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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): sugemalimab

Procedure No. PSUSA/00011080/202412

Period covered by the PSUR: 6 months to 19 December 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

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Scientific conclusions

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

In view of published PRAC recommendations on signals Coeliac disease and Pancreatic failure associated with immune checkpoint inhibitors, the PRAC concluded that the product information of sugemalimab 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 sugemalimab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing sugemalimab 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.