This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Sunitinib malate

September 18, 2018

Non-proprietary name

Sunitinib malate

Branded name (Marketing authorization holder)

Sutent Capsule 12.5 mg (Pfizer Japan Inc.)

Indications

Imatinib-resistant gastrointestinal stromal tumour

Unresectable or metastatic renal cell carcinoma

Pancreatic neuroendocrine tumour

Summary of revisions

“Acute cholecystitis” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of acute cholecystitis have been reported in patients treated with sunitinib malate in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 5 cases involving acute cholecystitis have been reported to date (including 2 cases for which a causal relationship to the product could not be ruled out.) No patient mortalities have been reported to date.

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