NHS Confederation – Written evidence (NIP0004)

Lords Protocol on Ireland/Northern Ireland sub-committee inquiry on the Northern Ireland Protocol Bill

October 2022

About us

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.

The NHS European Office - which is part of the NHS Confederation - is the conduit for the NHS to engage with the EU agenda. It covers a wide range of EU policy and legislative developments which have implications for the NHS.

The NHS Confederation convenes the Alliance for International Health Policy, which brings together the NHS, medical research, industry, patients and public health organisations in the UK and aims to safeguard the interest of patients, and the healthcare and research they rely on, as the UK develops its future relationship with the rest of the world. It began work as the Brexit Health Alliance in 2016.

Implications of the legislation for the NHS

1. The ongoing friction between the UK and EU over the interpretation and implementation of the Protocol on Ireland/Northern Ireland has the potential to have a negative impact on the NHS, the research it relies on and by extension, for patients.

2. Unless solutions to the impasse are found, the NHS Confederation are concerned that the resulting inaction, escalation or trade retaliation (permitted under the Withdrawal Agreement (WA) after consultation and arbitration processes) could harm some of the UK's most vulnerable citizens.

3. The Northern Ireland Protocol Bill offers Parliament the opportunity to scrutinise and address the practical difficulties arising from implementation of the Protocol to date.

4. The WA and Trade and Co-operation Agreement (TCA) reached between the UK and EU left several health-related issues unresolved[1], and progress is unlikely to be made until the Protocol impasse is unblocked.

Priorities for the legislation for the NHS

5. During the Bill's passage, the NHS Confederation wants to see the UK Government and parliamentarians to consider a number of issues.

6. Firstly, whether the provisions in the Bill intended to take immediate effect might be amended, instead empowering Ministers to make such provisions in future.

7. Secondly, whether the use of Article 16 of the Protocol, or the use of the dispute settlement proceedings set out in the WA, would be a more appropriate mechanism for addressing the difficulties engendered by implementation of the Protocol.

8. Thirdly, whether the Bill as it stands guarantees a satisfactory future process for democratic consent to the provisions of the Protocol in Northern Ireland.

9. Ensuring these matters are given full consideration and reflected in the legislation will help to command the confidence of the people and decision-makers of Northern Ireland in the long-term, reducing the risk of retaliatory measures taken by the EU that have negative impacts of health in the UK.

10. In addition, there are a number of clauses in the Bill that the NHS Confederation want to see retained as the Bill makes its way through the legislative process.

11. Retaining Clause 15(1) (e) that cites *"safeguarding animal, plant or human health or welfare"* as a justification for (further) exclusions. This would be consistent with government assurances that Brexit would 'do no harm' to health, during the passage of the EU (Withdrawal) Act 2019.[2]

12. Retaining 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

[1] https://www.nuffieldtrust.org.uk/news-item/protocol-politics-mean-hard-times-ahead-for-health-in-northern-ireland

[2] https://hansard.parliament.uk/Lords/2019-03-04/debates/7EC961AC-FE07-40A0-B536-5B3AF37949AA/EuropeanUnion(Withdrawal)Act2018(ConsequentialModificationsAndRepealsAndRevocations)(EUExit)Regulations2019

the provisions of Clause 15 of the Bill empowering future ministers to exclude, modify or restore further elements of the WA or TCA.

Issues of concern regarding the Protocol for the NHS

13. The NHS Confederation believes the following issues are unlikely to be resolved until the impasse over the Protocol is unblocked and have the potential to have a negative impact on health in the UK.

Supply chain to the NHS

14. 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 ("go-slow"), or if quotas, tariffs or other retaliatory measures are applied. This would exacerbate the existing global supply chain shortages and economic pressures affecting the NHS, in common with the rest of the UK economy. The UK is not, and cannot become, 'self-sufficient' in all the products the NHS needs.

15. In addition, the Medicinal Products Working Group envisaged in the TCA has never been set up as a result of the stalling 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 (ideally by mutual recognition) 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.

Medicines for Northern Ireland

16. The EU legislation allowing medicines from Great Britain to be marketed in Northern Ireland expires at the end of 2024, creating future 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 with rare conditions) are affected. Some new products – or specific uses of new products, such as for certain patient groups – have not been authorised in NI, or may reach the NI market later.

17. Practical measures to reduce unnecessary regulatory barriers, for example agreeing shared access by the UK and EU regulators (the Medicines and Healthcare products Regulations Agency[3] and the European Health Management Association[4]), to common repositories of information from

[3] https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
[4] https://ehma.org/

manufacturers seeking product authorisation, would avoid duplication and accelerate patient access to new and better treatments.

Exchange of data

18. 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.

19. Transfer of digital data underpins business transactions and crucially for the NHS, transfer of patient data improves healthcare and health outcomes through research and helping to tackle cross-border health threats. A retaliatory decision by the EU to review and refuse data adequacy should negotiations on the implementation of the NI Protocol break down would imperil these activities, to the detriment of patient health outcomes and the health sector, as well as the wider economy.

20. 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.

Research and innovation

21. The agreement in principle in the TCA 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.

22. Consequently, scientists and researchers working in the UK, including healthcare researchers trialling treatments for cancer, rare diseases and others, are losing opportunities for future partnerships and collaboration that may offer hope to patients.

23. 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 initially hope to rival the size and scope of the pan-EU programme.

Clinical trials

24. 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.

25. Evidence from the UK research community is that this could be prohibitively expensive for non-commercial sponsors such as universities. Discussions that could alter or ameliorate this situation are not taking place owing to ongoing EU-UK friction due to disagreement regarding the NI Protocol.

6 October 2022