Nuffield Trust – Written Evidence (UST0024)

The Nuffield Trust is an independent health think tank. We aim to improve the quality of health care in the UK by providing evidence-based research and policy analysis and informing and generating debate.

This submission aims to answer the questions set out by the Sub-Committee regarding the issues in play for the NHS from a US-UK trade deal. It focuses in particular on the topic of medicines pricing as highlighted by the Committee, examining how both intellectual property and price negotiation could affect this. It also examines issues of the rights of private healthcare providers in relation to the NHS, and other issues relatively little discussed so far.

Overall, we conclude that while the Government's high level pledges that medicines prices will not rise and no "privatisation" will take place will allay some concerns, they are lacking in the detail really necessary to understand the proposed UK response to likely US demands.

1. Drug pricing: processes and price setting

1.1. Overview

The UK currently limits the prices of medicines paid for by the NHS through several layers of controls. At an aggregate level, the Voluntary Scheme for Branded Medicines agreed between the UK and most major pharmaceutical companies caps overall spending growth on these products at 2% per year, with companies having to pay a rebate if it rises too fast.[1]

For specific products, the National Institute of Health and Care Excellence and the Scottish Medicines Consortium investigate how much a drug will improve or save lives to determine whether it is worth the price being charged[2]. This supports a system of bargaining where NHS leaders in the four countries often then try to agree a discount so that they can spend an amount in line with the lives to be saved.

The United States generally lacks these measures. Congress has actually made additions to a law, following industry lobbying, which prohibit the government from negotiating to get medicines at competitive prices.[3] Perhaps unsurprisingly, prices in the USA tend to be far higher: one

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[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761834/voluntary-scheme-for-branded-medicines-pricing-and-access-chapters-and-glossary.pdf

[2] https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance

[3] https://www.politifact.com/factchecks/2017/jan/17/tammy-baldwin/tammy-baldwin-federal-government-prohibited-negoti/

recent study found that its healthcare providers pay an average of three to four times as much as comparable countries for the same branded products.[4]

Any shift towards a system similar to that of the USA would be likely to have several negative effects for the NHS and healthcare in the UK in general:

- The NHS would face paying significantly more money for the same medicines.
- Given that the NHS's funding model means it will always have a limit on total spend set by the Treasury, there would be a pressure to limit the range and volume of other treatments to keep costs controlled.
- Incentives on companies to research and produce effective medicines would also be weakened, as saving and improving lives would no longer be linked as closely to the ability to charge higher prices.

1.2. The UK's positions

The UK's policy document states that "the price the NHS pays for drugs will not be on the table." It is not specific about exactly what changes this would rule out, though it does in particular note the existence of the Voluntary Scheme.[5] It could be argued that the role of NICE, described above, really relates to approval or otherwise rather than actual price negotiation, and that this might therefore not be covered by the pledge.

1.3. The USA's positions, and examples from earlier negotiations

The USA's summary of negotiating aims commits it to "Seek standards to ensure that government regulatory reimbursement regimes are transparent, provide procedural fairness, are non-discriminatory, and provide full market access for U.S. products."

We can gain more insight into what this might mean by looking at earlier US negotiations with developed countries possessing medicine price control initiatives. In its negotiations for the US-Australia Free Trade Agreement from 2001 to 2005, changes to the Australian system of controlling and limiting prices, the Pharmaceutical Benefits Scheme, were a high priority. An Australian parliamentary committee noted that "It could be argued that US negotiators could not sign up to a trade agreement that did not show that at least some attempt had been made

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[4] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.05207

[5] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/869592/UK_US_FTA_negotiations.pdf

to open up the listing and pricing arrangements of the PBS to market competition."[6]

Important political context is that President Trump has been critical of high medicines prices in the USA, expressing a belief that these are caused by other countries bargaining down the prices they pay, and has instructed his Trade Representative Robert Lighthizer to make "fixing this injustice a top priority with every trading partner".[7] However, US ambitions in this area extend through multiple administrations.

1.4. Reflections on possible negotiating outcomes

It is unclear whether the UK's blanket commitment to medicines prices not rising necessarily rules out any changes to processes, as it is hotly debated even in retrospect whether changes in other US trade deals have made any real difference. It would be helpful to see clear UK stances on process changes to decisions to fund medicines, and on new principles like market-based pricing.

Earlier negotiations provide examples of the sorts of compromise that may be suggested.

In Australia, government representatives pledged in early stages of negotiation that "the PBS is not on the table".[8] However, it was placed on the table by US negotiators and ultimately a compromise provision was added. This contained the following key measures:

- Greater transparency of the process.
- A review process for decisions.
- The creation of a Medicines Working Group of federal officials from the two countries.[9]

The most controversial aspect of the process was a legal change which followed the trade agreement and was not explicitly linked to it, limiting the use of cheaper unbranded drugs as a reference point for the price of branded drugs. There is some evidence that this led to higher prices[10]: to

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6 https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Former_Committees/freetrade/report/final/ch04

7 https://www.whitehouse.gov/briefings-statements/remarks-president-trump-lowering-drug-prices/

8 https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Former_Committees/freetrade/report/final/ch04

9 https://ustr.gov/sites/default/files/uploads/agreements/fta/australia/asset_upload_file148_5168.pdf

10 https://www.researchgate.net/publication/228219374_Impact_of_the_Australia-US_Free_Trade_Agreement_on_Australian_Medicines_Regulation_and_Prices

what extent it was driven by US lobbying through the Medicines Working Group is very contested in Australia.[11]

In later negotiations with South Korea, the US began with fairly ambitious aims to largely remove the setting of prices through collective negotiation based on a review of medicines' merits.[12] However, the final impact even following a recent renegotiation was more modest. Rules on reimbursement had to be "fair, reasonable, and non-discriminatory". Prices could only deviate from "market-derived pricing" if authorities "appropriately recognize the value of the patented pharmaceutical product or medical device in the amount of reimbursement it provides". Companies were granted rights to appeal for higher prices based on evidence of safety or efficacy.[13]

It is important to note that while both Australia and South Korea failed to keep medicines pricing off the table, they certainly watered down US goals that were perhaps more ambitious than those set for the UK. The USA's somewhat limited record of success may reflect the unusual and unattractive nature of its domestic system.

The general thrust of US objectives would also tend to benefit the UK's domestic pharmaceutical industry, by allowing them to charge the NHS higher prices.

There are no significant differences in exposure across the UK countries. However, responsibility for decisions to pay for drugs (though not for the aggregate Voluntary Scheme) is devolved and Scotland has a separate system based around the Scottish Medicines Consortium. This should be specifically considered if any concessions about process are made.

2. Drug pricing: intellectual property

2.1. Overview

The intellectual property protections attached to new pharmaceutical products determine for how long companies can charge a price of their choice for a medicine, before they are open to unrestricted competition from unbranded copies. Because the drop in prices once companies no longer hold a monopoly tends to be steep, the question of intellectual property is important to both the industry and the NHS as a purchaser.

The UK and USA have similar systems of protection. For traditional medicines, the protection of patents is the most important factor. Both

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[11] https://theconversation.com/how-the-us-trade-deal-undermined-australias-pbs-32573

[12] https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=1051&context=ealr

[13] https://ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file899_12703.pdf

countries have default terms of twenty years, in the UK's case usually granted through the European Patent Office, a continent-wide organisation which is separate from the EU. There are also provisions in each to extend protection by up to five years to account for delays in approval. In Europe this is an EU policy which the UK intends to retain following Brexit.[14] [15] The US also allows for a one year "grace period" ahead of the actual filing of a patent.

For "biologic" medicines, which include for example many current cutting-edge cancer treatments, patents are usually less applicable because the products are based on living tissues. The most important protections are periods of "exclusivity", where competitors are prevented from using the data which proves that the product works. The USA protects data for 8 years and stops competitors using it for a further 4: the EU, and therefore the UK currently, protects data for 8 years and stops competitors using it for another 2 or 3.[16]

2.3. Negotiating positions

These issues are not mentioned at all in the public summary of US negotiating objectives. However, documents leaked during last year's General Election show that US representatives raised them several times during early talks with their UK counterparts. In November 2017 and March 2018 US negotiators raised biologic exclusivity periods and grace periods for patents as provisions they would "typically seek". [17] [18]

UK negotiators noted that "The impact of some patent issues raised on NHS access to generic drugs (i.e. cheaper drugs) will be a key consideration going forward." At a later meeting they gave presentations extolling the virtues of the UK system, arguing that it "facilitates a balance between generics, innovators and the public."[19] They also expressed concern that adopting US-style grace periods would threaten the UK's ability to continue working with the European Patent Office.

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[14] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0001:0010:en:PDF
[15] https://www.fieldfisher.com/en/services/intellectual-property/intellectual-property-blog/no-deal-patents-and-spcs-latest-government-guidance-the-picture-is-not-as-clear-as-it-might-at-first-seem
[16] https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharma-Incentives-Data-Exclusivity.pdf
[17] https://www.bilaterals.org/IMG/pdf/uk-ustradeinvestmentwgnov2017.pdf
[18] https://www.bilaterals.org/IMG/pdf/uk-ustradeinvestmentwgmar2018.pdf
[19] https://www.bilaterals.org/IMG/pdf/uk-ustradeinvestmentwgjul2018.pdf
[20] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/869592/UK_US_FTA_negotiations.pdf

The UK's more recent policy document does not explicitly rule out changes to intellectual property for medicines. However, it does rule out changes that "lead to increased medicines prices for the NHS", which any increase in protection would, and pledges to maintain consistency with the European Patent Convention.[20]

2.4. Reflections on possible negotiating outcomes

The apparent contention over exclusivity for biologic drugs is a significant feature in the earlier leaked discussions. For certain drugs the sums involved in a longer period could be very large for a year or two. NHS England reported savings of £100 million in 2017/18 from switching to generic ("biosimilar") alternatives to a single drug, Infliximab.[21] The difference may also affect whether the NHS will be able to provide drugs or not, especially if price control systems remain in place.

As for price controls, demands in line with US requests would also tend to be in the interests of the UK pharmaceutical industry, allowing them to charge higher prices. Patent law is a specifically reserved matter, and any changes would apply across the United Kingdom.[22]

It remains to be seen whether these areas will continue to be a US area of interest as talks begin in earnest. The UK's strong commitments not to increase the price of medicines leave little wriggle room to concede anything on this issue.

There is reason to think this may be a viable approach. The United States recently attempted to raise the period of data exclusivity to ten years in Canada and Mexico during its renegotiation of the USMCA, but this was eventually dropped in part because of the opposition of American elective representatives who hope to one day reduce their own period.[23] This suggests serious political difficulties if it tried to lock a twelve year maximum period into an agreement with the UK.

3. Procurement and other regulation relevant to the NHS

3.1. Overview

It is not feasible that a trade deal would affect whether the NHS is paid for publicly or privately. There are no precedents for similar agreements between developed countries to contain these kinds of provisions. Trade negotiators generally aim to open up existing domestic markets to foreign

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[21] https://www.england.nhs.uk/2018/07/nhs-saves-324-million-year-switching-to-better-value-medicines/

[22] http://www.legislation.gov.uk/ukpga/1998/46/schedule/5

[23] https://www.modernhealthcare.com/politics-policy/biologic-exclusivity-provision-stripped-revised-usmca-deal#:~:text=A%20provision%20of%20the%20United,administration%2C%20House%20Democrats%20announced%20Tuesday.

competitors, rather than create entirely new markets which did not exist before within a country.

However, trade agreements do contain provisions which affect the rights of companies competing to provide services paid for publicly. Since the 1990s, competition of this sort has been a feature of the English NHS, where state-owned NHS trusts compete for funding and contracts against private firms and charities. In all parts of the UK general practice and dentistry have worked since the NHS's inception by paying private contractors to provide the service.

Procurement provisions have the most direct effect here. They can create rights for foreign companies to bid for services and to compete on an even footing with state-owned companies. The UK is currently subject to European Union procurement law, which, reflecting the status of the European single market as the world's most ambitious trade arrangement, is wide-ranging and thorough. It means that major NHS contracts must be published publicly in the EU's official journal, and all foreign and domestic firms must have their bids treated fairly.[24]

At a policy level, campaigners have raised concerns that provisions which protect investors against the confiscation of their assets, which are common in trade agreements, may prevent the UK from reducing the access private companies have to the health service in future.[25] This is because removing certain profitable rights, for example the right of a health care business to tender for contracts, may remove the value of an investment. The term "indirect expropriation" is used to describe what is being forbidden here. It is relevant that the legislative proposals put forward by NHS England last year[26] and expected to come before Parliament this year include reducing some of the procurement regulations which guarantee access to private firms.

3.2. The UK's positions

The UK's policy document on a US trade deal is emphatic that "The NHS is not, and never will be, for sale to the private sector, whether overseas or domestic".[27] It is challenging to interpret the overall implications of these statements for procurement and investment protection policy. They

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[24] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0024&from=EN

[25] https://www.epsu.org/sites/default/files/article/files/FINAL_Legal_implications_of_TTIP_for_the_NHS_12_Feb_201511-21864.pdf

[26] https://www.england.nhs.uk/wp-content/uploads/2019/09/BM1917-NHS-recommendations-Government-Parliament-for-an-NHS-Bill.pdf

[27] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/869592/UK_US_FTA_negotiations.pdf

logically imply that the current legal rights of foreign and domestic companies to bid for NHS contracts do not amount to the NHS being "for sale", and as such do not necessarily rule out any further such provisions.

On procurement, the UK does commit that "the UK's obligations under the international Agreement on Government Procurement do not apply to the procurement of UK clinical healthcare services… this will not change in any future trade deal."[28]

At no point in the policy document does the UK explicitly commit to exempt decisions about health care provision from investment protection provisions. The UK does, however, commit to "Protect the right to regulate public services, including the NHS". "Right to regulate" clauses are an increasing presence in trade agreements, as a reaction to cases where indirect expropriation claims have been brought against governments for regulating in what they see as the public interest.

These clauses come in several types, and in some cases the exemptions they create do not apply to investment chapters. The exceptions tend to be based on the purpose of the proposed regulations, rather than on institutions such as "the NHS". Although the proposal is mentioned several times in the UK document, details are not very clear.[29]

3.3. The USA's positions

In contrast to the clear emphasis given to medicines pricing, there has never been any indication that provisions relating to the procurement of health services, or the protection of healthcare investments, are a particular priority for the United States.

The United States' summary of objectives commits to seeking "fair, transparent, predictable, and non-discriminatory rules to govern government procurement in the UK, including rules mirroring existing U.S. government procurement practices." It then lists a set of requirements for open and fair process which broadly align with existing UK and EU provisions. It also seeks "broad exceptions for government procurement" on a number of issues, including public health. [30]

The summary's demands on investment protection are simple and broad: "secure for U.S. investors in the UK important rights consistent with U.S. legal principles and practice… Establish rules that reduce or eliminate barriers to U.S. investment in all sectors". There is no reference to

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28 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/869592/UK_US_FTA_negotiations.pdf

29 https://www.iisd.org/toolkits/sustainability-toolkit-for-trade-negotiators/5-investment-provisions/5-4-safeguarding-policy-space/5-4-1-right-to-regulate/

30 https://ustr.gov/sites/default/files/Summary_of_U.S.-UK_Negotiating_Objectives.pdf

indirect expropriation, but it is important to note that this has been a common feature of US trade deals since the original incarnation of the North American Free Trade Association with Mexico and Canada.[31]

Proposals on state-owned enterprises may also be of relevance. The US objectives envisage "strong subsidy disciplines applicable to SOEs".[32] The Committee may want to scrutinise whether English initiatives like the Sustainability and Transformation Fund, which distributes funding to NHS trusts outside the usual channels, may be open to question under these provisions. During the leaked talks in March 2018, UK negotiators believed that US counterparts had intentionally probed whether the NHS would be subject to state owned enterprise rules, though they concluded "We do not currently believe the US has a major offensive interest in this space – not through the SOE chapter at least".[33]

3.4. Reflections on possible negotiating outcomes

The UK explicitly seeks to rule out clinical services from procurement provisions. The US does not, but it does seek a wide range of its own procurement exemptions, and in general terms the UK's language on procurement is more wide-ranging. There may be some negotiating tension relating to the British side being in general in favour of greater openness, while at the same time wanting a particular blanket exemption.

The US side proposes fairly unrestricted investment protection, without a right to regulate. The UK proposes a right to regulate, explicitly linked to the NHS. Neither side explicitly addresses the idea of indirect expropriation. This will be an important area of negotiation and it would be helpful to see more detail of the UK's proposed right to regulate, and a position on indirect expropriation.

State-owned enterprise provisions are not addressed explicitly by the UK side. As such it would be worth considering closely what implications US proposals might have for the National Health Service.

4. Other fields for consideration

4.1. Overview

In addition to the above areas of fairly defensive interest to the NHS, there are two areas where health care providers and suppliers might want provisions that maintain and improve their ability to work across borders. These are currently not discussed in the UK policy document, but an open debate of both advantages and disadvantages may be helpful.

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[31] https://www.iisd.org/pdf/2012/best_practice_indirect_expropriation.pdf
[32] https://ustr.gov/sites/default/files/Summary_of_U.S.-UK_Negotiating_Objectives.pdf
[33] https://www.bilaterals.org/IMG/pdf/uk-ustradeinvestmentwgmar2018.pdf

4.2. Telemedicine and recognition of professional qualifications.

Remotely provided clinical treatment within the UK has increased markedly during the coronavirus pandemic. Within the European Union, doctors are allowed to provide care across borders as long as they are licensed in their home jurisdiction: in the USA, however, doctors typically need to be licensed in the state where the patient is.[34] The UK policy document raises mutual recognition of professional qualifications as an aspiration, but does not specifically tie this to medicine or to services provided remotely.[35] It may be worth examining whether any thought has been given to this.

4.2. Regulation of medical devices.

The USA, along with Canada, Japan, Brazil and Australia, is part of an arrangement called the Medical Device Single Audit Program which allows regulators to simultaneously approve products for all five markets as long as they meet shared standards.[36] The UK's current policy is to seek continued alignment with the EU system after leaving the single market[37], a decision broadly welcomed by industry, but it is currently very unclear whether the EU will accept this.[38]

26 June 2020

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[34] https://www.gmc-uk.org/about/what-we-do-and-why/data-and-research/research-and-insight-archive/regulatory-approaches-to-telemedicine

[35] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/869592/UK_US_FTA_negotiations.pdf

[36] https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap

[37] https://www.researchgate.net/publication/341879996_Assessing_the_potential_impact_on_health_of_the_UK's_future_relationship_agreement_with_the_EU_analysis_of_the_negotiating_positions

[38] https://www.telegraph.co.uk/news/2020/05/14/european-commission-rejects-call-uk-testing-labs-certify-products/