22 May 2025
EMA/264545/2025
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): tremelimumab

Procedure No. EMEA/H/C/PSUSA/00011038/202410

Period covered by the PSUR:
21/04/2024 To: 20/10/2024

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

Annex IV

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

Scientific conclusions

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

In view of available data on polymyalgia rheumatica, the PRAC considers a causal relationship between tremelimumab in combination with durvalumab and polymyalgia rheumatica is at least a reasonable possibility. The PRAC concluded that the product information of products containing tremelimumab should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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

On the basis of the scientific conclusions for tremelimumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tremelimumab 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.