Briefing: December 2018

What the Brexit withdrawal agreement means for the NHS

Ahead of the meaningful vote on the Brexit withdrawal agreement and political declaration agreed with the EU, this briefing lays out what these documents mean for the NHS and social care. It also looks at the implications of two possible alternatives: a no deal Brexit, and arrangements where the UK stays in the single market.

Key Points

- The transition period and basic customs union included in the withdrawal agreement would reduce the risks of medicine and device shortages posed by a no deal Brexit.
- The longer term arrangements envisioned in the agreement and political declaration generally entail leaving the single market. Unless negotiating positions fundamentally change, this will produce extra costs for medicines and other supplies. It will incentivise companies to introduce new drugs later in the UK.
- Under the political declaration it will be difficult to negotiate access to reciprocal healthcare schemes such as the European Health Insurance Card for future generations.
- However, it should be possible to negotiate good continued access to the European market in medical devices, and continued participation in the EU's flagship science funding programmes.
- Some see opportunities for the NHS from Brexit in the ability to change rules on procurement and working time. The Northern Ireland protocol in this agreement would allow changes to procurement rules, but not working time regulations. These would be live issues in negotiations for the future relationship.
- Although the rights of existing migrants would be secured, the agreement and declaration envisage the end of the free movement of labour for the future. This poses problems for the NHS and social care, which have relied on European workers to manage staffing shortfalls. The UK could avoid these issues by unilaterally retaining an open system for these workers.

The transition period and citizens' rights

Part Two of the withdrawal agreement permanently secures the rights of UK citizens who live in the EU and EU citizens who live in the UK.[1] This level of certainty may help to keep the over 165,000 NHS and social care workers who are from the European Economic Area (EEA) in this country. Given the troubling levels of vacancies in both sectors[2][3], this would be a significant benefit.

Articles 30 and 31 secure access to reciprocal healthcare schemes, like the European Health Insurance Card (EHIC) and the S1 scheme which allows expat pensioners to access care. This only applies to people who have already crossed the border when transition ends. The nearly 200,000 UK pensioners using S1 in Europe could keep accessing care on the same basis as local residents. [4] However, after the transition British citizens would no longer be able to go abroad and start using EHIC or S1.

Part Four of the withdrawal agreement creates a transition period, which would keep the UK in the single market and customs union until the end of 2020 and could be extended by up to two years more. [5]

This would avoid a sudden disruption to the supply of medicines and medical devices. During the period, the UK would continue to access imports from the European Economic Area (EEA) as it does now. There should not be any additional costs for the NHS. Workers from the EEA will also still be allowed to come, as they are now. This would be especially positive for social care: the Migration Advisory Committee has concluded the sector currently relies on continued EEA migration to continue delivering services. [6]

[1] https://digital.nhs.uk/data-and-information/find-data-and-publications/supplementary-information/2018-supplementary-information-files
[2] https://www.skillsforcare.org.uk/NMDS-SC-intelligence/Workforce-intelligence/publications/The-state-of-the-adult-social-care-sector-and-workforce-in-England.aspx
[3] https://improvement.nhs.uk/resources/quarterly-performance-nhs-provider-sector-quarter-2-201819/
[4] https://www.nuffieldtrust.org.uk/research/getting-a-brexit-deal-that-works-for-the-nhs
[5] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/759019/25_November_Agreement_on_the_withdrawal_of_the_United_Kingdom_of_Great_Britain_and_Northern_Ireland_from_the_European_Union_and_the_European_Atomic_Energy_Community.pdf
[6] https://www.gov.uk/government/publications/migration-advisory-committee-mac-report-eea-migration

The United Kingdom will be a "rule taker" during the transition. It will not be represented in the European Parliament, Commission or Council, which make laws covering medicines, medical devices, and clinical trials. Article 7 also appears to rule out UK representation in the committees which oversee the regulation of medicines. [7]

The Northern Ireland protocol

A special Northern Ireland protocol in the withdrawal agreement lays out a "backstop" future relationship where Northern Ireland would stay in some areas of the single market, and the whole UK would enter a basic customs union with the EU. This would kick in if a future relationship could not be secured that prevents a hard border in Ireland.[8]

The backstop would eliminate quotas and tariffs between the UK and EU, reducing the administrative difficulties discussed below that a no deal Brexit would cause in getting key supplies into the UK.

The backstop alone would not keep England, Wales or Scotland in the EU regulatory system and agencies for medicines, medical devices, or science and research. Becoming effectively a separate market in this way would increase the regulatory burden on companies, especially in medicines which are highly regulated.[9] Countries outside the two major medicines markets of the EU and USA typically receive new drugs later as they are a lower priority. In Canada, according to the consultancy Charles River Associates, the delay averages 144 days.[10]

No economic modelling so far has looked specifically at the additional costs for medicines or devices likely to result from the backstop relationship. Wider modelling of a customs backstop scenario by the UK in a Changing Europe assumes barriers to trade would rise by 3%, compared to 8% in a no deal scenario. [11]

[7] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/759019/25_November_Agreement_on_the_withdrawal_of_the_United_Kingdom_of_Great_Britain_and_Northern_Ireland_from_the_European_Union_and_the_European_Atomic_Energy_Community.pdf

[8] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/759019/25_November_Agreement_on_the_withdrawal_of_the_United_Kingdom_of_Great_Britain_and_Northern_Ireland_from_the_European_Union_and_the_European_Atomic_Energy_Community.pdf

[9] https://www.nuffieldtrust.org.uk/research/brexit-relationship-eu-shape-nhs

[10] https://www.crai.com/sites/default/files/publications/LS%20Insights-Brexit-July-2016.pdf

[11] http://ukandeu.ac.uk/wp-content/uploads/2018/11/The-economic-consequences-of-Brexit.pdf

The backstop in itself gives no access to the incoming new EU system for regulating clinical trials, or the Framework Programmes which fund and co-ordinate research across Europe. It would not secure future access to EHIC or any other reciprocal healthcare schemes.

Northern Ireland would still be partially within the EU regulatory system for medicines and medical devices under annex 5 of the protocol[12]. However, this does not include key provisions which would allow approvals in Northern Ireland to sell medicines into the EEA, limiting any resulting incentive to invest in the country. Northern Ireland would also not be covered by the new clinical trials provisions, except where these concern the manufacturing of medicines to test.

Annex 4 of the protocol commits the UK to maintain a "level playing field" in some areas of regulation. Two areas of regulation that some influential voices in the NHS have expressed an interest in changing after Brexit are working time regulations, which some see as limiting medical training,[13] and procurement rules, which some see as an unnecessary burden on the commissioners who plan and fund care in the English NHS[14]. Part 3 of Annex 4 would appear to rule out changes to working time, but there are no commitments on procurement.

The future relationship

A political declaration alongside the agreement sets out aspirations for a future relationship between the UK and EU, including a free trade agreement.

The Chequers white paper committed the Government to a very close future relationship with the European Medicines Agency, one where "medicines only go through one approval mechanism to access both markets".[15] However, this declaration does not mention this, and its wider provisions are difficult to reconcile with such a relationship. The declaration

[12] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/759019/25_November_Agreement_on_the_withdrawal_of_the_United_Kingdom_of_Great_Britain_and_Northern_Ireland_from_the_European_Union_and_the_European_Atomic_Energy_Community.pdf
[13] https://www.bmj.com/content/349/bmj.g5947
[14] https://www.hsj.co.uk/service-design/stevens-uk-may-reshape-nhs-competition-rules-after-brexit/7016187.article
[15] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/725288/The_future_relationship_between_the_United_Kingdom_and_the_European_Union.pdf

repeatedly commits to end the free movement of people, and to upholding the "indivisibility" of the freedoms of the single market.[16]

Because it falls short of single market levels of access, modelling by the University of Sussex and the Government suggests a free trade agreement would add administrative burdens and push up the prices of medicines, machines and equipment - but significantly less so than under a no deal scenario. [17] [18] Assuming that a deal like this would also avoid the sharp drop in sterling linked to a no deal outcome, our calculations suggest extra annual costs of around £400m a year for the NHS across the UK, rather than £2.3bn in the case of a no deal Brexit[19].

This assumes the NHS's roughly £3bn spending on medical devices would be pushed up by around 4%, as implied by Government impact assessments.[20] Meanwhile, £5bn in future spending on generic and cheaply imported medicines would be pushed up by around 5%, as calculated by the University of Sussex.[21] A no deal scenario would have a much larger impact because sterling would be expected to fall sharply, extra costs would be higher, and the severity of the situation would make it difficult to hold down medicine prices.

The declaration does not cover EHIC, any other reciprocal healthcare programmes, or clinical trials. As these relate to the free movement of people and services, which this document envisages the UK no longer being subject to, it seems likely that British citizens and researchers would lose access to these programmes and permissions.

However, EU agreements with other countries suggest several areas where a deal like this could secure significant benefits for the industries that work with and supply the NHS. For instance, Australian standards bodies are allowed to issue the CE mark which permits open sale of medical devices into the EU.[22] Turkey has a place on the European

[16] https://www.consilium.europa.eu/media/37059/20181121-cover-political-declaration.pdf
[17] http://blogs.sussex.ac.uk/uktpo/publications/which-manufacturing-sectors-are-most-vulnerable-to-brexit/
[18] https://www.parliament.uk/documents/commons-committees/Exiting-the-European-Union/17-19/Cross-Whitehall-briefing/EU-Exit-Analysis-Cross-Whitehall-Briefing.pdf
[19] http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-and-social-care-committee/impact-of-the-brexit-withdrawal-agreement-on-health-and-social-care/oral/93050.html
[20] http://blogs.sussex.ac.uk/uktpo/publications/which-manufacturing-sectors-are-most-vulnerable-to-brexit/
[21] https://www.parliament.uk/documents/commons-committees/Exiting-the-European-Union/17-19/Cross-Whitehall-briefing/EU-Exit-Analysis-Cross-Whitehall-Briefing.pdf
[22] https://archive.industry.gov.au/industry/IndustryInitiatives/TradePolicies/TechnicalBarrierstoTrade/Pages/ECAustMRA.aspx

Standardisation Committee which sets the standards for this.[23] Regulators in several countries have the right to certify that medicines are being manufactured to a standard that allows sale into the EU. [24]

It should be possible for the UK to become an associate member in the EU's Framework Programmes which play a major role in funding and co-ordinating science and research. Being associated means institutions like hospitals and universities are fully eligible to take part, although the UK would not be able to vote on overall priorities.[25]

Labour regulations and procurement rules are mentioned in the declaration as areas which will be covered by the future agreement. There is not enough detail to tell whether this would commit the UK to keep following current EU rules on working time and procurement. EU trade deals generally do not go this far,[26] but the EU has been especially emphatic about maintaining a "level playing field" with the UK.[27]

Modelling of the wider economy suggests a future relationship of this sort would slow down the UK economy, cancelling out extra money for public services freed up from not paying into EU budgets. The UK in a Changing Europe calculate the net effect at 0.4% to 1.8% less money for the Exchequer.[28]

The declaration envisages the end of free movement of labour between the UK and EU. A tighter immigration policy as a result would create problems for the NHS and social care. Calculations by the Nuffield Trust, The King's Fund and the Health Foundation show that on current trends the NHS in England faces a staffing shortage of 250,000 by 2030. [29] A reduction in EEA migration, already visible in some key groups, would worsen this, making our worst-case scenario of a 350,000 shortfall more likely.

In social care, reliance on EEA workers has been rising sharply over the last five years, going from 5% to 8% of the workforce and helping to control a worrying increase in vacancies.[30] The Migration Advisory Committee concluded that "this is a sector that could

[23] https://standards.cen.eu/dyn/www/f?p=CENWEB:5:0:::::
[24] https://archive.industry.gov.au/industry/IndustryInitiatives/TradePolicies/TechnicalBarrierstoTrade/Pages/ECAustMRA.aspx
[25] http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/3cpart/h2020-hi-list-ac_en.pdf
[26] https://www.nuffieldtrust.org.uk/research/brexit-relationship-eu-shape-nhs
[27] https://ec.europa.eu/commission/publications/slides-level-playing-field_en
[28] http://ukandeu.ac.uk/wp-content/uploads/2018/11/The-economic-consequences-of-Brexit.pdf
[29] https://www.nuffieldtrust.org.uk/research/the-health-care-workforce-in-england-make-or-break
[30] https://www.skillsforcare.org.uk/NMDS-SC-intelligence/Workforce-intelligence/publications/The-state-of-the-adult-social-care-sector-and-workforce-in-England.aspx

face even more serious problems if EEA migration was restricted."[31] Of course, the end of free movement of labour would not prevent the UK from unilaterally maintaining an open immigration system for these sectors.

A no deal Brexit

Unless Parliament agrees either the current deal or an alternative arrangement with the EU by March 29th, a no deal Brexit will occur. For NHS supplies, this would create a very sharp uptick in red tape and trade barriers. The British Retail Consortium estimates 44 barriers to trade in medicines would exist.[32] It also anticipates delays at the border as private and government services struggle to cope. The Government is drawing up plans for the stockpiling of supplies which come from or via the EU – which includes an estimated two thirds of all NHS medicines. However, the Secretary of State for Health has been clear that risk cannot be wholly eliminated.[33] There would be a risk to products made within the UK, which may rely on ingredients imported from the EU.

The increases in trade barriers would push prices upwards. In a no deal scenario, this would tend to be intensified by a fall in the value of sterling and the introduction of tariffs: although medicines and medical devices are not subject to tariffs, other supplies like food would be. We have calculated that total additional costs to the NHS across the UK would be around £2.3bn, although the unprecedented nature of a no deal Brexit creates considerable uncertainty around this estimate.[34]

In order to soften the onset of these barriers, the UK Government will keep accepting medicines and medical devices signed off in the EU in several key respects – temporarily for medicines and indefinitely for devices.[35] While helping to reduce immediate problems in getting supplies into the UK, these measures would further incentivise companies to shift investment and research into the EU.

[31] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/741926/Final_EEA_report.PDF
[32] https://brc.org.uk/news/2018/brc-blog-the-cost-of-a-no-deal
[33] https://www.parliament.uk/business/committees/committees-a-z/commons-select/health-and-social-care-committee/inquiries/parliament-2017/brexit-health-impact-of-no-deal-inquiry-17-19/
[34] https://www.nuffieldtrust.org.uk/news-item/how-much-would-nhs-costs-rise-if-there-s-no-brexit-deal
[35] https://www.gov.uk/government/publications/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal

A no deal Brexit would provide no framework to negotiate continued smooth access to EU markets for medical devices, or to EU science programmes. Reciprocal healthcare programmes would not be secured even for those already using them, leaving the 190,000 UK expats who rely on the S1 programme to access healthcare in a potentially very difficult position. We have warned that if these individuals had to return to the UK, in addition to the personal difficulties caused, additional need for up to 1000 hospital beds would be created that the health service is ill equipped to meet.[36]

The sharper economic slowdown caused by a no deal Brexit would go even further in cancelling out money freed up by not paying EU subscriptions. This would make it difficult to fund the planned £20bn increase in NHS England's budget without large tax rises or cuts, or to address the severe financial pressure in social care.

A no deal Brexit would also be likely to lead to a hard border between Northern Ireland and the Irish Republic: the 2007 Lisbon Treaty governing the EU largely requires the same policies to be applied at all borders[37]. This would pose serious problems for healthcare in Northern Ireland, as services including children's heart surgery and urgent heart attack care are currently provided across the border.[38]

Alternatives which would keep the UK closer to the EU

Some MPs are advocating that the UK seeks an alternative deal in which it stays in most or all the single market. If still combined with leaving the EU, this would create a status similar to that of EEA states like Norway.

This would mean that the UK would continue to be part of the EU system for regulating medicines and medical devices, removing disincentives to invest and introduce new drugs, and reducing extra costs. UK citizens would retain full access to EHIC and other reciprocal healthcare schemes. There would be no option to change rules on working time or procurement.

The UK would be a "rule taker" at the highest level, following EU laws without involvement in the institutions that create it. However, it could expect to be involved in

[36] https://www.nuffieldtrust.org.uk/research/getting-a-brexit-deal-that-works-for-the-nhs
[37] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A12012E%2FTXT
[38] http://ukandeu.ac.uk/how-brexit-could-affect-the-health-service-in-northern-ireland/

key regulators: Norway and other EEA states, for example, sit on the Human Medicines Committee that oversees key medicine approvals.[39]

The UK would still have to make significant contributions to EU budgets, but economic forecasts suggest this would be more than balanced out by a less marked slowdown in our economy.[40]Staying in the single market but not being in a customs union with the EU, which is Norway's current status, means some checks would still be required at borders. The University of Sussex calculates that this would mean a 2% increase in the cost of medicines. Government modelling suggests machinery and equipment would also face some upward cost pressure.[41] [42] An extension of the Norway model often called "Norway plus" would involve also having a customs union with the EU[43]. In this instance, it is not clear that there would be any additional costs.

Another option, often advocated via a second referendum, would be for the UK to retain full membership of the EU. For the NHS and medical industries this would be similar to the "Norway plus" model, but the UK would retain a full role in making laws on medicines, medical devices, research, procurement and labour rights. Full members have to pay slightly more into the EU than states in the EEA.

Summary

The documents agreed with the EU would have a complicated impact on the NHS across the critical areas of funding, supplies and staffing.

The transition period and the basic customs union included in the withdrawal agreement would delay and soften the shock of a no deal scenario. The political declaration is hit and miss for the health service. A trading framework would help with the costs and availability of supplies, and it should be possible to use it to keep cooperating closely on science and medical devices. However, as currently put together, it looks as though the commitments on medicines regulation and reciprocal healthcare that the Government sought have not

[39] https://www.ema.europa.eu/documents/other/committee-medicinal-products-human-use-rules-procedure_en.pdf
[40] https://www.parliament.uk/documents/commons-committees/Exiting-the-European-Union/17-19/Cross-Whitehall-briefing/EU-Exit-Analysis-Cross-Whitehall-Briefing.pdf
[41] http://blogs.sussex.ac.uk/uktpo/publications/which-manufacturing-sectors-are-most-vulnerable-to-brexit/
[42] https://www.parliament.uk/documents/commons-committees/Exiting-the-European-Union/17-19/Cross-Whitehall-briefing/EU-Exit-Analysis-Cross-Whitehall-Briefing.pdf
[43] https://www.ft.com/content/833dd0b6-f168-11e8-938a-543765795f99

been achieved. Because the direction of travel indicated is a clear exit from the single market, negotiating for these will be very difficult.

Staying in the single market and customs union would solve these problems, although it would also mean losing some of the possible flexibilities relating to Brexit. The clearest conclusion of all across each of these areas is that leaving without any agreement would be the worst outcome for health and social care in the UK. In addition to the widely discussed risks it would create for vital supplies, it would also have a damaging effect on NHS costs, staffing, research, and investment in medical industries. For health and social care, any deal likely to be on the table would be better than no deal.

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Published by the Nuffield Trust.

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