

# **Alzheimer Europe statement on the re-examination of the marketing authorisation application for donanemab by the European Medicines Agency**

**16 July 2025**

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### Background

Dementia affects over 9 million individuals across Europe, with numbers projected to double by 2050. Alzheimer's disease (AD), the most common form of dementia, has been a major focus of research efforts to identify new treatments. Among these, anti-amyloid therapies such as lecanemab and donanemab (monoclonal antibodies designed to remove amyloid plaques in the brain) are leading a new era of disease-modifying medicines that can delay clinical progression by targeting the underlying pathology of Alzheimer's disease (AD).

Lecanemab, an anti-amyloid therapy marketed by Eisai and Biogen, was approved by the European Medicines Agency (EMA) in November 2024, following re-examination by the EMA's Committee for Medicinal Products for Human Use (CHMP). The European Commission granted EU authorisation for the medicine on 15 April 2025, marking the introduction of a first disease-modifying therapy for AD in the European Union.

A marketing authorisation application (MAA) for donanemab, an anti-amyloid therapy marketed by Eli Lilly, was submitted to the EMA in spring 2023. The application was based on results from Lilly's Phase 3, TRAILBLAZER-ALZ2 clinical trial of donanemab, which demonstrated significant slowing of cognitive and functional decline, in participants with mild cognitive impairment or mild dementia due to AD.

On 27 March 2025, the CHMP issued a negative opinion on donanemab, for the treatment of early symptomatic AD. In their decision, the CHMP cited an unfavourable benefit-risk balance: although donanemab slowed clinical decline over the 76-week study period, amyloid-related imaging abnormalities (ARIA) occurred in 36.8% of treated participants, compared to 14.9% of those receiving placebo. Consequently, the CHMP concluded that, even in a restricted population, the benefits did not outweigh the risks of serious adverse events.

Following the refusal, Eli Lilly requested a re-examination of the negative opinion for donanemab. Re-examination started on 2 June 2025 and the CHMP now has 60 days to re-examine its opinion, with a final outcome expected by the end of July.

### Alzheimer Europe's position on the refusal of donanemab by the EMA

Alzheimer Europe regrets this negative opinion by the CHMP. People living with Alzheimer's disease and their families had welcomed the positive opinion on lecanemab in November 2024 and had similar hopes about the introduction of an additional treatment for patients in Europe. The CHMP recommendation means that Europeans with early Alzheimer's disease may not have



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access to an additional anti-amyloid treatment which is available to patients in many other countries and regions.

This position statement, issued in response to the CHMP opinion, identifies five key areas of concern for the European dementia community:

### 1. Refusal of donanemab risks creating disparities and worsening health inequalities

At the time of writing, thirteen global regulators have approved donanemab. The US Food and Drug Administration (FDA) granted traditional approval to lecanemab in July 2024. Similar approvals were adopted in the UAE (March 2024), Qatar (October 2024) Japan (October 2024), United Kingdom (October 2024), China (December 2024), Bahrain (December 2024), Mexico (January 2025), Kuwait (January 2025), Singapore (March 2025), Taiwan (April 2025), Brazil (April 2025) and Australia (May 2025).

The EMA refusal of donanemab is at odds with the decisions by regulatory authorities in these countries. This negative decision also contrasts with its approval of lecanemab, a drug with a broadly similar benefit-risk profile to donanemab.

Alzheimer Europe supports the independent assessment of medicines across regions and values the EMA's scientific rigour. However, it is difficult to understand the EMA's rejection of a drug which has been approved by 13 other regulators based on the same scientific evidence – depriving European patients from accessing an additional treatment available in many other countries.

### 2. Approval of donanemab would support patient autonomy and provide choice for clinicians, patients and families

Countries where lecanemab and donanemab are marketed have developed detailed recommendations for information and treatment, including criteria for inclusion and exclusion, and guidelines for monitoring side effects. This provides a solid foundation for supported, shared decision-making involving patients, families, and physicians. As donanemab and lecanemab differ in dosing and stopping guidelines, rejecting donanemab would remove one option for patients and clinicians to choose a disease-modifying therapy that may best fit individual needs and preferences.

Patients and their families should have the right to discuss treatment options and make informed choices based on their individual circumstances, preferences and values. A negative decision on donanemab would undermine patient autonomy, raising ethical concerns about balancing regulatory caution with the patient's right to choose.



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### 3. Targeted risk management strategies could enhance the benefit-risk profile of donanemab

Alzheimer Europe welcomes the attention the CHMP pays to patient safety when evaluating new medicines. The organisation was encouraged by the considered approach that the EMA took in approving lecanemab, identifying patients most likely to benefit from treatment whilst excluding those at greatest risk of harmful side-effects (in particular people with two copies of the ApoE4 gene).

Alzheimer Europe had hoped that a similar approach would be used for the authorisation of donanemab with a controlled access programme, rigorous safety monitoring requirements and the obligation for the company to conduct a post-authorisation safety study. This would generate real world data on donanemab in the European context, supporting the ongoing refinement of treatment strategies to enhance the drug's benefit-risk profile.

Regulatory authorities that have approved donanemab have implemented robust risk management strategies to address safety concerns, also considering modified dosing and administration modalities to reduce the risk of side effects. On 9 July 2025, the US Food and Drug Administration (FDA) approved an updated titration regimen that gradually increases the dose of donanemab over 4 months, substantially reducing the incidence of ARIA whilst maintaining clinical efficacy. Exclusion of people with two copies of the ApoE4 gene, as mandated by regulatory authorities in the UK and Australia among others, can further improve the risk benefit ratio. Emerging evidence also supports the feasibility of enhanced safety monitoring, such as screening for superficial siderosis to exclude these individuals at elevated risk.

These and other measures help ensure that patients who may benefit from donanemab treatment are not unnecessarily excluded, while prioritising the safety of those at highest risk.

### 4. Donanemab treatment can provide meaningful benefits to patients with early AD

TRAILBLAZER-ALZ2 was an 18-month, placebo-controlled Phase 3 trial, demonstrating that donanemab could slow clinical decline by 35% on the integrated Alzheimer's Disease Rating Scale (iADRS), which equates to a delay in disease progression of approximately 5.3 months. Beyond clinical endpoints, donanemab also produced meaningful benefits based on patient-reported outcomes. Participants receiving donanemab experienced between 37-53% less decline in quality of life, as measured by the QoL-AD scale.



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While donanemab is associated with important side effects that require careful consideration of eligibility and safety monitoring, treatment may help preserve quality of life and reduce caregiver burden, measures that are highly meaningful for patients and their families.

### 5. Approval of donanemab could drive healthcare systems investment and maintain European competitiveness in R&D

The introduction of anti-amyloid therapies has the potential not only to improve clinical outcomes, but also to accelerate health systems reform. The Alzheimer Europe 2018 European Carer's Report showed that nearly half of the caregiver respondents to a survey across five countries felt that diagnosis came too late, with an average wait of 2 to 3 years for diagnosis. In countries such as Japan and the US, where both donanemab and lecanemab are available, approval has prompted expansion of biomarker testing, development of new clinical pathways, and infrastructure investments.

However, European healthcare systems may struggle to adopt these changes without regulatory momentum. This has implications beyond patient care: failure to approve donanemab may discourage companies from conducting clinical trials, delaying access to emerging therapies for European patients.

International experiences demonstrate how anti-amyloid approval can act as a catalyst for healthcare systems change, spurring the development of new clinical guidelines and increased biomarker testing. The availability of an additional anti-amyloid drugs should further incentivise healthcare systems to adapt, to promote access to innovative therapies and create streamlined processes for patients to receive timely diagnoses and patient-centered care.

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### The way forward

Alzheimer Europe recognises the importance of a thorough and independent assessment by the European Medicines Agency. However, the negative opinion on donanemab raises important concerns for patients, carers, clinicians, and health systems across Europe.

We urge the CHMP, in its re-examination, to carefully consider how a refusal of donanemab may affect equity, choice, and patient autonomy. Thirteen regulatory authorities around the world have approved donanemab based on the same scientific evidence currently being reevaluated. The EMA's negative opinion stands in contrast to these decisions and to its own approval of lecanemab, a medicine with a similar benefit-risk profile. A continued refusal would reduce access



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to an additional disease-modifying therapy that is already available to patients in many other countries.

Donanemab offers a further treatment option for people with early Alzheimer's disease, with a different dosing regimen and stopping rules. Alongside lecanemab, it could support more personalised decision-making between patients, carers and clinicians, taking into account individual risk factors, preferences and treatment needs. Countries that have approved donanemab have implemented detailed safety protocols and targeted eligibility criteria. These measures help balance safety with access and could be adapted for use in the EU.

We encourage the EMA and the company to work together to define a clear patient population where the benefits of treatment outweigh the risks. The exclusion of patients with superficial siderosis, ApoE4 homozygotes and patients on anticoagulants could be part of such a strategy, as well as requirements for safety monitoring, eligibility restrictions, controlled access and the collection of real-world data through patient registries. Alzheimer Europe is encouraged by the availability of flexible dosing and titration strategies to reduce the risk of side effects without compromising clinical benefit.

Regulatory decisions also have broader consequences. Delays in access to new therapies risk slowing down investment in health systems and in research. The approval of additional treatments like donanemab could support reforms in diagnosis, care planning and service delivery, improving outcomes for people with dementia and their families.

Alzheimer Europe remains committed to a holistic approach to Alzheimer's disease and dementia, where innovative new treatments are included alongside counselling, support and adequate care of people with dementia and their carers throughout the disease process. The organisation therefore reiterates its call for continued research into other treatment options, including symptomatic therapies and treatments for people in more advanced stages of dementia.