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

Lenalidomide hydrate

January 10, 2017

Non-proprietary name

Lenalidomide hydrate

Brand name (Marketing authorization holder)

Revlimid Capsules 2.5 mg and 5 mg (Celgene K.K.)

Indications

a) Multiple myeloma

b) Myelodysplastic syndrome associated with a deletion 5q cytogenetic abnormality

Summary of revision

1. Precautions with regards to reactivation of hepatitis B virus should be newly added in the Important Precautions section.
2. Precautions that reactivation of hepatitis B virus may occur should be added in the "Infections" subsection in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of reactivation of hepatitis B virus have been reported in patients treated with lenalidomide hydrate 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.

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

A total of 13 cases associated with reactivation of hepatitis B virus have been reported (including 4 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

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