20 September 2012
EMA/591330/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Trajenta

linagliptin

On 20 September 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending on a grouping of variations to the terms of the marketing authorisation for the medicinal product Trajenta. The marketing authorisation holder for this medicinal product is Boehringer Ingelheim International GmbH. 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.

Furthermore, the CHMP adopted changes to the summary of product characteristics of Trajenta to include the results of a study conducted in elderly patients.

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 grouping of variations to the marketing authorisation has been granted by the European Commission.

For information, the full indication(s) for Trajenta will be as follows[2]:

Trajenta is indicated in the treatment of type 2 diabetes mellitus to improve glycaemic control in adults:

as monotherapy

- in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment.

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

as combination therapy

- in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control.
- in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.
- **in combination with insulin with or without metformin, when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.**