Question for written answer E-000880/2025
to the Commission
Rule 144
Hilde Vautmans (Renew)

Subject: Approval of medicines for Alzheimer's disease

The European Medicines Agency (EMA) is evaluating lecanemab and donanemab, two treatments for early Alzheimer's disease.

On 14 November 2024, following re-examination, the EMA's Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion on lecanemab. However, after its Standing Committee meeting of 24 January 2025, the Commission requested that the CHMP review new safety data and clarify the wording of risk minimisation measures in Annex II. A response is expected after the CHMP's February plenary meeting.

Given the limited treatment options for Alzheimer's disease and the fact that lecanemab and donanemab are already approved in several countries (China, Japan, the UK and the US), delays in Europe risk leaving patients without timely access to new therapies.

In the light of the above, can the Commission clarify:

1. What new safety data on lecanemab prompted the request for a review of the CHMP opinion?

2. If the CHMP addresses the Standing Committee's concerns, will the Commission grant marketing authorisation without further delay?

3. What is the Commission doing to ensure that Alzheimer's treatments available in other countries are also accessible to EU patients in a timely manner?

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