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

Everolimus (Afinitor tablets 2.5 mg, 5 mg, Afinitor dispersible tablets 2 mg, 3 mg)

June 5, 2018

Non-proprietary name

Everolimus

Branded name (Marketing authorization holder)

a. Afinitor tablets 2.5 mg, 5 mg (Novartis Pharma K.K.)

b. Afinitor dispersible tablets 2 mg, 3 mg (Novartis Pharma K.K.)

Indications

a.

1. Unresectable or metastatic renal cell carcinoma
2. Neuroendocrine tumor
3. Unresectable or recurrent breast cancer
4. Renal angiomyolipoma associated with tuberous sclerosis complex
5. Subependymal giant cell astrocytoma associated with tuberous sclerosis complex

b.

Subependymal giant cell astrocytoma associated with tuberous sclerosis complex

Summary of revision

“Impaired wound healing” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of revision items

As a result of the review of the recent partial change approval application for Certican Tablets 0.25 mg, 0.5 mg, and 0.75 mg, it was decided to add “Impaired wound healing” to

the “Clinically Significant Adverse Reactions” section in the package insert based on the results data submitted with respect to corresponding clinical studies as well as the opinions of expert advisors.

MHLW/PMDA concluded that similar revision of the package insert for Afinitor Tablets 2.5 mg, 5 mg, and Afinitor Dispersible Tablets 2 mg, 3 mg was also necessary. This decision was made in consideration of the fact that the same active ingredient is used and in higher dosages in these products and also in light of 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

No cases involving impaired wound healing have been reported to date with respect to these products.