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Summary of investigation results

Simeprevir sodium

July 8, 2014

Non-proprietary Name
Simeprevir sodium

Brand Name (Marketing Authorization Holder)
SOVRIAD capsules 100 mg (Janssen Pharmaceutical K.K.)

Indications
Improvement of the following viremia in patients with serogroup 1 (genotype I [1a] or II [1b]) chronic hepatitis C:

a. Patients with high blood HCV RNA level who are treatment-naïve
b. Patients who are non-responders or relapsed to therapy including interferon

Summary of revision
'Sepsis' and 'cerebral haemorrhage' should be added in Clinically significant adverse reactions section.

Background of the revision and investigation results
Cases of serious infections including sepsis have been reported in patients treated with combination therapy of simeprevir sodium, peginterferon and ribavirin. Cases of disseminated intravascular coagulation (DIC) resulting in cerebral haemorrhage or infarction have also been reported in patients who had serious infections including sepsis after combination therapy with simeprevir sodium, peginterferon and ribavirin. In some cases, patients died of those adverse reactions. The MHLW/PMDA discussed whether alerts were required in the package insert. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that 'sepsis' and 'cerebral haemorrhage' should be added in Clinically significant adverse reactions section. 'Cerebral infarction' was not required to be added in the package insert because some cases of cerebral infarction had been reported in patients without DIC and a causal relationship between cerebral infarction and combination therapy including simeprevir sodium was not clear.

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The number of reported adverse reaction and fatal cases in the last 3 fiscal years in Japan

A total of 15 infection, or cerebral haemorrhage or infarction-associated cases has been reported (including 7 cases in which causality could not be ruled out). Of the 15 cases, 6 fatalities have been reported (including 3 cases in which causality could not be ruled out).

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