

How we can protect patients as we approach the end of Brexit transition

Key points

- The Brexit transition period will finish at the end of 2020, at which point the UK and EU's relationship will be governed by the signed [EU Withdrawal Agreement](#) and a potential free trade agreement (FTA).
- FTA negotiations have continued over the summer and autumn, but little progress has been made, with time pressures and red lines on both sides limiting potential for compromise. As such, the potential for a non-negotiated outcome or a 'light deal' is emerging more strongly.
- Whether the UK leaves with or without a trade deal with the EU, the end of the transition period will have a significant impact on health, care and the wider sector. Services and businesses need to know as soon as possible what will change and what they need to do to prepare.
- In addition, the COVID-19 pandemic has hit the UK hard. The healthcare system not only has a responsibility to safeguard population health and wellbeing, but needs to do so from a position of rebuilding services and stocks, with a less-than-certain winter approaching.
- On behalf of the health sector and in the interest of patient safety and wellbeing in the UK, the Brexit Health Alliance would like to highlight the impacts of EU exit for health and what should be in place to minimise disruption to patients and medicines, healthtech¹ and services.

¹ 'Healthtech' (health technology) is defined to include medical devices, diagnostics and digital health technologies.

- In this briefing, the Brexit Health Alliance highlights the key agreements that are required to protect patients as part of the UK's future relationship with the EU from 1 January 2021. It also lays out the considerations required to protect patients in the case of a non-negotiated outcome. With no agreements in place on these issues, the adjustment for the NHS and sector more widely will be significant and could affect the health and wellbeing of patients and citizens.

The Brexit Health Alliance is calling for the UK government to:

- redouble efforts to reach a deal that protects patients, the continuity of supply of medicines and healthtech and medical research, especially in the context of the ongoing COVID-19 pandemic
- urgently clarify arrangements to support patients, healthcare providers and researchers in the event of FTA talks being unsuccessful and allow sufficient time for preparations across the sector.

The timeline for negotiations

The Brexit transition period will end on 31 December 2020, at which point the UK will leave the EU Single Market and Customs Union. The UK and EU's future relationship will then be governed by the signed EU Withdrawal Agreement and a possible UK-EU free trade agreement (FTA), which is currently being negotiated. If no agreement is found and no new partnership is in place in time, UK-EU trade arrangements will revert to World Trade Organization rules and other cooperation arrangements in the health sector will end.

The EU has said an agreement needs to be reached by October to allow time for ratification by the end of 2020. The next European Council meeting is scheduled for mid-October, when the EU envisages political approval could be given by EU heads of state and governments.

This means there is little time for ongoing negotiations to find agreements and the potential for a non-negotiated outcome is emerging more strongly. This was further emphasised by David Frost, the UK's chief negotiator, in his recent comment that 'an agreement is still very much possible, but equally very far from certain.'

Whether a new relationship is agreed or not, the end of the Brexit transition period will impact patient access to medicines and healthtech (health technology); international collaboration on health security; how UK citizens access healthcare; and international research collaboration into innovative treatments, such as those needed to fight COVID-19.

How our health sector could be impacted by no deal or a light deal at the end of 2020

There is a risk that the UK could leave the EU with a light deal or without an FTA at the end of the Brexit transition period in December 2020. Should talks end without an FTA agreed, only UK citizens already settled as residents in EU countries and falling within the scope of the EU Withdrawal Agreement will continue to enjoy the same rights to healthcare as they do now. A light deal would see the relationship defined by the Withdrawal Agreement and a barebones FTA, which compromises only on a subset of the shared UK-EU issues that have been discussed to date.

If no agreements around medicines are included in the deal, the UK will need to set up its own regulatory processes outside of the EU's regulatory network. This could mean that companies choose to bring new products to the larger EU market first, and that the UK could see new treatments later. For medical devices like ventilators and personal protective equipment, it will be important that the new UK conformity assessment (UKCA) process maintains the attractiveness of the UK market.

Further, new border arrangements and additional requirements on goods, as well as regulatory barriers, could cause delays in release of medicines and medical technologies on to the UK market. This issue is highlighted in our briefing published in June 2020. The Association of British HealthTech Industries estimates that 70 per cent of products, wherever manufactured, coming to the NHS are ultimately imported from the EU, and one in five devices used in specialised procedures arrive overnight or 'just in time.'

It could become more difficult to conduct UK-EU clinical trials and share data between UK and EU researchers. Despite both the UK and EU sides agreeing on the benefits of UK participation in EU framework programmes, such as Horizon Europe, the detail and extent of participation is yet to be agreed. Without association to Horizon Europe, joint research projects would become more difficult to progress as long-established collaborative networks that facilitate cooperation would be lost.

The UK will lose access to EU clinical trials infrastructure, which risks disrupting UK participation in cross-border clinical research and, in turn, damaging the prestige of the UK research environment and affecting patient access to the newest most innovative treatments.

The extent of collaboration as a third country on areas such as data exchange, drug authorisations and vaccine procurement are unclear. The UK would no longer be part of regulatory agencies or systems for monitoring the safety of medicines, or the European Centre for Disease Control that coordinates updates on pandemics. Along with Germany, the UK provides the vast majority of data to the EUDAMED vigilance system for medical devices.

Finally, for UK citizens living, travelling or working in the EU, or vice versa, both sides have stated that they are looking for an agreement similar to the European Health Insurance Card (EHIC), to include reciprocal healthcare cover for urgent, unplanned treatment. If an agreement is not reached, the UK will need to seek reciprocal healthcare deals with each individual EU country, who may or may not be inclined to agree. This will mean that the EHIC will cease to apply from January 2021, among other social security benefits for UK citizens who decide to live, travel or work in the EU.

How we can protect patients

The best outcome for patients is a comprehensive deal. Exiting the transition period at the end of the year with an EU-UK FTA in place would prevent tariffs on many goods traded between the EU and UK, as well as reducing non-tariff barriers and border delays. A deal would create an environment and structure that are more conducive to agreeing further cooperation. For instance, it could increase the chances of the EU unilaterally granting the UK's data regime equivalence, and increase the scope for EU and UK customs authorities to co-operate to mitigate the day-one impact of exiting the transition period.

When it comes to protecting patients, there is still time for negotiations to reach agreements that will ease the impact on the health service and sector. The Brexit Health Alliance proposes that the government continues to work with the EU to agree key reciprocal arrangements, as proposed in the UK approach to negotiations.

For medicines, the establishment of a mutual recognition agreement (MRA) that includes Good Manufacturing Practice compliance certification, inspections and batch testing between the EU and UK, would avoid the risk of significant supply chain disruptions by eliminating duplication and delays in conformity assessment. Regulatory and customs cooperation would also support the continued availability of medical devices for both UK and EU patients. Both negotiating teams should take seriously their responsibilities to patients, particularly in the context of COVID-19. Alongside MRAs, the UK and EU should be open to exploring ongoing regulatory cooperation between the European Medicines Agency and Medicines and Healthcare products Regulatory Agency, such as input and access to patient safety databases, which ensures that the medicines available are of the highest standard.

For the UK to continue important work in pan-EU clinical trials, the UK's future regime should be as compatible as possible with EU regulation and ultimately seek harmonisation with the underpinning EU-wide infrastructure and systems. UK-EU clinical trials benefit patients across Europe, particularly in rare and paediatric disease areas where there are often few participants in any one country, making international collaboration vital. This would further be supported by the easy movement of researchers, innovators, and specialist technicians.

What is next

The health service and sector face challenges on multiple fronts

It is now a matter of weeks before an agreement has to be reached and healthcare is by no means top of the agenda. Failure to reach an agreement, which now looks more and more likely, will result in the health sector facing significant adjustment to prepare for the end of the year. These are the same organisations and staff who are working to recover services after the first wave of COVID-19 infections, manage the second wave, or source vital medical products and ingredients for testing.

Given the expectation that additional pressure on the health system created by COVID-19 is likely to continue into and past the winter of 2020, a time when the service is annually stretched, we expect the sector to continue to experience a significant burden and risk being overwhelmed.

Whether there is a deal or no deal outcome, there are likely to remain outstanding questions for the long-term relationship in health between the EU and the UK. Although the Brexit Health Alliance recognises that there has been significant no-deal planning, particularly around the supply of medicines and medical devices, there are still gaps and many of these plans are not long-term solutions.

Recommendations to protect patients

As emphasised, a negotiated outcome to the FTA negotiations is the best outcome for patients. However, if it becomes impossible for agreements to be made, the NHS and wider sector should be as prepared as possible for January 2021, to be able to protect patients alongside a second wave of the COVID-19 pandemic.

The Brexit Health Alliance asks that the UK government uses the next weeks to deliver on the future relationship agreements on health as outlined in their negotiating mandate, and provides more clarity on the preparations and support for the sector if there is non-negotiated outcome to talks:

	Urgent asks from a deal in October	Clarity on preparations for no deal
<p>Supply of medicines and medical devices</p> 	<ul style="list-style-type: none"> • Mutual recognition agreement on Good Manufacturing Practice and batch testing. • Ongoing regulatory cooperation, such as input and access to patient safety databases like Eudravigilance. • Zero tariffs and quotas on medicines or medical devices, including active pharmaceutical ingredients and intermediates used in manufacturing, research and clinical trials. 	<ul style="list-style-type: none"> • More guidance on technical information, such as the handling of decentralised and mutual recognition procedures, handling of variations to marketing authorisations and new assessment routes. • Clarity on how the Border Operating Model will work. • Clarification on the impact of the Northern Ireland Protocol and its implementation in relation to medicines. • A new sovereign UKCA process designed to foster the highest possible level of regulatory cooperation.
<p>Access to healthcare</p> 	<ul style="list-style-type: none"> • UK and EU citizens to continue to benefit from simple and safe access to treatment in the EU at local, affordable cost. 	<ul style="list-style-type: none"> • Clarity on alternative arrangements for access to healthcare for UK citizens living, travelling or working in the EU.
<p>Protect public health</p> 	<ul style="list-style-type: none"> • Participation in key EU data-sharing platforms and alert systems, such as Early Warning and Response System, for timely sharing of information about health threats. 	<ul style="list-style-type: none"> • More guidance and detail on how we can maintain as close coordination as possible without deal agreements.
<p>Maintain scientific collaboration and innovation</p> 	<ul style="list-style-type: none"> • Full association to the Horizon Europe programme. • Agreement to continue collaboration on research and clinical trials, with a view to building closer links in future. • Mutual recognition of professional qualifications for researchers. • Continued free flow of personal data. 	<ul style="list-style-type: none"> • More guidance and detail on how we can deliver continuity for vital medical research and innovation.

Brexit Health Alliance

The Brexit Health Alliance was established to make sure that the interests of those who use health services, as well as healthcare commissioners and providers, educators, researchers and the healthcare industry, are reflected in the Brexit negotiations.

The alliance includes members from across the devolved administrations and as such its work applies across the whole of the UK, including where health is a devolved matter.

For further information about the work of the Brexit Health Alliance, please visit: www.nhsconfed.org/BrexitHealthAlliance

Brexit Health Alliance members

Co-chairs Danny Mortimer, Sir Hugh Taylor

Secretary Kate Ling

Members

- Academy of Medical Royal Colleges
- Association of Medical Research Charities
- Association of British HealthTech Industries
- Association of the British Pharmaceutical Industry
- Association of UK University Hospitals
- BioIndustry Association
- Faculty of Public Health
- Medical Schools Council
- National Voices
- NHS Confederation (including the Mental Health Network, NHS Clinical Commissioners and NHS Employers)
- NHS Providers
- Northern Ireland Confederation for Health and Social Care
- Richmond Group of Charities
- Scottish NHS Chief Executive Group
- The Welsh NHS Confederation