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): pembrolizumab

Procedure No. EMEA/H/C/PSUSA/00010403/201703

Period covered by the PSUR: 4 September 2016 to 3 March 2017

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for pembrolizumab, the scientific conclusions of CHMP are as follows:

Cumulatively, a total of 785 reports containing 819 events of pneumonia were identified in the safety database. Of the 785 reports, 757 were considered serious and in 134 events the outcome was fatal. Given the seriousness of the event, the lack of imbalance observed in clinical trials against comparators (chemotherapy and ipilimumab) associated with the occurrence of pneumonia and the reflection of the adverse drug reaction (ADR) in the SmPC of similar products (ipilimumab, nivolumab), a causal relationship between pembrolizumab and pneumonia cannot be excluded. The PRAC therefore recommends adding this possible ADR to the SmPC with a frequency of uncommon and to update the Package Leaflet accordingly.

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

Grounds for the variation to the terms of the marketing authorisation(s)

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

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