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Going it alone

Health and Brexit in the UK

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Overview

On 1st January 2021, the UK left the single market, ending a year of limbo following its departure from the European Union on 31st January 2020. This marked the end of the application of European law and institutions which underpinned many elements of health and health care in the UK. Regulations on medicines and devices, laws on the buying and selling of care, trade agreements, and rules on migration which had previously worked across most of a continent, were repatriated to the UK.

The free movement of goods, services and people between the UK and EU ended, and the UK Government regained a free hand in reshaping how all these areas worked for the first time in 30 years or more. Meanwhile, two documents, the 2019 Withdrawal Agreement, which includes the Ireland/Northern Ireland Protocol and the 2020 Trade and Cooperation Agreement (TCA), set out the new relationship of the UK with the EU, as well as special provisions for Northern Ireland's de facto continued membership of the single market. These agreements include provisions directly related to health, on issues such as pandemic management or the movement of human organs. However, other provisions indirectly have wide-ranging implications for health, as discussed in our report.

This report is an interim output from the Health and International Relations Monitor project, funded by the Health Foundation. It considers the impact of leaving the EU and changing international relations for health, looking both at what has already happened and at what NHS, government and business figures expect in future. We consider changes in health across six key areas: medicines and devices, international trade agreements, devolution, procurement, workforce, and Northern Ireland. In our full report, to be published next Spring, we intend to examine in more depth Brexit's impact on two of the building blocks of health most affected – workforce and living standards.

Two articles already available on the Nuffield Trust website consider the specific issues of medicines shortages and the ramifications for health of the UK's decision to seek accession to the CPTPP trading bloc covering parts of Asia and the Americas.

The 'second wave' of the Covid-19 pandemic arrived in the UK over the winter of 2020 to 2021. As a result, the first few months of Brexit were also among the most extraordinarily difficult, and critical for health in the history of the UK. This exceptional context concealed or delayed the impacts of Brexit in some key areas – as well as accelerating or intensifying them.

Key findings

- A large proportion of our interviewees identified workforce-related issues such as staffing, sustainability and wellbeing as their most pressing concern following the introduction of new immigration rules that put EEA applicants and those from the rest of the world on the same footing. Our research supports these findings. The health and social care sector is plagued by workforce shortages and uncertainty with regard to future staffing. The pandemic has impacted the reliability of data in this area, as surveys and underlying population assumptions have been significantly disrupted. Moreover, the impact of Brexit is almost impossible to disentangle from that of Covid-19 at this point in time. Nevertheless, the situation in social care, where new immigration rules effectively halt immigration from the EEA, appears to be deteriorating rapidly. For nursing there has been a shift from EEA staffing back to a high level of migration from the rest of the world. Detailed plans to address the change in labour availability, both sustainably and ethically, are lacking.
- The medicines, medical devices and life sciences industry in the UK faces great uncertainty. The UK now enforces outdated versions of EU rules on devices, border bureaucracy has increased dramatically, and clear plans are lacking to keep these areas of health care attractive or competitive. We heard that these factors are a deterrent to investment in the UK, and they appear to be linked to a drop in UK exports and a higher level of shortages during the Covid-19 pandemic. The implementation of full customs controls on 1st January 2022 will add further complications for those importing supplies.
- Governments in Scotland, Wales, and Northern Ireland are concerned that they have lost some of their control over health protection, improvement of health outcomes and health-related funding. More specifically, the 2020 Internal Market Act in effect prevents the devolved governments from imposing rules on products like tobacco or unhealthy food which are not mirrored elsewhere in the UK. The replacement of EU structural funds typically awarded to poorer areas in devolved administrations with the UK

Shared Prosperity Fund controlled by Westminster, with little indication as to how it will be distributed, also risks cutting out devolved administrations or potentially decreasing their health funding.

- Pledges to keep the NHS and medicines prices “off the table” in trade negotiations mean little without specific commitments on key areas such as patent protections and investment rules. Transparency and engagement with the health sector have both been limited.
- Possibly reflecting this, there does not appear to be a clear agenda to bring any benefits to health in the UK through trade agreements.
- An 11th hour proposal from the European Commission on 17 December 2021 to resolve the serious problems faced by Northern Ireland in terms of medicines supply needs to complete the legislative process before 31 December 2022. The proposal, if adopted, would alleviate some, but not all of the concerns about product supply to the NHS in Northern Ireland. Unilateral provisions to accept incoming goods from Great Britain will not, by themselves, suffice. With brinksmanship in negotiations, especially around the Northern Ireland Protocol, companies have little certainty of what will unfold, even weeks before the end of current transitional provisions, and there is a worryingly wide range of views about which proposals, among the iterations put forth by the UK and EU, will actually address the expected problems.
- Changes to English rules for procuring health care goods and services which aim to reduce bureaucracy and reduce the need for competitive tendering, are perhaps the most advanced policies for divergence from EU rules. However, similar changes would in fact already have been possible using mechanisms allowed within EU law. Some participants in the NHS welcomed these reforms. However, others identified a risk that they would facilitate unethical or unsafe procurement, open commissioners up to lawsuits, or enable the formation of unaccountable cartels.

Methodology

With an unprecedented, fast-moving and partially secretive landscape of policy and operational change following Brexit, we used a combination of qualitative research, data analysis, existing literature and policy documents from the UK or EU to gain a picture of initial effects. We began by collectively examining possible changes in health-related issues due to Brexit across nine areas:

- health systems delivery
- health systems workforce (including social care)
- health systems financing
- information systems
- medical supplies
- leadership and governance
- communicable diseases
- non-communicable diseases
- public health capacity and governance.

We focused on fields where we believed immediate changes following exit from the single market were likely; it would be possible to detect and analyse these; and there was a significant impact on health. These comprised trade, devolution, medicines and medical devices, procurement, and issues specific to Northern Ireland.

Our qualitative research programme included interviews with around 20 people from the medicines and devices sector, academia, UK and devolved government bodies, the NHS, and independent charities and representative bodies. We also held two roundtables on trade and procurement with a further 26 external attendees. As a result of our findings, we added workforce as a sixth theme: despite our concern that Covid-19 would render it very difficult to attribute any impact on workforce specifically of Brexit, interviewees within the health service tended to see an immediate impact or risk.

Drawing on these sources, we identified and analysed sets of data that were relevant to answering the key questions we identified. The data were either publicly available or obtained under the Freedom of Information Act. They covered medicine shortages, medicines trade, science funding, engagement by the Department of International Trade with the health sector, and workforce where possible. The disruption of both actual patterns of work and the ONS Labour Force Survey by Covid-19 meant our workforce findings rely largely on qualitative data.

We examined all major UK, devolved and EU policy documents relating to Brexit and decisions enabled by Brexit which were relevant to our themes, building on our previous extensive analysis of the TCA, Withdrawal Agreement, and negotiating positions leading to these.

1 Workforce: the biggest worry

On the basis of the data available to us, we estimated that truly unpicking the workforce impact of Brexit from that of Covid-19 would be difficult for at least the next year or two, and aimed to focus on it later in our project. Our interviewees generally agreed that workforce continued to be a concern. For those close to operational roles in the NHS and social care, it was almost always at the top of their list of worries relating to the UK's changed international position – and they provided valuable insights on the early changes they were seeing and feared that they might see.

Difficulties with data

The pandemic has complicated our ability to quantify the impact of Brexit. The Migration Observatory has highlighted its concerns with the reliability of migration figures provided by the Office for National Statistics (ONS),¹ including the interruption of the passenger survey from the second quarter of 2020, the reliance on projections that forecast a regular population increase – which plateaued in 2020 – and changes in survey methods that may have decreased response rates.

We will, therefore, conduct a thorough analysis of emerging data and more reliable figures, such as the 2021 census when it becomes available, and visa applications when the workforce market approaches pre-pandemic levels.

Nursing and social care

New immigration rules, which came into place on 1st January 2021, still permit the recruitment of EU professional health staff.² This category includes scientists, doctors or nurses. However, bureaucratic hurdles and costs are

greatly increased. Conversely, these are now somewhat lowered under the new rules for migrants from outside the EEA.

As in our previous report, roundtable participants and interviewees across the UK were deeply concerned with ongoing staffing shortages in nursing and social care.

EU-trained joiners to the ‘nurse and health visitor’ group in England, from within and outside the NHS, levelled or slightly decreased between October 2017 and October 2020. The number of EEA-trained nurses on the NMC steadily declined between September 2016 and March 2021.³ Fewer nurses left their staff group or the NHS than might have been expected, presumably due to Covid-19 restrictions and limited opportunities for professional mobility.

Migration from beyond the EEA has continued at a very high level, with 9,000 nurses trained in the rest of the world joining the register even during the pandemic year of 2020/21. This is close to the highest ever level of EEA migration. This was seen as a compensating strategy by our interviewees. This approach raises its own set of issues. As discussed below, its sustainability is still unclear.

For adult social care in England, significant shortages persist, with vacancy rates in the independent sector now having climbed back to beyond pre-pandemic levels (8%), from 5.8% in June 2020 to 8.2% in August 2021 (they are at 6.8% overall). Turnover, at 28.4%, is far higher than for the NHS. This figure represents an increase of around 8% from 2012-13, with a 2% decrease in 2020-21.⁴

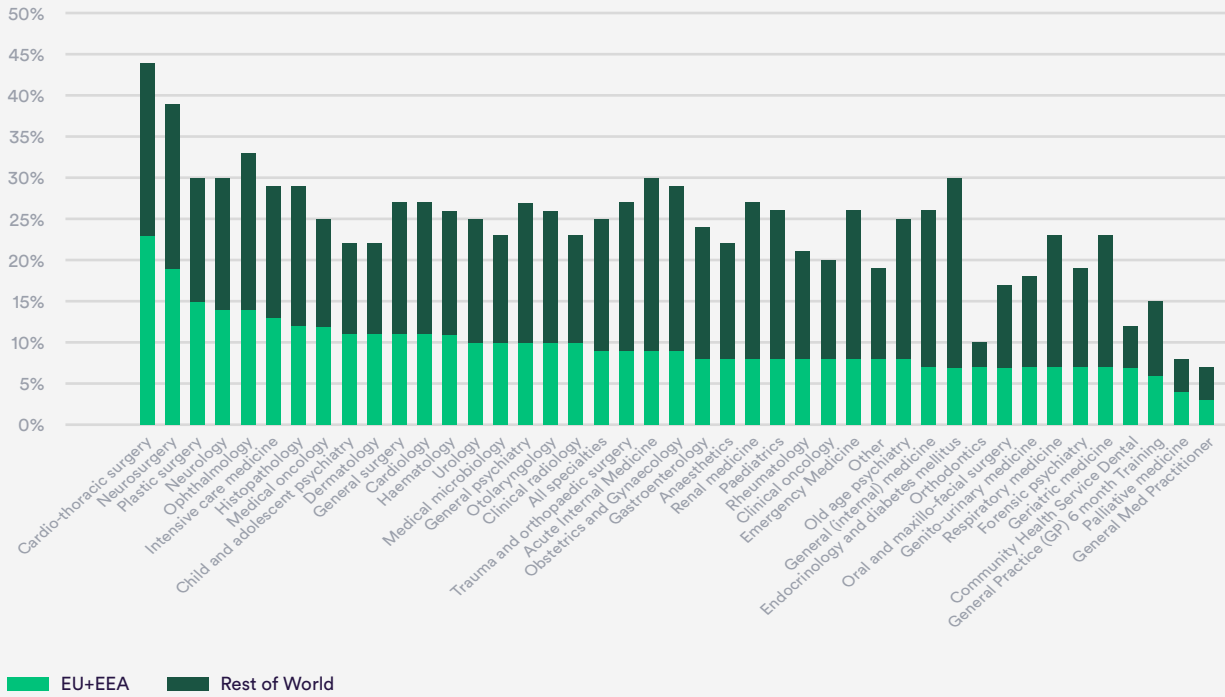
Staffing in recent years has been dependent on an increasing EU migrant workforce: EU workers in 2012-13 represented around 4.7% of the social care workforce, increasing to 7.2% in 2020-21. Meanwhile, migration restrictions a decade ago caused the number of non-EU migrant workers to decline. The salary and educational requirements of the new immigration rules now make it essentially impossible to recruit for ordinary frontline roles from the EU or beyond.

Several interviewees told us that these trends were mitigated by inflow from the hospitality sector during the pandemic. However, as hospitality recovers, it can offer more competitive pay packages, something the social care sector is in no position to do. A concerning early data point appearing to confirm particular difficulty following the end of national lockdowns is shown in the 2021 CQC State of Care report, which found social care vacancy rates in England climbing very rapidly to over 10% in September.⁵

Recruitment difficulties eventually have an impact on the quality of care. A survey commissioned by the Scottish Government in 2018 already pointed to difficulties in recruiting for nursing and social care posts, citing issues such as the quality of applicants and pay, and less frequently Brexit.⁶ Similar concerns were raised for more senior nursing and Allied Health Professional (AHP) roles by another Trust interviewee.

Other workforce categories are also affected. At one end of the spectrum, shortages among often poorly paid HGV drivers, intensified by Brexit, appear to be affecting medicine supplies.⁷ Among the most highly paid and qualified, certain medical specialties tend to be especially reliant on EEA staff. Our analysis of NHS Digital data shows that among large specialties, the most dependent on doctors of EEA and EU nationality were cardiothoracic surgery (23%) and neurosurgery (19%) (see figure 1 on next page).⁸ There is a risk that future migrants might be disincentivised from moving to the UK by additional visa costs and administrative hurdles, as will employees of pharmaceutical companies relocating from abroad.⁹

Figure 1: Proportion of English NHS trust and CCG doctors by non-UK nationality, 2017



Health and wellbeing

At the moment, the health and wellbeing of staff is tightly linked with Covid-19 and the extraordinary strain the last 20 months has put on the health care workforce, with many interviewees raising absenteeism, burnout, and non-return from planned leave, in addition to staffing gaps caused by infection and isolation requirements.

Interviewees noted an increase in hate crimes and discrimination, and more generally a hostile environment, which several linked to Brexit. Several mentioned initial poor awareness of the settled status application procedure and deadlines with EEA staff, unwillingness to apply for it by the actual deadline of June 2021, and some raised instances of unspecified numbers of EEA workers rejecting UK-based positions that might have been offered to them.

Little relevant data at individual level exist to test these ideas. However, the annual NHS staff survey does appear to support some of the concerns raised above. The survey splits staff by ethnic identification, rather than national origin. Most EEA staff would identify as non-British white, and a minority as from different black, Asian and other ethnic groupings.

Survey data between 2015 and 2020, for all staff groups, show a steady increase in 'BME' staff reporting discrimination, from 14% to 17% (from patients and members of the public), and from 12% to 15% (from managers and colleagues). Over the same period, 'other white' staff rates are relatively stable between 11% and 13% from all groups. However, there is a significant spike in both these staff categories identifying ethnicity as grounds for discrimination: this rises from 18% in 2017 to 84% in 2020 for 'BME' staff, and from 12% in 2017 to 62% in 2020, for 'other white' staff.

In-depth polling and qualitative work would be needed to determine whether the salience of Brexit as a political and social issue is involved in these trends, compared to other possible factors such as increased confidence with calling out racial discrimination. If it does play a role, the data suggest it may affect all minority groups, even those largely not comprised of EEA nationals.

Will they still want to come?

In light of issues discussed above, it is unclear what plans are in place to promote the UK as an attractive place to work and do business, for EU workers and for the rest of the world. One interviewee noted that prior to Brexit, the DHSC had dedicated international offices to address the practical and any cultural differences in a range of countries where staff were recruited. As the focus of recruitment moves beyond the EU, international recruitment drives are increasingly delegated to individual agencies, though their relative capacity or efficiency is unclear.

The NHS is aligned with the WHO's code of Practice for ethical recruitment. This prohibits new hires from 47 countries on the Workforce Support and Safeguard List, which would be particularly vulnerable to workforce emigration.¹⁰ This complicates the task of hiring individuals from countries that would be prime targets for recruitment drives. Comparable ethical issues

exist for countries not on this list, but still far poorer than the UK, as several interviewees noticed.

We also heard criticisms of the overall workforce strategy at an English level, with the NHS people plan having been delayed for well over a year.

The picture is more challenging still for social care. A number of organisations, including the Association of Directors of Adult Social Services (ADASS) and the Nuffield Trust, have called for radical reform in pay, progression, training and immigration rules.¹¹ In contrast, other higher-income Commonwealth countries or, in the EU, Germany, have invested more strategically in recruitment drives and offer far higher pay.

It is therefore uncertain that there is an understanding throughout government of the extent to which the UK's position as a professional destination has been affected, and of the need to promote and demonstrate the benefits of working here to retain its attractiveness.

2 Medical products and sciences: doubt and difficult choices

Leaving the single market at the end of 2020 marked a radical shift for the import, export, and development of medicines and medical devices in the UK. The single market regulations which governed these markets were removed, leaving separate EU and UK systems which in most cases no longer allowed for free exchange with the country's neighbours. Brexit has also changed the environment for the life sciences which create and research these products. Our interviewees described wide-ranging changes to regulation, expectations and attitudes, and the ability to work with industries and scientists based in the EU.

This chapter explores the initial impacts of Brexit, and the attempts to respond to them, in Great Britain. Northern Ireland faces a different set of effects, explored separately.

Drift, uncertainty and friction

Interviewees who worked on medicines and devices described relief that mitigation strategies by government and business had averted widespread shortages, but also a deep sense of uncertainty about the future for the medicines and devices industry in the UK.

As we described in our last report,¹² the government and supplier firms introduced an array of complex and costly measures to avoid an expected shock to the supply of medical products as the UK left the single market. These appear largely to have succeeded in avoiding an immediate increase in shortages, as explored in our separate article.¹³

Nonetheless, as of Autumn 2020, significant shortages of blood tubes had emerged, resulting in the rationing of some types of care in the UK. While there was a shortfall in many different countries, statements from the main supplier, Becton Dickinson, suggest the severity in the UK is partially due to “border challenges”¹⁴ – likely to be associated with Brexit. An interviewee suggested problems with the supply of pipettes, reflecting similar dynamics. This suggests that because the drivers surrounding the difficulty in bringing products to the UK are largely permanent or recurring, they may outlast any specific initiatives to deal with them.

It is important to note that the full implementation of UK customs checks has not actually taken place yet. Some of the most potentially disruptive requirements, such as goods being taken for control at different inland sites, and full customs and tariffs applied at the point of entry, will begin on 1st January 2022.¹⁵

In the medium term, interviewees emphasised the uncertainty they now faced about regulation in Great Britain, the barriers to export and cooperation, and the impact this had had on perceptions and willingness to invest.

One key issue was a lack of clarity over whether the UK would stop accepting medical devices with the CE mark which EU bodies award to show regulatory compliance from 1st July 2023, insisting on a “UKCA” mark granted by its own regulatory system.¹⁶ This is official policy, but was viewed as expensive or even impossible by business interviewees due to the duplication involved in going through separate EU and UK processes, and the lack of capacity to grant UKCA marks. The Regulatory Horizons Council report recently commissioned by the UK government noted “high risk of patients losing access to certain devices after the ‘hard-stop’ of 30th June 2023”, and recommended that the deadline be extended for certain products.¹⁷ Whether this will happen remains unclear.

Very similar issues exist for unilateral UK acceptance of medicines approved by the European Medicines Agency. Industry interviewees we spoke to tended to hope, or even assume, that the UK would continue to rubber-stamp decisions made in the EU, with one describing it as the “only realistic route”. However, official policy is to end this at the start of 2023.¹⁸ It is also unclear whether the UK will indefinitely accept batch testing of medicines,

something which would be costly to relocate to the UK. The MHRA has already abandoned an immediate two-year deadline here.¹⁹

Another area of uncertainty is the unstable equilibrium in which Great Britain has already in practice diverged from the EU by not applying the most recent changes to EU law, leaving it lagging behind reforms intended to improve safety and cooperation:

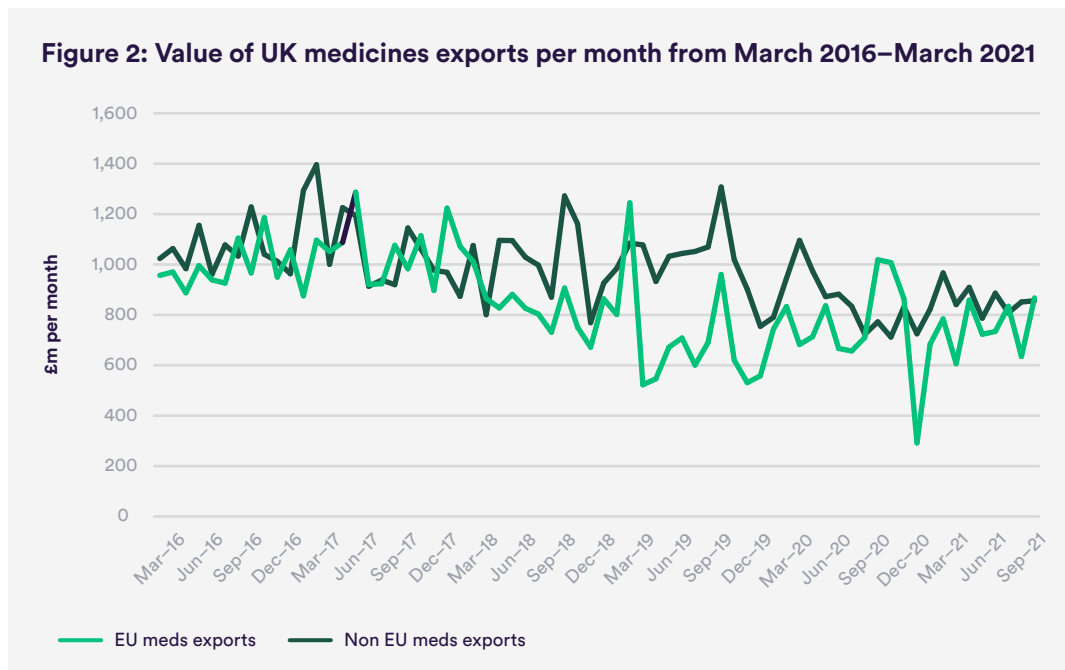
- The UK has not implemented the 2017 EU Medical Devices Regulation, which now applies in the EU with a different classification of devices based on risk and a higher level of oversight of manufacturers. This was a response to safety concerns epitomised by the PIP breast implant scandal, which may have harmed tens of thousands of women.²⁰
- The UK has not implemented some aspects of the 2011 EU Falsified Medicines Directive. This introduces a system of unique identifiers and security seals on each pack of medicines, to guard against fraudulent products.
- The UK is not included in the new system created by the 2014 Clinical Trials Regulation, which creates a streamlined system to approve clinical trials in the EU through a single portal where approvals by one member state can be accepted elsewhere.

These provisions largely do apply in Northern Ireland, still effectively part of the single market, with consequences discussed below. The rest of the UK, though, is now following an old version of EU rules – missing reforms which were largely brought in to improve safety and reduce fraud. For each of these, government communications have implied that this is not a conscious direction of policy, but simply a stop-gap until a different approach is taken up, leaving these areas misaligned with neighbouring markets but without clarity over future regulatory direction.

The recent consultation on medical devices regulation from MHRA provides an indication of the direction of travel.²¹ It would make changes to classifications and the way the safety of products is monitored and accounted for which largely mimic changes in the EU, while also creating a new ‘Pathway for Innovative MedTech’ which allows firms to leapfrog the usual process with

a monitored experimental rollout. Products approved elsewhere, including in the EU, could go through an “abridged process”²²

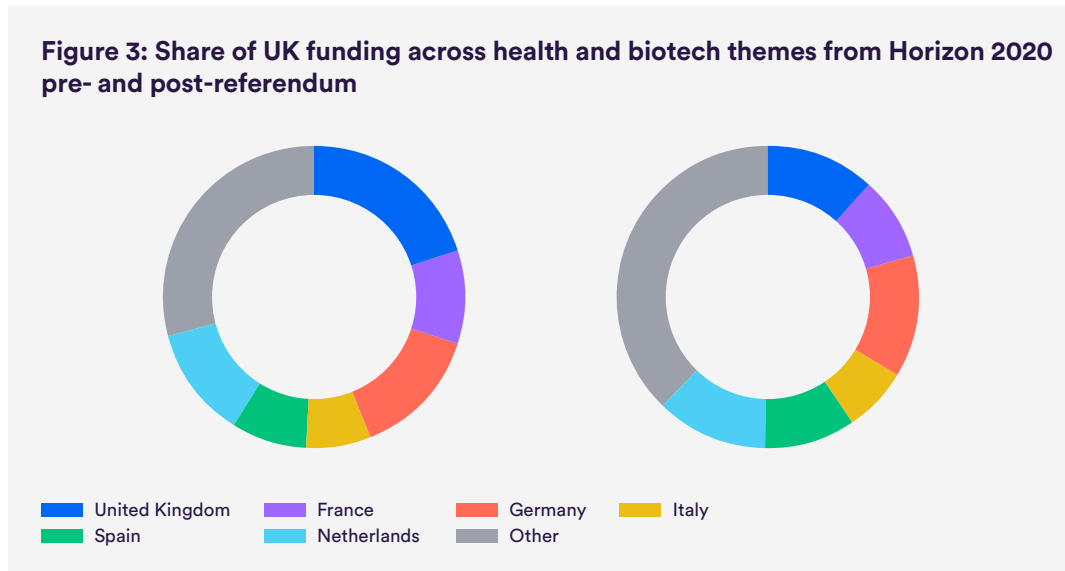
Meanwhile, the unilateral allowances the UK has made for approvals, medical device assessment, and batch testing are not reciprocated by the EU. Across the period of the UK’s departure, a drop in exports from around £1bn worth a month to around £700m a month appears to be visible in trade data for medicines, as shown below in figure 2, especially to the EU – though not, as yet, for devices. If prolonged or permanent, this is likely to reduce employment in the UK, and if the UK is less able to serve as a place to export from, this may damage the business case for producing or importing products needed within the country.



Our interviewees generally believed that the lack of clarity over future regulation; barriers to export whether specific to medicines or due to a general hard customs border; and a lack of a UK voice in the EU had created a perception among global business, researchers and funders that the UK was a less appealing place to carry out work and launch products. A common sentiment was that “companies hate uncertainty more than anything”. One firm told us “Brexit was a factor” in a specific, major shift of scientific and management activities from the UK to the EU: another told us that the UK was now “insignificant as an investment area”.

Recent data on life sciences investment and R&D expenditure, which might show whether or not this is having an impact, is lacking. In the period following the EU referendum but before the UK’s departure from the EU, data from OLS show a decline in UK clinical trial recruitment, though R&D spending and manufacturing employment remained steady.²³

Existing research has shown that data from Horizon 2020, the former flagship EU science funding programme, show a drop in the UK share of funding following the referendum (see figure 3).²⁴ Our analysis shows this clearly to be the case across the health and biotech themes associated with life sciences. This implies uncertainty alone has been a significant driver of investment away from the UK.



At the time of writing this report, the UK’s entry to Horizon Europe continues to be delayed in the context of disputes over the Ireland/Northern Ireland Protocol. Joint letters from EU and UK scientists have recently been published warning that this is endangering collaboration.²⁵

Difficult choices

The overall picture is of the UK failing to establish a strategic approach to attracting investment, research, and available, well-priced products for the NHS. Instead, a defensive approach has centred around avoiding immediate disruption to health service supplies, continuing to accept EU regulation for imports, and applying older forms of it domestically due to a lack of capacity to keep up. The practical steps taken here by GB are at odds with a public narrative about the benefits of divergence from the EU, seen as largely rhetorical by some interviewees.

The recent report from the Regulatory Horizons Council on medical devices, and the recent Life Sciences Vision more widely,²⁶ indicate the beginning of policymaking for a longer term future. The latter emphasises a “sovereign regulatory environment”, which is very different to the reality today.

A number of difficult choices will face the UK, with the approach currently unclear. The UK will have to choose whether to accept indefinitely EU approvals of medicines and assessment of medical devices. This will be optimal in reducing costs for business, and continuing to make it profitable for them to supply the NHS with new and existing products. However, it will mean surrendering regulatory autonomy to another jurisdiction which is unaccountable to patients in the UK, whose rules are already different to those the UK applies domestically, and which may become more so over time.

The “rubber stamping” role also implies a reduced role for the MHRA, and a strong incentive for firms to introduce products later in the UK than its neighbours. This appears directly at odds with the Life Sciences Vision’s aspirations for the UK to be a sovereign regulator, “set regulatory standards” globally and develop “innovative regulatory models” which bring medicines to approval faster and with more assessment after the point of launch.

The MHRA’s consultation on medical devices implies a regulator which generally follows global norms and accepts approvals overseas, with details to be confirmed later, but which also carves out a subset of products for intensive, faster approval. Similar approaches have long been discussed for medicines.

While broadly supported by our interviewees, this approach raises a number of knotty questions. Interviewees tended to see industry as having a single view of the UK, at least at global executive level: interesting new routes to market in certain areas may not be enough to challenge a general view that going through regulation in the US and EU needs to take priority. The recent announcement of 25% cuts to the MHRA workforce, driven by a loss of fees as companies use approval in Europe to access the UK market, appears more consistent with a rubber stamping model.²⁷ Interviewees noted signs of tension with the workforce inside the regulator, with some unhappy at what they saw as a loss in responsibility. An analysis by Global Counsel notes the UK's very constrained number of approved bodies to certify medical devices.²⁸

If the UK generally accepts the approvals of other countries but also runs unique, untested, and innovative routes into its own market, other countries may not want to accept UK approvals in return because they see its approach as untested. That would reduce the appeal of coming to this country first.

The UK is also beginning the process of considering whether to adopt similar provisions to the Falsified Medicines Directive, Medical Devices Regulation, and other EU regulation emerging over the coming decade. One interviewee expressed hope that the UK might continue to use older regulations, and refuse to mirror any new EU legislation on transparency or control over prices. The European Commission's 'Pharmaceutical Strategy'²⁹ review of policy includes, for instance, proposed legislation on 'health technology assessment', and changes to IP rules on biosimilars, which would encroach on national sovereignty to judge value for money for new medicines and to offer market-led prices for new biologicals. If the UK does not track EU developments, it could remain a competitive market to introduce products early, through offering fewer demanding standards for companies, or higher returns on investments. However, this approach seems at odds with an aspiration to drive global standards.

On clinical trials, the UK Taskforce for Innovation, Growth and Regulatory Reform (TIGRR) report presents a range of reforms to try to create a competitive regime within the UK, modelled on rapid trials during Covid-19.³⁰ However, these assume the existence of a "world-class" and widely recognised regulator. Some also appear to assume changes to data protection regulation in the UK which are difficult to reconcile with the pledge to retain the

“adequacy” status which the EU has granted due to similarity in regulatory standards.³¹ Adequacy status, and the free flow of data it results in, has consistently been a high priority for life sciences in the UK.

Our interviewees were clear that the wider tensions in the UK-EU relationship, especially around Northern Ireland, leave our associate membership in Horizon Europe, which funds major international science projects, under a permanent cloud. They recall the EU’s use of access to the earlier Horizon 2020 as a negotiating tool in disputes with Switzerland. This is a concern whether or not this situation actually arises, because, as shown above, there appears to be evidence that uncertainty or negative perceptions of the UK following the EU referendum drove funding away during the earlier programme.

3 Off the table? The place of health in UK trade policy

Control over trade policy has been highlighted by the UK government as a major advantage of leaving the EU under the Trade and Cooperation Agreement, and commitments on health are given central stage in its policy documents.³² The UK's first months outside the single market have seen an ambitious push for new agreements reflected in the bid to join the Pacific CPTPP trade bloc, and an agreement in principle with Australia.

Trade negotiations tend to be opaque, with little information on negotiating positions available to the general public or even key stakeholders beyond economic actors. Health organisations are not always well represented in government consultations on new trade policies, which tend to focus on economic, rather than social or environmental, outcomes. For these reasons, we prioritised looking into how health is being considered in the formulation of UK trade policy.

Under-developed health agenda

We found evidence that the UK's trade policy regarding health is poorly understood and possibly underdeveloped. The Department of International Trade (DIT) generally refused to engage in our work. It may internally hold more detailed positions or impact assessments, but if so, these do not appear to be shared even within the public sector policy apparatus, let alone with NHS or health stakeholders in general. The UK government has not committed to the routine evaluation of the impacts of its trade policies on health and health care, and the UK Parliament has only limited ability to scrutinise new trade deals.

The two primary commitments made in UK policy documents³³ regarding health are consistently:

- “The NHS will not be on the table”, sometimes expanded to “the NHS will not be for sale to the private sector, overseas or domestic”.
- “The price the NHS pays for medicines will not be on the table”, or “the UK will not be signing up to any provision that would have an impact on the cost of medicines on the NHS”

These claims address two of the major sets of concerns around trade agreements, particularly those with the USA and with the CPTPP trade bloc it played a role in creating originally. Protections for investment and cross-border services in trade agreements could make it difficult to reform the health service in a way that would remove the current access of foreign private firms to internally tendered contracts in the English NHS. Various measures which would have the effect of making the NHS pay more for medicines – as health services do in the USA – have long been a concern,³⁴ although perhaps more under the previous administration in Washington.

Our interviewees believed that both commitments are considerably less clear-cut than they appear. They are not phrased in the actual language of trade deals, and say little about the specific provisions the UK would seek.

The obvious way to interpret the NHS “not being on the table” is that it would be entirely excluded from coverage by services or investment chapters in trade deals.

Specifically, this would mean that it would be listed as an exclusion in trade deals using the “negative list” approach, covering anything that is not explicitly excluded in a deal; and that it would not be placed on the list of areas covered in the case of a “positive list” approach, where a trade deal covers only areas that are explicitly included in a deal. However, these dual commitments have never been explicitly stated and officials we spoke to were less than fully confident that there was an absolute commitment to this.

If this is or becomes the UK’s position, it is still far from straightforward. The boundaries of “the NHS” are not simple because especially in England, the

health service works partly through the private sector, and across the UK it is becoming increasingly integrated with social care.

The pledge on medicines pricing is also quite ambiguous, and one official described this area as “the biggest concern” they saw. The possible problems in trade deals would primarily include longer IP protections stopping cheaper generic products being available to the health services; and limitations on the UK’s system of negotiating prices or its principle of refusing to pay for products that are not cost effective. Neither of these would necessarily drive up the cost of a particular existing medicine, but they would still result in NHS costs expanding over the years without getting anything more that is of benefit to patients.

“Patent linkage” is a common part of the US trade negotiation agenda which involves medicines regulators refusing to approve generic drugs where the company who first brought the product to market may still have a legal claim to them. It can have a significant impact on the ability of cheaper drugs to come to market: different countries have carefully negotiated what they sign up to with the USA³⁵ to limit the impact on costs. A form of this exists in the CPTPP agreement on which the UK is currently negotiating access, but it is not mentioned in the UK’s “strategic approach” document.

Reflecting on the details that are still unclear in UK policy, one official expressed a concern to us that “there will probably be areas where the UK has signed up to provisions in trade agreements that weren’t fully understood at the time either due to the speed of negotiations or due to not having the negotiating experience of other countries”.

A third area of significant concern for health is the risk that trade deal commitments on market access and investment protection may weaken the UK’s ability to impose regulations that improve the health of the public. This might include, for example, limiting or taxing the sale of alcohol, tobacco or unhealthy or unsafe food. While trade deals between developed countries usually contain exclusions for regulations protecting public health, these can contain loopholes.³⁶ Whether a measure is defined as being to protect public health might also depend on attitudes to the precautionary principle. This idea that it is right to restrict activities for which data is unclear, which the UK has

inherited in EU regulations, is not shared by countries like the USA leading to high profile trade tensions in the past.³⁷

A source of regret which emerged at our roundtable was that while these defensive issues have at least been prominently noted and discussed, policy on how the health sector might actually benefit from trade agreements seemed to be at a very early stage. “We’ve naturally had to focus on the defensive side”, one official told us, due to the speed at which the UK was trying to sign agreements.

While attendees described how NHS trusts did successfully export services – usually through sites they owned abroad or through health tourism – there seems to be little policy in place about expanding or supporting this. Direct cross-border provision of health care from the territory of one country into another is becoming ever more possible with greater uptake of remote care, especially following the Covid-19 pandemic,³⁸ but interviewees seemed unaware of any policy in train about encouraging this or guaranteeing safety, and we could not find references in policy documents.

Interviewees we spoke to in the life sciences believed that there was scope for ambitious international agreements to benefit the UK, particularly if multilateral cooperation and funding agreements similar to the EU’s Horizon programmes could be entered into.³⁹ Again, there was little sign that this is being explored.

Lack of involvement and transparency

Our roundtable attendees and interviewees outside government told us that the health sector had not been engaged very much on these issues and that transparency had been lacking. The exception was the pharmaceutical and devices sector, who reported better access but tended to have a different agenda, prioritising, for example, the UK pushing for stronger intellectual property protections for medicines in poorer countries.

This reflects wider analysis⁴⁰ suggesting that the UK’s current approach to trade is not well set up for the transparency, accountability, participation opportunities, integrity or capacity needed to secure good outcomes for health among other areas.

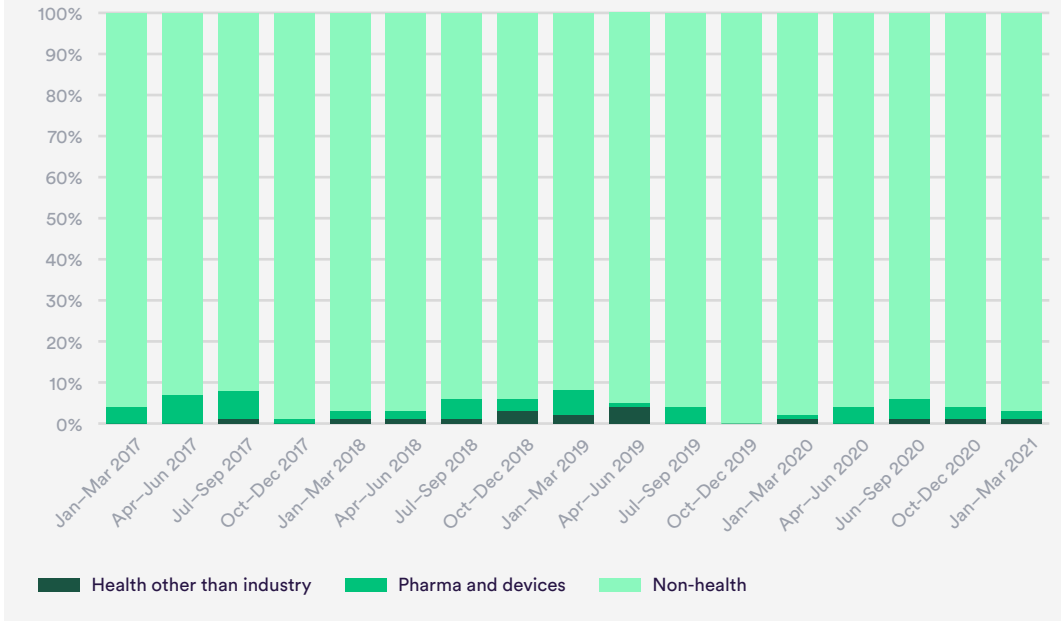
The EU's transnational democratic institutions create constant pressure for greater transparency, forming a focal point for stakeholder lobbying from different countries typically with some support from the Parliament and Commission. The Union announced a new package last year in response to pressure to be more open, though it still leaves most live documents confidential.⁴¹

Lack of transparency characterises multiple stages of the process in the UK. This can also be seen in the announcement of the concluded trade agreement with Australia, the UK's first new trade agreement not to be simply rolled over from the EU. No text has been published despite an agreement existing in principle, with no updates describing changed negotiating aims or directives from the UK government, as the EU occasionally did during recent negotiations with the UK⁴² and China.⁴³ At the point of announcement, heavily affected agricultural interests in the UK appeared to be unclear about what had been agreed.⁴⁴ The UK's legislation for scrutiny of international agreements gives Parliament limited powers to be consulted or to stop ratification.⁴⁵

An analysis of ministerial meetings with external stakeholders that DIT published supports the view that there has been comparatively little engagement with the health sector (see figure 4 below).⁴⁶ From the start of January 2017 to March 2021, ministers are recorded having met with representatives of the pharmaceuticals and medical devices industries on 83 occasions, from a total of 2541 meetings.

22 meetings are recorded across all other health related organisations combined: the NHS; regulators; private healthcare providers; patient groups; health insurance; hospital construction firms; and health unions. By comparison, 40 meetings are recorded as being attended by the single alcohol multinational Diageo. Although the lists may not be comprehensive, there is no apparent record of ministers meeting with the NHS Confederation or NHS Providers, the two main representative bodies for the health service.

Figure 4: Percentage of recorded ministerial meetings with the health sector compared with other industries, from 2017–2021



DIT does hold regular meetings with Trade Advisory Groups. These include⁴⁷ a Life Sciences group with representatives of the pharmaceutical and devices industry and parts of the public sector – though not the NHS – as well as a Trade Union Advisory Group,⁴⁸ which includes the British Medical Association. We submitted a Freedom of Information request for any meetings between DIT civil servants and ministers and the health sector regarding the CPTPP trade negotiations since the start of 2021. These showed CPTPP was discussed with these groups, and once separately with the BMA, but not with health organisations otherwise.

DIT refused to answer a number of other Freedom of Information requests about contact with the health sector, in general and in relation to specific negotiations. Unlike DHSC and NHSE, the Department declined to be interviewed for this project.

Conclusion

One theme discussed at our roundtable was that this closed approach and the limited development of health-related trade policy were interrelated. The limited engagement and lack of openness to health stakeholders stops the uncomfortable scrutiny of how the UK aims to protect the NHS in future trade deals. This removes the pressure to move towards more precise policies on protecting the health service's defensive interests. At the same time, it shuts out ideas and perspectives which might lead to more positive proposals for health.

Without more careful and public examination of trade and health decisions, there is a real risk that the issue will explode into the policy debate only when a signed agreement is presented, possibly derailing it. Worse yet, there might be no realistic point of leverage to stop an agreed deal with negative consequences for the NHS taking effect and playing out over several years. Meanwhile, the UK, supposedly on a quest to find better opportunities outside the EU, will have done little to explore any positive steps for health or life sciences.

4 Devolution and health

With major powers affecting health returning from the EU, a crucial question for the UK is how their distribution changes the balance of power between Westminster and the devolved administrations who are responsible for the NHS and public health in Wales, Scotland and Northern Ireland.

Taking away control?

Those we spoke to in devolved administrations tended to feel Brexit, or more accurately the UK government's approach to it, had removed some of their autonomy in making decisions improving people's health.

In particular, the 2020 Internal Market Act (IMA), which aims to maintain a single market in goods and services at a UK level was seen as "reversing a lot of the devolved powers" in health which had been flagship powers of the Cardiff, Edinburgh and Belfast governments ever since their establishment in the late 1990s.

The primary concern was with the IMA's mutual recognition principle, which states that goods sold in one part of the UK, meeting the requirements there, can be sold anywhere else in the UK.⁴⁹ This effectively means that devolved administrations could not apply restrictions on the characteristics, labelling and other traits of products sold there and have them applied to products from other parts of the UK with different rules. This has implications in particular for food, tobacco, and alcohol policy, in which Scotland and Wales have a history of innovating, in part because of the particular challenges of population health they face. These innovations were consistent with EU law.

There is ambiguous wording around differing "manner of sale" requirements such as price and time at which things can be sold. These are allowed but only if they do not "appear to be designed" to contravene the principle. A separate "non-discrimination principle" would stop any UK nation from simply stopping or deterring the sale of products from other parts of the UK in an attempt to control what is available.⁵⁰

One interviewee told us that he believed the European version of single market law left more space to justify interventions based on health than the IMA did. They pointed to the EU Court of Justice’s landmark decision on minimum alcohol unit pricing in Scotland, which ultimately allowed the UK Supreme Court to uphold the measure. Article 168 of the Treaty on the Functioning of the European Union states that “a high level of human health protection shall be ensured in the definition and implementation of all Union policies”.^{51,52} The IMA does not have a comparable principle that applies to it as a whole or to its mutual recognition principle. An exception to the non-discrimination principle for necessary measures to protect human health is weakened by including the ability for the Westminster Secretary of State to change it by issuing regulations.

“Can we take public health measures through what we would see as a necessary distortion of the market when the whole purpose of that Act was to make a single market and not be distorted?” one official from a devolved government asked. “The previous European legislation allowed for that, but the Internal Market Act has not made the same provision.”

Interviewees tended to express uncertainty and doubt rather than certainty that a specific set of policies would be prevented: “It’s speculative to say we will be restricted, but the suspicion is that we will be”.

In our last report,⁵³ we noted amendments made through the House of Lords which aimed to partially address these concerns by allowing divergence where a “common framework” agreement was reached across the UK. However, our interviewees’ verdict on this was that it made little difference. The exemption intrinsically requires Westminster approval and, with what was generally described as “seriously strained” relations following the IMA’s introduction in the first place, this was still felt as a loss of control over health policy.

Because the dynamic is largely that of a chilling effect, in the coming years it will be important to monitor policy processes and discussions in Scotland, Wales and Northern Ireland to see whether the threat of the IMA is a frequently cited deterrent to public health action – as well as watching for legal test cases. There is of course scope for a threat to be claimed for political purposes or used as an excuse for inaction.

An important first test will be the ongoing legal action the Welsh Government has taken against the UK government over the IMA, on the grounds that it infringes on devolved powers and gives the Secretary of State the ability to do so further.⁵⁴

Left out of the conversation?

Officials and stakeholders in devolved administrations generally felt that in those areas where Westminster had gained returning powers, consultation and involvement with them on health had been lacking.

This was particularly the case for international trade. Interviewees felt concerned that agreements would be passed to them with little discretion due to the IMA, and feared that a trade deal, particularly with the USA, would be “prohibitive and restrictive” on public health regulation. They generally did not appear confident that devolved health services, officials or politicians had routes of influence or even information on ongoing trade agreement processes. While DIT does have officials responsible for liaising with devolved administrations, we heard that they are separate from teams involved in decisions and negotiations.

This is a particularly acute concern for Northern Ireland, whose unique status effectively inside the EEA single market for goods means that it has different health interests and risks to consider. For example, any cloud over the UK’s position in the European Patent Convention, which some legal sources suggest may be a consequence of accession to CPTPP,⁵⁵ would be dangerous for a health system which may soon be forced to be part of, and reliant upon, the European medicine and devices market.

The replacement of EU structural funds for less developed areas with the UK Shared Prosperity Fund represents the clearest case of all of the reshuffling of powers due to Brexit being used to reduce the powers of the devolved administrations. Local economic development is an important field of health policy. Evidence shows that poverty and lower living standards are strongly linked to chronic illness and mortality, intensifying the effect of the lifestyle and behavioural factors on which public health efforts traditionally focus.

Apart from being used to try to address regional economic inequalities, EU structural funds were given specifically for health-related purposes, such as supporting activities of the Life Sciences Hub Wales.⁵⁷ Wales, Scotland and Northern Ireland all received more structural funds than England, with Wales highest by far at €780 per person in the six years before Brexit.⁵⁸

Whereas structural funds in the EU were allocated to Scotland, Wales and Northern Ireland based on priorities determined by their devolved governments, the IMA provides for their replacements to be distributed by a single UK framework working directly with local authorities.^{59,60}

Whatever the merits of this, interviewees pointed out that the Welsh, Scottish and Northern Irish governments are where responsibilities and strategies sit for health, health care and increasingly social care. Their being “left out” or “cut out”, as interviewees both within and outside devolved governments put it, will create a position where alignment of local funding with the goal of improving health is less likely. In Wales in particular, reviews have found that the system for local development is already overcomplicated by multiple schemes and arrangements between UK, Welsh and local governments: a new set misaligned from many others may not help.⁶¹

The IMA also explicitly reserved the right for Westminster to set controls on subsidies, although actually granting them will remain with the devolved administrations.⁶² Depending on the exact nature of the new regime compared to that inherited from the EU, this too may remove some health policy options, for example granting funding to life sciences firms or trying to shore up medicines supply lines.

5 Procurement: delivering divergence?

When the UK Government announced proposed changes to procurement rules, it stated that “the end of the Transition Period provides an historic opportunity to overhaul our outdated public procurement regime...to design something that delivers for our communities and our businesses”.⁶³ Procurement, the process whereby billions of pounds worth of health supplies and services are secured by public contract, could therefore be seen as a flagship case for divergence in health policy following Brexit, and one where proposals are advanced and specific unlike in medicines or devices.

Participants in our roundtable, however, were not convinced that leaving the single market had presented dramatically new possibilities. They identified a range of risks and opportunities of the new proposed rules.

The rules as EU members

The UK’s health procurement regime currently rests on two pieces of legislation. First, the 2013 National Health Service Patient Choice, Procurement and Competition Regulations, n.2 (PCPCR)⁶⁴ under section 75 of the 2012 Health and Social Care Act, create an obligation to open public tenders for health care contracts above a specific value (£615,278), enshrining procedures and principles for public procurement, broadly aligned with the EU’s.

Secondly, the 2015 Procurement and Contract Regulations (PCR) in England, Wales and Northern Ireland, and their equivalent in Scotland,⁶⁵ implement and almost exactly transpose the 2014 EU Public Contracts Directive. They set out the principles of equality, non-discrimination, transparency and open competition to member states, again with open tendering above a threshold, currently set at 750,000 Euro.

Procurement is different between the UK's constituent nations, and for goods as opposed to services. Part of the procurement of goods is conducted centrally, by NHS Wales Shared Services in Wales, by NSS Procurement in Scotland, in Northern Ireland by the Procurement and Logistics Service, and in England by NHS Supply Chain. In all countries, various goods and services such as consultancy and cleaning are purchased by the bodies that deliver care. Clinical services are commissioned locally by providers from the private sector.

In England, clinical care itself is also systematically purchased or “commissioned” from within and outside the NHS. The purchasing of clinical services (with the exception of the pandemic) falls to local Clinical Commissioning Groups (CCGs) and to NHS England. These bodies are distinct from service providers such as GPs, hospitals or private entities. In Scotland and Wales, the health boards which receive budgets also directly provide most clinical care instead of purchasing it.

The financial scale of purchases in health that are subject to procurement rules is very large. In England in 2019-20, primarily before Covid-19, the NHS and other parts of the DHSC spent £18 billion on supplies and services. £91 billion, which represents a large majority of the department's total budget, was paid to NHS trusts and private providers through the internal market.⁶⁶

What are the main changes proposed, and was Brexit a precondition for them?

At the end of the transition period on 1st January 2021, the UK's obligations under EU rules and related regulations officially ended. The UK acceded to the WTO General Agreement on Procurement (GPA) as an independent state. The UK's accession schedules exclude the NHS, while the Trade and Cooperation Agreement (TCA) signed in 2020 with the EU excludes health in general.

It is worth noting, however, that GPA principles and procedures underlie and are therefore similar to those of the EU Directive more generally, and are continuously referred to in the UK's new proposed legislation.

A raft of reforms has since been proposed. After the official Brexit date in 2020, the PCR was amended⁶⁷ to repatriate elements such as notification and publication procedures for procurement to the UK that had previously fallen to EU institutions.

The 2021 Health and Care Bill, along with restructuring the English NHS and enhancing central control over it, would remove s.75 of the 2012 Act. A consultation has been carried out on a proposed new NHS “provider selection regime” (PSR),⁶⁸ with the intention that this would be used as the basis of new regulations under the Act to replace the current system for clinical services. The PSR states an aim to reduce the “bureaucratic” requirements on commissioners to run open tenders, increasing their scope to opt for more limited tenders or to forgo the procedure altogether.

For the procurement of goods and services, a new Green Paper, “Transforming Public Procurement”,⁶⁹ lays out proposals for change across all sectors, replacing the 2015 Regulations which applied the EU directive. The Green Paper does not, in its current form, cover health services proper, as future procurement is still being discussed in the context of the NHS Long-term Plan. However, the health care sector participated in the consultation exercise leading up to the Paper. Other aspects of health are not excluded, and it is conceivable – if not absolutely certain – that similar rules will eventually apply to the procurement of health services.

Roundtable participants and interviewees varied in their views about what the previous regime had meant for the NHS, and whether it had created and enforced a true internal market up until now. Some believed clinical commissioning groups would often fill the requisite procedure and paperwork to produce the appearance of competitive tendering in services where there was little real competition.

Others noted that CCGs would use tendering and procurement to private entities as a “stick” for public providers, sometimes precluding a necessary discussion about how and why performance might have fallen short. This could lead to a “more complicated failure”. Others still believed that the NHS routinely infringed procurement rules, and that this was routinely overlooked.

Participants in our roundtable did agree, however, that EU membership and the PCR had not constrained the UK's freedom to shape its health commissioning to the extent that the government implied.

In EU directives and implementing regulations, procurement is defined broadly as “the acquisition of works, supplies or services for consideration by means of a public contract...through purchase, leasing or other contractual forms”, from “economic operators” providing these works, supplies or services.⁷⁰

However, Recital 5 of the parent Directive's preamble states that member states may “contract out or externalise the provision of services that they wish to provide themselves or to organise by means other than public contracts within the meaning of this Directive”. Article 41 leaves some scope for national measures protecting health, so long as these are compatible with the Treaty for the Functioning of the EU (TFEU).

Meanwhile, Recital 32 of the preamble states that public contracts awarded to ‘controlled legal persons’ should not be subject to the Directive's procurement rules. Service provision by operators fulfilling specific conditions, such as in customer choice systems, would also fall outside the rules (art.4)

This has been interpreted as meaning that states may decide to take public services such as health out of the remit of procurement in two ways. Firstly, a public authority can control its provider, which then no longer counts as an ‘economic operator’. Procurement law is therefore not in play. In an English context this would mean changing the semi-autonomous nature of NHS foundation trusts. Secondly, in a ‘qualified provider’ model, patients choose their care provider and money simply follows them, an approach already used to some extent in England and more extensively elsewhere in Europe.⁷¹

On the one hand, then, Brexit does allow the UK to design different procurement rules in an attempt to reduce bureaucracy in the NHS. On the other hand, England did not avail itself of the opportunity to remove most of this bureaucracy from within the single market – by bypassing the system altogether.

We heard that only 5% to 10% of contracts for clinical services actually go out for tender in the UK, generally to domestic suppliers (our participants did urge some caution with exact figures, for the reasons of circumvention and paperwork formality described above). This is a far greater proportion than other prominent member states such as France and Germany, which prefer the accredited qualification provider model to outsource health services, with far lower administrative costs. Consequently, some participants suggested the UK was the author of its own complications. In contrast to procurement of clinical services, procurement for goods and medical devices in the UK – both domestic and cross-border – is far more frequent. It has also taken place under the EU regime.

This seems to suggest that Brexit may not necessarily have legally enabled the removal of certain requirements. However, politically, its symbolism might have provided the political space for government to exert its own control over procurement policy. NHS England, in turn, might have been able to capitalise on the appeal of divergence from the EU to a pro-Brexit political current, and with it the “new” ability to drop procurement rules. This may have enabled it to make the case for a less competitive health service to a governing Conservative party historically keen on expanding marketisation in public services.

Opportunities and risks

The effect of the new proposed rules on the English NHS

Our participants and interviewees identified both opportunities and risks linked to the new regime.

On one hand, several NHS stakeholders agreed with the PSR’s aim to streamline – or ‘radically simplify’ – procurement and make it more flexible, reducing the burden of paperwork and procedure. Participants did not always agree on whether this would shift the current balance of public and private service provision: one interviewee welcomed the opportunity to regain some grounds from contracts with large private providers with deeper pockets and larger legal teams than their NHS counterparts; another saw an opportunity in greater flexibility to continue or expand positive work with local community

organisations or social enterprises, so long as solid business cases are presented and monitoring is put in place.

One interviewee broadly supportive of the change was unsure whether the overall number of procurement tenders would in fact decrease, even if the balance between public and private providers does. Several participants, nevertheless, pointed to the potential advantages of a new and simplified provider regime for integrated care partnerships and for continuity of care in sensitive areas such as community services and mental health.

On the other hand, one participant noted that this same flexibility could lead individual local areas to produce their own procurement rules and fragment the new commissioning landscape instead of unifying it. Several suggested a risk of collusion and ‘cartelisation’, rather than privatisation, of commissioned services, as highlighted by the Competition and Markets Authority (CMA) in its consultation response to the Green Paper.⁷² This could, essentially, switch one form of complexity for another and remove a source of pressure on providers to do better. Lack of financial and governance clarity with new integrated care partnerships would further complicate these new arrangements.

Discretion and poor accountability

Further concerns were raised with whether the new proposed rules contain the clarity and accountability needed for good governance. The existing regime details a number of options for procurement: open competition (which could be called classic procurement); restricted tendering under a number of forms; and drawing a list of accredited qualified providers for patients to choose from.

The new regime combining Green Paper and PSR proposals claims to simplify and clarify its predecessor. However, the substance of clarifications is often difficult to identify, and at times the proposals add to existing ambiguities.

In the Green Paper there is prominent language around a shift from choosing the ‘most economically advantageous’ to the ‘most advantageous’ tenders, moving away from purely economic to wider social rationales. The new regime

would, then, allow commissioners to give greater weight, for example, to environmental priorities, within a hierarchy of criteria including price.

However, the Social Value Act (2012) already imposes on public authorities a duty to make such considerations,⁷³ and the existing EU regime explicitly allows the social and environmental characteristics of bids to be taken into account.⁷⁴ Moreover, setting aside the question of how social value would be scored against other criteria, if price is another component, the cheaper bid would still be raising the overall bidding score; our stakeholders were not entirely convinced of the novelty or effectiveness of this reform.

The new regime also claims to simplify procurement rules by removing some of the many available routes for limited tender under the PCR. However, the PSR consultation also opens a new route for contracts to be renewed. It does this partly drawing on the language of the PCR,⁷⁵ which envisages a ‘negotiated procedure without competition’ in cases including the absence of tenders, lack of competition for technical reasons and emergencies.⁷⁶

Under the PSR route, commissioners could renew a contract if they consider performance to date has been ‘sufficiently good.’ They may do so taking ‘appropriate steps to ensure that the service will continue to deliver well.’ Another new option consists in ‘identify[ing] a suitable provider’, in other words foregoing competitive tender. This may take place ‘for a new/ substantially changed arrangements’, ‘where the provider no longer wants to carry on’ but also, more ambiguously, where ‘the decision-making body wants to use a different provider’ so long as commissioners have “carefully considered other potential options/providers”.

Without a tender, it may be harder to ascertain whether all available options have been considered on the market. While an NHS monopoly or limited competition may frequently be a reality, it is risky to assume so as a matter of law.

Finally, open tenders are worded as a choice to be taken for new or substantially changed tenders, following the same relevant criteria, *if* a suitable candidate is not identified. This suggests a strong incentive for non-competitive procurement to be a default under the new regime. This may be bureaucratically advantageous, but at the same time looks considerably less transparent.

The ambiguity in the proposals, coupled with the shift from a comprehensive set of ‘rigid’ legal rules to a combination of statute and statutory guidance, seem to further detract from the clarity the reforms seek to bring. It has also been pointed out that in addition to administrative costs, this will involve significant investment in training the commissioning authorities and civil servants who will be responsible for the oversight of these new arrangements – and concrete provisions for this have yet to be produced.⁷⁷

Difficulties with litigation

Our interviewees also raised the risk that options for renewal and selection without tender could lead to litigation before, in addition to after, the award of contracts. This would increase administrative costs when they might be cut elsewhere. Providers have a notice period of six weeks following the award decision of commissioners to make suitable representations. This was judged by our stakeholders to be short – and could be further shortened to four weeks at commissioners’ discretion.⁷⁸

Meanwhile, both the PSR and the Green Paper remove previous routes for challenge and scrutiny. For instance, there will no longer be recourse for providers to legally challenge through Monitor, the healthcare regulator, and for damages through the PCPCR.⁷⁹ The Green Paper proposed capping any damages – which could be awarded by successfully contesting the commissioning body’s decision.⁸⁰ Following consultation, the cap was removed.

Beyond this and in the absence of EU referral institutions, only judicial review would be available as an appeal route for dissatisfied bidders. The room for discretion in proposed criteria for decision-making – as detailed above – would make it difficult to prove a decision was made in excess of the powers given to a public authority or was procedurally unfair. This raises the possibility that contracts could be harder to challenge or even easier to perform poorly without accountability. It might also act as a disincentive from bidding at all, especially for smaller providers with fewer time and monetary resources.

Crisis without end?

In the wake of the pandemic, the Green Paper also expands on the limited tendering procedure of the PCR, by adding a new category of ‘crisis’.⁸¹ A crisis is defined as “an event which clearly exceeds the dimensions of harmful events in everyday life and which substantially endangers or restricts the life or health of people; “where measures are required to protect public morals, order or safety; or where measures are required to protect human, animal or plant life or health”.

Potential providers could apply for special crisis provisions to the Cabinet Office, which would make the final decision. Contracts awarded under this procedure would be exempt from automatic suspension (except where due procedure was not followed during the tender), which occurs when a bid decision is made without notice.⁸² The rule ostensibly expedites the competitive process and seeks to improve transparency.

However, participants highlighted opaque, costly and ultimately unsafe procurement exercises⁸³ at the height of the pandemic – most notably in sourcing PPE – which ran counter to the principle of transparency and advantageous tendering. While these occurred with EU rules fully in force, roundtable participants saw a risk that the Green Paper proposals could create even more space for poorly governed “crisis” procurement. The government will need to demonstrate that safeguards are in place for the procurement rules to be used in an effective and ethical manner.

Conclusion

It is difficult to make reliable predictions on the likely outcome of the new procurement regime in the UK. Our stakeholders are divided over the potential benefits and risks that it might present. These concerns are largely borne out by the UK Government’s summary to its consultation response. Roundtable participants were unanimous in considering that similar outcomes within the NHS could have been secured, through different means, without Brexit. The new impetus for them perhaps reflects a political shift that took place as a commitment to Brexit, and removing EU rules

displaced the commitment to free markets as the focal aim of the governing Conservative party.

While some in the NHS welcomed the greater latitude to decide when to avoid the competitive open market, others thought the new discretion could lead to conflicts of interest and litigation. Understandably, the perception of risk is coloured by the experience of pandemic procurement, as well as the changing context of new integrated care partnerships. Further uncertainty revolves around how devolved administrations choose to respond to the new legislation.

This suggests a need for greater clarity on the many ambiguities in the new arrangements, a stronger picture of how identified risks will be mitigated, and close monitoring as the regime is rolled out. While procurement may be an early example of post-Brexit divergence, it is too early to understand exactly whether and how it will change how the NHS works locally – and whether the advantages of a more flexible approach outweigh the risks.

The first step towards better understanding how these different issues evolve is better data. Simply recording the volume of contracts sought through different routes, for example, does not provide a sufficient way of achieving this. In order to understand whether both the process and the outcomes of procurement are as simple as they can be, are fair to both purchasers and providers, and are providing good value for money requires a range of data to be collected that is currently not in place. Given the relatively large role of procurement within the NHS and the potential scope for change that now exists for domestic policy, the first step towards understanding the impact of changes in this area would be the creation and collection of data that would help to clarify these issues and improve procurement in the NHS in the long term.

6 How health is affected by Northern Ireland's unique position

The position of health law and policy in Northern Ireland following the end of the transition period is complex, uncertain, fast-changing and characterised by significant mismatch between public and governmental narratives and the legal and policy realities on the ground. The uneasy settlement for the island of Ireland following the UK's departure from the EU continues to create a problematic position for all matters related to health. This is in part because of the *general* settlement in the Withdrawal Agreement's Ireland/Northern Ireland Protocol, and in part because of the specificities of health provision on the island of Ireland. Here some health infrastructure is shared, the health workforce regularly crosses the border, patients are accustomed to accessing some health services on either side of the border, and health is one strand of the institutional structures put in place to secure peace following the Belfast-Good Friday Agreement 1998.

Medicines and supplies

Four fifths of prescription medicine in Northern Ireland,⁸⁴ and much of the medical devices supply, has historically come from Great Britain. In our research last year⁸⁵ we found widespread alarm from both government and industry about the impact on supply when the Protocol kept Northern Ireland largely in the single market for these products, while the rest of the UK left.

The current position concerning all products used within the NHS in Northern Ireland hides this uncertainty. This is because of various 'standstill periods'⁸⁶ currently in place which have the effect of removing or modifying the full effect of the application of the Ireland/Northern Ireland Protocol. Initial difficulties in early 2021 with new customs formalities and the associated paperwork have

to some extent been resolved, as the logistics sector has come to terms with new requirements.

If these were to come to an end, without the competing EU and UK proposals discussed below being put in place, there were multiple concerns about supply both of products purchased and used by the NHS in Northern Ireland, and about over-the-counter, and open sale medicines, devices and other products. Particular problems highlighted in our interviews included:

- The application of the EU Falsified Medicines Directive in Northern Ireland but not Great Britain will mean products supplied via the UK need to have identifiers and tags de-activated and re-activated, logging them in both cases. This adds considerable cost and complexity.
- The (disputed) requirement to carry out batch testing within Northern Ireland or the EU will mean normal UK supply chains cannot be used.
- If Northern Ireland is effectively to be part of the Republic of Ireland (RoI) market because of these changes, this implies a smaller set of products approved through national procedures relative to the larger UK.
- Concerns about aligning with the RoI market because the culture and practices of the NHS in RoI differ significantly from in the UK.
- The practice of pharmacy in the Republic of Ireland generally involves a lower level of over-the-counter medicines being offered, and so merging into its markets implies less choice in this category.

The direction of travel, unless something changes, is of a small Northern Irish market, where new products or new indications for existing products, reach patients later than in England. There is a genuine possibility that some products become difficult for the NHS in Northern Ireland to source: some companies have already given notice⁸⁷ of intention to cease supply in six months' time. One interviewee told us that holders of two thousand medicines licences “may terminate supplies”.

Talks between the EU and UK staggered on into winter 2021 to try to resolve this among other issues. On 17 December, the EU published a new set of proposals⁸⁸ aimed at allowing Northern Ireland to continue to be supplied largely through the UK. These, if adopted by the EU legislature in their current form, would go much further than an earlier July 2021 ‘non-paper’⁸⁹ building in part on expanded proposals in October. They would be a legislative solution on medicines, amending primary EU law. They would allow regulatory functions for medicines supplied to Northern Ireland to be carried out by entities already established in Great Britain as long as EU rules were applied. They would allow for a three-year suspension on the need to deactivate Falsified Medicine Directive (FMD) unique identifiers for products passing from the EU to Great Britain. Current transitional provisions would be extended until 31 December 2022, or when legislative changes came into effect.

However, these proposals do not reinstate free movement for medicines, and do not cover other products that the NHS in Northern Ireland needs, which are also supplied from GB. They would require adherence to EU rules for some regulatory processes within Great Britain (where these apply to products for Northern Ireland), and reports earlier in the year suggest this may be unpalatable⁹⁰ to Westminster, although ECJ oversight now seems to have been conceded.⁹¹

Our interviewees differed sharply on the earlier EU proposals. Some believed that they would almost entirely resolve the issues they anticipated, and thought the UK government was irresponsibly playing politics by not accepting them. Others, though, especially at the higher volume end of the market, felt that earlier EU proposals were “unworkable” and even internally incoherent, because they would still require separation of Great Britain and Northern Ireland supply chains, even inside Great Britain. Whether the December proposals will resolve this is unclear. The movement of products across the border in the Irish sea is still an import or export, with all the expense entailed. It will remain the case that the criteria by which the UK approves medicines for Northern Ireland – still based on EU law – may differ from those for the rest of the UK, possibly still creating some of the problems with dual portfolios raised by the generic medicines industry.⁹²

The UK government had proposed a ‘fundamental rethink’ in its July 2021 Command Paper⁹³ whereby medicines would simply not be subject to the Protocol. UK minister Lord Frost announced in October⁹⁴ that a legally drafted version of these would be shared with the Commission: it was unavailable at the time of writing. Nearly all interviewees felt this would resolve the problems in a narrow sense, but most also felt that it would not be accepted, because it would either reinstate a border between the Republic and Northern Ireland, or allow unregulated medicines to flow into the EU. Even one who was supportive of it conceded it would mean an effective border where FMD attributes would need to be applied and disapplied, though they felt this was manageable.

People, health and the border

For service provision and movement of health care professionals, the public narrative around the position of people living in Northern Ireland focuses heavily on the arrangements known as the ‘Common Travel Area’ (CTA). These are embodied in a parallel set of domestic laws, policies and practices in Northern Ireland and the Republic of Ireland. The CTA was significantly assisted by common membership of the EU, with the provisions relating to free movement of people, and coordination of social security, flowing from EU law. Post-transition, it has been claimed⁹⁵ that the CTA’s provisions will provide continuity, and that people’s entitlements will continue as before, albeit on a different legal footing.

While this may be the case for British and Irish nationals, the CTA does not cover the position of EU-26 nationals, or ‘third country’ nationals. EU-26 nationals, and third country national family members, who are resident in Northern Ireland are entitled to apply for ‘settled status’ to secure their residency rights, from which their access to the NHS in Northern Ireland flows. Although the Settled Status Scheme was launched in March 2019, it was not extended to family members of Irish citizens in Northern Ireland until⁹⁶ August 2020 (family member) and July 2021 (dependent relatives).

There are concerns that the social care workforce, especially frontier workers, will be affected by the lack of clear information specific to Northern Ireland about entitlements (for instance, under the Withdrawal Agreement) and

requirements (for instance of the Settled Status Scheme). Some matters concerning qualifications recognition have been dealt with at the level of professional organisations. However, the rules in the EU-UK Trade and Cooperation Agreement are unlikely to provide a basis for the deep cooperation that would be necessary to sustain ongoing all-island professional and health sector educational networks in the longer term. In practice, workforce effects are masked by Covid-19 which has flattened the levels of (?) general health and social care workforce migration, and also means that many in the health sector are still working from home, rather than regularly crossing the Ireland/Northern Ireland border.

Likewise, effects of the complex and overlapping new rules on patient mobility are yet to appear. While there are a few examples of patients being unable to access all-island health care, it seems that practices on the ground are largely continuing as before 1st January 2021, irrespective of the technical legal entitlements – at least for English-speaking patients who present as ‘British’, ‘Irish’ or both. The UK and Ireland have agreed a one year partial extension⁹⁷ to the Patients’ Rights Directive, embodied in the CTA. NGOs have expressed concerns about the lack of clarity in communications from the NI Health and Social Care Board or Department of Health and Social care as to how the new rules work, and what choices a patient in Northern Ireland might have to access care south of the border. For example, it is unclear how the MoU on the Patients’ Rights Directive interfaces with entitlements under the Withdrawal Agreement (which does not appear to have been drafted with frontier workers at the Northern Ireland border in mind) or with the UK’s new GHIC.⁹⁸

The ongoing operation of the Ireland/Northern Ireland Protocol is subject to its ‘democratic consent’⁹⁹ procedures. Under this, Members of the Northern Ireland Assembly will decide, by simple majority, whether the provisions on trade in products, as well as the single electricity market and state aid provisions, will continue to apply. The first such vote will be in late 2024. These provisions add to the uncertainties outlined above.

7 Discussion

A number of running themes connect all the areas in which we have examined the health sector's experiences during the first year of Brexit's full effects.

The first is ongoing uncertainty, and a sense of disappointment that the struggles to reach a Withdrawal Agreement and trade agreement with the EU have not provided legal or policy stability. The UK's ongoing battles over the Northern Ireland protocol not only make it very difficult to plan for medical supplies and services within Northern Ireland, but also cast a looming shadow over engagement with the Horizon Europe science programme and the continued existence of the measures in the TCA. This appears to be driving negative perceptions among those responsible for investment, and there is evidence that uncertainty in previous years damaged UK access to life sciences funding.

For the devolved governments running health and care services in Scotland, Wales and Northern Ireland, the UK government's use of Brexit to apparently centralise power through the Internal Market Act and replacements to the Structural Funds creates doubt about the policy levers they still hold now and in the future.

Another theme is the lack of clear UK policies for health in the crucial areas of competency brought back from the EU. Difficult decisions about the future of medicines regulation are yet to be taken, and the UK is currently simply using an outdated version of the EU system for medical devices. The UK has published more concrete plans for changes to procurement law. But here, too, we heard considerable doubt about their impact. Some believed they would lead to more litigation, others less; some believed they would mean less tendering in the English NHS, others disagreed. Most agreed that considerable ambiguities existed.

On trade policy, even as British negotiators charge out to secure new agreements at breakneck speed, the key pledges to protect the NHS and medicines prices are in fact difficult to understand, and key details are yet

to be determined. A positive agenda to use trade policy better to serve the interests of health in the UK – through global science collaboration and safely providing care across border – seems to be largely lacking.

In many areas, as a result, the likelihood that the EU will reform and change faster in the coming decade, diverging from a shared starting point, is at least the same as that of the UK strategically diverging from the EU.

The decision-making process in many of these areas is marked by secrecy and a lack of engagement. There are no regularly published figures on problems with medicine and devices supply chains. Little engagement seems to have taken place between the Department for International Trade and the health sector. Even the devolved administrations felt their input had been limited. Beyond trade, the level of trust between Edinburgh, Cardiff, Belfast and London on governance changes after Brexit generally appears to be very low.

In some areas, it is not clear that reliable and up-to-date data are available, even within government. The collection and reliability of migration data have been severely disrupted by the pandemic, and there are several worrying gaps where workforce may be most affected by Brexit: in Northern Ireland generally, and for social care across the countries. Information on life sciences investment is difficult to come by.

In almost any other year, leaving the Single Market would have been the major theme of pressures and changes in health in the UK. In 2021, the impact of Covid-19 obscured its impact and demanded the attention of leaders and representative bodies while crucial decisions were put to one side. In our next report, we expect that impacts on migration, investment and living standards, and their consequences for health, may become more visible. The UK may also make more progress with policies in trade, medical products and procurement. The story of how this historic shift in the economic and demographic links between the country and its neighbours affects health is only just beginning.

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