



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/2910/2017

European Medicines Agency decision

P/0038/2017

of 30 January 2017

on the refusal of a paediatric investigation plan and on the refusal of a deferral and on the granting of a waiver for ambrisentan / tadalafil (EMA-002030-PIP01-16) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Glaxo Group Limited on 9 September 2016 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 December 2016, in accordance with Article 18 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and of its own motion in accordance with Article 12 of said Regulation,

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 refusal of a paediatric investigation plan and on the refusal of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision refusing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision refusing a deferral.
- (4) 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 ambrisentan / tadalafil, 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 refused.

Article 2

A deferral for ambrisentan / tadalafil, 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 refused.

Article 3

A product-specific waiver for ambrisentan / tadalafil, 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 granted.

Article 4

This decision is addressed to Glaxo Group Limited, 980 Great West Road, TW8 9GS – London, United Kingdom.

EMA/PDCO/862717/2016 **Corr**

London, 16 December 2016

Opinion of the Paediatric Committee on the refusal of a Paediatric Investigation Plan and a deferral and on the granting of a product-specific waiver

EMA-002030-PIP01-16

Scope of the application

Active substance(s):

Ambrisentan / tadalafil

Condition(s):

Treatment of pulmonary arterial hypertension

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Glaxo Group Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Glaxo Group Limited submitted for agreement to the European Medicines Agency on 9 September 2016 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 18 October 2016.

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 said Regulation as the measures and the timelines do not bring expected significant therapeutic benefit;
- to refuse a deferral in accordance with Article 21 of said Regulation;
- to grant a product-specific waiver for one or more subsets of the paediatric population on its own motion in accordance with Article 12 of said Regulation and concluded 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)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Norwegian Paediatric Committee member agrees 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.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of pulmonary arterial hypertension

The waiver applies to:

- the paediatric population from birth to less than 1 years of age;
- for film-coated tablet, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe;

and to:

- the paediatric population from 1 to less than 18 years of age;
- for film-coated tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.