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

Pomalidomide

August 6, 2015

Non-proprietary name

Pomalidomide

Brand name (Marketing authorization holder)

Pomalyst Capsules 1 mg, 2 mg, 3 mg, and 4 mg (Celgene K.K.)

Indications

Relapsed or refractory multiple myeloma

Summary of revision

“Hepatic function disorder and jaundice” should be newly added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of hepatic function disorder and jaundice have been reported in patients treated with pomalidomide overseas, and the company core datasheet ((CCDS))* has been updated. 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

No case associated with hepatic function disorder has been reported.

NOTE:

*CCDS is prepared by the marketing authorization holder and covers materials relating to safety, indications, dosing, pharmacology, and other information concerning the product.

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