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Summary of Investigation Results

Pomalidomide

January 26, 2021

Non-proprietary name

Pomalidomide

Branded name (Marketing authorization holder)

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

Indications

Relapsed or refractory multiple myeloma

Summary of revisions

“Progressive multifocal leukoencephalopathy (PML)” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of PML have been reported in patients treated with pomalidomide in Japan and/or overseas. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 3 cases involving PML have been reported to date (A causal relationship between the drug and event is reasonably possible for these cases.)

No patient mortalities have been reported to date.

Pharmaceuticals and Medical Devices Agency

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The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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