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

pregabalin

September 16, 2014

Non-proprietary Name
pregabalin

Brand Name (Marketing Authorization Holder)
Lyrica Capsules 25 mg, 75 mg, and 150 mg (Pfizer Japan Inc.)

Indications
Neuropathic pain and fibromyalgia-associated pain

Summary of revision
'Fulminant hepatitis' and 'hepatic dysfunction' should be added in Clinically significant adverse reactions section.

Background of the revision and investigation results
Cases of fulminant hepatitis or hepatic dysfunction have been reported in patients treated with pregabalin in Japan. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reaction and fatal cases in the last 3 fiscal years in Japan
A case of fulminant hepatitis, in which a causality could not be ruled out, has been reported. (The reported case was fatal, and the causality of the death could not be ruled out.)

A total of 10 cases* associated with hepatic dysfunction have been reported (including 7 cases in which a causality could not be ruled out). No fatalities have been reported.

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*Cases in which laboratory test results showed AST ≧ 500 U/L, ALT ≧ 500 U/L, or total bilirubin ≧ 10 mg/dL.

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