



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): lecanemab

Procedure No. PSUSA/00011132/202507

Period covered by the PSUR: 6 months to 05 July 2025

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Scientific conclusions

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

In view of available data on amyloid related imaging abnormalities (ARIA) from pivotal clinical trial(s), spontaneous reports including 3 fatal cases of ARIA (intracerebral haemorrhage > 1 cm in diameter) from the current PSUR period and in view of a fact that EU SmPC and Patient card already mention that ARIAs can be life-threatening events, the PRAC considers necessary to update Package Leaflet to follow the safety information in the SmPC and Patient card. The PRAC concluded that the product information of products containing lecanemab 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 lecanemab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing lecanemab 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.