



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): nivolumab

Procedure No. EMEA/H/C/PSUSA/00010379/201801

Period covered by the PSUR: 4 July 2017 to 3 January 2018



Scientific conclusions

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

Pericardial disorders: Considering the number of cases reported in EudraVigilance, the data observed in clinical trials, the increasing number of post-marketing cases (some of them assessed as related by both the investigator and the MAH), the close aetiology with known risk of myocarditis and the disproportion observed in the current period in both FAERS and Vigibase, pericardial disorders (considering pericarditis, pericardial effusion, cardiac tamponade, and Dressler's Syndrome) should be included in section 4.8 with a frequency calculated from incidence in clinical trials.

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

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for nivolumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing nivolumab is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation should be varied.