This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

Simeprevir sodium

January 9, 2015

Non-proprietary Name
simeprevir sodium

Brand Name (Marketing Authorization Holder)
Sovriad Capsules 100 mg (Janssen Pharmaceutical K.K.)

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

a. Treatment-naïve patients with high blood HCV RNA load
b. Patients who have failed to respond to, or have relapsed after, therapy including interferon

Summary of revision
'Leukopenia and neutropenia' should be added in the Clinically significant adverse reactions section.

Background of the revision and investigation results
Cases of adverse events suggestive of leukopenia and/or neutropenia have been reported in patients treated with combination therapy of simeprevir sodium, peginterferon and ribavirin in Japan. Following an investigation based on the opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package inserts was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan
A total of 77 cases of adverse events suggestive of leukopenia and/or neutropenia has been reported (including 10 cases in which causality could not be ruled out). No fatalities have been reported.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp