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

Epoprostenol sodium

July 9, 2019

Non-proprietary name

Epoprostenol sodium

Branded name (Marketing authorization holder)

Flolan for Injection 0.5 mg, 1.5 mg (Glaxo Smith Kline K.K.), and the others

Indications

Pulmonary arterial hypertension

Summary of revisions

“Thrombocytopenia” should be added to the Clinically Significant Adverse reactions section.

Investigation results and background of the revision

Cases of thrombocytopenia have been reported in patients treated with epoprostenol sodium in Japan. Also a cautionary statement concerning thrombocytopenia is included in the package insert of drugs with similar indication in the Clinically Significant Adverse Reactions section. MHLW/PMDA concluded that revision of the package insert of epoprostenol sodium was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

Pharmaceuticals and Medical Devices Agency

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

A total of 18 cases involving thrombocytopenia have been reported to date (including 3 cases for which a causal relationship between the drug and event could not be ruled out).

No patient mortalities have been reported to date.

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