European Medicines Agency

Doc. Ref. EMEA/94177/2009
P/35/2009

EUROPEAN MEDICINES AGENCY DECISION

of 24 February 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for sunitinib malate (Sutent) (EMEA-000342-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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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 Pfizer Limited on 27 June 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 9 January 2009, 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 an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision granting a Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting 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 sunitinib malate (Sutent), hard capsule, 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 deferral for sunitinib malate (Sutent), hard capsule, 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 3

A waiver for sunitinib malate (Sutent), hard capsule, 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 Pfizer Limited, Ramsgate Road, CT13 9NJ Sandwich, United Kingdom.

Done at London, 24 February 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency

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EMEA-000342-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

Scope of the application

Active substance:
Sunitinib malate

Invented name:
Sutent

Condition(s):
Gastro-intestinal stromal tumour

Pharmaceutical form(s):
Hard capsule

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Pfizer Limited

Information about the authorised medicinal product:
See Annex II

Basis for opinion

Pursuant to Article 16(1)of Regulation (EC) No 1901/2006 as amended, Pfizer Limited submitted for agreement to the EMEA on 27 June 2008 an application for a waiver under Article 13 of said Regulation.

The procedure started on 31 July 2008.

Supplementary information was provided by the applicant on 31 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 agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
- to grant a deferral in accordance with Article 21 of said Regulation,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, 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.

London, 9 January 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on 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)

Gastro-intestinal stromal tumour

B. WAIVER

- **Condition**

Gastro-intestinal stromal tumour

The waiver applies to:

– Children from birth to less than 6 years for hard capsule for 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**

Gastro-intestinal stromal tumour

- **Proposed PIP indication**

Treatment of gastro-intestinal stromal tumour

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

From 6 years to less than 18 years

- **Formulation(s)**

Hard capsule, oral use

- **Studies**

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	2	Open-label, single-agent, single-arm, multi-centre, dose escalation trial of sunitinib to evaluate safety and pharmacokinetics in children aged 2 to less than 18 years with refractory solid tumours. Open-label, single-agent, single-arm, multi-centre trial of sunitinib to evaluate safety and pharmacokinetics in children aged 6 years to less than 18 years with gastro-intestinal stromal tumours.

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 June 2014
Deferral for some or all studies contained in the paediatric investigation plan:	Yes

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Package size
EU/1/06/347/001	Sutent	12.5 mg	Capsule, hard	Oral use	bottle (HDPE)	30 capsules
EU/1/06/347/002	Sutent	25 mg	Capsule, hard	Oral use	bottle (HDPE)	30 capsules
EU/1/06/347/003	Sutent	50 mg	Capsule, hard	Oral use	bottle (HDPE)	30 capsules
EU/1/06/347/004	Sutent	12.5 mg	Capsule, hard	Oral use	blister (Aclar/PVC)	28 capsules
EU/1/06/347/005	Sutent	25 mg	Capsule, hard	Oral use	blister (Aclar/PVC)	28 capsules
EU/1/06/347/006	Sutent	50 mg	Capsule, hard	Oral use	blister (Aclar/PVC)	28 capsules