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

Panitumumab (genetical recombination)

August 6, 2015

Non-proprietary name

Panitumumab (genetical recombination)

Brand name (Marketing authorization holder)

Vectibix Intravenous Infusions 100 mg and 400 mg (Takeda Pharmaceutical Company Limited)

Indications

KRAS wild-type, incurable, unresectable, advanced/recurrent colorectal cancer

Summary of revision

“Toxic epidermal necrolysis” should be added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of toxic epidermal necrolysis have been reported in patients treated with panitumumab (genetical recombination) 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 case of toxic epidermal necrolysis has been reported (a causal relationship to the product could not be ruled out for this patient). The patient was a fatal case (a causal relationship between the product and the fatal outcome could not be ruled out for this patient).

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp