Academy of Medical Royal Colleges

Academy of Medical Royal Colleges submission to the House of Commons Science and Technology Select Committee 'Brexit, Science and Innovation Summit' inquiry

Prepared on behalf of the Academy Council by the Faculty of Pharmaceutical Medicine, the Royal College of Anaesthetists and the Royal College of Radiologists

Introduction and Background

The Academy of Medical Royal Colleges (the Academy) is the coordinating body for the UK and Ireland's 24 medical Royal Colleges and Faculties. Its aim is to ensure that patients are safely and properly cared for by setting standards for the way doctors are educated, trained and monitored throughout their careers. Healthcare is complex and increasingly there are a number of issues where a cross-specialty perspective is needed. It is the Academy's job to ensure this work is carried out effectively and then implemented by policy makers, regulators and clinicians. This unique oversight gives it a leading role in the areas of clinical quality, public health, education, training and doctors' revalidation.

Our comments focus on the impact of Brexit on medical, health and pharmaceutical science and innovation and its potential impact on patients. Much of what we discuss, though, will be similarly relevant in other areas of science.

This submission has been led by Professor Alan Boyd, President of the Faculty of Pharmaceutical Medicine, on behalf of the Academy of Medical Royal Colleges' Council, and with contributions from Dr Liam Brennan, President, Royal College of Anaesthetists and Professor Nicola Strickland, President of the Royal College of Radiologists.

The Academy would also welcome the opportunity to attend the Summit to discuss our comments in more detail with the Committee.

Comments in Response to this Initiative

Leaving the EU has far reaching implications for medical research. Clinical medicine has received more funding from EU government bodies than any other discipline in the UK, with universities alone receiving around £120m a year (based on 2014/15). The increase (growth rate) of funding from the Government for clinical research (12%) is slower than the growth rate of the EU's clinical research funding (17%)[1]. Medical research is vital to UK economy, contributing £7.6 billon[2]. The Government has committed to underwriting existing funding under the Horizon 2020 scheme but there needs to be long term commitment to ensure that medical research is adequately funded and the UK can keep its status as a world leader.

In relation to healthcare services, the UK is a net beneficiary for research grants and one of the most successful countries at securing funding from the EC. The EU research and innovation budget for 2014-2020 is around €120bn[3]. A lack of access to EU-wide clinical trial research projects will have a direct

[1] The Academy of Medical Sciences, The role of EU funding in UK research and innovation https://acmedsci.ac.uk/file-download/47156233

[2] Iredale, J, Brexit and Science, where do we go from here *QJM: An International Journal of Medicine*, Volume 109, Issue 10, 1 October 2016

[3] 'Overview of EU funds for research and innovation', EU Parliament, September 2015

impact on our ability to secure good patient outcomes, particularly for rare conditions. Projects funded by the EU have enrolled over 340,000 patients[4] to clinical trials so far[5] with the UK leading the way in Europe for conducting clinical trials.[6] The Chancellors announcement[7] of additional research and innovation funding is welcome but it is vital that this funding is secured long term.

There is a risk that, due to the multi-national nature of large pharmaceutical companies, they may not invest in UK R&D sites and may choose to conduct clinical trials outside the UK and will preferentially file for regulatory approval with the European Medicines Agency (EMA) or in other jurisdictions first, before the smaller UK. In addition, any increase in costs for UK research, particularly clinical research will make the UK appear less attractive for investment. The UK may also lose our direct voice in Europe, opportunity to influence policy and to access funding. This is highly likely to have serious consequences for patients in the UK, as they may be denied the opportunity to participate in innovative research and may experience delays in accessing new medicines.

The HM Government Paper 'Collaboration on science and innovation: a future partnership paper' stresses the leading role of Europe and UK, in particular, in research; and the need to ensure that the partnership with EU and non-EU countries continues for the benefit of the international community after Brexit. As part of any continuing partnership across Europe, the UK should promote its research leadership and expertise. The future partnership should enable working together to enable research into matters of value and importance to communities. There should be greater opportunity across Europe for the recipients of grants to be guided by priorities established by external stakeholders: for example, by following the UK initiative of engaging with the public and patients through Patient, Carer & Public Involvement & Engagement (PCPIE).

If the UK Government commits to match funding EU sources, its essential to continue to get *access to key technologies that single countries simply cannot fund* on their own (e.g. CERN, the David Attenborough research vessel). The enrichment that comes from being part of EU-wide collaborative groups is absolutely essential for good science to keep flourishing in the UK. The risks are that UK influence on what research is done, and participation in whatever is done, is diminished. The UK has a great science base, but will suffer if organisations and individuals are marginalised/excluded from international projects, as has happened in Switzerland, for example

Some resources maintained by the EU (e.g. Eurostat) are freely available and contain data from non-EU countries already; it would be sensible for the UK to continue contributing. European Reference Networks (ERNs) are virtual advisory networks with coordinators based in 24 hospitals across Europe that aim to tackle complex or rare diseases that require highly specialised knowledge and treatment. The networks provide patients with rare diseases access to expertise from other countries and provide support to doctors so that they can provide the best treatment possible. The UK currently plays an active role in the ERNs, leading on a quarter of the networks. The UK's withdrawal from the EU places the UK's access to these ERNs at risk, which could have an impact on the UK's ability to be a part of these learning networks as well as potentially having an impact on patient outcomes.

Data sharing between Europe and the UK is essential for public health, medical research and patient safety. The General Data Protection Regulation (GDPR), which comes into effect May 2018, will provide important protections for individuals, while also allowing data to be shared within the EU. It

[4] 'What implications could Brexit have for NHS patients?', NHS Confederation, July 2016
[5] 'What implications could Brexit have for NHS patients?', NHS Confederation, July 2016
[6] 'Patient access to medical innovation under threat from Brexit' ABPI, May 2016
[7] https://www.gov.uk/government/news/chancellor-philip-hammond-guarantees-eu-funding-beyond-date-uk-leaves-the-eu

is currently unclear whether the data will continue to be shared when the UK leaves the EU. Sharing data for Europe-wide clinical trials is one example of where data sharing enhances the ability for patients to access new treatments. The UK must retain the GDPR and harmonise legislation on data sharing with the EU to enable it to either be considered equivalent to EU regulation or have an adequacy arrangement[8]. Without a clear data sharing framework, the UK's influence would be greatly reduced and patient safety put at risk.

EU Scientists, doctors, medical staff and all those in healthcare research and delivery are anxious about the future and need to be reassured that their expertise and skills are valued in the UK. The UK Government needs to do everything possible to enable free movement. We need to ensure these people still want to come to UK post-Brexit. This may mean we need to ease potential visa restrictions. It would be desirable therefore to make a special exemption from any new visa system for these groups of people, if this were possible. If visa requirements for academics become as strict for EU citizens as currently for non-EU, it may be a lot more work and money, the hurdles will be higher and put the institutions and the people off. Equivalence (or not) of medical qualifications may have an impact on the ability of European clinical academics / scientists to work on projects in the UK. However, this issue exists for other non-EU countries as well (Australia, NZ, N America, S Asia for example). *Continuing the free flow of scientists* is one of the key challenges because science is a global enterprise with the top talent being very mobile, who will choose to live and work elsewhere if it becomes too difficult in the UK.

Despite the risks that Brexit poses we are fortunate that the UK boasts a world-renowned science base, so we will probably never be marginalised. However, it is inevitable that the changes that occur will mean a loss of investment, innovation and productivity, and have an impact on the health of patients and the public. The UK must continue to work cooperatively and proactively with EU member states, whilst also seeking new partnerships around the world. Only through a cooperative future partnership can benefits and progress be shared. Research bodies and national governments should be open to encouraging such arrangements for the benefit of all. Recent science cooperation deals (e.g. the Joint UK-China Strategy for Science and UK-US Science and Technology Agreement) provide a suitable model for collaboration with other countries post-Brexit, including the EU. The deal has a strong focus on driving growth from research right through to the commercialisation of new technologies.

Conclusion

The risks of Brexit to healthcare and medical science are many and varied, ranging from an effect on the movement of scientific talent to waning influence on and participation in what is now a global research enterprise. It is unlikely that the close links established already with EU scientific communities can be replicated or replaced anywhere else in the world. There is a real risk that UK patients will be left behind by delayed access to innovative drugs, and by a lack of participation in the important clinical trials process as multinationals exit what is a small market, made more difficult by regulatory friction.

The Academy of Medical Royal Colleges urges the Government to do all it can to avoid these risks and emphasises that we are available to support and advise on these matters if requested to do so.

[8] Adequacy arrangement: Data adequacy is a status granted by the European Commission to non-EEA countries who provide a level of personal data protection that is 'essentially equivalent' to that provided in European law. It can also be awarded to specified sectors of an economy or international organisations. Currently 12 countries have this status. Source: Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.