EMA/258873/2018

# European Medicines Agency decision

P/0147/2018

of 7 May 2018

on the acceptance of a modification of an agreed paediatric investigation plan for sunitinib (Sutent), (EMEA-000342-PIP01-08-M07) 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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# European Medicines Agency decision

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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, the decision P/0045/2012 issued on 29 February 2012, the decision P/0108/2015 issued on 1 June 2015, the decision P/0321/2016 issued on 2 December 2016 and the decision P/0263/2017 issued on 4 September 2017,

Having regard to the application submitted by Pfizer Limited on 3 January 2018 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 23 March 2018, 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 an opinion on the acceptance of changes to the agreed paediatric investigation plan.

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

[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), capsule, hard, oral use, 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.

EMA/PDCO/10393/2018
London, 23 March 2018

# Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000342-PIP01-08-M07

## 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):**

Capsule, 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 3 January 2018 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, the decision P/0045/2012 issued on 29 February 2012, the decision P/0108/2015 issued on 1 June 2015, the decision P/0321/2016 issued on 2 December 2016 and the decision P/0263/2017 issued on 4 September 2017.

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

The procedure started on 23 January 2018.

## Scope of the modification

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

## Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

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

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the 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;
- 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 with gastro-intestinal stromal tumours (and younger children with other tumours)

### 2.1.3. Pharmaceutical form(s)

Hard capsule, oral use

### 2.1.4. Measures

| Area | Number of studies | Description |
|---|---|---|
| Quality-related studies | 0 | Not applicable |
| Non-clinical studies | 0 | Not applicable |
| Clinical studies | 3 | **Study 1**<br>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 (ADVL0612)<br>**Study 2**<br>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 (A6181196)<br><br>**Study 4**<br><br>Open label, single-arm, multi-centre trial to evaluate pharmacokinetics, safety and activity of sunitinib in children from 18 months to less than 18 years of age (and in adults) with high-grade glioma or ependymoma (ACNS1021) |
| Extrapolation, modelling and simulation studies | 2 | **Study 3**<br><br>Measure to extrapolate efficacy to the paediatric population.<br><br>**Study 5**<br><br>Modelling and simulation study to develop a population PK model and predict the PK profile and confidence interval of sunitinib in paediatric patients with gastro-intestinal stromal tumour. |
| Other measures | 1 | **Measure 6**<br><br>Retrospective analysis of medical records of paediatric patients (and young adults) with gastrointestinal stromal tumour included in three publications to provide information on sunitinib activity. |

# 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 September 2018 |
| 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