22 April 2021
EMA/285950/2021
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/00010403/202009

Period covered by the PSUR: 04 September 2019 to 03 September 2020

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

In view of available data on cholangitis sclerosing from literature and spontaneous reports including in some close temporal relationship, improvement following steroid treatment, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between pembrolizumab and cholangitis sclerosing is at least a reasonable possibility.

In view of available data on gastritis from clinical trials, the literature, and gastritis listed for the class product nivolumab, the PRAC considers a causal relationship between pembrolizumab and gastritis is at least a reasonable possibility.

The PRAC concluded that the product information of products containing pembrolizumab should be amended 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.