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

Interferon beta-1a (genetical recombination)

July 7, 2015

Non-proprietary name

Interferon beta-1a (genetical recombination)

Brand name (Marketing authorization holder)

Avonex Intramuscular Injection Syringe 30 µg and Avonex Intramuscular Injection Pen 30 µg (Biogen Japan Ltd.)

Indications

Prophylaxis of multiple sclerosis relapse

Summary of revision

1. The following information should be added to the Important precautions section:
   Patients should be instructed to contact a doctor if they experience the symptoms of liver disorder.
2. The serious liver disorder subsection in the Clinically significant adverse reactions section should be revised as ‘Hepatitis and hepatic function disorder’, and ‘Fulminant hepatitis’ should be added.

Background of the revision and investigation results

A case of fulminant hepatitis has been reported in a patient treated with interferon beta-1a 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
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The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A case of fulminant hepatitis has been reported (including a case for which a causal relationship to the product could not be ruled out). A fatal case has been reported (Including a case for which a causal relationship to the product could not be ruled out).

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