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

Telaprevir

February 17, 2015

Non-proprietary Name
telaprevir

Brand Name (Marketing Authorization Holder)
Telavic Tablets 250 mg (Mitsubishi Tanabe Pharma Corporation)

Indications
- Improvement of viraemia in any of the following patients with serogroup 1 (genotype I [1a] or II [1b]) chronic hepatitis C virus infection:
  - Treatment-naïve patients with high blood HCV RNA load
  - Patients who have failed to respond to, or have relapsed after, therapy including interferon
- Improvement of viraemia in patients with serogroup 2 (genotype III [2a] or IV [2b]) chronic hepatitis C virus infection who have failed to respond to, or have relapsed after, interferon monotherapy or interferon and ribavirin combination therapy

Summary of revision
The following information should be added in the Precautions for dosage and administration section:

A reduced initial dose should be considered in patients with risk of renal impairment associated with telaprevir.

Background of the revision and investigation results
An interim analysis of the use-results survey showed that a non-reduced initial dose (full initial dose), higher age, increased baseline creatinine, and diabetes mellitus or hypertension as comorbidities are risk factors for serious renal impairment in patients treated with telaprevir. 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
Not available (This safety action was based on the use-results survey)

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