Direktoratet for medisinske produkter 3 Jun 2026

Reference: 26/13856 - Comments on the consultation regarding the proposed dispensing regulations for new Alzheimer's Disease treatments

Eisai welcomes the opportunity to provide comments on the proposed regulations for dispensing lecanemab. We support the Norwegian Medicines Agency's aim of ensuring safe and prudent use of the treatment. Lecanemab is approved in 53 countries, and with post marketing experience supporting its established safety profile. It is therefore important that the Norwegian framework enables a safe, professionally sound and practically feasible introduction.

At the same time, we believe some elements of the proposal needs to be adjusted to ensure clarity, proportionality and alignment with clinical practice.

Organisation of dementia care

The proposal does not fully reflect how dementia assessment and treatment are organised in Norway. Geriatricians and specialists in geriatric psychiatry often play a central role in diagnosis, biomarker interpretation, MRI assessment and ARIA management.

We therefore believe that psychiatrists with documented expertise in dementia, including geriatric psychiatry, should also be eligible to requisition lecanemab, provided treatment follows established protocols and risk-minimisation measures.

A broader, competence-based requisition structure would better align with clinical practice.

Function based regulation of treatment sites

Eisai is concerned that the proposed use of the term "hospital" could be interpreted as limiting treatment to hospitals only, which is unnecessarily restrictive. This may exclude specialised clinics with appropriate expertise, even when they have cooperation agreements with hospitals and access to MRI and emergency support.

EMA's approval and risk minimisation measures do not require hospital-based administration nor on site MRI. What matters is that the treating unit has the necessary competence, diagnostic access and the ability to manage adverse reactions. Nordic experience shows that specialised clinics can safely provide treatment under such conditions.

Restricting treatment solely to hospitals could reduce patient access and limit capacity without improving safety.

Suggested adjustments to the dispensing regulation

We recommend that the disclosure provisions be based on functional and qualitative criteria rather than organisational affiliation. Treatment should be permitted at units that:

- have specialist competence in neurology, geriatrics or geriatric psychiatry

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- can document access to MRI
- have procedures for managing serious adverse reactions, including formalised cooperation with hospitals for emergency assessment and admission

Similarly, the right to requisition should include psychiatrists with documented dementia expertise when other professional requirements are met.

A function-based regulatory approach is better suited than an institution-based one to ensure safe treatment and follow-up while avoiding unnecessary limitations on capacity and patient access.

Eisai hopes that the Norwegian Medicines Agency will take these considerations into account in the development of the final dispensing regulations for new Alzheimer's Disease treatments.

Kind regards,

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