



# Summary of investigation results Products Containing Vildagliptin, Sitagliptin phosphate hydrate

April 21, 2016

## Non-proprietary name

- a. Vildagliptin
- b. Vildagliptin/Metformin hydrochloride
- c–d. Sitagliptin phosphate hydrate

## Brand name (Marketing authorization holder)

- a. Equa Tablets 50 mg (Novartis Pharma K.K.)
- b. Equmet Combination Tablets LD, HD (Novartis Pharma K.K.)
- c. Glactiv Tablets 12.5 mg, 25 mg, 50 mg, 100 mg (Ono Pharmaceutical Co., Ltd.)
- d. Januvia Tablets 12.5 mg, 25 mg, 50 mg, 100 mg (MSD K.K.)

## Indications

- a, c-d. Type 2 diabetes mellitus
- b. Type 2 diabetes mellitus
  - Only for which treatment with concomitant vildagliptin and metformin hydrochloride is judged to be appropriate

## Summary of revision

“Pemphigoid” should be newly added in the Clinically significant adverse reaction section.

## Background of the revision and investigation results

Cases of pemphigoid have been reported in patients treated with products containing vildagliptin and with sitagliptin phosphate hydrate in Japan. 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.



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

- a. A total of 28 cases associated with pemphigoid have been reported (including 8 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.
- b. No case associated with pemphigoid has been reported.
- c-d. A total of 7 cases associated with pemphigoid have been reported (including 3 cases for which a causal relationship to the product could not be ruled out). Of the 7 cases, 1 fatal case has been reported (a causal relationship between the product and the fatal outcome could not be established for this patient).