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

Ustekinumab (genetical recombination)

October 18, 2016

Non-proprietary name

Ustekinumab (genetical recombination)

Brand name (Marketing authorization holder)

Stelara Subcutaneous Injection 45 mg Syringe (Janssen Pharmaceutical K.K.)

Indications

The following diseases with an inadequate response to conventional therapy:
Psoriasis vulgaris, Psoriatic arthritis

Summary of revision

“Interstitial pneumonia” should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of interstitial pneumonia have been reported in patients treated with ustekinumab in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 16 cases associated with interstitial pneumonia have been reported (including 6 cases for which a causal relationship to the product could not be ruled out). Of the 16 cases, 1 fatal case has been reported (a causal relationship between the product and the fatal outcome could not be established for this patient).

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