

Outcome of UK negotiations with the EU and the impact on the NHS and health sector







A [trade and cooperation agreement](#) was concluded between the UK and EU on Christmas Eve 2020. This deal addresses many of the issues that the NHS Confederation has raised as asks from the government on behalf of members regarding Brexit and the NHS over the last four years.

There is a lot of good news, but some significant changes compared with the arrangements that applied until the end of the post-Brexit transition period on 31 December 2020. In this briefing, we review the agreements made in the UK-EU deal that will impact health and care in the UK and flag changes, both as a result of the deal and regardless of the deal.

What was agreed in the Brexit deal and what changes

Summary

Topic	NHS Confederation asks	What was agreed	What changes
Continuity of supply of medicines and medical devices	A mutual recognition agreement (MRA) on good manufacturing practice and batch testing.	<ul style="list-style-type: none"> ✓ The UK and EU have agreed to recognise some of each other’s checks on medicinal products to streamline conformity assessment via an agreement on mutual recognition of inspections of manufacturing premises. ✗ However, not all stages in the approval process are covered, such as batch testing. 	From 1 January 2021, the UK leaves the EU framework for medicines and devices regulation and traders and suppliers will face bureaucratic changes. The agreement makes it less likely inspections and certifications will need to be completed twice, which should help avoid delays in getting medicines to patients. However, for some other regulatory requirements, goods signed off in the EU will be accepted in both the EU and UK, but UK-approved goods only in the UK.
	Zero tariffs and quotas on medicines or medical devices, including APIs and intermediates used in manufacturing, research and clinical trials.	<ul style="list-style-type: none"> ✓ Zero tariffs and quotas on goods was agreed, to qualify GB goods need to meet Rules of Origin requirements. ✗ The deal will not remove the need for customs declarations and paperwork. ✓ However, the EU and UK have agreed some cooperation, for example, allowing for simplified forms for those eligible for trusted trader schemes. 	No changes to tariffs or quotas for qualifying goods but formalities to move medical products in and out of the UK will increase, so it could be more difficult to get supplies to the NHS or sell competitively into Europe, at least initially.

Topic	NHS Confederation asks	What was agreed	What changes
Continuity of supply of medicines and medical devices (...continued)	Ongoing regulatory cooperation, such as input and access to patient safety databases like Eudravigilance.	 The agreement contains a medicinal products annex that says the UK and EU will 'endeavour to consult one another, as permitted by their respective law, on proposals to introduce significant changes to technical regulations or inspection procedures' and 'to cooperate with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed scientific or technical guidelines.'	There will be some cooperation and information sharing in this area, but it is yet to be seen how this will work in practice.
Access to healthcare	UK and EU citizens to continue to benefit from simple and safe access to treatment in the EU at local, affordable cost.	 There are agreed social security coordination measures aimed at protecting the entitlements of EU citizens temporarily staying in, working in, or moving to the UK, and of UK nationals temporarily staying in, working in or moving to the EU.	Travellers back and forth, including frontier workers and their family members, will still be able to access care like locals do. Provision for pre-planned care for those with ongoing needs, like dialysis, will continue. Providers can continue to use processes already in place to recover these costs from EU member states.
Health security cooperation	Participation in key EU data-sharing platforms and limited access (on request and ad hoc) to alert systems, such as the EU's Early Warning and Response System (EWRS), for timely sharing of information about health threats.	 Agreement to share information on health risks, such as pandemics, plus ad-hoc access on specific request to the EU EWRS tool.  The agreement provides for a future memorandum of understanding between the European Centre for Disease Prevention and Control and the relevant UK body.	EWRS access will be available when necessary and requested, which will allow the UK to share and receive information on public health threats.
Research cooperation	Third country association to the Horizon Europe programme.	 The agreement gives the UK access to Horizon Europe in return for a financial contribution.	British scientists will still be able to be included in flagship Horizon Europe funding programmes.
	Mutual recognition of professional qualifications for researchers.	 The agreement sets up a framework for possible future mutual recognition of professional qualifications on a profession-by-profession basis through the Partnership Council, but no new qualifications will be recognised on day one.	The UK government is considering future recognition arrangements for incoming professionals after the end of 2022 but will continue to recognise EEA qualifications in the meantime.

Topic	NHS Confederation asks	What was agreed	What changes
Workforce	Current EU health and care staff to be able to continue to work and live in the UK.	<ul style="list-style-type: none"> ✓ Both sides have committed not to lower the overall level of labour and social protection, unless they impact competitiveness on either side. 	Freedom of movement will end. The 'non-regression' commitments not to lower standards do not ensure the UK and EU match each other, but make it less likely that there will be big changes to fundamental rights at work, occupational health and safety standards, or fair working conditions.
Data	Continued free flow of personal data.	<ul style="list-style-type: none"> ✗ Data adequacy is not included in the agreement. ✓ However, a joint declaration published alongside the deal makes clear that the EU will undertake an adequacy assessment. ✓ Both sides say they are committed to facilitating cross-border data flows and the deal prohibits either side requiring that data be stored or processed in their territory. ✓ The deal specifies there should be high standards of protection for personal data and privacy. 	<p>The EU still has to decide whether to deem the UK's data protection regime adequate, although is more likely to now a deal is reached.</p> <p>A temporary arrangement has been agreed to allow continued EU-to-UK transfers from 1 January 2021 for four months (extendable to six) to prevent organisations having to rely on alternatives such as standard contractual clauses.</p>

Detail and guidance topic by topic

Access to medicines and medical devices in the UK

The UK, specifically the NHS, relies on trade with the EU for the continuity of supply of medicines and medical devices. From 1 January 2021, the UK leaves the EU framework for the regulation of these products and traders and suppliers will face bureaucratic changes. Although mutual recognition of conformity assessment, which makes this kind of trade quicker and easier, will broadly fall away after the end of the year, specific, limited, facilitations have been agreed for medicinal products. The facilitations limit the change at the end of the year and aim to avoid the risk of significant supply chain disruptions by eliminating duplication and delays in assessing whether the goods reach required standards.

The EU and UK's agreement sets up a system for the two sides to recognise one another's Good Manufacturing Practice inspections of medicines facilities. However, it does not cover other stages in the process, such as batch testing, so from next year the UK will not be a legal place to test medicines for sale in the EU. The agreement also has provisions on customs and trade facilitation, including trusted trader schemes, to reduce friction at the border and an institutional framework of committees providing for future discussions on the facilitations.

Despite the agreements, from 1 January the outcome will be that for many regulatory requirements, medicines signed off in the EU will be accepted in both the EU and UK, but UK-approved goods will only be accepted in the UK. This could pose a risk to the competitiveness of UK goods in the longer term and, more immediately, it will add bureaucratic hurdles for businesses that export.

Medical devices are under decentralised regulation by third-party bodies designated by national regulators such as the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. Upon certification, devices can display the CE mark, allowing them to circulate freely in the EU. The UK leaves this certification process on 31 December, but CE marks will be recognised for two and a half years in Great Britain, and indefinitely in Northern Ireland, to address supply issues in the short term.

In addition, the UK and the European Atomic Energy Community (Euratom) have agreed a separate Nuclear Cooperation Agreement to demonstrate a commitment to cooperation on civil nuclear, including on the supply and availability of medical radioisotopes.

Specific information for NHS organisations:

- The [plan set out by DHSC](#) in November and December 2020 to ensure the continuity of medical supplies for the UK at the end of the transition period remains in place. This includes stockpiling, re-routing and air freight of medicines with short shelf lives, if required.
- In addition, the government has been working with suppliers to ensure adequate mitigations are in place for non-clinical goods and services, such as hospital food and laundry.
- The advice for patients is to continue to order their prescriptions as normal. adult social care providers should also continue to order medicines, medical products and any non-clinical goods as normal.
- COVID-19 PPE continues to be available via the PPE Portal, and you should allow more time for non-clinical goods to arrive: an extra 72 hours where you rely on 'just in time' supply chains.
- Refer to the 30 December 2020 [letter to NHS organisations](#) from NHS England and NHS Improvement, which provides detailed advice on reporting a supply disruption issue.
- For further guidance on medicines and medical devices regulation from 1 January 2021, visit gov.uk for [all MHRA post-transition period information](#).

EU health and care staff and qualifications

Any EU citizen currently living in the UK, including health and care staff, can stay in the UK without their immigration or employment status needing to change. However, they need to apply before July 2021 for the UK government-run EU settlement scheme, to ensure they will have the right to stay legally in the UK in future.

The UK will implement a new points-based immigration system for people wanting to come and work in the UK from 1 January 2021. Most healthcare workers will meet the entry criteria, but most care workers will not. There will be no regression for fundamental rights at work, occupational health and safety standards and fair working conditions. The rules may diverge in future and there is no requirement to align going forward, but it should not result in lower standards than at present.

Although no new qualifications will be recognised from 1 January 2021, the deal does set up a framework for possible future mutual recognition of professional qualifications on a profession-by-profession basis through the Partnership Council. The UK has agreed a [two-year standstill period](#), during which UK regulators of healthcare professionals will continue to recognise EEA qualifications. Once this period ends, regulators like the General Medical Council can work with EU equivalents to agree new processes for recognising each other's qualifications.

Specific information for NHS organisations:

- Information on the process for EU citizens to apply for the EU settlement scheme is available on [NHS Employers' web page](#). Those who already have valid permanent residence documentation can exchange it for settled status for free.
- There are [further resources and detail](#) available from the Cavendish Coalition on the UK's future immigration system and the impact of the end of Brexit transition on health and social care staff.

Access to healthcare

In the Protocol on Social Security Coordination included in the agreement, people temporarily staying in another country – such as UK nationals on holiday in the EU – will have access to necessary healthcare, under arrangements similar to the existing European Health Insurance Card (EHIC) scheme. Reciprocal healthcare cover, under similar rules as apply now, is available for certain categories of cross-border workers, and for state pensioners who retire to the UK or EU. This also includes provisions to enable individuals to secure authorisation to receive planned medical treatment, funded by their home country.

Specific information for NHS organisations:

- The new UK Global Health Insurance Card (GHIC) will be available from the new year, replacing the existing EHIC. However, people will still be able to use their EHIC after 1 January 2021 when travelling to the EU (or to the UK), as current cards will remain valid until their expiry date.
- EU-wide arrangements for planned care and reciprocal healthcare will continue, so providers can continue to use processes already in place to recover these costs from member states.
- As free movement will end from 1 January 2021, EU citizens who move to the UK after that for more than six months will be subject to immigration control and will pay the immigration health surcharge as part of their visa application. Where a member state continues to cover their healthcare costs in full, certain groups will be able to seek reimbursement of the surcharge.
- The immigration surcharge will not apply to health sector workers or their family members.
- Short-term visitors to the UK who are not covered by the reciprocal healthcare agreement, including former UK residents, may be charged for NHS treatment.

Health security and research cooperation

Currently, the UK and the EU cooperate on cross-border public health, which has been particularly important in the context of COVID-19. The trade agreement provides mechanisms for this to continue, enabling the EU to grant the UK ad hoc access to its Early Warning and Response System and to take part in the EU Health Security Committee for the exchange of information and coordination on serious cross-border threats. The agreement also provides for a future memorandum of understanding between the European Centre for Disease Prevention and Control and the relevant UK body.

On research cooperation, in exchange for a contribution to the EU budget, the UK will join the forthcoming Horizon Europe research program, which will spend €85 billion over the next seven years. This means researchers can continue to cooperate and work together on clinical trials. A draft agreement on the details of this arrangement will be submitted to a new specialised committee for discussion and adoption in 2021.

Cooperation is supported by the ability of the UK and EU to share information. Data sharing requires a unilateral EU decision to confirm that the UK data protection regime is 'adequate' to allow personal data to flow from the EU to the UK. As the EU is unlikely to complete its assessments before the end of December, a temporary arrangement has been agreed to allow continued EU to UK transfers from 1 January 2021, initially for four months (extendable to six months). This is conditional on the UK not changing its data protection law in the interim.

Specific information for NHS organisations:

- Maintain, or to continue to put in place, alternative data transfer mechanisms to mitigate against any disruption to data flows in the future.
- The NHS Confederation published a [review of the most recent government guidance](#) and a checklist of actions for NHS data protection officers.
- Continue to check [gov.uk for the latest updates](#).
- For further guidance on clinical trials and other issues affecting medicines and devices regulation in the UK from 1 January 2021, visit gov.uk for all [MHRA post-transition period information](#).

What happens next

The UK-EU future relationship agreement reduces the considerable uncertainty regarding what happens to people's rights to access healthcare, the flow of medical products and cooperation on medical research and health security from 1 January 2021. However, despite the agreement's provisions, the new relationship between the UK and EU will result in more complex and time-consuming procedures compared with the rules that applied when the UK was a member of the EU.

This is particularly true in the area of the supply of medical products, where the most obvious day-one changes will take place. Continuity of supply preparations undertaken by DHSC will remain in place to help mitigate against potential disruptions caused by new customs and border processes. This will help to ensure that the NHS will continue to be able to access medicines and medical products as needed.

Despite the agreement of a deal, there remains a risk of disruption at the border associated with the UK leaving the Single Market and Customs Union at the end of the year. For this reason, the request from NHS England and NHS Improvement is that organisations keep in place the plans and mitigations stood up for the end of the transition period until further notice.

In terms of what we can expect from the next weeks and months, the focus will now shift from negotiating a deal to its implementation. There may be a tough period immediately ahead for the NHS as we manage the impact of new arrangements operationally, COVID-19 continues to surge and the usual winter period of highest-pressure approaches. However, the contingencies put in place and tested this year are robust and we expect further information and support to emerge from the government and NHS England and NHS Improvement.

Further information and resources

Key advice and guidance for NHS organisations:

- NHS England and NHS Improvement [letter to NHS organisations on the outcome of UK negotiations with the EU and key messages for NHS organisations](#), including annexes on reporting supply disruption issues.
- DHSC [letter to the health and care sector about the UK–EU Trade and Cooperation Agreement](#).
- DHSC [guidance for the health and care sector from 1 January 2021](#).

UK-EU Trade and Cooperation Agreement documents:

- UK government published [agreements reached between the United Kingdom of Great Britain and Northern Ireland and the European Union](#).
- Summary texts on the agreement, including an [EU brochure](#), [overview](#) and [UK summary](#).
- House of Commons Library [analysis of the agreement](#).

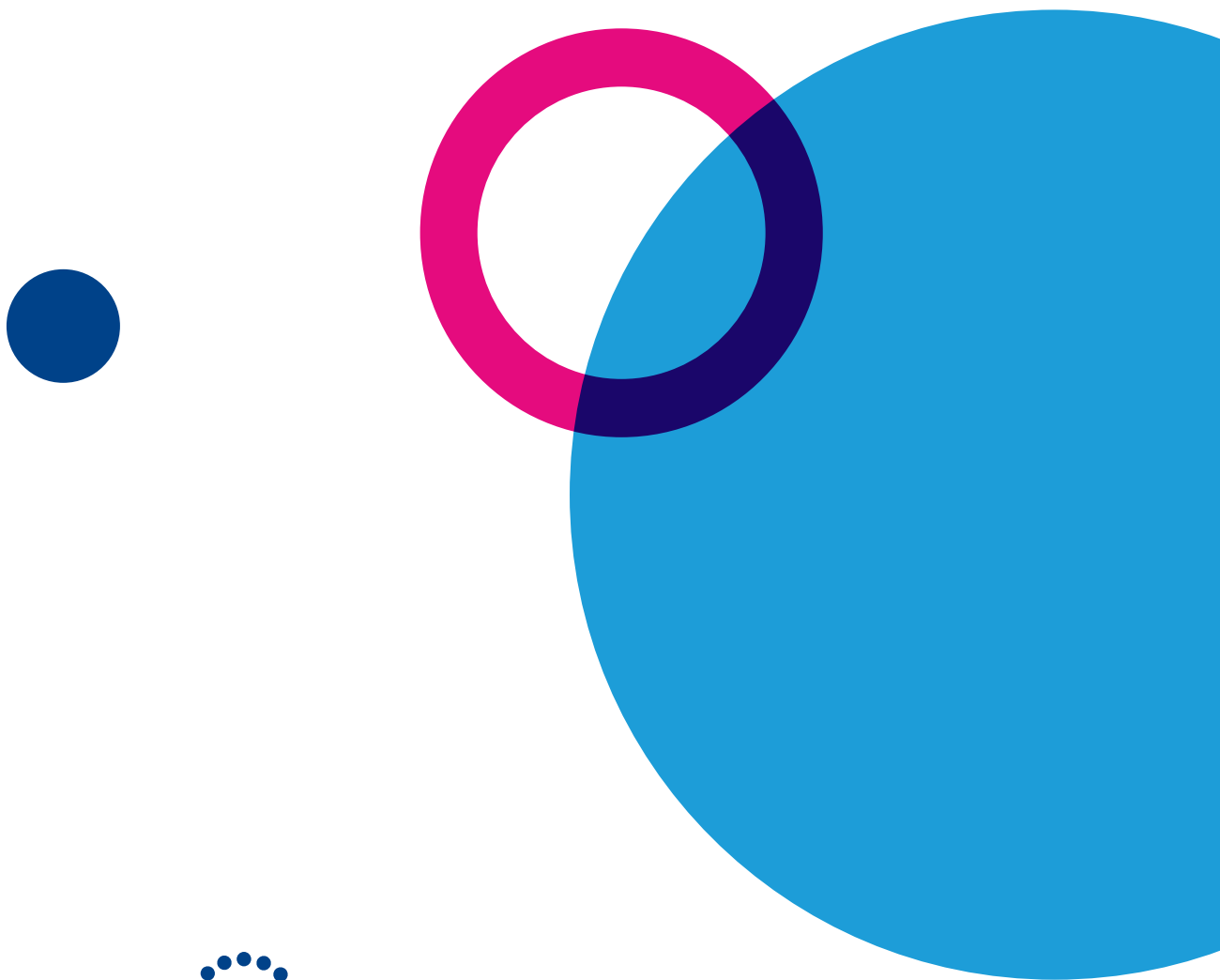
NHS Confederation materials:

- [Brexit latest updates](#) page.
- [Summary of the agreements relevant to health and care](#).

About the NHS Confederation

The NHS Confederation is the membership body brings together and speaks on behalf of organisations that plan, commission and provide NHS services in England, Northern Ireland and Wales. We represent hospitals, community and mental health providers, ambulance trusts, primary care networks, clinical commissioning groups, integrated care systems.

To find out more, visit www.nhsconfed.org



18 Smith Square, Westminster, London SW1P 3HZ

Tel 020 7799 6666

Email enquiries@nhsconfed.org

www.nhsconfed.org

Follow the NHS Confederation on [Twitter](https://twitter.com/nhsconfed) @nhsconfed

If you require this publication in an alternative format, please email enquiries@nhsconfed.org

© NHS Confederation 2020. You may copy or distribute this work, but you must give the author credit, you may not use it for commercial purposes, and you may not alter, transform or build upon this work. Registered Charity no. 1090329