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Committee for Medicinal Products for Human Use (CHMP)

Yervoy

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: ipilimumab

Procedure No. EMEA/H/C/002213/PSUV/0020

Period covered by the PSUR: 25 September 2012 – 24 March 2013

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Yervoy, the scientific conclusions of PRAC are as follows:

A review of cases of anaphylaxis or cytokine release syndrome events identified a total of 6 cases: two of the 6 cases had limited information for assessment. Nevertheless, there have been cases of anaphylactic reactions, resulting in hospitalization in at least one patient; and for which stopping the medication and supportive care was needed in all reported cases. Due to the characteristics of the cases (rapid time to onset and severity of the events) the PRAC considered that anaphylactic reactions should be included in section 4.8 of the SmPC, with a frequency based on clinical trials, i.e. very rare (<0.01% (1/12881)). The package leaflet is updated accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Yervoy, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance IPILIMUMAB is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.