



17 January 2013  
EMA/CHMP/35984/2013  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Onglyza saxagliptin

On 17 January 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Onglyza. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb/AstraZeneca EEIG. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows:

" Onglyza is indicated as triple oral therapy in combination with metformin plus a sulphonylurea when this regimen alone, with diet and exercise, does not provide adequate glycaemic control"

For information, the full indications for Onglyza will be as follows<sup>2</sup>:

Onglyza is indicated in adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control:

as dual oral therapy in combination with

- metformin, when metformin alone, with diet and exercise, does not provide adequate glycaemic control.
- a sulphonylurea, when the sulphonylurea alone, with diet and exercise, does not provide adequate glycaemic control. in patients for whom use of metformin is considered inappropriate.
- a thiazolidinedione, when the thiazolidinedione alone with diet and exercise, does not provide adequate glycaemic control in patients for whom use of a thiazolidinedione is considered appropriate.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

<sup>2</sup> The text in bold represents the new or the amended indication.



as triple oral therapy in combination with

- **metformin plus a sulphonylurea when this regimen alone, with diet and exercise, does not provide adequate glycaemic control**

as combination therapy with insulin (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.