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

Secukinumab (genetical recombination)

October 23, 2018

Non-proprietary name

Secukinumab (genetical recombination)

Branded name (Marketing authorization holder)

Cosentyx for s.c. injection 150 mg syringe, Cosentyx for s.c. injection 150 mg pen (Novartis Pharma K.K.)

Indications

The following diseases in patients who were not sufficiently responsive to conventional therapies:

Psoriasis vulgaris, psoriatic arthritis, and pustular psoriasis

Summary of revisions

1. “Patients with active Crohn’s disease” in the Careful Administration section should be revised to “patients with inflammatory bowel disease”.
2. “Inflammatory bowel disease” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of inflammatory bowel disease have been reported in patients treated with secukinumab in Japan. 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.

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

A total 12 cases involving inflammatory bowel disease have been reported to date (including 6 cases for which a causal relationship with the product could not be ruled out.)

No patient mortalities have been reported to date.

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