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# Summary of Investigation Results

## Cetuximab (genetical recombination)

March 30, 2021

**Non-proprietary name**

Cetuximab (genetical recombination)

**Branded name (Marketing authorization holder)**

Erbitux Injection 100 mg (Merck Biopharma Co., Ltd)

**Indications**

RAS wild-type, incurable, unresectable, advanced/recurrent colorectal cancer
Head and neck cancer

**Summary of revisions**

“Hypomagnesaemia” should be added to the Clinically Significant Adverse Reactions section.

**Investigation results and background of the revision**

Cases of hypomagnesaemia have been reported in patients treated with cetuximab (genetical recombination) in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

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

A total of 5 cases involving hypomagnesaemia have been reported to date (including 3 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported to date.

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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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