

# Facing the future

A recent Parliament Magazine debate heard that cases of dementia, including Alzheimer's disease, are set to double in the next two decades. **Martin Banks** reports

It affects an estimated 7.3 million people in Europe and, after cancer, is the health issue which most concerns the public. Despite this, a debate organised by the Parliament Magazine, heard that dementia remains something of a 'Cinderella-type' poor relation when it comes to funding and cooperation and that the burden on the people who care for sufferers is "very substantial". The mood among most of the participants was summed up by Enda Connolly, of the Health Research Board in Ireland, who described Alzheimer's as "one of the biggest health challenges" facing the EU and its member states, before adding, "Unfortunately, there is currently insufficient being spent to address the very pressing issue."

The roundtable debate, entitled "facing the future" and held in association with Sanofi, took place on 21 September, which was designated 'world Alzheimer's day'. The first session looked at European collaboration on dementia while

#### Key Alzheimer's facts

- It takes between 10 and 32 months to get Alzheimer's disease diagnosed
- One in five carers spend more than 10 hours per day caring for an Alzheimer's patient
- There are 36 million people with dementia worldwide
- An estimated €17bn is currently invested in 374 Alzheimer's programmes
- Alzheimer's is the second biggest health fear after cancer

the second focused on what needs to be done to address the predicted doubling in dementia cases over the next 20 years.

Opening the two-hour debate, Belgian MEP Frederique Ries, a member of the European Alzheimer's Alliance, pointed to a parliamentary resolution adopted by MEPs in January this year, which demands "more action, research and coordination" into the disease. She said the number of sufferers in Europe, including 150,000 in Belgium alone, was "almost certainly" an under-estimate as many cases remain undiagnosed. "There is hope for the future and one day I hope a cure can be found but this is most probably many



*"Dementia remains something of a 'Cinderella-type' poor relation when it comes to funding and cooperation"*



## Up to the challenge?

**It is vital to increase coordination when it comes to tackling neurodegenerative diseases, writes Enda Connolly**

Investment in research on neurodegenerative diseases such as Alzheimer's and Parkinson's is lagging seriously behind those of others such as cancer and cardiovascular diseases. Neurodegenerative diseases significantly reduce healthy life expectancy, quality of life and collectively are the leading cause of disability in the elderly. The increase of prevalence of neurodegenerative diseases above 65 years is almost exponential and Alzheimer's disease represents about 70 per cent of the cases of dementia, affecting an estimated six million European citizens, a number which is expected to increase to 10.7 million by 2040.

Available treatments for neurodegenerative diseases are only symptomatic and have very limited effects, while treatments that may prevent or stop the progression of neurodegeneration are still lacking. As a consequence, social and healthcare supports are central in the management of these disorders resulting in a major human burden and hidden growing economic costs. In this context, a new innovative action that allows European countries to share more effectively their strengths in publicly-funded research is tackling this 'grand challenge' of neurodegenerative diseases and Alzheimer's disease in particular. The EU joint programme on neurodegenerative disease research (JPND) is a 23 country-led initiative which aims to increase the coordination of national funding, thus allowing a synergistic use of shrinking research budgets in the current difficult economic climate.

The first goal of this initiative is the creation of a strategic research agenda (SRA) which is due for completion before the end of 2011. The SRA is address-

ing all aspects of the challenge, from the most basic research, to research in social sciences, through to clinical and translational research. This joint strategy will deliver, for the first time, a common view of what European countries need to do in neurodegenerative disease research over the coming decade. The ultimate aim of JPND is to address the challenge of neurodegenerative diseases more effectively and to find new treatments. This requires building research capacity within neurodegenerative disease areas, reducing duplication of new and existing research activities as well as forming connections with a wide range of other initiatives and stakeholders. JPND is also working to implement solutions that can alleviate, even partially, the plight of families and the economic burden brought about by the increasing prevalence of these diseases in Europe's ageing population.

In this regard, during the preparation of the SRA, JPND launched two joint transnational calls which made €23m available to researchers in 22 countries. The next stage, currently being planned, will see JPND develop a programme of research through large-scale initiatives that will deliver the SRA within the next 10 years.

In the face of reducing national health budgets and exploding healthcare costs, increasing the efficiency of national and European investments in disease research to improve Europe's competitive position in this area has never been of greater importance. JPND is increasing the opportunity to accelerate research efforts over the next decade, which can only serve to improve the efficiency of European countries strategies and investments to address the enormous challenge of neurodegenerative diseases.

*Enda Connolly is an executive board member of the EU joint programme for neurodegenerative disease research (JPND)*



## It could be us

**The fight against Alzheimer's is more than a medicinal issue – it is about improving the quality of life for patients and carers, says Frédérique Ries**

Alzheimer's and other types of dementia are not only diseases, they are social tragedies which impact the patients families' daily life. The impressive figures of nearly 10 million people suffering from dementia in Europe, with Alzheimer's accounting for the vast majority of them can't leave us indifferent. And we all know that this number of sufferers of Alzheimer's disease is underestimated due to difficulties in early diagnosis.

As far as the European parliament support is concerned, I know that a lot of MEPs are aware of the situation, for example of the difficulties to put in place a national or regional efficient action plan for early diagnosis of Alzheimer's. However, there remains a big gap between member states in terms of access to medicines at the different stages of the disease and the crucial issue of refunds. This is why we think that this serious threat deserves a coordinated action also at the EU level. It is therefore important to focus on a multidisciplinary approach embracing diagnosis, prevention, treatment and support for the recipients of care and for their families. It is also crucial to emphasise better national

practices and private-public partnerships. This is globally the message I delivered in January 2011 during the debate with European health commissioner John Dalli.

Another point I raised was the current lack of volunteers during the clinical trial phase. This is a strong appeal from researchers. And we have, as politicians and co-legislators to answer it. More volunteers are needed for the clinical studies if we hope to find a cure one day, which we must. About this, the upcoming revision of the clinical trials directive is a golden opportunity to provide a concrete response and to give hope to the families affected. Of course, we know that it will take many years before finding treatments which act directly on the disease. And the treatments currently available on the market are not efficient enough, as they act on symptoms, but not on lesions. At the end of the day, the fight against this disease is not only a medicinal issue. It is also vital to promote activities like art-therapy or music-therapy which improve quality of life of the patients, but also of carers.

As the writer Nicholas Sparks, whose grandparents suffered from the disease, wrote, "Alzheimer is a thief of hearts, souls and memories." It could have been our family. It could be us.

*Frédérique Ries is a member of parliament's environment, public health and food safety committee and the European Alzheimer's alliance*





## The time is now

### European policymakers must act now to minimise the economic burden of an ageing population, writes Martin Seychell

Currently, more than 7.3 million Europeans are affected by Alzheimer's disease and other dementias and the related costs are estimated at a staggering €177bn per year (direct costs and costs of informal care). With our ageing society, forecasts indicate that these figures are set to double every 20 years. Even if these projections turn out to be overstated, it is clear that we face a very serious problem. We need to take steps to ensure that the burden is minimised. As with all diseases that affect people worldwide, our efforts will bear more fruit if we work together at global, European, national and local level, and with a broad range of actors – policymakers, NGOs, industry and groups representing healthcare professionals, patients and carers. The commission is well placed to coordinate this multi-partnered effort.

In 2009, the commission adopted a communication on Alzheimer's disease and other dementias. The three main areas of action are early diagnosis and health promotion, improving the knowledge base and research coordination and sharing best practice on caring for people with dementia. There are many examples of action at EU level in all three areas. The commission has channelled more than €85m towards research into dementias between 1998 and 2006 alone. Various

projects involving many EU countries are currently underway, for example: improving the coordination of research; streamlining drug discovery and uptake; creating a better dialogue between professional and informal carers. In addition, the commission has recently launched a reflection process on chronic diseases together with member states and stakeholders.

I would like to highlight a new initiative which is an integral part of the EU 2020 strategy: The innovation partnership on active and healthy ageing. This partnership aims to explore innovative solutions for keeping Europeans active and healthy as they age. By working together across the research and innovation chain with all levels of government, with many sectors and a wide range of public and private partners, we are looking at how to best translate innovative ideas into tangible products and services that really respond to the needs of older Europeans.

We need to acknowledge that Alzheimer's disease is an important public health challenge. The commission is addressing Alzheimer's and other dementias from every angle and I think we are making progress. Next year, is the "European year of active ageing and solidarity between the generations". This will provide us with a particularly good opportunity to galvanise support and raise the political profile of Alzheimer's disease across Europe.

*Martin Seychell is deputy director general for the commission's health and consumers DG*

## Getting results

### Alzheimer Europe wants to see greater investment in tackling the neurodegenerative disease, says Jean Georges

In 2006, Alzheimer Europe (AE) and its 34 member organisations from 30 European countries adopted the Paris declaration of the political priorities of the European Alzheimer movement. This declaration called on the European institutions to develop a coherent strategy and for member states to adopt national Alzheimer plans. In addition, AE called for greater investment in research, better coordination of national research efforts and the exchange of information and best practices between European countries on dementia policies, approaches to care, legal and ethical issues which affect people with dementia and their carers. The progress achieved in the past five years has truly been astounding. AE is particularly grateful to the personal commitment of French president Nicolas Sarkozy who, during his country's EU council presidency, gave a much needed impetus to greater European collaboration in the field of dementia. Our campaign found equal support in the European parliament: more than 50 members have joined the European Alzheimer's Alliance chaired by Françoise Grosseleté MEP, and close to 60 per cent of its members adopted a written declaration calling on the European commission to start the development of a European action plan against Alzheimer's disease (AD). The joint programming

initiative on neurodegenerative diseases and the 'Alcove' project, the European joint action on dementia funded by DG Sanco are direct and tangible results of this concerted campaign.

Despite these encouraging signs, public investment in AD remains lower than for other major diseases. Yet the need for European collaboration is as evident now as it was five years ago when AE adopted its Paris declaration. The number of people with dementia in Europe is estimated at 7.3 million, according to research carried out by AE in its commission financed "EuroCoDe – European collaboration on dementia" project. The same research found that the cost to society was significant representing an estimated €160bn in 2006.

The disease also has a significant impact on families – an AE survey revealed that 50 per cent of carers reported spending over 10 hours a day caring for the person with dementia in the later stages of the disease. And a recent public opinion survey carried out by AE and the Harvard school of public health in France, Germany, Poland, Spain and the US, respondents rated AD as the second most feared disease after cancer. Significant majorities (from 60 per cent in the US to 85 per cent in France) of the public supported an increase in funding for research and the care of people with AD. It is also worth pointing out that no new drug treatment for AD has been approved in the past five years, despite significant research efforts in the field.

*Jean Georges is executive director of Alzheimer Europe*





## In the know

### The Alcove European network aims to improve wellbeing for dementia sufferers, explains Christine Barr

Alzheimer cooperative valuation in Europe (Alcove) is a two-year European joint action co-financed by the European commission. This project was born from a need to promote the sharing of experiences in dementia health policies. Alcove aims to improve knowledge and promote the exchange of information on dementia to preserve health, quality of life, autonomy, and dignity of people living with dementia and their carers in EU member states.

The last 50 years in Europe have seen a dramatic increase in healthy life expectancy. However, this period has also seen a corresponding elevation in diseases linked to ageing, particularly dementia. Alzheimer's disease and other dementias have become a public health priority at the EU level given their high prevalence, cost, and profound impact on society. By improving knowledge and developing preventive and care recommendations to facilitate policy and healthcare decision making in European countries, Alcove will contribute to the wellbeing of people living with dementia.

This open network of 30 partners from 19 EU member states aims to capitalise on work conducted during previous European studies and through working with other networks in the field to meet its main objectives. These are: establishing a

sustainable European network for the exchange of experiences and knowledge; informing and advising decision-makers, healthcare professionals, care-givers, and citizens; and reducing the risks associated with psychotropic drugs, particularly those of antipsychotics, in individuals living with dementia.

Alcove is divided into three transversal work packages and four core packages, respectfully led by France (coordination), Spain (dissemination), Slovakia (evaluation), Italy (epidemiology), UK (early diagnosis), Finland (care and services), and Belgium (rights and dignity). It aims to answer the following questions: how to improve data for better knowledge regarding dementia prevalence; how to improve access to dementia diagnosis as early as possible; how to improve care for people living with dementia and particularly those with behavioural disorders; how to improve the rights of people living with dementia, particularly with respect to advance declarations of will.

Alcove will place a special focus on limiting the overuse and misuse of antipsychotics in Alzheimer's disease. At the six-month mark, Alcove has successfully laid the foundation for its upcoming workload by implementing standard operating protocols and monitoring and feedback tools. A global work plan has been established and the communication and exchange of information between Alcove and other EU projects on Alzheimer's disease and dementia have begun.

*Christine Barr is project manager of the Alcove initiative*

years away yet," said Ries.

Her comments were echoed by Martin Seychell, deputy director general for DG health and consumers at the European commission, who estimates that as many as 19 million people in Europe are currently affected, directly or indirectly, by Alzheimer's. He said, "Unfortunately, Alzheimer's is a part of the ageing process and what we need is a better understanding of the disease, to raise its profile and earlier diagnosis. We are making progress on these things but there is still a long way to go."

The debate heard from another expert, Thomas Rooney, about current problems of recruiting patients for clinical trials on Alzheimer's. Clinical trials are crucial, he said, not least because, currently, only four medications have been approved for treatment of Alzheimer's. He also pointed out that these drugs treat the symptoms but do not stop or reverse the progression of the disease. Rooney, of Sanofi, said that one of the consequences of poor patient recruitment was that it often takes a long time to start a clinical trial. "We simply do not have enough patients to do the trials," he said. He added, "It is a problem and there is a clear need for better recruitment for these trials. It is obvious that we need to better explain to people why it is important to take part in clinical research."

He also called for improvements in the "design" of clinical trials and increased sharing of information of data from previous trials. Another current issue highlighted during the lively debate was the burden of care faced by people whose loved ones or dependents suffer from dementia. Christine Barr, project manager with the Alcove initiative which aims to provide advice and information for carers, said that sufferers continue to suffer a "stigma" attached to Alzheimer's. "We have to realise that these people have rights too and these should be respected," she said.

Representing the Polish EU council presidency, Filip Domanski, health attaché at the Polish permanent representation in Brussels, reassured participants that dementia "will remain a priority" during his country's six-month term in office.

Closing the debate, Jean Georges, executive director of Alzheimer Europe, pointed to a survey showing that one third of respondents said they know someone who suffers from dementia. "It is also a very costly disease," he said, adding, "In 2008, it was estimated that the cost to the EU is €160bn, of which 60 per cent goes on the provision of informal care." He added, "It is not surprising, then, that people are becoming increasingly concerned about this disease. My hope is that while we are currently seeing national budgets are being cut back, I hope we can look back in 20 years and say that this vulnerable group of people were not overlooked."★



# Alzheimer Disease: Addressing the R&D challenges

## 3 questions to John Alam - Vice President

Therapeutic Strategic Unit Aging, Research & Development – SANOFI

### \* Why do we need new therapies for Alzheimer's Disease?

With 7.3 million people in Europe affected by dementia there is clearly a large unmet medical need for new therapies. Only 4 medications are currently approved for the treatment of Alzheimer's which have variable efficacy that decreases with time and that only treat the symptoms with little or no effect on disease progression. It has been almost 10 years since the last new therapy was approved in Europe for Alzheimer's, so we urgently need new therapies to better treat the symptoms and to prevent or reverse the progression of the disease.

### \* What are the challenges facing R&D for Alzheimer's Disease?

Alzheimer's is a complex multifactorial neurodegenerative disease that starts to damage the brain several years before patients develop cognitive problems. Together with the lack of diagnostic biomarkers and measures to monitor disease progression, this leads to high patient heterogeneity and very long and costly clinical trials, making it difficult to demonstrate therapeutic efficacy and contributes to the high attrition rate. The difficulty to recruit very early stage "prodromal" Alzheimer patients also leads to delays in evaluating new disease modifying therapies that would be expected to be more effective in patients where the disease was not too advanced.

### \* What are the needs and future perspectives for R&D for Alzheimer's Disease?

More translational research centers with an integrated approach from preclinic to clinic are needed to improve the predictability and reduce the attrition of R&D. A better understanding of Alzheimer's pathophysiology and the factors for risk and resilience compared to normal aging are also required to identify new drugable networks and develop more predictive animal models. Industry also has to provide more access to clinical trial data to improve the design of future clinical trials. Clinical trial results for the most advanced Alzheimer therapies are expected in 2012-2013 and for other promising treatments in the next few years. However, the outcome of these trials is unlikely to impact the need to pursue new therapies, since the future treatment paradigm for Alzheimer's will be based on a patient centric polypharmacy approach, rather than a single "magic bullet" therapy, including non-pharmacological and lifestyle interventions.

Meanwhile, closer collaborations between industry and key stakeholders are needed to "de-risk" drug development for Alzheimer's. EU initiatives, such as the Innovative Medicines Initiative (IMI) project "PharmaCog" and the Joint Program on Neurodegenerative Diseases are important examples of such collaborations that have been launched since the French Presidency of the EU in 2008 and that need to be extended to have a direct impact on drug development and for the benefit of patients and their families.