	7 tablets
EU/1/07/414/002	Galvus	50 mg	Tablet	Oral use	Blister (PA/Al/PVC//Al)	14 tablets
EU/1/07/414/003	Galvus	50 mg	Tablet	Oral use	Blister (PA/Al/PVC//Al)	28 tablets
EU/1/07/414/004	Galvus	50 mg	Tablet	Oral use	Blister (PA/Al/PVC//Al)	30 tablets
EU/1/07/414/005	Galvus	50 mg	Tablet	Oral use	Blister (PA/Al/PVC//Al)	56 tablets
EU/1/07/414/006	Galvus	50 mg	Tablet	Oral use	Blister (PA/Al/PVC//Al)	60 tablets
EU/1/07/414/007	Galvus	50 mg	Tablet	Oral use	Blister (PA/Al/PVC//Al)	90 tablets
EU/1/07/414/008	Galvus	50 mg	Tablet	Oral use	Blister (PA/Al/PVC//Al)	112 tablets
EU/1/07/414/009	Galvus	50 mg	Tablet	Oral use	Blister (PA/Al/PVC//Al)	180 tablets
EU/1/07/414/010	Galvus	50 mg	Tablet	Oral use	Blister (PA/Al/PVC//Al)	336 tablets
EU/1/07/414/018	Galvus	50 mg	Tablet	Oral use	Blister (PA/Al/PVC//Al)	336 (3x112) tablets