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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 Anagliptin

March 20, 2018

#### Non-proprietary name

Anagliptin

### Brand name (Marketing authorization holder)

Suiny Tab. 100 mg (Sanwa Kagaku Kenkyusho Co., Ltd.)

Indications Type 2 diabetes mellitus

#### Summary of revision

"Pemphigoid" should be added to the Clinically Significant Adverse Reactions section.

#### Investigation results and background of the revision

Cases of pemphigoid have been reported in patients treated with anagliptin in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the evidence currently available and as a result of consultation with expert advisors.

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

A total of 7 cases associated with pemphigoid have been reported (including 1 case for which a causal relationship with the product could not be ruled out). No patient mortalities have been reported to date.

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