



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): tremelimumab

Procedure No. EMEA/H/C/PSUSA/00011038/202404

Period covered by the PSUR:
21/10/2023 To: 20/04/2024



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 myelitis transverse, the PRAC considers a causal relationship between tremelimumab in combination with durvalumab and myelitis transverse is at least a reasonable possibility. The PRAC concluded that the product information of products containing tremelimumab should be amended accordingly.

In view of available data on rhabdomyolysis from the literature and spontaneous reports, the PRAC considers a causal relationship between tremelimumab in combination with durvalumab and rhabdomyolysis 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.