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

Dulaglutide (genetical recombination)

May 9, 2019

Non-proprietary name

Dulaglutide (genetical recombination)

Branded name (Marketing authorization holder)

Trulicity Subcutaneous Injection 0.75 mg Ateos (Eli Lilly Japan K.K.)

Indications

Type 2 diabetes mellitus

Summary of revision

“Severe diarrhoea and vomiting” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Several cases of severe diarrhoea and vomiting have been reported in patients treated with dulaglutide for which a causal relationship to the drug could not be ruled out. Of those, some cases subsequently had dehydration which led to acute kidney injury. Based on the results of their investigation of the currently available evidence and in consultation with expert advisors, MHLW/PMDA concluded that it was necessary to add “severe diarrhoea and vomiting” to the Clinically Significant Adverse Reactions section and a cautionary statement that they may subsequently cause dehydration, leading to acute kidney injury.

Pharmaceuticals and Medical Devices Agency

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

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

A total of 7 cases involving severe gastrointestinal disorders have been reported to date (including 3 cases for which a causal relationship to the product 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