



20 October 2011
EMA/CHMP/834742/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Onglyza saxagliptin

On 20 October 2011, 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:

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

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Onglyza will be as follows²:

Add-on combination therapy

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

- in combination with metformin, when metformin alone, with diet and exercise, does not provide adequate glycaemic control.
- in combination with 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.

¹ 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.

² The text in bold represents the new or the amended indication.



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