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Summary of Investigation Results

Relugolix

September 8, 2020

Non-proprietary name

Relugolix

Branded name (Marketing authorization holder)

Relumina Tablets 40 mg (Aska Pharmaceutical. Co., Ltd.)

Indications

Relief of the following symptoms associated with uterine fibroids: menorrhagia, lower abdominal pain, lumbar pain, and anemia

Summary of revisions

1. “Patients with submucosal fibroid” should be added to the Careful Administration section.
2. A statement that severe abnormal uterine bleeding may occur in patients with submucosal fibroid should be added to the Important Precautions section.

Investigation results and background of the revision

Cases of severe abnormal uterine bleeding have been reported in patients treated with relugolix in Japan and all the reported cases for which a causal relationship between the drug and event was reasonably possible were of patients with submucosal fibroid or those strongly suspected to have submucosal fibroid. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

Pharmaceuticals and Medical Devices Agency

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

Cases involving severe abnormal uterine bleeding

A total of 13* cases have been reported to date (including 10 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported to date.

(Japanese market launch: March 2019)

*: Including 1 case where the presence of uterine fibroids was unknown.

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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