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Opening statement

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Introduction

I am a professor of EU law, and I have been researching and teaching the European Union's health law and policy since the 1990s.

I have been asked to talk with you today about the legal implications of Brexit for the Irish health sector, particularly focusing on future EU-UK relationships. My work on Brexit and health law is supported by the UK's Economic and Social Research Council.

As your Committee noted in its May 2017 report on the subject, the implications of Brexit for health is a matter about which there is significant uncertainty. Although things have developed since then, we will not have legal certainty until the terms of the UK's withdrawal from the EU are legally defined, and the terms of any future EU-UK relationships. Planning for Brexit in the health sector, like other sectors, is a question of contingency planning for unknown possible futures. Unlike other sectors, though, the health sector involves people's bodily safety, dignity, and, ultimately, their lives.

One thing that is certain is that the effects of Brexit on health will be significant, and will be negative (Fahy et al 2017, 2019). The effects will also fall unevenly. They will fall most heavily in the UK, especially in certain geographical areas and among certain social groups. But the effects of Brexit on health *outside* the UK will *also* fall unevenly (Hervey, 2020). And, as the Committee is aware, Ireland is one of the places outside the UK in which negative Brexit health effects will be most keenly felt.

The other key point from our research so far is that the effects of Brexit on health will differ, depending on the type of Brexit. In short, 'No Deal' Brexit is worse for health.

The current legal position

Let me outline briefly what we do know about the legal position, before turning to outline some of the specifics for health.

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We know that 'No Deal' Brexit did not take place on 31 October 2019. And we know that if the Johnson government gets re-elected on 12 December 2019, it will try to secure agreement from the UK Parliament for the October 2019 Withdrawal Agreement. Apart from the Protocol on Northern Ireland, that is substantively the same as the May Withdrawal Agreement, and it works by securing continued application of EU law as far as possible in the UK until December 2020.

At that point, the theory goes, the EU and UK will have negotiated one or more future agreements. But of course, as Professor Maher has clearly outlined, there is no certainty about that, and indeed the amount of time it takes to negotiate trade agreements suggest further extensions will be required, and so we are facing another kind of 'No Deal' at the end of 2020.

Even if the EU and UK agree a trade agreement, we have only a political declaration on such an agreement. What we can glean from that is that the direction of travel under the Johnson government is more like a 'Canada-style' free trade agreement than the political declaration attached to the May agreement, not something modelled on, say, Norway's relationship with the EU. But of course the details of this are all quite fluid, as outlined by Professor Maher.

Outline of issues for health

If we have a No Deal in December 2020, we are facing all the same kinds of problems for health as have already been flagged by this Committee when it considered the implications of No Deal in October 2019. But even if or when there is a free trade agreement, with a Canada-style free trade agreement, many aspects of the current arrangements will be on a totally different legal footing.

One way that the Committee might wish to conceptualise the contingency planning needed in the Irish health policy sector is as follows. A hypothetical Member State of the EU that is not reliant on the UK post-Brexit for health products, substances of human origin, health services, health professionals or anything to do with health is a Member State which has reduced the risks of Brexit for health to virtually zero. Now of course, that is an entirely hypothetical situation, but it could be a useful way to understand the Irish governmental planning for health post-Brexit. Where being such a hypothetical Member State is neither possible nor desirable, what are the alternatives? Where are the Irish reliances on the UK in the health sector, and how can steps be taken to reduce risks associated with each? Steps to reduce risks can of course involve a combination of either or both of reducing reliance, or securing a robust legal basis for continued reliance.

Products

The key issues here are about supply chains implicating the UK. As Professor Maher has explained, there is to be a separate arrangement for goods entering Ireland from

Northern Ireland. But goods entering Ireland from Great Britain are to be treated as goods entering the EU from outside of the EU. This means putting in place measures to secure continued supply of such products, thinking of WTO rules if No Deal is in mind; and of the as-yet-unknown rules for the future EU-UK trade relationship as intimated – but no more – in the Political Declaration.

There are, as the Committee is already aware, specific issues about products which cannot be stockpiled, like radioisotopes, especially in a No Deal situation.

For pharmaceuticals and medical devices, equipment and consumables, recognising that such products will in practice come from or via the UK into the future is key to planning in Ireland. Even zero-rated products in terms of tariffs (such as pharmaceuticals) will be subject to regulatory checks when entering the EU from Great Britain.

The Committee might seek information about how future reliance on Great Britain could be reduced: this is, of necessity, a longer term strategy. The Committee might seek information on the costs of such a strategy, considering the question of whether such a strategy is, on balance, desirable. In the alternative, if it is not possible to reduce reliance on Great Britain, how can steps be taken to secure continued reliance?

In September 2019, the European Commission (2019a) reported that:

> "As outlined in the fifth Brexit Preparedness Communication of 12 June 2019 [European Commission 2019b], the European Medicines Agency was already close to ensuring regulatory compliance for almost all centrally authorised [medicinal] products in April 2019, while further work was needed for products authorised at national level. Significant progress has been made since then, with more than 80% of nationally authorised products well on track to be in regulatory compliance by 31 October 2019."

The Withdrawal Agreement and the EU's No Deal contingency planning allows for some short-term smoothing of regulatory rupture, for instance for batch testing of medicines (European Commission 2019c).

For medical devices, the European Commission (2019a) reported in September 2019 that not all manufacturers have taken steps to transfer certificates to an EU27 Notified Body. The Health Products Regulatory Agency's website (2019) gives information about two of the four UK Notified Bodies currently certifying medical devices: BSI UK have established in the Netherlands and are transitioning their certificates; UL International (UK) have partnered with another Notified Body.

But the longer term direction of travel indicated by the Political Declaration suggests that Ireland should consider risks associated with regulatory divergence. The Political Declaration to the effect that the UK and EU would like to 'explore the possibility of' inter-agency cooperation between the European Medicines Agency and the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) (clause 23) is obviously far from the current position where marketing authorisations for medicines

are either granted at EU level or are mutually recognised across all EU Member States.

Substances of human origin

As far as I have been able to discern, the Committee's work to date has not considered the effects of Brexit on blood, plasma, human tissue and cells, or human organs. It was reported in August 2019 (O'Regan 2019) that the Irish Blood Transfusion Service was stockpiling with a view to mitigating the risks of delays at ports in the event of a No Deal Brexit.

In terms of securing safety of substances of human origin once the UK is outside of the rules and systems that require Member States to report any unexpected adverse effects on patients arising from substances of human origin, it may be that the Committee is satisfied that the WHO and Council of Europe mechanisms will be sufficient post-Brexit, for sharing information between countries.

People

The UK's House of Lords (2017) and De Mars et al (2018) explain the overlapping legal and informal arrangements appertaining to the position of people with regard to cross-border health care on the island of Ireland. In summary, they are:

- EU Law
- The Good Friday Agreement 1998 which incorporates the pre-existing 'Cooperation and Working Together'
- The Common Travel Area

For health professionals with UK qualifications working in the Irish health sector, those qualifications already recognised before Brexit will continue to be recognised, allowing for continuity (European Commission, 2018: 3). After Brexit, recognition of UK qualifications will be a matter for each Member State (Directive 2005/36/EC, Article 2 (2)). The Committee has recommended in its May 2019 report that Ireland continues to recognise UK medical qualifications post-Brexit.

The practical position of health professionals with UK qualifications within the Irish health sector will be affected by Common Travel Area arrangements. UK nationals who are resident in Ireland have CTA rights (to be treated as 'not foreign' in terms of rights to work, family benefits, access to education, access to public health services and so on) which should make retention of current health professionals and recruitment of new health professionals from the UK easier. Obviously health professionals from other EU Member States (with UK qualifications) will be able to continue to rely on EU law, and be treated the same as Irish citizens within the scope of EU law.

For patients, it is important to unpick the legal basis of current arrangements carefully in order to secure continuity of the current situation. The Common Travel Area's legal form is parallel domestic legislation, rather than a formal legal agreement between states. The *intention* appears to be that the main change here in terms of access to health care will be in legal form (from EU law to domestic law in each state) rather than in content. The Memorandum of Understanding on the CTA (MoU 2019), while not formally legally binding, expresses the intention of the respective governments:

> 9. The CTA affords Irish citizens residing in the UK and British citizens residing in Ireland the right to access emergency, routine and planned publicly funded health services in each other's state, on the same basis as citizens of that state.

But this intention only goes part of the way in securing continuity.

The CTA's access to health care provisions are based on *residence*, whereas EU law gives rights to health care to *visitors.* So the CTA provisions will not, as they currently stand, be a post-Brexit basis for temporary provision of cross-border health care in Northern Ireland where the patient is resident in Ireland (or vice versa). The reciprocal health care arrangements under CAWT are based on informal service level agreements and Memoranda of Understanding: they do not give entitlements to patients to cross border treatment in the way that EU law does.

One group of patients that is not covered directly by the CTA is EU26 nationals residing in Ireland and falling under the scope of the Irish health system because of their rights in EU law. Where provision is currently made for cross-border care with the NI health system (for instance, complex ENT treatment for children in Southern Trust hospitals in Northern Ireland (House of Lords, 2017, para 104)), there is at least arguably an obligation in EU law that those EU26 nationals are to be treated the same way as other Irish residents in terms of access to health care provided through informal arrangements under CAWT. Of course, no obligation in EU law can be imposed upon the UK post-Brexit. If it is accepted that they exist, Ireland's continuing obligations in EU law in the CAWT arrangements could perhaps be clarified. And it is worth considering solidifying the legal underpinnings of the CAWT arrangements pertaining to crossborder health care, perhaps in the future EU-UK relationship(s).

Conclusion: regulatory alignment key focus

The Committee is right to identify regulatory alignment as a key legal question for planning going forward. Many of the challenges for health raised by Brexit are easier to meet if the UK and Ireland, as an EU Member State, remain aligned in regulatory standards and approaches across the range of areas that affect health care and health policy.

Many aspects of alignment are within EU competence, and are outwith the unilateral control of Ireland as an EU Member State. For most regulatory matters for health-

related products; and many for substances of human origin, Ireland will need to exercise influence through the EU institutions. But some aspects of health-related regulation, and most aspects of health services provision remain within Irish competence. Ireland may continue to recognise UK medical qualifications. It may continue to organise its health service provision including cooperation with the Northern Irish health trusts. There are aspects of the post-Brexit legal position that could be clarified, particularly the impact on health service provision of the ending of the application of EU law on free movement of patients and crossborder health service provision.

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