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Accompanying the

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT AND TO THE COUNCIL**

on a European initiative on Alzheimer's disease and other dementias

Summary of the Impact Assessment

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1. PROBLEM DEFINITION

Dementias are neurodegenerative diseases that have varying aetiologies. The most common forms of dementia in the European Union are Alzheimer's disease (about 70% of cases), and vascular dementia (less than 30%)¹.

There are currently over six million people with dementia in the European Union² and it is predicted that this number will double in the next 20 years³. The World Health Organisation 2004 update report on the Global Burden of Disease estimates the total prevalence of Alzheimer's disease and dementia in Europe at 7.3 million⁴.

1.1. Mental Capital and Well-Being, Diagnosis, and Early Intervention

Although there is evidence that a healthy lifestyle can help prevent Alzheimer's disease and dementia⁵, the **possibility and importance of prevention and early intervention** are not sufficiently known or acted on throughout the EU.

Alzheimer's disease remains under-diagnosed in the EU. Although improving diagnosis will mean that a greater proportion of people with dementia benefit from health and social care, **early diagnosis** can ensure that interventions take place when they are most effective, **delaying the progression of the disease** and offering the potential to minimise the total cost of care for individual patients.

1.2. Research

There is a **lack of coordination of research**, which is hampering potential for action at the European level. In particular, there is also a **lack of healthcare and social care research**, where gaps in knowledge exist to explore the efficacy of models of care for Alzheimer's and dementia patients including the care of the frail and elderly.

There is a **lack of updated epidemiological information** on the prevalence and incidence of Alzheimer's disease and dementias to help direct research and action and plan healthcare and social care provision in the future. Due to under-diagnosis of Alzheimer's disease in the EU, the magnitude of the problem is unclear because figures of prevalence are based only on diagnosed cases.

1.3. Solidarity, Treatment, Care and Financing

Although there are good practices emerging across the EU with regard to **diagnosis, treatment, care, and financing** of responses to these conditions, these are not being shared sufficiently throughout the Union.

Although early provision of support at home can decrease institutionalization by 22%⁶, **best practices in terms of early support are not being shared**. More research will also be needed in this area also as to inform MS how financial resources could be spend on health infrastructure through cohesion spending.

¹ Alzheimer's disease: Scientific, medical and societal implications, Synthesis and recommendations. Collective expert report from INSERM (French National Institute for health and medical research), 2007.

² Alzheimer Europe (2006) Dementia in Europe Yearbook 2006.

³ Ferri *et al.* (2005) The Lancet 366: 2112-2117.

⁴ http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf

⁵ Alzheimer Europe (2008) Dementia in Europe Yearbook.

⁶ Gaugler JE, Kane RL, Kane RA, Newcomer R (2005) The Gerontologist 45:177-185.

For some aspects, like the **expected workforce shortages** in the formal long-term care sector and the financing of social protection for people with neurodegenerative conditions and their families, there are needs not only to spread and develop good practices, but also to develop concepts and solutions on a macro level, both nationally and at European level.

1.4. Rights, Autonomy and Dignity

Articles 25, 26, and 35 of the **Charter of Fundamental Rights of the European Union**⁷ (2000/C364/01) refer to the situation of patients suffering from Alzheimer's disease and other dementias. Furthermore, the **United Nations Convention on the Rights of Persons with Disabilities**⁸ protects the rights to non-discrimination and respect for dignity and autonomy of Alzheimer's patients.

Across Europe, there is **no consensual view on ethical issues** surrounding vulnerable adults; discrimination is compounded by ageism, exclusion, lack of recognition of the mental capital of older people, **stigma associated with dementia**, and the complicated cross-border issue of the legal rights of mental guardians.

2. ANALYSIS OF SUBSIDIARITY

A Commission initiative in the field of Alzheimer's disease reflects the need to respond to the priority attached to European action on this issue by the Member States, as shown by the Council Conclusions⁹ adopted under the French Presidency on 16 December, 2008. Furthermore, the Written Declaration of the European Parliament¹⁰ (0080/2008) calls on the Commission, Council, and governments of the Member States to develop an action plan to tackle Alzheimer's disease.

Political leadership at the European level can play an important role in awareness-raising and would encourage MS to set Alzheimer as a political priority, in particular in the context of an ageing society and the future costs it will incur.

A DG RTD proposal for a Council Recommendation for Joint Programming of research in the field of neurodegenerative diseases, including Alzheimer's disease, is planned for adoption at the same time; this timing provides us with a valuable opportunity to coordinate further EU-level activities in this area.

The EuroCoDe project has up provided accurate qualitative and quantitative data and analysis of the burden of Alzheimer's disease in the EU; however, the project finished July 2009, and there is now a need to evaluate what the options are for taking this work forward. Without further action, the progress achieved by the project could well be lost.

3. OBJECTIVES

3.1. Acting early to promote well-being in old age

- Promoting good physical and mental health;
- Identifying and promoting best practice in early diagnosis;
- Improving prevention, and early diagnosis and intervention.

⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2000:364:0001:0022:EN:PDF>

⁸ <http://www.un.org/disabilities/documents/convention/convoptprot-e.pdf>

⁹ http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/lsa/104778.pdf

¹⁰ <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+WDECL+P6-DCL-2008-0080+0+DOC+PDF+V0//EN&language=EN>

3.2. Better understanding of Alzheimer’s disease and dementia through a shared European effort

- Supporting targeted research on key problems at European level; develop Alzheimer’s as a pilot of Joint Programming;
- Developing further the current accurate comparable epidemiological data;
- Promoting the sharing and pooling of knowledge and data at EU level;
- Promoting research into social care models including sharing of best practices in the training of dementia caregivers.

3.3. Supporting national solidarity with regard to dementias

- Mapping and describing better the existing and emerging good practices related to treatment and care and improving the dissemination of such practices;
- Developing quality frameworks for medical and social care services for people with dementias;
- Empowering national and international Alzheimer’s associations and relevant patients’ organisations.

3.4. Respecting the rights of people with dementias

- Recognising the mental capital of older adults and reducing the stigma associated Alzheimer’s disease and other dementias;
- Sharing best practice on respecting the rights of vulnerable adults and tackling patient abuse.

4. POLICY OPTIONS

4.1. Baseline Option – No new EU action

This option would only continue current actions in the field of Alzheimer’s disease and dementia that are currently in progress. As the EuroCoDe project has now finished, this work will now stop and will not be taken further except through calls for proposal within the scope of the current Health Programme¹¹.

Current projects and proposals under the Framework Programme for research would continue. Moreover, actions in the individual Member States would continue. However, in MS with no political commitment and awareness of the dementia challenge will see little progress.

4.2. Report taking forward the work of the EuroCoDe project

The Commission will continue to support the development and publication of the Dementia in Europe Yearbooks, published by Alzheimer Europe. A new project or operational grant funded through the Health Programme would support this initiative in taking forward the work of the completed EuroCoDe project.

Policy actions under this option would be limited to continued collection of consensual and comparable prevalence rates for dementia in Europe, and participation in international fora to disseminate the data.

¹¹ http://ec.europa.eu/health/ph_programme/pgm2008_2013_en.htm

4.3. Commission Communication

A Commission Communication would be a formal statement of the Commission's support to Member States in areas of public health, social protection, research, and legal rights in order to ensure coherent overall actions. A Communication would be adopted jointly with a proposal from the Directorate-General for Research for a Council Recommendation for Joint Programming of research in the field neurodegenerative disease, including Alzheimer's disease and dementia.

Further actions would be supported within the scope of currently available programmes and resources, in particular through the current Health Programme and the Framework Programme for Research and Technological Development. Cooperative actions between several Member States could be achieved through voluntary participation in a Joint Action financed under the Health Programme.

4.4. Formal Programme and European action plan

The establishment of a European action plan would be supported by a specific new programme with additional funding beyond existing allocations. This would provide a single detailed and funded strategy for Alzheimer's disease and other dementias at Community level, and would develop specific projects on Alzheimer's disease and other dementias in a similar way to the previous specific initiative on Alzheimer's disease and other dementias used during the period 1996-1998. The establishment of the formal programme would enable a greater degree of funding to be available to achieve the objectives in a more comprehensive manner.

5. ANALYSIS OF IMPACT

It has been considered that any initiative that improves the situation for Alzheimer's and dementia patients will bring social benefits, such as improving equity of access, support their dignity, and help combat stigmatisation. Furthermore, any initiative that promotes coordination and supports more efficient use of resources will bring economic benefits.

Quantitative information given here is therefore limited to the current economic and social burden of dementia, costs of action plans at national level, expected dementia trends in the future, and finally evidence from policy interventions at national level.

Environmental impact is negligible and will not be considered further.

5.1. Baseline Option – No new EU action

The socioeconomic burden of Alzheimer disease, the major contributor to dementia, is growing rapidly in Europe due to increasing lifespan and a decreasing ratio of working to retired populations. As already highlighted, the total direct and informal care costs of Alzheimer's disease and other dementias in 2005 were €130bn for EU27 (€21 000 per patient); 56% of costs were informal care¹².

As a result of inaction, there will be no immediate burden on public authorities at different levels of government, nor any additional funding requirements at EU-level. However, in the longer term, costs in public healthcare provision on long-term care in the Member States will increase with the increasing burden of an ageing society, without the benefit of coordinated sharing of experience and best practice across the EU.

¹² Alzheimer Europe (2008) Dementia in Europe Yearbook 2008.

5.2. Report taking forward the work of the EuroCoDe project

A report would highlight the relevant issues regarding Alzheimer's disease at European level and achieve thorough and up-to-date knowledge on the magnitude, prevalence, and incidence of the disease. Without the political support of the Commission, it is unlikely that Alzheimer's disease and dementia would be a priority.

The budgetary cost of analysis and reporting would be covered through EU funding, possibility through the establishment of a similar action to the completed EuroCoDe project. The previous EuroCoDe project cost €1 423 190 (with €843 000 funded by the Commission through the Health Programme).

5.3. Communication

A Communication would ensure that the process would have the involvement of all relevant stakeholders, recognizing the relevant issues regarding Alzheimer's disease at European level. Thorough knowledge on the magnitude, prevalence, and incidence of the disease would be achieved. This would provide a solid basis for planning prevention, early intervention and health and social care provision. Such an action could contribute to reducing the inequity gap of healthcare service provision and best practice in primary prevention.

The technical work involved, coordinated notably through the relevant strands of the Mental Health Pact, would be subsidized by the EU through support from the existing Health Programme and Framework Programme for Research and Technological Development. By centralising efforts, this will be more efficient and less burdensome for national health systems and public authorities.

There may well be some direct cost and administrative burden for public authorities at different levels of government in the short term as they attempt to implement recommendations resulting from associated projects of the initiative, and through voluntary participation in joint actions.

A Communication would stimulate research and development.

5.4. Formal Programme and European Action Plan

An action plan would have many of the impacts already highlighted under the Communication option. There are also additional impacts that need to be considered.

A stand-alone initiative and Alzheimer's Plan would undermine the EU approach of focussing primarily on the causes of ill health, rather than attempting to have disease-specific strategies.

A substantial level of funding above the *status quo* might be required from EU, and a new budget line might need to be established.

6. COMPARING THE OPTIONS

Option	EU Contribution & Efficiency	Scope & Effectiveness	Political Acceptance & Coherence	Proportionality & Member State Commitment
Baseline	There would be no further contribution or coordination from the EU in the field of Alzheimer's disease and dementia other than current action already underway. This would not require any additional funding, however would be very in effective an maintain current		This option does not meet the expectations of the Member States as expressed through the	Although there would be no additional commitment required of the MS, this option would not contribute to tackling any of the problems no achieve

	inefficiencies.		Council or the Parliament at all.	any of the objectives outlined in this impact assessment.
Report	A report would provide up-to-date EU-level comparable data on the prevalence and incidence of Alzheimer's disease and dementia. MS action alone could provide this information, however without guaranteeing comparability.	This option requires support through funding of another project similar to the successful EuroCoDe project. Funding would be achieved through the current Health Programme. Other Framework Programme and MS actions would continue.	This option would not meet the expectations outlined in the Council Conclusions or the Written Declaration of the Parliament, which calls for a more comprehensive approach in the field of AD and dementia.	There would be no formal commitment necessary from the MS as this option would be entirely funded through the Health Programme. However, this option is not pass the proportionality test, as it would not be sufficient to meet the objectives outlined.
Communication	A Communication would support coordinated efforts across the EU in areas such as sharing of best practice and research. This would increase efficiencies and provide the political support for a more coherent approach to AD.	This option includes a joint adoption of a proposal for a Council Recommendation on Joint Programming of research in the field of AD. Cooperative actions in the MS could be supported through a Joint Action funded through the Health Programme.	This option would essentially meet the four key objectives outlined in the Council Conclusions as well as clearly establishing Alzheimer's disease and dementia as a political priority.	The actions would be legally non-binding and any Joint Programming or Joint Action would involve voluntary participation of the MS. This action would also be proportionate to the objectives described in Section Error! Reference source not found..
Action Plan	An action plan would achieve the same EU-level objectives as a Communication whilst providing a single detailed and funded strategy.		As additional funding beyond existing allocations would be required, this would make this option less feasible within the current financial perspectives, and would take longer to put in place. However, it would clearly meet the expectations of the Parliament and Council.	Given the differences in organisation and delivery of health services and medical care throughout the EU, this option would raise subsidiarity issues. As the objectives in Section Error! Reference source not found. could be substantially met through a less formally binding initiative, it would need to be clear that the additional cost and harmonisation involved in this option was proportionate to the additional benefits.

Based on this assessment, the preferred option is to bring forward proposals for a Community strategy for Alzheimer's disease set out in a **Commission Communication**. A Commission Communication would be proportionate to the objectives without overstepping the principles of subsidiarity.

7. MONITORING AND EVALUATION

This initiative does not require the collection of new statistical data, but it rather addresses the problem of incompatible and incomplete sources of data, and focuses on developing a methodology on how to use existing data in a coherent manner. A data set for core progress indicators for the key objectives will be established based on the ongoing works of the initiative.