



Research report April 2024

The future for health after Brexit

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Executive summary

Following on from our 2022 report looking at the health landscape six years on from Brexit, this report aims to look deeper at key trends we identified in the supply of products needed for health, the life sciences, migration and the health and care workforce. It also looks at the options and priorities for addressing the issues raised. The report concludes by examining what the prospects are for enhanced cooperation with the EU and its institutions so that health in the UK can be improved.

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 UK.

Key findings

- Multiple indicators show that the past two years have seen constantly elevated medicines shortages, in a new normal of frequent disruption to crucial products, which if anything worsened in 2023. This has placed a significant burden on pharmacists, and has affected the medicines available to patients. The English NHS had to increase medicine prices to deal with supply problems on a scale which cost £220 million more in one year than the same products would have at their previous costs.
- These shortages reflect significant problems in the global medicine market, which are also having a serious impact in EU countries. However, Brexit has also contributed to difficulties by lowering the value of sterling and removing the UK from EU supply chains. In future it will pose the additional risk of being left out of EU measures to respond by shifting medicine between member states, buying products jointly, and trying to bring manufacturing back to Europe.
- The UK has intensified its reliance on migration following Brexit as a source for both health and social care workers. An expansion in social care

workers in England is entirely due to migration from outside the EU; more EU and UK staff have left than joined the social care workforce.

- Health care migration draws heavily on countries placed on the World Health Organization’s ‘red list’, which applies to countries judged to have too few trained clinicians for employers and recruiters from other countries to be allowed to recruit them. There are now 45,000 staff from red list countries in the English NHS, a 30% increase in just one year. One in five nurses trained outside the UK or EU who joined the UK register came from these countries in 2022/23.
- Heavy reliance on migration without the underpinning of EU free movement of labour means a permanent risk of political choices suddenly affecting staffing availability. The recent decision to end the rights of social care workers to bring their dependants to the UK illustrates that the sector’s access to migration is subject to unpredictable change.
- Life science and medicine regulation in Great Britain is now often lagging behind such regulation in the EU, caught between the strategies involved in trying to diverge and the demand from industry to align. The EU’s new law on artificial intelligence opens up a significant point of divergence from the UK and risks dividing off markets for medical devices. This could create a difficult situation in Northern Ireland, which has to align with EU rules on devices, but potentially with UK rules on artificial intelligence. In most other cases, the UK has moved towards realigning with the EU, but in a way that the life sciences industry has found unpredictable.
- There is a similar pattern across both the movement of people and products, with the UK rapidly moving away from initial efforts to take a different course after Brexit and returning to strategies used during the period of EU membership, but with additional frictions.
- Medicine authorisations for products that the EU approves centrally are typically slower in Great Britain than they would be if it were still a member state. From December 2022 to December 2023, four drugs authorised by the European Commission had been approved faster in Great Britain than in the EU; 56 had been approved later in Great Britain; and 8 had not been approved at all in Great Britain as of March 2024.

- Our research with stakeholders suggests that, despite some recovery in relations between the EU and the UK, rebuilding the EU-UK health relationship at a formal level is not currently a priority for EU institutions and representative bodies, which have gone through an exhausting and at times bitter negotiation process with London, and are faced with many ambitious health reforms in train in Brussels.

Key recommendations

- The health sector cannot rely on big formal changes to the EU-UK relationship any time soon. How much change is possible will depend on what the UK is willing to offer across all sectors. But UK organisations are already rebuilding and maintaining links to EU counterparts. Provisions in the EU-UK Trade and Cooperation Agreement already set out areas for the UK government and the EU to cooperate over, and there is more that could be achieved here.
- If formal agreements between the EU and UK were reopened, which would require either real give and take across sectors or an ambitious framework to cooperate over health specifically, there are certain provisions that would be significantly positive for life sciences, medicine supply and other aspects of health security in the UK. These include mutual recognition of batch testing for medicines, and anything that is possible in smoothing clinical trials across the two jurisdictions. However, it is important not to assume that it will be possible to eliminate all or even most of the frictions that Brexit has caused through renegotiation within the confines of what would be essentially a trade agreement – far from a return to a single market.
- There are steps well within the powers of the UK government to address these problems, which do not require renegotiating with the EU. Better anticipation of medicine shortages, more openness about shortages in line with other European countries, being careful that sudden squeezes on cost do not drive instability and having a plan for the EU's stockpiling and medicine transfer schemes would all be positive steps which require no international negotiation.

- Building on the English NHS Long Term Workforce Plan and its equivalents in the other UK countries to create a sustainable domestic health care workforce, and expanding this to social care, could eliminate many of the underlying risks that leave the NHS and care sector so exposed to changes in migration policy and so dependent on sometimes ethically dubious international recruitment. Similarly, there is a credible policy agenda to improve the attractiveness of life sciences in the UK, which could help to balance losses in access to the EU's clinical trials system, and previously science funding.
- The UK government should be honest about the many areas where alignment has proven the best option, and where it has chosen to continue with rules and strategies developed during the period of single-market membership. Having to follow different regulatory processes in different countries is commercially unwelcome, and successive UK governments have often listened to the pleas of businesses to avoid this. Setting this out more clearly would help to avert uncertainty, which affects services and industries that deal with data regulation, medical devices and the migration of care workers.

1 What has happened to the supply of products needed for health since Brexit, and why?

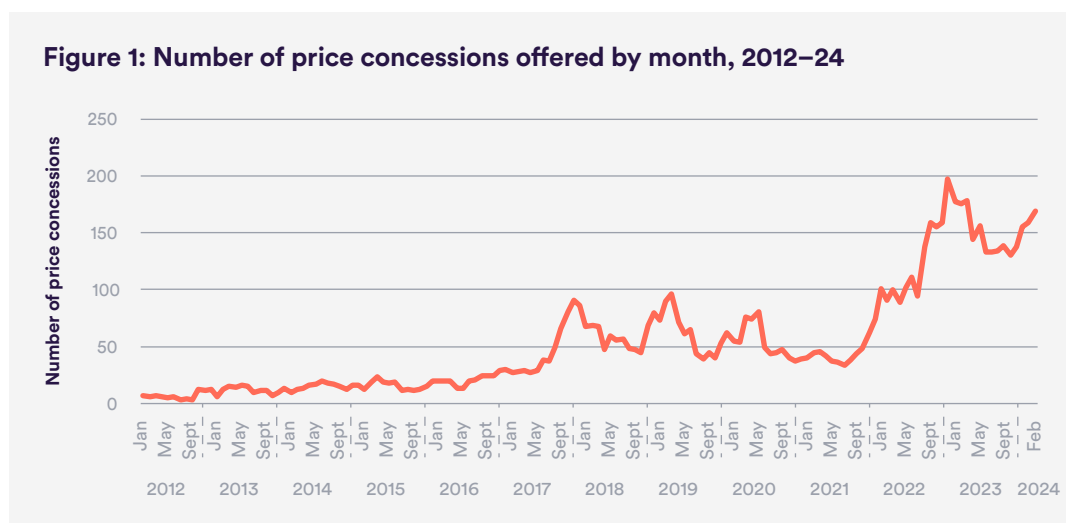
The supply of pharmaceuticals and medical devices to patients is the most critical and direct role for internationally traded products in supporting health in the UK. We noted in our previous report on health and Brexit that, while stockpiling and new routes into the UK had averted an immediate catastrophic impact from leaving the single market, every sign suggested that by autumn 2022, medicine shortages in the UK had reached historic highs.¹ For this report, we convened a roundtable of key stakeholders and conducted interviews to dig further into whether this was continuing, why it had occurred and what might be done about it.

Medicine supplies in the UK: key trends

All available indicators suggest that serious problems securing the medicines that NHS patients need continued or worsened through the remainder of 2022 and throughout 2023.

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/sites/default/files/2022-12/1671199514-health-and-brexit-web.pdf.

Price concessions are offered by the Department of Health and Social Care (DHSC) when pharmacists find that they cannot secure products at the price set out in the NHS list for repaying them.² They indicate that the price is no longer enough to import medicines into the UK, or to compete with other countries. In the four years up to mid-2016, the number of price concessions that had to be issued never exceeded 20 in a given month, and was often in single figures. Since this time, it has been consistently far higher, reaching a peak of 199 in late 2022 and remaining highly elevated ever since (see Figure 1).



Source: Community Pharmacy England (2013) 'Price concession archive'³

These price concessions now make up a significant cost to the NHS prescribing budget. A precise calculation is not possible with the available data, because they do not show the exact day of dispensing, and the pack sizes for which concessions are granted may not cover all the medicines of a particular type. However, an analysis for this report of prescribing data from October 2022 to September 2023 looked at the average 'net ingredient' cost of drugs in the months for which they were on the concessions list, compared with their average cost in any months within the previous six in which they

2 Community Pharmacy England (2020) 'Price concessions', last updated 15 March 2024. <https://cpe.org.uk/funding-and-reimbursement/reimbursement/price-concessions>. Accessed 20 March 2024.

3 Community Pharmacy England (2013) 'Price concession archive', last updated 4 March 2024. <https://cpe.org.uk/funding-and-reimbursement/reimbursement/price-concessions/archive>. Accessed 20 March 2024.

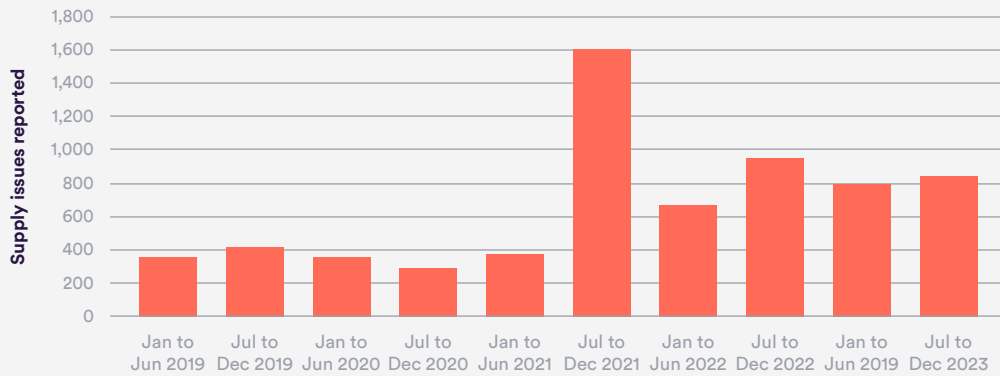
were not on the list. This was a highly cautious approach, discounting those medicines that were on the list for so long that there was no available reference price within six months. Total excess costs for medicines in the months when they were on the concessions list, above and beyond their recent average costs, came to £220 million.^{4,5}

This massive expansion of extra payments to secure medicine has been accompanied by general price increases in recent years. The drugs dispensed from English community pharmacists in August 2023 would have cost 8% less at their 2021 prices, equivalent to £800 million in extra spending. NHS spending on drugs dispensed as generic rose sharply in 2022/23 after several years of being relatively flat.

Yet shortages appear to be considerably elevated nonetheless. Under 2018 regulations intended to prepare for Brexit, pharmaceutical suppliers must notify the Secretary of State for Health and Social Care if there is ‘likely to be a supply shortage’ affecting patients.⁶ Up until mid-2021, most six-month periods saw around 300 to 400 such notifications (see Figure 2). An alarming spike in 2021 illustrated fears over the ability to supply Northern Ireland after the UK left the single market.⁷ Since then, the volume has stabilised but at a level around twice as high as previously – despite the resolution of many immediate supply fears for Northern Ireland through a series of grace periods, followed by the Windsor Framework agreement between the UK and the EU.⁸

- 4 NHS Open Data Portal (various years) ‘Prescription cost analysis (PCA) monthly administrative data’. <https://opendata.nhsbsa.net/dataset/prescription-cost-analysis-pca-monthly-data>. Accessed 20 March 2024.
- 5 Community Pharmacy England (2013) ‘Price concession archive’, last updated 4 March 2024. <https://cpe.org.uk/funding-and-reimbursement/reimbursement/price-concessions/archive>. Accessed 20 March 2024. Accessed 20 March 2024.
- 6 Legislation.gov.uk (2018) ‘The Health Service Products (Provision and Disclosure of Information) Regulations 2018’. www.legislation.gov.uk/uksi/2018/677/regulation/29/made. Accessed 20 March 2024.
- 7 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 20 March 2024.
- 8 Nuffield Trust (2023) ‘Nuffield Trust response to Windsor Framework on Northern Ireland: Mark Dayan responds to the Windsor Framework agreed between the UK and EU’. www.nuffieldtrust.org.uk/news-item/nuffield-trust-response-to-windsor-framework-on-northern-ireland. Accessed 20 March 2024.

Figure 2: Number of anticipated medicine supply issues reported to the DHSC, 2019–23

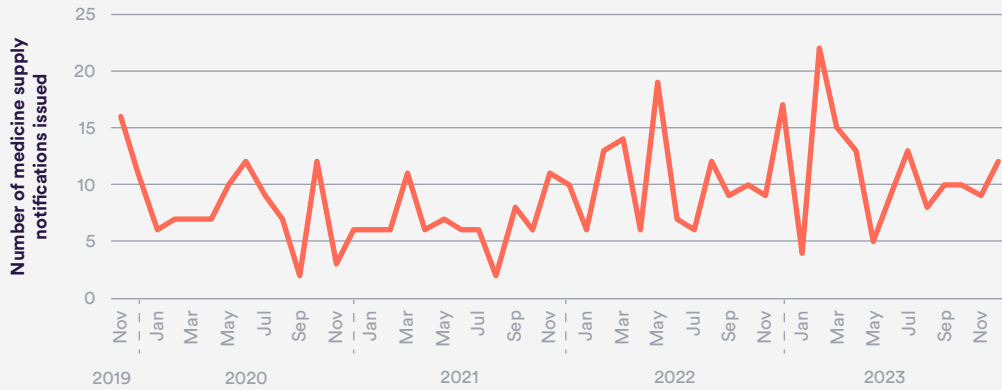


Source: Freedom of Information request to the DHSC

The DHSC and a team in NHS England issue alerts to hospitals and general practitioners (GPs) when shortages are likely to have an impact on patient care or ways of working. Since 2019, medicine supply notifications have been a category of these, generally issued for the higher tiers of ‘clinical escalation’, when supply problems are ‘likely to carry moderate to high patient safety risk’.⁹ The number issued each month fluctuates (see Figure 3), but was consistently elevated in 2022 and 2023, with a monthly average of seven in the previous two years, rising to over 10.

9 Medicines and Healthcare products Regulatory Agency (2022) ‘Update from the CAS helpdesk’. www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103953. Accessed 20 March 2024.

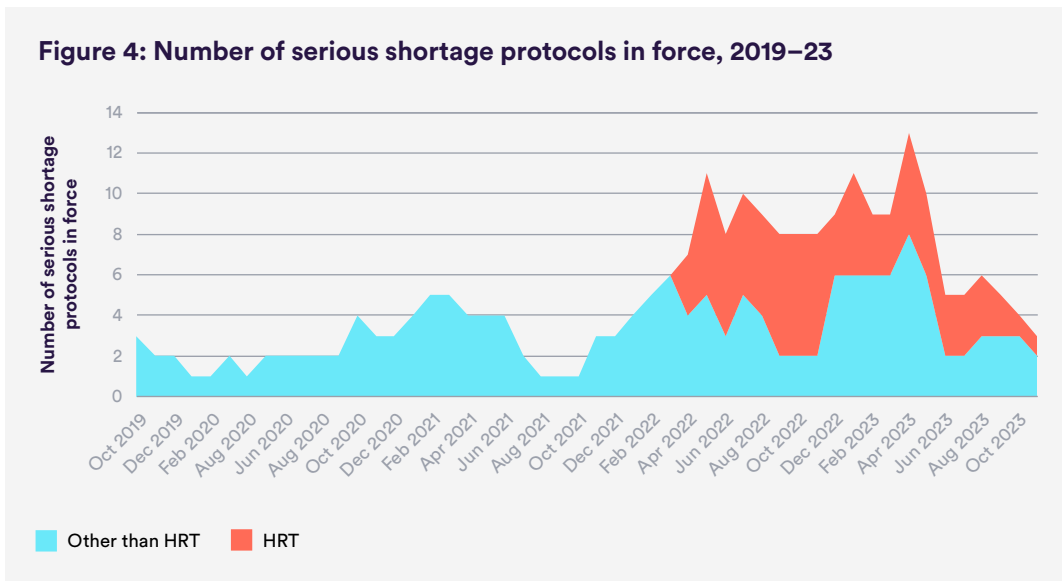
Figure 3: Number of medicine supply notifications issued by the DHSC and NHS England, 2019–23



Source: Freedom of Information request

The most serious administrative response to a medicine shortage in England is the declaration of a ‘serious shortage protocol’, allowing pharmacists to give patients something different from what they have been prescribed – for example, a different strength of pill, or a liquid formulation instead of a pill. This was intended as a rare tool when other measures had been exhausted, but multiple protocols have generally been in force since their introduction. There were sharp spikes in 2022 and 2023 (see Figure 4). These were largely, but not uniquely, associated with the shortage of hormone replacement therapy (HRT), which failed to expand enough in supply after prescribing rose sharply with increased awareness, caps on prescription charging through prepayment and clinical acceptance that the products were safe and effective.¹⁰

10 Appleby J (2022) ‘Chart of the week: hormone replacement therapy prescriptions rise 42% in one year’. www.nuffieldtrust.org.uk/resource/chart-of-the-week-hormone-replacement-therapy-prescriptions-rise-42-in-one-year. Accessed 20 March 2024.



Source: NHS Business Services Authority

Charities working with patients have reported troubling increases in helpline calls associated with particular shortages. Epilepsy Action reported five times as many calls in early 2024 as a year earlier, associated with worrying shortages of the key medications carbamazepine, sodium valproate, and lamotrigine.¹¹

Contributors to this project told us that they tended to view several of these measures as potentially understating the scale of medicine shortages in the UK. They believed that, in certain circumstances where there was a risk of losing contracts, suppliers might delay notifying a possible shortage, even as pressures mounted, in the hope of restoring provision at the last moment. DHSC and NHS England continued to press to improve this. At the same time, the DHSC and NHS England would sometimes push back against reports from pharmacists of shortages as being localised and not reflective of a genuine national problem. However, it is unclear why persistent local shortages should exist at a scale some found difficult to deal with if there is enough product in the UK as a whole: the market is national and the wholesaling industry is sophisticated.

11 Epilepsy Action (2024) 'Epilepsy medicine shortages continue'. www.epilepsy.org.uk/epilepsy-medicine-shortages-continue

The picture in the EU

As we noted in our previous report on health and Brexit,¹² this predicament is far from unique to the UK. There is every indication that medicine shortages would be a major problem in the UK even as an EU member state.

The Pharmaceutical Group of the European Union (PGEU) polls community pharmacists across the EU, Kosovo, North Macedonia and Türkiye about the issues they face with shortages. In 2022, it found that all countries experienced shortages. Three-quarters said that the situation was worse than the year before, and nine in 10 said it had resulted in interruption to treatment. Manufacturing disruption was perceived as the most common cause, followed by quotas (presumably a response to existing problems) and increases in demand.¹³

Solutions differ between member states and range from generic substitution, to offering alternative dose sizes or mixtures. However, this can only be achieved through doctors issuing a new prescription. In France, patients cannot change the pharmacy they use to access medication. As a result, the PGEU survey recommends:

- measures to improve EU harmonisation, transparency and supply
- compensation for financial loss
- increased professional competence for pharmacists (for example, Spain authorised pharmacists to issue alternative dosages of paediatric amoxycillin).

The most recent survey of the European Association of Hospital Pharmacists, which polls doctors, nurses, pharmacists and other health professionals in Europe, including the UK's Guild of Healthcare Pharmacists, shows that a

12 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/sites/default/files/2022-12/1671199514-health-and-brexit-web.pdf.

13 Pharmaceutical Group of the European Union (no date) *Medicine Shortages: PGEU survey 2022 results*. PGEU. www.pgeu.eu/publications/medicine-shortages-pgeu-survey-2022-results. Accessed 20 March 2024.

clear majority of hospitals experienced shortages in 2023.¹⁴ Respondents cited many interlinked factors, including:

- shortages of active ingredients (the most frequently cited area being antibiotics)
- manufacturing and supply-chain issues
- poor planning
- demand
- medicine pricing.

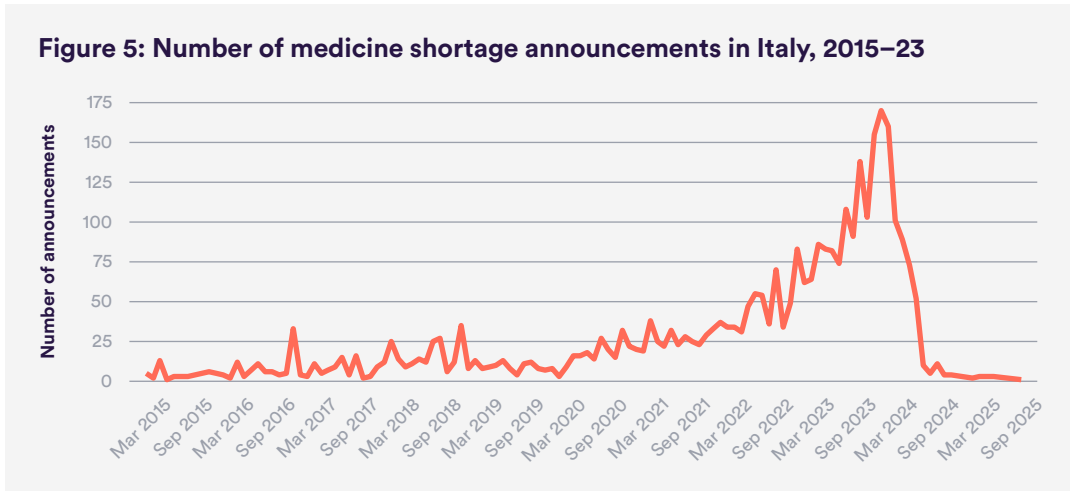
Reporting and monitoring take place at national, regional, hospital and manufacturer levels, often simultaneously, and often not in a way that enables effective information-sharing. This leads to issues such as:

- interruptions or delays in care
- substitution for less effective medicines that could have different side-effects
- financial loss from substituting for more expensive medications – through increased co-payment or cost to the state
- reduced patient trust.

Updated analysis for this report of national shortages data in Italy and Germany shows both countries experiencing spikes in shortages, with 2023 appearing to have been a very difficult year in both.

In Italy, the national agency for pharmaceuticals (*Agenzia Italiana del Farmaco*) updates and publishes a shortage registry each week. This includes data on ongoing medicine shortages, their anticipated or backdated start and, where available, their anticipated end. It specifies the reason for the shortages and possible alternatives where these are available. Figure 5 shows that there was a significant increase in new, anticipated shortages between September 2022 and December 2023.

¹⁴ European Association of Hospital Pharmacists (2023) *EAHP 2023 Shortage Survey Report*. EAHP. www.eahp.eu/practice-and-policy/medicines-shortages/2023-shortage-survey. Accessed 25 March 2024.

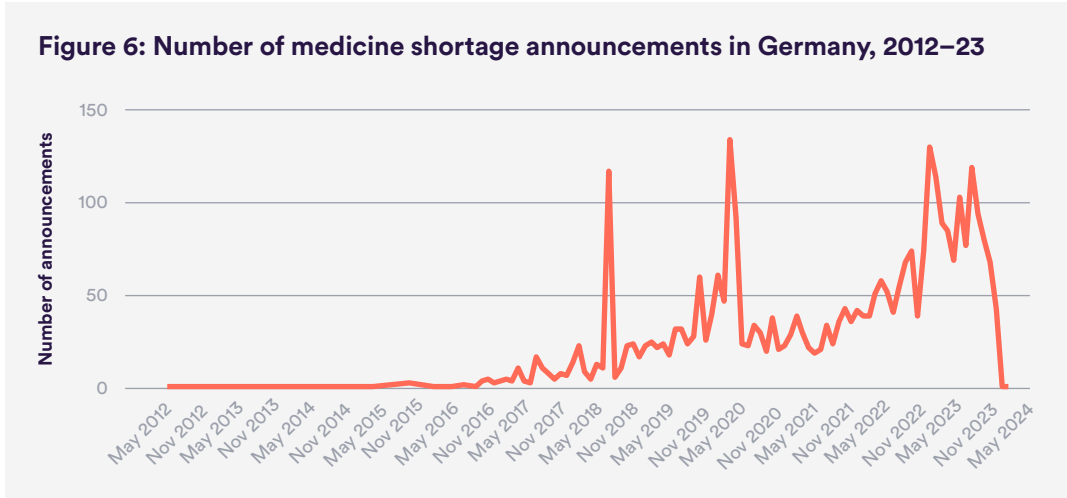


Note: Chart includes anticipated shortages.

Source: Agenzia Italiana del Farmaco

The register counts active pharmaceutical ingredients (APIs), individual dosages, means of administration and, where relevant, brand names and producers, separately. During the peak period, the highest number of anticipated shortages, grouped APIs, occurred for two antibiotics, co-amoxiclav (36) and amoxicillin (20), paracetamol (19), the anti-psychotic olanzapine (14) and the magnetic resonance imaging (MRI) contrast agent, gadoteric acid (13). Higher use of antibiotics is to be expected for respiratory and ear infections in the autumn and winter months, which may partly explain shortages, which were also affected by production.

Germany has experienced several peaks in medicine shortage announcements in the past four years – first around February 2020, then steadily increasing from around June 2020 to November 2022 – but they decreased suddenly after August 2023 (see Figure 6). The German register specifies the date of the shortage, the anticipated end and the type of problem – but not the solution to the shortage. Like Italy, it lists dosages, means of administration and brands separately for the same API, and counts a medicine twice if the shortage recurs. While the peak in early 2020 was fairly spread out, substances such as levothyroxine (for hypothyroidism), midazolam (a benzodiazepine sleeping medication), amoxicillin, paracetamol and fentanyl had higher occurrences of shortage. During the mid-2023 peak, oxycodone, hydromorphon and morphine (three opiate painkillers), a statin (rosuvastatin), two antibiotics (amoxicillin and cefaclor) and insulin had higher shortage rates.



Source: www.bfarm.de/EN/Medicinal-products/Information-on-medicinal-products/Supply-shortages/_node.html

The European Commission and member states have been active in trying to respond to medicine shortages, with leaders often highlighting it as an urgent priority.¹⁵ And the Commission issued guidance on monitoring supply and addressing medicine shortages in April 2020, updated in 2023.¹⁶ This includes initiatives to:

- improve communication, monitoring, planning, early warning systems and consumer awareness
- optimise supply (and supply alternatives) and use in hospitals and pharmacies
- encourage support between member states, for instance by reducing national stockpiling and enabling cross-border supply.

15 European Commission (2023) ‘Commission steps up actions to address critical shortages of medicines and strengthen security of supply in the EU’, press release, 24 October. https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5190. Accessed 20 March 2024

16 European Commission (2023) Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions: Addressing medicine shortages in the EU. https://commission.europa.eu/document/download/da376df1-c70e-48ba-8844-3024f25746b6_en?filename=Communication_medicines_shortages_EN_0.pdf

Despite the guidance, information, planning and responses vary significantly at member-state level.

Why has this happened? Will it worsen?

A roundtable with officials, pharmacists and representatives of different parts of the medicines industry convened to inform this project allowed us to explore the drivers of shortages in greater depth than before, as well as examining possible options to improve this difficult situation, as we outline below. We also spoke to several other industry sources, some of whom asked to remain unnamed.

A clear picture emerged of underlying fragilities at a global and UK level, not fundamentally rooted in Brexit but exacerbated by it in some specific ways, especially through some companies removing the UK from their supply chains. Contributors told us that a downward push in prices and the dominance of ingredient and formulation manufacturing operations in China and India had created a thinner market, with fewer different suppliers for many products and with pressure on profitability. Inflation associated with the reheating of the global economy after the height of the Covid-19 pandemic, and with the war in Ukraine, had then made supply less profitable. At the same time, severe lockdowns had caused specific manufacturing difficulties in China.

These changes plausibly made shortages more probable through direct interruptions to production, and incentivised suppliers to pull back from unprofitable markets, while removing backup suppliers from the market. They also led to an increase in lead times for ordering products to several months, creating a less flexible market with a limited ability to move quickly and fill in gaps in supplies, even when it was possible.

Three factors affected the UK more uniquely, each with a different timing and area of effect.

The first relates to changes to demand – to the patterns of medicines that doctors prescribe in the UK – which are most convincingly involved in the widespread shortages of HRT. The number of prescriptions dispensed for

these products increased by 40% in the single financial year of 2021/22.¹⁷ As is demonstrated by the end of the majority of serious shortage protocols for this product shown in Figure 4, these had become less prominent by 2023.

The second factor is UK policy and NHS decisions around medicines pricing and financing. Contributors told us that they believed that the drug ‘tariff’ – the price list for reimbursing pharmacists – had, on average, been raised fairly generously during the Covid-19 pandemic, an era of relatively unconstrained NHS budgets. There had then been an attempt to squeeze prices back down in 2022 and 2023 as the health service in England saw its budget pulled back under firm control.¹⁸ This was unintentionally difficult timing, coinciding with the global manufacturing and supply problems discussed above. Analysis of the price of medicines prescribed in the community somewhat supports this. The prices of the equivalent products rose by 5.4% from August 2021 to August 2022, but only by 2.7% from August 2022 to August 2023.

This jump in spending around Covid-19 itself may be best understood as a breakdown of a previously strong drive to hold prices down. Additional data published by the NHS Business Services Authority shows a sharp increase in generics costs from £2.9 billion to £3.7 billion in 2022/23 – but before the pandemic, costs had actually been squeezed down even in cash terms. While obviously affected by dramatic events, this see-sawing in prices may not be ideal for a stable, predictable market which combines good value for the NHS with enough expected profitability to attract supplier in a low-margin industry.

The period of high inflation also resulted in large clawbacks from suppliers of branded medicines under the 2019 voluntary scheme for branded medicines pricing and access (VPAS), agreed between government and industry. This ran from 2019 to 2023,¹⁹ and meant that where branded medicine spending rose above agreed levels, companies had to pay a proportion of revenue back to

17 Appleby J (2022) ‘Chart of the week: hormone replacement therapy prescriptions rise 42% in one year’. www.nuffieldtrust.org.uk/resource/chart-of-the-week-hormone-replacement-therapy-prescriptions-rise-42-in-one-year. Accessed 20 March 2024.

18 Gainsbury S (2023) ‘Health and care finance tracker’. www.nuffieldtrust.org.uk/resource/health-and-care-finance-tracker. Accessed 20 March 2024.

19 Department of Health and Social Care (2018) ‘Voluntary scheme for branded medicines pricing and access’. www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access. Accessed 20 March 2024.

the DHSC on behalf of all four UK governments. By 2023, as inflation pushed prices up and with a proportion of the clawback from 2022 being delayed, this reached 26.5%.²⁰ While initiatives like this are not uncommon in Europe, this was an anomalously high level.

The British Generic Manufacturers Association argued that the elevated clawback rate had an impact on shortages because it affected not only on-patent drugs – typically high price but a very low proportion of volume – but also the branded generics that its members made. It noted that, in certain months, these products made up half of all drugs reaching certain thresholds for supply issues noted by the DHSC and NHS England, out of proportion to their share of supply.²¹ The mechanism in play here would likely be market withdrawal or manufacturing disruption in the context of reduced ability or willingness to compensate by other firms, which we heard from several sources was a common dynamic for supply issues.

The third factor is a UK-specific change in the conditions of supplying medicines: Brexit. We discussed in our earlier report on health and Brexit that the evidence on timing strongly suggests that the EU referendum and its effect on the value of sterling were linked to the beginning of the period when high levels of price concessions were required to handle shortages.²²

20 Department of Health and Social Care (2022) 'The 2019 voluntary scheme for branded medicines pricing: payment percentage for 2023'. www.gov.uk/government/publications/the-2019-voluntary-scheme-for-branded-medicines-pricing-and-access-payment-percentage-for-2023. Accessed 20 March 2024.

21 British Generic Manufacturers Association (no date) 'Spiralling VPAS rebate starts to bite as record number of medicines face supply issues'. www.britishgenerics.co.uk/view-news/spiralling-vpas-rebate-starts-to-bite-as-record-number-of-medicines-face-supply-issues.html. Accessed 20 March 2024.

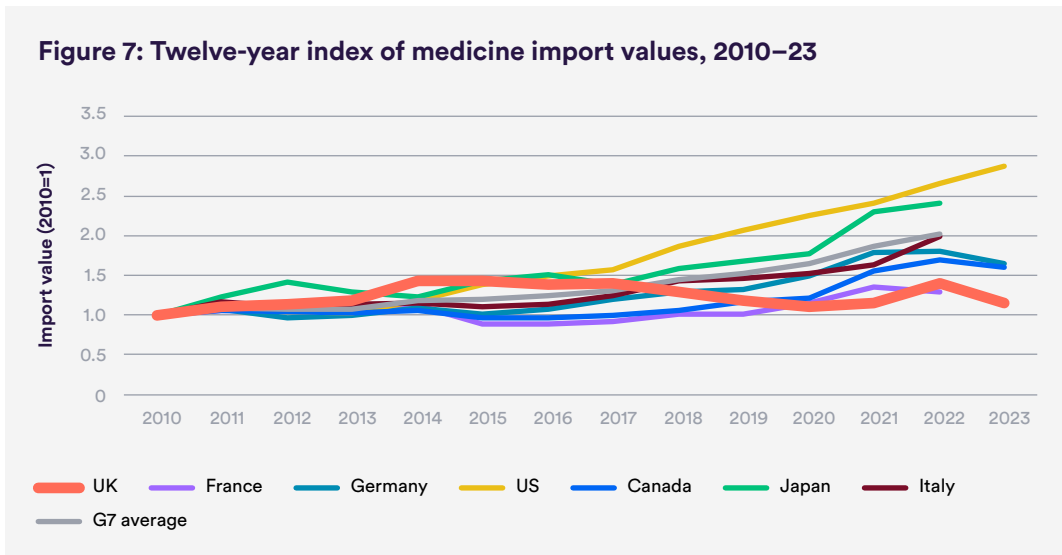
22 McCarey M, Dayan M, Jarman H, Hervey T, Fahy N, Bristow D and Greer SL (2022) *Health and Brexit: Six years on*. Nuffield Trust. www.nuffieldtrust.org.uk/sites/default/files/2022-12/1671199514-health-and-brexit-web.pdf.

Contributors to this report underlined why leaving the single market at the end of 2020 contributed to the trend towards increased problems with supply. These effects are based on the regulatory and trade barriers created by the UK's withdrawal under the EU-UK Trade and Cooperation Agreement (TCA):

- customs checks at the border
- the operation of the Falsified Medicines Directive system of tags and identifiers in the EU, but not in Great Britain, resulting in costly steps to remove and reapply them (Northern Ireland was subject to the Falsified Medicines Directive, but this is to be disapplied under the revised Northern Ireland Protocol)
- the split in the authorisation of medicines to be marketed between a European system at member-state and European Medicines Agency level, and a Great Britain and UK system under the Medicines and Healthcare products Regulatory Agency (MHRA), resulting in additional requirements for applications, processes and labelling
- the EU not recognising the medicine batches that are tested in the UK as valid for sale in the single market, nor the professionals who oversee this process.

Contributors told us that these barriers had encouraged a shift in supply chains away from physical routes that included the UK. A significant proportion of this had happened before the UK's actual departure from the EU, as firms braced for the worst-case scenario of a 'no deal' Brexit, with even more barriers dangled over them throughout 2018 and 2019.

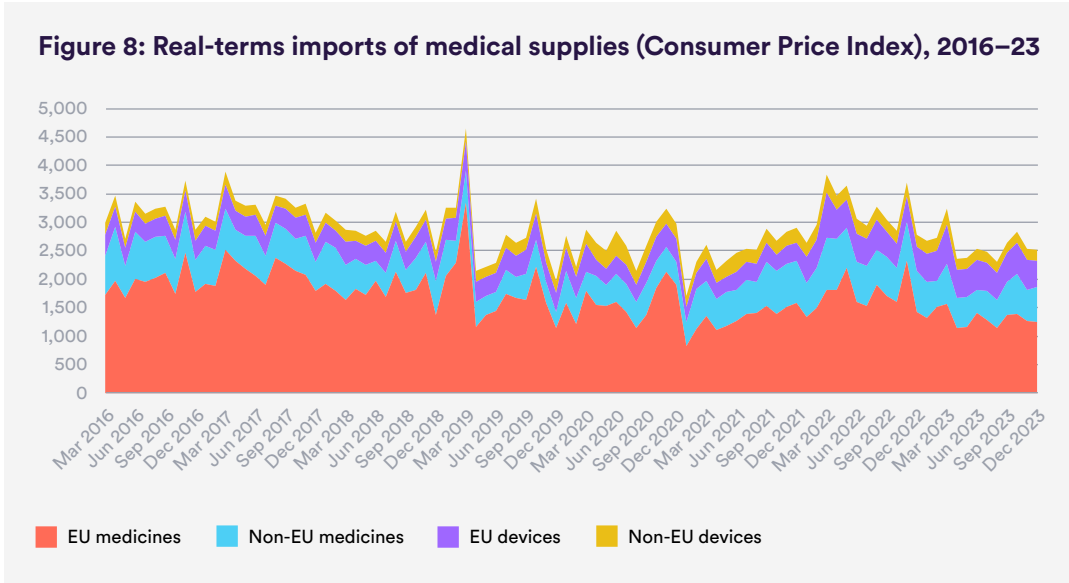
Data from the United Nations on total imports of medicines show a marked downward trend in medicine imports to the UK (see Figure 7). Along with France, the UK's medicine imports show an unusual failure to rise as most other countries' imports did. The UK, in particular, shows a slowdown since 2017, shortly after the EU referendum. This is of course not mirrored in a comparable reduction in medicines actually used in the UK.



Source: United Nations Comtrade Database

Figure 8 shows patterns across medicines and medical device imports from UK data, adjusted for inflation and split out across EU and non-EU countries of origin. This shows that when rising prices are accounted for, imports per value of medicine were lower in 2023 than before the EU referendum – despite increases in the volume used and the NHS budget over this period. Interestingly, while non-EU imports fell less during some periods, and both rebounded to some extent during the height of Covid-19, both EU and non-EU medicines showed a similar fall by 2023, of around 20%.

We heard from contributors that these trends may relate to companies choosing not to store, test and distribute medicines in the UK as frequently, for what remains, even today, largely a European market. Two commented that this is likely to have weakened the UK’s position in situations of shortage, by increasing the cost of unplanned shipments, substitution or market entry, and possibly even through shifts in political and cultural connections.



Source: Authors’ analysis of HM Revenue and Customs ‘UK trade info’ (www.uktradeinfo.com) and ONS ‘inflation and price indices’ (www.ons.gov.uk/economy/inflationandpriceindices)

Two contributors from industry also told us that they believed that at least some suppliers of generic medicine had left the market entirely rather than pay for the duplicate paperwork and labelling required. “The price is too low, the volumes aren’t there. So economically it wasn’t interesting anymore... they may have stayed in the UK or they may have stayed in Europe, but they didn’t stay in both.”

Analysis for this report using the English NHS Prescription Cost Analysis showed that the total number of different medicine types that pharmacists dispensed remained stable between 2016 and 2022, at around 21,000. It might have been expected to rise slightly as new discoveries and practices emerged, but we see that the number of different products per type of chemical fell by 8%, from 7.1 to 6.6. To some extent this supports the idea of a ‘thinner’ market, where there are fewer alternative suppliers due to a combination of a price squeeze and the logistical and cost impacts of leaving the EU.²³ Our interviews suggest that Brexit and pressure on price may have played an overlapping role.

23 NHS Open Data Portal (various years) ‘Prescription cost analysis (PCA) monthly administrative data’. <https://opendata.nhsbsa.net/dataset/prescription-cost-analysis-pca-monthly-data>. Accessed 20 March 2024.

Medical devices, covering a huge range of tools, consumables and machines used in health care treatment, from scalpels to pacemakers, show an entirely different trend, with no meaningful shift in imports, as shown in Figure 8, or exports. This appears to be consistent with Brexit playing a significant role for medicines but not for devices, because this sector differs in two key ways. First, the UK has continued to recognise EU regulatory approvals for devices, there have been a series of delays to introducing its own system and the UK has continued to recognise batch testing in the EU, meaning that there is no comparable barrier to products leaving Great Britain for Europe. Second, as we have heard from stakeholders throughout this project, warehousing and distribution for devices and consumables have typically been focused in Belgium, the Netherlands and adjoining countries, not in the UK; there may have been less of a position in global supply chains for the UK to lose.

Food and other imported goods

This section primarily discusses products used in the clinical delivery of health care. But health care services depend on a much wider range of traded goods to function, and the availability and pricing of other products affects the underlying health of people and populations. The NHS Confederation has highlighted that a lack of ability to access food is associated with several health conditions and risk factors, affecting the number of people who need care.²⁴ An LSE study separating different food products based on their exposure to trade barriers and EU trade suggests that the period 2020–23 saw exceptional increases in food prices of around 25%, but that this would have been only 18% without the impact of Brexit.²⁵ It is probable that this has had an impact on health. However, fully understanding this effect would require deeper research into how much it affected groups at risk of food insecurity, and to what extent foods required for a balanced diet were affected more or less than others.

24 NHS Confederation (2022) Why preventing food insecurity will support the NHS and save lives. www.nhsconfed.org/long-reads/why-preventing-food-insecurity-will-support-nhs-and-save-lives.

25 Bakker JD, Datter N, Davies R and De Lyon J (2023) Brexit and consumer food prices: 2023 update. <https://cep.lse.ac.uk/pubs/download/brexit18.pdf>.

What are the future prospects for supplies of medicines and medical devices?

Global market conditions defined by high inflation and the after-effects of Covid-19 pandemic shutdowns should gradually subside as we move further from the events that caused them. This means that the global picture for medicine shortages should improve, or at least stabilise at the current difficult level, in most respects. However, further risks also exist for the UK.

The core effects of Brexit described above, which has increased UK fragility by splitting it from European supply chains, authorisations and collective efforts to respond to shortages, are likely to continue unless there are major shifts in UK policy or bilateral agreements, discussed below.

From this year, the previous VPAS agreement on branded medicine, which patterns of shortage suggest may have contributed to shortfalls of branded generic medication, is being replaced. The new voluntary scheme imposes a blanket 10% clawback rate on older products, with penalty top-ups for not reducing prices.²⁶ This reduces the risk of inflation spikes producing a sudden jump in clawbacks for parts of the bulk medicines market, and therefore sudden squeezes in profits that might make suppliers withdraw, as was the risk with the earlier system.

It also allows total spend to grow by a faster rate of around 4% from 2025 onwards, which may reduce pressure on the market. However, if the wider NHS budget does not match this expansion in the next parliament, alongside pressures on pay, there is a risk that this will squeeze unbranded medicines spend, which is what the NHS relies on for the vast bulk of supply.

One further pressure point may come from the significant and broadening measures that the EU is taking to deal with the shortages that its member states face.

²⁶ Department of Health and Social Care (2023) '2024 voluntary scheme for branded medicines pricing, access and growth: summary of the heads of agreement'. www.gov.uk/government/publications/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth-summary-of-the-heads-of-agreement/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth-summary-of-the-heads-of-agreement. Accessed 20 March 2024.

In early 2024, the EU launched a ‘Critical Medicines Alliance’ between its member states, industry and other stakeholders.²⁷ For a list of over 200 critical medicines, including antibiotics and insulin, this will involve the European Commission, the European Medicines Agency and the medicines regulators of the member states, working together to monitor supply chains and areas of threatened disruption. The actions taken may include ‘recommendations for companies to diversify suppliers or increase production within the EU’,²⁸ tax breaks and grants to encourage this, coordination of stockpiling and the use of procurement contracts and the regulatory process to compel firms to maintain supply to the EU.

From the point of view of the UK, this carries two risks: first, that firms will be incentivised to increase production or storage in the EU over the UK, enhancing the apparent shift away from its place in supply chains; and second, that firms will be encouraged or required to prioritise EU states when supply is scarce by contractual and policy measures across 27 countries with tremendous buying power within the same geographical market. It is also possible that this could benefit the UK too, by diversifying production within Europe and reducing some of the fragility caused by relying on single suppliers far away. Contributors to our project said that this was important for the UK to consider strategically, and that the EU's emphasis on working with other countries created an opportunity to start building cooperative collaboration.

Three other ongoing policy shifts in the EU also have implications for responding to medicine shortages in the UK, particularly in extreme and widespread cases. The Voluntary Solidarity Mechanism, developed by the European Medicines Agency's shortages steering group, set up by a new 2022 regulation, allows member states facing shortages to ask for the assistance of other states in procuring supplies under limited conditions.²⁹ This could

27 European Commission (2023) ‘Stepping up action to prevent shortages of medicines in Europe’. https://commission.europa.eu/news/stepping-action-prevent-shortages-medicines-europe-2023-10-24_en. Accessed 20 March 2024.

28 European Medicines Agency (no date) ‘Availability of critical medicines’. www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-and-availability-issues/availability-critical-medicines#ema-inpage-item-64278. Accessed 20 March 2024.

29 European Medicines Agency (2023) ‘MSSG Toolkit on recommendations on tackling shortages of medicinal products’. www.ema.europa.eu/en/documents/other/mssg-toolkit-recommendations-tackling-shortages-medicinal-products_en.pdf.

effectively mean that in a recurrence of continent-wide shortages, as seen with antibiotics in 2022/23, the UK and its suppliers are behind EU member states in the queue to obtain supplies from countries where there is no shortage.

The EU also has established plans to purchase some key medicines prone to shortage jointly, notably the antibiotics for which shortages proved so dangerous in the winter of 2022–23.³⁰ There has also been an ongoing push, with far from definitive success, against export bans between member states, coupled with significant use of export bans at an EU level during the most intense phase of the Covid-19 pandemic.³¹ This leaves the UK more isolated, as an EU wall is more likely to be erected to control the movement of goods in emergency situations.

The picture for medical devices in the future is uncertain. Quigley and others (2023) argue that the new UK system for regulating medical devices is unnecessarily ‘fragmented, complex and unwieldy’ (with a dual system of regulation for Northern Ireland and Great Britain). It remains unfinished business, with deadlines for firms to stop using the EU system repeatedly pushed back. Quigley and co-authors are concerned about the expected regulatory divergence between Northern Ireland and Great Britain when the UK eventually brings in the UK Conformity Assessed (UKCA) mark for GB devices, and no longer recognises CE (Conformité Européenne) marks for GB supply.³² This has been repeatedly delayed in the face of concerns about losing access to crucial products.³³

30 Stepping up action to prevent shortages of medicines in Europe – European Commission (europa.eu).

31 European Commission (no date) ‘Coronavirus response to flow of protective equipment in the internal market’. https://single-market-economy.ec.europa.eu/single-market/single-market-emergency-instrument/coronavirus-response-flow-protective-equipment-internal-market_en. Accessed 20 March 2024.

32 Quigley M, Downey L, Mahmoud Z and McHale J (2023) ‘The shape of medical devices regulation in the UK? Brexit and beyond’, *Law, Technology and Humans* 5(2), 21–42. <https://lthj.qut.edu.au/article/view/3102/1423>. Accessed 20 March 2024.

33 Dayan M, Hervey T, Fahy N, Vlachakis E, McCarey M, Flear M, Greer S and Jarman H (2023) ‘Parallel, divergent or drifting? Regulating healthcare products in a post-Brexit UK’, *Journal of European Public Policy* 30(11), 2540–72. <https://openaccess.city.ac.uk/id/eprint/30702>. Accessed 20 March 2024.

When the new system is in place, medical devices supplied to Great Britain from the EU will face the dual regulatory burden of securing a UKCA mark. This will risk a more decisive break, and previously unseen disincentives to launch and supply products in Great Britain. Meanwhile, devices destined for the Northern Ireland market will continue to need a CE mark from an EU-approved Notified Body, imposing a dual regulatory burden on GB-based and import suppliers who supply both markets.

2 What has happened to life sciences in the UK since Brexit?

Medical innovation and research make an important contribution to health in the UK. They create additional options for treatment and diagnosis, and drive long-term improvements in health care. Research is also intermeshed with clinical careers, and what makes the UK and the NHS an attractive place for doctors, scientists and researchers to work.

Context: all is not well

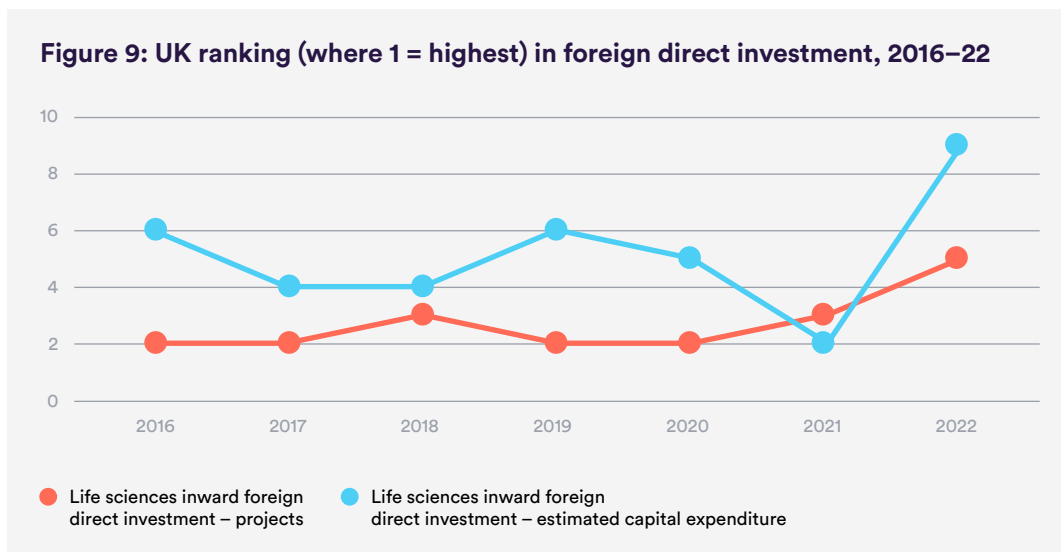
Several government reviews in the past seven years have highlighted problems facing the sector, traditionally one of the UK's most productive and globally competitive, and set out priorities to act on them.

The 2023 commercial clinical trials review³⁴ noted that 'numbers of patients enrolled onto commercially-led studies supported by the NIHR [National Institute for Health and Care Research – a government funding body] dropped by 44% between 2017 to 2018 and 2021 to 2022'. It noted as key problems to address that local NHS approvals could be slow, willingness was often limited, transparency was lacking and there was 'a loss of strategic capacity and capability in other regulators, especially the MHRA [Medicines and Healthcare products Regulatory Agency]'.

34 Department for Science, Innovation and Technology, Department of Health and Social Care and Office for Life Sciences (2023) 'Commercial clinical trials in the UK: the Lord O'Shaughnessy review – final report'. www.gov.uk/government/publications/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review-final-report#part-2-problem-statements-and-significant-actions. Accessed 20 March 2024.

The earlier 2021 Life Sciences Vision took a much broader view and was framed around the-then UK successes during the Covid-19 pandemic, such as the rollouts globally of the AstraZeneca vaccine and dexamethasone as a treatment.³⁵ It noted, however, the long record of struggles in terms of relatively slow NHS uptake, and difficulties in data availability. A foreword by the-then Prime Minister, Boris Johnson, promised to ‘utilise the full breadth of our regulatory freedoms from Brexit’, and the report envisaged ‘speed and agility’ in regulators, with ‘the opportunity to set regulatory standards in areas of rapid innovation’.

Life Sciences Competitiveness indicators,³⁶ published to track the UK’s performance in this domain, show a decline, as of 2022, in ranking across six of the relevant areas, updated to the period after the UK left the single market, and an improvement in only one. Foreign direct investment declined markedly in 2022 following many years in which the UK ranked more highly (see Figure 9).



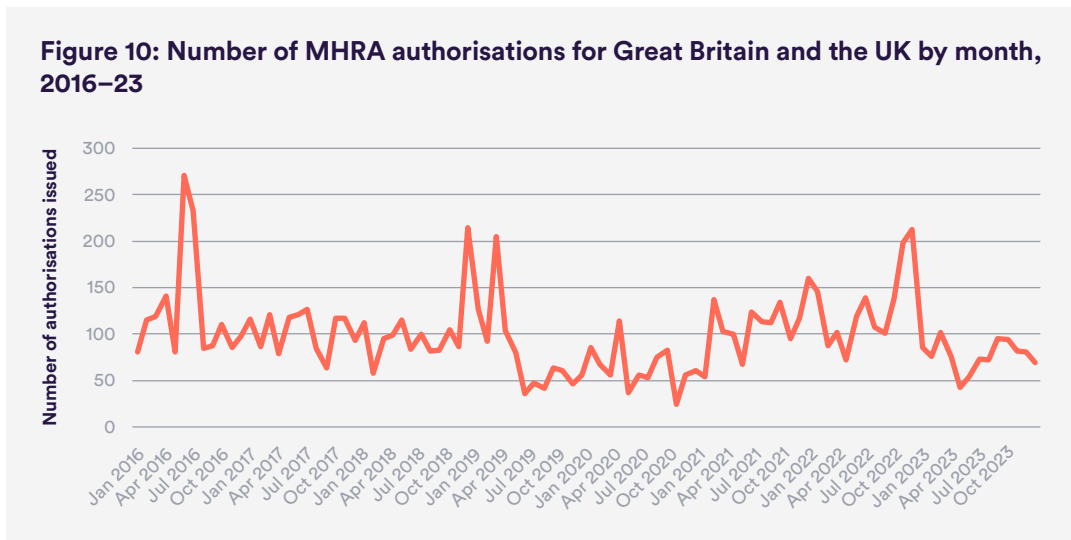
Source: Life Sciences Competitiveness Indicators (DHSC, DSIT, Office for Life Sciences)

35 HM Government (2021) *Life Sciences Vision*. GOV.UK. <https://assets.publishing.service.gov.uk/media/612763b4e90e0705437230c3/life-sciences-vision-2021.pdf>.

36 Department for Science, Innovation and Technology, Department of Health and Social Care and Office for Life Sciences (2023) ‘Life sciences competitiveness indicators 2023’. www.gov.uk/government/publications/life-sciences-sector-data-2023/life-sciences-competitiveness-indicators-2023. Accessed 20 March 2024.

The capacity to examine and approve new medicines

We found clear evidence that Brexit and the policies that followed it created problems for innovation and research. Stakeholders consistently told us that they believed a significant issue for introducing both innovative medicines in the UK, and new lines of existing medicines, was the slow rate at which the MHRA was able to grant approvals as a now free-standing regulator responsible for all types of products. This is broadly supported by looking at the total number of authorisations that the MHRA issued for Great Britain and the UK (see Figure 10).³⁷



Source: Medicines and Healthcare products Regulatory Agency (various years) ‘Marketing authorisations: lists of granted licences’.

There was a marked slowdown from March 2019, which may be connected to the move that month of the European Medicines Agency from London to Amsterdam, disrupting some of the regulatory networks in London.

With the UK’s exit from the single market at the end of 2020, the MHRA’s remit expanded to cover authorisations that previously would have been

³⁷ Medicines and Healthcare products Regulatory Agency (various years) ‘Marketing authorisations: lists of granted licences’. www.gov.uk/government/collections/marketing-authorisations-lists-of-granted-licences. Accessed 20 March 2024.

issued centrally by the European Commission, on advice from the European Medicines Agency. However, monthly authorisations in this period averaged 104. This is slightly below the average of 111 issued each month across 2016, 2017 and 2018, when the MHRA was not responsible for many types of complex medicine, and could rely on the European Commission and European Medicines Agency to approve these products for the UK.

As we noted in our recent article on the regulation of health care products post Brexit, the UK has faced a serious challenge in struggling to attract and approve medicines as quickly as the EU, a larger market with a better-resourced regulator.³⁸ Its response has leant on a ‘reliance route’, fast-tracking medicines that the EU has already approved; since January of this year, it is introducing options for a wider range of accelerated approvals for products already authorised elsewhere.³⁹

Earlier studies have shown that since the UK’s exit from the single market, it has approved fewer new medicines that would be centrally approved in the EU than the European Commission has.⁴⁰ Analysis for this report shows that the UK had still not authorised a significant number of products as of late 2023, and that there was also typically a delay where products had been authorised, illustrating dependence on the reliance route as the regulator struggled to keep up with demands on it.

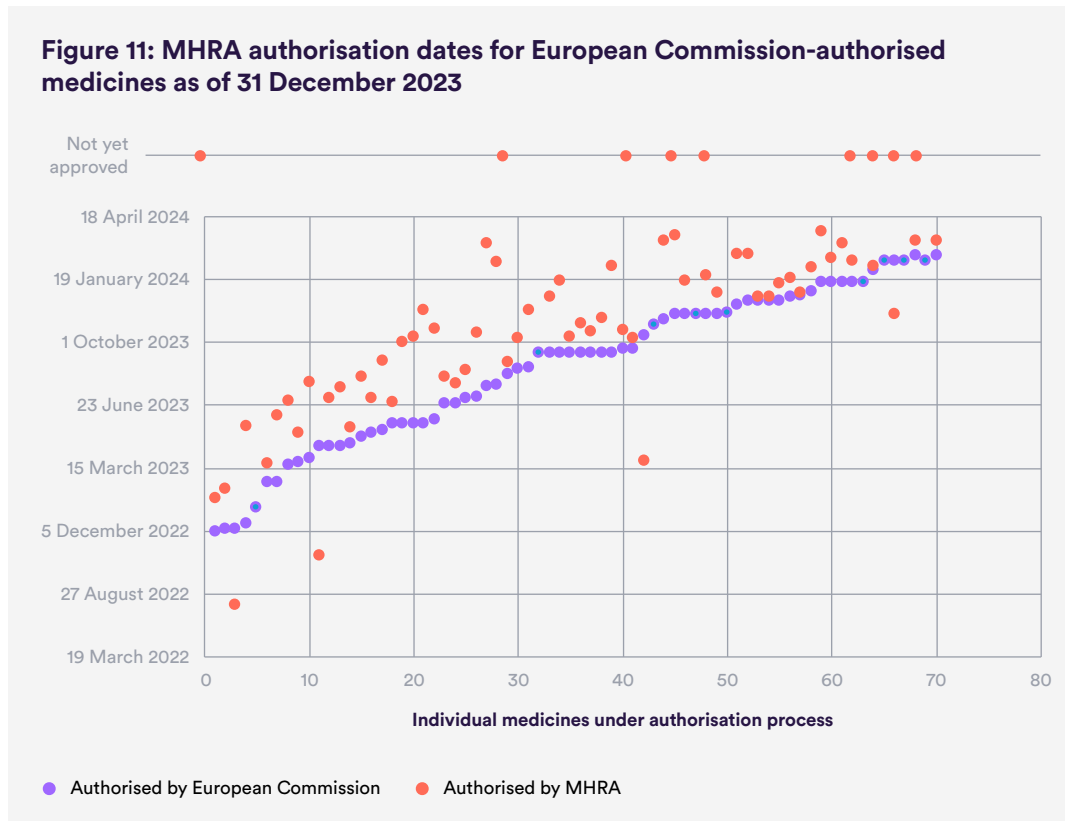
Figure 11 shows MHRA authorisation dates for each drug authorised centrally by the European Commission, advised by the European Medicines Agency, between December 2022 and December 2023, compared with their authorisation date in the UK. These are drugs to treat major conditions such as cancer, new active substances and drugs derived from biotechnology – generally among the most innovative, costly and scientifically novel. Drugs are not included if the MHRA had already approved another manufacturer’s

38 Dayan M, Hervey T, Fahy N, Vlachkis E, McCarey M, Flear M, Greer S and Jarman H (2023) ‘Parallel, divergent or drifting? Regulating healthcare products in a post-Brexit UK’, *Journal of European Public Policy* 20(11), 2540–72. www.tandfonline.com/doi/full/10.1080/13501763.2023.2213721. Accessed 20 March 2024.

39 Medicines and Healthcare products Regulatory Agency (2023) ‘International recognition procedure’. www.gov.uk/government/publications/international-recognition-procedure. Accessed 20 March 2024.

40 Hofer M (2023) ‘Post-Brexit medicine approvals’. www.imperial.ac.uk/business-school/ib-knowledge/health/post-brexit-medicine-approvals-what-we-know. Accessed 20 March 2024.

supply of the same product (for ‘small molecules’), as it could be argued that this might simply reflect the UK having different but equally valid suppliers in its market. This leaves a total of 52 products. Products that the MHRA did not approve during this period are represented by dots at the very top of the chart.



Note: The cut-off date for MHRA authorisation for the same cohort of medicines represented here is 28 March 2024.

Sources: Marketing Authorisations Granted (MHRA) www.gov.uk/government/publications/marketing-authorisations-granted-in-2023

Union Register of medicinal products (European Commission) https://ec.europa.eu/health/documents/community-register/html/index_en.htm

Overall, as the chart shows, as of 28 March 2024, four of the drugs authorised in Europe the previous year had been approved faster in the UK; 56 had been approved later in the UK; and 8 had not been approved at all in the UK. As can be seen in Figure 11, a delay of one to four months is a common pattern; it is probable that several products not approved in the UK yet will be, with some delay. As of the end of March 2024, for example, the MHRA had not approved the lymphoma drug pirtobrutinib, approved by European Medicines Agency in October. An illustration of a time lag using the reliance route on

an EU decision is that MHRA approved the breast cancer drug elacestrant in December 2023, three months after the EMA did so in September.

This does not necessarily mean that patients in the UK will receive new products more slowly – many other factors affect how quickly health services roll out new products after authorisation. For example, the UK has a firm cost-effectiveness test, and the English NHS in particular is struggling to overcome other causes of lag.⁴¹ However, these delays do illustrate an additional hold-up compared to that if the UK remained within the EU. They suggest that the attractiveness of the UK as a place for innovation is less, its regulatory capacity is less, or both.

Medicines approvals are in fact one of the earliest areas where the UK engaged in strategic divergence from the EU, by introducing new procedures, most notably the Innovative Licensing and Access Pathway.⁴² While still running essentially on inherited EU law, this takes advantage of the fact that outside the single market the UK now takes decisions about which medicines to approve nationally, at a level which also holds responsibilities for judging their cost-effectiveness (for England and Wales) and funding them. For medicines granted an ‘innovation passport’ to join this route, they can undergo parts of both processes together and receive guidance from regulators on the evidence needed.⁴³

Our contributors were generally positive about the Innovative Licensing and Access Pathway as an attractive new feature of the UK’s life science landscape. A pattern of general alignment with the EU, but with an aspiration for competitive new routes for certain new products, has often been described to us as a preferred UK strategy in multiple domains. To an extent, it is working in medicines authorisation. But in its current version, with acceleration for only a few products, this does not prevent the general pattern of regulation from being slower.

41 Life Sciences Council (2023) ‘The Innovation Ecosystem Review Programme’. www.england.nhs.uk/aac/wp-content/uploads/sites/50/2023/09/aac003a-annex-a-annex-a-lsc-nhse-innovation-ecosystem-paper.pdf.

42 Medicines and Healthcare products Regulatory Agency (2021) ‘Innovative Licensing and Access Pathway’. www.gov.uk/guidance/innovative-licensing-and-access-pathway. Accessed 20 March 2024.

43 Medicines and Healthcare products Regulatory Agency (2021) ‘Innovative Licensing and Access Pathway’. www.gov.uk/guidance/innovative-licensing-and-access-pathway. Accessed 20 March 2024.

Research and clinical trials

As well as affecting manufacturing, approval and supply, the new regulatory and institutional divide between the UK and the EU has also changed how medical products are researched and tested. We argued in a recent article on the regulation of health care products post Brexit that the common pattern across both areas has been that faster-moving EU policy, or politically driven UK desires to diverge, have thrown up frictions, causing concern or disruption. Rather than trying to aggressively compete through diverging sharply, the UK state has generally adopted a policy of moving more slowly, and attempting to realign with the EU or accept EU processes.⁴⁴

The EU's 2014 Clinical Trials Regulation came into effect only after the UK left the single market at the end of 2020.⁴⁵ It creates a single Clinical Trials Application System (CTIS), offering shared forms and single applications for trials run in different European countries, and reduces administrative burden for researchers and pharmaceutical companies. Other parts of the new regulation streamline the amount of safety reporting that researchers need to carry out. This divergence in the content of regulation comes alongside the split Brexit caused in its operation. Most notably, this means that the responsible researcher who formally sponsors a clinical trial can no longer be recognised in the EU if they are in the UK.

These divergences are not discussed extensively in the UK government's review of clinical trials,⁴⁶ but the science and health sector in the UK, and contributors to this report, have repeatedly highlighted them as a problem.

44 Dayan M, Hervey T, Fahy N, Vlachkis E, McCarey M, Flear M, Greer S and Jarman H (2023) 'Parallel, divergent or drifting? Regulating healthcare products in a post-Brexit UK', *Journal of European Public Policy* 20(11), 2540–72. www.tandfonline.com/doi/full/10.1080/13501763.2023.2213721. Accessed 20 March 2024.

45 European Union (2014) 'Consolidated text: Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (text with EEA relevance)'. <https://eur-lex.europa.eu/eli/reg/2014/536/2022-12-05>. Accessed 21 March 2024.

46 Department for Science, Innovation and Technology, Department of Health and Social Care and Office for Life Sciences (2023) 'Commercial clinical trials in the UK: the Lord O'Shaughnessy review – final report'. www.gov.uk/government/publications/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review-final-report#part-2-problem-statements-and-significant-actions. Accessed 20 March 2024.

The NHS Confederation has warned that the loss of sponsor recognition ‘could be prohibitively expensive for many non-commercial sponsors such as universities, and in the long run could make it harder for UK-based researchers to lead pan-European clinical trials’.⁴⁷

The UK finally entered Horizon Europe – the flagship EU science funding programme, which commenced from the start of 2021 and is widely viewed as important for participation in leading projects – in stages through late 2023, as an associate member.⁴⁸ This was anticipated under the EU-UK Trade and Cooperation Agreement (TCA), but in practice the EU delayed it in response to UK threats to ignore the Northern Ireland Protocol to the 2020 Withdrawal Agreement.

Horizon Europe is a significant platform for life sciences research, incentivising cross-country collaborations in a way that domestic funding tends not to do. Perhaps more importantly, collaboration is a mechanism for the exercise of soft power, as regulatory processes and publicly funded research interact, and the UK remains a highly respected place for life sciences research. Under the new arrangements, UK organisations may now receive Horizon Europe funding, and even lead consortia, and this has been in place since 1 January of this year.⁴⁹ Unlike full members, countries associated with Horizon Europe are subject to ‘corrections’. In the event that the UK receives more funding (above an 8% threshold over two years) than it contributes, an automatic correction applies under the EU-UK TCA.⁵⁰ Given the patterns of success rates of UK institutions before Brexit, the net gain in terms of research income is therefore likely to be lower than pre-Brexit.

47 NHS Federation (2022) ‘Post-Brexit issues for the NHS’. www.nhsconfed.org/publications/post-brexit-issues-nhs. Accessed 20 March 2024.

48 Prime Minister’s Office, 10 Downing Street, Department for Science, Innovation and Technology, Donelan M and Sunak R (2023) ‘UK joins Horizon Europe under a new bespoke deal’, press release, 7 September. www.gov.uk/government/news/uk-joins-horizon-europe-under-a-new-bespoke-deal. Accessed 20 March 2024.

49 European Commission (2023) ‘Joint statement by the European Commission and the UK government on the UK’s association to Horizon Europe and Copernicus’. https://ec.europa.eu/commission/presscorner/detail/en/statement_23_4375. Accessed 20 March 2024.

50 European Commission (2023) ‘Questions and answers on the UK’s association to Horizon Europe and Copernicus’. https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_4373. Accessed 20 March 2024.

The lengthy period of uncertainty over Horizon Europe will likely have seen UK universities and researchers avoid or miss funding opportunities that will never return. Funding awards tend to be weighted towards the early years of the programme. Despite the offer of funding matched by the UK government during the period when it was not available from the EU, UK institutions and researchers accounted for just 5% of participants in the first two years of Horizon Europe, compared with 10% during its predecessor before Brexit.⁵¹ UK science bodies repeatedly warned that a lack of access to EU grants had made it more difficult to bring in research staff.⁵²

However, the opportunity to begin to mend relationships and exercise soft power through collaboration is significant in life sciences, and indirectly for health and the NHS. One interviewee from industry said that the UK's reintegration into Horizon Europe is critical because "we need the research to be in Europe and we need the UK to be part of that Europe". Another suggested that there is a benefit to the EU too in terms of attracting work from global multinationals that have to choose which continent to fund research in.

Formal participation in European Reference Networks, which connect scientists and clinicians at universities and hospitals across Europe to treat and study very rare diseases, has not been restored for UK partners. But we reported before that a few of the networks have found 'legal workarounds', and these seem to be continuing.⁵³ For example, MetabERN, the European Reference Network for Hereditary Metabolic Disorders, is still collaborating with five UK partners, on what they describe as 'a voluntary basis'.⁵⁴ Presumably, this means that patients based in those voluntarily collaborating hospitals may access trials, but that no resources are flowing into the UK from European Reference Network funding.

51 Matthews D, Brent T and Naujokaitytė G (2023) 'Here's what the first two years of Horizon Europe look like in numbers'. <https://sciencebusiness.net/news/Horizon-Europe/heres-what-first-two-years-horizon-europe-look-numbers>. Accessed 20 March 2024.

52 Smith J (2023) 'Cancer research scientists urge UK to reach a deal on Horizon Europe'. <https://news.cancerresearchuk.org/2023/08/25/cancer-research-uk-urges-government-to-reach-deal-on-horizon-europe>. Accessed 20 March 2024.

53 Hervey, T, Antova, I, Flear, M, Wood, M (London 2024) *Not What the Bus Promised*.

54 MetabERN (no date) 'Who we are'. <https://metab.ern-net.eu/about-us-3/#whoweare>. Accessed 21 March 2024.

3 What has happened to migration and the health and care workforce since Brexit?

In previous reports we noted the UK's longstanding and exceptional reliance on international migration as a source of health and care workers.^{55,56} The period before 2016 saw heavy migration from the EU and the European Economic Area (EEA) as the NHS faced increased demand for nurses following safety scandals at Mid Staffordshire Hospital in England, domestic training of clinicians generally slowed down, and the social care sector sought to maintain enough workers in the face of funding cuts.⁵⁷

After the UK left the single market at the end of 2020, EU and EEA staff were subject to the same immigration rules as those from the rest of the world. This entailed greater bureaucratic and monetary cost to obtain visas. We noted that the UK rapidly adopted a new system, which allowed high levels of health and care worker immigration to continue despite Brexit, bringing in a Health and Care Visa⁵⁸ with reduced fees and setting required salaries for most clinicians at the NHS pay scale, meaning most jobs were eligible.

55 www.nuffieldtrust.org.uk/research/going-it-alone-health-and-brex-it-in-the-uk

56 www.nuffieldtrust.org.uk/sites/default/files/2022-12/1671199514-health-and-brex-it-web.pdf

57 Dayan M and Palmer B (2019) 'Stopping the staff we need'. www.nuffieldtrust.org.uk/sites/default/files/2019-12/1575384724_migration-election-briefing-web.pdf.

58 Home Office, Department of Health and Social Care, Hancock M and Patel P (2020) 'Government launches Health and Care Visa to ensure UK health and care services have access to the best global talent'. www.gov.uk/government/news/government-launches-health-and-care-visa-to-ensure-uk-health-and-care-services-have-access-to-the-best-global-talent. Accessed 20 March 2024.

Most front-line social care workers were initially left out of the opening up of migration rules until they were added to the ‘shortage occupation list’ in February 2022,⁵⁹ with visa and immigration rules then being liberalised to make them eligible for health and care worker visas (part of the ‘skilled worker’ route into the UK) – although many of them may still not have met the shortage occupation list salary threshold of around £20,960 a year.

The following sections recap these past trends, and update trends and policy developments through 2022 and 2023, a period when the NHS began focusing on attempts to recover from the intense heights of the Covid-19 pandemic and restore previous standards of access to care, while social care continued to face growing need and a lack of reform or major funding improvements.

Nurses

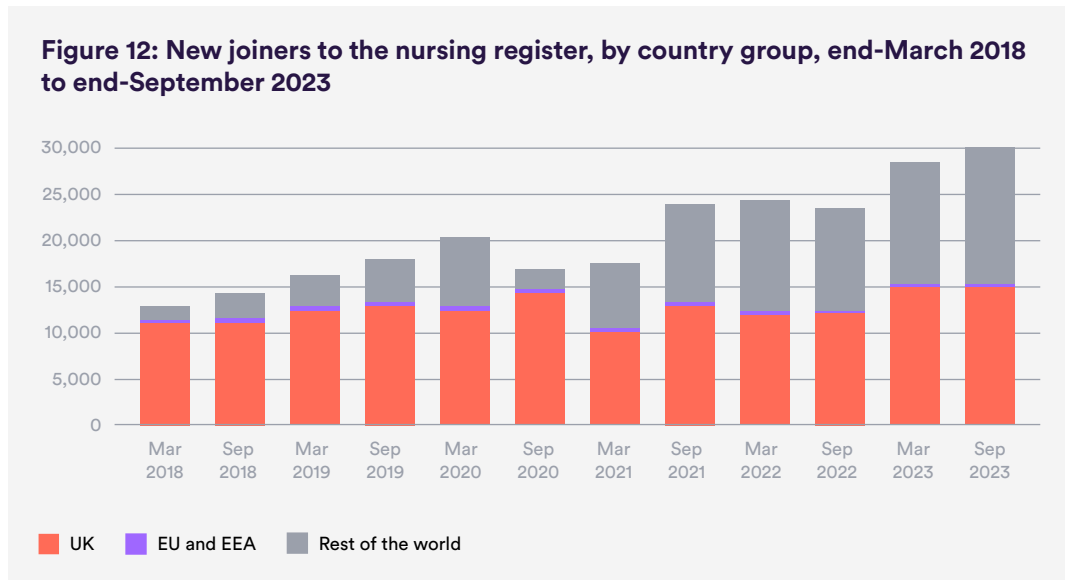
In nursing, the number of EU staff began to fall immediately following the Brexit vote and a simultaneous tightening of language requirements. However, with new migration rules making the vast majority of NHS roles eligible to hire internationally, recruitment drives from the rest of the world were very visible, markedly so from 2021. The result was a rapid increase in the movement of qualified nurses to the UK, largely from outside the EU. We noted in our previous report on health and Brexit that the number of staff trained in World Health Organization (WHO) ‘red list’ countries – those deemed officially too understaffed to actively recruit from – rose rapidly as part of the expansion of non-EU staff. This trend has continued, which is explored below in greater depth.⁶⁰

The two years up to March 2023 continued previous nursing trends: between April 2021 and March 2023, 47,057 nurses joined the UK register from abroad beyond Europe, just behind 52,171 nurses from the UK. The number of nurses joining the register from EU and EEA countries trailed behind at 1,339. In the

59 UK Visas and Immigration (2020) ‘Skilled Worker visa: shortage occupations’. www.gov.uk/government/publications/skilled-worker-visa-shortage-occupations#full-publication-update-history. Accessed 20 March 2024.

60 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/sites/default/files/2022-12/1671199514-health-and-brexit-web.pdf.

same period, 49,847 UK nurses left the register, followed by 3,889 EU/EEA nurses and only 3,645 nurses from the rest of the world. Nurses trained outside the UK therefore entirely drove the sizeable net increase in the total number registered, even as the domestically trained workforce shrank (see Figure 12).



Source: Nursing and Midwifery Council

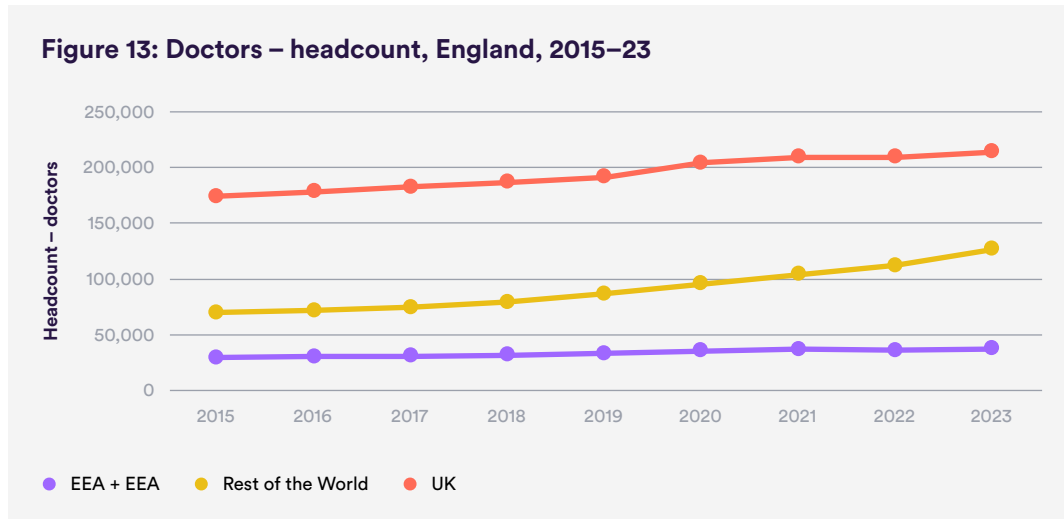
It should be noted that numbers on the UK register represent individuals who work both in the NHS and in the private sector. Also, they do not exactly reflect the number of individuals working as nurses, in the UK, full time. Some will cease to work in the UK but not leave the register, for example.

Doctors

In medicine, the overall growth in the number of EEA-trained doctors on the register remained relatively steady after the EU referendum. However, we have noted previously the disparities between individual specialties. Anaesthesia and cardio-thoracic surgery were among the professions that saw a falling off in EU recruitment at the qualified specialist level, even as shortages remained.⁶¹

61 McCarey M and Dayan M (2022) 'Has Brexit affected the UK's medical workforce?'. www.nuffieldtrust.org.uk/news-item/has-brexit-affected-the-uk-s-medical-workforce. Accessed 20 March 2024.

As in nursing, though not to as extreme a degree, a marked rise in non-EEA doctors registered in the UK began before covid-19. The increase in the number of doctors from the rest of the world seen after the UK left the EU continued to accelerate between March 2022 and March 2023 (see Figure 13).



Source: General Medical Council

Over 30,500 doctors from abroad excluding Europe (known as international medical graduates) joined the UK register from September 2020 to March 2023; just under 17,000 of those (or around 55%) between April 2022 and March 2023.

Again, these numbers represent both private and NHS doctors, and indeed those who while still meeting the requirements and paying the fees for UK regulation choose not to practice here.

The number of EU, EEA and Swiss doctors on the UK register remained relatively stable during the period. However, within this region, the proportion who had trained in Southern, Central and Eastern Europe, as well as the Baltic countries, increased relative to those from North-western Europe.⁶² From September 2020 to June 2023, the number of doctors from North-West Europe fell by 650. The number from Southern, Central, and Eastern Europe and the

62 We used the same regional country groupings as the General Medical Council: General Medical Council (2021) 'Our data about doctors with a European primary medical qualification in 2021'. www.gmc-uk.org/-/media/documents/eea-pmq-report-2021-final_pdf-88482214.pdf.

Baltic countries rose by almost 1,500. This may reflect shifting relative pay levels and perceived attractiveness of the UK, especially for North-western European countries.

Individual specialties

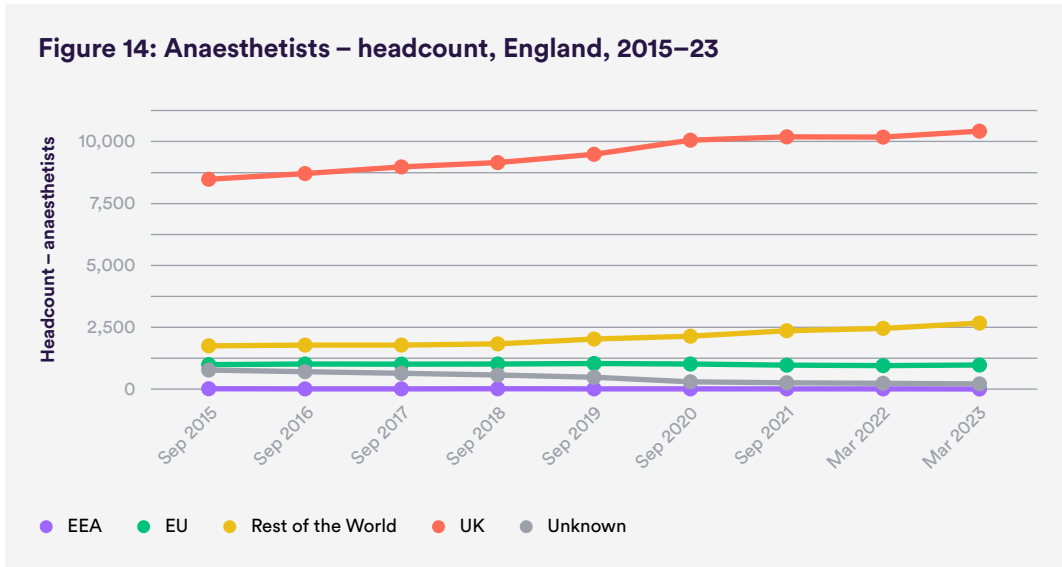
For this report, we conducted interviews to follow up on **anaesthetics**, one of the individual medical specialties we had looked at before in a separate short analysis, and found that it had relatively heavy recruitment from the EU and EEA before the EU referendum, which then tailed off.⁶³ We aimed to understand where its substantial use of EU and EEA staff had come from, the effect of Brexit and how its training and recruitment pipeline was affecting ongoing shortages.

Our stakeholders did not necessarily see a role for Brexit in staffing issues in relation to anaesthetics. They highlighted other interlinked factors:

- the reluctance of many doctors to take up posts outside London
- the sub-specialisation of anaesthetics, which not all hospitals are able to offer
- the high burnout rate of anaesthetists from the pandemic
- entry on training programmes being competitive and requiring results that will tend to favour wealthier or better-supported candidates
- problems with retention.

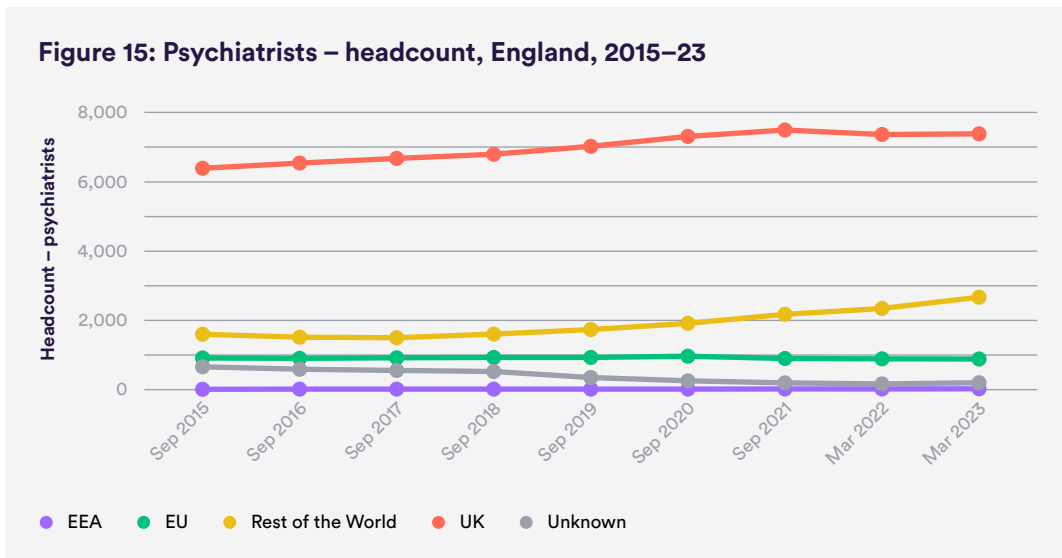
Figure 14 shows, for England, a continuation of the identified trend since the EU referendum, with the numbers of anaesthetists with EU and EEA nationalities flatlining, and a relatively slow growth of UK and other overseas staff over the course of 2023.

63 McCarey M and Dayan M (2022) 'Has Brexit affected the UK's medical workforce?'. [www.nuffieldtrust.org.uk/news-item/has-brexit-affected-the-uk-s-medical-workforce#:~:text=The%20overall%20number%20of%20EU,by%20around%201.7%25%20or%2033](https://www.nuffieldtrust.org.uk/news-item/has-brexit-affected-the-uk-s-medical-workforce#:~:text=The%20overall%20number%20of%20EU,by%20around%201.7%25%20or%2033.). Accessed 20 March 2024.



Source: NHS England

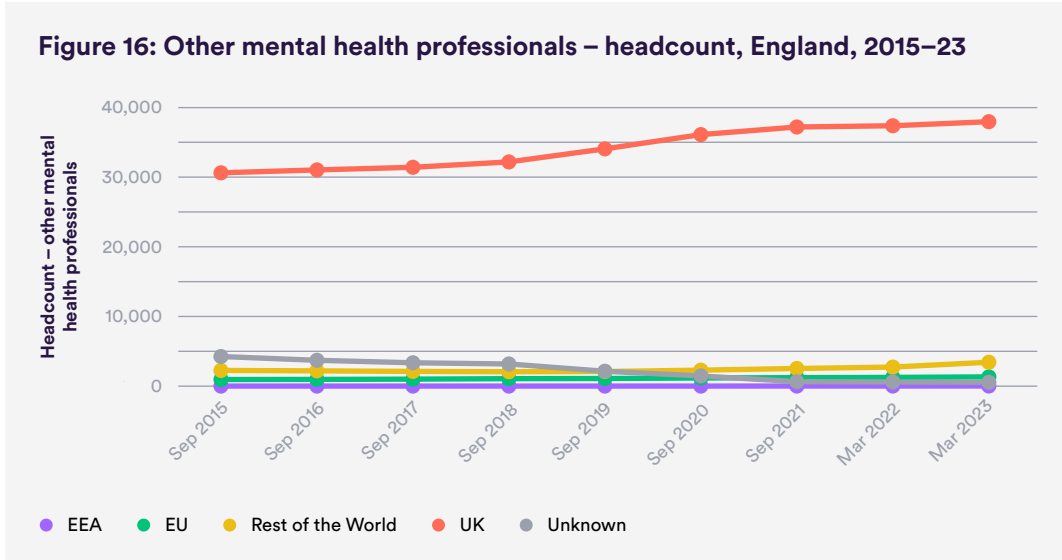
Recruitment of **psychiatrists** from the rest of the world (in England) continued to accelerate in 2022 and 2023, while EU and EEA numbers did not change, and UK numbers rose very slightly (see Figure 15).



Source: NHS England

The number of **other mental health professionals** (including psychiatric nurses and staff supporting nurses) from the rest of the world did not significantly increase in England, and increases in UK staff slowed down significantly after September 2020 (see Figure 16). This seems to signal

challenges with recruitment and retention for these positions, even with relative salary competitiveness.



Source: NHS England

These figures, combined with general continued pressure on funding and infrastructure, paint a bleak picture for future recruitment and the provision of mental health services even as the national Mental Health Investment Standard has led to a recovery in funding.⁶⁴

Social care

In social care, all international recruitment plummeted in 2020 and 2021 as the Covid-19 pandemic struck the UK in March 2020, and early 2021 saw EU and EEA workers no longer able to migrate to fill roles in the sector. However, the addition of care workers as a shortage occupation created a dramatic shift.

64 NHS Confederation (2023) ‘Health leaders call for action to tackle “national emergency” in mental health services’. www.nhsconfed.org/news/health-leaders-call-action-tackle-national-emergency-mental-health-services. Accessed 20 March 2024.

In the first year, 2022/23, nearly 60,000 migrant care workers, almost all from outside the EU, were given visas to enter the UK.⁶⁵ This caused the proportion of English care workers with a non-UK, non-EU nationality to jump from 10% to 14% in a single year – an unprecedented shift.⁶⁶

As with nursing, this seems to be almost solely responsible for a general improvement in the recruitment situation. International recruitment went from 20,000 in 2021/22, to 70,000 in 2022/23. However, in 2022/23, 30,000 UK workers and around 5,000 EU workers left the care workforce. Skills for Care reports that in 2022/23, vacancies in England – for both the public and private sectors – decreased by 7% to 152,000 (around 9% of the total available posts) over the year.⁶⁷ This represented an overall increase of 20,000 care workers – far below the expansion in non-EU migrant staff.

In December 2023, the Home Secretary, James Cleverly, announced that care workers would no longer be allowed to bring their spouse, children or other dependants with them when they entered the UK on work visas.⁶⁸ He noted that ‘approximately 120,000 dependants accompanied 100,000 care workers and senior care workers in the year ending September 2023’, illustrating how widespread this has been. Part of a series of measures in reaction to unprecedented levels of overall net migration into the UK, this caused widespread concern from social care representative bodies, with a coalition of health and care organisations labelling it ‘disastrous’.⁶⁹

65 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/#:~:text=The%20UK%20immigration%20system%20admitted,over%20the%20past%20five%20years>. Accessed 20 March 2024.

66 Skills for Care (2023) *The State of the Adult Social Care Sector and Workforce in England*. Skills for Care. www.skillsforcare.org.uk/Adult-Social-Care-Workforce-Data/Workforce-intelligence/documents/State-of-the-adult-social-care-sector/The-State-of-the-Adult-Social-Care-Sector-and-Workforce-2023.pdf.

67 www.skillsforcare.org.uk/Adult-Social-Care-Workforce-Data/Workforce-intelligence/publications/national-information/The-state-of-the-adult-social-care-sector-and-workforce-in-England.aspx

68 www.gov.uk/government/news/new-laws-to-cut-migration-and-tackle-care-worker-visa-abuse

69 Thomas R (2023) ‘Sunak warned “disastrous” visa changes could cut care workers by thousands’, Independent, 12 December. www.independent.co.uk/news/health/rishi-sunak-visa-change-care-workers-b2462418.html. Accessed 20 March 2024.

This illustrates an important but easily overlooked shift in how health and social care in the UK can recruit after Brexit. Without EU migrants holding an intrinsic right to free movement for work, there is a considerable political risk that governments will suddenly introduce measures that reduce the ability of both EU and non-EU workers to access the UK labour market. A pattern of moving between pragmatic openness to address the failure to train domestically and sporadic clampdowns can already be seen for non-EU staff across the past 20 years.⁷⁰

‘Red list’ recruitment

In our previous report on health and Brexit, we highlighted the issue of recruitment from lower-income countries with vulnerable health care systems and a level of staffing among doctors and nurses that falls under a specific threshold.⁷¹ These countries – such as Nigeria or Pakistan – feature on a ‘red list’ in the UK’s code of practice for the recruitment of international health and social care personnel,⁷² which mirrors the World Health Organization’s (WHO’s) ‘health workforce support and safeguards list’. Active recruitment from these countries is forbidden; ‘passive’ recruitment, such as individuals applying autonomously from those countries, is permitted. Countries can be taken off the red list if they reach a mutually beneficial agreement with the UK.

Several countries have memoranda of understanding (MoUs) with the UK. Nepal is the only one to have previously been included on the red list. Other countries such as Kenya were not added to the UK’s red list, in line with WHO guidance in 2023, because although they are on the WHO’s list, they had signed an MoU with the UK. These MoUs generally commit to a willingness to exchange staff and knowledge. With India, for example, we heard of a mutually

70 Dayan M and Palmer B (2019) ‘Stopping the staff we need’. www.nuffieldtrust.org.uk/sites/default/files/2019-12/1575384724_migration-election-briefing-web.pdf.

71 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/sites/default/files/2022-12/1671199514-health-and-brexit-web.pdf.

72 Department of Health and Social Care (2023) ‘Code of practice for the international recruitment of health and social care personnel in England’. www.gov.uk/government/publications/code-of-practice-for-the-international-recruitment-of-health-and-social-care-personnel/code-of-practice-for-the-international-recruitment-of-health-and-social-care-personnel-in-england. Accessed 25 March 2024.

beneficial exchange in staff and remittances. However, in the absence of wider, enforceable relationship frameworks, the MoUs are not legally binding and involve parties with very asymmetrical resources.

Between 2019 and 2022, staff numbers from red list countries rose significantly in the English NHS, by about 60%, from just under 22,000 to almost 35,000. This trend was visible across English NHS trusts, with some of them seeing far more significant increases, or even sourcing most of their international staff from those countries. This is a rate which calls into serious question whether recruitment is entirely passive.

In our previous report on health and Brexit we highlighted ethical concerns with this type of recruitment:

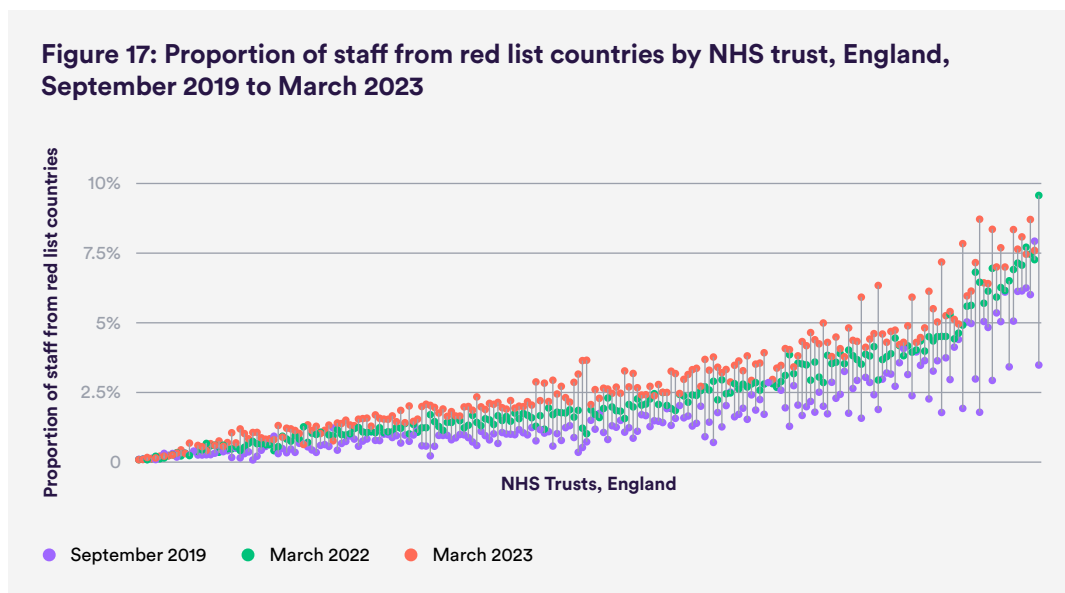
- questionable and abusive employment practices reported in the private sector
- a weakening of health services in lower-income countries, where around 90% of shortages occur
- further delaying meaningful workforce planning and reform by hiring staff who would work with conditions that UK staff are not willing to accept, with far less security.

The red list increased from 47 to 55 in August 2023, including countries such as Laos and Zimbabwe, in line with the WHO's updated list. The UK code of practice for the international recruitment of health and social care personnel was also updated,⁷³ ostensibly to improve monitoring for employers accredited as 'ethical' (these include the private sector and the NHS) and disciplinary action for those who infringe the code. However, this monitoring is not systematic, as it takes the form of random spot checks. If recruiters lose their accreditation, this is normally temporary (the period having been

73 Department of Health and Social Care (2023) 'Code of practice for the international recruitment of health and social care personnel in England'. www.gov.uk/government/publications/code-of-practice-for-the-international-recruitment-of-health-and-social-care-personnel/code-of-practice-for-the-international-recruitment-of-health-and-social-care-personnel-in-england. Accessed 25 March 2024.

extended from six months to a year), although it may become permanent. This approach does not convincingly display a willingness to enforce the code.

Repeating our analysis of NHS staffing data in England that we did in our previous report on health and Brexit, we found 45,500 staff from red list countries using the 2020 list and, excluding Nepal, this was a 30% increase in one year overall. Increases took place across NHS trusts (see Figure 17).



Source: NHS England

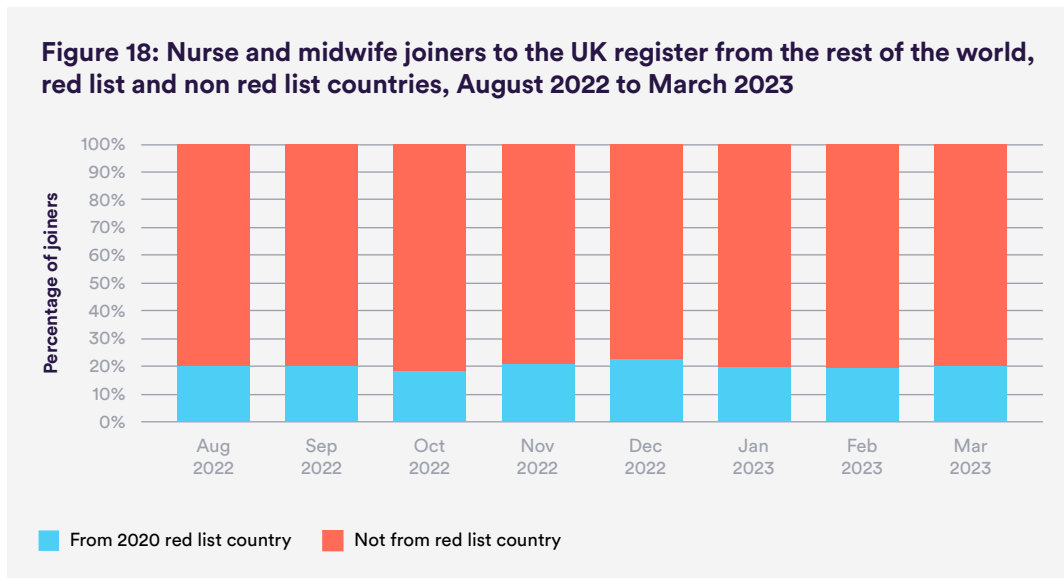
A significant and increasing proportion of overseas nurses and midwives joining the UK register across the 2021/22 and 2022/23 financial years (9,023 or around 19%) came from red list countries.⁷⁴

Similarly, over 10,500 (or around 35%) of new international medical graduates joining the UK register came from red list countries.⁷⁵

74 For our analysis we used the red list as it stood in 2020. The list was updated in August 2023. Nepal was the only country previously on the red list that was removed, as Nepal and the UK signed an MoU in August 2022. It is not included in the red list count. In total, 274 Nepalese nurses joined the register between April 2021 and August 2022, and 203 joined between September 2022 and March 2023.

75 As above, we used the 2020 red list, excluding Nepal.

Figure 18 shows the percentage of nursing and midwifery joiners from the rest of the world who were from red list or non red list countries between April 2021 and March 2023.



Source: Data supplied upon request by Nursing and Midwifery Council

In our last report on Brexit and health, stakeholders were very concerned with the recruitment of care workers from red list countries to the independent sector, due to unethical employment practices and poor job and immigration security. In 2023, around 15% of new international recruits to England were Nigerian.⁷⁶ Figures appear to be lower in Scotland, Wales and Northern Ireland. For Scotland, this may be attributable to competitive wage and qualification strategies presenting barriers for entry.⁷⁷

76 Skills for Care (2023) *The State of the Adult Social Care Sector and Workforce in England*. Skills for Care. www.skillsforcare.org.uk/Adult-Social-Care-Workforce-Data/Workforce-intelligence/documents/State-of-the-adult-social-care-sector/The-State-of-the-Adult-Social-Care-Sector-and-Workforce-2023.pdf#page=55. Accessed 20 March 2024.

77 Migration Advisory Committee (2023) 'Migration Advisory Committee (MAC) annual report, 2023, accessible'. www.gov.uk/government/publications/migration-advisory-committee-annual-report-2023/migration-advisory-committee-mac-annual-report-2023-accessible#chapter-2-health-and-social-care-revisited. Accessed 20 March 2024.

The latest data from the Migration Advisory Committee confirm these trends: of 142,800 skilled worker visas for the UK, 48% were granted to care workers, 99.9% of them from outside Europe. Four out of five of the top recruitment countries for care workers are on the red list.⁷⁸

Taken together, the flatlining or tapering of European staff, the difficulties with domestic recruitment and long-term retention, and the stark increases in international recruitment – increasingly from red list countries – suggest an exacerbation of the UK’s reliance on short-term recruitment boosts to make up for domestic shortages, instead of long-term planning. However, without the EU single market, and were the UK to implement ethical recruitment procedures, its pool is reduced.

International health and care workers enable the NHS to survive; they often start on lower pay⁷⁹ and work with poorer conditions than domestic workers will accept. While UK governments have at times announced an intent to reduce immigration and reduce exploitation, they have not improved the regulation of international recruitment, and despite workforce plans setting out longer-term strategies to boost training, as of late 2023 the domestic supply of staff clearly remained inadequate.

78 Migration Advisory Committee (2023) ‘Migration Advisory Committee (MAC) annual report, 2023, accessible’. www.gov.uk/government/publications/migration-advisory-committee-annual-report-2023/migration-advisory-committee-mac-annual-report-2023-accessible#chapter-2-health-and-social-care-revisited. Accessed 20 March 2024.

79 Migration Advisory Committee (2023) ‘Migration Advisory Committee (MAC) annual report, 2023 (accessible)’. www.gov.uk/government/publications/migration-advisory-committee-annual-report-2023/migration-advisory-committee-mac-annual-report-2023-accessible#chapter-2-health-and-social-care-revisited. Accessed 20 March 2024.

4 What options and priorities might exist for the UK to address these problems?

The impact of Brexit so far has been largely as a supporting factor in several of the long-running problems facing health, in a period rocked by a long spell of low capital spending and slow funding growth followed by a historic pandemic. It is tempting to assume that the solutions lie in achieving a relationship with the EU that helps to address these problems – and we explore the options in depth below. But our conversations with contributors to this project and our analysis of regulatory change show that the most feasible solutions to many of the issues that Brexit has created are actually within the UK’s hands to carry out unilaterally.

The current relationship with the EU is firmly outside the single market. Addressing many of these issues through renegotiation and reconnection would require a huge overhaul, would take several years and would be feasible only based on political considerations well beyond the domain of health. In the short term, the UK has considerable latitude for action in the health sector, which has increased in many regulatory areas due to Brexit itself. Despite extensive rhetoric, the UK has actually moved slowly and inconsistently to deploy this at times, and has often left industries and health officials unsure about its approach. Probably due to the limited capacity of regulators and politicians, the awkwardness of admitting that leaving the EU posed real difficulties and optimism about the inherent benefits of Brexit, the hard work

of establishing viable strategies for life outside the single market and European institutions has been relatively slow.⁸⁰

Safeguarding and stabilising medicine supplies

The UK's system for the reporting of medicine shortage issues, for informing health systems about them and for working with firms and markets to address them is much stronger than it was before preparations for Brexit began in 2018. A medicines supply team in the DHSC receives the notifications of impending problems that firms are required to give under law, conducts a risk assessment taking into account alternatives and clinical dangers, notifies NHS bodies and tries to manage the risks. It works with medicine supply and market teams in the different health services of the UK countries, and these bodies together comprise a Medicines Shortage Response Group, which advises on the most serious shortages.⁸¹

We also heard that regulators, such as the Medicines and Healthcare products Regulatory Agency (MHRA), played a helpful role in multiple instances adjusting authorisations or providing guidance to allow suppliers, prescribers and dispensers to give patients medicine that still covered their needs. People we heard from were generally unanimous that an intense period of preparations in 2018 and 2019, which anticipated a possible sudden 'no deal' Brexit, had been effective in terms of avoiding immediate shortages and left a legacy of capacity on this point.

However, we heard a number of concerns from stakeholders that could be addressed with no international renegotiation. The UK, in common with

80 Dayan M, Hervey T, Fahy N, Vlachakis E, McCarey M, Flear M, Greer S and Jarman H (2023) 'Parallel, divergent or drifting? Regulating healthcare products in a post-Brexit UK', *Journal of European Public Policy* 30(11), 2540–72. <https://openaccess.city.ac.uk/id/eprint/30702>. Accessed 20 March 2024.

81 Department of Health and Social Care (2021) 'DHSC reporting requirements for medicines shortages and discontinuations'. https://assets.publishing.service.gov.uk/media/608058a98fa8f51b9401005f/DHSC_Reporting_Requirements_for_Medicines_Shortages_and_Discontinuations.pdf.

many other countries,⁸² struggles to persuade firms to consistently report shortages in a timely fashion. This is all the more crucial because the long lead times for ordering products following the Covid-19 pandemic mean that meaningful action can take many months. It is also important to make sure suppliers feel confident that they can order more supplies and still expect demand when they arrive. Many of the most harmful diseases happen in disease clusters and could be predicted and understood only by looking above the level of individual products to whole markets of supply and demand. In some cases, such as medication for attention deficit hyperactivity disorder (ADHD), the drivers and dynamics of shortage were spotted and worked on relatively thoroughly; it is unclear that shortages of HRT or antibiotics were anticipated despite the predictable nature of some of their drivers, such as an accelerating trend of HRT prescriptions delayed by the Covid-19 pandemic.⁸³

One key insight emerging from our research is the comparative paucity of data for the UK on medicines shortages. France and Germany publish detailed, transparent and publicly accessible information even when medicines are merely experiencing supply pressures, dates of expected pressures, the anticipated end of pressures and the firms involved.⁸⁴ The UK has a set of different alert and update mechanisms, which are circulated to various groups, only some of which are published openly.⁸⁵ This in turn makes it difficult to have an informed national conversation about periods or areas of particular problems.

Those involved in community pharmacy told us that they often experienced shortages of products not officially classed as experiencing supply issues, and DHSC and NHS England teams told us that these were only localised

82 Ravela R, Airaksinen M and Lyles A (2023) 'State of the European Union's early notification obligation for drug shortages: enforcement and compliance in eight European countries (2020–2022)', *Journal of Pharmaceutical Policy and Practice* 16, 135. www.ncbi.nlm.nih.gov/pmc/articles/PMC10629130. Accessed 20 March 2024.

83 Appleby J (2022) 'Chart of the week: hormone replacement therapy prescriptions rise 42% in one year'. www.nuffieldtrust.org.uk/resource/chart-of-the-week-hormone-replacement-therapy-prescriptions-rise-42-in-one-year. Accessed 20 March 2024.

84 ANSM (no date) 'Disponibilité des produits de santé'. <https://ansm.sante.fr/disponibilites-des-produits-de-sante/medicaments>. Accessed 20 March 2024.

85 NECS Medicines Optimisation (2020) 'Supply issues & shortages – DHSC and NHSE&I guide'. [https://medicines.nescu.nhs.uk/supply-issues-shortages-dhsc-and-nhsei-guide/#:~:text=Tier%20%20\(low%20impact\)%3A,%E2%80%93%20when%20logged%2Din](https://medicines.nescu.nhs.uk/supply-issues-shortages-dhsc-and-nhsei-guide/#:~:text=Tier%20%20(low%20impact)%3A,%E2%80%93%20when%20logged%2Din). Accessed 20 March 2024.

problems. It is unclear why localised shortages should be prevalent in a fairly sophisticated national market with proportionately low transport costs. It may be that this reflects a bar set at a higher level, or the diversity of problems emerging. A more transparent approach including products that are still only facing limited or localised issues could help.

UK government or professional bodies could survey community pharmacists or their representative groups to track their experience of shortages, as the Pharmaceutical Group of the European Union (PGEU) does at a basic level across the entire EU. This should enable more monitoring of how well pharmacists understand reporting and response options, and what they see as the dynamics and drivers of problems.

We also heard concerns that squeezes to listed prices had made medicine supplies more fragile by driving suppliers out. It is imperative to achieve the best possible value in a context of extreme funding pressure in the NHS, but this needs to be modelled in the full context of the risk of shortage with the financial cost of price concessions, risks to patient care and the implications for workforce costs in pharmacies where a significant amount of time must be spent searching for scarce products. We heard a perception that periods of austerity for pricing in 2023, after the Covid-19 pandemic had greatly reduced in intensity, came after a period of significant price increases around 2022; any inconsistency over time risks contributing to sporadic shortages while still not delivering best value.

For branded medicines, the 2024 voluntary scheme for branded medicines pricing, access and growth (VPAG) between industry and government⁸⁶ is not likely to repeat the sudden spike in clawbacks demanded from the medicines industry caused by its predecessor (the 2019 voluntary scheme for branded medicines pricing and access – VPAS), which protected the NHS financially but made little sense as a policy instrument in its wider effect on the medicines market. The wider lesson is to monitor carefully the implications for market depth and stability in a new world of regular shortages – keeping a watchful eye on the negotiating incentives of industry to claim a risk of

86 Department of Health and Social Care (2023) '2024 voluntary scheme for branded medicines, pricing, access and growth'. <https://assets.publishing.service.gov.uk/media/657b2977095987001295e139/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth.pdf>.

shortages. The new scheme financially penalises existing medicines where their prices are not reduced over time. While the general logic is obvious, this may be difficult in instances where branded generics in fact have relatively low profit margins and there are few alternative suppliers.

Officials in the DHSC will be tracking the progress of the key EU shortages initiatives outlined above. They should liaise with industry about whether plans to shift production to the EU under the Critical Medicines Alliance, or the joint procurement for antibiotics and other products planned from the next winter onwards,⁸⁷ will have implications for supply into the UK. The unpredictable and widespread nature of shortages implies that this should take into account how issues will play out under future difficult circumstances, even with no present problems. During the Covid-19 pandemic, the UK was successful in competing with EU joint procurement for vaccines, but this came at the cost of paying considerably more per dose.⁸⁸

In 2020, the UK announced and explored its own programme to increase domestic production of vital products, including pharmaceuticals: ‘Project Defend’. There are a number of risks in attempting to move production to the UK, including simply raising costs, dropping a supply chain that connects the UK to large-scale production in Asia – which forms the backbone of world supply – and the fact that a medium-sized country could only ever produce a fraction of medicine types itself. However, it could reduce transport costs, provide more certain access and cut lead times, which we heard are now even longer than in 2020. Sam Roscoe at the UK Trade Policy Observatory suggested in commentary at the time that an initiative such as this could be helpful if it was targeted to fill in likely gaps, for example by having factories in the UK ready to add supply in three or four months’ time for critical products and supporting this by three- to four-month stockpiles.⁸⁹

87 European Commission (2023) ‘Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions’. <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX%3A52023DC0672>. Accessed 20 March 2024.

88 Dyer O (2021) ‘Covid-19: countries are learning what others paid for vaccines’, *BMJ* 372, n281. www.bmj.com/content/372/bmj.n281. Accessed 20 March 2024.

89 Roscoe S (2020) ‘Building supply chain resilience: a reflection on “Project Defend” and the reshoring of manufacturing’. <https://blogs.sussex.ac.uk/uktpo/2020/05/28/building-supply-chain-resilience-a-reflection-on-project-defend-and-the-reshoring-of-manufacturing>. Accessed 20 March 2024.

Regulation and management for the life sciences, medicines and medical devices sector

Stability and strategy

Both the smooth running of supply chains and services, and innovation in life sciences, would also be better served by ensuring greater regulatory stability over time. In many cases, alignment with the EU would be a successful strategy. The UK is already adopting this strategy in many domains; but in some cases, it has in practice simply added uncertainty by suggesting that it will not. The sheer volume of regulation and the safety and economic risks of getting it wrong mean that the limited capacity of the British state leads to continuity as a default.

Here, the difference between rhetoric and reality is striking. In terms of medical devices regulation, the post-Brexit system has yet to be fully implemented, with repeated extensions to the shut-off date after which manufacturers can no longer rely on EU approvals. This system and the accompanying UK accelerated routes are now not to begin implementation until July 2025, and even that timeline is ‘subject to ongoing review’.⁹⁰ However, the repeated delays to compulsory UK compliance for the sale of devices in Great Britain means that what has in practice been a period of considerable stability has not felt like this to the industry itself. It naturally will tend to call into doubt whether the investment and reorientation needed to register in the UK will ever in fact be required.

⁹⁰ Medicines and Healthcare products Regulatory Agency (2023) ‘Timeframe for accepting CE marked medical devices in Great Britain extended’. www.gov.uk/government/news/timeframe-for-accepting-ce-marked-medical-devices-in-great-britain-extended. Accessed 20 March 2024.

Retaining ‘data adequacy’ status – a level of recognised alignment that permits the free exchange of data with the EU – has been a priority for the life sciences sector throughout the Brexit process.⁹¹ In 2022 and 2023, the UK presented two successive Data Protection and Digital Information Bills. The first of these was reportedly paused in the face of concerns about losing the data adequacy status, with the second being welcomed by some stakeholders as reducing the risk.⁹² While the UK government’s statements emphasise that they believe the Bill to be consistent with adequacy, they have not stated that the measures are conditional on not affecting the renewal of adequacy status, causing some stakeholders we spoke to have a degree of remaining uncertainty.

In clinical trials, meanwhile, the UK has published a full set of proposals for a reformed domestic system.⁹³ In many ways, this mirrors changes in the EU, closing once again the gap created by changes implemented after the UK left the EU, and people we spoke to often saw it in this light. However, it has not generally been publicly framed in this way.

Unlike medical devices and clinical trials, the regulation of medicines themselves has not yet been the subject of any concrete proposals at a legal level, diverging from inherited EU law. Arguably, despite this it has been the area with the most genuine divergence in action, such as the Innovative Licensing and Access Pathway described in Chapter 2. There are reasons to be concerned that any actual or proposed shifts in medicines regulation would be particularly disruptive. Aspects of medicines regulation are still aligned with the EU, under the EU–UK Trade and Cooperation Agreement (TCA), and divergence would mean breaching or renegotiating that agreement. Equally, the Windsor Framework settlement creates a complex legal reality in Northern Ireland where medicine is supplied under EU laws, but with the UK regulator filling the role of providing.

91 Dayan M, McCarey M, Hervey T, Fahy N, Greer SL, Jarman H, Stewart E and Bristow D (2021) *Going It Alone: Health and Brexit in the UK*. Nuffield Trust. www.nuffieldtrust.org.uk/sites/default/files/2021-12/1639914471_nuffield-trust-health-and-brexit-in-the-uk-web.pdf.

92 Department for Science, Innovation and Technology and Donelan M (2023) ‘British businesses to save billions under new UK version of GDPR’. www.gov.uk/government/news/british-businesses-to-save-billions-under-new-uk-version-of-gdpr. Accessed 20 March 2024.

93 Medicines and Healthcare products Regulatory Agency (2023) ‘Proposals for legislative changes for clinical trials’. www.gov.uk/government/consultations/consultation-on-proposals-for-legislative-changes-for-clinical-trials/proposals-for-legislative-changes-for-clinical-trials. Accessed 20 March 2024.

In both medicines and medical devices, the UK has actively explored and started to recognise and accept stages of approval done in other countries as well as the EU.

This model of the UK as a decision recipient by default has several advantages. It reduces demands on the regulator, and in some cases means that the UK is not reliant on decisions by companies over whether the regulatory process is worth beginning. However, as the case of medicines authorised by the EMA illustrates, it means later approval is likely to be the general pattern. Particular initiatives such as Project Orbis for cancer drugs⁹⁴ and the Medical Device Single Audit Program⁹⁵ aim to pool UK regulatory capabilities with those of other countries to streamline approvals across several countries. These offer a way around those limitations, but are currently limited in the stages and products they cover.

Regulatory process

Rather than framing the regulatory independence that flows from Brexit as a good in its own right, a focus on the content of the regulatory decisions that are taken with that newfound freedom and, crucially, the processes that surround such decision-making, would be beneficial. The UK may already have missed opportunities to adopt effective regulatory reform: the Medicines and Medical Devices Act 2021 is a case in point (as, for example, Quigley and others argue⁹⁶).

The EU is often criticised for its opacity, distance from stakeholders and executive dominance; Westminster decision-making with the same features can hardly be expected to secure a ‘Brexit benefit’ for the NHS. We heard a range of different views on what an optimal regulatory settlement for

94 Medicines and Healthcare products Regulatory Agency (2020) ‘Project Orbis’. www.gov.uk/guidance/guidance-on-project-orbis. Accessed 20 March 2024.

95 U.S. Food & Drug Administration (no date) ‘Medical Device Single Audit Program (MDSAP)’. [www.fda.gov/medical-devices/cdrh-international-affairs/medical-device-single-audit-program-mdsap#:~:text=The%20Medical%20Device%20Single%20Audit,authorities%20participating%20in%20the%20program.&text=MDSAP%20Official%20Observers%3A,European%20Union%20\(EU\)](http://www.fda.gov/medical-devices/cdrh-international-affairs/medical-device-single-audit-program-mdsap#:~:text=The%20Medical%20Device%20Single%20Audit,authorities%20participating%20in%20the%20program.&text=MDSAP%20Official%20Observers%3A,European%20Union%20(EU)). Accessed 20 March 2024.

96 Quigley M, Downey L, Mahmoud Z and McHale J (2023) ‘The shape of medical devices regulation in the UK? Brexit and beyond’, *Law, Technology and Humans* 5(2), 21–42. <https://lthj.qut.edu.au/article/view/3102>. Accessed 20 March 2024.

medicines, devices, life sciences research and innovation should be for Great Britain, focused on, among other things:

- the desirability of Great Britain as a market for innovation
- timely access of NHS patients to publicly funded treatments
- the balance between incentivising generics supply over proprietary brands.

The point here is not that our research suggests one particular regulatory balance between all the competing interests, but rather that all the relevant stakeholders need to be at the table, in a transparent and evidence-led discursive process, if policy outcomes are to have any chance of being optimal.

At present, the rhetoric of ‘freedom’, ‘sovereignty’ and ‘global Britain’ are stifling this kind of measured policy discourse, and silencing important voices. Behind closed doors, changes in policy course towards continued alignment with the EU in many areas, and the experiences we heard from contributors to this report, indicate that industry, government and some stakeholder groups do select between trade-offs. But ministerial speeches have never framed the issues in this way, and thus in the judgement of the authors, the implications of different global regulatory strategies for innovation and life sciences cooperation are relatively rarely discussed within NHS or public health discourses.

Serious consideration to committing to a stable alignment approach has been particularly rare in open government discussion, although several stakeholders we spoke to and the UK Trade and Business Commission have recommended it.⁹⁷ Stable dynamic alignment with the EU would offer clarity and certainty for industry planning, and may be particularly appropriate in certain areas, such as recognising CE marking for medical devices and equipment, or data protection.

97 www.tradeandbusiness.uk

Working within a wider context

We would also suggest that such a policy discussion should be informed by active discussion of the policy direction of our large and proximate neighbour. The EU has recently changed medical devices regulation; it is working on a major review of medicines regulation, including aspects of clinical trials; and it is actively pursuing artificial intelligence (AI) regulation. The EU's ongoing reform of medicines regulation has the potential for the EU to become a less attractive place for investment, and the UK's position can, and should, be informed by what is happening over the Irish border and across the English Channel. There may be opportunities associated with selective active divergence (for example, in better aligning health technology assessment and patient access with marketing approval processes – something the EU seeks, but has thus far lacked the competence and political will to achieve). The data on the MHRA licensing process is worrying in this regard, as we heard from stakeholders that if the UK becomes slower on medicine-to-market approval, with no change to the speed of getting medicines to NHS patients, then it is likely to gradually become less appealing to the industry. Regulatory capacity to implement policy choices may thus be more important than more upstream regulatory alignment with the EU, or even agreement on matters such as batch-testing recognition, currently missing from the EU-UK TCA. For medical devices, we heard some criticisms of the rollout of the EU's new medical devices legislation; there may be opportunities to create a better domestic medical devices regulatory system for Great Britain.

But a 'wait and drift' approach is unlikely to be optimal, as both the uncertainty and the potential dual regulatory burden for suppliers seeking to supply both Great Britain and the EU have a chilling effect on industry behaviour. This is evidenced by our data confirming that, faced with the possibility of a 'no deal' Brexit, global industry actors reconfigured their supply-chain logistics, and have not necessarily reintegrated Great Britain into them. For example, the EU is aggressively pursuing a particular position on AI regulation, including in life sciences; but discussions in Great Britain are taking place without much reference to the EU's position. Yet, if life science research collaborations are to continue with EU partners, or if product supply of medical devices will be affected by AI compliance, in practice, Great Britain will need to be compliant with the EU's AI regulatory position, just as Great Britain is recognised as compliant with the General Data Protection

Regulation (GDPR). Better, therefore, to be honest about dynamic alignment, where this is the current GB policy position.

Workforce: finding a stable footing

For most countries, planning and securing a health and social care workforce is primarily a matter of domestic policy. The UK is anomalous in relying on migration to secure a significant proportion of its doctors, nurses and care workers to such a degree – to the point, in fact, where workers qualified overseas are currently the main source of new clinicians joining the workforce for several professions.

Successive waves of migrant workers have played an essential role in the history of the NHS and social care in the UK. It is difficult to imagine a functional health system at all without their contribution. But an appropriate sense of gratitude should not blind us to the disadvantages of this approach. It means that the availability of different staff groups is determined by the global labour market, not planning in the UK. This leaves the NHS facing, for example, a much lower capability to obtain mental health nurses than general hospital nurses from other countries.⁹⁸ It leaves services constantly at risk from political moves to cut immigration back. There is considerable evidence, discussed above, that it removes trained staff in large numbers from developing countries that desperately need them. We have previously warned that there are worrying cases of staff being mistreated in a context where so many of them depend on their employer’s visa to carry on with their lives in the UK.⁹⁹

The UK’s constituent countries have long held control over nearly all the levers that determine whether an adequate domestic workforce exists – training, pay, terms and conditions, operational management and professional regulation. In England, the new NHS Long Term Workforce Plan sets out training

98 Phiri P, Sajid S, Baykoca A, Shetty S, Mudoni D, Rathod S and Delanerolle G (2022) ‘International recruitment of mental health nurses to the national health service: a challenge for the UK’, *BMC Nursing* 21, 355. www.ncbi.nlm.nih.gov/pmc/articles/PMC9743101. Accessed 20 March 2024.

99 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/sites/default/files/2022-12/1671199514-health-and-brexit-web.pdf.

ambitions up until to 2036/37¹⁰⁰ and envisages a gradual lowering of the need for migrant workers based on this. Meanwhile the Scottish government¹⁰¹ and the Welsh government¹⁰² have both recently announced significant initiatives to expand training.

Other significant issues contributing to the failure to secure the right level of domestic staff across all the roles that health services need are well known:

- Attrition from training and in the early years of work is a serious problem, meaning, for example, that large past increases in GP trainees made little impact on the actual numbers progressing into a career. Examples of more radical and targeted policies to address this exist in many countries. For instance there is reason to believe that student loans forgiveness could be a well-targeted policy.¹⁰³
- Rates of staff leaving have recently been elevated in the UK. The English NHS Long Term Plan includes targets to improve retention, but reasons for leaving are not fully understood and more ambitious action based on better evidence is needed.¹⁰⁴
- The UK countries, in particular England, have seen industrial action and renegotiated pay settlements. These highlight the need for reform to the pay review system.¹⁰⁵

100 NHS England (2023) *NHS Long Term Workforce Plan*. NHS England. www.england.nhs.uk/publication/nhs-long-term-workforce-plan. Accessed 20 March 2024.

101 Scottish Government (2023) 'Expanding Scotland's medical workforce'. www.gov.scot/news/expanding-scotlands-medical-workforce-2. Accessed 20 March 2024.

102 Morgan E (2023) 'Written statement: expansion in training places for the health professional workforce in Wales'. www.gov.wales/written-statement-expansion-training-places-health-professional-workforce-wales-0. Accessed 20 March 2024.

103 Palmer B, Rolewicz L and Dodsworth E (2023) *Waste Not, Want Not: Strategies to improve the supply of clinical staff to the NHS*. Nuffield Trust. www.nuffieldtrust.org.uk/research/waste-not-want-not-strategies-to-improve-the-supply-of-clinical-staff-to-the-nhs. Accessed 20 March 2024.

104 Palmer B and Rolewicz L (2022) 'The long goodbye? Exploring rates of staff leaving the NHS and social care'. www.nuffieldtrust.org.uk/resource/the-long-goodbye-exploring-rates-of-staff-leaving-the-nhs-and-social-care. Accessed 20 March 2024.

105 Palmer B (2023) 'Basis of negotiation: recommendations to improve the NHS pay review process'. www.nuffieldtrust.org.uk/news-item/basis-of-negotiation-recommendations-to-improve-the-nhs-pay-review-process. Accessed 20 March 2024.

- Successfully managing new staff groups such as physician associates so that they add to workforce capability in a safe way is key, with greater attention paid to regulation and ensuring a consistent scope of responsibilities.

In social care, pay and conditions are crucial factors in competitiveness in hiring from the domestic workforce. The Migration Advisory Committee, which the government set up to adjudicate occupations on shortage, has repeatedly warned that migration is necessary solely because the sector is not able to succeed in attracting staff in the UK. The Committee stated in a 2022 report that: ‘Persistent underfunding of the care sector by successive Governments underlies almost all the workforce problems in social care... Higher pay is a prerequisite to attract and retain social care workers.’¹⁰⁶ While the increase in the National Living Wage this year will increase pay considerably, it is likely to continue a dynamic where social care pay rates are squeezed against the lowest-paid sectors in the economy, with care workers receiving ever less of a premium for the vital responsibilities they must deliver on compared with shop or bar workers.¹⁰⁷

There is no doubt that restoring free movement of labour with the EU would make it easier for the NHS and social care to attract staff from the EEA, provide those workers with greater security if they did come to the UK and offer greater policy stability. But this is far from the political agenda at the UK level. Given the signs of diminishing UK attractiveness to Western European migrants discussed above, and with the UK now considerably closer to average EU income per head than it was in 2016,¹⁰⁸ there is reason to think it might not attract as large a pool of extra care labour as it did during its period of membership of the EU. Reducing the UK’s tendency towards sporadic massive staff shortages in the first place is the surest way to give greater stability.

106 Migration Advisory Committee (2022) ‘Adult social care and immigration (accessible)’. www.gov.uk/government/publications/review-of-adult-social-care-2022/adult-social-care-and-immigration-accessible#chapter-4-recommendations. Accessed 20 March 2024.

107 Dayan M (2023) ‘Time to worry about the social care squeeze’. www.nuffieldtrust.org.uk/news-item/time-to-worry-about-the-social-care-squeeze. Accessed 20 March 2024.

108 <https://stats.oecd.org>

Reciprocal health care

The EU-UK TCA secures the continuation of several reciprocal health care agreements available to UK and EU citizens during the period of EU membership. This includes the right to emergency care while travelling, signalled by European (now Global) Health Insurance Cards, and the S1 initiative, which allows, for example, retirees moving from the UK to the EU to take their entitlement to care with them.¹⁰⁹ Since the EU referendum, the UK government has at times raised concerns and warned travellers about risks from medical tourism by UK patients outside the EU, in countries such as Türkiye,¹¹⁰ which now compete on a more even footing with EU suppliers of cosmetic and planned care.

Northern Ireland

The agreement of the Windsor Framework between the UK and the EU in early 2023 is an important step forward in creating a status under EU-UK treaties for Northern Ireland that is consistent with avoiding serious disruption to medicine supply.¹¹¹ But further decisions and developments with important consequences for health lurk in the near future.¹¹²

This year will see the application of the ‘democratic consent’ mechanism, which determines whether provisions of the Northern Ireland Protocol on individual rights, travel, customs and medicines and devices regulation will continue to apply. The UK government has specified that this will be a vote

109 European Commission (2021) ‘The EU-UK Trade and Cooperation Agreement’.

https://commission.europa.eu/strategy-and-policy/relations-non-eu-countries/relations-uk/eu-uk-trade-and-cooperation-agreement_en. Accessed 20 March 2024.

110 GOV.UK (no date) ‘Foreign travel advice: Turkey’. www.gov.uk/foreign-travel-advice/turkey/health. Accessed 20 March 2024.

111 Nuffield Trust (2023) ‘Nuffield Trust response to Windsor Framework on Northern Ireland: Mark Dayan responds to the Windsor Framework agreed between the UK and EU’. www.nuffieldtrust.org.uk/news-item/nuffield-trust-response-to-windsor-framework-on-northern-ireland. Accessed 20 March 2024.

112 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 20 March 2024.

among members of the Northern Irish Assembly.¹¹³ As of April 2024 the voting intentions of parties remain unclear, creating considerable uncertainty. Polling data show that while the proportion of Northern Irish voters opposed to the Protocol has somewhat reduced, the intensity of opposition remains strong, with almost a quarter only willing to vote for candidates who are opposed to it.¹¹⁴

The relevant articles would stop applying after two years, a comparable notice period to the entry into force of key provisions of the original Protocol relationship associated with a dramatic surge in medicine shortage notifications in late 2021.¹¹⁵ Exactly what would happen is unclear: the EU-UK Joint Committee set up under the Withdrawal Agreement would make recommendations to both parties. Throughout the consent process and the subsequent possible response, health in Northern Ireland is likely to be best served by not jeopardising the benefits of the original Protocol for the movement of people and medical devices, or the unique arrangement for medicine created in the 2023 Windsor Framework.

The Windsor Framework also still requires flexible and careful implementation. It will mean a shift in labelling as medicines in line with UK authorisations are once again being accepted, shifting Northern Ireland away

113 HM Government (2019) 'Declaration by Her Majesty's government of the United Kingdom of Great Britain and Northern Ireland concerning the operation of the "democratic consent in Northern Ireland" provision of the Protocol on Ireland/Northern Ireland'. https://assets.publishing.service.gov.uk/media/5daaabbfe5274a5cb0df8351/Declaration_by_Her_Majesty_s_Government_of_the_United_Kingdom_of_Great_Britain_and_Northern_Ireland_concerning_the_operation_of_the__Democratic_consent_in_Northern_Ireland__provision_of_the_Protocol_on_Ireland_Northern_Ireland.pdf.

114 Queen's University Belfast (2023) 'Three years of polling on the Protocol reveals the depth of the new division in Northern Ireland'. www.qub.ac.uk/News/Allnews/2023/Three-years-of-polling-on-the-Protocol-reveals-the-depth-of-the-new-division-in-Northern-Ireland.html. Accessed 20 March 2024.

115 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 20 March 2024.

again from EU product approvals.¹¹⁶ This could still cause some disruption and cost for firms. There will be a difficult balance between being flexible enough not to cause suppliers to pull out, but not so flexible that they simply do not bother making changes on the assumption that this will be another threatened Brexit provision left to languish in endless delay. Building on mutual commitment to improving the status of Northern Ireland, rather than undermining it, will be crucial.

The EU's new Artificial Intelligence Act, presented as a European Commission proposal in 2021¹¹⁷ and reaching provisional agreement between the European Council and European Parliament in late 2023,¹¹⁸ would open up a sharp divergence with the UK, with uncertain implications for Northern Ireland. It sets out a comprehensive regulatory framework for AI, with requirements for transparency, human oversight, testing and explanation depending on risk. Medical devices that are regulated as such are high risk. This could include both pure software and software built into physical products.¹¹⁹ Northern Ireland follows EU medical devices regulation under the Northern Ireland Protocol, but would by default be aligned with the UK's AI regime – or lack thereof, given that UK ministers have expressed a short-term policy of refraining from regulation.¹²⁰ This raises possible problems. Medical devices could be legal in Northern Ireland but not in the EU, potentially creating a

116 Medicines and Healthcare products Regulatory Agency (2024) 'Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework'. www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework. Accessed 20 March 2024.

117 European Union (2021) 'Proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative Acts'. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52021PC0206>. Accessed 20 March 2024.

118 Council of the European Union (2023) 'Artificial Intelligence Act: Council and Parliament strike a deal on the first rules for AI in the world'. www.consilium.europa.eu/en/press/press-releases/2023/12/09/artificial-intelligence-act-council-and-parliament-strike-a-deal-on-the-first-worldwide-rules-for-ai. Accessed 20 March 2024.

119 Burges Salmon (2022) 'The EU's proposed AI Act: a quick guide for healthtech'. www.burges-salmon.com/news-and-insight/legal-updates/healthcare/the-eus-proposed-ai-act-a-quick-guide-for-healthtech. Accessed 20 March 2024.

120 Financial Times (2023) 'UK will refrain from regulating AI "in the short term"', *Financial Times*, 16 November 2023. www.ft.com/content/ecef269b-be57-4a52-8743-70da5b8d9a65. Accessed 20 March 2024.

border that would be difficult to enforce and leaving cross-border services at legal risk. Meanwhile, given that Northern Ireland is in practice part of the EU market for medical devices, patients there may not be able to access product types available in the rest of the UK, creating concerns about disparities. An alternative would be to incorporate artificial intelligence regulation into the body of single market law which continues to apply to Northern Ireland under Article 13 of the Protocol which allows for this, splitting it off from Great Britain. Depending on how it was applied, this could leave Northern Ireland separated from digital services relating to health care based elsewhere in the UK.¹²¹

The Stormont Brake introduced by the Windsor Framework would allow Members of the Northern Ireland Assembly to request the UK government block any new law, possibly resulting in EU remedial actions – a potentially significant dynamic across other areas of medical product and life sciences regulation in future as well.

Perhaps the furthest-reaching impact of Brexit and the Protocol on health in Northern Ireland was its contribution to the inability to form a devolved government from early 2022 until the agreement to reform a government in January 2024. This held back changes to hospital service locations, staff pay and policy and social care, which had previously enjoyed political consensus, in the context of a system failing to deliver timely treatment to a far worse degree than elsewhere in the UK.

Article 2 of the Northern Ireland Protocol commits the UK to ensuring that Brexit does not cause a ‘diminution of rights, safeguards or equality of opportunity’,¹²² as set out in the 1998 Belfast Agreement, which refers to human rights quite broadly. It has been prominent in recent asylum and legacy cases, but it is still only really beginning to be used, for example in the

121 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 20 March 2024.

122 GOV.UK (2020) ‘Protocol on Ireland/Northern Ireland’. https://assets.publishing.service.gov.uk/media/5da863ab40f0b659847e0184/Revised_Protocol_to_the_Withdrawal_Agreement.pdf.

Angesom case.¹²³ This is a recent judgement of the (NI) High Court, concerned with the rights to privacy and family rights under Article 8 of the European Convention on Human Rights of an asylum seeker who had been moved from Northern Ireland to Scotland.¹²⁴ Part of his argument was that this move meant he was outside the scope of the protection of the EU Charter, so that his rights had been diminished within the meaning of the Protocol. The Court determined that his rights had not been diminished, in part because protection under the Human Rights Act was equivalent to the same protection under the Charter. This is a problematic assumption. Further judgments here may have implications for how the courts treat cases of diminution in a health care context.

In many regards, the hiatus in Stormont has meant very little new law-making relevant to Northern Ireland, which probably dampens the possibility of Article 2 claims in relation to devolved issues, for the time being. Medical negligence cases and access to treatment for prisoners have previously been issues where human rights agreements protected under Article 2 have had implications for health and health care.

123 Judiciary NI (2023) 'King's Bench Division (judicial review): in the matter of an application by Aman Angesom for judicial review and in the matter of a decision by the Secretary of State for the Home Department and the Human Rights Commission and the Equality Commission intervening'. www.judiciaryni.uk/sites/judiciary/files/decisions/Angesom%27s%20%28Aman%29%20Application.pdf.

124 Judiciary NI (2023) 'King's Bench Division (judicial review): in the matter of an application by Aman Angesom for judicial review and in the matter of a decision by the Secretary of State for the Home Department and the Human Rights Commission and the Equality Commission intervening'. www.judiciaryni.uk/sites/judiciary/files/decisions/Angesom%27s%20%28Aman%29%20Application.pdf.

5 What are the realistic prospects for enhanced cooperation with the EU and institutions within it to improve health in the UK?

Evidence from our roundtable, other engagement with stakeholders and studies on the wider economy confirms what was already known: geography matters. The UK's relationship with the EU will continue to be a significant one for the NHS and the health of citizens, not least because of the position of Northern Ireland. As noted earlier in this report, no obvious or simple bilateral solutions exist to the ongoing aspects of the challenges facing the NHS in the UK that are attributable, at least in part, to the changes that Brexit brought. The UK and its constituent countries face difficult policy choices as they respond to the changing global and European environment in the health and social care domain. That applies to finding domestic policies that improve resilience. But it also applies to building and rebuilding links with the EU to regain some of the benefits of smoother exchange and cooperation.

A difficult backdrop: the process of departure and the current EU–UK relationship

The process of leaving the EU was characterised by fraught EU–UK relations, especially over a misalignment of understandings of where each side had negotiating flexibilities to offer. Northern Ireland was a particular pressure point. In the final analysis, the EU was able to hold firm on the vast majority of its starting demands.^{125,126} The EU’s formal position was that a non-member of the EU/EEA could not have any of the benefits that flow from single-market membership. By contrast, the UK’s position was often opaque, reflecting tensions within government,¹²⁷ especially a tussle between a more practical, geography-based position associated with the Treasury and business interests, and a ‘global Britain’ position, focused on relationships with English-speaking countries irrespective of geography and associated with some ministers.¹²⁸ The legacy was serious damage to mutual trust and willingness to engage, to levels that would constitute a problematic relationship between any two neighbours. Regrettably, this extended deep into issues and institutions in health.

The year 2023 saw a change of course, welcomed by those stakeholders with whom we engaged, with the Windsor Framework representing a new (although potentially time-limited) settlement for trade relations on the island of Ireland. Not only Northern Ireland, but also the Republic of Ireland, Cyprus and Malta, needed more flexible market access rules to secure medicine supply in practice. The temporary measures originally

125 Gosty ska-Jakubowska A and von Ondarza N ‘The Barnier method: lessons learned from the EU’s institutional approach to the Brexit negotiations’ in Aktoudianakis A, Biskup P, Bodson B, Eisl A, Fabry E, Gosty ska-Jakubowska A and others (2020) *Towards an Ambitious, Broad, Deep and Flexible EU–UK Partnership?*. European Policy Centre. www.epc.eu/content/PDF/2020/6_Barnier_method.pdf.

126 European Council (2017) ‘Guidelines following the United Kingdom’s notification under Article 50 TEU’. www.consilium.europa.eu/media/21763/29-euco-art50-guidelinesen.pdf.

127 Siles-Brügge G (2018) ‘Bound by gravity or living in a “post geography trading world”? Expert knowledge and affective spatial imaginaries in the construction of the UK’s post-Brexit trade policy’, *New Political Economy* 24(3), 422–39. www.tandfonline.com/doi/full/10.1080/13563467.2018.1484722. Accessed 20 March 2024.

128 Heron T and Siles-Brügge G (2022) “Global Britain” and “post-geography”. <https://sites.utu.fi/bre/global-britain-and-post-geography>. Accessed 20 March 2024.

agreed will cease to apply at the end of 2024.¹²⁹ The Windsor Framework's more permanent flexibilities for medicines, which will enter into force on 1 January 2025, are conditional on the UK providing written guarantees on the monitoring of compliance,¹³⁰ especially of the labelling rules imposed on medicines going from Great Britain to Northern Ireland, and the European Commission accepting those guarantees – an example of the EU's continued rules-based approach.

Our data from Brussels-based stakeholders, and work by the UK in a Changing Europe,¹³¹ suggest that the EU currently has limited bandwidth for, or interest in, the UK's specific concerns, with the exception of the specific needs of Northern Ireland. We found EU institutional stakeholders frankly reluctant to engage with our work. This appeared to reflect in part a concern that it was risky to speak with UK stakeholders on the bilateral relationship below quite a formal level, likely fostered by years of divisive negotiation during which the UK adopted opaque positions, tried to conduct side-negotiations and at times appeared untrustworthy.

Given this context, changing the UK's formal relationships with the EU in ways that would be significantly beneficial to health and the NHS, while remaining outside the single market, is likely to be an arduous process. The authors of this report took part in an assessment before Brexit, which concluded that single-market membership was the relationship with the EU for the UK that

129 European Union (2022) 'Regulation (EU) 2022/641 of the European Parliament and of the Council of 12 April 2022 amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta (text with EEA relevance)'. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0641>. Accessed 20 March 2024.

130 European Union (2023) 'Regulation (EU) 2023/1182 of the European Parliament and of the Council of 14 June 2023 on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC (text with EEA relevance)'. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2023.157.01.0001.01.ENG&toc=OJ%3AL%3A2023%3A157%3ATOC. Accessed 20 March 2024.

131 Moloney D and Usherwood S (2023) 'What might the review of the Trade and Cooperation Agreement actually be like?'. <https://ukandeu.ac.uk/what-might-the-review-of-the-trade-and-cooperation-agreement-actually-be-like>. Accessed 20 March 2024.

would in fact be most beneficial for health in the round.¹³² However, it has implications far beyond health and is currently off the political agenda.

We comment here first on what would be beneficial for health and the NHS within the current formal terms of relationship between the EU and the UK (the Withdrawal Agreement, including the Windsor Framework) and the EU-UK Trade and Cooperation Agreement (TCA) and then look at what might be feasible outcomes in a renegotiated trade relationship.

An agenda for strengthening and deepening collaboration within the current formal arrangements

A clear message from those we spoke to is that there are opportunities to benefit health in the UK through enhancing cooperation with the EU now. This would make use of the structures that the Withdrawal Agreement and the EU-UK TCA already provide; or would build on collaborations between health systems, scientists and institutions that do not rely on much support from government or treaties.

Measures at this level do not rely on a willingness to renegotiate the TCA or other treaties. This does not avoid the need for trust and a spirit of sincere cooperation. However, it may be inherently valuable in that the necessary decisions will not require as much bandwidth from the EU, will not be contingent on single set-piece processes that could be derailed – like TCA renegotiation or a framework of health measures – and are less likely to be seen in the direct context of the difficult history of UK-EU negotiations to date.

Both the Protocol and the EU-UK TCA set up institutional spaces for dialogue between the EU and UK of relevance to health policy and the NHS, typically intended to connect a middle tier of officials. These spaces include the Trade

132 Fahy N, Hervey T, Greer S, Jarman H, Stuckler D, Galsworthy M and McKee M (2017) 'How will Brexit affect health and health services in the UK? Evaluating three possible scenarios', *The Lancet* 390(10107), 2110–8. [www.thelancet.com/journals/lancet/article/PIIS0140-6736\(17\)31926-8/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)31926-8/fulltext). Accessed 20 March 2024.

Specialised Committee on Technical Barriers to Trade, which envisages a working group on medicinal products. The intention is that this working group will discuss all pharmaceutical regulatory matters, which presumably could also include medicine supply.¹³³ The EU Council has agreed the working group rules of procedure¹³⁴ and industry stakeholders in particular are keen to have the working group up and running. Agendas and minutes may be made transparent, if the co-chairs agree.

Other relevant institutions include: the Trade Specialised Committee on Regulatory Cooperation (which has discussed technology innovation); the Specialised Committee, and Working Group, on Social Security Coordination (relevant for the migration of health and life sciences professionals, and cross-border health care); and the Specialised Committee on Participation in Union Programmes. For Northern Ireland, the institutional arrangements are more complex, and meetings have been taking place significantly more frequently, and involving a much greater specificity of topics for discussion. The Protocol Monitor, hosted by Queen’s University Belfast, gives detail.¹³⁵

The EU–UK TCA is not only a trade agreement. The security aspects of the agreement could be built on further in the health domain, for example through deeper collaboration on security threats from antimicrobial resistance. The first UK–EU Cyber Dialogue, held in London in December 2023, provides a possible model for similar dialogues in the health domain.¹³⁶ Article 702 sets out explicit processes and duties for cooperation on cross-border threats to health, including the measures that allowed the UK to work with the EU’s Early Warning and Response System during the Covid-19

133 GOV.UK (2023) ‘Minutes of the third Trade Specialised Committee on Technical Barriers to Trade, 18 October 2023’. <https://assets.publishing.service.gov.uk/media/656f5ae20f12ef070e3e02ae/technical-barriers-to-trade-meeting-minutes-18-october-2023.pdf>.

134 Official Journal of the European Union (2023) ‘Council decision (EU) 2023/2193 of 28 September 2023’. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023D2193>. Accessed 20 March 2024.

135 Queen’s University Belfast (no date) ‘Protocol Monitor’. www.qub.ac.uk/sites/post-brexit-governance-ni/ProtocolMonitor. Accessed 20 March 2024.

136 Foreign, Commonwealth and Development Office and Department for Science, Innovation and Technology (2023) ‘The first UK–EU Cyber Dialogue takes place in Brussels’. www.gov.uk/government/news/the-first-uk-eu-cyber-dialogue-takes-place-in-brussels. Accessed 20 March 2024.

pandemic. We heard that it is being actively explored as an avenue for wider cooperation on themes such as anti-microbial resistance.

The working group and the measures set out in Article 702 create significant space for discussion on cooperation around the security of medicines supply. The UK should explore this to the full. The difficult situation for both sides discussed above could lead to negative equilibria where a lack of cooperation harms both sides, although especially the UK: with competitive purchasing and stockpiling, overlapping attempts to reshore production or frittering away money while not improving the security of supply across the European market as much as could be the case. Measures to overcome this could include, at a minimum, the UK providing information so that EU capacity and actions can be taken into account in planning for specific products under the Critical Medicines Alliance, and an agreement to create processes to try to avoid the need for export bans. More ambitiously, they could extend to the UK planning jointly with the Critical Medicines Alliance to secure supplies for the European market, draw up a process to discuss individual medicine shortages and exchange notifications.

There is no reason that the UK's status as a 'third country' (that is, a country outside the EU) should inherently prevent cooperation in relation to mutual interests. EU health commissioner, Stella Kyriakides, closed her speech at the press conference announcing the shortages measures described above by saying that 'international cooperation is essential, especially in achieving more diversity in our supply chains'.¹³⁷ The UK is presumably responding, and is likely to see the logic and opportunity particularly to work with the Critical Medicines Alliance as some form of associate member. However, the level of ongoing ambition in this, and the decision about whether to try to establish coordination with less inherently open initiatives and processes such as joint procurement, will be one for ministers.

Despite Brexit, UK entities have remained engaged in several EU-wide stakeholder networks. For example, the Association of the British Pharmaceutical Industry is still a full member of the European Federation of

137 European Commission (2023) 'Opening remarks by Commissioner Kyriakides at the press conference on addressing medicine shortages in the EU'. https://ec.europa.eu/commission/presscorner/detail/en/speech_23_5261. Accessed 20 March 2024.

Pharmaceutical Industries and Associations. In other instances, UK-based stakeholders have remained engaged by changing membership status. For example, the National Pharmacy Association and the Pharmaceutical Society of Northern Ireland are now ‘observer members’ in the Pharmaceutical Group of the European Union (PGEU), representing community pharmacies.¹³⁸ We heard from contributors to this project that industry groups had helped to solve problems and answer queries that their members had about working across the UK and EU. Apart from individual benefits in specific areas, this helps to create a network between EU and UK health communities, with the potential to help rebuild cooperation and trust, which is often lacking following the acrimonious exit from the EU and Northern Ireland negotiations.

The availability of comparable health-related data is critical for robust policy-making. There is scope for the UK to cooperate with EU bodies, particularly Eurostat, to restore the pre-Brexit position where UK data could be compared with data from EU countries. We heard that being able to produce UK health care workforce data and other health statistical data that aligns to the definitions that Eurostat uses, for comparability, would benefit the EU, its member states and the UK.¹³⁹ Eurostat already presents data from non-member states, such as North Macedonia and Türkiye, alongside EU data in some publications.¹⁴⁰

Moving from inter-institutional spaces that involve Westminster and/or Stormont, a possible collaboration model about which we heard in our stakeholder events involves working at the inter-regional/sub-national level. Scotland, Wales and Northern Ireland remain engaged with EUREGHA – the European network for regional and local health authorities.

The only non-EU country that is a formal member of European Reference Networks (ERNs) for rare and complex diseases is Norway. Nonetheless, some of the reconfigured 24 ERNs have managed to find ways to continue to collaborate with the UK despite the formal position that UK-based institutions

138 PGEU (no date) ‘Our members’. www.pgeu.eu/observed-members. Accessed 20 March 2024.

139 Eurostat (no date) ‘International cooperation’. <https://ec.europa.eu/eurostat/web/international-cooperation>. Accessed 20 March 2024.

140 Eurostat (2022) ‘Healthcare personnel statistics – nursing and caring professionals’. https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Healthcare_personnel_statistics_-_nursing_and_caring_professionals. Accessed 20 March 2024.

may no longer be partners in ERNs. Our research suggests that informal relationships are continuing to support some collaboration, and that a few ERNs may have used contractual relationships to support some benefits of the continuation of former membership. There is scope for those approaches that have worked to be diffused across all 24 ERNs.

Possible options for changing the formal relationship with the EU

A more ambitious approach for the health policy sector would be for the UK to seek to renegotiate its formal relationship with the EU. This could mean a renegotiation of the EU-UK TCA, additional freestanding mutual recognition agreements on regulation or a framework of changes specifically focused on the health sector.

Here we focus on relationships that fall short of full EU or single-market (EEA) membership, which would require realignment with single-market law across goods, life sciences services and people; and would involve a high degree of agency participation, with concomitant payments into agency budgets. However, we do include consideration of relationships modelled on a range of existing EU agreements with third countries, up to and including the ‘association agreements’ the EU has drawn up with close neighbours such as Ukraine and candidates for accession to the EU.

In outlining these options, we are not implying that the UK is entitled to assume access to any of them (a narrative that sometimes imbued domestic discussions of the EU-UK TCA). International agreements are the result of negotiations, in which each side has to trade off concessions in order to gain advantages. Achieving a significantly deeper formal relationship with the EU would require major political prioritisation from the UK, and genuine thought to what the UK offerings would be in return for beneficial arrangements concerning the NHS or health.

A health-specific framework would require foundations of trust and cooperation on both sides, likely building on measures discussed above, and will often in reality require the UK to be willing to follow an EU lead on law,

regulation or market-shaping initiatives. The EU's commitment to 'health in all policies' has seen the sector at times prioritised for close relationships with the UK beyond what might generally be considered, with examples perhaps including the EU-UK TCA provisions on health security and Travellers' and pensioners' health coverage. This could help move the conversation away from industrial policy clashes in other sectors, and might sit alongside areas of perceived common interest in other forms of security. However, this is a context more conducive to cooperation in the less economically competitive areas of policy.

In our conversations with stakeholders for this project about future options, three areas of regulating health care products featured prominently. One key trade barrier for medicines supply – mutual recognition of batch testing of pharmaceuticals – features in several EU mutual recognition agreements (with Australia, Canada, Israel, Japan, New Zealand, Switzerland and the United States).¹⁴¹ The modalities and scope of each agreement are different, for example in terms of which products are covered. The Israel agreement is the most comprehensive, covering all industrial products, but it is based on legislative and administrative infrastructure alignment with the EU. The EU-UK TCA covers such mutual recognition for inspections of factories to ensure good manufacturing practice, but does not extend to tests of batches. These must still be done in the EU, by individuals based in the EU, for medicines coming from Great Britain.

Agreeing the mutual recognition of batch testing is a common request from the pharmaceutical industry, in both the UK and the EU.¹⁴² It would not necessarily require changes to the TCA itself: in many cases these mutual recognition agreements stand separately. Participants in the Civil Society Forum, which was created to provide input on the working of the TCA, have

141 European Medicines Agency (no date) 'Mutual recognition agreements (MRA)'. www.ema.europa.eu/en/human-regulatory-overview/research-and-development/compliance-research-and-development/good-manufacturing-practice/mutual-recognition-agreements-mra. Accessed 20 March 2024.

142 European Federation of Pharmaceutical Industries and Associations (2020) 'Joint letter on the need for a mutual recognition agreement between the EU and UK'. www.efpia.eu/news-events/the-efpia-view/statements-press-releases/need-for-a-mutual-recognition-agreement-between-the-eu-and-uk. Accessed 20 March 2024.

called for it to be explored.¹⁴³ This would remove the largest regulatory barrier keeping medicines from moving freely between Great Britain and the EU, restoring a degree of flexibility. The complexities of negotiation, despite the ample precedents, are illustrated by the fact that EU exporters have little to gain as the UK still recognises EU tests – a common pattern. This might be relatively straightforward given the number of international precedents to include in a cross-sectoral mutual recognition agreement.

Second, access to and full participation in the EU’s verification system for securing its market against falsified medicines for the whole of the UK, and not only Northern Ireland, would be beneficial. The EU has such an arrangement with Ukraine, and a press release from September 2023 confirms that steps are being taken to accelerate Ukraine’s regulatory capacity and infrastructure to align with the EU’s.¹⁴⁴ This process has been agreed in the context of Ukraine’s eventual accession to the EU.

Third, many countries – including currently the UK – unilaterally recognise EU CE marks for medical devices and/or equipment, but the EU does not reciprocate. The EU has mutual recognition agreements, covering medical devices/equipment conformity assessment, with countries such as Australia and Switzerland.¹⁴⁵ These agreements mean that a conformity assessment carried out by conformity assessment bodies in either party gives access to the market in the other party. They involve permanent institutional infrastructure, with decision-making powers. Our stakeholder research suggests some equivocation over whether such a mutual recognition agreement with the EU would be beneficial – partly because the UK has remained in alignment through its continued acceptance of EU assessments. This gives the EU little

143 Foreign, Commonwealth and Development Office (2023) ‘Second Civil Society Forum of the UK-EU Trade and Cooperation Agreement, 7 November 2023: conclusions’. www.gov.uk/government/publications/uk-eu-trade-and-cooperation-agreement-civil-society-forum-2023/second-civil-society-forum-of-the-uk-eu-trade-and-cooperation-agreement-7-november-2023-conclusions. Accessed 20 March 2024.

144 Medicines for Europe (2023) ‘Medicines for Europe gears up for Ukraine’s future accession to the EU’. www.medicinesforeurope.com/wp-content/uploads/2023/09/Medicines-for-Europe-gears-up-for-Ukraine.pdf.

145 Official Journal of the European Community (1998) ‘Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia’. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A21998A0817%2801%29>. Accessed 20 March 2024.

incentive for such an agreement in itself, although it is possible it could be included within a wider move towards mutual recognition.

There would also be opportunities elsewhere, across science, mobility, research and health security. Outside the single-market context, the UK could seek a deeper and more permanent cooperation with the EU's health security institutions and processes. For example, participation in the EU's Early Warning and Response System for infectious diseases could be secured through a memorandum of understanding, building on the provisions for ad-hoc access included in the TCA. The European Centre for Disease Prevention and Control works with partner entities in accession and other neighbouring countries, as part of its international cooperation activities.¹⁴⁶

As noted above, the UK could seek to negotiate formal re-entry to the European Reference Network system, and the governance structures of the 24 networks, as an analogous activity to the UK's role in Horizon Europe. It may be conceivable that the unprecedented inclusion of the UK in EU reciprocal health care measures like European/Global Health Insurance Cards could also extend to the mutual recognition of prescriptions and the right of patients to travel for funded treatment set out under the 2011 Cross Border Healthcare Directive.¹⁴⁷ These measures relate primarily to the policy goal of health, with limited economic implications, and, if agreement could be reached, might naturally sit within a health framework.

Another possible collaboration with not only the EU, but also other European countries, which could be revisited to the indirect benefit of health and the NHS, would be membership of the Erasmus+ Programme which supports initiatives for students and trainees to learn abroad. Institutional and practical support for student and researcher migration would indirectly affect the available pool of talent for the NHS (and social care) workforce. A range of

146 European Centre for Disease Prevention and Control (no date) 'International cooperation'. www.ecdc.europa.eu/en/about-us/who-we-work/international-activities. Accessed 20 March 2024.

147 Official Journal of the European Community (2011) 'Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011'. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32011L0024>. Accessed 20 March 2024.

possible modes of collaboration, including third-country association (for example, with Iceland, Norway and Türkiye), could be explored.¹⁴⁸

More ambitiously, an agreement securing mutual recognition of clinical trials sponsorship and full UK access to the EU’s Clinical Trials Information System would be highly beneficial both to patients involved in trials and to the UK life sciences sector. Currently, the UK continues to recognise EU sponsors, but the EU does not reciprocate. There is no precedent for any third country outside the EU having this status, and it would need to be negotiated as a new solution. It would be an ambitious request. However, we did hear from stakeholders that Europe across both the EU and the UK does compete as a bloc with other markets and locations for research funding from private firms, and the UK’s entry in Horizon Europe will continue to make it clearly a part of this bloc. If a health framework could capture themes of innovation as well as security, these would be a high ambition for potential inclusion.

Any national discussion of enhanced cooperation with the EU in the health policy domain should balance any detriments. It would need to be based on a realistic assessment of where active divergence would be beneficial, for example against what is possible from further cooperation, including through deepening the existing EU–UK trade agreement.

For industrialised economies, the welfare benefits arising from trade agreements flow equally from the removal of tariffs (already a feature of the EU–UK TCA) and the deep commitments to remove ‘non-tariff barriers’, or in other words, from regulatory alignment (as explored in a recent study¹⁴⁹). Much of the literature on the health effects of trade agreements focuses on the negative aspects – for example, analysis of the Comprehensive Economic and Trade Agreement (CETA) shows that intellectual property rights would be extended in Canada, delaying the availability of cheaper generics for the national health system. However, this type of analysis is only partially applicable to the EU–UK relationship, where the UK began from a position

148 European Commission (no date) ‘Erasmus+: eligible countries’. <https://erasmus-plus.ec.europa.eu/programme-guide/part-a/eligible-countries>. Accessed 20 March 2024.

149 Dhingra S, Freeman R and Huang H (2022) ‘The impact of non-tariff barriers on trade and welfare’, *Economica* 90(357), 140–77. <https://onlinelibrary.wiley.com/doi/full/10.1111/ecca.12450>. Accessed 20 March 2024.

of regulatory alignment in January 2021. Amid all the narrative about ‘deglobalisation’, especially post-Covid-19 pandemic, it will be important for the UK not to lose sight of the ways in which the unravelling of deep trade agreements ‘can undo some of the welfare gains’ from past deeper integration of its economy with those of its proximate neighbours.¹⁵⁰

Table 1 provides a summary of the changes that would need to be made to the EU–UK relationship to realise improvements in health in the UK, in three key areas: workforce mobility; medical products and life sciences; and infectious diseases.

Table 1: Required changes to the EU–UK relationship to realise improvements in three key areas

Changes in the EU–UK relationship to benefit health in the UK	Possible through cooperation now	Would require renegotiating the EU–UK TCA or securing health-specific agreements	Would require rejoining the single market (EU or EFTA + EEA)
Workforce mobility	<ul style="list-style-type: none"> • Realigning statistics • Cooperation between professional bodies 	<ul style="list-style-type: none"> • Return of the mutual recognition of qualifications 	<ul style="list-style-type: none"> • Free movement of labour, with rights for individuals and policy stability
Medical products and life sciences	<ul style="list-style-type: none"> • Cooperation on medicines security • Reintegration into Horizon 2020 	<ul style="list-style-type: none"> • Mutual recognition of batch testing or elements of clinical trial regulation • Inclusion in falsified medicines systems 	<ul style="list-style-type: none"> • End of regulatory barriers at the UK–EU border • Medicines approved at EU level and authorised in the UK

150 Dhingra S, Freeman R and Huang H (2022) ‘The impact of non-tariff barriers on trade and welfare’, *Economica* 90(357), 140–77. <https://onlinelibrary.wiley.com/doi/full/10.1111/ecca.12450>. Accessed 20 March 2024.

Infectious diseases	<ul style="list-style-type: none"> • Cooperation on anti-microbial resistance in international forums and policy • Coordination of antibiotic supply measures 	<ul style="list-style-type: none"> • Formal permanent access to the EU's European Early Warning and Response System 	<ul style="list-style-type: none"> • Carrying out joint procurements during pandemics
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Above all, one key lesson from Brexit for health is that trade policy needs to be carried out with attention to its health effects.¹⁵¹ Only a strong system of governance can result in the benefits of international trade for health being felt, and reduce its potential detriments. Otherwise, the risk of poor policy design and implementation is high, with commitments to health being left ‘on paper only’, rather than practically implemented to the benefit of the NHS, patients and the population as a whole.

151 Dhingra S, Freeman R and Huang H (2022) ‘The impact of non-tariff barriers on trade and welfare’, *Economica* 90(357), 140–77. <https://onlinelibrary.wiley.com/doi/full/10.1111/ecca.12450>. Accessed 20 March 2024.

Interviewees and roundtable attendees

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Richard Devereaux-Phillips, Director of Strategy,
Association of British HealthTech Industries

Rick Greville, Director for Distribution and Supply Chain,
Association of the British Pharmaceutical Industry

Robert Smith, Manager for Trade & (Interim) Regulatory Policy,
Association of the British Pharmaceutical Industry

Sean Phillips, Head of Health & Social Care, Policy Exchange

Leslie Galloway, Chairman, Ethical Medicines Industry Group

Paul Fleming, Technical Director, British Generic Manufacturers Association

David Broome, pharmacy contractor

Fin McCaul, pharmacy contractor

Joel Reland, Research Associate, UK in a Changing Europe

Bernadette Sinclair-Jenkins, Medicines and Healthcare products
Regulatory Agency

Amy Tortoishell, Deputy Director for Continuity of Supply,
Department of Health and Social Care

Claymore Richardson, Head of Strategy and Policy Medicines Supply,
Department of Health and Social Care

Martin Sawyer, Chief Executive, Healthcare Distribution Association

Freddie Sloth-Lisbjerg, President, Council of European Dentists

Nikoleta Arnaudova, Senior Policy Officer, Council of European Dentists

Ulrike Matthesius, International Affairs Committee Secretary, British
Dental Association

Eddie Crouch, Chair, British Dental Association

Pascal Garel, Chief Executive, HOPE European Hospital and
Healthcare Federation

Christopher Breyel, Executive Director,, MedTech Europe

James Sharples, Senior EU Policy and Funding Executive, Scotland Europe

Michele Calabro, Director, European Regional and Local Health Authorities

Rosie Richards, Head of Health and Pharmaceuticals, UK Mission to the
European Union

George Valiotis, Executive Director, European Health
Management Association

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