NHS European Office

NORTHERN IRELAND CONFEDERATION FOR HEALTH AND SOCIAL CARE

The Northern Ireland Protocol

An NHS Confederation briefing

August 2020

The Northern Ireland (NI) Protocol was signed by the EU and UK as part of the Brexit Withdrawal Agreement and sets out an outline for changes that will take effect when the UK leaves the EU at the end of December 2020. It aims to avoid a hard border on the island of Ireland in the event of a no-deal Brexit, protect the Good Friday Agreement and ensure that Brexit does not destabilise NI.

However, dispute about the interpretation and implementation of the NI Protocol is proving to be an obstacle to 'goodwill' in the Brexit process.

This briefing provides some context around the agreement, the issues it raises for health and social care services, what the protocol means in terms of change for players in the health sector, and explores developments since its agreement.

Key points

- The significant integration between NI and the Republic of Ireland (RoI) on a range of health and social care issues means Brexit could affect the sector's professionals as well as services and patients in areas including:
  - trade and regulation of medicines and medical devices
  - data
  - mutual recognition of professional qualifications (MRPQ)
  - public service delivery
  - EU funding and cross-border working.
- Implementation of the protocol is a major issue for the EU – if the UK government sought to renege on its commitments, the integrity of the EU customs border could be at risk.
- Outside of the honouring of the protocol as signed in January 2020, the key priority now is to find a way to practically operationalise it.
- There is little time to put in place the operational measures for the protocol to function, and there are reports of little preparation having been put in place to date in areas such as trade, despite new border arrangements due to come into force on 1 January 2021.
- The NHS Confederation will continue to follow developments, analyse the implications for the health sector in the UK and push for as much clarity as possible on the implementation of the NI Protocol from 1 January 2021.

1. Background

The Northern Ireland Protocol was signed by the EU and UK as part of the Brexit Withdrawal Agreement. It aims to avoid the introduction of a hard border on the island of Ireland in the event of a no-deal Brexit, protect the Good Friday Agreement and ensure that Brexit does not destabilise NI.

An obstacle to 'goodwill' in the Brexit process is a looming dispute about the interpretation and implementation of the NI Protocol. There is a belief in Brussels that the British government might look to change the protocol, with mistrust heightened by the UK government's rejection of a proposal to set up a European Commission office in Belfast to supervise new border arrangements. Implementation of the protocol is a major issue for the EU – if the UK government sought to renege on its commitments, the integrity of the EU customs border could be at risk.

Outside of the honouring of the protocol as signed in January 2020, the key priority now is to find a way to practically operationalise it. In May, the government published The UK's Approach to the NI Protocol, which offers some insight to the arrangements that will be required to see NI remain in the UK customs territory while also remaining in practice part of the EU single market for goods.

There is little time to put in place the operational measures for the protocol to function. Using trade as an example, despite new border arrangements due to come into force on 1 January 2021, there are reports of little preparation having been put in place to date and a question of how the system will work for the c.2,500 trucks that cross the Irish Sea to and from NI per day.

The implementation of the protocol will be overseen and monitored by an EU-UK joint committee, as well as by an Ireland/NI specialised committee that sits underneath it. Arrangements on retaining those aspects of EU law covering trade are dependent on periodic consent from the Northern Ireland Assembly, with the first vote to take place in 2024.

The first meeting of the Ireland/NI specialised committee took place on 30 April 2020. At this time, little detail has emerged except to underline the importance of the UK setting out its plans regarding implementation measures prescribed by the protocol and providing a detailed timetable. The NI committee in July expressed their concern that 'in spite of the importance and urgency of the work to be done by the joint committee and specialised committee in order to implement the protocol, they have met a combined total of three times.' The consensus is that exchanges in the specialised committee now urgently need to be followed up by tangible measures.

2. The key issues for health

There is significant integration between NI and the Republic of Ireland (RoI) on a range of health and social care areas, which means Brexit could affect the sector's professionals as well as services and patients. Issues include: trade and regulation of medicines and medical devices; data; mutual recognition of professional qualifications (MRPQ); public service delivery; and EU funding and cross-border working.

Trade and regulations

The Withdrawal Agreement agreed to separate the post-Brexit regulatory treatment of NI from Great Britain (GB). NI remains de facto in the EU single market and customs union and will become subject to EU jurisdiction indefinitely. The most detailed interpretation of the NI Protocol was published by the European Commission in March 2020, which interprets the protocol as meaning movement of medicines from GB to NI is classified as importation into the EU. Regulatory governance and medical supply chains are inextricably linked because they impact products' regulatory status and ability to move without disruption across borders.

Questions of interpretation and enforcement of regulations in NI will be decided by the EU and ultimately the European Court of Justice. However, NI would remain part of UK customs territory constitutionally so HMRC, not EU officials, and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) should administer the necessary controls. For example, the MHRA remains responsible for placing the goods on the market and monitoring products once sold, but they will have to be approved through European procedures because NI would be treated as a member state in terms of regulatory decisions.

In terms of physical checks, the government paper The UK's Approach to the NI Protocol states that 'some limited additional processes' would be necessary for goods arriving in NI from GB, but that the government saw no need 'to construct any new bespoke customs infrastructure.' Based on more recent UK government guidance from August 2020, on moving goods under the NI Protocol, we now know that UK authorities will apply EU customs rules to goods entering NI from January 2021 so there will be new administrative process for traders, notably new electronic import declaration requirements, and safety and security information. As some of the detailed procedures will depend on the outcome of discussions within the UK-EU joint committee, further details are expected be set out in due course. There will be no change for the movement of goods covered by the protocol between NI and EU member states, including RoI, so there will be no new paperwork; no tariffs, quotas or checks on rules of origin; nor any barriers to movement.

In terms of medicines and medical devices, these goods are not generally checked at the EU border. Their safety is maintained by behind-the-border checks, such as those carried out by trading standards officers, and product authorisations. Medicines brought from GB into NI will be considered 'imported medicines' so will have to have a marketing authorisation granted under EU law. Medicines sold in NI will have to be labelled with the details of the holder of the marketing authorisation or their local representative. Both must be located either in NI or an EU member state, not in GB.

The concern is that there will be delays in the import and export the medicines and medical devices that need to continue to reach patients as quickly as possible. Avoiding delays caused by tariffs and regulatory barriers requires the UK and EU to reach agreement on shared standards, such as manufacturing and inspection, so that goods can be licensed for rapid release onto the UK market, or vice-versa.

With potential new checks and a lack of clarity on how the regulatory framework will apply, this could create unnecessary delays. However, some easements are possible. For example, it is expected that medicines and medical devices marketed in NI will be recognised by MHRA as compliant to be placed on the GB market. This will make it easier for products to flow into GB, but does not work in the other direction.

An NI Affairs Committee inquiry recently suggested that the proposed future arrangements create new barriers to free trade within the UK internal market. It confirmed goods moving from GB to NI would attract 'new administrative requirements and associated costs,' warning that NI businesses 'will trade at a competitive disadvantage with other UK firms' with the people of NI facing higher costs of living and reduced choice as a result. To prevent any disincentive to trade, the committee recommended the government commits to covering all the costs to business for complying with the protocol, and that those trading across the Irish Sea get clarity on the required preparations by 1 October 2020.

Data

Divergence in data standards could make information sharing between institutions, such as hospitals and businesses, more difficult unless there is an agreement on data adequacy. An adequacy decision would permit transfers of personal data for the purposes of the General Data Protection Regulation (GDPR) to the UK, as part of the Brexit deal. With the two negotiating sides prepared to contemplate ending the transition period with no trade agreement in place, an agreement on data cannot be taken for granted and planning needs to take that into account.

An example of what this means in terms for NI organisations:

A health and wellness organisation working in the border area of NI, which has participants who reside in the RoI, might collect and store information relating to these people. If the organisation works on a funded project with a partner located on the other side of the border and personal data is transferred between them, then the GDPR's provisions on international transfers would be triggered after the UK has left the EU, regardless of where the participants reside.

As the UK government has stated its intention to allow personal data to flow freely to the EU and EEA after Brexit, then data transfers from the UK can continue be made as before. However, transfers to the UK must satisfy the appropriate safeguards set out in the GDPR. Under no deal, as there will be no adequacy decision for the UK on the date of exit, the best option may be the incorporation of standard contractual clauses. Both organisations will need to ensure that these are in place before the date of exit so that any transfers from the EU to UK can continue to occur.

Source: NICVA

Public services

The Good Friday Agreement provides for the creation of the North/South Ministerial Council to facilitate cooperation between NI and the RoI and covers collaboration on various cross-border healthcare services. In addition, the Common Travel Area guarantees reciprocal access to healthcare, but Brexit may present some practical challenges, like for the sharing of data.

This has created a question in NI around whether residents will continue to be able to access public services across the border. NI patients often travel to hospitals in the RoI for specialist services and vice versa. For example, children with heart defects have been treated in Dublin since the closure of services in Belfast, while cancer patients from Donegal receive radiotherapy in Derry.

Further clarity is required on how all-island healthcare services will continue unimpeded in the event of a no-deal Brexit when provision will no longer be underpinned by EU law on the free movement of people and services and the possibility of land border barriers regulating the movement of goods.

MRPQ and cross-border workers

The NI Protocol makes provisions for the continuation of the Common Travel Area, which allows British and Irish citizens to travel, work freely and access education, social security and healthcare services in either the UK or Ireland. However, this will not apply to third country (including EU) nationals, who will be subject to UK and Irish immigration rules. This could be a problem for third country national doctors who live in RoI and normally cross the border to work in NI – and the reverse.

In terms of professional qualifications, healthcare professionals whose qualification was recognised on either side of the UK/EU border before the end of the transition period will continue to be registered. If they apply for registration before the end of the transition period on 31 December 2020, even if their registration is granted after this date, then they will benefit from the grandfather rights in the Withdrawal Agreement.

In Ireland, an amendment has been passed to the Medical Council of Ireland law to add UK qualifications to the list of qualifications whose holders are exempt from sitting a further examination (PRES), which means that holders of UK qualifications who apply after 31 December 2020 can be fast-tracked. In the UK, the General Medical Council has agreed to fast-track applicants with EEA qualifications for professional registration, regardless of their nationality, for at least the first two years after the end of transition.

If there is no trade deal between the UK and EU, the no deal Medical Act amendments will be enacted on 1 January 2021. This creates a new route to recognition for holders of an EEA qualification whereby if their qualification is listed in Annex V, it is sufficient as evidence of skills, knowledge and experience. The applicant will only need to have their qualification primary source verified and provide evidence of English language competence, as any other international medical graduate (IMG) would. As one of the exemptions for having to pass a language test is where a qualification was fully taught in English, this will exempt holders of an Irish qualification from having to sit a language test.

The no deal Medical Act amendments are mirrored in the Nursing Act, Midwifery Act, Dental Act and Pharmacy Act. They will be in place for a maximum of two years, unless revoked sooner by the government. After that time, all those from EEA countries are likely to fully follow the GMC's IMG route until or unless mutual recognition of qualifications is agreed across the board.

EU funding

NI and RoI border counties have benefitted greatly from sources of EU funding, mainly INTERREG and PEACE. The region was allocated €283m of INTERREG VA Programme funding (2014-2020) designed to help overcome the issues relating to the existence of a border. €240m was provided through the European Regional Development Fund, the remaining €43m was match-funded by the Irish government and the NI Executive.

The content of this programme has four core objectives, which include providing health and social care services on a cross-border basis. Various services have been rolled out, including Children's Services Multiple Adverse Childhood Experiences programme, which secured €5 million, and an acute hospitals services project, which secured €10 million through this funding.

The Special EU Programmes Body recently clarified that even in the event of a no-deal Brexit, funding under the current INTERREG programmes will continue until conclusion in 2023. It is anticipated that funding programmes will continue after Brexit as part of the EU funding budget 2021- 2027 and it is hoped that sufficient allocation of funds will be forthcoming regardless of how the UK exits the EU.

3. Asks for health and next steps

The NHS Confederation, alongside partners in the Brexit Health Alliance (BHA), have identified the issues facing the NI border as some of the most pressing. The BHA recently drew attention to the issues of access to medicines and medical devices after Brexit in a paper in June 2020: Negotiating a New Relationship with the EU that Safeguards Patient Access to Medicines and Medical Technologies. The BHA asks that clarification on the interpretation of the NI Protocol is provided urgently and that the UK is pragmatic in its implementation in relation to medicines and medical devices.

The paper highlights that since NI will stay bound by the rules of the EU's single market, in areas such as product requirements and medicinal safety, this will impact trade in terms of regulation, approval, packaging, commercialisation, and supply and monitoring of medicines and devices, which may require re-design. Life sciences companies have advised that any adjustments to regulatory systems and supply chains can take more than a year to implement.

The central BHA ask is for a mutual recognition agreement (MRA) to be included in future relationship agreement, as described in the draft treaty text sent to the EU in June, but there is no clarity on where the negotiations are on this currently. It is hoped an MRA will minimise delays in products reaching UK and EU patients and is similar to existing arrangements the EU has with many third countries. The lack of an MRA is not expected to impede the movement of goods in the other direction from NI to GB. From the European side, European biotech and pharmaceutical trade associations, such as EFPIA, have also written to the European Commission calling for the negotiations to prioritise health and patients' access to medicines by agreeing to this request.

Other of the NHS Confederation's industry partners have called for a technical working group of industry, regulators and health systems to be established under the new joint committee mechanism, so that everyone has enough clarity and time to plan and implement any changes needed to avoid disruption to patients.

Preparations to implement the NI Protocol

The EU-UK joint committee and specialised committees will continue to meet to monitor the implementation of the Withdrawal Agreement, but the UK has a legal responsibility to ensure that the protocol is fully operational by the end of the transition period on 31 December 2020. After the end of transition, the protocol creates new possibilities of future legal divergence between NI and GB. The extent of this divergence will depend, in part, on the outcome of talks on the future relationship.

Although a successfully concluded free trade agreement (FTA) between the EU and UK would, in some respects, reduce some border friction, even an ambitious agreement could not avoid them. Given the scale of the implementation task, the government and agencies will need to plan for a 'base case scenario,' as they have done for no deal, assuming no zero-tariff FTA. The

UK government will need to have a clear picture of trade flows from GB to NI, and in particular, their end destination, to be able to define the extent to which goods are likely to travel on into the RoI. The joint committee will require assurance that border arrangements are appropriately designed for the scale and nature of trade.

Practically, the UK government will need to scale-up existing systems for customs administration. This involves expanding existing processes and IT systems currently in place for trade between the UK and the rest of the world and applying them to the Irish Sea trade route. UK agencies will need to build capacity to manage the increase in customs formalities, including recruiting and training additional customs officers.

NHS European Office

The NHS European Office is the conduit for the NHS to engage with the EU agenda. Hosted by the NHS Confederation, we are the representative body for the range of NHS organisations in England on EU affairs and we regularly seek input from NHS representatives to help us assess potential implications for the NHS of EU policy and legislation, in order to develop our position papers and influence our lobbying strategies at European level.

Our work includes:

- monitoring and influencing EU policy and legislation in the interest of the NHS
- playing a key role in analysing the implications of the UK's vote to leave the EU on the NHS
- facilitating access to EU funds for NHS bodies and their partner organisations
- supporting pan-European collaborations and sharing successful EU practices.

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NORTHERN IRELAND CONFEDERATION FOR HEALTH AND SOCIAL CARE

Northern Ireland Confederation for Health and Social Care

The Northern Ireland Confederation for Health and Social Care (NICON) is the voice of the organisations in the integrated health and social care system (HSC). Its members include all HSC trusts and the regional organisations (HSC Board, Public Health Agency, Business Services Organisation and the Patient and Client Council), five of the smaller HSC bodies and the five local commissioning groups.

NICON's purpose is to:

- influence policy and other areas of interest (including providing an employers' voice) on behalf of members
- support and brief members
- inform and influence the media and politicians about key issues in the HSC
- connect members with other stakeholders and with the UK NHS Confederation.

For more information, visit www.nhsconfed.org/nicon

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