14 December 2017
EMA/CHMP/807424/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Yervoy

ipilimumab

On 14 December 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 Yervoy. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

The CHMP adopted an extension to the existing indication as follows[2]:

> "Yervoy is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults**, and adolescents 12 years of age and older (see section 4.4).**"

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

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