



Independent Commission  
on UK - EU Relations



# CRITICAL CONDITION: THE IMPACT OF BREXIT ON HEALTH AND SOCIAL CARE

# ABOUT

# INDEPENDENT COMMISSION ON UK - EU RELATIONS

The Independent Commission is a politically neutral, timebound commission which examines the impact of the Trade and Cooperation Agreement (TCA) and the Windsor Framework on the UK.

As well as looking at impacts on different sectors of the economy we look more broadly at impacts on sectors including security and defence, health, education and human rights.

Members of the Commission are leaders in business, journalism, civil society and academia. They work with a team of expert advisors.

The intended outcome of the Commission is to recommend changes to the TCA and Framework which if implemented would improve outcomes for UK sectors and the people who live and work in the UK.

Our recommendations will be developed in collaboration with UK and EU politicians and relevant officials. We confer with parliamentarians from all parties as well as with regional, devolved and local politicians and party staff.

As well as informing parliamentarians and political parties the Commission will inform the public of its work, both to highlight and explain challenges created by current arrangements and potential amendments.

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# 1 FOREWORD

This key report from the Independent Commission on UK-EU Relations summarises much of the work carried out on the effects of Brexit on the NHS and health since 2016. It includes a strong evidence-base and several excellent studies (I should say, in many of which I have been involved). The Commission has augmented these with roundtable and interview data from relevant health policy stakeholders.

The report highlights some very important questions for health and the NHS across the UK. The special situation of Northern Ireland is perhaps the most critical. Both product supply and workforce remain fragile aspects of the NHS in Northern Ireland. The gains to peace made through the health aspects of 'Cooperation and Working Together', following the 1998 Agreement, are too precious to be lost.

Across England, Scotland and Wales, NHS workforce challenges are the most critical. Recruitment from countries outside the EU has increased, but the workforce gaps are still significant, and there is no credible plan to move to greater reliance on British staff.

Product supply to the NHS relies on global trade, the complexities of which were illuminated by the COVID-19 pandemic. As a small country, the UK has some hard questions to answer about where to place itself in these global trade patterns, and the research that leads to new products in the global market.

Alignment with the EU, as has been chosen for medical devices and equipment for Northern Ireland, allows for cheaper supplies. Regulatory divergence from the EU could be used to meet other policy goals (greater patient safety, incentivise industry investment or early product launch, for example), but risks increased costs associated with being a smaller market.

Above all, there is a need for regulatory consistency and clarity, something that has been lacking as the Brexit deadlines are continually deferred. There is no 'obvious right answer', but the pros and cons of different positions should be acknowledged, as this report does, and debated.

What is needed now is a calm, evidence-led, realistic, and detailed discussion about where the UK (or rather, where GB and Northern Ireland) wants to place itself in terms of its global relationships when it comes to health and the NHS.

The relationship with the EU will continue to be the most important one for the UK, which shares its only land border with the EU, and where dense trade relations still apply. The relative size of the UK (GB) is an important contextual factor.

There is no point in ideological statements about 'global Britain' 'leading the world': if we want to continue global health leadership we need to forge alliances through which to do this. Our most obvious partners remain our European neighbours. This isn't 'Remain/Rejoin ideology'; it's hard-headed and practical. What we need now is political leadership to step up.

Tamara Hervey, Jean Monnet Professor of EU Law, City, University of London



## 2 INTRODUCTION



There are few sectors more important than health and social care. So much so that it in fact feels odd to think of it as a “sector”. It is quite literally a matter of life and death, and so anything that affects it requires careful interrogation. That is absolutely the case when it comes to the United Kingdom’s relations with the European Union. There are serious issues to address and clear areas for immediate action in relation to them. It is - for obvious reasons - vital they are explored.

With this in mind we set out to carry out original research into current problems and potential solutions. This involved primary research, augmented with our own secondary research. The resulting report cuts through a complex area to flag some key areas of concern. We could not have done this without the stakeholders who have fed into our research.

The impacts of the United Kingdom’s withdrawal from the European Union on health and social care are of concern to those within and outside of the sector. Health care impacts us all, social care most of us as users or the family and friends of users. We cannot ignore our collective responsibility to ensure that both health and social care are as good as they can possibly be.

In terms of unwanted and damaging impacts of our departure from the EU on health and social care medicine regulation sits front and centre. This is understandable given

that our exit from the European Union largely (although not exclusively) consists of withdrawal from a trade area.

Here it is vitally important we understand that regulatory content and regulatory process are distinct, and both vital. Similarity and coordination between the UK and EU in both of these areas will

bring healthcare costs down and therefore help to save lives.

Mobility presents challenges as it does for virtually every sector. Over 45% of the NHS’s budget is spent on its workforce<sup>1</sup>; this is a sector where people are a bigger factor than most. There have been several alarming falls in numbers. Seeking to import staff from the rest of the world is no straightforward issue - many countries are on a “red list” for UK recruitment which bars health sector recruitment and exists out of ethical concern.

Other challenges include data. This is vital for research and therefore the entire sector is, indirectly, at the mercy of a reversal of the EU’s adequacy decision for the UK. That’s a reversal that is not entirely impossible given the UK’s apparent willingness to sign up to deals with other countries that demand looser data arrangements. Our lawmakers must tread carefully here.

Northern Ireland has a different outcome to the rest of the UK and faces different challenges. Among the noise around the Windsor Framework earlier this year the changes this brought to medicine for the Northern Ireland was largely lost. A huge shift towards UK regulation is now underway and there will be significant ramifications here.

1. [kingsfund.org.uk/audio-video/key-facts-figures-nhs](https://kingsfund.org.uk/audio-video/key-facts-figures-nhs)



## OUR METHOD

Following the departure of the UK from the EU and the signing of the TCA the health and social care sector has had to adapt to a new regulatory and commercial landscape.

Brexit has had a particularly significant impact on the mobility of workers in the sector, pharmaceutical production and scientific research, generating a variety of new requirements, administrative burdens and talent needs.

The Independent Commission on UK-EU Relations has conducted original research to investigate how the health and social care sector has been impacted by Brexit and what can be done to alleviate subsequent challenges.

The research has included a roundtable with health and social care stakeholders as well as individual interviews and our own secondary research. The below information draws from all three.

## ROUNDTABLE EVIDENCE: BROAD CONCLUSION

Participants noted that all involved must accept that being outside the EU will inevitably place the UK at a permanent disadvantage in health and social care, not least because of the reduction in economic growth that this will entail and the continuing shadow that it casts over domestic politics.

UK policymakers must also learn the lessons from Switzerland that it is unlikely that all issues will be resolved in a single negotiation round or a new agreement but, in the absence of dynamic alignment, as in Norway, negotiations are likely to continue indefinitely.

# 3 NEW COSTS AND BARRIERS

The impact of Brexit on trade and business is increasingly well documented.

Roundtable participants told us that the pharmaceutical and healthcare industry has been affected in similar ways to other sectors: increased trade barriers, reduced access to required labour and skills, increased costs, and reduced opportunities to collaborate with peers in the EU.

After Brexit, UK pharmaceuticals were initially treated in the EEA as third country imports, requiring duplicate batch testing by an entity with an import authorisation from an EEA national authority.

However, the UK Government made arrangements which enable pharmaceutical companies to import medicines to the UK from countries within the EU and EEA without having to engage in British batch testing or obtain certification from a UK 'qualified person'. More detail on regulation is contained in a section below.

Roundtable participants relayed that students and researchers have faced lengthy delays when ordering medicines, medical devices, equipment, and other inputs from the EU/EEA. In some cases they are shifting to US suppliers.

## NORTHERN IRELAND

- It is no secret that in many areas of Brexit the position for Northern Ireland is fundamentally different.
- Before the Windsor Framework Northern Ireland was much closer to the EU system of medicine regulation than the UK one. This was a significant problem given that Northern Ireland relied on Great Britain for 80% of its medicines. Research published in December 2022 suggested the number of products available in Great Britain but not Northern Ireland was well into triple figures. However the framework moves the dial in the other direction. Whilst there are clearly positives to this it does mean that Northern Ireland will lose access to medicines approved by the EU.
- Of course there are several other unique Brexit health and social care challenges for Northern Ireland. For example the island of Ireland sees large labour mobility across its border and therefore border fluidity of people needs to be maintained, and beyond regulation there is the issue of remaining GB/NI cross-border checks.
- It's worth noting that beyond medicine regulation there are many other areas of regulation where NI will continue to follow EU regulatory content and governance, such as medical devices.

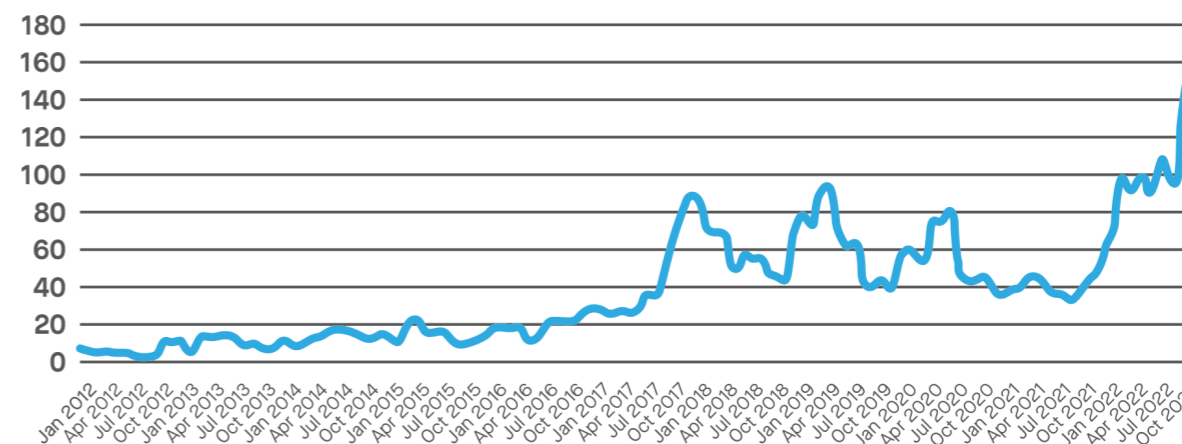
## DATA FLOWS

According to roundtable participants free flow of data transfers allows the industry to pursue research with fewer costs and complexities. However this is dependent on the continuity of data adequacy with the EU. If this decision is reversed it would severely disrupt medical research ["alternative and costly measures would have to be put in place for data to be shared within the context of projects that involve partners in the

UK and one or more EU member states"<sup>2</sup>].

It is worth noting here that there is a not-insignificant risk that this decision is reversed. For example the UK is set to join the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, where signatories commit to less stringent data standards<sup>3</sup>.

Price concessions granted by UK government for imported medicines, January 2012–November 2022



Graph courtesy of Nuffield Trust

## PRICING AND SHORTAGES

Roundtable participants noted that indicators show unusual spikes in medicine shortages. The number of price concessions granted by the Government when medicines cannot be found at the usual price has jumped repeatedly since 2016. The latest shifts, for example, illustrate how drops in the pound due to Brexit and the September 2022 Fiscal Statement appear to make it difficult for the NHS to obtain medicines under the cost

controls it has relied on, according to Tamara Hervey of City, University of London.

The Nuffield Trust has found that there is Brexit-related pressure on UK medicine imports from four sources: regulatory alignment and processes, a fall in the value of the pound, new requirements and paperwork at the GB-EU border, and heavy-goods vehicle shortages<sup>4</sup>.

2. [cambridge.org/core/journals/health-economics-policy-and-law/article/impact-on-the-nhs-and-health-of-the-uks-trade-and-cooperation-relationship-with-the-eu-and-beyond/57A170644C8C6B44AD909833E5433B28#article](https://www.cambridge.org/core/journals/health-economics-policy-and-law/article/impact-on-the-nhs-and-health-of-the-uks-trade-and-cooperation-relationship-with-the-eu-and-beyond/57A170644C8C6B44AD909833E5433B28#article)  
 3. [cambridge.org/core/journals/health-economics-policy-and-law/article/impact-on-the-nhs-and-health-of-the-uks-trade-and-cooperation-relationship-with-the-eu-and-beyond/57A170644C8C6B44AD909833E5433B28#article](https://www.cambridge.org/core/journals/health-economics-policy-and-law/article/impact-on-the-nhs-and-health-of-the-uks-trade-and-cooperation-relationship-with-the-eu-and-beyond/57A170644C8C6B44AD909833E5433B28#article)  
 4. [nuffieldtrust.org.uk/sites/default/files/2022-12/1671199514-health-and-brexit-web.pdf](https://nuffieldtrust.org.uk/sites/default/files/2022-12/1671199514-health-and-brexit-web.pdf)

## 4 REGULATORY DIVERGENCE



Roundtable participants expressed concern that post-Brexit regulatory divergence may leave the sector without a competitive regulatory framework and without influence in international policy. Roundtable participants told us that strategies pursued by UK policy makers limit the UK's future degrees of freedom, either because of trade or other agreements.

The UK is no longer subject to (or beneficiary from) the EU's internal goods market - rules for products moving from the UK to EU are governed by EU external trade law and products must comply with EU formalities and regulatory requirements.

Relevant regulatory standards in the UK were identical to EU law on 1 January 2021, as 'retained EU law'. However, the Withdrawal Act gives ministers power to amend this retained law to remedy 'deficiencies' including in relation to product standards. This applies to medicines, medical devices and equipment (although some underlying standards are internationally determined). The UK then enacted the Medicines and Medical Devices Act 2021. This gives ministers the power to change almost all aspects of regulation in this area. Furthermore, it should be noted that the EU has significantly changed its regulatory content for clinical trials of medicines and for medical devices since EU law ceased to apply in GB.

However, what is perhaps just as or even more important than actual regulatory divergence is the lack of mutual recognition in processes - i.e. UK and EU bodies failing to accept results of inspections carried out by the other party. Whilst the UK is recognising particular EU processes including batch testing - confirmed to be continuing on an indefinite basis at the end of 2022 - this is not reciprocated.

In medicines the EU does not recognise processes in countries other than EEA states as sufficient to secure access to the EU market. When the UK left the EU it was immediately divergent in terms of regulatory governance, necessitating the European Medicines Agency relocation to Amsterdam.

Participants also relayed to us the importance of regulatory alignment, with it significantly easing trade flows. They stated that no FTA gives better access to the EU market than EU membership and no FTA can replicate the benefits that flow from being part of the EU market. Indeed, research based on the experience of other free trade agreements (which typically have a similarly low level of alignment for medical products) suggests a 5% cost increase for pharmaceuticals<sup>5</sup>.

Participants told us that UK non-alignment in regulatory governance or process has already had an impact. The end of mutual recognition of multiple aspects of medical products regulation has meant higher costs and a greater burden on researchers, producers and importers. The need to go through a different process for access to the UK market, because different bodies are responsible, makes the UK less attractive as a market and a smaller global player.

5. [cambridge.org/core/journals/health-economics-policy-and-law/article/impact-on-the-nhs-and-health-of-the-uks-trade-and-cooperation-relationship-with-the-eu-and-beyond/57A170644C8C6B44AD909833E5433B28#article](https://www.cambridge.org/core/journals/health-economics-policy-and-law/article/impact-on-the-nhs-and-health-of-the-uks-trade-and-cooperation-relationship-with-the-eu-and-beyond/57A170644C8C6B44AD909833E5433B28#article)



## INSIGHT

Tamara K Hervey is the Jean Monnet Professor of EU Law at City, University of London. She spoke to us for this report.

The worst possible effects of the UK's departure from the EU on health and social care were avoided by the Withdrawal Agreement and the EU-UK Trade and Cooperation Agreement. But nonetheless the overall effect is negative (so far) across all the key aspects of a health system.

It is essential to think at a granular, detailed level when thinking about regulatory alignment in medical products (not just pharmaceuticals, also medical devices and equipment). Sweeping, over-simplified, and ideologically-based statements at best don't help and at worst obfuscate complex realities. We have to look at regulatory alignment of research, authorisation and approval, regulatory for safety and compliance in the market, and purchasing and providing. All these areas of medical products regulation are covered by EU law, to a greater or lesser extent. The UK leaving the EU means it - or rather GB, given the UK's obligations in the Ireland/Northern Ireland Protocol of the Withdrawal Agreement - is no longer obliged to remain aligned with the EU on these aspects of regulation of medical products.

The biggest change that could be made to the Trade and Cooperation Agreement in terms of improved outcomes overall would be to reverse the negative impact on the economy which flows from exclusion from the single market. This is a longer term and high ambition goal, given the narratives that have imbued public discussion of single market membership since 2016. But it should be moved towards being something we can talk about in a grown-up and honest way, as part of a serious national conversation that is evidence-led and not ideological haranguing.

I would make some key policy recommendations for a UK government wanting to improve Brexit effects on health and the NHS. One would be that we need an honest national conversation about this, involving all stakeholders. A conversation on the basis of the reality of the UK's position as a small market with a proximate large market, and the reality of the NHS in England, Scotland, Northern Ireland and Wales being measured against countries with similar levels of development.

There are of course many aspects of the NHS that are sub-optimal not because of Brexit, but because of other factors, like chronic long-term under-investment. These are made worse by Brexit but could and should be fixed irrespective of the UK's relationship with the EU.

Brexit changes to free movement have affected the health and social care sector. Whilst it should be straightforward to recruit EU doctors and nurses<sup>6</sup> (the new UK immigration system prioritises salary and qualifications and there's a specific route for qualified health care professionals) numbers have nonetheless been affected. This suggests less tangible factors are affecting mobility such as uncertainty over future mobility rights, as well as factors such as an increase in periodic costs and bureaucracy for visas. Furthermore, there are set to be severe difficulties in recruiting lower paid health professionals without specific qualifications, or those needed to fill the vast majority of social care roles<sup>7</sup>.

The changes compounded some long-standing trends<sup>8</sup>, including low numbers of doctors and nurses per head relative to similar countries, nursing and social care shortages, reliance on EU and other international recruitment, and low long-term planning to reduce this reliance by boosting domestic recruitment and retention.

The loss of free movement has had a significant impact on staffing within the NHS, according to roundtable participants. Particular areas are seeing issues, something that relatively stable overall figures - for example in relation to EU or EFTA doctors joining between September 2020 and October 2021 - have obscured. When looking at some specific figures the picture becomes clearer:

- Cardiothoracic surgery has historically been heavily reliant on European staff - and there's trouble here. The number of EU and EFTA cardio-thoracic surgeons in the

UK overtook that of UK-trained surgeons in 2014<sup>9</sup>. Numbers of inbound EU staff saw a 100% rise in the five years before 2016. This has slowed to almost nothing, with no increase in rest-of-world recruitment. Meanwhile, there has been 'serious' struggle when it comes to recruiting domestically<sup>10</sup>.

- European anaesthetics staff numbers are very high - but there's trouble here too. EU and EFTA recruitment has dropped from a rise of over 20% in the years before Brexit to just 5% in the following years. Non-EU recruitment has also fallen.
- The rate of EU and EFTA dentists joining the register has halved since the EU referendum, without a comparable increase in rest-of-world registration.
- The Nuffield Trust states "it is inarguable that registration of doctors from the EU and

6. [cambridge.org/core/journals/health-economics-policy-and-law/article/impact-on-the-nhs-and-health-of-the-uks-trade-and-cooperation-relationship-with-the-eu-and-beyond/57A170644C8C6B44AD909833E5433B28#article](https://www.cambridge.org/core/journals/health-economics-policy-and-law/article/impact-on-the-nhs-and-health-of-the-uks-trade-and-cooperation-relationship-with-the-eu-and-beyond/57A170644C8C6B44AD909833E5433B28#article)  
 7. [cambridge.org/core/journals/health-economics-policy-and-law/article/impact-on-the-nhs-and-health-of-the-uks-trade-and-cooperation-relationship-with-the-eu-and-beyond/57A170644C8C6B44AD909833E5433B28#article](https://www.cambridge.org/core/journals/health-economics-policy-and-law/article/impact-on-the-nhs-and-health-of-the-uks-trade-and-cooperation-relationship-with-the-eu-and-beyond/57A170644C8C6B44AD909833E5433B28#article)  
 8. [nuffieldtrust.org.uk/sites/default/files/2022-12/1671199514-health-and-brexit-web.pdf](https://nuffieldtrust.org.uk/sites/default/files/2022-12/1671199514-health-and-brexit-web.pdf)  
 9. [nuffieldtrust.org.uk/news-item/has-brexit-affected-the-uk-s-medical-workforce](https://nuffieldtrust.org.uk/news-item/has-brexit-affected-the-uk-s-medical-workforce)  
 10. [nuffieldtrust.org.uk/news-item/has-brexit-affected-the-uk-s-medical-workforce](https://nuffieldtrust.org.uk/news-item/has-brexit-affected-the-uk-s-medical-workforce), referencing [sciencedirect.com/science/article/pii/S2666273621002679](https://www.sciencedirect.com/science/article/pii/S2666273621002679)

EFTA was slower in the years after 2016 than the years before"<sup>11</sup>. The trust then discounts Covid, demand changes and workforce planning changes are major factors here and says that the campaign and result of the referendum is the "obvious" reason.

- In December 2022 the Nuffield Trust found that "Care workers from the rest of the world have not made up for a shortfall in EU and EFTA staff"<sup>12</sup>.

Beyond numbers there are some clear policy issues here, which roundtable participants highlighted.

- Deterrent factors. We should consider the loss of flexibility for workers, the lack of mutual recognition of professional qualifications (for qualifications not recognised before 31 December 2020; the

UK has decided to unilaterally recognise EU qualifications but only temporarily) and barriers to long term stability for arrivals such as the potential loss of freedom to bring family members to the UK.

- Ethical issues. The UK health system is not supposed to actively recruit staff from 'red list' lower and middle income countries that are identified as experiencing structural workforce shortages. However, recruitment from these countries has increased meaningfully in many English NHS trusts since the UK exited the EU single market and introduced new migration rules. For example, nurse registration from these countries has gone from around 600 a month before the Covid-19 pandemic to close to 1,000 a month in the summer of 2021.



11. [nuffieldtrust.org.uk/news-item/has-brexit-affected-the-uk-s-medical-workforce](https://nuffieldtrust.org.uk/news-item/has-brexit-affected-the-uk-s-medical-workforce)  
 12. [nuffieldtrust.org.uk/sites/default/files/2022-12/1671199514-health-and-brexit-web.pdf](https://nuffieldtrust.org.uk/sites/default/files/2022-12/1671199514-health-and-brexit-web.pdf)

# 6 RESEARCH AND INNOVATION

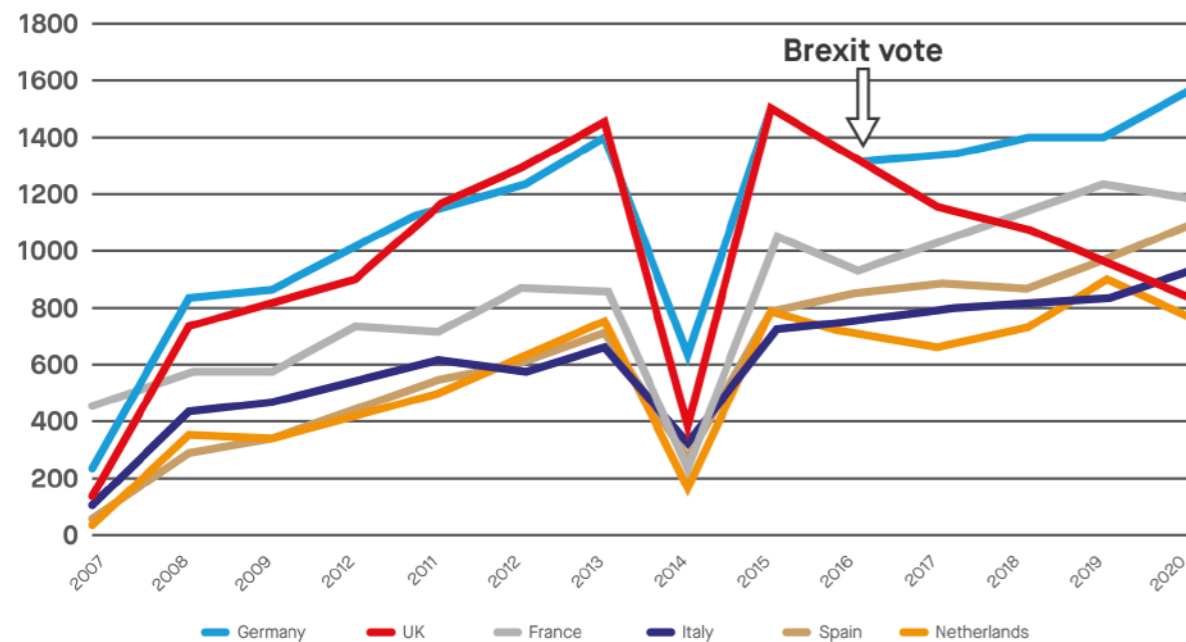


Roundtable participants reiterated that the more the UK moves away from EU institutions and formal frameworks the less attractive it will be as a place for global clinical trials to take place, with consequent reduced funding and research clout.

Whilst the TCA made provision for continued UK participation in research and technological development programmes this still has not come about. Furthermore looking at funding

from EU science programmes reveals a dip after the referendum for UK applicants even though formal access hadn't change, and didn't change until 2021<sup>13</sup>.

Funds (M EUR) won on EU science programmes 2007-2020



## HORIZON

Horizon is the EU's key funding programme for research and innovation. In the 2014-2020 Horizon programme the UK received the second highest amount of funding (€7.9 billion). Roundtable participants told us that exclusion from Horizon

is a major roadblock to progress in scientific and medical research and innovation.

The Trade and Cooperation Agreement gave the UK provisional associate status until both sides

13. [gov.uk/government/news/joint-statement-by-the-european-commission-and-the-uk-government-on-the-uks-association-to-horizon-europe-and-copernicus](https://gov.uk/government/news/joint-statement-by-the-european-commission-and-the-uk-government-on-the-uks-association-to-horizon-europe-and-copernicus)

agreed a ratification of a protocol. However, when the Northern Ireland Protocol dispute arose the EU 'seized' on Horizon as collateral<sup>14</sup>. The situation was not resolved until 7 September this year, when it was announced that the UK would rejoin<sup>15</sup>.

Whilst both Brussels and London have expressed confidence that with a "turbo boost" the UK can regain its leading Horizon position<sup>16</sup> the picture is not, in fact, so clear. As laid out in the above graph Horizon funding moved away from the UK after the

referendum result, even though the UK continued its membership initially.

We should note that there is a clear need for the Treasury to make sure that Horizon participation fees do not come out of general research public funding: if this were the case other research would obviously be impacted<sup>17</sup>. There is no current indication this will be the case but there were issues here in the approach to the UK's Horizon exit<sup>18</sup>.

## COLLABORATION

Participants told us lost access to key collaboration mechanisms such as the Clinical Trials Information System (CTIS) and European Reference Networks for Rare Diseases (ERNRD) is creating problems for the sector. As submissions in the UK will have to be carried out separately via the MHRA (UK Medicines and Healthcare products Regulatory Agency) they will not benefit from the simplifications provided by the new EU CTIS system.

The EU/EEA and UK are now separate regulatory entities for drug safety ("the science of detection, assessment, understanding and prevention of side effects"<sup>19</sup>). Parallel reporting through the appropriate channels in the EU (EudraVigilance gateway) and UK (MHRA gateway) is necessary and creates added costs and reduces the appeal of the UK as a place to do clinical trials and to launch new medicines.

14. [blogs.lse.ac.uk/politicsandpolicy/will-the-uk-find-its-way-back-to-horizon/](https://blogs.lse.ac.uk/politicsandpolicy/will-the-uk-find-its-way-back-to-horizon/)

15. [theguardian.com/science/2023/sep/07/horizon-brexit-eu-science-rishi-sunak](https://theguardian.com/science/2023/sep/07/horizon-brexit-eu-science-rishi-sunak)

16. [theguardian.com/science/2023/sep/07/what-does-rejoining-eus-horizon-scheme-mean-for-uk-research-and-innovation](https://theguardian.com/science/2023/sep/07/what-does-rejoining-eus-horizon-scheme-mean-for-uk-research-and-innovation)

17. [sciencebusiness.net/framework-programmes/news/uk-announces-eu250m-towards-horizon-europe-participation-cost-following](https://sciencebusiness.net/framework-programmes/news/uk-announces-eu250m-towards-horizon-europe-participation-cost-following)

18. [sciencebusiness.net/framework-programmes/news/uk-announces-eu250m-towards-horizon-europe-participation-cost-following](https://sciencebusiness.net/framework-programmes/news/uk-announces-eu250m-towards-horizon-europe-participation-cost-following)

19. [abpi.org.uk/careers/working-in-the-industry/research-and-development/drug-safety-pharmacovigilance/](https://abpi.org.uk/careers/working-in-the-industry/research-and-development/drug-safety-pharmacovigilance/)



# 7 RECOMMENDATIONS

The roundtable and our secondary research has highlighted some priority areas for improvement.

- Mutual recognition of batch testing. The UK unilaterally recognises the EU's batch testing which has led to confusion for the industry. UK sponsors of clinical trials operating in the EU need EU-based legal representation, adding significant expense and making it harder for UK based researchers to lead pan-European clinical trials.
- The UK should pursue mutual recognition of batch testing to reduce barriers to collaborative research and innovation. This would significantly reduce costs for the industry. Batch testing costs c.£3,600 per batch. It costs between £330m and £615m for importers to set up new batch testing.
- Working group on Medicinal Products: A more regular meeting of the Working Group on Medicinal Products, established in accordance with the TCA's governance structure, would assist the Trade Specialised Committee on Technical Barriers to Trade.
- Recognition of professional qualifications. The TCA contains a mechanism for later UK-EU agreement on mutual recognition of certain professional qualifications. These provisions could be used to build agreements to mutually recognise qualifications automatically, opening up access to migrant professionals and to regain what has been lost in terms of Britain's reputation as a desirable country in which to make a career in health or biomedicine.
- European Reference Networks. The numbers of patients involved in these networks of clinical experts on rare diseases are small but significant. There is scope for the UK to negotiate its way back in.
- Data. The UK should embed data protection dynamic alignment with the EU in the TCA



## 8 FURTHER READING

Further reading for monitoring developments:

- The Nuffield Trust Health and International Relations Monitor which tracks changes to policy and law is a very useful resource. It has published papers on topics such as post Brexit health in the UK, the Windsor Framework, Northern Ireland, health and Brexit six years on and the UK medical workforce. Find out more here.
- There are a number of papers in The Lancet which give a framework to track developments (here and here).
- There are also useful resources in the Cambridge University Press which set out thinking about different post-Brexit trade agreements, and their effects on health and the NHS (here and here).
- Hervey T. Brexit, Health and its potential impact on Article 2 of the Ireland/Northern Ireland Protocol, Northern Ireland human rights commission, March 2022.
- Dayan M, McCarey M, Hervey T, Fahy N, Greer S, Jarman H, Stewart E & Bristow D. Going it alone: health and Brexit in the UK, Nuffield Trust, December 2021.
- Hervey T & Flear M. Health Governance After Brexit: Law, Language and Legitimacy, Queen's University Belfast, June 2021.
- Hervey T, Wood D, Flear M & Antova I. Health Governance after Brexit: Law, Language and Legitimacy, University of Sheffield, February 2019.
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# CRITICAL CONDITION: THE IMPACT OF BREXIT ON HEALTH AND SOCIAL CARE



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