

Opening Statement of Professor Imelda Maher MRIA, Dean of Law and Sutherland Full Professor of European Law, UCD Sutherland School of Law to the Oireachtas Joint Committee on Health, November 6 2019

The Legal Implications of Brexit for Health Policy

1. Introduction

Whatever form it may eventually take, Brexit has profound implications for human health on the island of Ireland and for Irish citizens in Great Britain. Brexit will affect cross-border delivery of health services, production and regulation of and trade in pharmaceutical products and medical devices, etc. Key assumptions underpinning health services and products over the last decades will be changed.

In this opening statement I provide an overview of the two most important legal frameworks in relation to Brexit. First, I will comment on the revised Northern Ireland/Ireland Protocol and the revised Political Declaration from October. Second, I will review the 2019 MoU on the Common Travel Area (CTA) between Ireland and the United Kingdom. Professor Hervey will then delve into the more specific issues pertaining to health.

2. The Revised Ireland/Northern Ireland Protocol and the Revised Brexit Political Declaration

2(a) Withdrawal and a later Trade Agreement

Governance

The Withdrawal Agreement (WA) is the instrument under which the UK leaves the EU. This is, as you know, phase one and is governed by Article 50 TEU. It does a number of things including setting up a governance structure (Title II). The Joint Committee and its specialist committees operationalise the WA (Article 164). These committees could prove to be very important, but I note that the Agreement refers to the Joint Committee having an official (singular) appointed by the UK and by the EU to it which seems rather minimal given the range and complexity of matters to be addressed going into Phase II, under which the long term trade relationship between the UK and the EU will be defined. When the Phase II trade

agreement comes into effect, there will be new governance arrangements but here, there is reference again to a Joint Committee which suggests there will be a roll over between the Withdrawal Agreement and the new trade agreement (Part IV, Revised Political Declaration). The continuity is important to support as smooth as transition as possible.

The Form of the Phase II Trade Agreement

In the WA it says the new relationship could be an Association agreement. An Association Agreement is one entered into by the EU with neighbouring countries (Article 120). The main part of these agreements is a deep and comprehensive free trade area. This would be a close relationship. However, the revised protocol and political declaration loosen the binds between the UK and the EU compared to the deal agreed in December 2018. The Northern Ireland border remains invisible but the UK is free to enter into trade arrangements with non-EU states as it will not be in the customs union after transition so it is possible that the final agreement will not be as close as an association agreement.

The greater the divergence, the greater the disruption to trade and to consumers.

The Transition Period

The revised Political Declaration sets out a preliminary roadmap for that next phase of negotiation under Article 218 TFEU. Phase II will be much more involved legally. Trade deals are complex and the law is very detailed while the politics require a careful balancing. The time frame for negotiation of Phase II – the Transition Period - is up to the end of 2020 with an extension of another two years possible under the WA. During this phase, the UK will be outside the EU but will continue to apply the EU rules. The unravelling and redefining of 45 years of union membership is going to take more time than that and unless further extensions are sought, there will be a fall back to WTO rules which will greatly impede trade between UK and the EU (but for Northern Ireland). One exception to this is that the parties aim to have a system in place to allow transfer of data and data protection rules in place by the end of 2020 (Political Declaration Articles 8 and 9).

Parliamentary Approval of the new Trade Agreement

One further reason why it will take time to develop and bed down the new trade relationship is that unlike withdrawal, the trade agreement is likely to be what the EU calls a mixed agreement, which means that the competence/powers concerned lie with both the EU (which

unlike a state does not have full sovereign powers – only those powers given to it by the treaties), and the Member States. As trade agreements are international treaties, they have to be approved under each Member State’s constitution which, typically, requires parliamentary approval. This may mean up to 44 different parliamentary chambers across Europe approving that deal (and the risk of further delay, as occurred with the EU-Canada FTA). If there is no future trade agreement, then the UK/EU relationship will revert to WTO rules (“the hard Brexit”) except for Northern Ireland as the new protocol ensures no hard border once there is consent.

2(b) The Revised Northern Ireland/Ireland Protocol

The main changes of the revised Protocol are that

- (i) The infamous backstop has now been superseded;
- (ii) The UK is much freer to enter into trade deals as it will not be in the customs union;
- (iii) The Northern Irish land border will remain invisible;
- (iv) Northern Ireland will be part of the UK customs territory and of the EU customs regime.

Legal Status of the Protocol

Protocols have the same status as treaty provisions – they are simply more self-contained to focus on specific issues. This containment facilitated the renegotiation of the WA as the EU will not reopen the Agreement in its entirety – only two articles were changed in the October negotiations (Articles 184 and 185) and the changes are mainly related to the revised timeline. The Protocol will come into effect at the end of the transition period (but for some provisions mainly relating to setting up governance).

The Trade Rules under the Protocol

Northern Ireland has made up between 10%-12% of total exports from Ireland to the UK and between 7-8% of imports between 1996-2016. Given Northern Ireland has 3% of the population of the UK, this shows the depth of integration of the two markets which is mainly in relation to agriculture and food products. The new arrangement will allow this integrated trade pattern to continue but it is not clear the extent to which the UK will be by-passed for EU-destination goods to and from this jurisdiction.

In effect, once the transition period is over, goods coming into Northern Ireland from Great Britain will be subject to controls to ensure that the Single Market and VAT rules are met before the goods reach this island. Similarly, goods leaving Ireland for Great Britain will be subject to controls i.e. additional paperwork for customs and regulatory compliance which will lead to additional costs and time. Businesses can look for Authorised Economic Operator status but this may not be a cure-all to avoid all inspections for example. A high level of cooperation between Irish and British ports will be required partly to minimise delays, misunderstandings and disruption. Direct links to mainland Europe will become more common for Irish traders.

The Protocol states that Northern Ireland is part of the UK customs territory (Article 4). It is also part of the EU customs union and cannot impose any tariffs/taxes on goods from the EU different from those imposed on Northern Irish goods. In essence EU and UK customs unions will co-exist in Northern Ireland. When goods go from Great Britain to Northern Ireland and do not enter the EU, then a system of rebates will be given. The challenge is a risk of 'leakage' from Ireland to Great Britain via Northern Ireland or from Northern Ireland to Ireland (EU) of non-EU goods (i.e. goods from Great Britain or outside the EU that came through Great Britain), without the payment of relevant tariffs or compliance with relevant EU/British standards.

To address this, the specialist committee on implementation of the Protocol on Ireland/Northern Ireland (Article 165(c)DWA) is central. It is this committee that is tasked with setting the criteria for considering that goods brought into Northern Ireland from outside the Union is not at risk of subsequently being moved into the Union considering:

- (i) the final destination and use of the good;
- (ii) the nature and value of the good;
- (iii) the nature of the movement; and
- (iv) the incentive for undeclared onward movement into the Union, in particular incentives resulting from the duties payable.

This exercise starts immediately the Protocol is ratified by the parties.

The Protocol itself states that EU laws on the **Single Market** will continue to apply to Northern Ireland, (A5(4)) as listed and identified in the second appendix. These include sections on medical devices, chemicals and substances of human origin.

Northern Ireland also remains in the UK for the purposes of **VAT**. EU VAT rules apply for goods and exemptions granted by Ireland will extend to Northern Ireland to keep consistency on the island. The UK authorities will collect.

The relevant standards in Northern Ireland are British and EU **standards**. **Origin labelling** can now include UK(NI) so the special status of Northern Ireland is clear. Inspections to ensure compliance with EU standards can be carried out vis a vis Northern Ireland by British officials. Specifically, the Revised Protocol states that a qualified person in Northern Ireland can test and release a batch of a medicinal products imported into or manufactured in Northern Ireland.

Safeguards can be introduced where the application of the Protocol leads to serious economic, societal or environmental difficulties.

Governance

While respecting EU Law, the aim of the Protocol is to maintain the conditions that allow for continuing North-South cooperation in a range of fields including health. New arrangements can be entered into that build on the Good Friday/Belfast Agreement (Article 11). The terms of the Protocol continue after four years if a majority of the MLAs in Stormont are present and vote to continue. If there is cross community consent (majorities set out in the Protocol), the Protocol continues for 8 years.

The specialist committee oversees this protocol (A14). A working group meeting monthly will be concerned with information exchange and report into the Specialist committee which in turn reports to the Withdrawal Agreement Joint Committee. The specialist committee will consider matters brought to its attention by Northern Irish rights bodies. Should a health matter arise that has a rights dimension it may be raised with this body.

Note that the Preamble of the Protocol and the Withdrawal Agreement both state that the rights and obligations of Ireland under the rules of the Union's internal market and customs

union must be fully respected (presumably by the UK). The legal status of the preambles of international treaties is not clear.

Main Changes

The main changes from the previous Protocol is that the UK is no longer within the customs union. Northern Ireland is where British and EU customs and regulatory standards will meet, and this arrangement will continue as long as the Northern Ireland Assembly continues it in its periodic voting. There will be no physical border on the island, much beyond what we have today with occasional spot checks, number plate reading etc. The UK will undertake tax collection for the EU and there will be checks on goods in Great Britain going from there to Northern Ireland and vice versa. This ensures goods from outside the EU do not enter the EU without payment of proper tariffs and meeting the correct standards. The myth of technical solutions to a physical land border is gone and the UK is free to enter into international trade deals.

2(c) The Revised Political Declaration

The Declaration addresses the principles that will frame the future relationship and must be read in light of EU and UK obligations as members of the WTO. It is aspirational (it uses the word 'ambitious' repeatedly) and gives an indication of future direction only.

The Revised Declaration states that the EU and the UK will develop a comprehensive trading partnership while also acknowledging that they each retain their regulatory and economic autonomy to ensure they meet their own legitimate public policy objectives – of which a long list are provided including public health, social services, safety, public morals, social or consumer protection, privacy and data protection(para 18). Regard is also had to exceptions particularly in relation to security.

It is trite to say it is not clear what an ambitious trading relationship will look like. We know that each of the two Unions will have separate markets and distinct legal orders (Article 20) but envisage comprehensive arrangements to set up a free trade area, with deep regulatory and customs cooperation, and a commitment to a fair playing field (Article 21). The trade agreement will address all sectors and have no tariffs, fees, charges or quantitative restrictions with appropriate and modern rules of origin. All that is said about customs

arrangements is that they are to be in line with the broad principles of an ambitious trading relationship (Articles 19 and 22).

On regulations the parties are autonomous but are aiming to avoid unnecessary barriers to trade. The aim is to go beyond WTO rules in relation to technical barriers to trade (TBT) and sanitary and phytosanitary measures (SPS). For SPS the aim is to treat each Union as a single entity, including for certification and recognition of regionalisation on the basis of appropriate epidemiological information provided by the exporting party. The extent to which the UK will cooperate with agencies such as the European Medicines Agency (EMA), the European Chemicals Agency (ECHA) is to be explored, but there is no commitment beyond that. For technical barriers to trade, a common principles approach is to be taken for standardisation, technical regulations, conformity assessment, accreditation, market surveillance, metrology and labelling (Article 23).

The political declaration notes that there should be (yet again) ambitious, comprehensive and balanced arrangements on trade in services while respecting each Party's right to regulate (Title III). The aim is to go well beyond WTO commitments and drawing on recent EU FTAs with substantial sectoral coverage in line with Article V of the General Agreement on Trade in Services (GATS – part of the WTO), with appropriate exceptions. Specific mention is made to professional services but not to health services. Article V GATS allows members of the WTO to enter into regional trade agreements with each other designed to liberalise trade in services provided they have substantial sectoral coverage and eliminate substantially all discrimination. The agreement must not raise the overall level of barriers to trade in services with other GATS members not part of the regional agreement. This would require data on levels of trade with those states before the agreement – which may be hard to come by. There is very little law on Article V of GATS so its exact meaning and scope is not clear.

The new regime will address market access and non-discrimination under host state rules for the Parties' service providers to allow temporary entry for natural persons for business purposes in defined areas – this would allow e.g. physiotherapists, dentists or other self-employed health providers to operate in either state (article 29).

While the UK and the EU want to preserve their regulatory autonomy, the aim is to be transparent, efficient and compatible to the extent possible. Particular tools will be used e.g.

licensing and voluntary regulatory and cooperation with information sharing and arrangements for recognition of professional qualifications (Articles 31-34).

Note that under Title VII while the intention is to develop Intellectual Property Rights protections that go beyond those found in the WTO regime, each party will determine their own exhaustion of rights arrangements i.e. the duration of the protection afforded for e.g. trademarks and patents, which is significant for medicines and leaves open the option of different licensing regimes between the UK and the EU.

The commitment to a fair playing field means that the parties will uphold common standards in areas including competition and state aid, environment and tax (note Northern Ireland will be subject to EU state aid rules). The main difference between this and the original agreement, is that the commitment to a level playing field is in the political declaration rather than the legally binding withdrawal agreement. While the EU had concerns about the UK being a low-price competitor right on its boundaries, now the UK is not going to remain in the customs union the EU can impose tariffs to counter lower costs due e.g. to lower labour costs.

The UK would have been more closely aligned to EU regulations under the December 2018 Declaration than it is under this one. It is choosing greater freedom to enter into other trade agreements than to align itself too closely with the EU. Whether it chooses to do that in practice will only become apparent over time as the details of the trade arrangements with the EU are worked out. For now, the only certainty is change with greater administrative and other costs inevitable for EU(Irish)/Great Britain trade.

3. The Common Travel Area (CTA)

This is a free movement arrangement between the UK and Ireland for their citizens with reciprocal and associated rights. It significantly softens the implications of Brexit for Irish and British citizens in the two states. The revised Ireland/Northern Ireland Protocol (Article 3) and the Political Declaration (Article 54) expressly allow for the UK and Ireland to continue with and to develop the CTA, subject to fully respecting the EU Law rights of natural persons. As the CTA is a bilateral agreement that predates British and Irish accession to the EU, it did not require the consent of the 27 EU Member States to stay in place. Note that the Revised Political Declaration states that the future EU/UK relationship must allow for the UK to end free movement of people between the EU and UK.

Governance

The CTA was not written down until an MoU was signed in May this year between the British and Irish governments and it remains a legally non-binding and flexible arrangement to which both governments have expressed their commitment. Goodwill is critical for its ongoing operation. To that end, a committee of senior officials from the two jurisdictions will meet at least once a year in coordination with (non-specified) but structured intergovernmental arrangements and complementary to the pre-existing CTA Forum on Immigration matters. It is this committee that issues pertaining to Irish citizens going to the UK or those living in Northern Ireland and coming to Ireland will be addressed.

Rights and Privileges

The reciprocal rights listed in the MoU are rights to work/be self-employed; to social protection; social housing; education; and voting rights in parliamentary and local elections. These rights are relevant to medical staff looking to relocate to either jurisdiction. Specifically, in relation to education and work, the MoU notes that recognition of qualifications are essential to facilitate the right to work. The governments commit to ensuring comprehensive measures to be in place for recognition, covering all relevant professions. And finally, the CTA gives citizens the reciprocal rights to access emergency, routine and planned publicly funded health services.

It is important to note that the CTA does not extend to those who are not citizens of either state so EU nationals who are not Irish will not enjoy these rights and nor do non-EU nationals legally resident in either state.

de Mars, Murray, O'Donoghue and Warwick in their 2018 report drew attention to those CTA rights that enjoy legal protection and those which are more practice and custom. For example, access to public health care is covered by legislation, while reciprocal health care arrangements such as cross-border treatment are based on informal Service Level Agreements and an MoU. The right to work is also covered by legislation. Existing arrangements will continue but the fact the agreement is flexible means it may change over time.

The MoU was necessary because rights protected by EU Law that previously existed for Irish citizens in the UK, will no longer exist as a matter of EU Law and instead citizens will rely on

domestic legislation and this non-binding but very willing CTA MoU. The rights under the CTA are extensive and, provided the governments remain committed and continue to work together, there should be very little disruption to the experience of British and Irish citizens in the two jurisdictions.

4. Conclusion

These are uncertain times. While I have focussed on the most recent version of the Brexit arrangements, the path to their approvals are politically fraught. The CTA seems secure and uncontroversial.

For the trade relationship, the greater flexibility the UK now has vis a vis international trade may be sufficient to secure the Brexit agreement. Even if agreed, it is not at all clear when and what form the trade relationship will take and the threat of no-deal by default after transition remains though there seems little or no appetite for a no deal outcome given the dire economic warnings that come with it given the costs associated with the additional tariffs, customs, checks and controls (especially for heavily regulated goods like medical devices). Brexit costs, but no deal costs more. This realisation should lead to an agreement in Phase I and Phase II but uncertainty remains.

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