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 30, 2017

Non-proprietary name

Dulaglutide (genetical recombination)

Brand name (Marketing authorization holder)

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

Indications

Type 2 diabetes mellitus

Summary of revision

“Anaphylaxis, angioedema” should be added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of anaphylaxis have been reported in patients treated with dulaglutide (genetical recombination) overseas and the company core data sheet (CCDS) has been revised. In addition, angioedema-related symptoms have been frequently observed in the cases associated with anaphylaxis, and cases of angioedema have also been reported overseas. 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 to add the two events, anaphylaxis and angioedema.

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

A total of 2 cases associated with anaphylaxis have been reported (including no case for which a causal relationship to the product could not be ruled out). One fatal case has been

reported (including no fatal case for which a causal relationship to the product could not be ruled out).

No cases associated with angioedema have been reported.