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

On 26 June 2018, Pfizer Limited officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application to extend use of Sutent to the treatment of patients at high risk of kidney cancer returning after surgery.

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).

Sutent has been authorised since July 2006 and contains the active substance sunitinib.

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.

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 specific enzymes known as protein kinases that are 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.

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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).

How far into the evaluation was the application when it was withdrawn?

The evaluation had finished and the CHMP had given a negative opinion. The company had requested a re-examination of the negative opinion, but this re-examination had not yet finished when the company withdrew the application.

What was the recommendation of the CHMP at that time?

Based on the review of the data, at the time of the withdrawal, the CHMP had given a negative opinion, recommending that the marketing authorisation for Sutent not be changed to add the treatment of patients at high risk of kidney cancer returning after surgery.

The CHMP considered that the evidence that Sutent delays the return of the cancer was not convincing. When data from patients at highest risk of cancer returning were looked at separately, the benefits of Sutent were still not convincing. In addition, the medicine has known side effects that affect patients' quality of life.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Sutent in the treatment of patients at high risk of kidney cancer returning after surgery did not outweigh its risks.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that it was withdrawing because the data provided do not allow the CHMP to conclude that the benefit outweighs the risks.

The withdrawal letter is available here.

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

The company informed the CHMP that there are no consequences for patients currently included in clinical trials using Sutent.

If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.

What is happening with Sutent for treatment in other uses?

There are no consequences for Sutent in its authorised uses.