European and External Relations Committee

The EU referendum and its implications for Scotland

Written submission from Alzheimer’s Research UK

Summary

There are currently 850,000 people living with dementia in the UK, including over 43,000 in Scotland, with no treatments that alter the course of the disease. Until recently, research into dementia has been largely neglected, with the amount spent on dementia dwarfed by what is spent on comparable conditions such as cancer and heart disease. We desperately need long-term, sustainable research funding that is proportionate to the economic and social impact of the condition.

The UK has been a world leader in the fight against dementia over the past six years. The foreword to the Prime Minister’s challenge on dementia 2020 stated that the UK should be the best place in the world to undertake research into dementia and other neurodegenerative diseases. However we must now ensure that our role as global leader on dementia research is not lost as we start negotiations to exit the European Union (EU).

UK membership to the EU has been broadly favourable for the dementia research environment across a number of important factors. As negotiations to depart begin, it is essential that minimal disruption occur to the current research environment, as advances in dementia research could potentially be delayed and avenues of inquiry abandoned as a result. Alzheimer’s Research UK urges policy makers to make supporting dementia research in the following areas a top priority:

- Scientific representation during Brexit negotiations
- Continued access to EU funding programmes and schemes which are vital for dementia research
- Scientists and other staff supporting the research environment must have continued mobility – both UK nationals to Europe and vice versa
- Continued support for collaboration and allowing the UK to remain a positive force in developing a harmonized research environment across the EU
- Access to new treatments when they become available as part of a continued relationship with the EMA

Priorities for Government negotiating a new relationship with the EU

Continued access to EU funding schemes and programmes: The UK is a world leader in dementia research, funding more in the area relative to other disease areas than other EU member states.¹ In the historically underfunded field of dementia research, EU investment is particularly critical. EU funding has become an important source of support for the research environment in the UK, and the loss of access to EU funding programmes could have a significant impact for major and pilot projects.

¹ Alzheimer’s Society Research Report. Table B3. 2015.  
as well as grants for equipment for dementia researchers. Funding through just one of the strategic budget areas of the EU in 2013 produced over 20,000 publications in prominent peer-reviewed journals, including 909 in the area of neuroscience.²

“Over the last 10 years, around 70% of my funding for research has come through EU grants. If the UK loses its access to EU funding, the government will have to compensate for this or UK research will lose out financially, on top of losing out by not being able to engage in large EU projects in which collaboration with the top labs in Europe is essential…Collaboration is a two-way process, the UK was gaining by being able to be part of EU consortia and the research in European consortia was stronger by having top UK labs in them, both parties will end up losing out.” – Researcher from an EU member country, currently working in the UK.

1. The EU FP7 investment strategy (the most recent for which data in this area has become available) included a funding stream for brain research with a particular emphasis on the translation of basic discoveries into clinical applications. In the first three FP7 calls, 30 neuroscience projects were funded totalling €135 million (£115 million.) Projects ranged from basic to clinical research, including the identification of genes and molecules present in brain diseases, the pathophysiology of diseases, and the development of new therapies and diagnostic tools.³ Research relevant to neuroscience was also funded in other health priority areas, leading to an additional €247 million (£210 million) dispersed to an additional 49 research projects.

2. Dementia researchers in the UK, supported by funds from Alzheimer’s Research UK, have been successful in leveraging significant additional investment from the EU for cutting edge dementia research projects. Pilot, equipment and major project grants have all been means to strategic collaborative funding from the EU research funding frameworks:
   • An Alzheimer’s Research UK funded researcher acts as the co-coordinator of the Innovative Medicines Initiative (IMI), a €48 million EU-funded public-private partnership. This came as a result of over £850,000 from an Alzheimer’s Research UK major project grant on combinatorial biomarkers for dementia prodromes, prediction, pathology and progression.
   • An Alzheimer’s Research UK pilot study granted to investigate alpha-synuclein in plasma as a possible diagnostic marker for synucleinopathies led to further funding to participate in the EU-wide project NEUROSCREEN - Early, differential and progressive blood and cerebrospinal fluid test for neurodegenerative dementia – and Marie Curie Training Network NEURASYN - Alpha-synuclein-related brain diseases - worth a total of €7,570,000.
   • An Alzheimer’s Research UK grant awarded to in 2007 to purchase laboratory equipment, including a microscope for live cell imaging and a plate reader, helped a UK research group to secure a total of €1.3 million

from the European Commission to work on stem cells as models for biological assays of new drugs and predictive toxicology.

- The EU has prioritised neurodegeneration research including dementia, recognising it to be an area of dispersed activity and low funding compared to other disease areas. This has led to Joint Programming in Neurodegenerative Research (JPND) funded by the EU in 2011 to produce a co-ordinated strategy that addresses the challenge of neurodegenerative diseases and to align actions and strategies across countries. Whilst calls issued by JPND are funded by contributions from participating countries rather than central EU funds, the JPND initiative has seeded a large number of UK collaborations with EU countries.

There is no foundation to assume that additional funds would be directed from the UK Government to medical research to support losses to current EU-funded projects. Further, centralised EU-level funding facilitates international collaborations and centres of excellence that are a complement to UK funding streams, but which could not be easily replaced by a domestic funding stream. Therefore, access to EU funding must be maintained in order to provide the greatest opportunity to accelerate advances in the dementia research field.

“A pause of funding will leave excellent researchers stranded which will lead to a decreased research output. This will be noticed by the general public in 10 years as there will most likely a drop in new breakthroughs and potentially treatments.” — Researcher from an EU member country, currently working in the UK

Maintaining mobility for researchers and staff: Some 26% of academic staff in UK universities are non-UK nationals, filling essential functions within the research environment. Academic and industry employer groups have voiced serious concern over current immigration policy for non-EU citizens, particularly in light of skilled worker caps and issues within the existing visa system. Extending these issues to include the current EU workforce within the UK would have wide-ranging implications for the research sector and almost certainly negatively impact the small dementia research field. For every seven scientists working in cancer, there is only one working in dementia research, and the loss of even a fraction of the workforce could have an enormous impact on progress.

“I and many colleagues are EU citizens, and we have some concerns about our future rights in the UK. Without freedom of movement, I might not have come to the UK in the first place (over 10 years ago), but may have pursued my career elsewhere (e.g. Canada or US).” - Researcher from an EU member country, currently working in the UK

Both UK and EU researchers may already be experiencing professional obstacles, and a protection for their ability to remain in the UK and receive funding in their field should be considered at the forefront of negotiation. The UK must support mobility for those who contribute to the advancement of science and research to maintain the

---


5 Marjanovic et al. A review of the dementia research landscape and workforce capacity in the UK. Report by RAND Europe for the Alzheimer’s Society. 2015. www.rand.org/t/rr1186
UK’s world-leading environment. While there is an opportunity to address migration issues for both EU and non-staff in research settings, it must be achieved with minimal burden or disruption for those EU nationals already engaging in research in the UK.

*Ensuring harmonised regulation of research:* Recent areas of consideration for the EU, including the use of health data and animal models, have had important implications for dementia research where the slow progression of diseases in the brain present unique and difficult challenges to the development of treatments. In both cases, the UK has been a leader in good policy and been effective in influencing EU regulation to responsibly support medical research. A regulatory landscape that remains aligned in the near future, though potentially cannot be maintained long-term, provides the greatest stability for dementia research and in the current environment is the most advantageous relationship for UK scientists.

“Now we can order and ship goods and samples seamlessly across the EU, just as easily as within the UK. In contrast, ordering materials, equipment, or biological samples and materials from outside the EU is far from seamless - because of the time taken for Customs clearance, delivery always takes longer, there are always additional costs, we often have to deal with additional queries from Customs or the shipping agent before goods can be released, and sometimes even harmless materials (e.g. antibodies) are held up for so long that they arrive unusable.” - *Researcher from the UK, currently working in the UK.*

Researchers in the UK currently benefit from the ease and reliability of ordering goods such as materials, equipment or biological samples as part of the Single Market. Should customs processes between the EU and UK be reintroduced, the speed and efficiency of research could be impeded. An associated increase in costs could also necessitate that a proportion of research funding be deflected away from research itself and towards administrative burdens.

Additionally, the EU has prioritised addressing some of the technical, linguistic and cultural barriers that exist in research, making previously unavailable data sets and resources accessible to UK scientists. A portion of the diseases that cause dementia are rare or ultra-rare (each affecting less than 0.1% of the UK’s population6) and the ability to study large population groups has numerous benefits. Large data sets that advanced the study of genetics and cancer have begun to unravel complex risk factors for dementia, informing public health initiatives across Europe. The availability of EU survey data also facilitates Researchers in the UK currently benefit from the ease and reliability of ordering goods such as materials, equipment or biological samples as part of the Single Market. Should customs processes between the EU and UK be reintroduced, the speed and efficiency of research could be impeded. An associated increase in costs could also necessitate that a proportion of research funding be deflected away from research itself and towards administrative burdens.

---

Additionally, the EU has prioritised addressing some of the technical, linguistic and cultural barriers that exist in research, making previously unavailable data sets and resources accessible to UK scientists. A portion of the diseases that cause dementia are rare or ultra-rare (each affecting less than 0.1% of the UK’s population\textsuperscript{7}) and the ability to study large population groups has numerous benefits. Large data sets that advanced the study of genetics and cancer have begun to unravel complex risk factors for dementia, informing public health initiatives across Europe. The availability of EU survey data also facilitates longitudinal studies, which have a critical role in understanding long term conditions like dementia. While alternative data sets and population groups exist outside of the EU, there would be a period of disruption to the medical research environment as a whole if researchers were to no longer be able to access EU resources of this type because of regulatory barriers.

“The UK risks a decline in the number of patients that can be recruited for participation in multi-centre trials. Many of the Alzheimer’s patients that have taken part in my research have been tested in other EU countries.” - \textit{Researcher from the UK, currently working in the UK.}

\textit{Protecting access to patients:} It is vital there is no delay for UK patients as a result of the exit negotiation in accessing new treatments for dementia when they become available. For the biomedical industry, the UK is only 3\% of the global market, whereas Europe is the largest single global market.\textsuperscript{8} The EMA collaborates closely with MHRA in conversation with other regulators around the world to support advancing treatments for dementia. However, the EMA is positioned to take forward conditional licensing and parallel review processes alongside the US Food and Drug Administration that would bring increased efficiency to the European market, making licensing authorisation attractive to industry.

Treatments for dementia are still in the development stage, but drug development experts and others in the field anticipate specific challenges for the licensing and uptake of the first generation of disease-modifying treatments because of the expense and difficulty in showing efficacy. Delay and expense in accessing treatments could be caused by a departure from the EU that separates the UK Medicines and Healthcare products Regulatory Agency from the close working relationship it maintains with the EMA.
