



**Alzheimer's Disease  
International**

*The global voice on dementia*

Alzheimer's Disease International  
15 Bluelion Place  
London, SE1 4PU  
United Kingdom

Ms Emer Cooke  
Executive Director  
European Medicines Agency  
Domenico Scarlattilaan 6  
1083 HS Amsterdam  
Netherlands

**Re: EMA assessment of new therapeutics for Alzheimer's Disease**

Dear Ms Emer Cooke,

Cognisant of a number of new disease modifying therapies for the treatment of Alzheimer's disease currently undergoing, or soon to be assessed by the European Medicines Agency (EMA), I write to you in my capacity as CEO of Alzheimer's Disease International to reiterate our offer to aid the EMA with the assessment of unmet need for those living with dementia and their carers in this area. Alzheimer's Disease International is the federation of 105 Alzheimer and dementia association from around the world and a non-state actor in official relations with the World Health Organization. We have 37 European member nations in our association.

As you are aware, dementia is the 7<sup>th</sup> leading cause of death globally, with 55 million people living with dementia globally. 7.8 million of which are estimated to be living in the 27 European Union Member States. Dementia also disproportionately affects women, both in terms of those most at risk of developing the condition but are also those most likely to adopt caring responsibilities, with evidence suggesting that two-thirds of carers for dementia are women. Global caring responsibility for those living with dementia is estimated to stand at 133 billion hours each year, the equivalent of 67 million full time workers. The economic impact is also profound, with the condition predicted to cost the global economy \$1.3 trillion USD annually, a figure set to increase to \$2.8 trillion USD annually by 2030.

We write in conjunction with the expectation in our community that there will soon be important decisions taken by EMA relating to therapeutics for Alzheimer's disease. While we do not seek to provide commentary on the merits of any particular therapy for Alzheimer's disease, in particular in relation to areas such as efficacy or safety, of which we delegate to the experts within the Committee for Medicinal Products for Human Use (CHMP), Alzheimer's Disease International does believe that those living with dementia have the right to take an active role in their healthcare, in consultation with healthcare professionals and their families. Having noted that there are considerable safety implications of some treatments in other disease areas, which are often associated with moderate increases in life expectancy, for example oncology (particularly in the early stages of treatment development), it is our hope that the CHMP and EMA will consider new therapeutics for Alzheimer's disease under the same lens, particularly as currently there are no approved disease modifying therapies for Alzheimer's disease in the EU. In summary, it is our strong belief that those living with Alzheimer's disease should be provided with something, as fundamental and basic as a choice to decide how to manage their condition, be that with or without medical intervention.

As a global organisation we have also noted how approvals have been granted in other regions of the world and are concerned that lack of approval in Europe may result in wealthier individuals being able to seek those choices elsewhere in the world, whereas for those nations under the aegis of EMA or those on lower incomes, maybe denied those choices.

We look forward to hearing from you. Alzheimer's Disease International stands ready and willing to support the EMA by any means possible.

Yours faithfully

A handwritten signature in black ink, appearing to read 'Paola', with a small dot at the end.

**Paola Barbarino**, CEO  
Alzheimer's Disease International