EMA/181225/2018
EMEA/H/C/000687/II/0065

Update of 23 March 2018:

The company that applied to change Sutent's marketing authorisation has requested re-examination of the CHMP's February 2018 opinion. Upon receipt of the grounds of the request, the CHMP will re-examine its opinion and issue a final recommendation.

23 February 2018

Refusal of a change to the marketing authorisation for Sutent (sunitinib)

On 22 February 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of a change to the marketing authorisation for the medicinal product Sutent. The change concerned an extension of indication in patients at high risk of kidney cancer returning after surgery.

The company that applied for the change to the authorisation is Pfizer Limited. It may request a re-examination of the opinion within 15 days of receipt of notification of this negative opinion.

What is Sutent?

Sutent is a cancer medicine currently authorised for treating the following cancers:

- gastrointestinal stromal tumour (a cancer of the stomach and bowel);
- pancreatic neuroendocrine tumours (tumours of the hormone-producing cells in the pancreas);
- metastatic renal cell carcinoma (kidney cancer that has spread to other parts of the body).

Further information on Sutent's current uses can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

Sutent contains the active substance sunitinib.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

What was Sutent expected to be used for?

Sutent was expected to be used to delay or prevent the return of kidney cancer in patients who have had surgery and are at high risk of their cancer coming back.

How does Sutent work?

The active substance in Sutent, sunitinib, is a protein kinase inhibitor. This means that it blocks some specific enzymes known as protein kinases involved in the growth and spread of cancer cells and the development of new blood vessels supplying them. By blocking these enzymes, Sutent can reduce the growth and spread of the cancer and cut off the blood supply that keeps cancer cells growing.

What did the company present to support its application?

The company presented results of a main study comparing Sutent with placebo (a dummy treatment) in 615 patients at high risk of their kidney cancer coming back after surgery. Patients were treated for around a year and the study looked at how long it took for the cancer to come back (disease-free survival).

What were the CHMP's main concerns that led to the refusal of the change to the marketing authorisation?

The CHMP considered that the evidence that Sutent delays the return of the cancer was not convincing. When data from those patients at highest risk of cancer returning were looked at separately, the benefits of Sutent were still not convincing.

Given the known side effects of the medicine, the Committee concluded that the benefits did not outweigh the risks and recommended that the change to the marketing authorisation of Sutent be refused.

What consequences does this refusal have for patients in clinical trials?

The company informed the CHMP that the negative opinion does not have any consequences for patients currently included in clinical trials with Sutent. There are no ongoing clinical trials with Sutent being used for cancer treatment after surgery and no compassionate use programmes with Sutent in Europe.

What is happening with Sutent for its currently authorised uses?

There are no consequences on the use of Sutent in its authorised indications.