



19 September 2019  
EMA/504760/2019  
Committee for Medicinal Products for Human Use (CHMP)

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

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### Trulicity dulaglutide

On 19 September 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Trulicity. The marketing authorisation holder for this medicinal product is Eli Lilly Nederland B.V..

The CHMP adopted a change to the existing indication as follows:<sup>2</sup>

#### **“Type 2 Diabetes Mellitus**

Trulicity is indicated **for the treatment of** ~~in~~ adults with **insufficiently controlled** type 2 diabetes mellitus **as an adjunct to diet and exercise** ~~improve glycaemic control as:~~

- **As Monotherapy** ~~When diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications~~
- **In addition to other** ~~Add-on therapy~~ **for the treatment of diabetes.** ~~In combination with other glucose lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see section 5.1 for data with respect to different combinations).~~

**For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, see sections 4.4, 4.5 and 5.1.”**

Detailed recommendations 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 a decision on this change to the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> New text in bold, removed text as strikethrough

