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

Clopidogrel

Prasugrel hydrochloride

December 8, 2020

Non-proprietary name

a. Clopidogrel

b. Prasugrel hydrochloride

Branded name (Marketing authorization holder)

a. Plavix Tablets 25 mg, 75 mg (Sanofi K.K.), and the others

b. Efient Tablets 2.5 mg, 3.75 mg, 5 mg, 20 mg; Efient OD Tablets 20 mg (Daiichi Sankyo Co., Ltd.)

Indications

a.

· Prevention of recurrence following ischaemic cerebrovascular disorder (except cardioembolic stroke)

· The following ischaemic heart diseases for which percutaneous coronary Intervention (PCI) is indicated:

Acute coronary syndromes (unstable angina, non-ST-elevation myocardial infarction, ST-elevation myocardial infarction)

Stable angina pectoris, old myocardial infarction

· Prevention of thrombus/embolus formation in peripheral arterial disease

b.

The following ischaemic heart diseases for which percutaneous coronary Intervention (PCI) is indicated:

· Acute coronary syndromes (unstable angina, non-ST-elevation myocardial infarction, ST-

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

elevation myocardial infarction)

· Stable angina pectoris, old myocardial infarction

Summary of revisions

In the Precautions concerning Dosage and Administration section and the PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION section, a statement should be added that this drug should be co-administered with aspirin during dual anti-platelet therapy (DAPT) and the latest Japanese and overseas guidelines or other relevant sources should be referred to for the post-DAPT administration.

Investigation results and background of the revision

The Japanese guidelines have been revised. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

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

Not applicable.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).