

(English version)

**Question for written answer E-000913/25
to the Commission
Vladimir Prebilič (Verts/ALE)
(4 March 2025)**

Subject: Approval of new drug for Alzheimer's disease

The European Medicines Agency approved the use of a new drug for treating Alzheimer's disease in November 2023. However, according to publicly available information, its actual use in the EU still requires the Commission's approval. Both patients and their relatives have high expectations for this new drug and it could significantly contribute to improving their health and quality of life.

1. What are the prospects for this drug to be approved as soon as possible?
2. If it is not approved at this stage, is there a timeline in place for the process to be finalised?

Submitted: 4.3.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(13 May 2025)**

On 14 November 2024, the Committee for Medicinal Products for Human Use (CHMP), following a re-examination procedure, adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Leqembi, for the treatment of early Alzheimer's disease in a restricted population of patients. It is for use in people who have only one or no copy of the ApoE4 gene and who have amyloid beta plaques in the brain.

Based on the CHMP opinion, the Commission prepared a draft decision, which was submitted for written consultation of the Member States in the Standing Committee on Medicinal Products for Human Use ⁽¹⁾. During this consultation, some Member States raised scientific questions, prompting the request for a plenary meeting, which was held on 24 January 2025. Following the meeting, the Commission consulted the CHMP on those scientific questions. The CHMP considered this request and concluded on 27 February 2025 that its November 2024 opinion recommending 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 2025 ⁽²⁾ and of the Appeal Committee on 7 April 2025 ⁽³⁾. According to the procedures laid down in the legislation ⁽⁴⁾ and based on the EMA opinion, on 15 April 2025, the Commission adopted the decision to authorise Leqembi, which is published on the Union Register for Medicinal products ⁽⁵⁾.

⁽¹⁾ https://health.ec.europa.eu/document/download/ba9e5b07-00d8-4e68-b539-0c9ac7c3c0f3_en?filename=2011_09_13_human.pdf.

⁽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>.