Changing perceptions, policy and practice to improve the lives of people affected by dementia

Mr Olivér Várhely
European Commissioner for Health and Animal Welfare
European Commission
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Luxembourg, 3 April 2025

Copy to: Dr Ursula von der Leyen, President of the European Commission
Dr Emer Cooke, Executive Director, European Medicines Agency
Dr Bruno Sepedes, Chairperson, Committee for Medicinal Products for Human Use
Ms Sandra Gallina, Director-General, Directorate-General for Health and Food Safety
Ms Olga Solomon, Chairperson, Standing Committee on medicinal products for human use

Re: Marketing authorisation for lecanemab for the treatment of early Alzheimer's disease

Dear Commissioner,

On behalf of Alzheimer Europe, the umbrella organisation of 41 national Alzheimer's associations from 36 European countries, I am writing to you today to express our grave concerns about the ongoing delays in the review process for the marketing authorisation of lecanemab for the treatment of early Alzheimer's disease.

As you are undoubtedly aware, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion on 14 November 2024 by a majority vote which it reaffirmed by consensus at its meeting of 24 February 2025. Unfortunately, the Standing Committee on Medicinal Products was unable to reach a qualified majority decision at its meeting of 21 March and has now referred the decision to the Appeal Committee which will be meeting on 7 April.

Alzheimer Europe welcomes the very careful approach taken by the European Union in evaluating the efficacy and safety of these first disease modifying treatments for people with Alzheimer's disease and supports the independent assessment of medicines and the rigorous scientific evaluation conducted by the CHMP. Together with our national member associations, we also welcome the focus of the EMA on patient safety and fully support the considered approach of the CHMP which excludes people carrying two copies of the ApoE4 gene, as well as individuals receiving anticoagulant therapy from the indication, as these individuals are at greatest risk of harmful side-effects.

The CHMP has also mandated additional measures to reduce risk, including a controlled access programme, regular MRI scans for safety monitoring, and a post-authorisation study to assess the effectiveness of these risk minimisation measures. Our organisation is reassured by real-world evidence showing that it is possible to use lecanemab safely in clinical practice, as demonstrated by experiences in the US, Japan and other countries where lecanemab is approved.

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We therefore hope that the Appeal Committee will affirm the positive opinion of the CHMP by a qualified majority, enabling Europeans to access this first disease modifying treatment for early Alzheimer's disease.

Should the Appeal Committee not be in a position to come to a qualified majority decision, we would like to strongly urge the European Commission to make use of its discretionary right foreseen in article 6 of ***Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers*** which stipulates that in cases "where no opinion is delivered, the European Commission **may** adopt the draft implementing act."

We would like to highlight the following key reasons which we already presented in the position (in attachment) addressed to the EMA and CHMP after the initial negative opinion on lecanemab of 26 July 2024:

- A negative decision on lecanemab would deprive Europeans with early Alzheimer's disease from accessing a medicine that is available in other countries, as it has been approved by regulatory agencies in China, Israel, Japan, Hong Kong, Macao, Mexico, South Korea, the United Arab Emirates, the United Kingdom and the US.
- The narrowing of the indication and the adoption of risk minimisation measures show that risk management approaches are feasible as is also demonstrated by the authorisation of medicines for many other conditions with similar risk/benefit ratios.
- Lecanemab has been shown to provide meaningful benefits to patients and carers that go beyond the impact on cognition and include positive results in clinical trials on quality of life of patients and caregiver burden.
- Since the CHMP has followed the scientific consensus of other regulatory agencies which authorised lecanemab, it would be disappointing to see this scientific evaluation overturned for potentially more political and socio-economic reasons.

Finally, we would like to point out the impact that a negative opinion on lecanemab could have on the attractiveness of the European Union as an important centre for research and development in the Alzheimer's field. At a time when the European Commission highlights the importance of competitiveness and innovation, it would be the wrong signal, in our opinion, to close Europe to innovative treatments that have been assessed as having a positive risk/benefit ratio by Europe's own agency.

We would be very grateful, if you could share this position with colleagues attending the Appeal Committee and remain at your disposal for any additional information.

Yours sincerely,

Jean Georges
Executive Director

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