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

Asunaprevir and Daclatasvir hydrochloride

September 15, 2015

Non-proprietary name

a. Asunaprevir

b. Daclatasvir hydrochloride

Brand name (Marketing authorization holder)

a. Sunvepra Capsules 100 mg (Bristol-Myers K.K.)

b. Daklinza Tablets 60 mg (Bristol-Myers K.K.)

Indications

a and b

Improvement of viremia in patients with serogroup 1 (genotype 1) chronic hepatitis C or compensated cirrhosis type C

Summary of revision

“Thrombocytopenia” should be newly added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of thrombocytopenia have been reported in patients treated with asunaprevir and daclatasvir hydrochloride in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

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

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

A total of 8 cases associated with thrombocytopenia have been reported (including 8 cases for which a causal relationship to the product could not be ruled out*1). No fatality has been reported.

NOTES:

*1 The causal relationship to combination therapy of asunaprevir and daclatasvir hydrochloride was evaluated.

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