



26 January 2017
EMA/CHMP/44144/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Synjardy

empagliflozin / metformin

On 26 January 2017, 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 Synjardy. The marketing authorisation holder for this medicinal product is Boehringer Ingelheim International GmbH.

The CHMP adopted a change to the existing indication as follows²:

"Synjardy is indicated ~~in~~ **for the treatment of** adults ~~aged 18 years and older~~ with type 2 diabetes mellitus as an adjunct to diet and exercise ~~to improve glycaemic control~~

- in patients **insufficiently** ~~inadequately~~ controlled on their maximally tolerated dose of metformin alone
- in ~~patients inadequately controlled with metformin~~ combination with other glucose-lowering medicinal products **for the treatment of diabetes, in patients insufficiently controlled with metformin and these medicinal products**, including insulin (see sections ~~4.5 and 5.1 for available data on different combinations~~)
- in patients already being treated with the combination of empagliflozin and metformin as separate tablets.

For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the population 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.

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

² **New text in bold, removed text as strikethrough**

