



# 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.