Leqembi's Approval for Alzheimer's Treatment Marks a Turning Point: Balancing Hope, Risk, and Real Lives

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This week marks a watershed moment as the European Commission approves Leqembi - the first drug authorised by the European Medicines Agency (EMA) to slow the progression of early-stage Alzheimer's Disease.

This landmark decision follows a protracted and controversial process, including an extraordinary escalation to an appeal committee. On 15 April, the EMA approved Leqembi, just weeks after rejecting a similar drug, Kisunla, based on the benefit-risk profile. Both Leqembi and Kisunla are available in other regions, including the UK.

In recent years, there have been many pivotal moments for anyone with an interest in dementia and disease-modifying therapies. High-profile approvals and rejections of new treatments have sparked wave after wave of media coverage, research discussions and public discourse about their benefits and risk.

But what about the people navigating life with the condition? Those who have received a dementia diagnosis, the people who support them, their families and loved ones? As policymakers, clinicians, researchers and non-governmental organisations publicly debate the merits and risks of these treatments, we must pause and ask: Are we losing sight of the people at the heart of this conversation?

The discourse around clinical trials and disease modifying therapies is (rightly) dominated by the benefit versus risk debate. The risks - brain swelling and brain bleeds - are clearly documented in the trial data. Adverse events are relatively straightforward to measure; put simply, they either happened, or they didn't.

However, when the conversation turns to benefits, it is more abstract – though no less important. We must remember that there is a person who will bear the risk and a person who will stand to benefit, and the impact on their life is not abstract.

Decisions about dementia therapies are deeply personal. Just as a person with late-stage cancer may refuse chemotherapy in favour of a more comfortable, albeit possibly shorter life, choices about dementia treatments are not just about science - they are about values, personal meaning and how each individual defines quality of life. Ultimately, it is the person with dementia and their family who will bear the risks, undertake the demanding treatment regimen and hopefully reap the possible benefits.

In many diseases, mortality drives decision-making but that is not an outcome measure that we use as often in the context of dementia. We must consider autonomy, quality of life and personal meaning.

For example, Leqembi is associated with a reduction of 0.45 points on a standardised measure of cognition and day-to-day function. This statistic is regularly cited by those who criticise the approval of the therapy, arguing that this slowdown in progression is insufficient and not clinically meaningful. Reducing the complexity of life to statistics can be misleading as they do not fully capture how we as people live in and navigate the real world around us - no family has 1.3 children or 1.7 cars. A statistical half point does not truly tell us whether an intervention enables a person to maintain employment a little longer, help children or grandchildren with homework, or inject hope into a household struggling to come to terms with a diagnosis.

The therapies driving this debate are intended for the early stages of Alzheimer’s Disease, but misconceptions about early, moderate and late-stage dementia remain pervasive. Many associate dementia exclusively with its later stages, and there is an assumption that people beyond the first few months of the condition have no independence, quality of life, or ability to meaningfully participate in decision-making. This narrative is false and fuels stigma, reinforcing harmful value judgements about the lives of people with dementia and their families. The future arrival of disease-modifying therapies to Ireland is an opportunity to evolve our understanding.

Needs, wants, preferences, and values fluctuate and change over time. It is essential that we do not impose our current personal value system on what we imagine life to be like with dementia. For a person to make a real informed decision about receiving any clinical therapy, we must dismantle societal stigma and challenge the prevailing narrative about life with dementia. We must highlight the ability to live well with the right support, while not shying away from the very difficult and often devastating aspects. If we fail to eliminate stigma and if we fail to provide the right services and supports to all people affected by dementia, we risk distorting the decision-making process.

Now, as our focus shifts to timelines and access to Leqembi, we must remember that people living with, and worried about, dementia are waiting too. Integrating these clinical therapies for dementia into the healthcare system requires substantial investment, and there is no doubt that the debate over their merits, risks, costs and practical implications will rage on - this time, much closer to home.

This moment cannot be about one individual therapy; many more agents are advancing through the clinical pipeline that show great promise. As we enter this new era, there are people at home anxiously following the discourse. Regardless of personal views, we must acknowledge that every delay, every conflicting opinion, and every layer of complexity adds to the uncertainty they already feel and sends a message about how we value people affected by dementia.

The science continues to evolve- but so too must our conversations and understanding. These therapies bring complex decisions, underpinned by hope, uncertainty, and deeply personal meaning. People living with dementia - and their families - must not be forgotten in this moment. Their voices, values, and lived experiences must shape the path forward. Because ultimately, it’s not just about what treatments do. It’s about what matters to the people they are intended to help.

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