



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2013
EMA/547838/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Yervoy ipilimumab

On 19 September 2013, 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 Yervoy. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb Pharma 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 change to the indication, extending the use of the medicine to previously untreated patients. The change adopted is as follows:

"YERVOY is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults ~~who have received prior therapy.~~"

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.

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.

