



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 27 July 2009**

**12392/09  
ADD 1**

**SAN 202  
SOC 459  
RECH 237**

**COVER NOTE**

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from: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 24 July 2009

to: Mr Javier SOLANA, Secretary-General/High Representative

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Subject: COMMISSION STAFF WORKING DOCUMENT  
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  
Impact Assessment

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Delegations will find attached Commission document SEC(2009) 1040 final.

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Encl.: SEC(2009) 1040 final



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 22.7.2009  
SEC(2009) 1040 final

**COMMISSION STAFF WORKING DOCUMENT**

*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**

**Impact Assessment**

{COM(2009) 380 final}  
{SEC(2009) 1041}

## COMMISSION STAFF WORKING DOCUMENT

### *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

### *Impact Assessment*

#### 1. EXECUTIVE SUMMARY

There are currently over six million people with dementia in the European Union; the most common form of dementia is Alzheimer's disease accounting for about 70% of dementia cases. It is predicted that this number of dementia patients will double in the next 20 years.

Dementias are one of the most important causes of disability in the elderly, and it is therefore necessary to take all available steps that can help to reduce this burden. The condition has very substantial impacts on public expenditure that will increase even further in the future in the context of an ageing society.

The problems posed by Alzheimer's disease and dementia can be categorized as a lacking in four key areas: (i) **promotion** of mental well-being, **preservation** of mental capital, **prevention** of onset, and **early intervention**; (ii) **research** coordination; (iii) **solidarity, treatment, care, financing**; and (iv) **rights, autonomy, and dignity**. A lack of coordination and coherence in these areas is hampering development in Europe in tackling the increasing problem of Alzheimer's disease and dementia in a society caring for an ageing population.

A Commission initiative in the field of Alzheimer's disease reflects broader mental capital work underway in many Member States and at EU level. Specifically, it responds to the priority attached to European action on this issue by the Member States, as shown by the Council Conclusions<sup>1</sup> adopted under the French Presidency, and the Written Declaration of the European Parliament on the priorities in the fight against Alzheimer's disease.

Based on tackling these problems through specific objectives outlined in this impact assessment, four policy options are proposed; a baseline option would not take forward any additional work in the field of Alzheimer's disease and dementia, however the remaining three options propose mechanisms that could achieve these objectives with varying degrees of efficiency and efficacy.

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<sup>1</sup> [http://www.consilium.europa.eu/ueDocs/cms\\_Data/docs/pressData/en/lsa/104778.pdf](http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/lsa/104778.pdf)

## **2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES**

### **2.1. Identification**

The Lead Directorate-General for this initiative is the Directorate-General for Health and Consumers (DG SANCO).

Associated Directorates-General are the Directorates-General for Employment, Social Affairs and Equal Opportunities (DG EMPL), Research (DG RTD) and Justice, Freedom and Security (DG JLS).

### **2.2. Organisation and Timing**

The Commission Communication on Alzheimer's disease and other dementias has been included as a priority initiative in the Commission Legislative Work Programme 2009.<sup>2</sup>

The roadmap was completed in December 2008, and an interservice meeting with DG RTD and DG EMPL was held on 29 January, 2009.

The Impact Assessment Steering Group (IASG) was established, with the following DGs nominating representatives: SANCO, RTD, EMPL, JLS, ESTAT, SG, ENTR. DGs BUDG, ECFIN, SJ, and ENV were invited but no nomination was made. The Impact Assessment Steering Group first met on 13 March, with subsequent meetings held on 17 March and 23 March, 2009.

A meeting of the European Union Panel of Experts on Alzheimer's Disease and Dementia was convened on the 17 March to coincide with the second meeting of the IASG.

The Impact Assessment was submitted on 25 March and the Impact Assessment Board was consulted on 22 April, 2009.

### **2.3. Consultation and Expertise**

The **European Pact for Mental Health and Well-being**<sup>3</sup> was established at an EU High-Level Conference "Together for Mental Health and Well-being," taking place in Brussels on 13 June, 2008. The implementation of the Pact focuses on five priority themes: (i) Prevention of Suicide and Depression, (ii) Mental Health in Youth and Education, (iii) Mental Health in Workplace Settings, (iv) Mental Health in Older People, and (v) Combating Stigma and Social Exclusion. Within the context of the priority on Mental Health in Older People, a collaborative effort involving researchers, policy makers and stakeholders from across the EU established a consensus paper<sup>4</sup> providing an analysis of trends as well as proposing a framework for action, and includes Alzheimer's disease and other dementias as a key challenge in age-related mental health.

The **Impact Assessment Steering Group** (IASG) met on 13 March, 17 March, and 23 March, 2009. The comments received from these two meetings and the contributions from the other services have been incorporated into this impact assessment as comprehensively as

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<sup>2</sup> [http://ec.europa.eu/atwork/programmes/docs/clwp2009\\_roadmap\\_priority\\_initiatives\\_en.pdf](http://ec.europa.eu/atwork/programmes/docs/clwp2009_roadmap_priority_initiatives_en.pdf)

<sup>3</sup> [http://ec.europa.eu/health/ph\\_determinants/life\\_style/mental/docs/pact\\_en.pdf](http://ec.europa.eu/health/ph_determinants/life_style/mental/docs/pact_en.pdf)

<sup>4</sup> [http://ec.europa.eu/health/ph\\_determinants/life\\_style/mental/docs/consensus\\_older\\_en.pdf](http://ec.europa.eu/health/ph_determinants/life_style/mental/docs/consensus_older_en.pdf)

possible. The minutes of these three meetings can be found in the 9. Annexes (Section 9), but the discussions essentially focussed on the clarification and restructuring of the problem definition, and elaboration and confirmation of the objectives.

The **European Union Panel of Experts on Alzheimer's Disease** was established in January, 2008, on the basis of the work of the EuroCoDe (European Collaboration on Dementia) Project. The Panel was convened to advise and assist the Commission on identifying actions on best practices for prevention, treatment, protection, and patients' rights. The Panel of Experts met on 17 March, 2009. The minutes of this meeting are attached as an annex (Section 9). The Panel broadly endorsed the impact analysis and options considered by the Commission, whilst also providing many references and data that enabled to more clearly define the context of the problem in the field of Alzheimer's disease and dementia, to further develop the option of a platform for voluntary cooperation at European level, and to reinforce the impact analysis of Community action in this area. Their comments have been taken into account in this impact assessment, in particular through including substantial additional information contributed on the problem and impacts, and refining the options to include a mechanism for voluntary cooperation.

The **Impact Assessment Board** was consulted on 22 April, 2009. Following the Board's opinion (attached as an annex in section 9), the following modifications have been made.

- In the Problem Definition (Section 3.4), greater emphasis of the existing disparities in the situation concerning Alzheimer's in the Member States has been made.
- Furthermore, the problem definition on rights, autonomy, and dignity have been clarified and expanded, particularly referring to the United Nations Convention on the Rights of Persons with Disabilities.
- Under Current Action (Section 3.3), reference has been made to the EU Disability Action Plan and the anticipated Communication on Reducing Health Inequalities.
- In the policy options, there is further clarification of the complementarity of the proposed Council Recommendation for Joint Programming of research in the field neurodegenerative disease, including Alzheimer's disease and dementia with a Commission Communication.
- An additional table comparing the policy options against a baseline scenario and a clear set of criteria has been added. Furthermore, a preferred option has been clearly identified.
- The data needs have been clarified. The Monitoring and Evaluation (Section 8) has been expanded.
- A separate Executive Summary has also been prepared.

### 3. CONTEXT AND PROBLEM DEFINITION

Dementias are neurodegenerative diseases that have varying aetiologies: neurodegenerative vascular causes, following e.g. atherosclerosis and stroke; toxic causes, following, e.g. chronic alcohol abuses; and metabolic/inflammatory causes, e.g. from an increase in the production or accumulation of a specific protein ( $\beta$ -amyloid protein).

The most common forms of dementia in the European Union are Alzheimer's disease (about 70% of cases), and vascular dementia (less than 30%).<sup>5</sup> Other causes are Pick's disease, Binswanger's diseases, Lewy-Body dementia, and alcoholic dementia, amongst others.

### **3.1. Health and Social Burden of Alzheimer's disease and Dementias**

Dementia is a terminal disorder characterized by a decline in mental ability that usually progresses slowly, in which memory, thinking, and judgement are impaired, and personality may deteriorate.

The earliest and most frequent manifestations of Alzheimer's disease and dementias are benign memory disorders relating to loss of short-term recollection and, in most cases, concerning details of everyday life. There is then a slow evolution of the symptoms characterized by organizational and programming disorders (executive functions), language difficulties (aphasia), difficulty in movement (apraxia) and defective recognition of objects, places and persons (agnosia).

In addition to the effects of the disease on the patient, the consequential progressive loss of autonomy and inability to make decisions increases the burden on caregivers. It is difficult to put a figure on the number of caregivers for persons suffering from Alzheimer's disease, but it could be estimated that in every family with a patient there could be an average of three persons directly concerned by the disease. That means an estimated 19 million Europeans are directly concerned by dementias.

The societal and economic burden of Alzheimer's disease, the major contributor to dementia, is growing rapidly in Europe due to increasing lifespan and a decreasing ratio of working to retired populations. The suffering of millions of individuals and their families, as well as the costs to the European healthcare systems, are dramatic. Dementia is one of the main causes of disability later in life, ahead of some cancers, cerebrovascular disease, and ischaemic heart disease.

All stakeholders involved, including academic institutions, industry, patients' associations and funding agencies, are well aware of the challenge ahead and of the necessity to support research on Alzheimer disease and on neurodegenerative diseases in general. Alzheimer's disease and dementia is the fourth leading cause of burden of disease (DALYs) in high-income countries.

Our shared European fundamental values mean that, across the European Union, we have a collective responsibility to ensure that people can age with dignity, in good health, and with same rights for health and social care as any other population group.

### **3.2. Economic Burden of Alzheimer's disease and Dementias**

There are currently over six million people with dementia in the European Union<sup>6</sup> and it is predicted that this number will double in the next 20 years.<sup>7</sup> The World Health Organisation

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<sup>5</sup> 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.

<sup>6</sup> Alzheimer Europe (2006) Dementia in Europe Yearbook 2006

<sup>7</sup> Ferri *et al.* (2005) The Lancet 366: 2112-2117

2004 update report on the Global Burden of Disease estimates the total prevalence of Alzheimer's disease and dementia in Europe at 7.3 million.<sup>8</sup>

The European population is ageing, and the oldest old (persons aged over 80) are the fastest growing cohort in most European countries. Considering 70% of diagnosed Alzheimer's patients are aged 75 and over, with the increasing proportion of the elderly in many populations, the number of dementia patients will also rise. Dementia is one of the most important causes of disability in the elderly. It is expected that dementia, of which Alzheimer is currently the most common form, will feature among the main challenges for healthcare systems in the upcoming decades.

The following table shows that the prevalence of dementia and Alzheimer's is closely linked to age (although it also appears early in some cases) and seems to affect elder women slightly more than men.

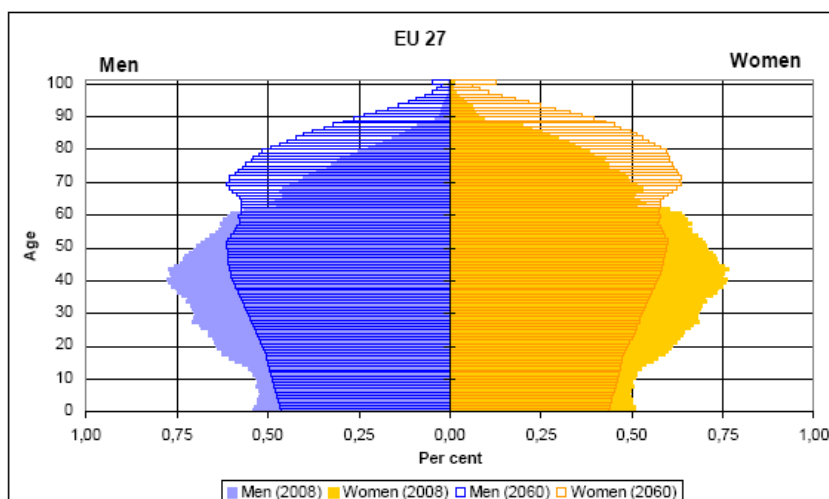
– Age group	– Male	– Female
– 30-59	– 0,16 %	– 0,09 %
– 60-64	– 1,58 %	– 0,47 %
– 65-69	– 2,17 %	– 1,10 %
– 70-74	– 4,61 %	– 3,86 %
– 75-79	– 5,04 %	– 6,67 %
– 80-84	– 12,12 %	– 13,50 %
– 85-89	– 18,45 %	– 22,76 %
– 90-94	– 32,10 %	– 32,25 %
– 95-99	– 31,58 %	– 36,00 %

– Source: European Community Concerted Action on the Epidemiology and Prevention of Dementia group EURODEM

Alzheimer's disease and dementia presents a common challenge to all Member States; figures for dementia prevalence in the EU represent roughly a similar proportion of the population in all Member States. Furthermore, with the ageing of European society, both the absolute figures and percentage of the overall population with dementia have increased substantially over the past 45 years. According to estimates, the number of people with dementia over the age of 60 in the EURO A region will increase from 4.9 million in 2001 to 9.9 million in 2040.<sup>9</sup>

<sup>8</sup> [http://www.who.int/healthinfo/global\\_burden\\_disease/GBD\\_report\\_2004update\\_full.pdf](http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf)

<sup>9</sup> <http://www.dementia-in-europe.eu/?lm2=OWQAUJKRXAEZ>



Source: Eurostat, EUROPOP2008 convergence scenario.

Dementias pose particular challenges to the way health care is provided nowadays: Dementia patients need coordinated care and today's healthcare systems, which have been set up with a focus on acute care, may not necessarily be equipped to deal with dementia patients without organisational restructuring. Dementias are expected to put additional strains on the healthcare budgets of ageing societies, in particular if healthcare systems do not manage to adapt to the new challenges and improve efficiency in delivery of care for dementia patients. Achieving to accommodate the needs of dementia patients within the limits of available healthcare budgets will ultimately determine the performance of the future healthcare provision in Europe.

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 care.<sup>10</sup>

Policy measures which can either reduce disability, limit the need for formal care amongst elderly citizens with disabilities, favour formal care provision at home rather than in institutions or, more generally, improve the cost-effectiveness of long-term care provision will contribute to limit the expected increase in public expenditure. It is therefore necessary to take all available steps that can help to reduce this burden.

### 3.3. Current Actions

Given the expected importance of dementia and Alzheimer for the healthcare systems in Europe in the medium-term future, it is not surprising that Member States have started recognising the need for specific strategies for Alzheimer's and dementia; France<sup>11</sup>, Norway<sup>12</sup>, and the United Kingdom (England<sup>13</sup> and Scotland<sup>14</sup> only) have already established plans. The scope of these plans vary; the French plan covers 44 distinct measures and costs €1.6 billion over five years, whereas the English National Dementia Strategy is backed by

<sup>10</sup> Alzheimer Europe (2008) Dementia in Europe Yearbook 2008

<sup>11</sup> [http://www.premier-ministre.gouv.fr/IMG/pdf/plan\\_2008\\_2012.pdf](http://www.premier-ministre.gouv.fr/IMG/pdf/plan_2008_2012.pdf)

<sup>12</sup> <http://www.regjeringen.no/upload/HOD/Dokumenter%20KTA/DementiaPlan2015.pdf>

<sup>13</sup>

<http://www.dh.gov.uk/en/socialcare/deliveringadultsocialcare/olderpeople/nationaldementiastrategy/index.htm>

<sup>14</sup> <http://www.scotland.gov.uk/Topics/Health/health/mental-health/servicespolicy/DFMH/dementia>



£150 million over the first two years and includes the introduction of a dementia specialist into every general hospital and care home and for mental health teams to assess people with dementia. However, these do not cover all the costs of care related to dementias; it is not possible to separate out costs for dementias from health and social care expenditure in general, and so these figures are underestimates of real expenditure.

A few other Member States are currently considering similar action, such as Italy and Spain. However, there are also Member States of the European Union where Alzheimer and other dementia have not been given special attention yet – despite the fact that all EU Member States are expected to have similarly high percentages and growth rates of elderly.

At the EU level, the following actions have been carried out so far:

**EUROCODE** (European Collaboration on Dementia)<sup>15</sup> Project, coordinated by Alzheimer Europe, was selected for funding from 2006 to 2009 through the Health Programme. Deliverables of the project included:

- (i) Devise new consensual prevalence rates for dementia
- (ii) Guidelines on diagnosis and treatment;
- (iii) Guidelines on non-pharmacological interventions;
- (iv) Prevention strategies;
- (v) Analysis of socio-economic cost of Alzheimer's disease;
- (vi) Inventory of social support systems.

This project, which ended in 2008, prepared the ground for harmonised data gathering on epidemiology and started developing the knowledge base on best practice.

**Dementia in Europe Yearbooks** have been published by Alzheimer Europe in 2006, 2007, and 2008.

**European Pact for Mental Health and Well-Being**, adopted in 2008, focuses on four priority themes: prevention of suicide and depression, mental health in youth and education, mental health in workplace settings and mental health in older people.

**The Open Method of Coordination (OMC)** in the social field provides a framework for the EU Member States to reform their social protection systems on the basis of policy exchanges and mutual learning. Within the OMC, Member States identify common challenges and agree common objectives<sup>16</sup> for universal access, quality, and sustainability in healthcare and long-term care. In national strategic reports,<sup>17</sup> Member States set out how they will develop their policies to meet the common objectives.

The EU support Member States' actions in addressing common challenges and objectives through the OMC by facilitating dialogue about experiences and the exchange of good

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<sup>15</sup> [http://ec.europa.eu/health/ph\\_projects/2005/action1/action1\\_2005\\_10\\_en.htm](http://ec.europa.eu/health/ph_projects/2005/action1/action1_2005_10_en.htm)

<sup>16</sup> [http://ec.europa.eu/employment\\_social/spsi/common\\_objectives\\_en.htm](http://ec.europa.eu/employment_social/spsi/common_objectives_en.htm)

<sup>17</sup> [http://ec.europa.eu/employment\\_social/spsi/strategy\\_reports\\_en.htm](http://ec.europa.eu/employment_social/spsi/strategy_reports_en.htm)

practices regarding healthcare and long-term care. It also supports the development of innovative good practice through its funding programmes. The exchange can take place in peer-reviews, with a limited number of participants focusing on a specific theme, or in conferences with wider discussions.

Following notions in the 2008 National Strategic Reports and the synthesis in the 2009 Joint Report<sup>18</sup>, a specific peer review will be held in France in May 2009 on “Alzheimer's disease and other related diseases: how to cope with crisis situations occurring in the patient's home?” (focusing on non-medical treatment). This will be followed by a conference in September, under the Swedish Presidency of the Council, on Healthy and Dignified Ageing, including a workshop on coordination of care for persons suffering from Alzheimer's disease and other dementias. In addition, the Commission services is considering to arrange in mid-2010 an additional conference, whose specific content will depend on the results of the above mentioned 2009 events and other sources.

**Framework Programmes for Research (FP5, FP6, and FP7):** €20 million was invested in FP5 (1998-2002), and increased to €65 million in FP6 (2002-2006) for research on Alzheimer's disease and other dementias. Efforts in this area have been reinforced in FP7 (2007-2013) within the Health theme through the areas on brain research and a new activity on ‘Optimising the delivery of health care to European citizens’. Furthermore ageing is an overarching issue throughout the whole Health theme during FP7. This new action line within the Health Theme aims at developing new research methods and generating the necessary scientific basis to underpin informed policy decisions on health systems and more effective and efficient evidence-based strategies of health promotion, disease prevention, diagnosis, and therapy. It will reinforce health policy driven research at the European level serving to support the Programme of Community Action in the field of health (2007-2013). Areas covered include mental health, promotion strategies for healthy ageing, long-term care, and equality of access to care, and health systems.

Funding of €29 million has already been committed to the subject of dementia and Alzheimer's disease as a result of the first two calls for proposals in the brain research area. In addition, the Framework Programme has allowed for the coordination of national research activities in this area through the ERA-NET projects ERA-AGE and NEURON. The latter, involving 11 Member States, issued a first joint call for proposals for a value of €18.5 million in January 2008.

While no public health project on dementia has been funded to date in FP7; there are three research projects addressing health systems and the long term care of the elderly resulting from the second call – ANCIEN, INTERLINKS and SHELTER. These are focussing on different aspects within the organisation, provision, and quality of long term care of the elderly in Europe. The overall budget for these projects is €8 million. Furthermore, other topics in the second call were also relevant to the ageing research agenda, such as continuity of care, disease management programmes, health outcome measures and population ageing, trends of population health, and a road-map for research. In the third Health call published in September 2008, a topic on "organisation of dementia care" was included and as a result, there is likely to be one funded project in the near future. Another relevant topic in the call focuses on ageing cohorts, for which there is likely to be one funded project in the near future. Results of research projects funded under the third pillar will only start to contribute to the

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<sup>18</sup>

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0058:FIN:EN:PDF>

evidence base in a couple of years time, thus continuous monitoring and feedback to policy makers will be essential.

Exploring incentives at national or European level is being encouraged, to strengthen research into dementias and development of medicinal products. An example of action is the **Innovative Medicines Initiative**<sup>19</sup> (IMI) that aims to support the faster discovery and development of better medicines for patients and enhance Europe's competitiveness by ensuring that its biopharmaceutical sector remains a dynamic high-technology sector. The IMI platform was launched under the 6th Framework Programme for Research (FP6) as a gathering of stakeholders, led by the pharmaceutical industry.

It is estimated that the total **public funding in the Member States** allocated to dementia research in Europe amounted to €57 million in 2005.<sup>20</sup>

The EU also supports the EADC (European Alzheimer's Disease Consortium)<sup>21</sup> a fully functional network of **European centres of excellence** working in the field of Alzheimer's disease. The centres increase basic scientific understanding of and develop ways to prevent, slow, or ameliorate the primary and secondary symptoms of Alzheimer's disease by facilitating trans-European research.

The **Commission Communication on Joint Programming**<sup>22</sup> (COM(2008) 468 final), adopted on 15 July 2008, presented a mechanism whereby Member States engage voluntarily in a common research agenda. By enhancing cooperation among those that develop and manage research programmes, it aims to increase the efficiency and impact of national public research funding in strategic areas. Research on Alzheimer's disease is specifically mentioned.

In April 2009, the Directorates-General for Employment and Social Affairs (EMPL) and Economic and Financial Affairs (ECFIN) plan to issue a joint **Communication "Addressing the economic and budgetary impact of an ageing population in the EU: Past achievements and future challenges (2009 Ageing Report)." The Communication will specifically highlight the challenges faced by healthcare systems caring for an ageing population, as well as the increasing public spending on long-term care. In order to address these challenges, the Communication will propose actions in three key fields: pensions, healthcare, and long-term care; financial services and taxation; and education, training, and research and development.**

Enabling people with disabilities to enjoy their rights is the main purpose of the **European Disability Strategy** (2004-2010) and the facilities provided by the EU **Disability Action Plan** (DAP) 2003-2010<sup>23</sup> will be used as appropriate.

The European Commission has announced a **Communication on Reducing Health Inequalities** in the EU in its work programme for 2009 as an initiative on "Solidarity in Health". One aim of this Communication is to support Member States' actions to tackle health inequalities, notably by highlighting possible ways to prevent and address health inequalities,

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<sup>19</sup> [http://imi.europa.eu/index\\_en.html](http://imi.europa.eu/index_en.html)

<sup>20</sup> P. Sobocki et al (2006) Resource allocation to brain research in Europe; Eur. J Neurol 24: 1-24.

<sup>21</sup> <http://eadc.alzheimer-europe.org/introduction.html>

<sup>22</sup> [http://ec.europa.eu/research/press/2008/pdf/com\\_2008\\_468\\_en.pdf](http://ec.europa.eu/research/press/2008/pdf/com_2008_468_en.pdf)

<sup>23</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0738:FIN:EN:PDF>

by encouraging greater policy coordination and best-practice exchange and through financial support via the Structural Funds and other EU funding instruments.

### 3.4. Problem Definition

Considering the work and achievements of previous and current actions in the field of Alzheimer's disease, and given the importance of dementia diseases in developed societies in the near future, it is needed to reflect further on the future policy and within this and in particular the role the EU can play here. Highlighting the public understanding of the problem, a national study showed that people aged over 65 are more worried about developing dementia (39%) than cancer (21%), heart disease (6%) or stroke (12%).<sup>24</sup>

The problems posed by Alzheimer's disease can be considered as a lack of coherence and coordination, both at the national and EU level, in four key areas. These key areas are identified and explained in this section.

#### Mental Capital and Well-Being, Diagnosis, and Early Intervention

Although there is evidence that a healthy lifestyle can help prevent Alzheimer's disease and dementia,<sup>25</sup> 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. Diagnosis of Alzheimer's disease is particularly difficult in the initial and final stages of the disease. At the outset, symptoms are discreet and may be masked by or confused with difficulties related to the normal ageing process. At the final stages of cognitive and behavioural degeneration, it is difficult to find, from examination, specific marks of a disease. Many criteria for the diagnosis of Alzheimer's disease have been put forward, chief among these are the ICD-10 (World Health Organization, 1993), DSM-IV (*American Psychiatric Association*, 1994) and NINCDS-ADRDA (*National Institute of Neurological and Communicative Diseases and Stroke/Alzheimer's Disease and Related Disorders Association*, 1984).

Dementia is a terminal disorder, but people may live with their dementia for 7-12 years after diagnosis; however, currently **only a third of people with dementia receive a formal diagnosis** or have contact with specialist services at any time during their illness. This underdiagnosis is in part due to the aforementioned difficulties in diagnosing dementias; for example, in the United Kingdom, only 31% of general practitioners believe they have received sufficient basic and post-qualifying training to diagnose and manage dementia.<sup>26</sup>

#### 3.4.1. Research

There is a **lack of coordination of research**, which is hampering potential for action at the European level, including identifying mechanisms to ensure feedback on the emerging

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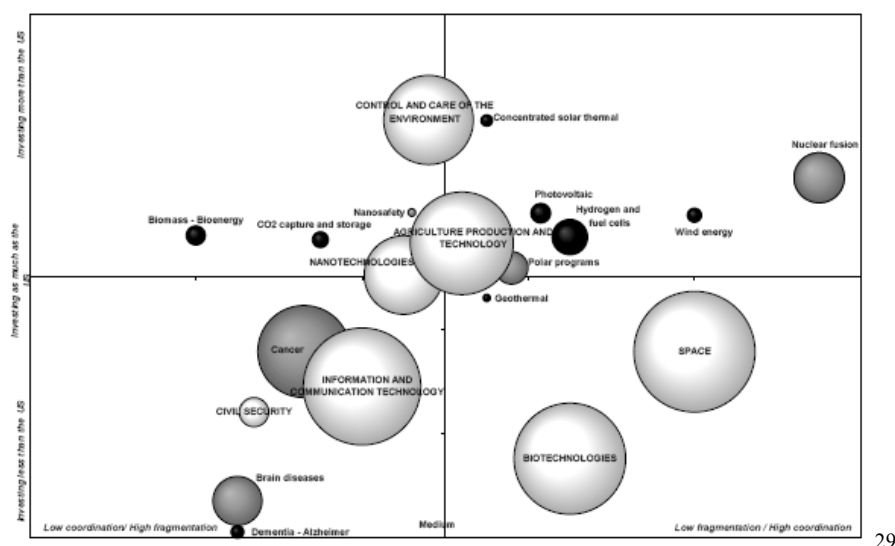
<sup>24</sup> Alzheimer's Society (2008) Dementia: Out of the Shadows

<sup>25</sup> Alzheimer Europe (2008) Dementia in Europe Yearbook

<sup>26</sup> National Audit Office (2007) Improving services and support for people with dementia

evidence base generated by EU research projects to stakeholders, in particular policy makers. There are no effective health care treatments for stopping dementia, which is why the social care aspect plays an important role in treating the disease, with family members an integral part of this process. 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. In particular, the effects of behavioural and psychological symptoms of dementia (BPSD) include distress both for the person with dementia and their family carers, and, in cases of early institutionalization<sup>27</sup>, for residential care staff. BPSD decreased by 60% after two months of the implementation of staff education and training programme (e.g. group teaching session for staff, individual instruction cards, and interactive coaching sessions), but further research is needed to make best use of these approaches.<sup>28</sup>

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.



The graph above shows the size of research public funding, an assessment of the degree of coordination/fragmentation at European level, and the relative size of European public funding compared to the US for some Science & Technology fields. Dementia and Alzheimer's research score very poorly for all of these different criteria (the smallest bubble at the bottom left hand corner): public funding, coordination of research efforts at European level, and the relative size of European public funding compared to the US.

### 3.4.2. 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

<sup>27</sup> Balestreri *et al.* (2000) International Psychogeriatrics 12: 59–62.

<sup>28</sup> Deudon *et al.* (2009) Int J Geriatr Psychiatry 24: 1–10.

<sup>29</sup> Commission Communication on Joint Programming COM(2008) 468 final

sufficiently throughout the Union. There is both a need for better descriptions of more existing and emerging good practices, as well as improving the dissemination of the information and strengthening specific exchange and dialogue about such practices and experiences.

An Alzheimer Europe survey and other studies in this field confirm that people with Alzheimer's disease do not have equal access to dementia treatments in Europe. Rather, access is subject to a great many restrictions and there is huge variation in access between European countries.

Dementia is among the biggest challenges for future healthcare systems and budgets, and it will be indispensable for MS to reflect on efficiency improvements as to ensure the sustainability of healthcare budgets as stated in the Lisbon reform agenda. There seems to be room for exchange of best practice on how physical and technical infrastructure can best be adapted to the needs of dementia patients. To give just one example: although early provision of support at home can decrease institutionalization by 22%,<sup>30</sup> **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.

An inventory of dementia guidelines across Europe revealed that guidelines for psychosocial intervention have only been found in five countries. Furthermore, there are large discrepancies between the different European countries studied in the EuroCoDe project regarding the service provision for dementia patients. Occasionally, there was even evidence of disparity within countries. Similarly, the degree of governmental support also varies significantly between European countries, and the organisation of social support is often fragmented.

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.

Member States have varying levels of awareness of the importance of dementia as one of the most burdensome and demanding challenges for the future healthcare and health policy challenge and linked to that varying levels of awareness of the challenges posed on the current healthcare systems and the need for a strong political commitment and coordinated approaches.

#### 3.4.3. *Rights, Autonomy and Dignity*

Several articles of the **Charter of Fundamental Rights of the European Union**<sup>31</sup> (2000/C364/01) refer to the situation of patients suffering from Alzheimer's disease and other dementias. Article 25 stipulates, "the Union recognises and respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural life." Article 26 "recognises and respects the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community." Finally, Article 35 states, "everyone has the right of access to

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<sup>30</sup> Gaugler JE, Kane RL, Kane RA, Newcomer R (2005) The Gerontologist 45:177-185

<sup>31</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2000:364:0001:0022:EN:PDF>

preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.”

The **United Nations Convention on the Rights of Persons with Disabilities**<sup>32</sup> states in Article 1 that:

“The purpose of the present Convention is to promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities, and to promote respect for their inherent dignity.

Persons with disabilities include those who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others.”

In this sense, Alzheimer’s disease patients can be included as having “long-term mental impairments” and thus have their rights to non-discrimination and respect for dignity and autonomy protected by the Convention as stipulated in Article 3.

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. These provide barriers to social inclusion and equal citizenship.

Studies have shown that around 50% of the public believe that there is a stigma attached to dementia.<sup>33</sup> Furthermore, carers can also experience **social exclusion** due to the effects of dementia on their loved ones; however, maintaining social contact helps to preserve autonomy and physical and mental well-being for longer, reducing the need for assistance and preventing social isolation and depression.<sup>34</sup>

### 3.5. Rationale for European Action

The policy challenge of tackling Alzheimer has been seen as part of ongoing debates on reforming healthcare and welfare systems, following up to Hampton Court 2005, the Lisbon reform agenda (here in particular the need to ensure financial sustainability of the health care system), the communication on an ageing Europe of April 2009 and finally also the renewed EU Sustainable Development Strategy. It also links more particularly with the work on improving the efficiency and effectiveness of healthcare and pension spending in the OMC on health care.

#### 3.5.1. Legal Basis

In the field of public health, Community action shall be directed towards the prevention of human illness and diseases as well as the improvement of public health in general. The principal responsibility for health services and medical care lies with the Member States, and it is thus primarily for Member States to respond to the challenge of dementias.

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<sup>32</sup> <http://www.un.org/disabilities/documents/convention/convoptprot-e.pdf>

<sup>33</sup> Alzheimer’s Society (2008) Dementia: Out of the Shadows

<sup>34</sup> Alzheimer Europe (2008) Dementia in Europe Yearbook

Nevertheless, as set out in Article 152 of the Treaty, the Community shall complement national policies, encourage cooperation between the Member States, and lend support to their action. There is substantial potential for Community added-value in addressing the specific problems set out above in order to help ensure effective and efficient recognition, prevention, diagnosis, treatment, care, and research for Alzheimer's diseases and other dementias in Europe.

As set out in Article 165 of the Treaty, the Community and the Member States shall coordinate their research and technological development activities to ensure that national policies and Community policy are mutually consistent. In close cooperation with the Member States, the Commission may take any useful initiative to promote coordination. The Competitiveness Council on 26 September 2008, identified Alzheimer's disease as a good area for testing innovative ways of pooling national expertise and resources on a voluntary basis, and invited Member States, with the help of the Commission, to explore proposals to establish closer and robust Member States collaborations in this respect. The December 2008 Competitiveness Council confirmed the necessity of launching a pilot Joint Programming initiative on neurodegenerative diseases, including Alzheimer's disease.

### 3.5.2. *Subsidiarity*

The subsidiarity test asks whether EU action is necessary (the '**necessity test**'), or whether action by Member States is sufficient to solve the problem. It asks whether action at EU level adds value to the work done by Member States (the '**added-value test**'), and it asks if the measures chosen are proportionate to the objectives (the '**boundary test**').

#### 3.5.2.1. Necessity Test

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 Conclusions<sup>35</sup> adopted under the French Presidency on 16 December, 2008. The Conclusions call on the Commission to adopt an initiative in 2009 focussed on:

- (i) Research;
- (ii) Prevention and diagnosis;
- (iii) Epidemiological information on prevalence and incidence;
- (iv) The ethical dimension of the disease.

The Written Declaration of the European Parliament<sup>36</sup> (0080/2008) calls on the Commission, Council, and governments of the Member States to develop an action plan to:

- (i) Promote research into aetiology, prevention, and treatment;
- (ii) Improve early diagnosis;
- (iii) Simplify procedures for patients and carers;

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<sup>35</sup> [http://www.consilium.europa.eu/ueDocs/cms\\_Data/docs/pressData/en/lsa/104778.pdf](http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/lsa/104778.pdf)

<sup>36</sup> <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+WDECL+P6-DCL-2008-0080+0+DOC+PDF+V0//EN&language=EN>



- (iv) Promote and support Alzheimer's associations.

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.

Moreover, effective planning and response to this substantial issue cannot be sufficiently achieved by Member States acting individually, as it depends on comparable data about the projected burden of the disease, availability of professional carers and impact on public finances across the EU as a whole. There is therefore a need for comparable data, which can only be collected at EU level, to allow for planning and adaptation of health services at the Member State level, and to manage the substantial impact of these conditions on future public finances across the EU.

The EuroCoDe project (see Section 3.3) has up until now provided accurate qualitative and quantitative data and analysis of the burden of Alzheimer's disease in the EU; however, the project has finished, and there is now a need to evaluate what the options are for taking this work forward. The project has provided a solid basis for taking forward the sharing of best practices through the recommendations it has established, and the analysis of the socioeconomic cost of Alzheimer's disease will need to be kept updated to provide a continued view of the burden of the disease. Without further action, the progress achieved by the project could well be lost.

#### 3.5.2.2. Added-Value Test

Through coordination of national and European research activities and other actions enabling greater exchange of best practice and cooperation, Community action would help make efficient use of the limited resources and available funding programmes in the European Union. In particular, the EU is well placed to coordinate cross-border research efforts in the area; by providing a shared basis diagnosis this will enable the currently fragmented patient populations to be integrated and thus provide a platform for the pharmaceutical industry to develop better responses in the future. Any resulting increase in efficiency of care would support future financial sustainability of national healthcare systems faced with an ageing society. Given the large sums involved for Member States, even a small additional improvement through European cooperation would add substantial value in real terms.

In addition, the main added-value of collaborative health research at Community level is obtained from trans-national cooperation, the integration of relevant activities and participants, and the concentration of European effort on fewer priorities. In particular, EU health research brings down barriers between countries, via multinational consortia and coordination of national funding programmes; enforces cooperation between different types of organisations: universities, research centres, hospitals, SMEs, large companies, foundations, or patients' organisations. With its increased focus on translating basic discoveries into clinical applications (translational research), it also promotes cooperation between scientific disciplines, bringing together researchers, engineers, clinicians and industrialists.

### 3.5.2.3. Boundary Test (Proportionality)

Alzheimer's disease and other dementias are not appropriate fields for either self-regulation or Community harmonisation; this would not be a viable solution for resolution of the problems identified, which cannot be effectively addressed by independent operators but which precisely require a collective approach also involving public authorities.

Community action should not interfere in the national or regional organisation of health services or medical care, which is the responsibility of Member States. Rather, action should focus on improving the knowledge and tools available to Member States in addressing this challenge, of which they can then make the appropriate use within their national and regional context. This is reflected in the options taken for this impact assessment, and described in more detail in the assessment of each below.

## 4. OBJECTIVES

In support of the Health Strategy and in particular to help ensure healthy ageing throughout the EU, the objective of Community action is to assist the Member States more efficient and effective prevention, early intervention, treatment, care and understanding of Alzheimer's disease and other dementias.

This is then broken down through the specific and operational objectives set out below.

### 4.1. Specific objective: Acting early to promote well-being in old age

Operational objectives:

- Promoting good physical and mental health (e.g. promoting a healthy cardiovascular system, encouraging education and learning throughout life) in order to help avoid cognitive decline. Half of all cases of dementias have a vascular component, thus control of vascular risk factors can also help prevent the development of dementia.<sup>37</sup>
- Identifying and promoting best practice in early diagnosis of Alzheimer's disease and dementia, in order to make best use of available interventions at the most effective early stages.
- Through these strategies to improve prevention, and early diagnosis and intervention delaying the progression of Alzheimer's disease, it is possible to prevent—or at least delay—progression of the disease, with benefits for individuals, families and social protection systems overall.

### 4.2. Specific objective: Better understanding of Alzheimer's disease and dementia through a shared European effort

Operational objectives:

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<sup>37</sup> Alzheimer Europe (2008) Dementia in Europe Yearbook

- Supporting targeted research on key problems related to Alzheimer’s disease at European level; develop Alzheimer’s as a pilot of Joint Programming of public research in the Member States in order to make best use of available resources.
- Further developing current accurate comparable epidemiological data as a reference point to assess the impact of these conditions and enabling monitoring of responses (data collection, potential additional monitoring of mental health and social networking). The EuroCoDe recommendations and the future European Health Examination Survey could provide a solid basis for this.
- Promoting the sharing and pooling of knowledge and data at EU level to avoid duplication of efforts, thus increasing efficiency.
- Promoting research into social care models including sharing of best practices in the training of dementia caregivers. There is a broad consensus that patient care should not be limited to pharmacological treatment but should also include non-pharmacological approaches, and these need further research to be applied effectively.

#### **4.3. Specific objective: Supporting national solidarity with regard to dementias**

Operational objectives:

- Mapping and describing better the existing and emerging good practices related to treatment and care for persons suffering from Alzheimer’s disease and other forms of dementia and improving the dissemination of such practices. This should also include supporting more widely the development of new good practices, where needed, by spreading information on how European Community programmes can help finance such developments in Member States.
- Supporting the development of concepts and solutions on a macro level, when needed, both at national and European levels and developing quality frameworks for medical and social care services for people with dementias.
- Empowering national and international Alzheimer’s associations and relevant patients’ organisations.

#### **4.4. Specific objective: Respecting the rights of people with dementias**

Operational objectives:

- Political leadership for the EU in recognising the mental capital of older adults and reducing the stigma associated Alzheimer’s disease and other dementias, for example through anti-discrimination and employment of older adults.
- Sharing best practice on respecting the rights of vulnerable adults and tackling patient abuse.

### **5. POLICY OPTIONS**

This section presents four policy options in tackling the issues of Alzheimer’s disease and dementia described. The initial “baseline option” assumes that no further action is taken, other

than those actions currently in progress. Each subsequent option described below builds on the actions of the previous option in a cumulative manner (e.g. the Communication option includes the actions outlined under the Report option, with the additional actions described).

### **5.1. 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 Programme.<sup>38</sup>

Current projects and proposals under the Framework Programme for research would continue. Moreover, actions in the individual Member States, such as research and establishment of national plans, would continue. This would probably include development of the knowledgebase as well as an improvement of early diagnosis in countries with comprehensive strategies; however, in MS with no political commitment and awareness of the dementia challenge will see little progress.

### **5.2. 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;
- Participation in international fora to disseminate the data.

As for the baseline option, current projects and proposals under the Framework Programme for research would continue, as well as actions in the individual Member States. There would still be reduced progress in MS with no political commitment and awareness of the dementia challenge.

### **5.3. 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 associated with Alzheimer's disease and other dementias within the EU, 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. Although an independent initiative, the Council Recommendation on Joint Programming and a Commission Communication on Alzheimer's Disease and dementia would strongly

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<sup>38</sup> [http://ec.europa.eu/health/ph\\_programme/pgm2008\\_2013\\_en.htm](http://ec.europa.eu/health/ph_programme/pgm2008_2013_en.htm)

complement each other in furthering development, coherence and coordination in the field of research both at the national and EU levels. The Joint Programming would thus make research efforts far more efficient, unlocking untapped potential without requiring new sources of funding. Furthermore, joint adoption would provide coherent political support to policy in this field.

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 in the field of Alzheimer's disease and dementia financed under the Health Programme.

Joint actions are activities carried out by the Community and one or more Member States.<sup>39</sup> In this case a specific Joint Action in the field of Alzheimer's disease will be funded through the Health Programme up to 50% (and in cases of exceptional utility, 70%), and will be included in the Call for Proposals by the Executive Agency for Health and Consumers.

The continued collection of consensual and comparable prevalence rates for dementia in Europe as would be achieved in the report option would be more complete and accurate following improvements in early diagnosis. In addition, actions that could be included in a Joint Action are the establishment of a European network for cooperation on the issues described above, such as:

- exchange of best practices on early diagnosis procedures and intervention;
- exchange of best practices on standards of care, training for caregivers, and financing of long-term care;
- discussion of the rights of people with dementia who should formulate recommendations on dignity, autonomy, social inclusion, and the legal guardianship of Alzheimer's and dementia patients.

#### **5.4. 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.

This formal programme and European action plan would also be adopted jointly with, and complemented by, a DG Research proposal for a Council Recommendation for Joint Programming of research in the field neurodegenerative disease, including Alzheimer's disease.

In the context of this option being the next cumulative step, it would include the scope of the actions detailed in the previous two policy options. However, whereas the Communication would achieve the objectives through the voluntary opt-in to a Joint Action, the establishment

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<sup>39</sup> Executive Agency for Health and Consumers: <http://ec.europa.eu/eahc/health/actions.html>

of an action plan would require a commitment for Member States to participate. 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.

## **6. ANALYSIS OF IMPACT**

Given the non-binding character of almost all the proposed actions and also, given that EU-level research spending represents only a minor share of overall public and private spending, the significance of the following assessment exercise can therefore only be limited.

The main three options have been assessed qualitatively in terms of scope, political acceptance, EU contribution, and Member States' commitment, as there is a significant lack of quantitative data as regards the impacts of policy actions targeted to improve dementia and Alzheimer's care.

The impact of the proposed Council Recommendation for Joint Programming of research in the field neurodegenerative disease, including Alzheimer's disease and dementia has not been included in this impact assessment, as this initiative will undergo its own impact assessment process lead by the Directorate-General for Research.

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.

### **6.1. Baseline Option – No new EU action**

#### *6.1.1. Current economic and societal burden of Alzheimer in Europe*

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 care.<sup>40</sup>

In high-income countries (with a gross national income per capita of US\$10 066 or more), 9.4% of the total disability-adjusted life years (DALYs) for persons aged over 60 are attributable to Alzheimer's disease and dementia. In comparison, it is only 4.8% for muscular-skeletal disorders, and 3.7% for diabetes mellitus.<sup>8</sup> Alzheimer's disease and dementia is, already today, the fourth leading cause of burden of disease (DALYs) in high-income

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<sup>40</sup> Alzheimer Europe (2008) Dementia in Europe Yearbook 2008

countries, following unipolar depressive disorders, ischaemic heart disease, and cerebrovascular disease.

As a result of inaction, there will be no immediate burden on public authorities at different levels of government (national, regional, local), 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.

Some Member States will continue to develop national plans and strategies; however, these will be independently established with coordination at EU-level through the Mental Health Pact strand on ageing.

## **6.2. Report taking forward the work of the EuroCoDe project**

### *6.2.1. Social Impacts*

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.

It would have the possible impact of prompting some minor changes within the Member States in terms of accessibility to care, albeit without any coordination at EU level. Without the political support of the Commission, it is unlikely that Alzheimer's disease and dementia would be a priority.

Such an option may lack full effectiveness in tackling the inequities across the Union regarding best practice in primary prevention, a fundamental path to avoid an escalating growth of the disease resulting from ageing population.

A report would not affect the social protection of the patients and of the informal caregivers.

### *6.2.2. Economic Impacts*

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).

Such an action would not carry any direct cost or administrative burden for public authorities at different levels of government (national, regional, local) in the short term. However, it would carry direct and indirect costs in the long term for national health systems owing to the deterioration of health and social welfare losses due to the illness. There would also be an 'opportunity cost' from the inefficiencies of fragmented actions and duplication of effort, as highlighted in the baseline option.

A report policy option would not stimulate Alzheimer's research, and continuing individual actions risk being inefficient and fragmented within Member States, who will not always be aware of what is being done in the different areas at Community level.

A report would not affect the economic and legal protection of the patients and of the informal caregivers.

### 6.3. Communication

#### 6.3.1. Social Impacts

The options that are under consideration are for technical cooperation, non-binding "soft" law and European-level cooperation, not harmonisation or binding legal measures. The initiative would also have a non-binding nature and the likely impacts are not expected to be burdensome to any group or sector.

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.

Early intervention has been shown to have positive effects on the quality of life of people with dementia (Banerjee *et al.*, 2007) and their family carers (Mittleman *et al.*, 2007).

A formal statement of intent in a Communication would prepare the ground for future actions on social protection of the patients and of the informal caregivers.

#### 6.3.2. Economic Impacts

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.

The dissemination of the information would be greatly facilitated with a minimal incremental increase in costs, as it would take advantage of already established web portals and networks.

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

Direct and indirect cost could be reduced in the long run for national health systems resulting from reduction of health and social welfare losses due to the prevention of illness and delaying the high-cost institutionalization (and terminal long-term care) of Alzheimer's and dementia patients. Analysis suggests that only a modest increase in average quality of life of people with dementia, plus a 10% diversion of people with dementia from residential care, is needed to be cost-effective.<sup>41</sup> If it were possible to delay the onset of Alzheimer's disease by five years it would decrease its prevalence by 50%,<sup>42</sup> and gain of between 0.01 and 0.02

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<sup>41</sup> Department of Health of the United Kingdom (2008) Consultation on a National Dementia Strategy

<sup>42</sup> Alzheimer Europe (2008) Dementia in Europe Yearbook



quality-adjusted life years (QALYs)<sup>43</sup> per person year, achieved through the provision of better care, has been shown in the United Kingdom to be sufficient to render action cost-effective.<sup>44</sup> These relatively small improvements seem very likely to be achievable with cooperation at European level.

Through earlier diagnosis and intervention in Alzheimer's disease and dementia can delay late-stage progression of the diseases and thus delay institutionalization. The 'opportunity cost' from the inefficiencies of fragmented actions and duplication of effort would also be reduced.

A Communication would stimulate research and development through permitting cooperation in the different areas of research and expertise, which would lead to a greater global knowledge and better identification of Alzheimer's, effectively centralising knowledge and avoiding duplication within the Union.

Future actions on economic and legal protection of the patients and of the informal caregivers could be encouraged through establishing Alzheimer's disease as a priority in Europe by raising political awareness in the Member States through a Commission Communication.

#### **6.4. 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.

##### *6.4.1. Social Impacts*

An action plan would provide detailed guidance at Community level, which would set out general principles that are then adapted to the circumstances of each health system.

A proposal for a European action plan would have the direct impact of seeking to bring about change to reduce current fragmentation and inequalities in this area. In addition, this would also have an impact on the formulation of European policy in this area.

Proposing such a comprehensive strategy specifically for Alzheimer's disease and related conditions needs to take place in the context of a fuller commitment to the "broad promotion of life-long mental capital," which is a currently established EU-level Public Health priority. Emphasis on this broader context is essential, as 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.

##### *6.4.2. Economic Impacts*

Although the technical work will be taken forward with support from the existing health programme, there could be additional cost, for example, if it were decided to integrate data collection on Alzheimer's disease and other dementias into the European statistical system.

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<sup>43</sup> The quality-adjusted life year (QALY) is a measure of disease burden, including both the quality and the quantity of life lived. It can be taken as a proxy for Healthy Life Years (HLYs) in this case.

<sup>44</sup> Banerjee & Wittenberg (2009) International Journal of Geriatric Psychiatry: Clinical and cost effectiveness of services for early diagnosis and intervention in dementia

A substantial level of funding above the *status quo* might be required from EU, and a new budget line might need to be established. EU-level funding from the Directorate-General for Research (DG RTD) cannot exceed certain levels, as other health research priorities have to be supported, according to the content of the FP7 Cooperation Specific Programme. EU-level DG RTD funding is also constrained in terms of duration, since the FP7 ends in 2013.

As for the Communication option, the direct and indirect cost could be reduced in the long run for national health systems resulting from reduction of health and social welfare losses due to the prevention of illness and delaying the high-cost institutionalization (and terminal long-term care) of Alzheimer's and dementia patients.

A comprehensive action plan would require a clear consensus that this was consistent with subsidiarity, given the differences in organisation and delivery of health services and medical care throughout the Union. However, this is in fact true for all the options for action, to a greater or lesser extent. A big initiative, if agreed, would stimulate research and development through permitting cooperation in the different areas of research and expertise, which would lead to a greater global knowledge and better identification of Alzheimer's, effectively centralising knowledge and avoiding duplication within the Union.

A synoptic overview of the different policy options and the extent to which they could achieve the identified specific objectives is presented in the following table.

	<b>Baseline Option</b>	<b>Report</b>	<b>Commission Communication</b>	<b>Formal Programme &amp; Action Plan</b>
<b>Specific Objective 1</b> <b>Acting early to promote well-being in old age</b>	No additional EU-level support resulting in little or no shared European effort.  Current projects and proposals under the Framework Programme for research would continue.	Although recommendations and some best practices exist, these will not be shared.	Recommendations for good physical and mental health will be promoted and best practices in early diagnosis and intervention will be shared.	Establishment of an action plan would achieve the same objectives as a Commission Communication but through requiring a commitment for Member States to participate.  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.
<b>Specific Objective 2</b> <b>Better understanding of Alzheimer's disease and dementia through a shared European effort</b>	Actions in the individual Member States would continue, however with little progress in those MS where AD has low political priority.	Further development of current accurate comparable epidemiological data.	Further development of current accurate comparable epidemiological data. Would promote research and the sharing of knowledge at EU-level	
<b>Specific Objective 3</b> <b>Supporting national solidarity with regard to dementias</b>		Little support for this objective.	Would promote sharing of good practices related to treatment and care, and empower AD associations.	

<b>Specific Objective 4</b>  <b>Respecting the rights of people with dementias</b>		Although recommendations and some best practices exist, these will not be shared.	Sharing of best practice on respecting the rights of vulnerable adults and tackling patient abuse.	
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## 7. COMPARING THE OPTIONS

The options can be assessed qualitatively on the basis of their contribution at EU level, their scope, to what degree they meet political expectations, and the subsidiarity dimension. The table below compares the proposed options based on these criteria.

<b>Option</b>	<b>EU Contribution &amp; Efficiency</b>	<b>Scope &amp; Effectiveness</b>	<b>Political Acceptance &amp; Coherence</b>	<b>Proportionality &amp; Member State Commitment</b>
<b>Baseline</b>	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 inefficiencies.		This option does not meet the expectations of the Member States as expressed through the Council or the Parliament at all.	Although there would be no additional commitment required of the MS, this option would not contribute to tackling any of the problems no achieve any of the objectives outlined in this impact assessment.
<b>Report</b>	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.
<b>Communication</b>	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	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	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	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 4.

	for a more coherent approach to AD.	through a Joint Action funded through the Health Programme.	political priority.	
<b>Action Plan</b>	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 4 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.

Furthermore, the four options can be assessed on their relative advantages and disadvantages, as presented in the successive tables below.

<b>Baseline Option</b>	
<b>Advantages</b>	<b>Disadvantages</b>
<p>This would not require any additional funding</p> <p>It would not require additional commitment from the MS</p>	<p>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.</p> <p>This option does not meet the expectations of the Member States as expressed through the Council or the Parliament.</p> <p>It would not contribute to tackling any of the problems nor achieve any of the objectives outlined in this impact assessment.</p>

<b>Report Option</b>	
<b>Advantages</b>	<b>Disadvantages</b>
<p>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.</p> <p>Other Framework Programme and MS actions would continue.</p> <p>There would be no formal commitment necessary from</p>	<p>This option requires support through funding of another project similar to the successful EuroCoDe project.</p> <p>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.</p> <p>It would not contribute to tackling any of the problems nor</p>

the MS as this option would be entirely funded through the Health Programme.	achieve any of the objectives outlined in this impact assessment.
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<b>Commission Communication</b>	
<b>Advantages</b>	<b>Disadvantages</b>
<p>Actions proposed would support coordinated efforts across the EU, such as sharing of best practice and research. This would increase efficiencies.</p> <p>It would provide the political support for a more coherent approach to Alzheimer's disease and dementia.</p> <p>This option would provide a framework for the proposal for a Council Recommendation on Joint Programming of research in the field of AD.</p> <p>Cooperative actions in the MS could be supported through a Joint Action funded through the Health Programme.</p> <p>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.</p> <p>This action would provide some flexibility to MS willing to act in the area of AD</p>	<p>The potential scope of added-value would be limited to the Member States that choose to participate in the Joint Programming or Joint Action.</p>

<b>Formal Programme and European Action Plan</b>	
<b>Advantages</b>	<b>Disadvantages</b>
<p>An action plan would address the same EU-level objectives as a Communication, but with stronger tools.</p> <p>It would provide the mandate for a more coherent approach to Alzheimer's disease and dementia also involving action by Member States, not just the EU.</p> <p>In addition, it would provide the financial support to MS, though a single detailed and funded strategy.</p> <p>It would clearly meet the expectations of the Parliament and Council.</p>	<p>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.</p> <p>This action would provide less flexibility to MS willing to act in the area of Alzheimer's disease and dementia, and would raise issues of subsidiarity and lack of respect for the responsibilities of the Member States for their health systems.</p>

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**, tackling the problems defined through focussed actions to achieve the objectives identified in Section 4. A Commission Communication would be we proportionate to the objectives without

overstepping the principles of subsidiarity as in Option 4, whereas the first two options would fail to meet many of the objectives identified.

## **8. 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. Such indicators could include:

- To develop indicators for monitoring prevalence, incidence, and risk factors on a comparable basis between the Member States; these indicators could be incorporated into the European Community Health Indicators (ECHI), Healthcare Quality Indicators (HCQI), and the Social Protection Indicators (SPI).
- Responsibility for monitoring these indicators will be with the European Union Health Information Committee (HIC).
- To monitor the coverage and content of strategies or plans established by the Member States on dementias.
- This will be monitored through actions in the planned Joint Action funded through the Health Programme.
- An increase in coordination between Member States within the DG Research Programme, for which a specific committee is proposed in the proposal for a Council Recommendation.
- An increase in EU-level DG Research funding on neurodegenerative diseases, including Alzheimer's disease, within the 7th Framework Programme (FP7).

## **9. ANNEXES**

- 9.1. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Towards Joint Programming in Research COM(2008) 468 final**
- 9.2. Minutes of the meeting of the Impact Assessment Steering Group – 13 March, 2009**
- 9.3. Minutes of the joint meeting of the Impact Assessment Steering Group and the European Union Panel of Experts on Alzheimer's Disease – 17 March, 2009**
- 9.4. Minutes of the meeting of the Impact Assessment Steering Group – 23 March, 2009**
- 9.5. Opinion of the Impact Assessment Board**