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Brexit and Health in Northern Ireland

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This briefing paper provides an overview of Brexit and the likely impact that it will have on the health service in Northern Ireland. It also covers other impacted areas within the remit of the Health Committee.

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Summary

While what will happen after 31 December remains largely uncertain at this time, particularly in relation to the implementation of the Ireland/Northern Ireland Protocol, the main areas within health that are likely to be impacted upon by Brexit are as follows:

1. Supply of medicines and medical equipment
2. Impact on staffing
3. Reciprocal and cross-border healthcare
4. Quality of blood, organs, tissue, etc.
5. Social care
6. Food safety and standards
7. Public health
8. Qualification standards
9. Medical research
10. Public procurement

Brexit may present some opportunities for the UK, in particular the opportunity to go further on public health regulation and to remove rules on competition and negotiate new trade deals.

However, it also presents the health and social care sector with a number of significant challenges, including:

- the potential impact on the health and social care workforce that relies considerably on staff who are EU nationals;
- the impact on future trading relationships, which could affect the affordability and supply of drugs and other products;
- a potential weakening of cross-border co-operation on public health and research; and
- a potentially negative impact on the wider economy, which could affect future funding for health and social care.

For NI, the situation is more complicated and the detailed implementation of the Ireland/Northern Ireland Protocol has yet to be agreed. The issue of potential delays, shortages and price rises for food, medicines, medical supplies and other health-related products coming into NI from GB is perhaps of greatest immediate concern.

The potential for future staff shortages, beyond those that already exist, is also a matter of great concern, particularly in the present climate of growing demands on the health and social care services and growing waiting lists for treatment.

1. Introduction

At 11pm on 31 December 2020, the Brexit transition period will end and the UK will leave the European Union (EU) Single Market and Customs Union. New border and customs procedures will then apply, and the signed EU Withdrawal Agreement and a potential free trade agreement (FTA) will govern the UK and EU's relationship. The government has already announced that it will implement new border controls between Great Britain (GB) and the EU in three stages, leading up to full implementation in July 2021. These new border controls do not apply to Northern Ireland, where arrangements are governed by a separate protocol in the Withdrawal Agreement, and the details have yet to be agreed.¹

UK goods entering the EU will face full customs controls, including customs declarations, animal product health paperwork and some border checks. Most of that paperwork will be required whether or not there is a deal. EU goods entering the UK will not face full customs administration until July 2021 under a phased-in approach.²

FTA negotiations have continued during the transition period, but little progress has been made, and the potential for 'no deal' or a 'light deal' is emerging more strongly.

Once the transition period ends on 31 December 2020, powers previously exercised at EU level that intersect with devolved competence will flow directly to the devolved administrations. In some areas, the UK Government and the devolved administrations have agreed that it will be necessary to maintain UK-wide approaches through common frameworks.

2. The Withdrawal Agreement and the Ireland/Northern Ireland Protocol

The Withdrawal Agreement establishes the terms of the United Kingdom's withdrawal from the EU. The Protocol on Ireland/Northern Ireland is part of the agreement and is designed to avoid a hard border on the island of Ireland, and to protect the all-island economy and the Good Friday (Belfast) Agreement, whilst safeguarding the integrity of the Single Market. It will become applicable at the end of the transition period.³

¹ DHSC letter to medicines and medical products suppliers: 3 August 2020 - <https://www.gov.uk/government/publications/letter-to-medicines-and-medical-products-suppliers-3-august-2020/letter-to-medicine-suppliers-3-august-2020>

² 'What happens if there's no Brexit trade deal?' Politico article, 2 October, 2020 - <https://www.politico.eu/article/what-happens-no-brex-it-trade-deal-eu-uk/>

³ European Commission, 24 January 2020, 'Questions and Answers on the United Kingdom's withdrawal from the European Union on 31 January 2020' - https://ec.europa.eu/commission/presscorner/detail/en/QANDA_20_104

The Protocol will align Northern Ireland to EU legislation on goods, sanitary rules for veterinary controls, rules on agricultural production/marketing, VAT and excise in respect of goods, and state aid rules.⁴

The European Union (Withdrawal Agreement) Act 2020 implements the Withdrawal Agreement, as agreed between the United Kingdom and the European Union (EU). It provides for the direct application of the Withdrawal Agreement provisions in domestic law where relevant, whilst also recognising the sovereignty of the Parliament of the United Kingdom. The Act also creates powers to make secondary legislation, where appropriate, to enable the Withdrawal Agreement to be implemented domestically.⁵

The Act also includes provision relating to facilitating access for Northern Ireland goods to the market in GB, as well as further provision to ensure no alteration to the arrangements for North-South co-operation can occur as a result of the Act.

2.1 Customs and regulations

Northern Ireland will remain part of the customs territory of the United Kingdom. It will therefore be able to benefit from future Free Trade Agreements (FTAs) that the United Kingdom may conclude with third countries, provided that this does not prejudice the application of the Protocol. Future UK FTAs may provide that goods produced in Northern Ireland have access to third countries on the exact same conditions as goods produced in other parts of the United Kingdom.

The EU's Customs Code will apply to all goods entering Northern Ireland. This avoids any customs checks and controls on the island of Ireland.

As far as customs duties are concerned, EU customs duties will apply to goods entering Northern Ireland if those goods risk entering the EU's Single Market. This applies to all goods that are not subject to further processing and that meet the criteria that the UK/EU Joint Committee will establish in order to determine the risk of the onward movement of those goods. For goods from third countries not considered to be at risk, the customs duties applicable in Northern Ireland will be the same as in the other parts of the United Kingdom.

The Joint Committee will establish the criteria for the risk assessments by the end of the transition period. The criteria will take into consideration issues such as the final destination of goods, the value, and the risks of smuggling.

The UK may reimburse duties levied according to Union law where the UK duty is lower, subject to EU state aid rules.

⁴ European Commission, 24 January 2020, 'Questions and Answers on the United Kingdom's withdrawal from the European Union on 31 January 2020' - https://ec.europa.eu/commission/presscorner/detail/en/QANDA_20_104

⁵ Explanatory Notes - <https://www.legislation.gov.uk/ukpga/2020/1/section/38/enacted>

All checks will be carried out by UK authorities, with appropriate supervisory and enforcement mechanisms for the EU.

2.2 VAT

The EU's VAT rules for goods will continue to apply in Northern Ireland.

The UK government's Revenue and Customs department (HMRC) will remain responsible for applying VAT legislation, including the collection of VAT, and the setting of VAT rates. The UK will keep revenues accruing from this tax. In addition, VAT exemptions and reduced rates applied in Ireland may also be applied in Northern Ireland.

At the fourth meeting of the Ireland/Northern Ireland Specialised Committee on 5 November, agreement was reached on the process for identifying Northern Ireland traders for VAT purposes and enabling them to reclaim VAT.

The UK plans to set out guidance to businesses on these issues where relevant shortly.⁶

2.3 Consent mechanism

The EU and the UK have agreed a consent mechanism to give the Northern Ireland Assembly a decisive voice on the long-term application of relevant EU law in Northern Ireland.

This consent mechanism concerns the substantive issues of regulatory alignment on goods and customs, the Single Electricity Market, VAT and state aid.

In practice, this means that four years after the end of the transition period, the Assembly can by simple majority give consent to the continued application of relevant EU law, or vote to discontinue its application, in which case the UK would notify the EU and the Protocol would cease to apply two years later.

Every four years thereafter, the Assembly can vote on the continued application of relevant EU law. If, however, a vote of the Assembly gathers cross-community support for the continued application of relevant EU law, the next vote can only take place eight years thereafter.⁷

3. Common Frameworks

In October 2017, the Joint Ministerial Committee (European Negotiations) agreed a set of principles to guide the development of common frameworks to ensure a common approach to

⁶ Northern Ireland Affairs Committee - <https://committees.parliament.uk/committee/120/northern-ireland-affairs-committee/news/120643/pharmaceutical-industry-to-answer-questions-on-postbexit-ni-drug-supply/>

⁷ European Commission, 24 January 2020, 'Questions and Answers on the United Kingdom's withdrawal from the European Union on 31 January 2020' - https://ec.europa.eu/commission/presscorner/detail/en/QANDA_20_104

policy areas that are currently governed by EU law and intersect with areas of devolved competence. The frameworks facilitate a consistency of approach, where administrations have determined that such consistency will be of benefit. They also allow for intra-UK policy divergence so that each administration can make decisions on the appropriate approach for its jurisdiction. The guiding principles for these frameworks have been agreed as follows:⁸

“1) Common frameworks will be established where they are necessary in order to:

- enable the functioning of the UK internal market, while acknowledging policy divergence;*
- ensure compliance with international obligations;*
- ensure the UK can negotiate, enter into and implement new trade agreements and international treaties;*
- enable the management of common resources;*
- administer and provide access to justice in cases with a cross-border element;*
- safeguard the security of the UK.*

2) Common frameworks will respect the devolution settlements and the democratic accountability of the devolved legislatures, and will therefore:

- be based on established conventions and practices, including that the competence of the devolved institutions will not normally be adjusted without their consent;*
- maintain, as a minimum, equivalent flexibility for tailoring policies to the specific needs of each territory, as is afforded by current EU rules;*
- lead to a significant increase in decision-making powers for the devolved administrations.*

3) Common frameworks will ensure recognition of the economic and social linkages between Northern Ireland and Ireland and that Northern Ireland will be the only part of the UK which shares a land frontier with the EU. They will also adhere to the Belfast Agreement.”

Subsequent to its restoration, the Northern Ireland Executive has signed up to the common frameworks programme and its principles.

The latest analysis of policy areas where common frameworks are required was published in September 2020. This sets out policy areas that will involve the implementation of non-legislative mechanisms, and those that are linked to forthcoming legislation. It also identifies

⁸ Common Frameworks Analysis, Cabinet Office, September 2020 -

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/919729/Frameworks-Analysis-2020.pdf

policy areas where the UK Government and devolved administrations will continue to cooperate without the need for a common framework. All frameworks are subject to the need to find practical solutions that respect the unique economic, social and political context of the land border between Northern Ireland and Ireland.

In its approach to common frameworks, the UK Government's stated intention is to uphold the conditions set out in the Ireland/Northern Ireland Protocol, and to remain in full accordance with the Belfast (Good Friday) Agreement.⁹

Section 12 of the EU Withdrawal Act provides that control of areas where EU and devolved law overlap will pass to the devolved institutions when the transition period ends.

However, it also allows UK ministers to freeze the devolved governments' ability to legislate in those areas where it believes legislative common frameworks will be needed. In any area where this power is used, the UK government would be able to set UK-wide regulations until new common frameworks are agreed.

4. The Internal Market Bill

The development of common frameworks has been complicated by the UK Internal Market Bill, which the government introduced in September.¹⁰

If passed as introduced, this bill would enshrine a "market access" commitment in law, which would ensure that anything that is acceptable for sale in one part of the UK will be acceptable in all other parts, and prevents governments from prioritising local businesses over those from elsewhere in the UK. This legislation will cut across many of the areas where common frameworks are due to be developed. It is not clear how the bill and the frameworks are intended to function alongside each other.

The Scottish and Welsh governments strongly oppose the Bill, which they argue would allow goods produced elsewhere in the UK to undercut local standards and would therefore unduly constrain their ability to implement their policy aims.¹¹

The UK Internal Market (UKIM) Bill is based on the principles of mutual recognition and non-discrimination to ensure there are no new barriers for businesses trading across the UK.

The UK government has argued that the Bill is necessary to underpin the functioning of the UK internal market after the end of the transition period. However, the Scottish and Welsh

⁹ Common Frameworks Analysis, Cabinet Office, September 2020 - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/919729/Frameworks-Analysis-2020.pdf

¹⁰ See Institute for Government on the Internal Market Bill - <https://www.instituteforgovernment.org.uk/explainers/internal-market-bill>

¹¹ Institute for Government 'Devolution: UK internal market' - <https://www.instituteforgovernment.org.uk/explainers/devolution-uk-internal-market>

governments are opposed to this approach. Instead, they would prefer to manage any possible new barriers to trade through mutually agreed common frameworks in specific policy areas.

The Bill as introduced, would also give ministers powers to amend how the UK could implement the Ireland/Northern Ireland Protocol if it cannot reach key decisions with the EU. An amendment has since been passed which would give the House of Commons a vote on the date on which these provisions will come into effect.

The Bill passed all stages in the Commons by 29 September and is now with the Lords. It is expected to return to the House of Commons in late November/early December for consideration of Lords amendments. The government intends to ensure that the Bill becomes law before the end of the transition period on 31 December 2020.¹²

The EU has begun the process of legal action against the UK over the Internal Market Bill. The EU might also bring legal challenges if the U.K. parliament passes the Bill and the government later uses the powers contained within the legislation.¹³

The strength of feeling against this Bill is succinctly captured in a letter to the Financial Times from the five Anglican Archbishops of the UK regions and the Republic of Ireland:¹⁴

“We are taking the rare step of writing together because the decisions implemented in this Bill will profoundly affect the future of our countries and the relationships between them... The Scottish Parliament and Welsh Senedd have made clear that the Bill’s weakening of both the principles and the effect of devolved policymaking is of constitutional significance. Moreover, if the Bill is made law without consent from devolved legislatures (as will happen if it is not amended to address their concerns), this will further undermine trust and goodwill among those who govern the different parts of the UK.

The Bill is, of course, not just concerned with domestic law. It currently asks the country’s highest lawmaking body to equip a government minister to break international law. This has enormous moral, as well as political and legal, consequences. We believe this would create a disastrous precedent.

It is particularly disturbing for all of us who feel a sense of duty and responsibility to the Good Friday (Belfast) Agreement — that international treaty on which peace and stability within and between the UK and Ireland depends. The UK negotiated the Northern Ireland Protocol with the EU to “protect the 1998 Agreement in all its dimensions”. One year on, in this Bill, the UK government is not only preparing to break the protocol, but also to breach a fundamental tenet

¹² Institute for Government ‘Devolution: UK internal market’ - <https://www.instituteforgovernment.org.uk/explainers/devolution-uk-internal-market>

¹³ See Politico article ‘EU bangs the Brexit negotiating table (but stays in the room)’, 1 October 2020 - <https://www.politico.eu/article/eu-launches-legal-action-against-uk-over-brex-it-law/>

¹⁴ Letter to Financial Times, 19 October 2020 - <https://www.ft.com/content/e2e8c1d6-edd4-46d2-bef8-8c69199dc151>

of the agreement: namely by limiting the incorporation of the European Convention on Human Rights in Northern Ireland law.

If carefully negotiated terms are not honoured and laws can be “legally” broken, on what foundations does our democracy stand?”

5. Key Areas for Health

While the outcome of all of this remains uncertain, particularly in relation to the implementation of the Ireland/Northern Ireland Protocol, the main areas within health that are likely to be impacted upon are as follows (areas marked with an asterisk will require common framework agreements):

11. Supply of medicines and medical equipment
12. Impact on staffing
13. Reciprocal and cross-border healthcare*
14. Quality of blood, organs, tissue, etc.*
15. Social care
16. Food safety and standards*
17. Public health*
18. Qualification standards*
19. Medical research
20. Public procurement*

5.1 Supply of medicines and medical equipment

5.1.1 Risk of border delays

Northern Ireland mainly receives its medical supplies via ferry from GB. It also has its own, but relatively small, life sciences industry that produces about 2 percent of the UK's pharmaceutical output.

Medicines could be caught up in delays at borders. While medicines are not subject to tariffs under the World Trade Organisation (WTO) rules, non-tariff barriers could hold up movement. Without a mutual recognition agreement on good manufacturing practice and batch testing, additional checks would be needed on medicines moving across the borders.

Around three quarters of medicines and over half of single-use medical products (such as syringes) that the NHS uses come into the UK via the EU, according to the Department of Health and Social Care (DHSC), so there is a risk that border delays arising from a 'no deal' scenario could affect this supply.

As part of trying to plan for possible delays at the major ports, the DHSC is establishing a dedicated shipment hub in Belgium for suppliers of urgently required medicines (those that are usually delivered from the EU to the UK with short lead times of 24 to 72 hours).¹⁵

5.1.2 Potential supply issues giving rise to price increases

Some materials used for medical procedures could be in short supply. For example, access to radioisotopes that are essential for various types of cancer treatment could be limited. The UK relies on importing nuclear radioisotopes and these come mainly from the Netherlands, France and Belgium. Approximately half a million scans are performed annually using imported radioisotopes. These cannot be stockpiled as they decay quickly. They could still be bought from some non-EU countries but supplies may be more expensive and not as reliable. The Royal College of Radiologists has recently expressed concern about the lack of logistical detail it has seen on contingency plans for isotope supplies.¹⁶

Other organisations have raised similar concerns. Diabetes UK, along with the Juvenile Diabetes Research Foundation (JDRF), remain unconvinced that the government's current plans are robust enough to guarantee no impact on supplies of treatments including insulin.¹⁷

The Department of Health says it is working in conjunction with colleagues in other NI and UK Departments and across the Health and Social Care system on arrangements that will maintain the supply of medicines, medical devices and other healthcare supplies should the UK leave the EU without a deal.

The Department also says that substantial planning has already been completed and work is continuing to ensure that supplies are available to support the normal day to day running of the health and social care services.

Hospitals, community pharmacies, GPs, dentists, care homes and other health and social care services have been advised that they should not stockpile supplies of medicines and prescribers should not issue additional prescriptions.

¹⁵ 'How will Brexit affect medicine supplies and your health?' 23 Feb 2019, Which? article by Anna Studman <https://www.which.co.uk/news/2019/02/how-will-brexit-affect-healthcare/>

¹⁶ 'How will Brexit affect medicine supplies and your health?' 23 Feb 2019, Which? article by Anna Studman <https://www.which.co.uk/news/2019/02/how-will-brexit-affect-healthcare/>

¹⁷ 'How will Brexit affect medicine supplies and your health?' 23 Feb 2019, Which? article by Anna Studman <https://www.which.co.uk/news/2019/02/how-will-brexit-affect-healthcare/>

They also say that “enhanced processes” have been put in place to deal with any potential disruption in supplies quickly and minimise any impact on patient care.

Stockpiling is already an issue. In August, the government called for six weeks of medicines stockpiles across the whole of the UK, but companies in Northern Ireland are reportedly going further and stockpiling for six months or more.¹⁸

Whatever form Brexit takes after the transition period, it is likely to impact the supply and pricing of medicines and medical devices. A no deal Brexit could cause serious disruption to supply and even shortages. A more orderly Brexit on agreed terms would mitigate the risk of shortages, but looks likely to increase the bureaucratic and regulatory requirements of importing medicine, which could in turn create price increases.¹⁹

5.1.3 Regulation issues

The Medicines and Healthcare products Regulatory Agency (MHRA) will become responsible for all medicines regulation in the UK from 1 January 2021. The MHRA has recently published guidance on what happens post-transition but the industry has said that they need more detail to help them navigate the practicalities of implementing the guidance due to the complexity of the regulations.

There is considerable uncertainty over what will happen to medicines moving into and out of Northern Ireland. From January, new medicines approvals granted by the EU will be applicable in Northern Ireland, while the MHRA will also be responsible for regulating medicines there.

The UK government has yet to provide details on how the Northern Ireland protocol will work in practice for medicines.²⁰ While the UK's Medicines and Healthcare products Regulatory Agency (MHRA) has published guidance on what will happen for many medicines and medical devices from 1 January, the Association of the British Pharmaceutical Industry has said that companies are "still waiting for detailed guidance on the regulation of medicines in Northern Ireland."²¹

As things currently stand, on 1st January, the MHRA will be responsible for regulating medicines in Northern Ireland. However, under the Withdrawal Agreement, Northern Ireland will also have to comply with EU customs rules and product standards.

¹⁸ “Brexit brinksmanship on medicines ‘risks lives,’ MEPs warn” Ashleigh Furlong, Politico article, 25 September, 2020.- <https://www.politico.eu/article/brexit-brinksmanship-on-medicines-risks-lives-meps-warn/>

¹⁹ King’s Fund article, Holmes, J., Baird, B. & McKenna, H., 31 October 2019, ‘Brexit: the implications for health and social care’ - <https://www.kingsfund.org.uk/publications/articles/brexit-implications-health-social-care>

²⁰ ‘What happens if there’s no Brexit trade deal?’ Politico article, 2 October, 2020 - <https://www.politico.eu/article/what-happens-no-brexit-trade-deal-eu-uk/>

²¹ ABPI response to MHRA guidance for the end of the transition period, 1 September 2020 - <https://www.abpi.org.uk/media-centre/news/2020/september/abpi-response-to-mhra-guidance-for-the-end-of-the-transition-period/>

Medicines moving from GB into Northern Ireland need to comply with EU drug regulations. If a medicine is approved by the EU, this approval will also apply to Northern Ireland. Medicines placed on the market in Northern Ireland will therefore be required to comply with EU medicines law and any additional UK requirements that might apply.

While drugs coming from the EU into Northern Ireland will automatically be compliant, those coming from GB may be subject to compliance checks. Medicines coming from GB to Northern Ireland are also likely to be classified as 'goods at risk' of onward movement to the Republic of Ireland.

On 5 November the UK Government announced that an agreement in principle had been reached with the EU for the phased introduction of post-Brexit medicines regulation. The agreement would give the industry until the end of 2021 to prepare for new regulatory arrangements. However, little further information has been given on the agreement and how it will operate.²²

Representatives from the UK's pharmaceutical industry body, the ABPI, were also due to be questioned on 9 November by the Northern Ireland Affairs Committee on how the Northern Ireland Protocol will affect the supply of medical drugs in Northern Ireland.²³

5.2 Impact on staffing

EU staff play a vital role in the NHS, and the government says the EU Settlement Scheme means that current NHS staff from the EU will be able to stay in the UK. However, the BMA says it is 'deeply concerned' about future immigration. For example, a no-deal scenario may discourage EU health professionals from wanting to come and work for the NHS and could lead to a reduction in staff. According to a BMA survey, 45% of EEA doctors said they were considering leaving the UK following the referendum vote. The lack of clarity on a future immigration system is also hindering the ability of the healthcare industry to plan future staff, according to the BMA.²⁴

Another outstanding issue is what is going to happen to EU nationals who miss the application deadline in June 2021 for the UK's EU Settlement Scheme.²⁵

Across NHS trusts there is currently a staff shortage among key groups of essential staff, including nurses, doctors, allied health professionals and care staff. International recruitment

²² Northern Ireland Affairs Committee - <https://committees.parliament.uk/committee/120/northern-ireland-affairs-committee/news/120643/pharmaceutical-industry-to-answer-questions-on-postbrexit-ni-drug-supply/>

²³ Northern Ireland Affairs Committee - <https://committees.parliament.uk/committee/120/northern-ireland-affairs-committee/news/120643/pharmaceutical-industry-to-answer-questions-on-postbrexit-ni-drug-supply/>

²⁴ How will Brexit affect medicine supplies and your health?' 23 Feb 2019, Which? article by Anna Studman <https://www.which.co.uk/news/2019/02/how-will-brexit-affect-healthcare/>

²⁵ 'What happens if there's no Brexit trade deal?' Politico article, 2 October, 2020 - <https://www.politico.eu/article/what-happens-no-brexit-trade-deal-eu-uk/>

is a key factor in addressing these vacancies. Brexit and immigration policy will have an impact on the ability of the NHS and social care providers to successfully fill these vacancies.²⁶

The Department of Health has not recorded the EU nationality of staff in Northern Ireland, but believes that the number of non-UK or non-Irish EU citizens working in the health and social care system here is small.²⁷

They say that significant efforts have been made to communicate with these staff to encourage them to apply under the EU Settlement Scheme.

HSC employers estimate that there are around 750 employees who live in the Republic of Ireland and cross the border to work, with half of these in nursing and midwifery. The NI Social Care Council estimates that there are around 400 individuals in the independent social care sector.²⁸

5.3 Reciprocal and cross-border healthcare

EU citizens are entitled to a European Health Insurance Card (EHIC) which gives access to medically necessary, state-provided health care during a temporary stay in another EEA country. Treatment is provided on the same basis as it would to a resident of that country, either at a reduced cost or for free. The cost of treatment under these schemes can be subsequently reclaimed from the visitor's country of residence via reciprocal health care agreements. Around 27 million people currently hold EHICs issued by the UK. In addition, under EU rules, people who come from elsewhere in the European Union to live in the UK, or who leave the UK to live in another EU country, have access to health care on the same basis as nationals of that country.²⁹

Uncertainty remains about the future of health care rights. Estimates of the number of people who will be affected differ among the available sources. However, it has been suggested that there are around one million British migrants living in other EU countries, compared with around three million EU migrants living in the UK. UK citizens living abroad tend to be older, and therefore more likely to use health and care services, than EU citizens living in the UK. Significant numbers of UK citizens returning to the UK would have implications for health and care services.

²⁶ King's Fund article, Holmes, J., Baird, B. & McKenna, H., 31 October 2019, 'Brexit: the implications for health and social care' - <https://www.kingsfund.org.uk/publications/articles/brexit-implications-health-social-care>

²⁷ Department of Health 'EU Exit - Frequently Asked Questions' - <https://www.health-ni.gov.uk/eu-exit-frequently-asked-questions>

²⁸ Department of Health 'EU Exit - Frequently Asked Questions' - <https://www.health-ni.gov.uk/eu-exit-frequently-asked-questions>

²⁹ House of Lords **European Union Committee**, 'Brexit: reciprocal healthcare', 28 March 2018 - <https://publications.parliament.uk/pa/ld201719/ldselect/ldEUcom/107/10702.htm>

After Brexit, whether we leave with or without a deal, UK citizens will face new barriers to accessing health care while in the EU. These barriers will differ between member states, each of which should have its own bilateral arrangements with the UK in due course. UK citizens may have to provide proof of residency, proof of current or previous employment, enter a social insurance scheme, or take out private insurance to access health care services in the EU after Brexit.

If we arrive at a no-deal scenario where British citizens face significant barriers to accessing health care in EEA countries, it is likely that some British emigrants currently resident within the EEA, particularly those with long-term conditions, will return to the United Kingdom for ongoing treatment. Around 200,000 British citizens currently access an EU scheme that guarantees health care provision to retirees, which risks being lost in the case of a no-deal Brexit meaning they would have to return to the UK for treatment. It is not known how many of the 800,000 other UK nationals living in EEA nations will be able to access or afford health care in the event of a no-deal Brexit.

To mitigate the potential impact of this, the UK government has proposed to all EU member states that, in the case of no deal, reciprocal health care rights continue for six months after the UK exits. The value of this offer depends on which states accept it.

Without an arrangement similar to the EHIC, costs will transfer to the individual – people travelling abroad in the EU would need to take out private travel insurance in the same way as they would when travelling outside the EU. UK citizens returning from the EU in the event of a no-deal Brexit will create additional demand for health and care services, although the impact and scale of this is uncertain.

In response to a recent Assembly Question from Mark Durken, the Minister of Health said that *“the EU Withdrawal Agreement provides a continuation of EHIC scheme to those who are in scope of the Agreement and also ensures that anyone relying on an EHIC before the end of the transition period will be able to continue to use that until their stay in another member state has completed.”*³⁰

Agreeing reciprocal healthcare arrangements is a reserved matter and therefore the responsibility of the UK Government. I would however support a continuation of an EHIC type scheme.

It is not clear at this stage whether an EHIC type arrangement will continue to apply to the UK as this will be subject to the ongoing negotiations between the UK and the EU.

Arrangements for the provision of specific cross border healthcare services made between the Department of Health in Northern Ireland and the Department of Health in Dublin (such as the Paediatric Congenital Heart Service or the North West Cancer Centre) should not be affected

³⁰ AQW 7712/17-22, answered on 12 October 2020 -

<http://aims.niassembly.gov.uk/terms/printquestionssummary.aspx?docid=309675>

as they are not based on EU legislation but arrangements underpinned by memoranda of understanding and service level agreements.³¹

The UK and Ireland have signed an overarching memorandum of understanding on the common travel area (CTA) which states that:

“The CTA affords British citizens residing in Ireland and Irish citizens residing in the UK the right to access emergency, routine and planned publicly funded health services in each other’s state, on the same basis as citizens of that state.”³²

The Department of Health is also continuing to work with DHSC and the Department of Health in Dublin to ensure that the reciprocal healthcare rights established under the CTA are maintained following EU Exit.

The Department says it is working with DHSC and the Department of Health in Dublin to ensure that the reciprocal healthcare rights established under the Common Travel Area are maintained following the UK leaving the EU. Arrangements for the provision of specific cross-border healthcare services made between the Department of Health in Northern Ireland and the Department of Health in Dublin (such as the Paediatric Congenital Heart Service or the North West Cancer Centre) will not be affected by the UK leaving the EU as they are not based on EU legislation.

The Department of Health has made regulations to ensure that, in a no deal, reimbursements for treatments facilitated under the EU cross-border healthcare directive and started before exit day will be honoured for up to one year.

The regulations also allow for the Directive to continue where the UK Government has reached arrangements with EEA states to continue existing reciprocal healthcare arrangements on a bilateral basis.³³

A common framework is being developed in the area of reciprocal and cross-border healthcare and will involve new legislation.³⁴

³¹ Department of Health ‘EU Exit - Frequently Asked Questions’ - <https://www.health-ni.gov.uk/eu-exit-frequently-asked-questions>

³² Department of Health ‘EU Exit - Frequently Asked Questions’ - <https://www.health-ni.gov.uk/eu-exit-frequently-asked-questions>

³³ Department of Health ‘EU Exit - Frequently Asked Questions’ - <https://www.health-ni.gov.uk/eu-exit-frequently-asked-questions>

³⁴ See Frameworks Analysis 2020 - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/919729/Frameworks-Analysis-2020.pdf

5.4 Quality of blood, organs, tissue, etc.

There are some medicines that are derived from blood plasma such as immunoglobulin, albumin, and clotting factors. As these are licensed medicines, they are included in the medicine supply plans.

The UK is largely self-sufficient in blood and blood components and does not routinely export or import these products, except for relatively small quantities of plasma which are imported by NHS Blood and Transplant for use in those born after 1996 as an agreed safety measure.

In very special cases NHS Blood and Transplant do export or import very rare blood for urgent clinical need, usually in single unit quantities. The NHS Blood and Transplant is leading on contingency planning at a national level for blood and blood components to ensure continuity of a safe blood supply, which includes requirements for Northern Ireland.³⁵

Two non-legislative common frameworks are being developed in this area in relation to blood safety and quality and organs, tissues and cells.³⁶

One of these will cover the quality and safety standards for blood and its components, including all steps in the transfusion process from donation, collection, testing, processing, and storage to distribution. The other will cover the quality and safety of human organs intended for transplantation, and tissues and cells for human application as part of medical treatment.

5.5 Social care

In the long term, the performance of the wider UK economy will be one of the most important influences on funding for the NHS and social care.

With Brexit negotiations ongoing, it is difficult to predict the economic outlook with any certainty. Some argue that it will have a long-term positive impact. However, the weight of opinion suggests that the net economic impact will be negative, with a range of independent economic forecasts suggesting that Brexit will limit growth and lead to increased borrowing, whatever form it takes. In the Office for Budget Responsibility's estimation, a no-deal Brexit of medium disruption would cost the UK economy £30 billion per year, while the Institute of Fiscal Studies have forecast that this scenario will see government borrowing almost double to £100 billion a year.

³⁵ Department of Health 'EU Exit - Frequently Asked Questions' - <https://www.health-ni.gov.uk/eu-exit-frequently-asked-questions>

³⁶ Common Frameworks Analysis, Cabinet Office, September 2020 - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/919729/Frameworks-Analysis-2020.pdf

Funding for public services is not directly and intrinsically tied to national economic performance and funding for the NHS is a political decision, so a recession or economic downturn may not necessarily lead to reductions in public spending in that area.

The NHS has benefited from the certainty of a multi-year funding settlement as part of the long-term plan. However, this spending announcement does not cover the health service in its totality, as it does not cover public health, spending on building and equipment or training budgets. It also does not cover the provision of social care, a sector which is fragile and particularly vulnerable to disruption that a disorderly Brexit may cause.

The NHS and social care are already struggling to manage within their existing budgets. If there are economic consequences arising from Brexit, which result in lower growth and politicians then choose to reduce public expenditure in response, then the implications for social care could be significant. Its budget is only set for one year ahead, it does not have the five years of certainty that the NHS does.

A no-deal Brexit could therefore have a very damaging impact on social care providers. Increased operating costs coupled with financial uncertainty could see providers exiting the market or going out of business entirely.³⁷

5.6 Food safety and standards

The Food Standards Agency (FSA) is responsible for protecting public health and consumers' wider interests in relation to food in England, Wales and Northern Ireland.³⁸ The FSA will be taking the lead on the development of two common framework agreements in this area.

A non-legislative common framework will deal with nutrition labelling, composition and standards. This will cover the nutrition and health claims made on food generally, on food for special medical purposes and weight control, on food intended for infants, on the addition of vitamins and other substances to food, and on food supplements.³⁹

A further common framework, which will involve legislation, will cover food and feed safety and hygiene. This will lay down: the general principles and requirements of food and feed safety and hygiene; food and feed law enforcement (official controls); food safety labelling; risk analysis; and incident handling. It will also set out an overarching and coherent framework for the development of food and feed legislation and lay down general principles, requirements

³⁷ King's Fund article, Holmes, J., Baird, B. & McKenna, H., 31 October 2019, 'Brexit: the implications for health and social care' - <https://www.kingsfund.org.uk/publications/articles/brexit-implications-health-social-care>

³⁸ Food Standards Agency - <https://www.food.gov.uk/about-us/who-we-are>

³⁹ Common Frameworks Analysis, Cabinet Office, September 2020 - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/919729/Frameworks-Analysis-2020.pdf

and procedures that underpin decision making in matters of food and feed safety, covering all stages of food and feed production and distribution.

Under the Ireland/Northern Ireland Protocol, goods sold in NI will continue to follow EU rules for food labelling, composition and standards. It is not clear at this time what will happen if the UK diverges from the EU rules, but it appears likely that there will be changes to labelling that apply to NI businesses from the end of the transition period.⁴⁰

As the end of the transition period draws near, the issue of food safety has given rise to much concern, particularly in relation to the movement of products of animal origin from GB to NI. Major suppliers and distributors for supermarkets have told the Government that NI could face food shortages in January due to checks and delays that might arise from the implementation of new import rules and the Ireland/Northern Ireland Protocol.⁴¹

First Minister Arlene Foster has said the EU is not being reasonable to require checks on food coming into NI from GB that it deems "at risk" of being moved into the Republic.

The European Commission has said while it takes warnings from supermarkets about food supplies "very seriously" goods entering NI from the UK will still need to be checked to meet EU rules on food safety.

At the end of the transition period, some food products arriving from GB will need to be checked. This includes any products of animal origin, such as meat, milk, fish and eggs, which the EU has strict rules on. Animal products will require an export health certificate, which could add substantial costs to supermarket goods coming into NI.

Arlene Foster and Michelle O'Neill wrote to the EU to urge "flexibility" in the operation of the new Irish Sea border when it came to essential food supplies. In their letter to the European Commission, the First Minister and deputy First Minister said:

*"It is hard to imagine a more fundamental aspect of everyday life than the purchase of daily food supplies. Hence we would ask you to recognise how important it is that the current consideration of the detail of how the protocol will be applied takes our unique context into account."*⁴²

The EU Commission responded as follows:⁴³

⁴⁰ 'Brexit: Food and drink labelling changes from 1 January 2021', 5 November 2020 -

<https://www.nibusinessinfo.co.uk/content/brexit-food-and-drink-labelling-changes-1-january-2021>

⁴¹ Belfast Telegraph, 10 November 2020 - <https://www.belfasttelegraph.co.uk/business/brexit/eu-demands-over-irish-sea-border-will-mean-food-shortages-in-northern-ireland-suppliers-warn-39732045.html>

⁴² Irish News, 11 November 2020 - <https://www.irishnews.com/news/northernirelandnews/2020/11/11/news/eu-reject-calls-for-no-checks-on-food-entering-northern-ireland-from-the-uk-after-january-2125993/>

⁴³ Irish News, 11 November 2020 - <https://www.irishnews.com/news/northernirelandnews/2020/11/11/news/eu-reject-calls-for-no-checks-on-food-entering-northern-ireland-from-the-uk-after-january-2125993/>

“The Withdrawal Agreement’s Protocol on Ireland and Northern Ireland prevents the return of a hard border on the island of Ireland...In order to do so, certain EU rules will continue to apply in Northern Ireland after the end of the transition period. That means that goods entering Northern Ireland from the rest of the UK, and the rest of the world, will need to meet EU rules on food safety. These rules are there to protect the health and safety of consumers in the single market, including consumers in Northern Ireland.

We are aware, of course, of the concerns raised regarding supermarkets and the import of food products into Northern Ireland. We take this issue very seriously – in the same way that we are taking very seriously every single issue regarding Northern Ireland. We are currently exploring all options available under EU law. Discussions on this will continue with our UK counterparts in the Joint Committee and the relevant Specialised Committee.”

5.7 Public health

Public health legislation for a number of policy areas, in particular food safety and nutrition, tobacco, alcohol, radiation, environment, housing standards, and chemicals is drawn from established EU legislation, standards and regulations, with relevant directives transposed into UK legislation.

EU legislation has had a significant impact in some areas, such as air quality, that cannot be successfully controlled at national level alone. In other areas, such as tobacco control, the UK currently leads the way in Europe, having gone further than required by a recent EU directive by introducing standardised packaging.

In May 2019, during the third reading of the European Union Withdrawal Act, the government signified its intention to transpose key legislation that maintains EU public health regulations, particularly the ‘do no harm’ duty of the Lisbon Treaty that means the government is required to consider ‘a high level of human health’ when making policy.

The EU also operates systems for the early warning of communicable diseases, managed by the European Centre for Disease Prevention and Control (ECDC). These systems facilitate the rapid sharing of information and technical expertise in response to potential pandemics, communicable diseases and other cross-border health threats.

Recent examples of collaboration include managing the H1N1 ‘swine flu’ pandemic and efforts to tackle anti-microbial resistance. Leaving the EU does not necessarily mean the UK has to leave the ECDC; both Norway and Switzerland (non-EU member states) work with the ECDC, but do not have a formal role in its decision-making.

Once the UK leaves the EU, it will be up to the government to decide whether it wants to go further and faster than the EU in matters of public health or instead implement less stringent public health standards. However, in some areas of public health, particularly those relating to

health security and air quality, it makes sense to continue current arrangements as closely as possible.⁴⁴

The DHSC will be taking the lead in the development of a non-legislative common framework agreement covering public health (serious cross-border threats to health) (notification system for pandemic flu, Zika etc.) This will focus on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, including preparedness and response planning.

5.8 Qualification standards

Legislation introduced on 7 March 2019 means health and social care workers with professional qualifications from EU and Swiss institutions who are currently registered can continue to practise in the UK as they do now, guaranteeing their ability to work in the HSC.

EU or Swiss qualified persons entering the UK after exit may also have their qualifications recognised, if we leave the EU without a deal.⁴⁵

A common framework agreement is being further developed, to cover the mutual recognition of professional qualifications in a number of areas, including health and social care.⁴⁶

5.9 Medical Research

5.9.1 Research

Members of the academic, pharmaceutical and medical communities have expressed concerns about the impact on the free movement of researchers across Europe and on the ability of UK researchers to attract research funding. The Russell Group of universities has published analysis highlighting the impact of Brexit uncertainty on recruitment and retention of academics in UK universities. In the year after the referendum there was an 11 per cent increase in EU academics leaving Russell Group universities.⁴⁷

⁴⁴ King's Fund article, Holmes, J., Baird, B. & McKenna, H., 31 October 2019, 'Brexit: the implications for health and social care' - <https://www.kingsfund.org.uk/publications/articles/brexit-implications-health-social-care>

⁴⁵ Department of Health 'EU Exit - Frequently Asked Questions' - <https://www.health-ni.gov.uk/eu-exit-frequently-asked-questions>

⁴⁶ Common Frameworks Analysis, Cabinet Office, September 2020 - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/919729/Frameworks-Analysis-2020.pdf

⁴⁷ Russell Group, 'Brexit and EU Academics', 8 August 2019 - <https://russellgroup.ac.uk/news/brexit-and-eu-academics/>

The UK has furthered its scientific research agenda through EU collaboration, as a result of access to European research talent and to important sources of funding. NHS organisations benefit from a range of EU funding schemes including Horizon 2020 and the European Structural Investment Fund (ESIF). The government has set an ambition for the UK to be a world leader in life sciences and medical research, but this will require it to address the loss of EU funding for research and development and the benefit from the collaboration of researchers and scientists across the EU.⁴⁸

While it may be possible to continue to participate in some research programmes after the UK leaves the EU (non-EU countries are able to participate in Horizon 2020 as associates or third countries, for example), it is unlikely that projects in the UK would be eligible to receive EU funding and the UK would have limited influence over work programmes.

Any restrictions on the movement of researchers could have a significant effect on research, with about three-quarters of researchers having spent part of their career in a non-UK institution and more than 28% of university academics currently from outside the UK.⁴⁹

5.9.2 Clinical trials

Clinical trials for new drugs are currently carried out at a national level but are subject to EU regulations, including registration of trials. Revised EU clinical trials regulations will not be in force in the EU at the time that the UK exits the EU and so will not be incorporated into UK law on exit day. The government expects to align, where possible, with these new regulations, subject to parliamentary approval. Any divergence between the UK and the EU on the regulation of clinical research would have a number of consequences, including:⁵⁰

- an impact on the status of UK-based patients who are participating in multinational EU clinical trials;
- recruitment issues for clinical trials, especially for rare diseases and paediatric medicine; if the UK becomes isolated it may be seen as a less attractive option for clinical trials recruitment; and
- an increased burden on researchers and clinical trials sponsors if two different systems operate in tandem in the EU and the UK.

⁴⁸ King's Fund article, Holmes, J., Baird, B. & McKenna, H., 31 October 2019, 'Brexit: the implications for health and social care' - <https://www.kingsfund.org.uk/publications/articles/brexit-implications-health-social-care>

⁴⁹ King's Fund article, Holmes, J., Baird, B. & McKenna, H., 31 October 2019, 'Brexit: the implications for health and social care' - <https://www.kingsfund.org.uk/publications/articles/brexit-implications-health-social-care>

⁵⁰ King's Fund article, Holmes, J., Baird, B. & McKenna, H., 31 October 2019, 'Brexit: the implications for health and social care' - <https://www.kingsfund.org.uk/publications/articles/brexit-implications-health-social-care>

Regulations on the transfer of personal data for research (currently overseen through the EU General Data Protection Regulation (GDPR) will also be affected by the Brexit deal.⁵¹

The UK currently lags behind comparable economies in investing national funds in research and development. Without access to EU funding, the UK risks falling further behind. Clarity about clinical trials regulations will also be important, particularly for research into rare diseases and paediatric medicine.⁵²

5.10 Public procurement and competition law

5.10.1 Procurement

At present, much UK public procurement is regulated by EU rules, coming from the main EU treaty and specific EU directives. After Brexit, there will be more freedom for the UK to set its own procurement rules (subject to any international agreements that the UK chooses to make, with the EU and other countries).

International agreements will likely limit domestic policy choices in various ways – for example, they would limit the government's ability to award contracts solely to British suppliers. However, they can ensure that certain public procurement opportunities are opened up to more potential suppliers in other countries – potentially leading to better value for money for the public sector in the UK. Such international agreements also open up opportunities for UK businesses to sell to the public sector in other countries.

The UK Government has taken steps to maintain the UK's membership of the WTO Agreement on Government Procurement (GPA), which involves an ongoing commitment for the UK to open up certain higher value public procurement opportunities to other countries, in exchange for their public procurement markets being opened up in a similar way.⁵³

The Cabinet Office will be taking the lead on a non-legislative common framework agreement that will cover public procurement contracts for supplies, services, works and concessions above certain financial thresholds awarded by the public sector and by utilities operating in the energy, water, transport and postal services sectors.⁵⁴

⁵¹ King's Fund article, Holmes, J., Baird, B. & McKenna, H., 31 October 2019, 'Brexit: the implications for health and social care' - <https://www.kingsfund.org.uk/publications/articles/brexit-implications-health-social-care>

⁵² King's Fund article, Holmes, J., Baird, B. & McKenna, H., 31 October 2019, 'Brexit: the implications for health and social care' - <https://www.kingsfund.org.uk/publications/articles/brexit-implications-health-social-care>

⁵³ King's Fund article, Holmes, J., Baird, B. & McKenna, H., 31 October 2019, 'Brexit: the implications for health and social care' - <https://www.kingsfund.org.uk/publications/articles/brexit-implications-health-social-care>

⁵⁴ Common Frameworks Analysis, Cabinet Office, September 2020 - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/919729/Frameworks-Analysis-2020.pdf

5.10.2 Competition law

The impact of EU competition and procurement laws on the NHS is contentious. A combination of the Competition Act, provider licences and the Procurement, Patient Choice and Competition Regulations continues to prohibit anti-competitive behaviour by NHS providers and commissioners. Leaving the EU would allow policy-makers to modify these arrangements and other relevant legislation. As the relevant EU directives are incorporated into UK law, the government would need to repeal or amend UK law if it wished to reverse current competition policy so there are unlikely to be changes in the short term.⁵⁵

Removing the overly rigid competition and procurement regime currently applied to the NHS is one of a number of recommendations for legislative change proposed by NHS England and NHS Improvement.

There has also been discussion about the impact of trade deals with the EU and with countries outside the EU, particularly the United States. The government has stated its intention to 'ensure we protect our ability to maintain control of the provision of public services, like the NHS, in new trade agreements'. However, its ability to do so will depend on the UK's future trading relationship with the EU and its success in trade negotiations with other countries, which have not yet been agreed.⁵⁶

6. Conclusion

A great deal of uncertainty still exists, despite being only a matter of weeks away from the end of the transition period.

Brexit may present some opportunities for the UK, in particular the opportunity to go further on public health regulation and to remove rules on competition and negotiate new trade deals.

However, it also presents the health and social care sector with a number of significant challenges, including:

- the potential impact on the health and social care workforce that relies considerably on staff who are EU nationals;
- the impact on future trading relationships, which could affect the affordability and supply of drugs and other products;
- a potential weakening of cross-border co-operation on public health and research; and

⁵⁵ King's Fund article, Holmes, J., Baird, B. & McKenna, H., 31 October 2019, 'Brexit: the implications for health and social care' - <https://www.kingsfund.org.uk/publications/articles/brexit-implications-health-social-care>

⁵⁶ King's Fund article, Holmes, J., Baird, B. & McKenna, H., 31 October 2019, 'Brexit: the implications for health and social care' - <https://www.kingsfund.org.uk/publications/articles/brexit-implications-health-social-care>

- a potentially negative impact on the wider economy, which could affect future funding for health and social care.

For NI, the situation is more complicated and the detailed implementation of the Ireland/Northern Ireland Protocol has yet to be agreed. The issue of potential delays, shortages and price rises for food, medicines, medical supplies and other health-related products coming into NI from GB is perhaps of greatest immediate concern.

The potential for future staff shortages, beyond those that already exist, is also a matter of great concern, particularly in the present climate of growing demands on the health and social care services and growing waiting lists for treatment.