Post-Brexit trade negotiations and health governance

The UK in a Changing Europe

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28th July 2020

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Our NHS is built on a foundation of clear ethical and political values. In his eulogy to equality and fairness, In Place of Fear, Aneurin Bevan clearly set out these values: 'Society becomes more wholesome, more serene, and spiritually healthier, if it knows that its citizens have at the back of their consciousness the knowledge that not only themselves, but all their fellows, have access, when ill, to the best that medical skill can provide'. Agree or disagree with Bevan, his values are clearly stated, and widely popular. Throughout the Covid-19 crisis the British public stood outside their homes every Thursday applauding these values, and the staff protecting them. Will those values survive or change post-Brexit, though?

Newly published research from our project Health Governance After Brexit indicates the need for greater transparency to show the implications of the current UK-EU and UK-US trade negotiations for the NHS, and health more generally. While both negotiations are principally about trade, they have profound implications for health, covering a range of issues from medical product certification and distribution, quality of regulation, and the broader relationship between public and private healthcare providers. Our research compares the negotiating positions of parties in both sets of trade negotiations, and evaluates the implications of those positions for health and the NHS. We analysed UK and EU documentation including draft negotiating documents from both sides, and papers detailing the UK's negotiating position in UK-US trade negotiations, as well as a range of documentary and academic evidence setting out the likely position the US will take in those negotiations.

The EU-UK negotiation

In our study of the EU-UK negotiation, we address multiple areas and indicators covered by the World Health Organisation's health system building blocks, highlight where the determinants of good healthcare may be at risk and the potential misalignment between negotiating positions.

Workforce

Our analysis suggests the EU and UK negotiating positions are consistent on workforce issues, reflecting the ending of free movement and repatriting immigration control to the UK. Both sides envisage limited 'mobility' provisions, visa-free travel for short-term stays, and arrangements for students, researchers and youth exchanges.

After the transition period ends, Common Travel Area rules allowing free movement for British and Irish citizens between their respective countries will still apply. None of the proposed provisions replicate EU free movement law or the Withdrawal Agreement position. The NHS will recruit from the EU on the same basis as it does for the rest of the world.

Medicines

The EU–UK agreement will cover trade in products, including pharmaceuticals, medical devices, medical equipment, personal protective equipment (PPE), and consumables. Substances of human origin, on the other hand (blood, plasma, human tissue, *etc.*) are not viewed as 'products' in EU law, and are not explicitly mentioned in either negotiating position. This will mean much greater continuity than in the 'no deal' scenario avoided as a result of the Withdrawal Agreement being passed. Here, the UK has sought to go further than the EU to maintain stability thus far in the negotiations.

Despite progress, potential pitfalls remain if no trade agreement is reached. Hindrances include rules of origin, possible anti-dumping and anti-subsidy duties, and economic safeguards protecting domestic

producers. While the agreement is likely to include 'customs facilitation' measures to reduce red tape at borders, significant changes will be needed to implement the agreement, for example on electronic paperwork for medical products and components. In November 2018 the Health and Social Care Committee estimated the cost of these changes at £400 million per year.

Non-tariff barriers

In terms of non-tariff barriers for medicines and medical products, the position from the UK perspective seems close to 'Canada Plus', and the UK documents mimic the EU–Canada Comprehensive Economic and Trade Agreement (CETA). While the EU's position refers only to cooperation with international standards bodies, the UK proposes detailed provisions on mutual acceptance of conformity assessments, including UK access to EU electronic information exchange systems. The UK also provides a detailed annex of proposals for medicinal product provisions along the lines of a similar EU-Israel agreement, while the EU has no equivalent position.

Information

On information sharing, the UK will be reliant on the World Health Organisation's (WHO) data structures, which do not have the same coverage or harmonisation as EU data systems. The EU's draft legal agreement does also include the possibility of temporary UK access to the EU Early Warning and Response System (EWRS), but this isn't included in the UK position. Both positions envisage autonomous data protection rules, and no common mechanism for health data protection.

Service Delivery

Here, the EU documents seem to suggest closer alignment than the UK. On working time legislation, the EU suggests a commitment that UK labour standards will not be actively reduced below levels required by EU law, but the UK position doesn't have a similar commitment. In terms of cross-border care, both sides envisage UK participation in the health aspects of the EU-run PEACE project, which – among many other things – governs the provision of cross-border healthcare on the island of Ireland. However, more general provisions on cross-border care and coordination of medical services are missing from both.

The UK-US negotiation

Compared to its UK-EU counterpart, the positions of both parties in the emerging UK-US trade negotiations are much less clear. Our research compares UK and US positions based on statements by both sides, and we find significant concerns with transparency and clarity.

Medicines assessment

The National Institute for Health and Care Excellence (NICE) evaluates medical products for cost-effectiveness before the NHS agrees to fund them. Private US health firms, including the industry's main trade group, Pharmaceutical Research and Manufacturers of America (PhRMA), argue NICE's activities create undue regulatory restrictions and costs. They suggest eliminating cost-effectiveness measures, and by extension bodies like NICE.

Intellectual property

The PhRMA also proposes the US should seek intellectual property protections meeting high international standards, including at least 12 years of regulatory data protection. This would prevent access to data by potential competitors to US pharmaceutical firms and is already enshrined in US legislation. Such a rule would limit competition and enhance the power of these firms in the UK medicines market.

Regulatory protection

Lastly, PhRMA also demand mutual recognition of regulatory provisions, in this case meaning the UK recognising less stringent US regulatory standards. In forthcoming negotiations, PhRMA may push for the elimination of good manufacturing practice as a criteria for medicine manufacture in the UK. In the EU, facilities manufacturing medicines for use in trials must be inspected to ensure they comply with such good practices, but in a US trade deal the UK would likely have to mirror much less stringent inspection criteria.

'Brexternalities'

Besides the impact on health in the UK context, our research also focused on the potential impact of trade negotiations on other EU countries, and particularly UK citizens in EU27 countries and EU countries with close ties to the UK in the field of health. We analysed three areas in particular where there may be a substantial impact of a trade deal: Spain, Malta and eastern European member states.

Spain

Estimates suggest around 190,000 UK pensioners reside in the EU, with Spain being a common destination. These people rely on EU rights to access health care. Removing those entitlements, and not replacing them with something else, would mean they would need to have private health insurance, a significant cost and burden, especially for those with chronic or multiple conditions.

Article 32 of the Withdrawal Agreement governs access to medical care for UK nationals living in EU member states after 31 December 2020. UK pensioners who have retired to Spain – or anywhere else in the EU27 – before that date will be able to access the local healthcare system; while for those who move thereafter, the EU's negotiating documents for the future agreement include continued access to healthcare for pensioners (only, not for others). The UK negotiation position does not reciprocate: EU nationals who retire to the UK after the end of the transition will not have access to the NHS.

Malta

Small EU states with close ties to the UK may be particularly badly affected by a trade deal that distances the UK from EU regulatory institutions. In Malta, for example, health authorities worked with the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), and 60-70% of medicines used in Malta are supplied by UK bodies.

Some large pharmaceutical companies may be reluctant to undertake the costs of securing additional regulatory compliance to supply the Maltese market, if ties to the UK market dependent upon the EU's regulatory processes are weakened. This could have a significant impact on the cost of medicines for end users in Malta.

Central and eastern Europe

A number of central and eastern EU member states have close links to the UK, with many of their nationals currently living and working in the UK. In 2017 the Standing Committee of European Doctors strongly urged the Barnier negotiating team to secure future mutual recognition of UK medical qualifications in the EU. This has been achieved in part in the Withdrawal Agreement, for ongoing recognition of qualifications that were recognized before the end of December 2020.

The UK and EU negotiation texts envisage a weaker form of mutual recognition of qualifications going forward. However, in practice, unless the UK departs significantly from EU standards, there may be relatively few changes. The key difference will be that individuals will no longer be able to enforce rights to have their qualifications recognized. We may therefore see central and eastern European medical professionals choosing other EU countries, as well as the US or Australia, as alternative destinations with better systems for recognizing medical qualifications and accommodating migrant health professionals.

Ireland

The potential impact of Brexit on Ireland, and particularly the Irish border, has been discussed extensively since the referendum result. In health, Brexit may have substantive impacts given the island of Ireland currently has a highly integrated cross-border health sector, protected by the Good Friday/Belfast Agreement and covering access to medical products, provision of health services and workforce arrangements.

The Northern Ireland Protocol in effect assumes that Northern Ireland is within the EU's customs territory, and so various cross-border health arrangements, for example cross-border ambulance travel, are protected. Nevertheless, in terms of patterns of trade in medicinal products, devices and medical equipment, issues remain unresolved in the UK-EU trade negotiations. The threat remains that a non-comprehensive free trade agreement between the UK and EU would put the cross-border health sector in Ireland at significant risk.

Comparing UK-US and UK-EU negotiations

While questions about UK-EU negotiating positions still exist, the evolution of the EU's negotiating position has been transparent. Documents published in February 2020 detail the evolution of the EU's position on the basis of discussion and agreement among the member states. By contrast, the UK's position was developed without consulting Parliament, and the UK's formal position was published in May, two months after the EU. The UK-US negotiations have been subject to even greater secrecy. The UK's position was published without debate in Parliament on 2 March 2020, and the UK has agreed on holding particular texts on the negotiations in confidence for up to five years.

So while we can see growing clarity around the UK-EU negotiating positions, the UK-US negotiation is opaque, and raises several questions about regulatory standards and commitments that might impact on core NHS values. How can cost-efficiency be maintained, and NHS costs kept down, in the event that US negotiators demand such regulatory processes be jettisoned? Will standards like good manufacturing practice be protected, or fall by the wayside under economic pressures? Bevan's values may be alive and well, and ministers say they will protect them in trade negotiations, but we are already seeing potential gaps emerging for competing models of healthcare provision to take priority.