1 Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine, London, UK

2 Department of Health Management and Policy, University of Michigan School of Public Health, Michigan, USA

3 School of Law, University of Sheffield, Sheffield, UK

4 Department of Health Policy, London School of Economics and Political Science, London, UK

Correspondence to: M McKee
martin.mckee@lshtm.ac.uk

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ESSAY

Risks to health and the NHS in the post-Brexit era

Trade deals negotiated as the next part of the Brexit process will have big implications for healthcare, and we need greater transparency say May van Schalkwyk and colleagues

May C I van Schalkwyk, [1] Holly Jarman, [2] Tamara Hervey, [3] Olivier J Wouters, [4] Pepita Barlow, [4] Martin McKee[1]

When it formally left the EU in January 2020, the UK entered the next stage of the Brexit process. This second phase—the transition period—is more demanding than the first. It involves the UK implementing the withdrawal agreement and negotiating trade deals with both the EU and US as part of its post-Brexit global free trade agenda, "Global Britain."

The UK needs to secure a trade deal with the EU to avoid a no deal Brexit at the end of the transition period. Trade policy influences products and services that are potentially beneficial or harmful to health, and this means that the decisions made during this phase will have important implications for health and the NHS.

Amid the covid-19 pandemic, the additional challenge of implementing large scale changes to UK trading arrangements is of great concern. Unsurprisingly, calls have been made for an extension to the transition period and for US-UK trade negotiations to be delayed. However, the UK government seems committed to ending the transition period on 31 December 2020, and a two week round of US-UK trade negotiations beginning on 5 May 2020 took place. Both the US and the UK have stated that a strong trading relationship is important to recovery from the pandemic.[1] The effects of the pandemic on the negotiations are difficult to predict. This is complicated by the uncertainty surrounding the UK's future trading relationship with the EU and the upcoming US presidential election.[2]

The unsuccessful negotiations on a Transatlantic Trade and Investment Partnership (TTIP) between the EU and US suggest that the UK-US trade discussions will not only raise many controversial issues but also attract those with vested interests who seek to influence the outcomes of such agreements.[3] The UK will be under great pressure to agree a trade deal that favours corporate interests, and especially those of the pharmaceutical industry, over public health (box 1). Fundamentally, the UK must choose how closely it wishes to align with, or diverge from, the US on these issues.

Box 1: What is on the table in the negotiations?

Early concerns about the consequences for the NHS of a potential trade deal with the US centred on US healthcare corporations taking over large parts of the NHS, summarised in the words, "NHS not for sale." Such concerns can be questioned given the limited scope for extracting profit from the relatively cheap NHS, although there is scope for carving out profitable niche markets such as some forms of elective surgery.[4] Instead, attention has turned to what might happen to drug prices, which are much cheaper in Europe than in the US.[5 6]

Responding to these concerns, the UK's secretary of state for trade said that "The government has been clear that... the price the NHS pays for drugs will not be on the table. The services the NHS provides will not be on the table. We will not agree measures which undermine the government's ability to deliver on our manifesto commitments to the NHS."[7]

Yet, like many aspects of Brexit, there is much more clarity about what the British government does not want than what it does. The US position is clearer. President Trump has argued that the high drug prices charged to US patients are subsidising the costs of medicines in Europe and other parts of the world.[8] In its written submission to the request for comments on negotiating objectives for a US-UK Trade Agreement issued by the Office of the US Trade Representative, the Pharmaceutical Research and Manufacturers of America (PhRMA, the industry's main trade group in the US) called for "the negotiation of a comprehensive and ambitious trade agreement between the US and the UK."[9]

PhRMA presented the current US trade deficit with the UK in biopharmaceuticals as an indication "of the significant need to negotiate a free and fair trade agreement that eliminates non-tariff barriers and fosters greater exports to this important market."[9] It called for deepening of trade relations and promoted the use of the recently negotiated US-Mexico-Canada Agreement as a "very strong base from which to negotiate a trade agreement with the UK."[9]

However, it should not be assumed that all the current objectives of the US government or drug industry will be translated into a final agreement. After protracted debate the House of Representatives approved the excision of a key term from the recently negotiated US-Mexico-Canada agreement that would have assured a minimum of 10 years of data exclusivity for newly approved biological medicines.[10]

But there is no room for complacency. The House of Commons European scrutiny committee has raised concerns about whether ministers are enabling adequate parliamentary, and by extension public, scrutiny of their decisions, especially when vital public interests such as health and healthcare systems are being discussed.[11] This is more important than ever when media attention is focused on the covid-19 response; the government's refusal in early May 2020 to legislate to retain the EU's food standards

in any future trade deals received limited coverage in the UK.[12]

Based on what can be ascertained on the goals of the UK, the EU, and the US, we highlight five concerns related to pharmaceutical policy, safety regulations, and trade governance that have implications for health and the NHS.

Undermining NICE

The National Institute for Health and Clinical Excellence (NICE) in England and its counterparts elsewhere in the UK have developed systems for appraising the cost effectiveness of medicines and other health technologies. Some commentators in the US, including the industry's main trade group, Pharmaceutical Research and Manufacturers of America (PhRMA), argue that NICE's activities create undue regulatory restrictions and costs—that is, "non-tariff barriers to trade." These commentators argue that such systems for appraising the cost effectiveness of health technologies should be eliminated. This is a logical extension of the US pharmaceutical industry's drive to constrain the use of economic evaluations in US medicines approval procedures, enshrined in the Patient Protection and Affordable Care Act.[13]

We can also expect that, as in the Korean-US trade agreement, PhRMA will demand "meaningful opportunities for input from manufacturers and other stakeholders ... both in the development and the specific implementation of all relevant laws, regulations, and procedures."[9] Such provisions could undermine the independence of NICE.

Extending intellectual property protection

Another core priority for PhRMA is to prolong the period during which brand name medicines are protected from competition from generic and biosimilar products. PhRMA has targeted the rules on intellectual property protection, especially for new biological products. Generic competitors for conventional medicines produce an identical molecule after patents expire, but this is more difficult for complex biological products. Competition therefore comes from what are termed biosimilars, which are similar in structure and effect to the original but whose development requires access to detailed data on the innovative product.

PhRMA proposes that the US "should seek [intellectual property] protections that meet the highest international standards, including at least 12 years of regulatory data protection ... for biologics."[9] This would prevent access to the data by potential competitors and is already enshrined in US legislation. However, the protection is longer than the maximum of 11 years in the EU and the eight years in Canada and Japan—and indeed the five years for traditional, chemically derived products in the US.

Even a single year extension could negatively impact access. Importantly, PhRMA also argues that 12 years of regulatory data protection should be the basis for all subsequent negotiations between the US and UK and other future trading partners.

Weakening regulatory protection

PhRMA's third priority, which at first sight may seem less controversial, is the mutual recognition of certain regulatory provisions, such as good manufacturing practice (GMP). Some elements of GMP are currently aligned between the US and EU and help to avoid unnecessary duplication. However, as the European Commission concluded during negotiations on the now abandoned TTIP, "neither full harmonisation nor mutual recognition seems feasible on the basis of the existing framework legislations in the US and EU."[14]

There are subtle but important differences between US Food and Drug Administration and European Medicines Agency standards for GMP. For example, EU regulations stipulate that facilities manufacturing medicines for use in trials be inspected to ensure they comply with GMP. They also require that facilities receive authorisation to manufacture investigational medicinal products, with a qualified person authorising release of individual batches after checking that they meet criteria for release, including adherence to GMP.[15]

Although we can only speculate about the health implications of departing from the EU regulations, given that their aim is to maximise product safety, it will be important to monitor the consequences carefully. However, once any change is embedded in a new trade deal, it will be difficult to go back.

Of course, a future US-UK trade agreement that aligned the UK with US GMP standards might make it easier for the UK based life sciences industry to access the US market. However, the corollary is that it would make it harder to comply with standards necessary to access the EU market, putting at risk trade with the UK's closest neighbours and threatening the domestic pharmaceutical industry.

Diverging at any cost

Other concerns do not relate specifically to US demands but to the UK's approach to future trade agreements. The UK's approach to negotiating with the EU states that "we will not agree to any obligations for our laws to be aligned with the EU's."[16]

Given the dominance of the EU in UK trade, accounting for 45% of exports compared with 19% to the US,[17] it is unclear how this will be achieved without doing severe damage to the British economy, unless the word "obligations" is interpreted loosely.

However, the government's stance is consistent with the approach observed throughout the Brexit process to prioritise political goals over economic and social ones, and sound bites over details. It is intrinsic to international trade agreements to embody obligations of regulatory alignment.

The precautionary principle, where safety must be established in advance rather than being assumed until proved otherwise, has been attacked. The principle has been described by the UK prime minister, Boris Johnson, as "mumbo jumbo," while the approach adopted in the US, where safety is assumed until harm is proved, has been promoted as a "science based" approach.[18]

The precautionary principle is often applied to chemical and other potential hazards to prevent harmful human exposures and environmental damage. By contrast, the US approach has been associated with an increased exposure to pollution and other toxic or environmental hazards, particularly for disadvantaged communities, further exacerbating environmental inequities.[19] Given UK ministers' apparent preference for the US over the EU as its main future trade partner, the UK may find itself abandoning the precautionary principle.

Decisions behind closed doors

The importance of a potential US-UK trade agreement for health in the UK makes it essential that UK negotiators hear concerns raised by the health community. Yet, British positions have remained secret,[20] despite the call by the House of Commons international trade committee that the government "operate from a presumption of transparency".[21]

By contrast, the EU's negotiating objectives for a future agreement with the UK, published on 25 February 2020, were developed

following publication of detailed documents on 3 February and agreed by all member states.[22] The UK's response was issued on 27 February after a cabinet discussion with no consultation with parliament,[16] and the UK's formal draft legal text of a future free trade agreement with the EU was published on 19 May, two months after the EU's.[23]

The UK's objectives for trade negotiations with the US were also not debated in parliament before their publication on 2 March 2020.[24] Concerns have been raised about the level of secrecy agreed to by the UK, including holding certain texts in confidence for up to five years after concluding any deal with the US.[25]

Importance of scrutiny

Scrutiny in this case is especially important given that views may differ within the government. On the one hand, NHS executives will seek to protect the health service from higher prices, and life sciences research charities seek continued regulatory alignment with the EU, seeing the bloc as a more important collaborative space than the US. On the other hand, some prominent supporters of the government's life sciences industrial strategy support many features of the US approach set out above, which they portray as a means of promoting innovation.[26]

These differences reflect wider divisions between those who argue that new post-Brexit trade partnerships are an essential route to prosperity and economic recovery from the covid-19 pandemic. Some call for a mitigated approach that balances economic integration with a degree of social protection, while others prioritise reducing the risk that stronger trading partners will be able to impose their interests. These contrasting views can be expected to have a heightened relevance in the context of the covid-19 pandemic as governments are being forced to reassess how they can build resilience and dependability in production while leveraging cost savings and efficiencies through global outsourcing and trade.

Complex trade negotiations also require that those with technical expertise have a seat at the table. The US Treasury has argued that it should lead on negotiations on financial services, for example. We do not know whether the UK delegation includes health or life sciences industry representatives, or both, and, if so, how influential they will be. How can we be confident that UK negotiators will bring appropriate stakeholder views to the table if we do not even know what expertise is included in the UK delegation?

Competing interests: MMcK receives funding for research and advice from the European Commission, is past president of the European Public Health Association, is a founder of NHS against Brexit (a civil society organisation), and is research director of the European Observatory on Health Systems and Policies, in which the European Commission is a member. TH is a Jean Monnet professor, formerly partially funded by the EU, and is principal investigator in Economic and Social Research Council governance after Brexit grant ES/S00730X/1. MMcK and TH are members of the advisory board NHS against Brexit, an NGO unaffiliated with the NHS, which campaigned to remain in the EU. TH is adviser to the House of Commons Health and Social Care Committee.

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