NHS Confederation

Collaborating on the future health of Europe

Building an EU-UK Health Protection Agreement

In partnership with

INDEPENDENT COMMISSION ON UK-EU RELATIONS

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NHS Confederation

The NHS Confederation is the membership organisation that brings together, supports and speaks for the whole healthcare system in England, Wales and Northern Ireland. The members we represent employ 1.5 million staff, care for more than 1 million patients a day and control £150 billion of public expenditure. We promote collaboration and partnership working as the key to improving population health, delivering high-quality care and reducing health inequalities.

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The Commission works with business and industry leaders, academics, UK and EU politicians and other experts to establish means by which the UK and EU can collaborate to the benefit of both sides.

We work broadly, looking at ways to improve trade and collaboration a range of other areas including defence and security, energy and climate collaboration, cultural ties and education.

Members of the Commission are leaders in business, journalism, civil society and academia.

As well as informing government and other political figures we inform the public of our work, both to highlight and explain challenges created by current arrangements and to indicate ways forward which would benefit both the UK and EU.

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Key points

- In a complex global landscape, with the threat of further pandemics and health crises, collective action on health across the continent of Europe is a necessary way forward.

- The negative impacts of EU Exit on the UK's health and that of EU member states have been largely mitigated as a primary and direct result of unilateral UK government action, and some bilateral action between the UK and EU.

- But there is scope for greater collaboration between the UK and EU on health matters which, if implemented, would bring financial and health benefits to both populations. In light of changing geo-political and economic factors, this type of collaboration will also support the UK and EU to mitigate future, unforeseen health and supply chain risks which may yet follow.

- That is why the NHS Confederation and Independent Commission on UK-EU Relations have joined forces to explore areas of collaboration, agreement and interoperability that the UK and EU need to develop together to maximise shared resources and collectively ensure the health of our populations is protected and improved.

- We recommend the UK government considers a **standalone Health Protection Agreement with the EU**, established separately to the complex arrangements under the Trade and Cooperation Agreement for goods and services, and building on the many examples of health cooperation already in place between the UK and the EU. It should include the following:

    1. A commitment to ongoing harmonisation to international standards for medicines and medical devices.
    2. A formal commitment to cooperation on critical medicines shortages, building on the UK's current association to the EU Critical Medicines Alliance.
    3. A formal commitment to cooperation on pandemic preparedness and vaccination.

4. A formal commitment to closer cooperation on medical research and innovation on medicines, clinical trials, medical devices, medical technologies, and artificial intelligence.

- None of these proposals undermine the regulatory or political autonomy of either the EU or the UK. Instead, arrangements would be consensual and subject to iterative change as part of Health Protection Agreement review mechanisms agreed by both parties.

Introduction

If we have learnt anything since 2020 – a year that saw the start of the COVID-19 pandemic and which marked the UK's official withdrawal from the EU – it is that health protection through prevention, treatment and forward-looking cooperation, unites the world. This is why the World Health Organization has value,[1] and why there are global commitments to environmental safety through international agreement, such as the Paris Agreement[i] and the Minamata Convention.[ii]

On a smaller scale, health unites continents, through:

- access to and receipt of supply chains that enable the production of medicines and vaccines
- the spread of disease, as people live, work and holiday across our geography
- the impacts of our unique climates on food production, population health and animal welfare.

While our institutions can change, our geography does not. Although politics can be upended, health needs remain commonplace, unavoidable and connected across communities, counties and nations. This is why the NHS Confederation and the Independent Commission on UK-EU Relations have joined forces to review the impacts of EU Exit on the health of our continent.

[i]The Paris Agreement is a **legally binding international treaty on climate change**. It was adopted by 196 Parties at the UN Climate Change Conference (COP21) in Paris, France, on 12 December 2015. It entered into force on 4 November 2016.

[ii]The Minamata Convention draws attention to a global and ubiquitous metal that, while naturally occurring, has broad uses in everyday objects and is released to the atmosphere, soil and water from a variety of sources. Controlling the anthropogenic releases of mercury throughout its lifecycle has been a key factor in shaping the obligations under the Convention.

In this paper we spotlight the areas of collaboration, agreement and interoperability that the UK and EU need to develop together to ensure we maximise shared resources and collectively ensure the health of our populations is protected and improved.

The European Commission already recognises the need for continental cooperation, which is why there is now an EU for Health Programme, introduced in 2021.[2] This has been developed despite member state independence in health policy, to maximise the benefits of collective action at continental level as well as the cooperation and innovation required by partnership between the public and private sectors.

The United Kingdom, as a G7 power and large services and life sciences economy, can add much value to this mission through the development of more formal mechanisms of engagement and cooperation than are presently in place. This report explores the mutual benefits to EU member states and the UK, alongside recommendations on how they might be achieved.

Key events since 2020

- At 11pm on 31 January 2020, the UK left the EU and entered a transition period.
- At 11pm on 31 January 2020, the transition period ended, and the United Kingdom left the EU single market and customs union.
- The EU/UK Trade and Cooperation Agreement (TCA), signed on 30 December 2020, was applied provisionally as of 1 January 2021 and entered into full force on 1 May 2021.

EU Exit in review

The true risks of EU Exit to the UK's health and care system always related to the potential for rapid deviation from European standards, associated systems and arrangements and the effect this could have on UK patient access – and therefore their health and safety.

The risk that political decision-making would be based on ideological rather than pragmatic, financial or improvement objectives was real in the immediate aftermath of the UK's exit from the EU and when transitional arrangements were being established. But the political rhetoric of 2019, which presented the risk of a "cliff edge" through a no-deal exit, changed significantly.

This resulted in the relatively static regulatory and operational position that now protects the UK health system and patients. In turn, this means that many of the potential risks identified prior to EU Exit have been avoided. However, there is no evidence from a health system perspective that any of the potential benefits of EU Exit have been secured.

The avoided risks have, for now, been deferred and this makes future decisions of the UK Government critical. This includes domestic decisions now under consultation on the future regulatory regime for medical devices, which would take effect in 2030, and its potential impacts on patient access if EU manufacturers are dissuaded, because of additional barriers, from maintaining UK market access.[3]

Current arrangements with the EU

The EU-UK Trade and Cooperation Agreement (TCA) concluded between the EU and the UK and which entered into force on 1 May 2021 sets out preferential arrangements in areas such as trade in goods and in services, digital trade, intellectual property, public procurement, aviation and road transport, energy, fisheries, social security coordination, law enforcement and judicial cooperation in criminal matters, thematic cooperation and participation in EU programmes.[4]

While the TCA makes commitments to cross-border cooperation on health matters, it does not contain specific provisions relating to health services or healthcare products supply other than to make these tariff-free in respect of both imports and exports (as with all other goods traded with the UK).

However, those parts of the TCA which relate to mobility, regulatory cooperation and rights to paid work in member states impact on the wider NHS role in international best practice, education and continued professional development, including in relation to commercial and not-for-profit opportunities it might seek out across the EU.

It is fair to say that the UK otherwise remains in transition, both from the European regulatory frameworks, of which we were a part for over 40 years, and towards any UK future systems and standards that are now in development.

For the English health and social care system, this transition relates primarily to our regulatory regimes for medicines, medical devices and professional qualifications; our access to EU and rest-of-world innovation, life sciences and clinical trials collaboration; and trading arrangements impacting our access to important supplies of healthcare products from EU partners or providers.

Unilateral action by the UK

The key risks associated with EU Exit for the UK's health and care system were addressed not via the TCA but by unilateral action in UK law and operational practice, as evidenced by the following:

- The recognition of CE-marked medical devices for placement on the UK market, subject to the requirement to register these with the Medicines and Healthcare products Regulatory Agency (MHRA) to enable post-market surveillance.

- The light-touch assessment of European Medicines Agency approved medicines prior to placement on the UK market, on the assumption of high clinical quality.

- The unilateral recognition of professional qualifications secured in EU states, such as for doctors, nurses and healthcare professionals. In respect of professional regulation, the UK was no longer governed by the EU Mutual Recognition of Qualifications Directive.

- This has led to the General Medical Council, Care Quality Commission and the royal colleges of nursing and midwifery unilaterally recognising overseas qualifications, with country-specific caveats, for doctors from EU countries. These changes meant up to 63,000 NHS staff and 104,000 social care workers who qualified in the EU could continue to practice in the UK with their training and experience accepted by all health and social care regulators.

- Our pragmatic operational approach to removing trade barriers, for example in relation to unilateral recognition of EU member state batch testing of medicines entering the UK market.

- The unilateral recognition of clinical trial sponsors established in an EU member state without the requirement for an equivalent sponsor to be based in the UK.

It remains unclear if the cessation of free movement rights, and so UK workforce dependency pivoting to non-EU countries (the health and social care visa), has had a skills impact on the UK health and social care workforce (either positive or negative).

Given UK regulatory and registration standards, this seems unlikely for doctors and nurses. Additionally, the UK will have retained EU national workforce as a result of the Home Office's EU Exit Settlement Scheme (where accessed).

However, in terms of access to appropriately trained health and care professionals, it is undoubtedly the case that applying a visa regime to trained EU nationals limits the pool within which the NHS is able to easily recruit, given the additional costs and limitations of that regime.

In summary, the actions taken by the UK had to be unilateral because they could not realistically form part of the TCA given that the UK retains the right, in any future system or regulatory change yet to be implemented, to diverge as part of the legal independence it now has from EU law and institutions.

However, similar unilateral action has **not** been taken to date by the EU as a bloc or by individual member states. This means there are different barriers for exports from the UK than for imports into the UK, most notably in relation to batch testing of medicines, medical devices and associated medical products.

Additional agreements between the EU and UK

Despite this, there have also been areas of significant cooperation between the UK and the EU. Most notably:

- The UK negotiated agreement with the EU, reflected in the Windsor Framework of 2023,[5] to ensure the access of British citizens in Northern Ireland to UK medicines supply, regardless of the origins of the medicine. This represents both a bilateral political and an operational success. The framework states that this "responds to the overwhelming calls from industry for stability and certainty and can give reassurance to patients and clinicians in Northern Ireland well into the future." It is also said to safeguard "frictionless access to the EU market for world-leading Northern Ireland pharmaceutical and medical technology firms." For medicines, the MHRA is now responsible for approving all drugs for the whole UK, and medicines can be supplied in single packs, within UK supply chains, with a single license. Individual packs of all medicines placed on the NI market should bear a label indicating 'UK only', indicating compliance with UK regulations and preventing sale of these products in the EU, via the border with Eire.

- The Windsor Framework also unlocked the political will to implement the element of the Withdrawal Agreement which legislated for ongoing UK access to the Horizon programme and its successor. UK organisations are now able to participate in Horizon Europe calls for proposals on the same terms as institutions from other associated countries.[6] Participation in Copernicus, the EU Earth Observation programme, also now enables UK access to a state-of-the-art capacity to monitor the earth and to its services, as well as provide the UK research community with access to unique data, which is often required on Horizon Europe projects.

- The UK negotiated third-country access to the EU's first Joint Action on a European Health Data Space – TEHDAS[7] – with a view to the future sharing of patient records across participating states to support healthcare delivery or for secondary research purposes.

- The UK negotiated associated status to the EU Critical Medicines Alliance, focused on the future production and supply of a list of critical medicines in light of wider supply chain impacts arising from geopolitical change.[8]

- The UK negotiated a data adequacy agreement, due to expire in 2025, with the EU to ensure assimilation to the EU GDPR standards and enable the ongoing exchange of data, including for health purposes, with adequate security provisions in place.[9]

- The UK has continued engagement with the EU Commission, led by the UK Mission for Health (Foreign, Commonwealth and Development Office), in relation to antimicrobial resistance and the solutions required at continental level to ensure the future health of all European populations.

- The UK negotiated with the EU to disapply new EU legislation in Northern Ireland due to take effect in 2025 which, had it been implemented, would have banned the use of amalgam in dental procedures. This would have created different rights to dental treatment, and associated cost, in Northern Ireland than in the rest of the UK, creating health inequity at a complex time for the Northern Ireland health system.

Conclusion and recommendations

The negative impacts of EU Exit on the UK's health, and that of EU member states and Europe as a continent, have been mitigated as a primary and direct result of unilateral actions by the UK and through piecemeal negotiation of specific associate agreements with the EU Commission.

These unilateral or negotiated actions have, in addition to the free trade arrangements secured in the Trade and Cooperation Agreement and the avoidance of a 'no deal' Brexit, served to protect the UK health system and its patients from the worst effects of EU Exit. They also demonstrate the pragmatic, mutually beneficial and patient-focused nature of the UK's relationship with the EU Commission since 2021, when the transitional period concluded.

Put together this provides for a solid foundation for future, closer cooperation, albeit not necessarily within the narrower confines of the Trade and Cooperation Agreement now due to be reviewed in 2026, which does not focus on health matters (this being uncommon for an international trade deal).[iii] The most specific health provisions within the TCA are limited to the mutual and ongoing access to healthcare when travelling across the EU and UK, though with some additional restrictions for certain health conditions, such as kidney dialysis. This is now referred to as the Global Health Insurance Card, replacing prior arrangements on use of the European Health Insurance Card (EHIC).

While it is feasible in reviewing the TCA to seek adaptations to existing content, for example to establish a mutual recognition agreement under Article 2, its scope is relatively limited in relation to wider considerations of health policy and health cooperation. This is also a position reflected in the EU Commission's comments to date, at both political and official level.

[iii] The TCA is due to be reviewed by the new Labour government and the EU Commission in 2026. That process is underway at official level with engagement via the UK and EU Domestic Advisory Groups.

We note that the Labour Party manifesto committed to securing a Veterinary Agreement with the EU to mitigate the impacts of border checks on phyto-sanitary products, the scope of which might be extended to include plants as well as animal products. This is a matter of health, pertaining to our access to high-quality food and plant products, which would be mutually beneficial. However, we think the scope of such an agreement, if secured, would also preclude wider matters of health policy and health access discussed here.

We therefore recommend that the government consider, at the right point and with the right sequencing, proposing and seeking to secure a **standalone Health Protection Agreement with the EU**. Such an agreement could incorporate the following and act as a foundation for medium-term expansion to other areas of health policy:

1. **A commitment to ongoing harmonisation to international standards for medicines and medical devices**, as these develop, without formal regulatory alignment and while maintaining individual systems for market authorisation, sale and surveillance and enforcement.

    — The agreement could go further and legislate for the mutual recognition of conformity assessment for medicines and devices, which could have consequential benefits in relation to the testing of new medicines and the batch testing of medicines being placed on the market for sale.

    — This would build on the unilateral actions taken by the MHRA in relation to EU medicines and medical devices which its public literature previously committed to maintaining in any future system changes in recognition of the quality of the EMA and EU Medical Device Regulation provisions and operations.

    — If mutual recognition were not to be agreed, the agreement could contain specific provisions for the testing of new medicines and the batch testing of medicines being placed on both markets as part of a trusted trader approach.

Importantly, we do **not** propose that such an agreement could or should include provisions relating to market access that could circumvent the content

of the Trade and Cooperation Agreement on tariff free trade, unless this is further amended following the planned review in 2026.

However, further cooperation in this manner could minimise costs for both EU and UK consumers of medicines and users of medical devices, while also serving to protect and streamline mutual supply chains that could otherwise be placed into jeopardy in the future as a result of geopolitical change.

2. **A formal commitment to cooperation on critical medicines shortages**, building on the UK's current association to the EU Critical Medicines Alliance.

    — This could include formally co-opting the UK into the Critical Medicines Alliance as well as the UK being compliant with any future agreed processes on this key area of health protection, while also being able to inform its scope and application.

    — It could include reference to harmonisation of prices and access to medicines, specifically during defined periods of shortage, to ensure the appropriate and proportionate pan-EU allocation of medicines across all populations. Separate consideration would be given to novel and newly licenced medicines and to generic medicines.

    — It could include reference to formal cooperation on the joint production of medicines, including at pace, where required during defined periods of shortage i.e. the collective maximisation of resources to protect population health.

3. **A formal commitment to cooperation on pandemic preparedness and vaccination**, noting and building on the success that each party had during the COVID-19 pandemic, but enabling closer cooperation on the authorisation and future production and supply of vaccines through regulatory and operational channels.

    — This should link to wider, WHO-led preparedness commitments at international level and enable a sub-WHO operational focus.

— It could include wider, formalised cooperation on prevention of future threats, including in relation to antimicrobial resistance as a key evolving health threat.

— It should include commitment to cooperation and partnership on yet-to-be-identified health threats, including as a consequence of global climate change and how this impacts the importation of disease to our continent.

— This could also involve a system of data exchange and analysis to identify and mitigate such threats before they eventualise.

4. **A formal commitment to closer cooperation on medical research and innovation** on medicines, medical devices, medical technologies and artificial intelligence.

— This could incorporate and potentially expand on the Horizon and Copernicus association provisions contained within the Trade and Cooperation Agreement and implemented in late 2023, including it could facilitate full UK membership of these initiatives with associated financial contributions.

— This expansion could also relate, for example, to creating mutually beneficial mechanisms in relation to the terms of introducing, and regulating, artificial intelligence and new medical technologies and devices into health and care systems across EU and monitoring the effectiveness, post-use and in light of clinical factors, of these technologies. This would build on existing EU and UK system proposals on the integration of health technology assessment and clinical review.

— It should provide for new legal commitments in relation to clinical trials, including recognition of clinical trial sponsors across the EU, and simplify the conduct of pan-EU trials and data use to ensure that these are barrier free for both parties.

— Provide for additional provisions on health data-sharing linked to the UK's association participation in the European Health Data Space to date since 2021, could also be extended to full membership.

— Given the importance of data to all these initiatives and to the wider promotion of patient health and research, establish permanent recognition of data adequacy across the UK and EU with supporting, binding principles on minimum data protection standards.[iv]

It is worth underscoring that none of the proposals would undermine the regulatory or political autonomy of either the EU or the UK. Instead, the proposed Health Protection Agreement would be consensual and subject to iterative review.

Nor does the proposed agreement offer either signatory any trading, economic or political advantage, given the truly mutually beneficial nature of its proposed scope and inclusions.

In making these proposals, the UK is not seeking to re-gain the benefits of EU membership without the responsibilities of the same. This is because health as an area of policy is not a formal pillar of the EU Treaty and so of the Commission's leadership. Instead, it was, prior to 2021 and remains, within the autonomous domain of each member state. This is why the concept of a Health Union of member states is in development and being supported by the EU Commission, as well as why EU4Health is available by association to non-member states.

Health, in respect of preventing future harm, maximising opportunities for collaboration and working towards the highest regulatory and safety standards, is unique. In a complex global landscape and given the threat of further pandemics and health crises – from antimicrobial resistance to the disruption of supply chains, from the benefits of medical technologies to the risks they pose to patient safety – it is right to take collective action, and to do so as the continent of Europe.

[iv] The UK has a data adequacy agreement with the EU due to expire in 2025 unless further extended on review.

With strong leadership on both sides – a re-elected Head of the EU Commission building on the wider agenda for pan-EU health, and a new British government keen to expand its relationship with the EU, and with a strong electoral mandate to do so – now is an important opportunity to seize.

This is not about trade, or free movement, nor current or previous politics. It is about geographical and capability-led pragmatism: working together, building on existing positive engagement and cooperation since 2021 to maximise the future opportunities for health protection in partnership and with purpose.

That health is unique is also why a bespoke approach to building this partnership should be taken, with prompt action on a Health Protection Agreement between the EU and the UK working to the advantage of all populations across the continent.

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