



Supporting healthcare as the UK leaves the EU

Collective “asks” as the UK negotiates to exit the EU

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Members

Academy of Medical Royal Colleges, Association of Medical Research Charities, Association of British Healthcare Industries, Association of British Pharmaceutical Industries, Association of UK University Hospitals, Bio Industry Association, Faculty of Public Health, Medical Schools Council, National Voices, NHS Confederation (including Mental Health Network, NHS Clinical Commissioners, NHS Employers, NHS Partners Network), NHS Providers, Northern Ireland Confederation, Richmond Group of Charities, Scottish NHS Chief Executive Group, Welsh NHS Confederation

Introduction

The Brexit Health Alliance has been established so that those who use health services, healthcare commissioners and providers, educators, researchers, the healthcare industry and those working to improve population health and wellbeing and to reduce inequalities in health can have a strong, collective, evidence-based voice as the formal process of leaving the EU gets underway.

The Alliance complements, but does not duplicate, the work of the Cavendish Coalition which focuses on the implications of Brexit for the health and social care workforce.

The Alliance does not take any stance on the merits or otherwise of Brexit. Our aim is to make sure that we are in the strongest possible position once the UK leaves the EU, and to this effect we advocate a negotiated implementation period that adequately reflects the time needed to achieve the following desired outcomes:

1. Maximum levels of research and innovation collaboration

- UK patients, the public, researchers and organisations can take part in pan-European research and innovation networks and clinical trials and that these can be supported by UK involvement in EU funding programmes such as Horizon 2020 (and its successors) and the EU Health Programme.
- A target of combined public and private UK R&D investment at 3 per cent of GDP by 2025 is set.
- UK patients can benefit from the UK leading and participating in European Reference Networks for rare and complex diseases post Brexit.
- An immigration system that is straightforward and welcoming to researchers, innovators, and their families, at all career stages and from all over the world.

2. Regulatory alignment for the benefit of patients and population health

- Patients and the public do not suffer from possible disruptions in the supply and trade of medicines, other health technologies and goods, or a reduction of standards or patient safety.
- Patients have early access to new medicines and medical devices by securing maximum cooperation and alignment with the EU on the regulation of medicines and medical devices to deliver proportionate, robust and effective regulation of medicines and medical devices in the UK.
- Pragmatic solutions allowing patients and the public to benefit from the UK's participation in EU systems such as data sharing networks, pharmacovigilance and the clinical trials portal and databases post Brexit.

3. Preservation of reciprocal healthcare arrangements

- UK nationals in the EU and vice versa can benefit from access to healthcare abroad through a system of reciprocal arrangements.
- If this is not possible, provisions should be made domestically for the planning and funding of healthcare for UK nationals currently in the EU and vice versa.
- No increased burden for UK healthcare providers in the event they will be required to handle new, more complex administrative and funding processes when providing care to EU citizens.

4. Robust coordination mechanisms on public health and wellbeing

- Strong coordination between the UK and the EU in dealing with pandemics, as well as other health threats, and more broadly on health promotion and disease prevention programmes. This could happen, for example, through the creation of a new EU-UK joint coordination mechanism on public health issues.

5. A strong funding commitment to the health and public health sectors

- High standards of population health and wellbeing and patient care through a strong focus on prevention of ill health and secure that any possible shortfall resulting from the economic impact of leaving the EU is offset.
- An appropriate funding level for both healthcare and population health that is linked to Gross Domestic Product.

Background document on work streams and desired outcomes

The Brexit Health Alliance will focus on the following five work streams:

1. Supporting maximum levels of research and innovation collaboration
2. Ensuring regulatory alignment for the benefit of patients and population health
3. Preserving reciprocal healthcare arrangements
4. Ensuring robust coordination mechanisms on public health and wellbeing
5. Securing a strong funding commitment to the health and public health sectors

1. Supporting maximum levels of research and innovation collaboration

This work stream will focus on how research could be impacted by leaving the EU and how we retain the UK's leading role in international medical research. Our aim will be to ensure that patients are able to benefit from world-class medical research in the UK post Brexit, including vital international research collaborations.

Science is a global endeavour. A recent Royal Society report demonstrates that 80 per cent of UK international research includes co-authors from the EU.¹ Subsequent EU funding programmes for research and innovation have supported and boosted these collaborations between researchers in the UK and across the EU.

The UK received €8.8 billion of EU science funding between 2008 and 2013. UK organisations have received €3.2 billion since 2014 through Horizon 2020, €420 million of this coming from the health strand of the programme. The formation of strategic partnerships is vital to the progression of medical research. The UK's access to EU funding programmes is about more than just financial benefit; the collaborative opportunities that are afforded are crucial.

The UK has also benefitted from the collaborative research partnership between the European Union and the European pharmaceutical industry, receiving €302.8 million from the Innovative Medicines

¹ <https://royalsociety.org/topics-policy/projects/uk-research-and-european-union/role-of-eu-researcher-collaboration-and-mobility/>

Initiative, the EU's flagship public-private partnership scheme that aims to speed up the development of better and safer medicines for patients, as well as significant funding in respiratory diseases, vaccine development, infectious diseases, and diabetes.²

A number of leading UK medical research charities are listed as participants or coordinators across Horizon 2020 projects and as partners in one of the 71 Innovative Medicines Initiative projects.

EU funding programmes and schemes facilitate research into rare diseases to a greater extent than national equivalents; co-ordination of the much larger pan-EU population allows engagement of a sufficient cohort of both researchers with appropriate expertise and patients able to participate in research.

Furthermore, in March 2017, 24 European Reference Networks³ for rare diseases were launched by the European Commission. They bring together healthcare providers across the EU/EEA to tackle rare medical conditions that require highly specialised treatment and a concentration of knowledge and resources. The NHS is involved in 23 of the 24 networks (approximately 40 NHS hospitals), with NHS trusts leading a quarter (6) of these networks. The legal basis for these networks is the European Directive on patients' rights in cross-border healthcare and thus membership is reliant on membership of the EU or EEA currently.

For Horizon 2020 and the forthcoming FP9,⁴ the loss of UK partners in EU backed research projects would impact the expertise available for these projects, and therefore the outcomes. On the other side of the coin, even if the UK matches science funding from current EU sources, UK science loses out by having many collaborations being made significantly more complex.

Research is international and intrinsically collaborative. Scientific breakthroughs are not developed in isolation – mobility is crucial to the highest standards of performance. Easy movement of researchers, innovators and specialist technicians gives the UK a competitive advantage by opening up access to skills and international networks. International movement is a feature of researchers' careers – 72 per cent of UK-based researchers spent time at non-UK institutions between 1996 and 2012. 27.7 per cent of academic staff at universities are from outside the UK – 31,600 from other EU nations and 23,000 non-EU internationals.

Possible desired outcomes:

- Secure that UK patients, the public and organisations can take part in pan-European research, innovation networks and clinical trials and that these can be supported through UK involvement in EU funding programmes such as Horizon 2020 (and its successors) and the EU Health programme.
- We support the ambition that public and private expenditure on R&D should be raised to 3 per cent of GDP by 2025.
- UK Patients can benefit from the UK participating in European Reference Networks for rare and complex diseases post Brexit.
- A migration system that is straightforward and welcoming to researchers, innovators, and their families, at all career stages and from all over the world.

2. Ensuring regulatory alignment for the benefit of patients and the public's health

This work stream will explore the implications that leaving the EU regulatory system for health could have on patient outcomes in the UK, with the aim of minimising any negative impact. Our priority will

² http://www.abpi.org.uk/our-work/library/industry/Documents/UK_Participation_in_IMI.pdf

³ http://ec.europa.eu/health/ern/toolkit_en

⁴ Horizon 2020 is the current EU Programme for Research and Innovation which runs till 2020. Framework Programme 9 will be the successor programme to Horizon 2020

be that UK patients continue to benefit from early access to the wide range of innovative health technologies available and that they do not miss out on the opportunity to access cutting edge treatments, including through clinical trials, as a result of the UK leaving the EU, along with ensuring the medical research in the UK can continue to thrive through regulatory alignment.

The UK is currently part of the EU's European Medicines Agency (EMA) network covering more than 500 million people. Divergence from the EU medicines regulatory system may result in the UK becoming a second-tier market after the US, EU and Japan, meaning that patients would gain access to new medicines later.⁵ The EU accounts for 25 per cent of all global pharmaceutical sales. On its own, the UK accounts for around 3 per cent. The experience of Switzerland (outside of the EMA network) shows that they have an average of around 6 months' delay for new licences compared to the EU.⁶

Medical devices used in the EU must obtain approval for CE Marking from registered notified bodies across the EU, which indicates a product's compliance with the applicable EU regulations. The existing devices framework could be a good example of how EU regulation can work in a flexible way, as many countries have a mutual recognition agreement with the regulatory regime.⁷ However, there are urgent issues that need to be addressed, particularly as two new EU Regulations on medical devices and in-vitro diagnostics have recently been approved and need to be implemented to a tight deadline. UK and EU organisations need legal certainty on what regime will apply in the UK going forward as soon as possible to be able to prepare.

Furthermore, it will be essential for providers of health products to have legal certainty from 'day one' of Brexit to ensure continuity of supply to avoid negative impacts for patients and the public's health both in the EU and UK. In the case of pharmaceutical products, this may be at risk where product licenses, issued with validity across the whole EU, are held in the UK (meaning potential disruption for the EU) or in the EU (meaning potential disruption for the UK).⁸

Similarly, for both pharmaceutical and medical devices, products rely on international supply chains. This means that throughout their life cycle, products are moved around different countries for material sourcing, manufacturing, packaging, sterilisation etc. It is not uncommon for a 'British' product to have touched 7 other jurisdictions before reaching the market place. If post-Brexit trading agreements make it harder to move things around, then supply could be affected. Similarly, completed products are often moved around. For example, the largest supplier of needles and tubes for blood collection in the NHS manufactures its products in Plymouth. They are then taken by road to Belgium and distributed back to the UK from there. If containers cannot move freely across borders, there is a possibility that supplies could be affected. These factors could also make the UK an unattractive market for producers and when supplies were low, the UK would not be a priority.

The European research landscape has also been supported by EU legislation, which has acted as a facilitator for the conduct of cross-European clinical research. Two examples are paediatric medicine and orphan drugs, where EU collaboration brings particular added value in allowing access to a significant population size for these conditions.

⁵ http://www.amchameu.eu/system/files/position_papers/amcham_eu_position_paper_-_brexit_and_the_future_eu-uk_relationship.pdf

⁶ <http://www.nhsconfed.org/blog/2017/02/brexit-white-paper-unveiled-what-next-for-the-nhs>

⁷ http://www.healthinparliament.org.uk/sites/site_apfhg/files/event/1199/fieldeventdownloads/brexitandthepharmaiindustry-finalrd0902.pdf

⁸ http://www.amchameu.eu/system/files/position_papers/amcham_eu_position_paper_-_brexit_and_the_future_eu-uk_relationship.pdf
http://www.amchameu.eu/system/files/position_papers/amcham_eu_position_paper_-_brexit_and_the_future_eu-uk_relationship.pdf

Taken together, between 6,000 and 8,000 rare diseases affect the daily lives of around 30 million people in the EU. The EU Orphan Drugs Regulation (2000) has increased R&D of medicines for rare diseases and attracted investment from pharmaceutical companies. From 2000-2015, 1,469 orphan designations and 103 marketing authorisations have been granted and rare diseases remain an ongoing priority for EU research funds.⁹ Since the introduction of the EU Paediatric Regulation, from 2006-2015, the number of children due to be included in registered trials jumped 6,000 per cent, meaning significant growth in research about children funded by the European pharmaceutical industry. Research that can ask 79 million European children to join studies will identify successful medicines more quickly than research that asks 11 million UK children to join studies. The EU is also a source of funding for multinational trials and infrastructure in paediatric medicine. During the 2006-2013 period, 19 pan-European research projects aimed at generating data about off-patent medicines in support of achieving market authorisation received EU funding. All these trials had UK involvement thanks to access to EU funds. British children will share the benefits of these trials with children in other countries.¹⁰

With regards to regulation of clinical trials, the implementation of the EU Clinical Trials Regulation (CTR), has been delayed. Given that the CTR may not come into force until after the UK has withdrawn from the EU, the implications of this delay on the regulation of trials in the UK need to be considered.

Furthermore, EU regulatory frameworks for medical research – spanning from clinical trials to data protection to the use of animals in research – help build consistent research standards between countries. Working within the same regulatory framework as EU partners opens up opportunities to collaborate and affords opportunities to work on a larger scale. Shared frameworks can facilitate the exchange of ideas, research samples and data. This can be particularly important for research into rare disease populations where multi-nation, multi-centre studies are the only way to access the number of patients needed for robust research.

Possible desired outcomes:

- Patients and the public do not suffer from possible disruptions in the supply and trade of medicines, other health technologies and goods, or a reduction of standards or patient safety.
- Patients have early access to new medicines and medical devices by securing maximum cooperation and alignment with the EU on the regulation of medicines and medical devices in the UK.
- Pragmatic solutions allowing patients and the public to benefit from the UK's participation in EU systems such as data sharing networks, pharmacovigilance and the clinical trials portal and databases post Brexit.

3. Preserving reciprocal healthcare arrangements

This work stream will look at the right to receive healthcare in another EU country, which is currently regulated by the EU. Leaving the EU may therefore have consequences for UK patients in terms of their ability to access cross-border healthcare. This could mean that, in the future, British citizens on holiday in Europe might no longer be able to use the European Health Insurance Card, which allows them to receive emergency or immediately necessary healthcare on the same terms as the residents of that country.

⁹ <http://www.eurordis.org/news/15-years-eu-orphan-medicines-regulation-next-chapter>

¹⁰ <http://nhsconfed.org/blog/2017/02/challenge-of-brexite-for-paediatric-research>

EU law¹¹ also allows Britons who are abroad for a longer period of time – such as pensioners living abroad, or UK citizens who work in another EU country – to be entitled to receive healthcare in the country where they live on the same basis as the local population.

The impact Brexit will have on people who rely on the EU's reciprocal healthcare arrangements should not be underestimated. Retired British citizens in the EU, disabled people, and people with multiple conditions could face particular challenges. It should be stressed that these EU rules are reciprocal and therefore uncertainty also exists on whether EU citizens will be entitled to receive healthcare in the UK following Brexit.

The Department of Health's oral evidence to the Health Select Committee confirmed that the average cost of treatment for a UK insured pensioner in the EU is less than the cost of treatment in the NHS: the average cost is around £2,300 per pensioner under existing arrangements, which is significantly lower than the average cost of treating pensioners in the UK, which is about £4,500.¹²

Alongside cost implications, there could also be a significant impact in terms of increased bureaucracy. An important issue for healthcare providers in this is how they would manage the process of payment for healthcare for EU national's post Brexit. Although the NHS is now preparing for upfront charging for elective care, the resource implications of broadening this out to a larger population either resident in or visiting the UK could be considerable.¹³

Possible desired outcomes:

- UK nationals in the EU and vice versa can benefit from access to healthcare abroad through a system of reciprocal arrangements.
- If this is not possible, provisions should be made domestically for the planning and funding of healthcare for UK nationals currently in the EU and vice versa.
- No increased burden for UK healthcare providers in the event they will be required to handle new, more complex administrative and funding processes when providing care to EU citizens.

4. Ensuring robust coordination mechanisms on public health and wellbeing

This work stream will look at potential implications of Brexit on public health, defined as “the art and science of preventing disease, prolonging life and promoting health through the organised efforts of society”.¹⁴ It will focus on ensuring a high level of population and public health is maintained through some form of access to EU coordination mechanisms and networks, such as those of the European Centre for Disease Prevention and Control and EU coordinated management of health threats, as well as a rights based approach to health and high standards of consumer protection.

There is a broad range of collaborative European initiatives in this area, as the EU has direct competence in public health and this is reflected both in EU policy and legislation.¹⁵

The EU's Health Programme plays an important role in preventing diseases, promoting healthy lifestyles, combatting cross-border health threats, ensuring innovative, efficient, sustainable and accessible healthcare and in fostering cooperation on these issues at European level. Technical expertise is also provided by agencies such as the European Centre for Disease Prevention and Control (ECDC), and the European Food Safety Authority (EFSA).

¹¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Ac10521>

¹² <https://www.publications.parliament.uk/pa/cm201617/cmselect/cmhealth/640/640.pdf>

¹³ <https://www.nhsproviders.org/news-blogs/blogs/five-key-brexit-issues-for-the-healthcare-sector>

¹⁴ <http://www.euro.who.int/en/health-topics/Health-systems/public-health-services>

¹⁵ <http://www.cambre-associates.com/news/245:the-possible-impact-of-brexit-on-european-public-health-%E2%80%93-and-why-we-should-be-wary.html>

Possible desired outcomes:

- Ensure future coordination between the UK and the EU in dealing with pandemics, as well as other health threats, and more broadly on health promotion and disease prevention programmes. This could happen, for example, through the creation of a new EU-UK joint coordination mechanism on public health issues. This would avoid the UK needing to coordinate with individual countries within the EU on these matters, which will be a huge administrative burden for all parties.

5. Securing a strong funding commitment to the health sector and the public's health

With our health service facing an unprecedented financial challenge, this work stream will seek to promote solutions to minimise any potential additional pressures which may result from Brexit, as well as advocating for any loss of EU funds for the sector to be offset by alternative funding. This will include the need for an assessment of the impact on the NHS of leaving the single market and/or the customs union.

Currently the UK spends a lower percentage of GDP on healthcare than similar economies. The UK is sixth out of the G7 nations for healthcare investment, with only Italy spending less.

Possible desired outcomes:

- Ensure high standards of population health and wellbeing and patient care through a strong focus on prevention of ill health post Brexit and secure that any possible shortfall resulting from the economic impact of leaving the EU is offset. Our members are willing to helpfully supply information to government to support them in assessing the impact on the NHS of leaving the single market and/or the customs union.
- A high funding level for both healthcare and population health that is linked to Gross Domestic Product.