Northern Ireland Protocol Bill

October 2022

Background

Unless solutions are found to the ongoing friction between the UK and EU over the interpretation and implementation of the Northern Ireland Protocol, patients, and the health system and research they rely on will be at risk.

The introduction of the Northern Ireland Protocol Bill offers Parliament the opportunity to debate how to address the practical difficulties arising from implementation of the protocol.

What's at risk

The following have been identified by health leaders as issues unlikely to be resolved until the impasse over the Protocol is unblocked:

NHS supply chain

The supply of medicines, health technologies and other essential supplies could be disrupted and costs increased if customs, paperwork and regulatory checks at the UK/EU border are more stringently enforced due to ongoing friction, or if quotas, tariffs or other retaliatory measures are applied. This would exacerbate existing global supply chain shortages and economic pressures affecting the NHS. The UK is not, and does not have the capability to become, 'self-sufficient' in all the products the NHS needs.

In addition, the Medicinal Products Working Group envisaged in the TCA has never been set up as a result of the freezing of UK-EU relations. This group could play an important role in developing practical improvements in regulatory co-operation between the UK and EU, such as simplifying, standardising and minimising duplication of requirements for batch testing and authorisation of products. Measures such as these would minimise bureaucratic barriers to importing and exporting products. The EU already has such arrangements with other third countries but the current situation has acted as a barrier to a functioning arrangement with the UK to date.

Medicines for Northern Ireland

The EU legislation allowing medicines from Great Britain to be marketed in Northern Ireland expires at the end of 2024, creating uncertainty.

In addition, given the size of the NI market, companies may consider it unviable to seek authorisation via the NI-only (NIMAR) route for new medicinal products, especially where small numbers of patients (for example, those with rare conditions) are affected. Some new products – or specific uses of new products for certain patient groups – have not been authorised in Northern Ireland, or may reach the Northern Irish market later.

Practical measures to reduce unnecessary regulatory barriers, for example agreeing shared access by the UK and EU regulators (the Medicines and Healthcare products Regulatory Agency and European Medicines Agency) to common repositories of information from manufacturers seeking product authorisation, would avoid duplication and accelerate patient access to new and better treatments.

Access to health data

The decision by the EU to grant data "adequacy" to the UK's data protection regime means that data can flow freely between the UK and EU without complex and costly alternative transfer mechanisms. Transfer of digital data underpins business transactions and crucially for the NHS, transfer of patient data for healthcare, research and tacking cross-border health threats. A retaliatory decision by the EU to review and refuse data adequacy if friction over the Protocol continues, these activities would cease to the detriment of patients and the NHS, as well as the wider economy.

The EU requires countries with data sharing agreements to maintain equivalent, not identical, data protection regimes, so UK data reforms that satisfy EU regulatory equivalence could be positive. Conversely, if the EU revokes the UK data sharing agreement, costly and burdensome alternative transfer mechanisms will need to be put in place for personal data to continue to flow.

Health leaders were concerned to hear Government is planning to make changes to the legislation around GDPR could risk jeopardising the existing UK-EU data sharing agreement. They are urgently seeking clarification on the plans.

Research and innovation

The agreement in principle in the Trade and Cooperation Agreement for the UK to associate to the Horizon Europe research programme, worth €95.5 billion (£84.1 billion) of research funding between 2021 and 2027, has not been actualised as a result of the impasse over the Protocol.

Consequently, scientists and health researchers operating in the UK - including those trialling treatments for cancer and for rare diseases - are losing opportunities for future partnerships and collaboration that may offer hope of a better life to patients. Whilst the UK Government decisions to underwrite the costs for UK project partners who have already applied for Horizon Europe funding and to launch a UK-led substitute scheme are welcome, such a scheme could not hope to rival the size and scope of the pan-EU programme for many years, if at all.

Clinical trials

UK organisations sponsoring EU-wide clinical trials testing new or improved treatments for medical conditions must now have EU-based legal representation, adding to cost and bureaucracy and discouraging innovation.

The UK research community believe that this could be prohibitively expensive for non-commercial sponsors particularly such as universities. Discussions that could alter or ameliorate this situation are not taking place owing to ongoing EU-UK friction.

Calls to Government

- Approach the process of passage of the Northern Ireland Protocol Bill with a commitment to allow the space and time for the negotiation of mutually acceptable solutions.
- Work to ensure Clause 15(1) (e) of the legislation that cites "*safeguarding animal, plant or human health or welfare"* as a justification for (further) exclusions is retained in the legislation. This would be consistent with Government assurances that Brexit would 'do no harm' to health.
- Work to ensure the provisions in Clause 15 (3) of the Bill exempting certain articles of the Protocol (Articles 2,3 and 11 covering the rights of individuals, the Common Travel Area and North-South Co-operation) from the provisions of Clause 15 of the Bill empowering future ministers to exclude, modify or restore further elements of the Withdrawal Agreement or Trade and Cooperation Agreement are also retained in the legislation.
- Consider carefully whether the use of Article 16 of the Protocol, or the use of the dispute settlement proceedings set out in the Withdrawal Agreement, would be a more appropriate mechanism for addressing the difficulties engendered by implementation of the Protocol, and if introducing that mechanism in the legislation could unblock the barrier to progress currently impeding negotiations.
- Consider carefully whether the Bill as it stands guarantees a satisfactory future process for democratic consent to the provisions of the Protocol in Northern Ireland, and reflect on what could be modified to ensure 'buy-in' from the people of Northern Ireland, ensuring the future stability and longevity of the Protocol.

Suggested interventions

- Will the Minister acknowledge on the record the assurance from Government made in this place in 2019 by the then-Minister that Brexit will do no harm to health?
- Will the Minister commit to doing all he can to ensuring Clause 15(1) (e) to safeguard "*animal, plant or human health or welfare"* as a justification for (further) exclusions is retained in the legislation?
- Can the Minister tell us what discussions he has had with the new Secretary of State for Health and Social Care on the implications of this legislation for the NHS and wider health sector, and if he has not, will he commit to seeking a meeting on this with her?
- Can the Minister tell us if the new Secretary of State for Health and Social Care or the Secretary of State for Northern Ireland has had any discussions with the Ministers responsible for health in Ireland and Northern Ireland?
- Can the Minister tell us what discussions he has had with the new Secretary of State for Digital, Culture, Media and Sport on the implications of the policy she set out at Conservative Party Conferences regarding GDPR, and what the introduction of this

policy would mean for the Protocol and those living in Northern Ireland with rare diseases?

Should you need any more information please don't hesitate to be in touch via externalaffairs@nhsconfed.org.

About the 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.

Our international work aims to safeguard the interests of patients, the NHS and the research they both rely on, as the UK develops its future relationship with the EU and the rest of the world.