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, 2019

Non-proprietary name

Lenalidomide hydrate

Branded name (Marketing authorization holder)

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

Indications

- Multiple myeloma
- Myelodysplastic syndrome associated deletion 5q cytogenetic abnormality
- Relapsed or refractory adult T-cell leukemia/lymphoma

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 lenalidomide hydrate overseas including cases reported during the previous 3 fiscal years. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

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

No cases involving PML have been reported to date.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp