

EN
E-000880/2025
Answer given by Mr Várhelyi
on behalf of the European Commission
(6.5.2025)

The request for a review of the opinion of the European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) regarding the medicinal product Leqembi (lecanemab) was based on a discussion with Member States during the Standing Committee phase pointing to a scientific publication in January 2025¹, citing safety signals identified post-marketing in the United States of America. The CHMP was also asked to consider whether the wording of the risk minimisation measures related to the authorisation of Leqembi was clear enough to ensure correct implementation.

The CHMP considered the request and concluded in February 2025 that the marketing authorisation of Leqembi did not need to be updated. Following the response from the CHMP, the Commission consulted the Member States on the draft Commission decision to authorise Leqembi. No qualified majority in favour of the decision was reached at the meetings of the Standing Committee on 21 March 2025² and of the Appeal Committee on 7 April 2025³. According to the procedures laid down in the legislation⁴ and based on the EMA opinion, on 15 April 2025, the Commission adopted the decision to authorise Leqembi⁵.

The Commission is aware of the high unmet medical need for effective Alzheimer's treatments. The EMA is currently assessing two medicines for the treatment of Alzheimer's disease: donanemab and blarcamesine. Once these evaluations are concluded, the outcomes will be made public on the EMA website and the Commission will prepare draft decisions based on the CHMP scientific opinions.

The Commission is committed to ensuring patient access to medicines as early as possible, while guaranteeing that any new medicine meets the EU standards of quality, safety and efficacy.

¹ Xing X, Zhang X, Wang K, Wang Z, Feng Y, Li X, Hua Y, Zhang L, Dong X. Post-marketing safety concerns with lecanemab: a pharmacovigilance study based on the FDA Adverse Event Reporting System database. *Alzheimers Res Ther.* 2025 Jan 8;17(1):15. doi: 10.1186/s13195-024-01669-4. PMID: 39780222; PMCID: PMC117.

² <https://ec.europa.eu/transparency/comitology-register/screen/documents/106397/1/consult?lang=en>

³ <https://ec.europa.eu/transparency/comitology-register/screen/documents/106785/1/consult?lang=en>

⁴ Articles 5 and 6 of Regulation (EU) No 182/2011: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0182>

⁵ Union Register of medicinal products <https://ec.europa.eu/health/documents/community-register/html/h1891.htm>