European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 14 October 2008

on the application for agreement of a Paediatric Investigation Plan for eltrombopag (EMEA-000170-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 GlaxoSmithKline Trading Services Limited 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 and a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 September 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 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 positive 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.

(4) It is therefore appropriate to adopt a Decision granting a 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

A Paediatric Investigation Plan for eltrombopag, film-coated tablets; powder/granules for dispersion, 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 agreed.

Article 2

A waiver for eltrombopag, film-coated tablets; powder/granules for dispersion, 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

A deferral for eltrombopag, film-coated tablets; powder/granules for dispersion, 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 4

This decision is addressed to GlaxoSmithKline Trading Services Limited, 6900 Cork Airport Business Park, Kinsale Road, Cork, Ireland.

Done at London, 14October 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

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

Doc. Ref. EMEA/PDCO/472835/2008
EMEA-000170-PIP01-07

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

Scope of the application

Active substance:
Eltrombopag

Condition(s):
Idiopathic thrombocytopenic purpura (ITP)

Pharmaceutical form(s):
Film-coated tablets
Powder/granules for dispersion

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
GlaxoSmithKline Trading Services Limited

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited 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 17 July 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 agree the paediatric investigation plan in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended,
- to grant a deferral in accordance with Article 21 of Regulation (EC) No 1901/2006 as amended,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended and concluded in accordance with Article 11(1)(b) of Regulation (EC) No 1901/2006 as amended, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

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

2. The measures and timelines of the agreed 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 Agency, together with its annex(es) and appendix(ces).

London, 19 September 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature of file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN <AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S)

Idiopathic thrombocytopenic purpura (ITP)

B. WAIVER

- **Condition**

Idiopathic thrombocytopenic purpura (ITP)

The waiver applies to:
Newborns and infants from birth to less than 1 year for film-coated tablets and powder/granules for dispersion, 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).

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Idiopathic thrombocytopenic purpura (ITP)

- **Proposed PIP indication**

Treatment of Chronic Idiopathic thrombocytopenic purpura (ITP)

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 1 year to less than 18 years

- **Formulation(s)**

Film-coated tablets and Powder/granules for dispersion, oral use

- **Studies**

Area	Number of studies	Description
Quality	1	Development of a powder for oral suspension in fixed single-dose sachets.
Clinical	1	Multicenter, placebo-controlled study to investigate the safety, tolerability and efficacy of eltrombopag in paediatric patients diagnosed with chronic Idiopathic Thrombocytopenic Purpura (ITP), from 1 year to less than 18 years old.

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 December 2014**
A deferral has been granted for initiation of some or all studies contained in the paediatric investigation plan:	**Yes**
A deferral has been granted for completion of some or all studies contained in the paediatric investigation plan:	**Yes**