EMA/321148/2015

European Medicines Agency decision

P/0108/2015

of 1 June 2015

on the acceptance of a modification of an agreed paediatric investigation plan for sunitinib (Sutent), (EMEA-000342-PIP01-08-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

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 European Medicines Agency's decision P/35/2009 issued on 24 February 2009, and the decision P/0045/2012 issued on 29 February 2012,

Having regard to the application submitted by Pfizer Limited on 20 November 2014 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 May 2015, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) Regulation (EC) No 1901/2006, an opinion on the acceptance of changes to the agreed paediatric investigation and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the 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

Changes to the agreed paediatric investigation plan for sunitinib (Sutent), caspule, hard, oral use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Pfizer Limited, Ramsgate Road, CT13 9NJ – Sandwich, United Kingdom.

Done at London, 1 June 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/214970/2015
London, 22 May 2015

Final opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000342-PIP01-08-M04

Scope of the application

Active substance(s):

Sunitinib

Invented name:

Sutent

Condition(s):

Treatment of gastro-intestinal stromal tumour

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Caspule, hard

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Pfizer Limited

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Limited submitted to the European Medicines Agency on 20 November 2014 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/35/2009 issued on 24 February 2009, and the decision P/0045/2012 issued on 29 February 2012.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 16 December 2014.

An Opinion was adopted by the Paediatric Committee on 13 February 2015 for the above mentioned product. Pfizer Limited received the Paediatric Committee Opinion on 23 February 2015.

On 25 March 2015 Pfizer Limited submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 23 April 2015.

A meeting with the Paediatric Committee took place on 21 May 2015.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report :

   1.1. to revise its opinion and

   - to agree to the changes regarding the measures and the timelines of the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   1.2. following re-examination, to amend the scope of the modifications of the paediatric investigation plan and the deferral and the waiver.

   The Norwegian Paediatric Committee member agrees 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 European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of 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).

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of gastro-intestinal stromal tumour

2.1.1. Indication(s) targeted by the PIP

Treatment of gastro-intestinal stromal tumour

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 6 years to less than 18 years

2.1.3. Pharmaceutical form(s)

Hard capsule, oral use

2.1.4. Measures

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	2	**Study 1:** 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 **Study 2:** 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

Extrapolation, modelling and simulation studies	1	**Study 3:** Measure to extrapolate efficacy to the paediatric population
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of gastro-intestinal tumour

   Authorised indication(s):

- Sutent is indicated for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) in adults after failure of imatinib mesilate treatment due to resistance or intolerance.

2. Treatment of renal cell carcinoma

   Authorised indication(s):

- Sutent is indicated for the treatment of advanced/metastatic renal cell carcinoma (MRCC) in adults.

3. Treatment of pancreatic neuroendocrine tumours

   Authorised indication(s):

- Sutent is indicated for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours with disease progression in adults. Experience with SUTENT as first-line treatment is limited (see section 5.1).

Authorised pharmaceutical form(s):

Capsule, hard

Authorised route(s) of administration:

Oral use