28 May 2020
EMA/345734/2020
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): durvalumab

Procedure No. EMEA/H/C/PSUSA/00010723/201910

Period covered by the PSUR: 01 May 2019 to 31 October 2019

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 durvalumab, the scientific conclusions of CHMP are as follows:

Further to a PRAC request, the MAH submitted a cumulative safety review and analysis of neurological immune-mediated adverse events reported with durvalumab from all sources. In view of the available data and considering the safety profile of other medicinal products of the same class, the PRAC concluded that the product information of durvalumab should be amended.

Sections 4.4 and 4.8 of the SmPC are updated to reflect that cases of meningitis, encephalitis and Guillain-Barre syndrome have been reported with durvalumab in ongoing and completed trials. The Package leaflet has been updated 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 durvalumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing durvalumab 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.