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

Glecaprevir hydrate/pibrentasvir

February 12, 2019

Non-proprietary name

Glecaprevir hydrate/pibrentasvir

Branded name (Marketing authorization holder)

Maviret Combination Tablets (AbbVie GK)

Indications

Improvement of viraemia in patients with chronic hepatitis C or compensated cirrhosis C

Summary of revisions

1. A cautionary statement concerning “Hepatic impairment, jaundice” should be added to the Important Precautions section.
2. A Clinically Significant Adverse Reactions section should be newly added and “Hepatic impairment/jaundice” should be listed within.

Investigation results and background of the revision

Cases of hepatic impairment, jaundice have been reported in patients treated with glecaprevir hydrate/pibrentasvir 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 11 cases involving hepatic impairment have been reported to date (including 5 cases for which a causal relationship with the product could not be ruled out.)

1 instance of patient mortality has been reported to date (a causal relationship with the

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product could not be established in this case.)

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