Summary of Investigation Results

Secukinumab

(genetical recombination)

January 21, 2020

Non-proprietary name

Secukinumab (genetical recombination)

Branded name (Marketing authorization holder)

a. Cosentyx for s.c. injection 150 mg syringe

b. 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, pustular psoriasis, and ankylosing spondylitis

Summary of revisions

“Erythroderma (dermatitis exfoliative)” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of erythroderma (dermatitis exfoliative) have been reported in patients treated with secukinumab in Japan and overseas. 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

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

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

A total of 3 cases involving erythroderma (dermatitis exfoliative) have been reported to date (including 1 case for which a causal relationship between the drug and event could not be ruled out).

No patient mortalities 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