Research report March 2025

Health in the UK after Brexit

Moving apart or stuck together?

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nuffieldtrust

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Executive summary

The Health and International Relations Monitor project is supported by the Health Foundation, an independent charity committed to bringing about better health and health care for people in the United Kingdom (UK). It has looked to explore how the dramatic changes to the UK's international relations following Brexit have affected health in all its dimensions – from the rupture in trading and institutions, to the newfound ability of the UK to regulate everything from medicine to migration in a way that differs from its neighbours. It has considered changes caused by every stage in this process, from the referendum on the European Union (EU) in 2016, through the negotiation of exit from the EU from 2017 to 2019, the Withdrawal Agreement this produced, the Trade and Cooperation Agreement between the EU and the UK, implemented in 2021, and the divergence and trade deals with other countries this process allowed for after the UK left the single market as 2020 ended.

In this report, the last in our series, we provide brief updates based on data and legal analysis for the issues of medicines supply, the migration of staff and procurement – all areas covered in our previous reports, but where a new reality after exiting the single market continues to be linked to rapid change.

We also explore four areas of crucial importance to health where Brexit has meant a new course for the UK – but where the impact has been little studied so far. These are artificial intelligence (AI), funding, professional qualifications and patients moving across borders. We held roundtables in London and Austria with industry, regulators and experts to explore AI regulation in depth. At each one, in a closed session under Chatham House rules, we presented our understanding of differences between the UK and EU systems and asked attendees to add their insight informed by much deeper knowledge of these new technologies, their uses and their regulation.

Key points

The UK has no single strategy for health and Brexit

- Five years on from leaving the EU, the UK is taking a very variable approach to divergence in law and regulation. In many areas, it has been sticking with the EU law it inherited, or even actively mimicking its larger neighbour. But in procurement, staff training and AI, it has taken different choices – though the extent of difference is often overstated. For migration, medicines and funding, meanwhile, the UK has struggled to find a new equilibrium.

- In all these areas, constant change in technology and in EU law and policy means that Brexit is not a policy issue that can be resolved but an ongoing source of tension and pressure. For sectors that often involve international trade, including AI, divergence will create an intrinsic cost from companies complying twice. This creates a standing disadvantage set against any intrinsic benefits.

- The UK's different strategies in important areas of health policy would complicate any fundamental move to realign with the EU, even as this is a preferred approach in other policy areas.

Artificial intelligence

- Against the AI Act passed by the EU last year, the UK has taken a fundamentally different approach to regulating AI. While the EU Act creates a system to classify and assess all uses of AI, the UK has told regulators in each sector to take their own approach based on shared principles.

- Rhetorically, the EU has emphasised safety and the protection of rights, while the previous UK government emphasised its openness to innovation and a desire to attract investors. But the reality is that for AI systems intended to treat or diagnose as medical devices, the UK and EU systems largely share technical standards, meaning differences in what is actually required can be minimal.

- The costs to business of having to follow two systems, even where they are similar, will remain a problem for the UK in AI medical devices. If divergence grows over time because of the different principles of EU regulation, AI firms will feel pressure to prioritise standards in the much larger EU market – the 'Brussels effect' – even if at least some see its rules as more burdensome than UK regulation.

- If the UK follows through on its plan to stop recognising EU medical device approvals in 2030, this will confront firms producing new products with the sharp choice of accepting the costs of an extra regulatory system, or not serving the market in Great Britain.

- Because it is based on separate types of products, the UK system has no obvious way to deal with AI systems that were never intended for health care being used in this way – something increasingly prevalent as generative systems are used across society, including by health professionals. Open AI's GPT-4.5 is not sold as a medical device, but it is beyond doubt that both patients and professionals have at times used it to inform diagnosis.

Procurement and the supply of medicines

- The UK's 2023 Procurement Act moves procurement away from EU law. A carve-out frees the English NHS from the requirement to go through as many full procurement processes – a requirement created originally by its unique attempt to run a market inside the public service since the 1990s.

- It also creates somewhat more space to prioritise local businesses, and social and environmental goals, rather than simply going with the lowest offer. However, it does not go as far as some had hoped in limiting space for corruption and exploitation by suppliers.

- The elevated and troubling level of medicine shortages we noted in earlier reports in this series is continuing, with no sign of improvement in key indicators. We have previously concluded that this is not primarily due to Brexit, with other EU countries also suffering significant shortages. However, data now confirm the UK to have had the lowest import growth

in medicines of any G7 country, driven by a reduction in EU imports. This does illustrate the particular impacts of leaving the EU.

NHS and social care professionals

- Following Brexit, the UK has continued to rely heavily on very high migration of health care staff from outside the EU – rather than to rely more on training and retaining staff domestically. In England, two thirds of the increase in registered nurses since the exit from the single market as 2020 ended has come from staff trained outside the UK or European Economic Area (EEA).

- By November 2024, one in 11 (9%) of all NHS doctors in England held a nationality from one of the countries listed by the World Health Organization (WHO) as having such a shortage of staff that other countries should not recruit from them.

- A recent collapse in inward migration of social care workers following a sudden tightening of policy illustrates how unstable this approach is without the stability of EU rights.

- The UK is on course to diverge meaningfully by cutting the number of hours of clinical training it requires for nurses to qualify, well below what EU law demands. While this is not outside the range that other comparable countries require, it will likely preclude any possibility of re-establishing the mutual recognition of nursing qualifications with the EU.

1 Staffing: an ongoing and unstable transformation

In previous research, we[1] and others[2] have noted a series of striking changes in the health and care workforce in the UK associated with Brexit:

- Recruitment from the EEA, which had proved a critical source of staff in the mid-2010s, slowed from 2016 onwards: slowly for doctors, care workers and other groups, and very dramatically for nurses, possibly due to the simultaneous introduction of more demanding language testing.

- Generally speaking this was not accompanied by an increase in the rate of recruitment of domestically trained staff, particularly not in social care where the domestic workforce has shrunk in some recent years in England.

- Particularly since the end of free movement of labour at the start of 2021, a remarkably steep and sustained increase in staff trained or holding nationalities outside the UK and EU has occurred. The new migration system, with its Health and Care Visa and 'shortage status' allowing social care workers to meet salary criteria for visas, has enabled inward flows of staff so high that they have often accounted for most or all of the expansion in workforces.

1 McCarey M, Dayan M, Jarman H, Hervey T, Fahy N, Bristow D and Greer SL (2022) *Health and Brexit: Six years on*. Nuffield Trust. www.nuffieldtrust.org.uk/research/health-and-brexit-six-years-on. Accessed 27 January 2025.

2 The Migration Observatory (2023) 'Migration and the health and care workforce'. https://migrationobservatory.ox.ac.uk/resources/briefings/migration-and-the-health-and-care-workforce. Accessed 27 January 2025.

In short, the UK's response to Brexit as a challenge for staffing has been to double down on reliance on staff trained elsewhere, switching the legal mechanism from free movement to unilateral law and the source countries from Europe to Africa and Asia.

This has enabled an almost unprecedented expansion in staffing, at least in health care. However, it carries two risks – one for the source countries, and one for the NHS itself.

Recruitment from 'red list' countries

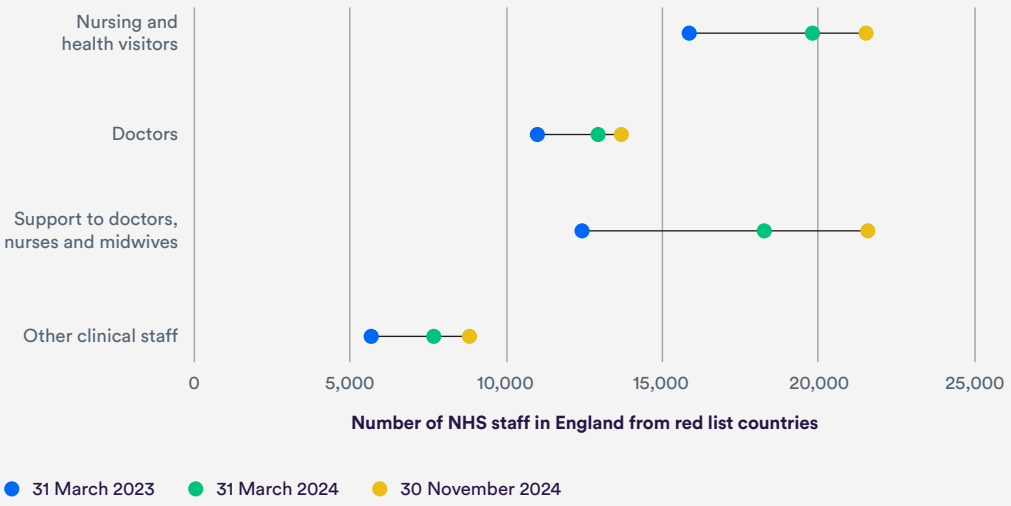
The Nuffield Trust and our co-authors have consistently found particular increases in NHS staffing from countries listed since 2020 on the World Health Organization (WHO) Health Workforce Support and Safeguards List. These are countries from which health services are not supposed to actively recruit, because they 'face the most pressing health workforce challenges related to universal health coverage'.[3]

In early 2023, the World Health Organization updated this list to cover 55 countries, from a previous 47, with one of which (Nepal) the UK had signed a memorandum exempting it from restrictions.[4] Information obtained for this report from NHS England shows that in the following year, NHS staff employed in trusts and management bodies in England from these so-called 'red list' countries continued to grow rapidly, not only in number but also as a proportion of the workforce (see Figures 1 and 2). Over 20,000 clinical staff from these countries, discounting those in roles such as management and administration, were added to the workforce. By November 2024, the data we obtained showed that 9% of all NHS doctors in England held a nationality from one of these countries.

3 World Health Organization (2023) 'WHO health workforce support and safeguards list 2023'. www.who.int/publications/i/item/9789240069787. Accessed 27 January 2025.

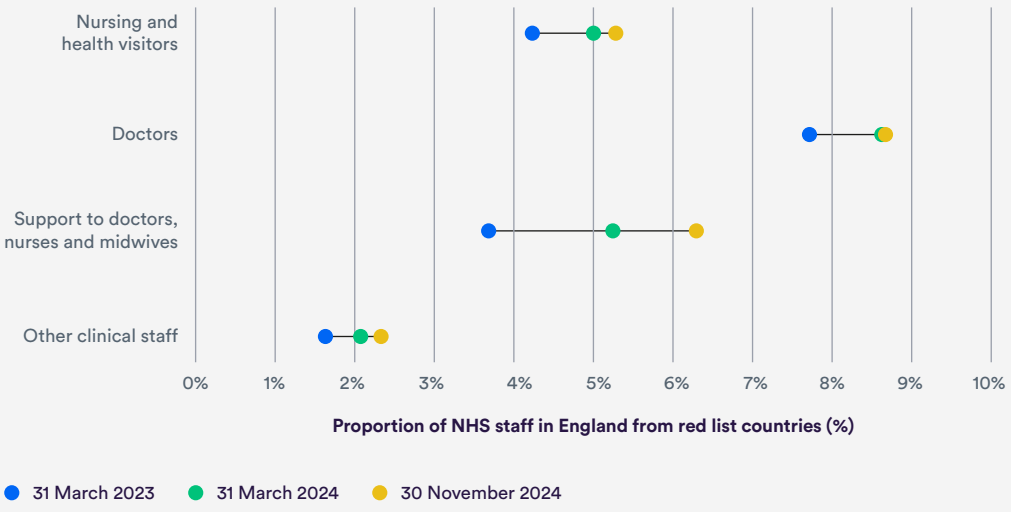
4 World Health Organization (2023) 'WHO health workforce support and safeguards list 2023'. www.who.int/publications/i/item/9789240069787. Accessed 27 January 2025.

Figure 1: Number of NHS staff in England from red list countries, 2023 and 2024



Source: Freedom of Information request made to NHS England

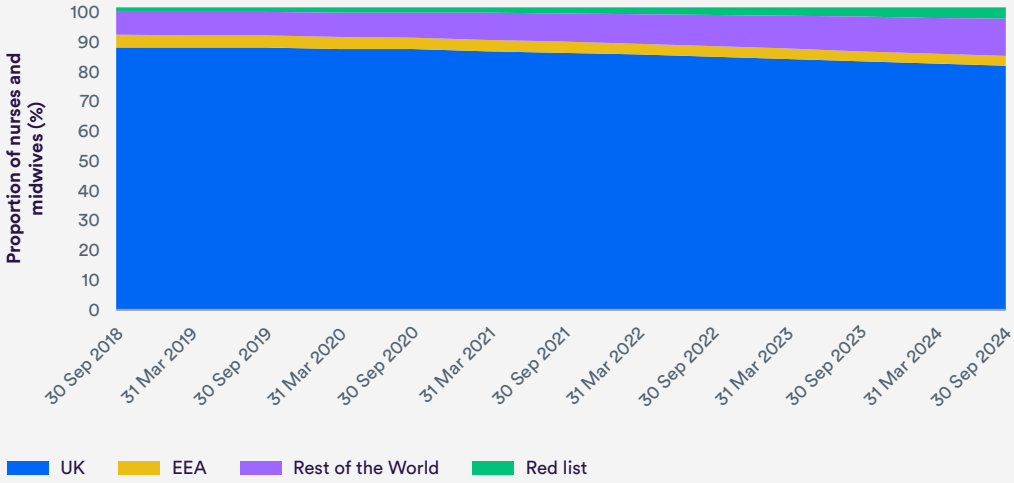
Figure 2: Proportion of NHS staff in England from 'red list' countries, 2023 and 2024 (%)



Source: Freedom of Information request made to NHS England

Analysis of data published by the Nursing and Midwifery Council for each of the four countries of the UK illustrates the increasing proportion of nurses and midwives trained outside the UK or EEA in recent years (see Figure 3). Unlike data from NHS England, this includes clinicians who may work in the private sector – or who may not actively practise.

Figure 3: Proportion of nurses and midwives by country of training (%), September 2018 to September 2024



Source: Nursing and Midwifery Council www.nmc.org.uk/about-us/reports-and-accounts/registration-statistics

Figure 3 also shows that a significant proportion of the rapid increase in staffing since the start of the Covid-19 pandemic is accounted for in particular by nurses and midwives trained in red list countries.

Breaking these figures down by individual countries or groups of countries is possible, and registered staff can be seen separately for each country of the UK – although around 6% cannot be allocated specifically to Scotland, England, Wales or Northern Ireland. Looking at the data in this way shows that:

- In England, two thirds of the increase in the number of registered nurses since exit from the single market as 2020 ended, up to September 2024, came from staff trained outside the UK or EEA. This represents 46,890 additional staff, against a total increase of 70,541.

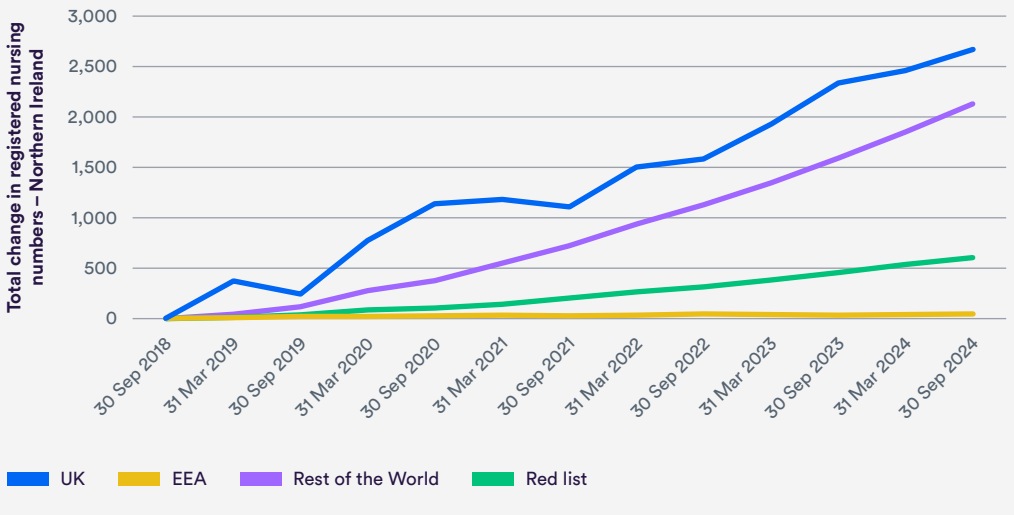
- Countries on the red list accounted for over a fifth of the total increase in the number of nurses over the same timescale – the number trained in these countries rose by 15,151, out of a total of 70,541.

- Rest of the world-trained nurses accounted for a lower proportion of the overall increase in Wales, Scotland and Northern Ireland.

- However, the number of registered nurses trained in red list countries more than doubled in those same three years in Wales, Scotland and Northern Ireland. Nurses trained in red list countries increased from 235 to 626 in Wales, from 301 to 1,053 in Scotland and from 193 to 653 in Northern Ireland.

Figures 4 to 7 show proportionate increases in red list and rest of the world nurses for each country of the UK, from a baseline of September 2018. Nigeria (46%), Ghana (21%) and Zimbabwe (16%) are the main red list countries contributing nurses to the UK workforce. Over 4,000 Zimbabwe-trained nurses and midwives are now registered to practise in the UK, equivalent to more than 11% of the total number practising in Zimbabwe.[5]

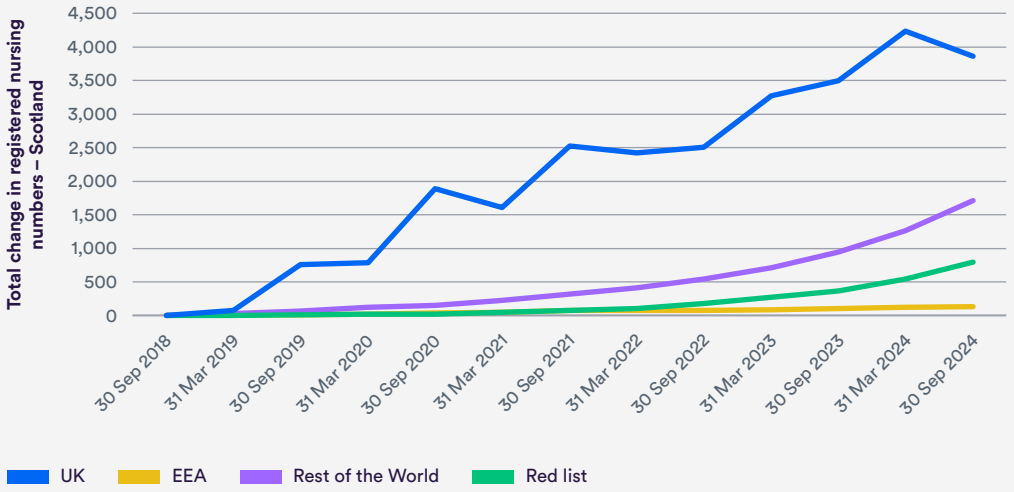
Figure 4: Total change in registered nursing numbers – Northern Ireland, September 2018 to September 2024



Source: Nursing and Midwifery Council

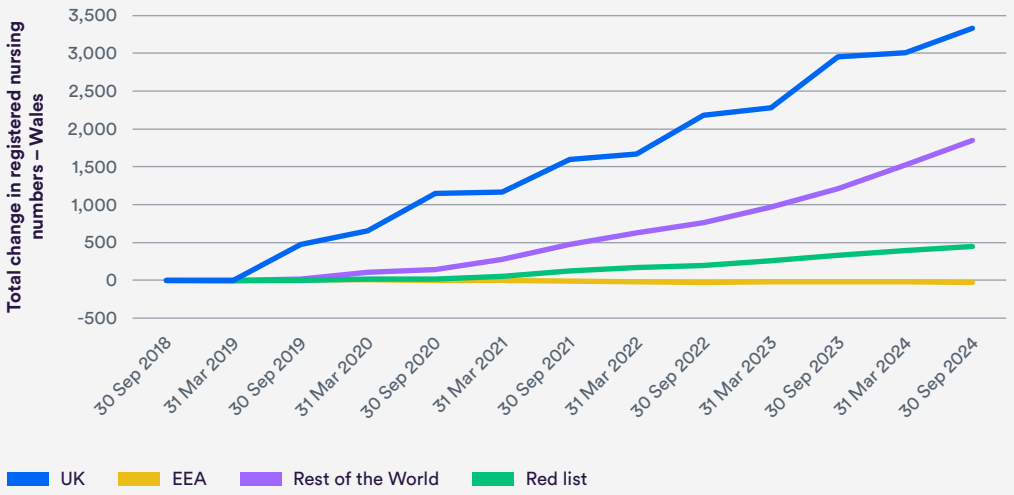
5 World Health Organization (no date) 'Global Health Workforce statistics database'. www.who.int/data/gho/data/themes/topics/health-workforce. Accessed 27 January 2025.

Figure 5: Total change in registered nursing numbers – Scotland, September 2018 to September 2024



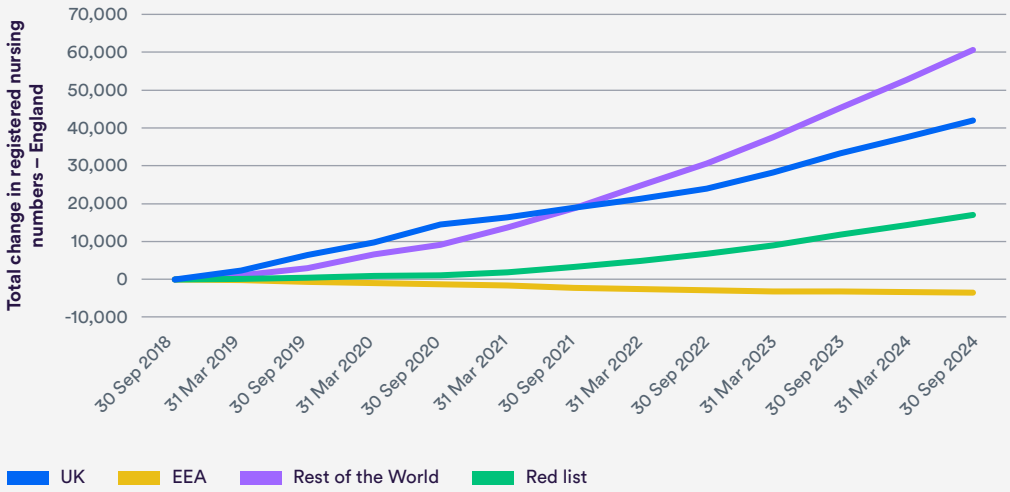
Source: Nursing and Midwifery Council

Figure 6: Total change in registered nursing numbers – Wales, September 2018 to September 2024



Source: Nursing and Midwifery Council

Figure 7: Total change in registered nursing numbers – England, September 2018 to September 2024



Source: Nursing and Midwifery Council

The position in Northern Ireland

Northern Ireland's unique geographic position, with both staff and patients crossing the border for health care on a significant scale, raises particular issues for staffing.

However, the trends we see remain broadly comparable to those in Scotland, England and Wales, with a shift away from EEA-trained staff and large increases in those trained in the rest of the world. As shown in Figures 4 to 7, UK-trained nurses still make up most of the recent staffing increases in Northern Ireland, Scotland and Wales, but not in England.

One concern about Brexit was that the loss of the ability to have qualifications in the 27 remaining EU members recognised in the UK, and vice versa, would deter staff because it made a cross-border career more difficult. However, a stakeholder we spoke to connected to staffing policy in Northern Ireland told us that "the impact of changes to mutual recognition of qualifications has actually been negligible".

Policy instability

The other clear risk to the switch to a reliance on staff trained outside the EEA is that without the treaty right to freedom of movement, migratory flows are subject to sudden and unpredictable changes from UK governments and politicians. This is largely the story of UK immigration policy for health and care staff, which has moved through previous cycles of being open and closed.[6]

Relying on global rather than single market migrants also means that they can move on globally with just as much ease as getting a visa for the UK, rather than being strongly incentivised to stay within the EEA. International staff move abruptly when employment opportunities expand in other countries and this will reflect the inconsistent attractiveness of the NHS as an employer. Data from The Health Foundation show that 12,000 nurses in 2022/23 applied for a certificate to transfer their UK registration to another country, four times as many as in 2018/19, and seven in 10 of these were nurses originally trained outside the UK and the EEA.[7]

As shown above, the inward migration of qualified health care staff remains extremely high – with no significant policy shifts since 2021. However, in social care the picture is very different.

Following a period of very high migration, the Home Secretary in late 2023 announced a package of restrictions: workers were banned from bringing spouses or children, and only providers registered with the Care Quality Commission could recruit.[8] At the same time, the Home Office began firmly

6 Dayan M and Palmer B (2019) *Stopping the Staff We Need? Migration choices in the 2019 general election*. Nuffield Trust. www.nuffieldtrust.org.uk/research/stopping-the-staff-we-need. Accessed 27 January 2025.

7 Bazeer N, Kelly E and Buchan J (2024) 'Nursing locally, thinking globally: UK-registered nurses and their intentions'. www.health.org.uk/publications/long-reads/nursing-locally-thinking-globally-uk-registered-nurses-and-their-intentions. Accessed 27 January 2025.

8 Home Office (2024) 'Home Secretary action delivering major cut in migration'. www.gov.uk/government/news/home-secretary-action-delivering-major-cut-in-migration. Accessed 27 January 2025.

enforcing the need for an existing vacancy to be demonstrated. The result was a remarkable collapse in numbers, with visa applications falling 83%.[9]

There were undoubtedly very real examples of fraudulent employers and exploitation under the earlier system, but this cycle of boom and bust makes very little sense as workforce policy for one of the UK's major public services. Unfortunately, it is typical of the instability that has often been seen in UK immigration policy beyond the consistent rules of free movement of labour as a treaty right.

9 Home Office (2025) 'Monthly monitoring of entry clearance visa applications'. www.gov.uk/government/statistics/monthly-entry-clearance-visa-applications/monthly-monitoring-of-entry-clearance-visa-applications. Accessed 27 January 2025.

2 Training: the sharpest divergence

The EU's system of mutual recognition of professional qualifications enables doctors and nurses trained in one country to practise in another without requalification. Established under Directive 2005/36/EC, and amended by Directive 2013/55/EU,[10] it requires minimum training standards and allows for automatic recognition of qualifications across member states. This system is designed to support professional mobility and address workforce shortages, especially in health care.

This system ceased to apply to the UK following exit from the single market: no provision for it to continue is contained in the EU–UK Trade and Cooperation Agreement.

The Directive specifies that recognised nursing degrees must include 4,600 hours of training over three years, of which half must be clinical in nature. From an early stage, the UK government stated and consulted on an intention to significantly reduce this.[11]

This represents probably the clearest policy initiative by the UK to directly diverge from previously mutually recognised EU regulation within health and care. Unlike for many aspects of medicines, devices and AI regulation, there is no active process of change underway on the EU side.

10 European Commission (2023) 'Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2023'. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32013L0055. Accessed 27 January 2025.

11 Nursing and Midwifery Council and Harlow Consulting (2021) *Review of Minimum Education and Training Standards in Nursing and Midwifery – Desk Based Research*. Benchmarking report. education-programme-standards-research-sept-2021---harlow-consulting-benchmarking-report.pdf

The specific proposal in the 2023 NHS Long Term Workforce Plan[12] is that: 'A reduction in placement hours from 2,300 to 1,800 over the course of a nursing degree would reduce pressure on our learners while significantly increasing placement capacity across the NHS.' It is intended to help raise capacity for domestic training. In this sense it serves as part of a plan that seeks to respond to the failure of domestic training to fill the requirements of the UK's health services after Brexit.

Other arguments in favour include that many countries have far shorter clinical training requirements, such as Australia with 800 hours, without clear issues in the credibility of qualifications or in health care outcomes. The UK and EU training requirement is relatively high in a global context, although other countries, including Australia, may have differences like smaller class sizes which allow for more intensive practical training.[13]

Aside from safety and quality, an important strategic consideration barely discussed in public is that implementing these changes would preclude the UK from easily realigning with the EU and restoring mutual recognition. This sits uneasily alongside the current government's manifesto commitment to 'secure a mutual recognition agreement for professional qualifications'[14] – although leaving out the health professions is a common feature of mutual recognition in trade agreements.

12 NHS England (2023) NHS Long Term Workforce Plan. NHS England. www.england.nhs.uk/publication/nhs-long-term-workforce-plan. Accessed 27 January 2025.

13 Palmer W, Reed S, Hemmingsw N, Julian S, Bodea M, Oaten R and Plotkin L (2024) *Practice learning in nursing and midwifery education An independent rapid review.* Research report, Nuffield Trust and Florence Nightingale Foundation. www.nuffieldtrust.org.uk/sites/default/files/2024-12/Nuffield%20Trust%20-%20FNF%20-%20NMC%20practice%20learning%20review_WEB_update.pdf

14 Labour (2023) 'Britain reconnected'. https://labour.org.uk/change/britain-reconnected. Accessed 27 January 2025.

3 Medicine shortages: no end in sight?

We noted in previous reports that the time since the UK's exit from the single market has seen a sharp and concerning increase in medicine shortages.[15] Based on interviews and analysing international data, we concluded that Brexit itself can be held only partly to blame. EU member states face many of the same problems as the UK, driven by fragile supply chains, the disruption of war and the Covid-19 pandemic, and a tightly competitive market for cheap, generic medicines, which account for the vast bulk of pharmaceutical treatment across the continent.

However, we have noted signs of unique patterns in the UK that likely do relate to its position outside the EU. And as the EU and its member states consider radical steps to address the problems they face, the UK's position in the same continental market but without shared institutions will pose very real difficulties.

The EU has continued to progress with its initiatives to address shortages. It deployed the Voluntary Solidarity Mechanism during 2024 to shift spare supplies between member states to cover shortages for the first time, with a limited number of cancer drugs. Recommendations were recently published for extensive reshoring of manufacturing for critical medicines, with legislation expected shortly.[16] As with AI and health funding, this rapid change challenges the UK to keep up and adapt.

In this chapter, we briefly update key indicators of medicine shortages. These show little sign that this serious crisis of access to treatment is improving.

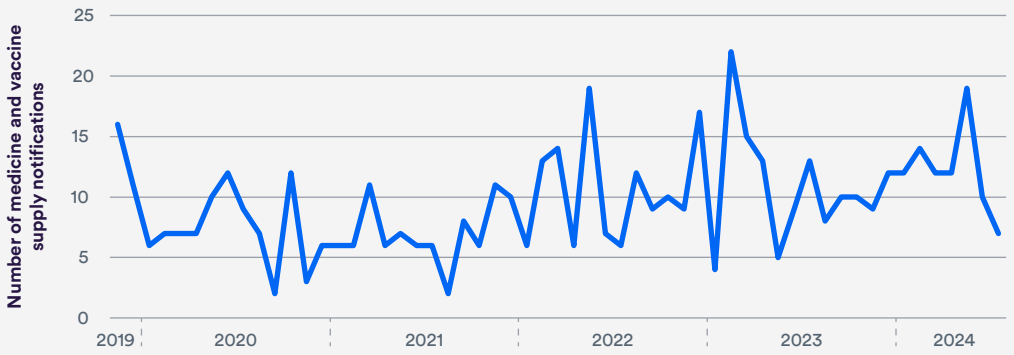
15 Dayan M, Hervey T, McCarey M, Fahy N, Flear M, Greer S and Jarman H (2024) *The future for health after Brexit*. Research report, Nuffield Trust. www.nuffieldtrust.org.uk/research/the-future-for-health-after-brexit

16 European Commission (2025) *Strategic Report of the Critical Medicines Alliance*. https://health.ec.europa.eu/document/download/3da9dfc0-c5e0-4583-a0f1-1652c7c18c3c_en?filename=hera_cma_strat-report_en.pdf.

Medicine supply notifications are issued by the Department of Health and Social Care and by NHS England. They relate to relatively serious shortages and are intended to alert pharmacists and NHS administrative staff to a significant degree of risk.

Notifications for the first seven months of 2024 were higher on average than they were averaged across the years 2020, 2021, 2022 or 2023 (see Figure 8). This was not a seasonal effect as they also exceeded the total number of notifications issued during the first seven months of any of those years, suggesting, if anything, a worsening situation.

Figure 8: Number of medicine and vaccine supply notifications, 2019 to 2024

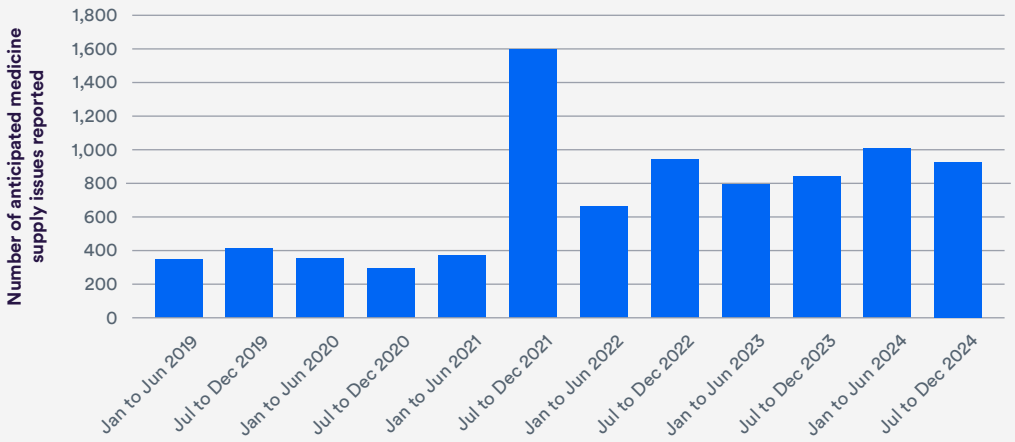


Source: Freedom of Information request to the Department of Health and Social Care

Firms are required under regulations to report emerging issues to the Department of Health and Social Care as soon as possible, or six months before the anticipated start of disruption. This is a much wider indicator, capturing almost any shortages, and many potential issues that never come to pass. Again, we see that firms reported more anticipated issues in the first half of 2024 than in the first six months of any year since 2019 (see Figure 9). Data for the full year of 2024 shows more disruptions were reported than in 2022 or 2023. An anomalous spike in late 2021 likely relates to fears over the place of Northern Ireland during negotiations.[17]

17 Dayan M, Hervey T, Flear M, Jarman H, McCarey M, Fahy N and Greer SL (2022) 'Protocol politics mean hard times ahead for health in Northern Ireland'. www.nuffieldtrust.org.uk/news-item/protocol-politics-mean-hard-times-ahead-for-health-in-northern-ireland. Accessed 27 January 2025.

Figure 9: Number of anticipated medicine supply issues reported to the Department of Health and Social Care

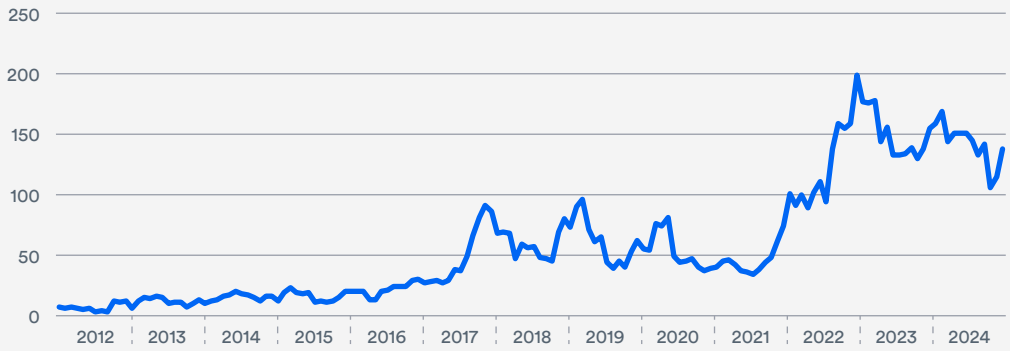


Source: Freedom of Information request to the Department of Health and Social Care

It is possible that firms have increased the rate at which they notify shortages, rather than there being an underlying worsening in the supply picture. However, other data seem to rule out that the latter has improved.

Price concessions are granted by the Department of Health and Social Care to head off shortages – in recognition of pharmacists being unable to find products at what is supposed to be the agreed price. Again, we see long-term deterioration (see Figure 10). The year 2024 saw the monthly average drop from around 200 a month to below 150, but this remains a level unthinkable a decade ago, when the number of concessions was consistently less than a tenth of this.

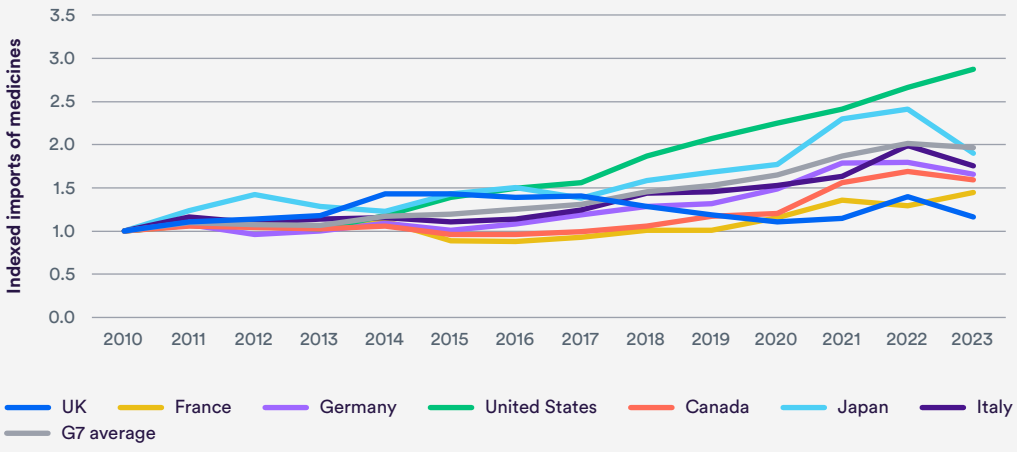
Figure 10: Number of price concessions granted by month, 2012 to 2024



Source: Pharmaceutical Services Negotiating Committee https://psnc.org.uk/funding-and-reimbursement/reimbursement/price-concessions

Trade data from the United Nations show that the UK now once again has the lowest rise in imports of medicines of all G7 countries since 2010 (see Figure 11). The total value has fallen by almost 20% since 2015, the year before the EU referendum, in cash terms – an indication of how medicine supply chains have shifted away from the UK. There is little sign of a stable recovery since, even though sterling remains at a similar level today as it did in 2016.[18]

Figure 11: Indexed imports of medicines by US$ value (2010=1), 2010 to 2023

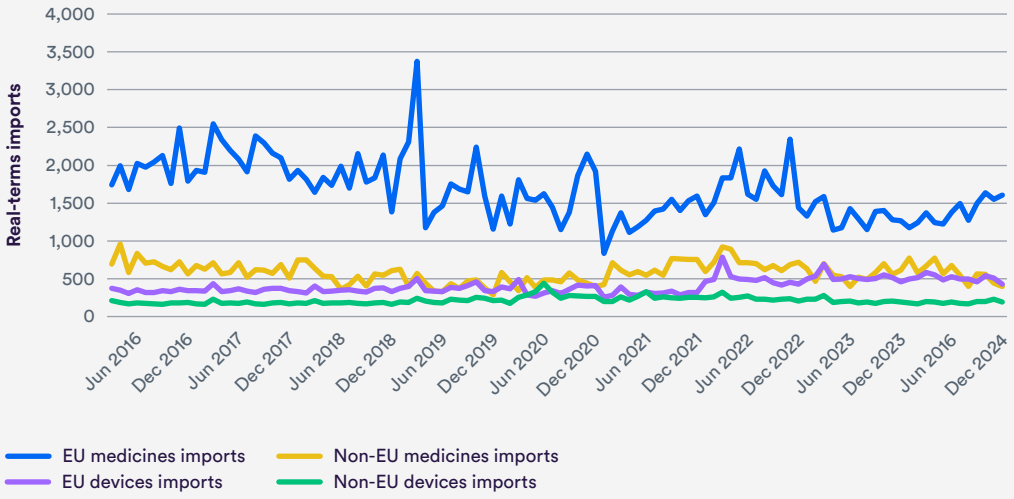


Source: United Nations (https://comtradeplus.un.org)

18 Bloomberg (no date) 'GBP–USD X-rate'. www.bloomberg.com/quote/GBPUSD:CUR?embedded-checkout=true. Accessed 27 January 2025.

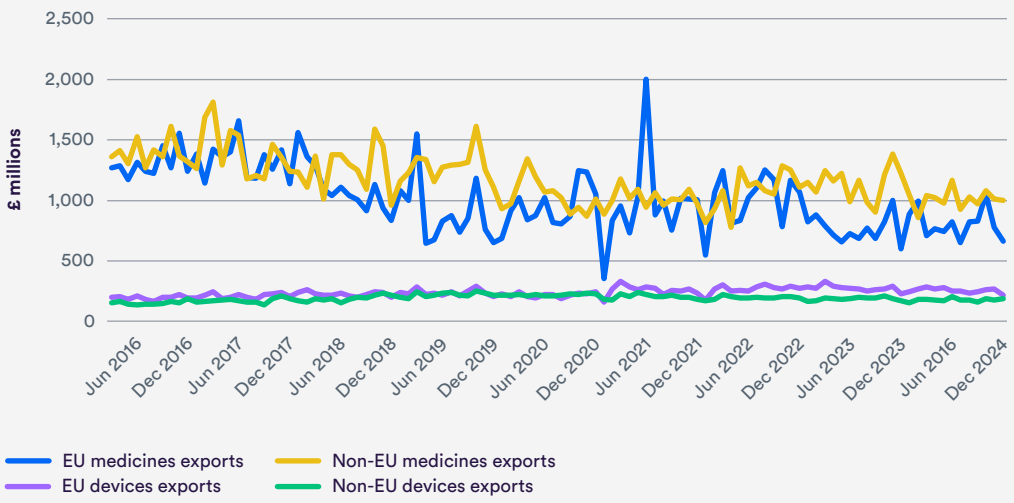
Domestic trade data from HM Revenue and Customs (HMRC) adjusted for inflation in the UK illustrates a decline focused clearly on imports from the EU (see Figure 12), adding to the evidence that new trade barriers related to Brexit are a likely explanation. An even sharper drop in exports is seen: medicines exports to the EEA are currently around two-thirds, on average, what they were before the EU referendum (see Figure 13).

Figure 12: Real-terms imports (consumer price inflation), March 2016 to December 2024



Source: UK Trade Info www.uktradeinfo.com/trade-data/ots-custom-table

Figure 13: Real-terms exports (consumer price inflation), March 2016 to December 2024



Source: UK Trade Info www.uktradeinfo.com/trade-data/ots-custom-table

Medicines imports in Northern Ireland

In previous work in this series, the authors of this report noted that Northern Ireland faced a unique set of problems in medicines supply.[19] This reflected the Protocol on Ireland/Northern Ireland agreed at the point of Brexit,[20] which aimed to avoid a hard border on the island of Ireland. Unlike Great Britain, which was separated from the EU market as medicine regulation broke into separate spheres, Northern Ireland essentially stayed in the single market for medicines – and was cut off from Great Britain.[21] This posed real supply risks given that 80% of Northern Irish medicines came from Great Britain – reflected in the alarming jump in companies warning of impending shortages in late 2021 as the new regime was scheduled to take hold.

These issues appeared to be largely resolved through the complex solutions pulled together in the 2023 Windsor Framework agreement, crucial measures of which are now being introduced as of 1 January 2025.[22] This removes Northern Ireland from the EU's system for tracking medicines, allows products to be tested in Great Britain for sale in Northern Ireland, and allows the UK regulator to approve innovative medicines for sale in Northern Ireland.

As implementation occurs, we continue to see signs that this brought relative stability. A stakeholder in the pharmaceutical industry we spoke to said that the Framework brought "clarity and safety". "What we really needed to see was a recognition that medicines were a special case and should be dealt with accordingly, and that is what we saw."

19 McCarey M, Dayan M, Jarman H, Hervey T, Fahy N, Bristow D and Greer SL (2022) *Health and Brexit: Six years on*. Research report, Nuffield Trust. www.nuffieldtrust.org.uk/research/health-and-brexit-six-years-on

20 UK Government (2019) 'Protocol on Ireland/Northern Ireland'. https://assets.publishing.service.gov.uk/media/5da863ab40f0b659847e0184/Revised_Protocol_to_the_Withdrawal_Agreement.pdf.

21 Dayan M, Hervey T, Flear M, Jarman H, McCarey M, Fahy N and Greer SL (2022) 'Protocol politics mean hard times ahead for health in Northern Ireland'. www.nuffieldtrust.org.uk/news-item/protocol-politics-mean-hard-times-ahead-for-health-in-northern-ireland. Accessed 27 January 2025.

22 Nuffield Trust (2023) 'Nuffield Trust response to Windsor Framework on Northern Ireland'. www.nuffieldtrust.org.uk/news-item/nuffield-trust-response-to-windsor-framework-on-northern-ireland. Accessed 27 January 2025.

However, implementation also brings costs for medicines suppliers. Under the Windsor Framework, the EU system of regulation still applies to most types of medicine that are not for certain major diseases or using innovative technologies. But more complex products, which would have previously been dealt with centrally by the EU, now fall under the UK regulator. Our contributor said that "we now have two slightly different… but very similar regulatory regimes operating in Northern Ireland". They suggested that finding a way to make this work would mean continued dialogue between the EU and UK.

Risks may include that Northern Ireland's complexity makes it a less attractive market for companies finding they need two separate systems of paperwork and reporting, or that error or confusion about which rules to follow means risks in medicines are not monitored as effectively.

The Windsor Framework also requires all medicines in the UK to be labelled as 'UK only' from 1 January 2025. This is an attempt to block their flow into the EU across an open border with different laws on either side. Concerns about the feasibility of this resulted in 2024 in several allowances being made by the UK government.[23] It will be crucial to monitor any signs of disruption if not all companies successfully complied with the requirement by 1 January 2025.

23 Greville R, Collier A and Maclagan R (2024) 'Getting ready for the Windsor Framework: ensuring continuity of UK medicines supply beyond 1 January 2025'. www.abpi.org.uk/media/blogs/2024/october/getting-ready-for-the-windsor-framework-ensuring-continuity-of-uk-medicines-supply-beyond-1-january-2025. Accessed 27 January 2025.

4 Artificial intelligence in health: separated by the cutting edge?

Artificial intelligence (AI) – particularly generative AI – is widely touted as among the most transformative emerging technologies. It already plays a role in health care, from remote monitoring to reading cancer scans,[24] and this is widely expected to expand. However, rapid developments and proliferation raise concerns for many, including about the safety of individuals and their data. How AI should be approached to ensure that it is safe and effective is one of the most urgent questions in health care regulation. It is also perhaps the question to which the EU and the UK have provided, since Brexit, the most apparently different answers.

The EU and UK approaches to AI regulation in health

The European Commission presented proposals for the AI Act in April 2021.[25] The Act was formally signed in June 2024 and entered into force on 1 August 2024.[26] Most provisions will apply fully from August 2026.

24 https://transform.england.nhs.uk/information-governance/guidance/artificial-intelligence

25 Council of the European Union (2024) 'Artificial Intelligence (AI) Act: Council gives final green light to the first worldwide rules on AI', press release, 21 May. www.consilium.europa.eu/en/press/press-releases/2024/05/21/artificial-intelligence-ai-act-council-gives-final-green-light-to-the-first-worldwide-rules-on-ai/#:~:text=Background,reached%20on%208%20December%202023. Accessed 24 January 2025.

26 Directorate-General for Communication (2024) 'AI Act enters into force'. https://commission.europa.eu/news/ai-act-enters-force-2024-08-01_en#:~:text=On%201%20August%202024%2C%20the,and%20deployment%20in%20the%20EU. Accessed 24 January 2025.

The new law was hailed as unprecedented because it is applicable to all uses of AI within the EU, regardless of purpose or sector. It assigns AI systems to one of four risk-based categorisations, the highest of which is banned outright. AI as a medical device is predominantly classified as 'high risk', which places a range of obligations upon providers and deployers alongside the standards and processes already required under the EU's Medical Device Regulation (MDR) or In Vitro Device Regulation (IVDR). It is likely that many other applications of AI in health care will also be categorised as high risk due to possible risks to the 'life and health of citizens'.[27] Obligations for deployers of high-risk AI systems include those relating to data collection and reporting, human oversight and a 'Fundamental Rights Impact Assessment', with the majority entering into force in August 2026.[28] As under the Medical Device Regulation and the In Vitro Device Regulation, only 'notified bodies' may undertake conformity assessments for high-risk AI systems.[29] A notified body 'is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market'.[30]

The UK's framework continues to rely on existing regulators to regulate applications of AI that fall within their remit. As part of an explicitly 'pro-innovation' approach, the former Conservative government published five 'principles' that regulators are expected to interpret and apply with regards to AI.[31] While the current Labour government has stated its intent to 'establish the appropriate legislation to place requirements on those working to develop the most powerful artificial intelligence models',[32] this appears to be aimed narrowly at certain cutting-edge systems. The government has recently stated its intent to follow the recommendations set out in a new

27 European Commission (no date) 'AI Act'. https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai. Accessed 24 January 2025.

28 European Artificial Intelligence Act (2024) 'Article 27: Fundamental Rights Impact Assessment for High-Risk AI Systems'. https://artificialintelligenceact.eu/article/27. Accessed 24 January 2025.

29 European Artificial Intelligence Act (2024) 'Article 31: Requirements Relating to Notified Bodies'. https://artificialintelligenceact.eu/article/31. Accessed 24 January 2025.

30 European Commission (no date) 'Notified bodies'. https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/notified-bodies_en. Accessed 24 January 2025.

31 Department for Science, Innovation and Technology (2023) 'A pro-innovation approach to AI regulation'. www.gov.uk/government/publications/ai-regulation-a-pro-innovation-approach/white-paper. Accessed 24 January 2025.

32 House of Commons (2024) 'King's Speech', *Hansard*, 17 July, volume 752. https://hansard.parliament.uk/Commons/2024-07-17/debates/2D7D3E47-776E-4B81-8E2A-7854168D6FED/King%E2%80%99SSpeech. Accessed 24 January 2025.

AI Action Plan, published in January 2025.[33] Its recommendations centre around innovation, deployment and capacity improvement. It broadly signals continuity on the general approach to safety and regulation, arguing that "The UK's current pro-innovation approach to regulation is a source of strength relative to other more regulated jurisdictions and we should be careful to preserve this".[34]

The Medicines and Healthcare products Regulatory Agency (MHRA) will hold sole responsibility for regulating AI medical devices in Great Britain. The MHRA also currently plans to accept EU conformity assessment for medical devices to be placed on the market in Great Britain until June 2030.[35] This continues a repeated pattern of extending GB recognition of EU regulatory standards in the health care sector, creating a perception among stakeholders that this is likely to be sustained for the foreseeable future.

It is likely that Northern Ireland will adopt many elements of the AI Act under the Protocol on Ireland/Northern Ireland – at least insofar as medical devices and other regulated products are concerned. Article 13 commits Northern Ireland to follow any change in the EU laws which the Protocol applies to it,[36] which include medical devices regulation, and in effect Northern Ireland remains entirely part of the EU regulatory sphere for these products. For other uses of AI in health care, it is less clear that there is a mechanism requiring the AI Act to be applied. The Secretary of State for Northern Ireland has indicated that wholesale application is a matter for the Withdrawal Agreement Joint Committee.[37]

33 Department for Science, Innovation and Technology (2025) 'AI Opportunities Action Plan: government response'. www.gov.uk/government/publications/ai-opportunities-action-plan-government-response/ai-opportunities-action-plan-government-response. Accessed 24 January 2025.

34 Department for Science, Innovation and Technology (2025) 'AI Opportunities Action Plan: government response'. www.gov.uk/government/publications/ai-opportunities-action-plan-government-response/ai-opportunities-action-plan-government-response. Accessed 24 January 2025.

35 Medicines and Healthcare products Regulatory Agency (2023) 'CE marking recognition for medical devices and in vitro diagnostics'. www.gov.uk/government/news/ce-marking-recognition-for-medical-devices-and-in-vitro-diagnostics. Accessed 24 January 2025.

36 UK Government (2019) 'Protocol on Ireland/Northern Ireland'. https://assets.publishing.service.gov.uk/media/5da863ab40f0b659847e0184/Revised_Protocol_to_the_Withdrawal_Agreement.pdf.

37 House of Commons (2025) 'Northern Ireland', *Hansard*, 15 January, volume 760. https://hansard.parliament.uk/Commons/2025-01-15/debates/5A22092F-999F-4727-A47C-325877AE30DF/NorthernIreland. Accessed 24 January 2025.

Northern Ireland primarily sources medical devices (unlike medicines) from the EU, and therefore disruption to supply from aligning with the EU may be limited. However, there may be issues in relation to access to software that is legal in the UK, in a context where Northern Ireland's health service, which is universal and gives a central role to GP referral, has many characteristics and needs that are similar to the other UK countries.

The rest of this chapter compares the UK and EU approaches to AI regulation, as relevant to health and health care, by applying a set of analytical lenses. The analysis draws on a review of existing literature and engagement with stakeholders in both the UK and EU. It then discusses implications for the UK and EU, future prospects and policy options. It is important to note that robust evidence of efficacy and safety is still limited for many applications of AI in health care.

Style versus substance

We carried out two roundtable sessions with stakeholders with expertise in AI regulation, one with an EU focus and one with a UK focus, to gather perspectives on this apparent divergence. There was not complete consensus on how different UK and EU AI regulatory regimes are in practice for AI as a medical device. However, the prevailing view was that they are more similar than political discourse implied because both rely on similar technical standards. We heard that the *principles* underpinning each are also similar, fundamentally in line with the Organisation for Economic Co-operation and Development's (OECD's) principles for trustworthy AI, to which the UK and EU are both named adherents.[38] This is an example of other institutional contexts being used for continued regulatory alignment across Europe.

Some stakeholders felt that the two regimes are constructed to appeal to different audiences, with the UK's 'pro-innovation' / enabling new technologies approach aimed at investors and the EU's 'pro-safety' / precautionary approach aimed at citizens. Public perception and trust were better supported as a policy focus by those at the EU-based roundtable, while

38 OECD.AI Policy Observatory (no date) 'OECD AI principles overview'. https://oecd.ai/en/ai-principles. Accessed 24 January 2025.

many at the UK-based roundtable doubted, based on previous evidence, that messaging at this level was effective in influencing public trust or uptake.

Article 27 – the Fundamental Rights Impact Assessment[39] requirement the AI Act is set to deliver for high-risk systems – is the clearest novel element the Act contains, with no such requirement having existed before globally. Its inclusion is strong evidence of (at least a narrative of) citizen rights and safety being at the core of the framing of the Act. However, this requirement is mired in practical uncertainty. While the European Commission loosely defines fundamental rights,[40] it is unclear how the impact assessment will be carried out, or who will carry it out. Without further detail, it is difficult to provide comparison to the provisions of the UK's regulatory approach.

Horizontal versus vertical

Beyond medical devices, the two regulatory regimes differ because the UK's is solely 'vertical', and applied in a different way to each type of regulated product, while the AI Act is 'horizontal', or universal, applying to all uses of AI. In the EU, sectors or applications previously subject to less specific regulation will see more change to how their AI is regulated. But medical devices have already been intensely regulated under the Medical Device Regulation or the In Vitro Device Regulation.[41,42]

Generally, the Act duplicates the standards that would already be applied to medical devices using AI under the Medical Device Regulation. Some roundtable attendees saw this as evidence that horizontal regulation is not appropriate, especially due to concerns that instances may arise where the Act conflicts with the Regulation – a risk the UK's approach avoids.

39 European Artificial Intelligence Act (2024) 'Article 27: Fundamental Rights Impact Assessment for High-Risk AI Systems'. https://artificialintelligenceact.eu/article/27. Accessed 24 January 2025.

40 European Commission (no date) 'Fundamental rights'. https://home-affairs.ec.europa.eu/networks/european-migration-network-emn/emn-asylum-and-migration-glossary/glossary/fundamental-rights_en. Accessed 24 January 2025.

41 Official Journal of the European Union (2017) 'Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices'. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745. Accessed 24 January 2025.

42 European Union (2017) 'Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices'. https://eur-lex.europa.eu/eli/reg/2017/746/oj. Accessed 24 January 2025.

While there is relative clarity in the UK regarding how AI that clearly falls in the medical device category is regulated, there are grey areas surrounding applications of AI that do not qualify as medical devices. AI used in a clinical context that is not marketed for diagnosis or treatment is outside the remit of the MHRA. However, large language models with broad capabilities widely available to health care staff are the types of AI with the most potential for drastic growth and impact. Some UK-based stakeholders warned that the development of general AI would be an ongoing source of pressure for the UK system.

While we heard some stakeholders in both roundtables express optimism that the UK approach is well prepared for the future within the field of devices, the AI Act offers a clear general framework, which covers new products from inception. It also sits alongside other horizontal EU law concerning the use of data, such as the General Data Protection Regulation (GDPR) and the upcoming European Health Data Space.[43] The new Product Liability Directive, which includes AI, should supplement these by improving rights in relation to defective products.[44]

However, there were concerns that the AI Act is not well designed to regulate generative AI, which became much more prevalent in the period after the legislation was originally conceived. Adaptions for these models were made as the Act was drafted,[45] but stakeholders raised questions related to their quality and comprehensiveness. The Act sets out a definition of the models to which these standards apply.[46]

43 European Union (no date) 'European Health Data Space'. https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en. Accessed 24 January 2025.

44 Rohrßen B and Tibi L (2024) 'Product Liability Directive – adoption by European Council'. www.taylorwessing.com/en/insights-and-events/insights/2024/10/product-liability-directive. Accessed 24 January 2025.

45 Barani M and Van Dyck P (2023) 'Generative AI and the EU AI Act – a closer look'. www.aoshearman.com/en/insights/ao-shearman-on-tech/generative-ai-and-the-eu-ai-act-a-closer-look. Accessed 24 January 2025.

46 European Artificial Intelligence Act (2024) 'Article 3: Definitions'. https://artificialintelligenceact.eu/article/3. Accessed 24 January 2025.

AI management systems standard

A source of potential future divergence identified was around the new ISO 42001 standard for AI management standards, developed by the International Organization for Standardization as a set of criteria for how AI-related risks and opportunities should be managed across an organisation.[47] It can be expected that the AI Act will lead to the EU adopting this via the European standards body CENELEC (the European Committee for Electrotechnical Standardization).

While the MHRA in the UK adopts medical device-specific ISO standards, ISO 42001 is not specific to medical devices, meaning it is unlikely that the MHRA will adopt it. ISO 42001 does not currently diverge significantly from provisions applied by MHRA, but future iterations or replacements of ISO 42001 could. This would lead to significant differences between how AI medical devices are regulated in the UK and EU.

Innovation and safety – trade off?

Roundtable attendees differed on the question of whether one regime was safer than another, and whether there was an important trade-off between innovation and safety. Some raised the concern that overregulation would affect competitiveness and innovation and claimed that both Medical Device Regulation and MHRA regulation were already sufficiently comprehensive. In both roundtables, attendees noted that highly regulated sectors, such as pharmaceuticals, can still see strong innovation. Some attendees believed it was crucial to create a regulatory environment that encouraged developers to bring their AI systems to market in their country or region first.

47 Dudley C (2024) 'The rise of AI governance: unpacking ISO/IEC 42001'. www.qualitymag.com/articles/98100-the-rise-of-ai-governance-unpacking-iso-iec-42001. Accessed 24 January 2025.

Costs and convergence

Related to the above, attendees broadly agreed that industry was averse to regulatory changes that increased time to market and financial costs. Some raised concerns that the AI Act would lead to increased bureaucracy by adding a layer of regulation deemed unnecessary. Contributors suggested that smaller developers of AI were at more risk of not being able to cope, allowing for greater market domination of larger firms with more regulatory capacity.

Additionally, as the UK is a relatively small market and the MHRA is set to keep recognising EU regulatory approval for at least several years, there is a reduced incentive to certify medical devices in the UK.[48] Information on registered medical devices from MHRA obtained under the Freedom of Information Act 2000 shows that, as of August 2024, only around half of the 600,000 medical devices on the UK market[49] had been registered under the UK's own regulatory system. Of these, only 455 were software.

From the perspective of industry, global consistency was an overarching preference, as this lowers costs. There was not seen to be much inherent logic in the UK diverging from EU considerably on AI regulation because of the much larger market size of its neighbour – another example of the regulatory 'Brussels effect' (the EU's influence on standards in other parts of the world).

Both the UK and EU have taken steps to reduce some of the cost burden on developers of AI regulation regimes. A key element of this has been the UK's creation of the AI Airlock[50] and the EU's creation of AI regulatory sandboxes.[51] In theory, these should give developers access to centralised infrastructure and guidance, which allows them to test products and demonstrate compliance. The UK AI Airlock is in its pilot phase until April 2025, while it is

48 Medicines and Healthcare products Regulatory Agency (2020, last updated 15 January 2025) 'Regulating medical devices in the UK'. www.gov.uk/guidance/regulating-medical-devices-in-the-uk. Accessed 24 January 2025.

49 Department of Health and Social Care (2024) 'Factsheet: medical devices overview'. www.gov.uk/government/publications/medicines-and-medical-devices-bill-overarching-documents/factsheet-medical-devices-overview. Accessed 24 January 2025.

50 Medicines and Healthcare products Regulatory Agency (2024) 'AI Airlock: the regulatory sandbox for AIaMD'. www.gov.uk/government/collections/ai-airlock-the-regulatory-sandbox-for-aiamd. Accessed 24 January 2025.

51 European Artificial Intelligence Act (2024) 'Article 57: AI regulatory sandboxes'. https://artificialintelligenceact.eu/article/57. Accessed 24 January 2025.

stipulated that the EU's sandbox will be operational in August 2026.[52] How effective either will be is therefore difficult to assess.

Capacity of UK bodies to regulate

Roundtable participants who were active in the UK market raised that UK regulators were in a poor position to implement any regime, regardless of substance. The MHRA was described as the best resourced among a group of very poorly resourced UK regulators, with its efficacy still heavily questioned. The Care Quality Commission (CQC), which also has a relevant regulatory role where AI products change how care works and there may be safety concerns, has been recently found to have significant deficiencies in organisational effectiveness.[53] It is likely to go through a phase of intense transition. Some roundtable attendees criticised the pace the National Institute for Health and Care Excellence (NICE) moves at, though tensions between the cost-effectiveness regulator and industry are inevitable. These raise concerns about a system that relies wholly on individual regulators to work effectively.

The AI Action Plan's adoption of the recommendation to 'commit to funding regulators to scale up their AI capabilities, some of which need urgent addressing', is a welcome acknowledgement of this issue.[54] The recommendation is accompanied by a requirement for liaison between regulators and government departments to identify future capability needs ahead of the 2025 spending review. With no funding currently committed, it is not possible to judge whether these measures will be effective.

52 Medicines and Healthcare products Regulatory Agency (2024) 'AI Airlock pilot call for applications'. www.gov.uk/government/publications/ai-airlock-pilot-call-for-applications. Accessed 24 January 2025.

53 Bliss A and Jones E (2024) 'Dash review of the CQC: what you need to know'. www.nhsconfed.org/publications/dash-review-cqc. Accessed 24 January 2025.

54 Department for Science, Innovation and Technology (2025) 'AI Opportunities Action Plan: government response'. www.gov.uk/government/publications/ai-opportunities-action-plan-government-response/ai-opportunities-action-plan-government-response. Accessed 24 January 2025.

Capacity of EU bodies to regulate

Concerns about the capacity of EU notified bodies to implement the AI Act were also raised in the roundtables. The implementation of the new EU Medical Devices Regulation saw serious delays to the point of near-breakdown as these bodies struggled to manage.[55] The general system of notified bodies as competing private regulators has been intensely scrutinised in the past. A focal point of concern towards this system, under its previous regulatory Directives, was French courts finding in 2017 that a German body that awarded regulatory clearance to harmful breast implants had neglected its duties and was liable for damages.[56]

Awareness and understanding of AI

Awareness and understanding of AI itself and AI regulation were seen as a barrier to compliance in both the EU and UK. This concerned all staff levels, including senior NHS management. It was raised that AI (such as OpenAI's ChatGPT) is currently being employed by some NHS staff in ways that could be in breach of the law, such as in the processing of secure data or aiding clinical decision-making, often due to a lack of awareness. Clinical liability in situations that involve AI was seen as highly problematic if clinicians do not have a robust understanding of how the AI they are using works. The AI Act does carry AI literacy requirements[57] but there was a high degree of scepticism among roundtable attendees as to whether these would deliver significant improvements in AI literacy.

55 MedTech Europe (2022) *MedTech Europe Survey Report: Analysing the availability of medical devices in 2022 in connection to the Medical Device Regulation (MDR) implementation*. MedTech Europe. www.medtecheurope.org/wp-content/uploads/2022/07/medtech-europe-survey-report-analysing-the-availability-of-medical-devices-in-2022-in-connection-to-the-medical-device-regulation-mdr-implementation.pdf.

56 Hervey T and McHale J (2015) *European Health Law*. Cambridge University Press.

57 European Artificial Intelligence Act (2024) 'Article 4: AI literacy'. https://artificialintelligenceact.eu/article/4. Accessed 24 January 2025.

Capacity to adopt AI within the NHS

Regardless of the regulatory regime, we heard that the capacity of the NHS to adopt digital technologies can act as a fundamental barrier to the sale and adoption of AI systems. Barriers raised by stakeholders in the UK include confused and unclear organisational policies and a lack of coordination.[58] Roundtable attendees also raised that NHS providers often currently fail to provide the necessary data for deployers to carry out post-market surveillance, which is an existing MHRA requirement.

The UK is also not taking part in the European Health Data Space, which imposes consistent standards and access methods to make it easier to access and analyse data generated from health care in the EU. This includes Northern Ireland, which will not be covered even though the regulation creating the new data rules builds on the Medical Devices Regulation, which does apply in Northern Ireland.

The future impact of divergence

AI will become an ever more important tool in health in the coming years, with rapid uptake not only in health systems but also by the public, bringing rapidly emerging opportunities and serious dangers. The UK's choice to make it one of only a few areas that will see a fundamentally different approach to EU regulation is important, but the impact will be driven as much by the quickly changing technology itself.

While the two regulatory approaches are structurally different, they have similar aims. Where AI is intended to diagnose, treat, predict or monitor illness as a medical device, both the EU and the UK build on a similar regulatory approach and are likely to rely on very similar technical requirements. Indeed, in many cases, the UK will rely on the EU to approve its devices for at least several more years – or longer.

58 Thornton N, Hardie T, Horton T and Gerhold M (2024) 'Priorities for an AI in health care strategy'. www.health.org.uk/publications/long-reads/priorities-for-an-ai-in-health-care-strategy. Accessed 24 January 2025.

Nevertheless, the AI Act does appear likely to bring additional costs by adding a supplementary layer of regulatory requirements. Some of our contributors across the EU and UK felt that this was a disadvantage to the EU approach, a disincentive to innovation and investment. On the other hand, its still-untested new forms of scrutiny, such as the Fundamental Rights Impact Assessment, do carry the potential to protect EU citizens in ways the UK does not. The potential for AI systems in the EU to become subject to new ISO requirements that are not medical device-specific could also mean a more demanding set of requirements than is applied by the UK's MHRA.

The AI Act promises to provide more scrutiny to types of AI system that do not fall so clearly into the basket of medical devices, or the other specifically regulated areas around which the UK system is built. This may pose a significant problem for the UK in future if staff and patients use general-purpose generative AI never intended for medical use, and not regulated as such, as a source of guidance, advice and even diagnosis. But the system created by the AI Act may also struggle to recognise and categorise such products.

The capacity of the NHS to adopt AI systems, meanwhile, is a barrier, which must be overcome regardless of regulatory approach in order to fully realise the benefits these systems promise.

The connections in geography, history, industry and people between the EU and the UK will push against divergence. A 'Brussels effect', where the developers and deployers of AI systems abide by EU rules beyond its borders, is likely to limit the impact of UK regulatory choices. If the MHRA ceases to accept devices with EU conformity assessment in 2030, this may increase the potential for divergence and associated costs for deployers, but will raise the problem that firms consider the UK simply too small a market to enter at all.

The connection to the EU will remain vital in practice. As the AI Act comes into force over the coming years, the UK government may choose to learn from its success or failure in regulating AI across the board, including where it is used for health care purposes for which it was not intended. But the global AI landscape is as uncertain as ever. One of the Trump administration's first

acts was to revoke an executive order aimed at reducing the risks of AI, and increasing AI transparency, in the US, showing that a move towards stricter AI regulation is by no means a universal direction of travel.[59]

The current UK government is currently remaining largely true to the central principles of the approach to AI regulation established under the previous administration. However, the commitment to take a new approach to regulating some of the most powerful AI systems[60] betrays the perception that some aspects of the existing approach are inadequate. The government's AI Action Plan does present AI as a policy priority but does not seek to alter the fundamental regulatory issues this chapter raises, such as the fragmentation of the UK's regulatory regime.[61]

Regulatory alignment is one approach to ensuring citizens have the best access to AI technologies, and the market will exert constant pressure on firms in the UK to follow EU rules. As in medicines and devices, cooperation with the EU to share knowledge on adverse events and risks may be very valuable – all the more so for systems so much less amenable to being judged safe in a single clinical trial. Against these forces, capturing any benefits from divergence will require careful strategy, a willingness to change course and a strong MHRA. And the power of rapid technological breakthroughs or major policy changes by global powers to completely change the field of play should not be underestimated. In short, it will be hard and ongoing work.

59 www.reuters.com/technology/artificial-intelligence/trump-revokes-biden-executive-order-addressing-ai-risks-2025-01-21

60 House of Commons (2024) 'King's Speech', *Hansard*, 17 July, volume 752. https://hansard.parliament.uk/Commons/2024-07-17/debates/2D7D3E47-776E-4B81-8E2A-7854168D6FED/King%E2%80%99SSpeech. Accessed 24 January 2025.

61 Department for Science, Innovation and Technology (2025) 'AI Opportunities Action Plan: government response'. www.gov.uk/government/publications/ai-opportunities-action-plan-government-response/ai-opportunities-action-plan-government-response. Accessed 24 January 2025.

5 Patients moving across borders

Britain's exit from the single market also meant the end of the EU law and processes that support people moving across borders to receive care.

- Citizens in the UK and the rest of the EU were mutually entitled to medically necessary health care during temporary stays in other member states under the European Health Insurance Card (EHIC) scheme.

- Retirees who had spent their working life in one country could be covered for health care in another, an entitlement conferred through an 'S1' form.

- An 'S2' form, with prior approval, gave patients the ability to cross borders to receive care publicly funded by their home country – something to which they had a right where there was an undue delay to treatment to which they were entitled.

- The most expansive measures were contained in a Cross Border Directive, which gave patients the right to access health care in any EU country and to be reimbursed for the care by their home country. Prior authorisation could again be required, and prescriptions were mutually recognised.

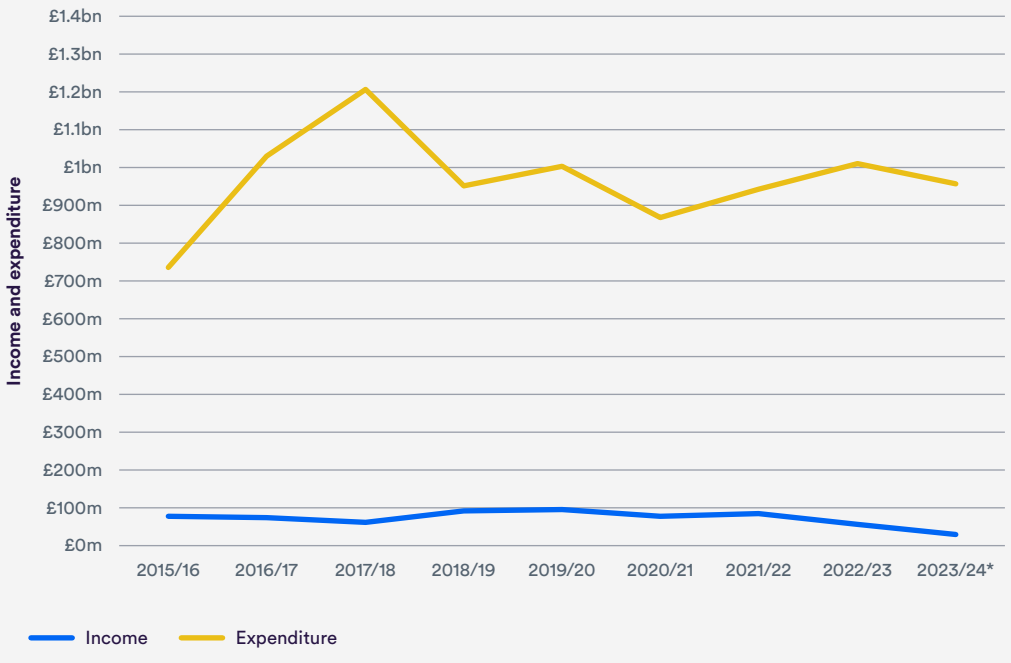
EHIC, GHIC, S1 and S2

In one of the clearest examples of the EU–UK Trade and Cooperation Agreement going far deeper than a normal trade deal, the agreement includes a Protocol on Social Security Coordination, which retains between the UK and the EU all the mechanisms for reciprocal health care classed as being of

this type.[62] These are the principles that underpin EHIC, S1 and S2. While the labels have sometimes changed – with the UK rebranding European Health Insurance Cards as 'Global Health Insurance Cards' (GHICs) – the institutions have continued on a similar basis.

Figure 14 shows UK Department of Health and Social Care income and expenditure in relation to reciprocal health care. Both are often received/paid some time after costs have incurred. For expenditure, it is notable that except for a peak following the EU referendum, possibly associated with nervous EU member states pressing their claims, expenditure has remained fairly constant. This suggests British residents are continuing to make use of reciprocal health care initiatives to a similar degree as before. Income, meanwhile, has reduced significantly, possibly reflecting reduced EU business and tourism travel to the UK.

Figure 14: UK Department of Health and Social Care income and expenditure in relation to reciprocal health care initiatives, real terms, 2015/16 to 2023/24



* 2023/24 figures are provisional and had not undergone final audit at the time of going to press.

62 European Commission (2021) 'Trade and Cooperation Agreement'. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2021.149.01.0010.01.ENG&toc=OJ%3AL%3A2021%3A149%3ATOC. Accessed 27 January 2025.

Source: Freedom of Information request to the Department of Health and Social Care. HM Treasury December 2024 Quarterly National Accounts www.gov.uk/government/collections/gdp-deflators-at-market-prices-and-money-gdp

From EHIC to GHIC

The new system for temporary visitors – which for UK residents means using GHIC to access care in Europe – is predominantly a like-for-like replacement for EHIC. However, unlike EHIC, GHIC can be used to access health care in a small number of non-EU countries and territories with which the UK has reciprocal health care agreements, including Australia, as well as in EU countries.[63]

In addition, while messaging from the Department of Health and Social Care that GHIC afforded continuity to citizens post-EU exit[64] was right in many cases, dialysis patients are one group that have seen significant restrictions on their access to care in the EU due to this change. While both schemes entitle British citizens to access dialysis services in the EU at no extra cost to the individual, they can no longer book dialysis directly with a privately operated dialysis unit. Instead, dialysis must be booked through a state-operated unit to be covered by GHIC,[65] although GHIC does cover scenarios where a state unit refers a patient to a private unit (such as due to capacity constraints). This places additional limitations on where individuals who require dialysis services can travel to. Additionally, we heard accounts of state-operated dialysis units refusing treatment under GHIC, or demanding upfront out-of-pocket payments, due to concerns about receiving reimbursement.

63 Department of Health and Social Care (2021) 'UK reciprocal healthcare agreements with non-EU countries'. www.gov.uk/guidance/uk-reciprocal-healthcare-agreements-with-non-eu-countries. Accessed 27 January 2025.

64 Department of Health and Social Care (2021) 'UK launches Global Health Insurance Card', press release, 11 January. www.gov.uk/government/news/uk-launches-global-health-insurance-card. Accessed 27 January 2025.

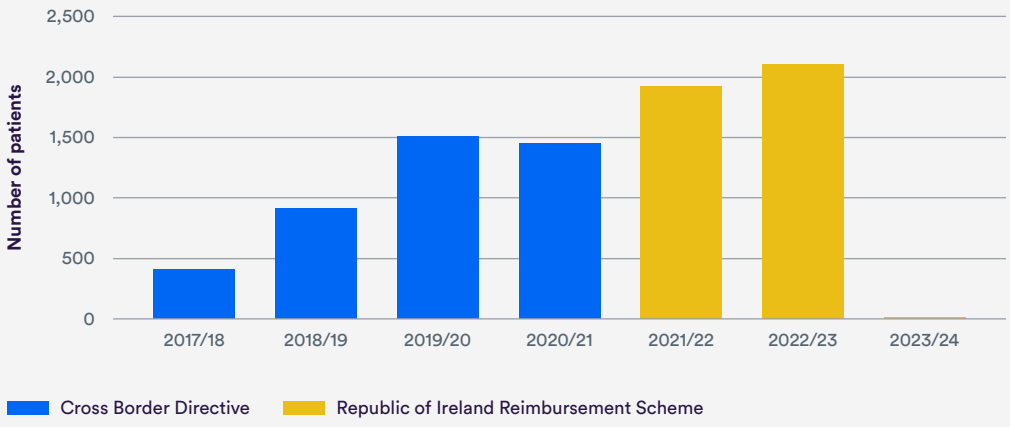
65 Kidney Care UK (no date) 'What are GHIC and EHIC cards?'. https://kidneycareuk.org/kidney-disease-information/living-with-kidney-disease/travelling-with-ckd/dialysis-away-from-base-dafb/#:~:text=What%20are%20GHIC%20and%20EHIC,are%20available%20free%20of%20charge. Accessed 27 January 2025.

The end of the Cross Border Directive: an uneven impact

The end of the Cross Border Directive saw no such replacement put in place between the EU and UK. The impact of this is being felt quite differently in Northern Ireland and Great Britain, reflecting a much greater effect of the Directive in the part of the UK where EU medical care is immediately available across an open border, and greater readiness to undergo more complex treatment.

Data obtained from the Department of Health in Northern Ireland show that over 1,000 patients had care in the EEA reimbursed under the Directive in each of the two financial years immediately before the UK's exit from the single market (see Figure 15). For two subsequent years, a 'Republic of Ireland Reimbursement Scheme' replaced this initiative. It was then cancelled in 2022/23. Just six patients in 2023/24, already having applied, were granted approval.

Figure 15: Number of patients from Northern Ireland receiving treatment in the EEA, reimbursed, 2017/18 to 2023/24



Note: The Cross Border Directive ceased to apply in December 2020.
Source: Freedom of Information request to the Department of Health, Northern Ireland

Data obtained from the Department of Health and Social Care at UK level show that, across 2018 and 2019, of 2,200 patients who received prior authorisation for care in the EEA, 2,029 (92%) came from Northern

Ireland. These would have been patients requiring hospitalisation or more specialised treatment.

By contrast, among patients who did not require prior authorisation under the Directive, likely for more minor procedures, most came from England. In total, over 5,000 patients were given approval for reimbursement after using this route in the three years before the UK's exit from the single market. No equivalent continued afterwards.

Research by UK in a Changing Europe shows that a small number of UK patients – under 200 each year – continue to receive previously authorised care in the EEA under the reciprocal health care provisions in the EU–UK Trade and Cooperation Agreement discussed earlier in this chapter.[66]

66 Vėlyvytė (2024) 'Brits (still) have the right to timely healthcare'. https://ukandeu.ac.uk/brits-still-have-the-right-to-timely-healthcare. Accessed 27 January 2025.

6 Has health lost funding from the European Union?

Structural funds

Upon leaving the EU, the UK lost access to the European structural and investment funds. Of these funds, the European Regional Development Fund and the European Social Fund(+) have been used to fund, among many other things, health and health care-related activities. These were replaced domestically by the UK Shared Prosperity Fund (UKSPF). However, the way this fund is spent is not necessarily the same. The Shared Prosperity Fund does not include the improvement of population health or health care in its three stated investment priorities,[67] and examples of Shared Prosperity Fund spending on specific health-related projects are not common at a local authority level.

In the funding period of 2014–20, the UK was planned to receive 40.5 million euros to fund health infrastructure, through the Regional Development Fund. This was only 0.37% of the total planned financing for the UK in this period. It was also only 0.24% of the total planned health infrastructure financing for all EU member states. No financing was planned for the UK under other health-related themes (with smaller funding pots).[68]

67 Local Government Association (no date) 'The UK Shared Prosperity Fund (UKSPF)'. www.local.gov.uk/topics/economic-growth/uk-shared-prosperity-fund-ukspf#:~:text=The%20UK%20Shared%20Prosperity%20Fund%20(UKSPF)%20is%20the%20government's%20domestic,%2C%20businesses%2C%20people%20and%20skills. Accessed 27 January 2025.

68 European Commission (no date) '2021–2027 cohesion policy overview'. https://cohesiondata.ec.europa.eu/cohesion_overview/21-27. Accessed 27 January 2025.

A total of £2.6 billion was pledged for the UK fund between 2022 and 2025.[69] The Sunak government claimed that this would deliver 'on the UK Government's commitment to match EU structural funds for each nation'.[70] However, there is no central data source that breaks down spending of the fund, meaning there is no reliable way to track past or planned spending on health or health care.

In the current EU Cohesion Policy funding period, 2021–27, there are two objectives specifically related to health and social care:

- 'equal access to quality social and healthcare services', funded through the Social Fund Plus
- 'access to health care', funded through the European Regional Development Fund.

Combined, these amount to nearly 19 billion euros of 'planned' spending.[71]

Pandemic recovery

As a result of leaving the EU, the UK was not eligible for the new EU funding streams created in the wake of the Covid-19 pandemic. The primary instrument for this was the EU Recovery and Resilience Facility (RRF), which made available 648 billion euros to invest in reforms and projects.[72] Of this, 357 billion euros were available as grants and 291 billion euros as loans. Country-specific allocations were determined by an allocation key accounting for pre-pandemic population, GDP per capita and average unemployment

69 Department for Levelling Up, Housing and Communities (2022) 'Government kickstarts £26 billion investment in communities as UK takes back control of EU funding', press release, 5 December. www.gov.uk/government/news/government-kickstarts-26-billion-investment-in-communities-as-uk-takes-back-control-of-eu-funding. Accessed 27 January 2025.

70 *Ibid*.

71 European Commission (no date) '2021–2027 cohesion policy overview'.

72 European Commission (no date) 'The Recovery and Resilience Facility'. https://commission.europa.eu/business-economy-euro/economic-recovery/recovery-and-resilience-facility_en. Accessed 27 January 2025.

rate.[73] Member states' recovery and resilience plans included approximately 37 billion euros of expenditure on health-related measures, of which around 25 billion euros were planned to be invested in health infrastructure.[74] There was very large variation in the proportion of total funds allocated to health-related measures by member states (ranging from 1.2% to 33.2%).[75]

It is difficult to calculate precisely how much the UK would have received from the Recovery and Resilience Facility, were it still an EU member state. However, assuming UK membership would expand the size of the overall funding package by approximately 10%, and that the UK received a proportion of the fund similar to that allocated to France, this would have totalled around 40 billion euros.[76] France, having received 40 billion euros, allocated 4.5 billion euros (or 11.3%) to health expenditure.[77]

There is no specific way to determine the proportion of UK government capital spending on the NHS that was used for post-pandemic recovery. Capital spending on health in England has generally been close to £10 billion a year recently, and is scheduled to further increase with proportional funding to Scotland, Wales and Northern Ireland.[78]

73 European Commission (2020) 'Questions and answers: Commission presents next steps for €672.5 billion Recovery and Resilience Facility in 2021 Annual Sustainable Recovery Strategy'. https://ec.europa.eu/commission/presscorner/detail/en/qanda_20_1659. Accessed 27 January 2025.

74 European Commission (2021) *Resilience and Recovery Scoreboard: Thematic analysis*. European Commission. https://ec.europa.eu/economy_finance/recovery-and-resilience-scoreboard/assets/thematic_analysis/5_Health.pdf.

75 *Ibid.*

76 European Commission (no date) 'Country pages'. https://commission.europa.eu/business-economy-euro/economic-recovery/recovery-and-resilience-facility/country-pages_en. Accessed 27 January 2025.

77 European Commission (2021) *Resilience and Recovery Scoreboard: Thematic analysis*. European Commission. https://ec.europa.eu/economy_finance/recovery-and-resilience-scoreboard/assets/thematic_analysis/5_Health.pdf.

78 HM Treasury (2024) *Autumn Budget*. GOV.UK. www.gov.uk/government/publications/autumn-budget-2024. Accessed 27 January 2025.

The impact on the health care sector

Although EU funding did, and would, form a very small proportion of overall health expenditure, this may have helped to compensate in areas where the UK has traditionally been relatively weak. For most of the past 25 years the UK has lagged behind comparable countries in the proportion of GDP it spends on health care capital investment, and the health service is burdened by a massive building repairs backlog, relatively low numbers of CT and MRI scanners, and other related issues.[79,80] Additionally, NHS capital budgets have regularly been raided to account for overspend in other areas.[81] Health care-related EU funding regularly goes towards infrastructure, and may have, to a limited extent, helped boost capital budgets. This funding would also have been ringfenced for infrastructure spend.

This kind of irreversible commitment is absent within the UK's approach to public finances, where cutting back investment spending at the last moment to subsidise overspending NHS trusts has been a repeated pattern in recent years in England. In Scotland, recent fiscal decisions have also tended to favour revenue over investment spending.[82]

The UK government has had the ability to fill these funding gaps from other sources, but this is an opaque landscape. Pandemic recovery spending is particularly difficult to compare because the UK did not use a mechanism similar to the EU Recovery and Resilience Facility to distribute recovery funding. The Shared Prosperity Fund does not appear to account for health-related gaps in funding previously provided by the EU, as this is not a focus area of the fund. A lack of centralised data makes it difficult to understand this issue in more detail.

79 Bulut M (2023) 'Would the NHS be in a better position had investment kept pace with comparable countries?'. www.nhsconfed.org/articles/would-nhs-be-better-position-had-investment-kept-pace-comparable-countries. Accessed 27 January 2025.

80 NHS Confederation (2023) 'NHS capital budgets must nearly double to ensure crumbling buildings and infrastructure are fit for 21st century patient care', press release, 28 November. www.nhsconfed.org/news/nhs-capital-budgets-must-nearly-double-ensure-crumbling-buildings-and-infrastructure-are-fit. Accessed 27 January 2025.

81 The King's Fund (2024) 'Capital investment in the NHS'. www.kingsfund.org.uk/insight-and-analysis/data-and-charts/nhs-capital-investment. Accessed 27 January 2025.

82 Scottish Parliament (no date) 'Total allocations'. https://digitalpublications.parliament.scot/ResearchBriefings/Report/2024/1/4/d19ce079-c10b-4a0f-b526-448852face3e#ec1b3806-2443-4424-b281-22a926ad7f0c.dita. Accessed 27 January 2025.

7 Procurement

Before Brexit, EU law directly shaped many areas of health – medicines, devices, clinical research – but generally left the running of health services untouched, reflecting their status as a member state competency. One field where it had a significant impact, often perceived as negative, was procurement law.

Following its departure from the single market, the UK announced significant changes, with the previous government highlighting this as a promising and positive area of 'ripping up EU regulations'.[83] In this chapter, we will look at what the true role of EU procurement law was; whether there are truly significant differences now; and what it means for the NHS and other areas crucial to health.

How the UK responded to EU procurement law

Before the application of EU law on public procurement[84] in the UK, the UK's approach differed significantly from that in other European countries.

Other European countries had their own legally binding rules on procurement, concerned with securing value for public money and preventing corruption (domestic objectives). The UK relied on 'soft law' guidance and professional training, rather than regulations based in hard law for different

83 Cabinet Office (2023) 'Procurement Bill to unleash opportunities for SMEs to be debated in Parliament'. www.gov.uk/government/news/procurement-bill-to-unleash-opportunities-for-smes-to-be-debated-in-parliament. Accessed 24 January 2025.

84 The relevant law consists in provisions of the Treaty on the Functioning of the European Union, and case law of the Court of Justice of the European Union (CJEU), consolidated and supplemented by directives. The key directive applicable in health care contexts is Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC [2014] L19/65, which has been significantly amended, supplemented and interpreted by CJEU case law. This creates a complex and unwieldy body of EU law.

specific areas of procurement. The UK approach allowed for more flexibility and variation between different government entities that purchased goods and services.

The EU's legal approach across all its member states also relied on rigid rules, but the basic aim underlying EU public procurement law is the opening up of markets to non-domestic suppliers (trade objectives).[85] When the UK implemented the EU public procurement directives, in effect it adopted a 'copy and paste' approach. This meant that the domestic objectives for public procurement law remained only in soft law, which is not legally binding, unlike in other EU member states where they sat alongside trade objectives in hard law, which is. This lack of a tailored pre-existing approach goes some way to explaining much of the UK health sector's dissatisfaction with the application of EU public procurement law.

Another unique factor was the decision to organise the English NHS, for most of the period from the 1990 NHS and Community Care Act, as an 'internal market'. This meant that even though the vast majority of health services remained owned by the government, they were classed as competitive economic 'undertakings'. Their contracts with local NHS payers to provide clinical services, from A&E to talking therapies, were subject to procurement law and the processes it required. This was a common source of resentment, often described as pointless bureaucracy and resulting in calls for its removal by the Labour opposition ahead of Brexit. The UK government introduced an NHS-specific version of these requirements in 2012, but this replicated broadly similar obligations, and introduced special enforcement within the health service.[86]

85 Arrowsmith A (2023) 'The evolution of procurement law in the United Kingdom: a common law perspective on regulating contract award procedures'. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4756144. Accessed 24 January 2025; [author/organisation] (2025: forthcoming) '[title of article]', *Public Procurement Law Review* 33.

86 Collins B (2015) *Procurement and Competition Rules: Can the NHS be exempted?* The King's Fund. www.kingsfund.org.uk/insight-and-analysis/reports/nhs-procurement-competition-rules. Accessed 24 January 2025.

Apart from allegations of pointlessness and bureaucracy in the English NHS, other common criticisms of procurement law before Brexit were that it did not allow government bodies to take into account supporting local or small businesses.

After Brexit: a different UK path

Leaving the single market meant this could change. On leaving the EU, the UK initially kept the EU public procurement directives as 'retained EU law'.[87] But the 2023 Procurement Act revokes this and replaces it with domestic law. It will have (mostly) come into effect on 24 February 2025[88] and applies to procurements 'commenced' thereafter.[89]

The UK remains bound by its international obligations, including in the EU–UK Trade and Cooperation Agreement (TCA) signed after exit from the EU,[90] and under World Trade Organization (WTO) law.[91] These create obligations to protect access for non-domestic traders to public contracts, and to maintain a level of transparency. They are nowhere near as rigid, detailed, comprehensive or readily enforceable as the obligations of EU law.

87 Public Procurement (Amendment) (EU Exit) Regulations (SI 560/2019); Public Procurement (Amendment) (EU Exit) (No.2) Regulations (SI 623/2019); Public Procurement (Amendment) (EU Exit) Regulations (SI 1319/2020).

88 Procurement Act 2023, c. 54, schedule 11, para 5, as specified in SI 2024/716 reg.2(2) and schedule 1 subject to savings specified in SI 2024/716 reg.5 as amended by SI 2024/959 reg.2(2) and (4)).

89 Government Commercial Function (2022) 'Transforming public procurement'. www.gov.uk/government/collections/transforming-public-procurement. Accessed 24 January 2025.

90 See Title VI and Annex 25. Article 276: 'The objective of this Title is to guarantee each Party's suppliers access to increased opportunities to participate in public procurement procedures and to enhance the transparency of public procurement procedures.'

91 The Agreement on Government Procurement DATE. www.wto.org/english/tratop_E/gproc_e/gp_gpa_e.htm. Accessed 27 January 2025.

Content of the new 2023 Procurement Act

The 2023 Procurement Act aims both to reflect the UK's new trade commitments and policies after Brexit and to achieve domestic objectives. It simplifies rules on the selection of providers of goods and services to public entities, based on the objectives and principles of:

> *(a) delivering value for money;*
> *(b) maximising public benefit;*
> *(c) sharing information for the purpose of allowing suppliers and others to understand the authority's procurement policies and decisions;*
> *(d) acting, and being seen to act, with integrity.*[92]

The principle of non-discrimination between suppliers continues,[93] subject to justification,[94] particularly taking into account the position of small and medium-sized enterprises – an attempt to address this concern.[95]

Exceptions to the 2023 Procurement Act: devolved administrations and clinical services in England

The full application of the 2023 Procurement Act to Scotland, Wales and Northern Ireland is only relevant to those public services that are not devolved, such as the army and navy.[96] For domestic services such as health, these jurisdictions can and do make their own rules, in a 'patchwork of complex UK-wide and nation-specific regulation'.[97] While the UK was a member of the EU, separate procurement regimes compliant with EU law emerged in each country of the UK. For example, Scotland developed rules

92 Procurement Act 2023, section 12 (1).
93 Procurement Act 2023, section 12 (2).
94 Procurement Act 2023, section 12 (3).
95 Procurement Act 2023, section 12 (4).
96 Procurement Act 2023, part 11.
97 See Butler LRA and Thomas J (2024) *UK Public Procurement Regulation and Devolution – Single UK Market or Postcode Lottery*. Paper presented at the 'Public Procurement: Global Revolution 2024' conference, University of Nottingham, 17–18 June, Nottingham.

on sustainable procurement, community benefits and fair work[98] and Wales's procurement regime includes the objective of promoting wellbeing, including of future generations.[99]

Scotland's public procurement rules in health will continue to apply as before, because Scotland had power to implement the previous EU procurement rules. Wales is experimenting with its own 'social value' procurement goals, which apply *inter alia* to health commissioning.[100] Northern Ireland has its own public procurement policy, which applies in health contexts.[101]

For England, the 2023 Procurement Act gives power to ministers, through regulations, to disapply its provisions to 'regulated health procurement':[102] that is, procurement under the National Health Service Act 2006.[103] This power has been exercised in England so that regulated health procurement is not covered by the new rules in the 2023 Procurement Act.[104] This covers health care services for the purposes of the health service in England, and other goods or services that are procured together with such services. Health care services (which includes 'facilities') are 'all forms of health care provided for individuals, whether relating to physical or mental health', including those also involving social care as part of the same service.[105] In Wales, a new Act has also amended the Procurement Act as it applies there, allowing Wales also to adopt specific regulations on the procurement of services provided as part of the health service.[106]

98 Procurement Reform (Scotland) Act 2014.
99 Future Generations (Wales) Act 2015.
100 Digital Health and Care Wales; Health Education and Improvement Wales as 'contracting authorities' – see Social Partnership and Public Procurement (Wales) Act 2023, schedule 1, para 2; Public Health Wales; Velindre NHS Trust (cancer service); Well-being of Future Generations (Wales) Act 2015, section 6, listing local health boards; Welsh Ambulance Services University NHS Trust.
101 Department of Finance (no date) 'List of public bodies to which NI public procurement policy applies'. www.finance-ni.gov.uk/articles/list-public-bodies-which-ni-public-procurement-policy-applies. Accessed 27 January 2025.
102 Section 120 for England; section 120A for Wales.
103 'section 12ZB of the National Health Service Act 2006 (procurement of health care services etc for the health service in England), whether or not that provision is in force'.
104 See Procurement Regulations 2024. www.legislation.gov.uk/uksi/2024/692/contents/made. Accessed 27 January 2025.
105 Health and Social Care Act 2012. www.legislation.gov.uk/ukpga/2012/7/contents, section 150. Accessed 27 January 2025.
106 Health Service Procurement (Wales) Act 2024. www.legislation.gov.uk/asc/2024/1/contents. Accessed 27 January 2025.

For those services, the general procurement law has been replaced by special guidance. This was implemented through the Health Care Services (Provider Selection Regime) Regulations 2023, which came into force on 1 January 2024.[107]

The Provider Selection Regime for the English NHS – addressing past concerns?

The Provider Selection Regime imposes obligations that are similar to, but not as wide as, those of the 2023 Procurement Act:

> *(1) When procuring relevant health care services, a relevant authority must act –*
> *(a) with a view to –*
> *(i) securing the needs of the people who use the services,*
> *(ii) improving the quality of the services, and*
> *(iii) improving efficiency in the provision of the services;*
> *(b) transparently, fairly and proportionately.*
> *(2) When acting with a view to the matters in paragraph (1)(a), the relevant authority may consider the value of providing services in an integrated way, including with other health care services, health-related services or social care services.*[108]

The Provider Selection Regime creates different routes to select a provider. Two of these offer wide exemptions from the usual requirement to be willing to offer a formal, open, competitive process. The 'direct award process' allows NHS bodies to simply give a contract to a provider that they are satisfied is the only one available, or which 'is satisfying its existing contract' and is likely to satisfy the new one. In short, it allows the seamless 'rolling over' of contracts with existing providers.[109]

107 Health Care Services (Provider Selection Regime) Regulations 2023. www.legislation.gov.uk/uksi/2023/1348/contents/made. Accessed 27 January 2025.
108 Health Care Services (Provider Selection Regime) Regulations 2023, Regulation 4 (1) and (2). www.legislation.gov.uk/uksi/2023/1348/contents/made. Accessed 27 January 2025.
109 Bevan Brittan (2022) 'The Provider Selection Regime'. www.bevanbrittan.com/insights/articles/2022/the-provider-selection-regime. Accessed 27 January 2025.

A ‘most suitable provider’ process allows contracting authorities to simply select, following notification, the provider that best suits criteria they draw up on suitability, economic viability and technical capacity.[110] This allows firms or NHS trusts to be awarded a contract, renewal or extension without the need for a further tendering process.[111]

For all other goods and services purchased by NHS England, the new Act applies. These include purchase of:

- medicines
- vaccines
- medical devices and equipment
- IT hardware and software
- administrative and other back-office services
- adult social care
- capital works
- business consultancy.

Those that can be reasonably supplied under a separate contract from the health care contract itself will fall under the new Act.

Implications of the 2023 Procurement Act

What does the Procurement Act itself mean for those other products and services that are not specially carved out in England’s Provider Selection Regime, or in Wales?

110 Health Care Services (Provider Selection Regime) Regulations 2023. www.legislation.gov.uk/uksi/2023/1348/contents/made. Accessed 27 January 2025.

111 Local Government Lawyer (no date) ‘Procurement and contracts’. www.localgovernmentlawyer.co.uk/procurement-and-contracts/308-procurement-features/55756-all-change-for-commissioning-health-and-social-care. Accessed 27 January 2025; Mills & Reeve (2023) ‘New year, new thresholds, new Provider Selection Regime’. www.procurementportal.com/blog/december-2023/new-year-new-thresholds-new-provider-selection-reg. Accessed 27 January 2025.

In other countries, a systemic preference for non-profit providers in sectors such as health and social care is constitutionally protected. The UK has no such provision.[112]

The 2023 Act requires that contracts be awarded to the supplier offering 'the most advantageous tender'[113] This departs from the previous regime, based on EU law, which focuses more specifically on price or cost. The new rules provide a space to experiment with giving preference to different forms of 'social purpose companies' whose articles of incorporation would reach beyond shareholder profit maximisation and include objectives of public service and benefit. Provided that public budgets permit, NHS England could contract for any goods or services on the basis of quality, including social value such as social, economic or environmental wellbeing, so long as it also took into account the principle of value for public money.[114]

Such approaches, also when combined with the 2023 Act's new transparency rules,[115] might improve matters in terms of extractive contracting, such as seen during the procurement of personal protective equipment (PPE) from very small and recently incorporated firms during the Covid-19 pandemic.[116] However, transparency rules alone are unlikely to reduce corruption or exploitation, and in this regard the Act did not go as far as some had hoped.[117]

112 In fact, a proposed clause in the Procurement Bill 2022–23 that suggested such a provision, was rejected in parliamentary debate. See Boeger, N (2024) *Rethinking governance in public service outsourcing*. Bristol University Press, p.103.

113 Procurement Act 2023, section 19 (2).

114 Procurement Act 2023, section 19 (1).

115 Procurement Act 2023, sections 52, 71 and 95.

116 Transparency International UK (2021) *Track and Trace: Identifying corruption risks in public procurement for the COVID-19 pandemic*, p 23. www.transparency.org.uk/sites/default/files/pdf/publications/Track%20and%20Trace%20-%20Transparency%20International%20UK.pdf. Accessed October 2024

117 For example, proposals on tax transparency; non-performance clawback clauses; and open-book accounting. See Boeger, above, p 69.

The new flexibilities in the 2023 Act are not explicitly available in the Provider Selection Regime, which is carved out of it, and applies to health services as is described above; instead, a 'level playing field' is supposed to apply to commercial, third sector and public providers.[118]

Overall, the divergence from EU law for NHS procurement of clinical services does address rules that, because of England's unique 'internal market', created a disproportionate administrative burden when the winning supplier was obvious all along. However, the new procurement regime for health achieves this by generally relaxing rules in a way that gives considerable advantages to existing suppliers.

Because England has relied on moving away from EU law to reduce demands on NHS procurement, instead of adjusting how the health service's 'internal market' works, realigning with the EU would mean an immediate reversion.

Meanwhile, the approach within the health service in England does less than it might to protect some other flexibilities that could be relevant to health. These might include developing long-running relationships with trusted locally based suppliers that also support local communities, rather than relying only on cost, capability and value for money.

118 See NHS England (2023) 'The Provider Selection Regime: statutory guidance', updated 22 August 2024. www.england.nhs.uk/long-read/the-provider-selection-regime-statutory-guidance. Accessed 27 January 2025.

8 Conclusion

Our survey in this report of several areas of crucial importance to health represents our final overview of health in the UK as it has been affected by Brexit – and the broadest. The UK state has begun, after a slow start in several areas, to respond to Brexit in its key health policies. But the level of progress is uneven, and very different strategies are being pursued.

In many areas, such as medical devices, the UK has been sticking with the EU law it inherited, or even actively mimicking its larger neighbour. But in procurement, staff training and AI, it has now taken different choices – though the extent of difference is often overstated. For migration, medicines and funding, meanwhile, the UK has struggled to find a new equilibrium. A historic shift to recruiting staff trained outside the UK or the EU is already in tension with the domestic politics of migration, ethical concerns and the limits to generating the right kind of staff through reliance on the training programmes of other countries.

In all these areas, constant change in technology and in EU law and policy means that Brexit is not a policy issue that can be resolved but an ongoing source of tension and pressure.

The UK's different strategies in professional regulation and AI would complicate any fundamental move to realign with the EU in these areas: UK nursing education would need to be redesigned again, back to the greater number of clinical training hours required under EU law. Yet it remains unclear whether the aspiration expressed by the current UK government for wide-ranging alignment can be met in the long term without a reconnection to the single market, which would require this.

In the long term, there are both political and legal reasons why a country might struggle to be divergent in some areas and aligned in others, taking a competitive stance in some areas and a cooperative one in others.

For sectors that often involve international trade, including AI, divergence creates an intrinsic cost from companies complying twice. This creates a standing disadvantage set against any intrinsic benefits. The UK's health sector will need to be alert to and honest about the difficult question of whether doing things differently is really delivering benefits. The 'reset' of relations planned for this spring may offer an option to truly align in certain areas, as we have discussed elsewhere,[119] but this will largely not be easy to negotiate.

The shift to recognising medical devices approved by a range of countries, and the switch to recruiting from outside the EU, also underline that health in the UK is inseparable from a global context, which extends to the United States and Asia. Having left its nearest large market, getting the supplies and the skills needed for health, health care and social care in the UK will require an ever-changing international policy effort in a way that was never true before Brexit.

119 Dayan M, Hervey T and Lobont C (2024) 'How could Britain and the EU work together to improve health?' Nuffield Trust blog. www.nuffieldtrust.org.uk/news-item/how-could-britain-and-the-eu-work-together-to-improve-health

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Nuffield Trust is an independent health and social care think tank. We aim to improve the quality of health care in the UK by providing evidence-based research and policy analysis and informing and generating debate.

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