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How will our future relationship with the EU shape the NHS?

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This briefing looks in depth at five key areas where the deals the UK reaches – or fails to reach – as it leaves the European Union (EU) will impact health and social care in this country. For each one, it looks at the options, alternatives and workarounds that will be possible under different models of Brexit.

The analysis draws on a series of roundtable events for policy leaders dealing with Brexit in health and social care; a review of Government, independent and academic literature; and consultation with experts and stakeholders. It considers in particular the impact of possible future agreements for ongoing trade and co-operation. But it also looks at some of the implications of whether or not we can even come to a deal on leaving the EU – which will itself be a prerequisite to agreement on an ongoing relationship.

Throughout, we assume that the basic negotiating stances of both the British Government and the European Commission will be broadly retained. This means an outcome where the UK is not subject to the European Court of Justice or to the free movement of people, is outside the single market and customs union, and is not allowed to cherry-pick partial access or to enjoy more favoured status than other non-EU countries.

This briefing does not look at issues relating to the immigration system and the funding levels chosen for the NHS after Brexit. As we have said previously, these factors, which lie largely within the UK's control, will have a more profound impact on the health service even than our future relationship with the EU. We will return to these in future briefings and research.

Key points

- The NHS and its patients rely on products, innovations, staff and industries whose place in the UK could be undermined as we leave the EU. Many of these issues – though not all – can be addressed if the UK and the EU reach careful, successful exit and trade deals.
- A scenario where the UK leaves without any deal would cause extensive problems for the NHS. It would risk a chaotic disruption to supplies of medical products, and a rise in prices that would push hospitals deeper into deficit. It would obstruct vital procedures provided across the border between Northern Ireland and the Republic of Ireland, and risk forcing tens of thousands of pensioners to return to seek care in an NHS which has no room for them. Even with an exit deal, failure to reach trade and co-operation arrangements could slow down access to cutting-edge treatments, worsen the risk of vital supplies decaying at the border, and damage medical research in several ways. If no common ground can be reached, it is in the interests of health and social care in Britain for negotiators to start looking for compromise.
- In some areas – medicines approval, life science regulation, and the Working Time Directive – there are glimmers of opportunity to do things differently after Brexit. However, in general, continued regulatory alignment will bring the most certain benefits. This means there is a need for the NHS leadership, organisations which represent NHS staff, and the life sciences industries to identify in concrete terms where they think it is worth the UK being free to diverge after Brexit and why, before talks reach these topics.
- Ways to co-operate on regulation and reciprocal health care depend on having a legal system to govern them which is accepted by both sides and accessible to all. This is likely to involve some role for the European Court of Justice, even if not directly applied to the UK. One of the most plausible alternatives would use the European Free Trade Area Court or something similar. The British Government should be careful not to extend the principle of leaving the jurisdiction of the European Court of Justice so far that it rules out these sensible options.

- Working together on research and regulation will be in the interests of European as well as British patients and citizens. It is in the best interests of all for EU negotiators not to carry understandable resistance to ‘cherry-picking’ so far that it rules this out.
- Trade deals along the lines the Government plans, either with the EU or with other countries, may make it difficult to change procurement or competition law even after we leave the EU. Rather than relying on Brexit, it is worth looking at how domestic changes could exempt the NHS from these laws if this is seen to be desirable.

What we need an exit deal to address

What we need a trade deal to address

Medicines and medical devices



Arrangements to keep using products already on the market

A system of approval which keeps, as much as possible, the ability for the NHS to draw on European supplies and innovation, and for British companies to get products approved in the UK for the European market

Regulation of science, staff and health care



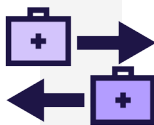
Provisions so that ongoing cross-border trials and data use are not disrupted

Rights to secure the place of the more than 155,000 EU staff working in health and social care

Agreements that data and experiments will still be able to cross borders with as little extra paperwork as possible

Any freedoms the UK medical and science communities might want to diverge from EU regulation on science and working hours

Customs and trade

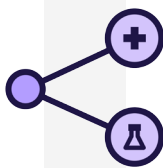


Stability and time to prepare, so that legal vacuums do not cause difficulty importing vital supplies

Customs systems which minimise disruption and delays, especially for time-sensitive materials for treatment

As few barriers to trade in supplies as possible, so that prices are not pushed up for financially vulnerable hospitals and social care companies

Health programmes and agencies



Continue or replace initiatives to fund health care innovations and studies in Northern Ireland

Ways to work with key European health programmes even if we cannot be members

Continued access as an associate to the EU's flagship science funding programmes

Reciprocal and cross-border health care



Security for British pensioners receiving health care abroad under EU programmes, to eliminate any chance that they are forced to return

An Irish border which patients can cross quickly for vital treatment in either direction

If possible, ensuring that future generations of travellers and retirees can also benefit from having care costs covered when they go between the EU and the UK

Overview

Seven months after the triggering of Article 50 began the UK's departure from the EU, negotiations on our future relationship with the Union are yet to begin in earnest. Public debate is focusing on the idea of a transition period; on the terms of our exit deal with the European Union, particularly citizens' rights under that deal; and on the size of the exit bill the UK will have to pay.

But it is the ongoing trading and co-operation agreements we end up with – or the lack of them – that will shape the framework in which many parts of Britain's economy and society function for decades. Even as the epitome of a domestic, national institution, this includes the UK's National Health Services. Health and health care are strongly entwined with EU law and policies.

This briefing looks at five key areas where agreements governing our future with the European Union will shape health and social care. These are the approval of medicines and devices; the regulation of science and health care; the general trading arrangements; our participation in EU health and science programmes; and reciprocal health care programmes. The exit deal will also have important implications for many of these – and the lack of one would effectively rule out moving talks on to a future relationship.

If handled badly, developments in each of these areas could seriously undermine the ability of health and social care in the UK, and in some cases in the EU as well, to keep delivering the best care to patients. The best outcomes can only be secured if we build the infrastructure for continued co-operation into the future. It must be a priority to avoid even a partial deal where our exit is secured but no framework exists for future trade and participation in EU programmes. Red lines should not be held sacrosanct at the expense of workable options for a legal framework. There are also some opportunities, which an appreciation for the overall risks of the situation we face should not blind us to. The NHS is held in unparalleled esteem by the British public, and it should use that to project a clear voice in making the case for what it needs.¹

Leaving the EU adds to the pressure facing NHS leaders across the UK, in a period of serious difficulties across staffing, finance and reform. A recent paper in *The Lancet*, looking across every way in which health and social care will be changed by Brexit, concluded that any deal will pose “substantial threats”²

But this is all the more reason to engage in the historic decisions that will start being taken in a few months' time. The NHS and its patients will be living with the agreement we reach, or our failure to reach it, for decades. We have a duty on their behalf to make the best of it.

The approval of medicines and devices

What we need

Almost all the products and services that are part of health care are influenced by the EU's single market and its legal order in one way or another – from the contracts that hospitals work under, to the gloves worn by surgeons. All will be influenced by the UK's departure. But the impact will be most pronounced where it touches on the availability of the products which are designed specifically to treat patients: medicines and medical devices.

The guiding principle for British and European negotiators should be what is good for patients, in the UK and across the EU. That means providing them with access to effective new and existing medicines and devices as soon as possible, at as low a price as possible. There is also a substantial benefit to the NHS of a thriving British pharmaceutical and medical devices sector, which helps create an environment in which staff can engage with cutting-edge technology. As an economic sector, it has also been estimated that the life sciences contribute £8.6 billion to the public funds which pay for the health service.³

The current system of a single market across the EU and the slightly wider European Economic Area (EEA) has met these goals, albeit not always perfectly. With the UK Government's commitment to leaving the single market and the jurisdiction of the European Court of Justice which oversees it, there is a need to look at how some of its benefits can be retained or replaced.

Finding a system that works for medicines

Medicines regulation in the EU currently involves several different procedures, all co-ordinated by the European Medicines Agency (EMA). Under the ‘centralised procedure’ used for new and cutting-edge drugs in vital areas of medicine, the EMA makes an assessment for the European Commission which formally approves medicines across the EU.⁴ This delivers financial savings by avoiding duplication of work, and makes the UK a priority for the introduction of the latest drugs as part of one of the world’s largest markets. This system does not cover assessments of how well drugs work and whether they should be funded by health systems like the NHS – this power has always stayed with member states.

The most ambitious option suggested for the period after we leave the EU is that we would retain a single process which would now cross two legal jurisdictions, British and European.⁵ Under this approach, the suggestion appears to be that pharmaceutical companies could approach either the British regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA), or the European regulatory system with a new product. The regulator would then carry out an assessment resulting in a recommendation made to both the European Commission and the British Government.

There would be an agreement that both decision-making bodies would tend to abide by the recommendations of either regulatory system. Decisions of the MHRA would be open to judicial review before UK courts, but would remain outside the jurisdiction of the European Court of Justice, even though the Commission taking decisions based on its evidence would be within its jurisdiction.

This would retain some of the practical form of the current processes. Much of the work that shapes the EMA’s recommendation is contracted out to the regulators of individual member states – in many cases (around a third) the MHRA.^{6,7} More informally, between the EMA and member state regulators, and among member state regulators, there is a high level of reliance on assessment reports originally carried out elsewhere.^{8,9} From that basis, the mutual trust and respect which would be needed to make such a system work have already largely been established.

The model is in effect a clever workaround for the UK’s refusal to be subject to the European Court of Justice. It would retain effective British membership

of the European medicines market, and benefit both European and British taxpayers or companies by averting the need for expensive duplication of work. However, it would risk creating more legal uncertainty compared with the current system. It might be difficult to negotiate with the EU, which is resistant to giving Britain special treatment, and it rests on a particular legal and political settlement, as discussed below.

A more feasible option short of this might be for the British regulator to stand alone, but to keep co-operating in other ways. For example, it could generally accept EMA judgements on new products, even without an agreement that the EMA would do the same. This would mean the UK got access to new medicines at the same time as the large, attractive EEA market.

Alternatively, the UK could use judgements from a range of international regulators – not just the EMA, but the US Food and Drug Administration (FDA) as well. The current system already involves procedures for accelerated mutual recognition of medicines approved nationally by other European member states.¹⁰ Some other countries, including Singapore, accelerate the recognition of medicines already approved by other developed countries.¹¹ This would leave the door open in future for the UK to co-operate with other countries outside the big US and EEA markets, like Australia and Japan, to create a new regulatory bloc big enough to be attractive in its own right. However, this would take time and is inherently uncertain: the short-term cost in delays might still be present.

If we were happy to rely heavily on work done by the EMA or the FDA, there is the scope for significant savings at least compared with a fully domestic model. However, if the UK did make heavy use of assessments elsewhere, this system may be likely to damage our pharmaceutical industry, incentivising investment and work to locate within the European (or US) market where the real decision would be taken.

If, on the other hand, we aimed to retain the ability to make decisive assessments domestically, it would give the UK the choice of developing a truly different regulatory system for drugs which currently have to go through the EMA's centralised procedure – prioritising speed over safety to a greater degree, or vice versa. We could also look at including the assessment of whether a drug worked well and should be funded by the NHS within the approval process, which might be an appealing proposition for makers of

new drugs. But a separate system would also mean some element of delay in British access to drugs; the European system losing British expertise; and the need for Britain to invest more in its own regulatory system – imposing a burden on taxpayers and companies on both sides of the Channel.

If enough progress has been made on the terms of departure, negotiations on the UK's permanent relationship could begin at the end of this year. Pharmaceutical companies, NHS leaders and their representatives should think now about where on this spectrum they want future regulation to fall, and present a coherent vision to the Government and the European Commission. The Brexit Health Alliance and the Association of the British Pharmaceutical Industry will be important forums for this.

Assuming the UK is no longer subject to the basic principles of the single market following Brexit, there is also a risk that the NHS would lose the ability to buy cheaper medicines from the EU. This so-called 'parallel trade' involves suppliers to the NHS buying identical medicines in other countries where they are sold at a cheaper price than in the UK – passing on some savings to the health service.

The end of this practice would be highly undesirable for the NHS and the taxpayers who fund it. Estimates for the benefit of the current system to the NHS vary wildly, but estimates of at least £100 million a year seem credible and the figure may be higher.^{12,13} However, within a context of continued close regulatory co-operation, it could be addressed by British legislation specifically preventing pharmaceutical companies from exercising intellectual property rights to limit imports from the European Union.¹⁴ This is something that could be encompassed in the Trade Bill, which the Government has said will go through parliamentary scrutiny.¹⁵

Finding a system that works for medical devices

Within the European Union, medical devices from surgeons' lancets to pacemakers are regulated, like many other products, through the CE marking scheme which certifies compliance with relevant EU law. Private and public bodies in member states, including several within the UK, are deemed 'notified bodies' with the right to grant this mark of approval.

Many medical devices must be imported from the European Union – a prominent recent example of something available nowhere else is the

ROSA brain surgery robot, made in France.^{16,17} As with medicines, there is sometimes a valuable option for NHS suppliers to buy from other European countries at below the UK price.¹⁸ As a minimum, the UK should continue to permit the sale of all products with a CE marking, to avoid forcing companies to have to go through a different regulation process which could take time and might put them off. This would likely remain the case by default under the Withdrawal Bill,¹⁹ so long as ministers do not change the relevant ‘retained EU law’, and in itself would not require an agreement with the EU.

However, as in medicines, the medical technology companies that work with the NHS and employ 94,000 people in the UK²⁰ would also face an incentive to leave the UK unless there is also some scope for UK bodies to clear products to be exported across the EU.

Leaving the EU means that the UK will no longer be able to shape the directives that set the standards: we will be rule-takers, not rule-makers. But there are precedents for us to apply these rules from outside the EU, and indeed, at some cost, we could also diverge and run our own system in parallel. For example, the UK could negotiate, as Australia²¹ has done, for its standards bodies to have the right to sign off medical devices as complying with EU rules, as well as having its own set of rules domestically. The British Standards Institute favours this approach, although they note that it would create pressure to stay close to the EU standards over which Britain would have far less influence.^{22,23,24}

Stumbling blocks

Any of these approaches for medicines or devices would need some kind of mechanism for resolving disputes. The UK has repeatedly ruled out remaining subject to the EU’s Court of Justice, which currently ultimately performs this function. There are problems for medicines and devices regulation under a number of the alternative options which could be considered.

The World Trade Organization has a semi-judicial system where states are the only parties who can bring cases. But this would risk shutting out small businesses – dominant especially in medical devices²⁵ – who will find it difficult to persuade governments to take up their cases.²⁶ Australia’s mutual recognition agreement is simply overseen by a committee,²⁷ but this might not work so well for the vastly greater volume of trade which takes place

between the UK and the EU. The Institute for Government believes that the EU will firmly resist a deal based on oversight by committees. A system like this already exists for relations between the EU and Switzerland: the EU is widely thought to be very unhappy with it, and it might be even less suited for the larger British economy which might be expected to generate more issues.²⁸ The investor-state dispute settlement provisions included in the Canada-EU trade deal are only designed to settle disputes between foreign investors and governments, not the range of actors who would need to be able to bring cases to facilitate anything like the dual jurisdiction approach for medicines described above.

One option is the model used by Norway, Iceland and Liechtenstein – members of the EEA, which makes them members of the single market, but not the EU. These countries have a special court called the EFTA Court, which resolves legal disputes under single market rules arising within their borders. For issues which arise in the EU itself, their companies and people can go to the European Court of Justice. Either bringing the UK within the jurisdiction of the EFTA Court or duplicating something similar would give the UK a workable option which would mean no European Court of Justice jurisdiction within its borders. It is for a scenario similar to this that the dual jurisdiction approach for medicines appears to be suitable.

Another alternative, suggested by the Institute for Government, would be a new model of arbitration, requiring no permanent judges but with a special authority to which individuals and businesses could appeal. It is not clear, though, whether the EU would accept this – and certainly, for them to do so it would still need to refer to the European Court of Justice.²⁹

Either the EFTA Court or this new model would mean that the ultimate source of appeal or referral for medicines and devices decisions made by the EU Commission would remain the European Court of Justice.^{30,31} But the other options suggested would give businesses and individuals little scope to appeal at all. From the perspective of patients, the NHS and the pharmaceutical industry these are the most promising options.

A second potential stumbling block is the resistance of EU negotiators to any element of ‘cherry-picking’, or ‘sector-by-sector participation in the single market’.³² The UK has little choice but to recognise this red line, but European Commission negotiators should equally recognise that this principle does not

rule out close co-operation, and that an over-zealous interpretation would bring costs to European companies, patients and taxpayers.

Finally, leaving without a trade deal in place would obviously rule out every dimension of co-operation discussed above. British and European taxpayers and companies would need to pay for duplicate regulation in medicines. Even if the UK unilaterally adopted regulatory alignment, British firms would not be able to get clearance from UK bodies to sell devices into Europe, even though they would still have to accept European standards to do so. Patients would face slower access to life-saving products, and the UK would become a less attractive place for medicines and devices manufacturers. Trade on World Trade Organization terms provides limited access to dispute resolution, especially for the small businesses that play an important role in the British health care devices industry. The NHS would bear any costs of difficulties in allowing the parallel trade in cheaper medicines and devices certified elsewhere in the EU. This damage would occur even under the less extreme variant of a 'no deal' Brexit, where we do have an exit deal but no future links beyond this.³³

Regulation of life sciences and health care

Many aspects of how science and health care are carried out are also shaped by EU institutions and law. Brexit opens up the possibility of moving away from these – but often at the cost of losing some of the benefits of alignment.

Procurement and competition

The laws intended to create fair competition between British firms, and British suppliers to the public sector – including the marketised English NHS – are on the British statute books. But they are backstopped by EU law, and hopes have been voiced by NHS England Chief Executive Simon Stevens,³⁴ among others, that we will have much more latitude to change them after Brexit.

Competition law aims to prevent companies from abusing a dominant market position – stopping them from becoming monopolies or fixing prices. It is mainly felt in the health service where NHS trusts attempt to merge. The UK system is directly codified in the Competition Act 1998 and Enterprise Act 2002. But it is underpinned by the principle of competition in the common market written into EU treaties all the way back to the 1957 Treaty of Rome.³⁵

Procurement law requires public sector bodies to advertise major contracts openly to any interested firm, and to give all firms willing to provide a service an equal competitive chance of winning it. For the NHS, this is applied via the Public Contracts Regulations 2015 and regulations under the Health and Social Care Act which enshrine the EU's 2014 Procurement Directive.³⁶ It is mainly felt in the English NHS where commissioners are required to advertise each contract to provide care and to let providers compete for them on a level playing field – in some cases, when they may feel they would prefer a more stable or co-operative arrangement.

Will we really have more room for manoeuvre after Brexit?

For procurement law, it may not be so simple. Future trade deals with the EU, and with other countries as pledged by the Government,³⁷ are likely to tie Britain's hands. To see why, we can look at the trade deals often discussed as models for our post-Brexit relationships with the EU. The Prime Minister has implied that the UK will seek a trade deal with Europe closer than the Comprehensive Economic and Trade Agreement (CETA) deal with Canada, but with more sovereignty retained compared with the EU's relationship with EEA countries like Norway.³⁸

EEA countries are subject to the Procurement Directive: if the UK followed this model, there would be no change whatsoever. At the other end of the spectrum, the EU's trade deal with Canada contains extensive provisions on procurement. It would appear to forbid any treatment of domestic suppliers differently to international ones, and mandates transparency and fairness in elements of the process.³⁹ As long as NHS commissioners purchasing clinical services are considered to be within the scope of such an agreement and carrying out procurement, a future UK-EU deal on this model would appear to prevent them from favouring, for example, NHS trusts or GPs.

It is not clear whether NHS commissioners are covered by CETA: the EU's accession documents specifically cover some English NHS bodies, but they are bodies which no longer actually exist.^{40,41} Other EU countries have negotiated CETA exemptions for aspects of their national health systems.

However, in future trade agreements with the EU itself, with countries with which the UK already has a trade agreement through the EU, and with other

countries, the important point is that any attempt to exempt the NHS internal market would appear as a significant step towards protectionism.

Limiting opportunities for firms to get NHS business may meet with opposition from the EU, which has consistently sought to open procurement in its trade deals.⁴² In deals with other countries it would be a tough task for British negotiators to reconcile this with the stated policy of the trade white paper. This not only positions the UK as a 'global champion for free trade', but specifically and repeatedly emphasises that the UK will 'push for' other countries to liberalise procurement.⁴³ In short, Brexit may simply mean replacing the backstops of single-market law with new ones.

If NHS leaders want to end the rule of procurement law in the English NHS, a simpler and more reliable approach which would work regardless of trading arrangements is already available. This would be to simply stop treating NHS provision agreements as commercial contracts between commercial bodies. This is the situation, broadly, in Scotland and Wales, reflecting the fact that EU procurement law already contains exemptions for 'non-economic' services which are not 'carried out in return for payment'.^{44,45}

The King's Fund believes that this would require re-establishing the Secretary of State's control over all NHS trusts and establishing that health service contracts were not subject to commercial law.⁴⁶ This might sit uneasily alongside the English NHS's current dependency on private contracts for almost a tenth of its capacity,⁴⁷ but the Scottish NHS does still manage to pay for private care without having a general internal market. It could be seen as undermining the ideal of the independence of foundation trusts – but in practice this has already been substantially undermined.

It may be more possible to exempt the NHS from competition law under future trade deals. CETA, for instance, delegates some responsibility for setting the coverage of its competition section to the EU and Canada's domestic systems, with specific provision for exclusions.⁴⁸

However, an important question is how necessary this is. Enforcement under the current system has recently seen several trust mergers permitted by the UK regulator on the grounds that even though they may reduce competition, the impact of this would be outweighed by the benefits to patients.⁴⁹ Even

more clearly than under procurement law, bringing all NHS trusts back into direct government control and ensuring that they were no longer treated like competing entities would remove them from the scope of the current system.⁵⁰

In short, if the NHS in England believes that it has a problem with procurement and competition law, Brexit may not be either necessary or sufficient for change.

The regulation of workers

For regulations which apply to staff and working practices, the UK may have room for manoeuvre after Brexit. Unlike procurement law, specific provisions on labour market regulation are not typically part of international trade deals. EU member states and institutions do have concerns about facilitating a ‘race to the bottom’ where the UK starts slashing regulation to undercut the rest of the continent.⁵¹ As such, they may well seek guarantees that we maintain certain standards, but there should be some room for negotiation on what and where these lie. Switzerland, which is almost a full participant in the single market, has not had to sign up to many aspects of labour market regulation.⁵²

Perhaps most significant for the NHS is the Working Time Directive, introduced by the EU in 1993 and successively implemented in the health service over the next two decades. This limits the time staff can work to 48 hours each week. As interpreted by the Court of Justice in key cases in 2000 and 2003, this includes time spent on call: while individuals can opt out, this cannot be done collectively.⁵³

This restriction had a profound impact on junior doctors, outlawing the long on-call hours previously relied on to combine learning and patient care, and creating tension as to how much time could be spent on training.⁵⁴ One effect was an increased adoption of shifts, rather than on-call work. Another, according to surveys, was simply a majority of trainees feeling pressured to report their hours falsely. Because the 2003 case means doctors must take compensatory rest immediately, emergency work can mean commitments from both junior and senior doctors have to be cancelled the next day. Submitting evidence to a 2014 review, many medical Royal Colleges concluded that the impact had been negative.⁵⁵

As we leave the EU, the Directive will pass into British law under the Withdrawal Bill. But there will then be latitude to adapt it by simply changing the law – or perhaps even by a wide use of the statutory instrument powers the bill gives ministers.⁵⁶

This will throw down the gauntlet to the NHS to think about how the Directive could be adapted or replaced as it applies to health care. There is a widespread recognition that a simple return to the old system is not feasible or desirable: extremely long hours had their own obvious disadvantages for staff and patients. Training and practice have adapted significantly. Several key provisions of the Directive have been incorporated into the latest round of the junior doctor contract. This creates another level at which changes would be necessary, and reflects the extent to which long hours have become less acceptable to professionals.⁵⁷ One option would be to loosen the rules for particular groups or specialties, enabling some classes of doctor to go back to an on-call model.⁵⁸ But there would be a need for realism about whether this would worsen the serious recruitment difficulties that exist within some specialties.

Leaving the EU may also create an opportunity for the UK to introduce new standards for professionals who come here to work from elsewhere in Europe. The current system means automatically having to recognise EU nursing and medical qualifications, applying tests only for language skills. The General Medical Council and Nursing and Midwifery Council believe it could be reformed for the better, allowing them to impose tests on the clinical competence and training of EU staff.⁵⁹

While it makes sense to test staff for the roles they will be carrying out within the NHS, this needs to be weighed against the risk of worsening a very serious staff shortage which is already likely to be intensified by Brexit. The recent imposition of a higher standard of language test on EU staff, for example, appears to be linked to the precipitous fall in migrant nurses from the EU. Monthly data suggests a drop of as much as 96 per cent – a far greater fall than the Brexit referendum appears to have caused for EU migrants generally.^{60,61} With the NHS facing a chronic shortage of tens of thousands of nurses, leading to concerns about safety,⁶² further restrictions would have to be very carefully applied.

People from the EEA who already work in the NHS, meanwhile, currently benefit from the security of being legally allowed to reside in Britain under the fundamental EU treaty principle of free movement of labour.⁶³ There are 60,000 EEA migrants working in the English NHS alone,⁶⁴ and they are disproportionately qualified doctors and nurses – thousands more work in the Scottish and Welsh health services.^{65,66} The same applies in social care, which many NHS patients and other British citizens rely on every day, where the number of European workers in England alone is 95,000 and growing fast.⁶⁷

It will be the immigration system the UK chooses for itself after Brexit that will determine whether we can keep drawing on staff from Europe. But for workers already here, the British Government has emphasised that their future rights depend directly on the exit deal.⁶⁸ While reducing future migration of nurses would in itself be a problem for the NHS, a mass exodus of staff already here in response to an uncertain legal future would be disastrous.

The impact could be especially pronounced in certain areas: in London, for example, one social care worker in eight comes from the EEA.⁶⁹ There are signs of progress in negotiations agreeing the rights of citizens,⁷⁰ but all this depends on finding workable legal options and on reaching an exit deal overall.

Regulations for the life sciences

EU law has long governed many crucial aspects of life sciences research – the field which creates cutting-edge knowledge and products to support NHS clinicians and British patients. Two regulations in particular currently moving towards implementation will become major pillars of the governance of medical research in the UK: the General Data Protection Regulation 2016 and the Clinical Trials Regulation 2014.

Scientific bodies have warned that health projects including those working on genomic medicine rest on the ability to share data across borders.⁷¹ But leaving the single market threatens the smooth flow of data in that there could be a requirement for checks on whether protections are in place in every instance in which information goes from the EU to the UK. This would be largely addressed if the UK's data protections were deemed as 'adequate', a formal classification by the European Commission when it considers other countries' commitments 'essentially equivalent' to EU regulation. Since, under the EU Withdrawal Bill, British legislation on the day of exit will be identical to

European legislation, this should be possible to obtain provided that the UK does not change it under the EU (Withdrawal) Bill powers or by subsequent legislation. However, the Commission and the Court of Justice would have the right to withdraw or amend this status at any point,⁷² making any deviation or failure to mirror changes to European law potentially costly.

The Clinical Trials Regulation introduces a single application system with one database, harmonising trial regulation across the EU. Based on their submissions to the parliamentary science committee, UK universities broadly favour remaining compliant with it so that clinical trials can run smoothly across Europe.^{73,74} This is particularly relevant for rare diseases, where there may not be enough patients in any one country to properly test a treatment.

There would be at least potential benefits for British life sciences and medicine in a settlement which allowed some deviation from EU regulations and directives. University College London has suggested that the UK should look for a settlement in which it starts in alignment, but can then move away to take up a global leadership role.^{75,76} The history of European Union science regulation is a chequered one: the Wellcome Trust describes an ‘inherent lack of dynamism’ and poor transparency. A particular complaint is the 2001 Clinical Trials Directive, widely seen as having driven medical research away from Europe due to excess bureaucracy – a situation being partially addressed by the new regulation, but only after 15 years.⁷⁷

However, there is a need for honest thought about whether the possible benefit of divergence is worth the definite burden of multiple regulatory systems on researchers and companies. And if the direction of divergence is towards a less cautious and conservative approach, the potential detriments of this for patients and people taking part in clinical trials also need to be considered. Others have argued that the EU’s system is already too weak in protecting people against the significant powers of, for instance, the global pharmaceutical industry.⁷⁸

As with every area of regulation, a sensible settlement depends crucially on a working legal system for enforcement. The EU will understandably resist a settlement where the UK initially benefits fully from alignment, but can then diverge from EU regulation where it likes. A set of impartial checks and balances which addresses their concerns about competitive deregulation would help smooth a deal. That is likely to require a court, or a new mechanism which refers to the European Court of Justice where matters of EU law are concerned.

A scenario where the UK leaves without a deal would be the worst outcome for clinical research. In addition to the long-term damage, there would be the immediate possibility of important cross-border trials and research no longer being approvable under EU law and being cancelled. It is not an exaggeration to worry that the life sciences industry that the NHS works with in Britain would risk going from being a world beater to facing relegation.

Customs and trade

Beyond the approval of medicines and devices and the regulation of health services, the NHS will also be affected by the wider trading relationship the UK has with the European Union in future. Medicines, devices and other products used by the health service often rely on supply chains which stretch across the EU. For example, the Brexit Health Alliance notes that “the largest supplier of needles and tubes for blood collection in the NHS manufactures its products in Plymouth. They are then taken by road to Belgium and distributed back to the UK from there.” Even products made within the UK may rely on components which themselves have to cross multiple EU borders.⁷⁹

The Government’s commitment to leaving the single market and customs union will mean a dramatic change. Where they now flow freely, goods will in future need to be formally declared at the border, and a proportion will need to be checked for security and – critically – regulatory compliance. The UK Government intends to mitigate this by ensuring the customs system is as streamlined as possible, minimising paperwork and the proportion of goods which are checked.⁸⁰ However, this is reliant on an IT system whose “successful delivery is in doubt”, according to the Institute for Government.⁸¹

The closer the future trade deal, the less the need for checks and the lower the chances of tariffs being applied. Disruption would be most severe if the UK leaves without a deal. Under this scenario, World Trade Organization rules would compel the EU to levy tariffs on many types of goods crossing the border, and the levels of checks required would rise to the much higher level currently applied to goods from outside the single market.⁸² A transition period would give suppliers and ports more time to prepare, but the ultimate considerations would remain the same.

For products subject to tariffs or cross-border supply chains, including vehicles, food and chemicals, delays or new costs at the border would be likely to increase costs to suppliers and ports,⁸³ and therefore likely to significantly increase prices. This would risk again leaving the NHS facing higher cost increases than anticipated, as happened with the devaluation of the pound following Brexit – resulting in higher deficits without additional funding.⁸⁴

Medical radioisotopes

A particular impact may be on those products with a limited lifespan, which will actually degrade if delayed at a border. For the NHS, this includes radioisotopes used for bone scans and to treat cancer.

While it is untrue that the UK's exit from Euratom will mean export of these products from the EU will necessarily be restricted, there will be a need to find and enforce a new regulatory system for cross-border trade. This will need to be ready to function smoothly at the point of entry to the UK for the many medical radioisotopes which decay rapidly into unusable or unstable substances in a matter of hours or days. Molybdenum-99 is the most important of these: it is used to produce material for the vast majority of the 415,000 nuclear imaging procedures in the English NHS each year.⁸⁵ Only particular reactors can generate it – none in the UK and with the closest in the Netherlands. Its half-life is just 66 hours.⁸⁶

Similar concerns apply to some biological therapies with short shelf lives, such as Holoclar, a stem cell therapy for treating eye burns (from fire or substances such as acid), which has to be imported from the EU and has a shelf life of 36 hours.^{87,88}

As well as lifespan, the managing of trade to alleviate shortages is another field where Brexit may bring new difficulties. Global shortages of molybdenum-99 are a periodical concern because it is only made in a few ageing reactors, which sometimes have to go offline. In the past, the Department of Health has worked with the European Commission on 'collective European solutions' to ensure that the UK and other European member states can cover vital needs. After Brexit, we will not be able to participate on the same basis.⁸⁹

Blood, organs and other human tissues

Also affected will be cross-border movements of blood, organs and other human tissues used for the NHS. Standards for these are currently set across the EU by particular directives. This means that import and export of these substances between the UK and other EU countries do not need a special licence,⁹⁰ and appears to support relatively close relationships between health care systems using and supplying them.

The European Commission has made efforts for some time to encourage the exchange of human organs across borders, largely through instituting reliable common standards and warning mechanisms. Perhaps reflecting a measure of success in building willingness to exchange these sensitive products, data on the 74 cases where British patients received organs for transplant from other countries in the last three years shows every single one has come from within the European Union.⁹¹ The Royal College of Surgeons has warned that Brexit may end the UK's participation in building systems for exchanging organs more extensively. For example, the European Commission has been looking into a shared form to facilitate rapid transfer of organs.^{92,93} A Brexit without a deal could lead to delays and disruption, which would make even the existing low level of imports more difficult.

Another concern is blood plasma, a component of blood which is used, for example, to treat people suffering uncontrolled bleeding. The UK cannot use domestic blood plasma in many cases because of the potential presence of Creutzfeldt-Jakob disease. Although some is brought from the US by a private firm, the NHS Blood and Transplant Authority relies on special arrangements with Austria for its supplies.⁹⁴ A 'no deal' Brexit would disrupt the legal basis for this, with imports from the EU to the UK suddenly requiring new paperwork and proof that our authorities met certain standards.

Health programmes and agencies

The EU organises several programmes and agencies which fund and co-ordinate medical research, and respond to rare and dangerous diseases. It is strongly in the interests of both British and European researchers and patients to maintain as much co-operation with these as possible.

This section looks at a selection of these. Apart from their individual advantages, there is an important collective benefit of these programmes: the collaboration of researchers and institutions across the UK and the rest of the EU which they encourage. This ties many NHS trusts, doctors and scientists into a wider web of expertise and learning. A report funded by British research bodies also makes the case that it is a major contributor to Europe's status as a scientific centre, and enables a broader pool of expertise to inform services and public policy.⁹⁵

Horizon 2020

EU funding programmes have been a major source of funding for British science. Attempts to break down how much the UK contributes suggest it gets out significantly more than it puts in.⁹⁶ Since 2014 the latest incarnation, called Horizon 2020, has funnelled €420 million into British health research.⁹⁷

Non-members of the EU are not eligible to be full members of Horizon 2020, or its successors. While the UK Government has said it will guarantee money won under Horizon 2020, this does not secure the biggest prizes of membership: eligibility for future funding rounds and the opportunity for UK scientists and institutions to join bids which will be at the forefront of global science. Already, Professor David Lomas of the Association of UK University Hospitals has reported people being “bumped off grant applications to the EU” as uncertainty looms.⁹⁸

However, a model of associate membership to Horizon 2020 for non-EU members does exist. Outside the EU, the UK will have no voting rights, although there may be scope for some influence through committees. Many associate members have access to funding in return for a contribution, and indeed some get out more than they put in⁹⁹ – although political realities may mean this could not be the case for the UK to the present extent. A special agreement must be reached for this to be possible.

There is no clear precedent for association to Horizon 2020 to be tied to membership of the single market. The EU's red line against cherry-picking participation should not rule out agreed co-operation in the interests of European science.

However, the European Union denied Switzerland access for some time to parts of Horizon 2020 in protest at a referendum which went against

Switzerland's agreement to honour freedom of movement.¹⁰⁰ This is not because there is a general link between the free movement of people and this specific programme: many Balkan and Middle Eastern countries, such as Israel and Turkey, have associate status in Horizon 2020 without freedom of movement.¹⁰¹ But it is a lesson that access to these programmes will be determined in the round, and the UK may need to concede in other areas if it wants to prioritise science.

More specifically, Switzerland's exclusion is an example of what can happen if there is no coherent dispute resolution system. Even if the EU were willing to accept a Brexit deal overseen by something short of a formal court, which seems far from certain,¹⁰² the risk would be that this sort of tit-for-tat retaliation could be seen as the only option to enforce compliance – leaving long-term status in all these programmes under a permanent shadow of doubt.

Other programmes

European Reference Networks are organisations which share knowledge and practices in caring for people with rare diseases, giving clinicians who may be among a handful of people working on a particular illness in their country access to colleagues and the highest available standards. The UK is a major player, leading a quarter of the networks. As the Government notes,¹⁰³ participation is limited to EU and EEA countries. Losing access again appears to be part of the unavoidable cost of leaving the single market, potentially with real costs for patients who could benefit from care elsewhere in Europe.

The European Centre for Disease Prevention and Control (ECDC) in Stockholm co-ordinates and supports EU countries in responding to infectious diseases. It monitors outbreaks of dangerous illnesses like Legionnaire's disease and tuberculosis, and provides guidance on how to treat them. Only EU members and the EEA states are members: there does not appear to be a way for the UK to remain. ECDC works with the World Health Organization's Europe branch, of which the UK is and will remain a member, but only with regards to certain diseases.¹⁰⁴

The British Government and the European institutions should examine ways in which the NHS and British scientists could continue to work with these initiatives. Given their nature, this is clearly likely to be in the interests of patients on both sides. For the ECDC, there is the precedent of memoranda

of understanding signed with US and Chinese disease control centres, as well as with the World Health Organization, which make arrangements for sharing intelligence and providing technical support where countries suffer outbreaks.¹⁰⁵

Northern Ireland is home to a specific EU initiative called the Special EU Programmes Body (SEUPB), which aims to support the peace process and improve cross-border co-operation. Several of the initiatives it funds have supported innovation in the Northern Irish NHS, including programmes to co-ordinate community and voluntary health care and to support children with mental health needs.¹⁰⁶ In the context of high-profile concern about funding and commitment for change in the Northern Irish NHS¹⁰⁷ it would be in the interests of patients, and in line with the commitment of both sides to supporting peace, to find a way to continue or replace SEUPB.

Reciprocal and cross-border health care

British citizens in general, and the NHS in particular, benefit considerably from the reciprocal health care arrangements the UK accesses as members of the European Union. The European Health Insurance Card (EHIC) scheme provides access to travellers moving between the UK and the rest of the EU, while the S1 scheme is predominantly used for pensioners to retire to other countries and access their health services on the same basis as a local.

It is difficult to quantify the effect of these schemes on easing travel and tourism across the UK – bearing in mind that most tourists to Britain come from other EU member states.¹⁰⁸ We can estimate the financial benefit that the UK derives from its citizens retiring to other EU countries where their health care is charged to the British Government at an apparently significantly lower rate than we would expect it to cost within the NHS. Our earlier work has suggested that if all British pensioners receiving health care under S1 had to access care in Britain, the additional resources required could be as great as 1,000 extra hospital beds and almost £500 million in additional funding – a daunting prospect for an intensely pressurised health service.¹⁰⁹

There is a clear national interest in retaining these programmes. A joint EU-UK document on the exit negotiations so far indicates that agreement has been reached on retaining S1 coverage for people already in other countries on the day of exit.¹¹⁰ This would avert the scenario of pensioners being forced back into reliance on the NHS at higher cost and against their will. But it is important to remember that even if negotiators are in full agreement about keeping S1, it can only happen if a wider deal is reached. This means at least an exit deal, but quite likely also agreement to some extent on a future relationship: it is worth recalling the EU's principle that "nothing is agreed until everything is agreed".¹¹¹

In both cases, this will depend on finding an agreed legal mechanism for the deal to be enforced. The EU has already set its mandate for the withdrawal agreement – as distinct from any trade agreement – and it involves the continued jurisdiction of the Court of Justice, or an alternative with 'equivalent guarantees of independence and impartiality'.¹¹² Making this compatible with the British position will not be easy.¹¹³

Even with success in securing S1 for those already using it, it would require specific provisions in a future relationship agreement with the EU to make it and EHIC available to future generations. While it may be in the interest of both sides to keep similar arrangements, the obstacles are formidable given the UK's intention to leave the single market. These schemes are directly underpinned by EU regulations: no country outside the single market has access to them. It would probably be necessary to wholly redesign a replacement scheme. As a result, even if a withdrawal agreement is reached that preserves the rights of pensioners already abroad, increased capacity in the UK health and social care system will likely be necessary to compensate for the fact that future generations of pensioners cannot be cared for in countries such as Spain.

Cross-border health care

Leaving the European Union will also have implications for the ability of patients to cross borders for the specific purpose of receiving health care.

Two routes under EU law allow British patients to have treatment in other European countries paid for by the NHS. The 2011 Cross Border Healthcare Directive allows people to go and receive treatment in another European

country, and then claim back the costs from the NHS. The NHS will only pay for procedures it carries out, at the rates it uses.¹¹⁴ The S2 scheme allows the NHS to directly pay a foreign provider to provide care that a British patient should receive but cannot.

While relatively little used, these schemes provide valuable options for patients. Again, as with S1 and EHIC, while it would be worth trying to maintain these arrangements, because these are rights under EU law there will be great difficulty in doing so from outside the single market.

Aside from these schemes, particular considerations apply to Northern Ireland, where arrangements for treating some rare and serious diseases are designed to work across the entire island of Ireland. The Northern Irish NHS believes its current facilities struggle to provide the range of services to properly care for children born with heart problems, and is already putting into practice plans for them to be sent to Dublin for operations.¹¹⁵ Conversely, people who suffer from heart attacks in the Republic of Ireland county of Donegal are currently taken over the border to be treated in Altnagelvin. They would otherwise have to be taken to Galway, a hundred miles away.¹¹⁶

While these arrangements do not depend on EU membership, a return to a hard border with checks could pose obvious risks. Both sides in negotiations are committed to avoiding the return of such a border,¹¹⁷ but practical issues remain formidable, and a complete ‘no deal’ scenario would be likely to entail exactly this.¹¹⁸

Conclusion

Health and social care are, on paper, among the sectors least influenced by the EU and the single market. As such, there is a risk they will be overlooked by both sides in negotiations. But this would be a serious mistake. Many different parts of EU law and EU institutions play an important role in enabling care to be delivered to the standards we see today. Suddenly ending them with no replacement would do serious damage to an already strained British NHS – and would cause real difficulties in other EU countries as well.

Some of these issues, such as the introduction of a customs border with the EU, cannot be fully resolved through negotiations. But for many, a way

through is possible. The worst will come only if a wrong turning brings us to a 'no deal' scenario: either in whole, if negotiations collapse entirely, or in part if political red lines on either side get in the way of future co-operation.

The national, institutional and political leaders of the NHS and life sciences in Britain, and their European counterparts, need to continue making the case for the impact on patients to be on the table as a factor as negotiations come to the crunch.

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