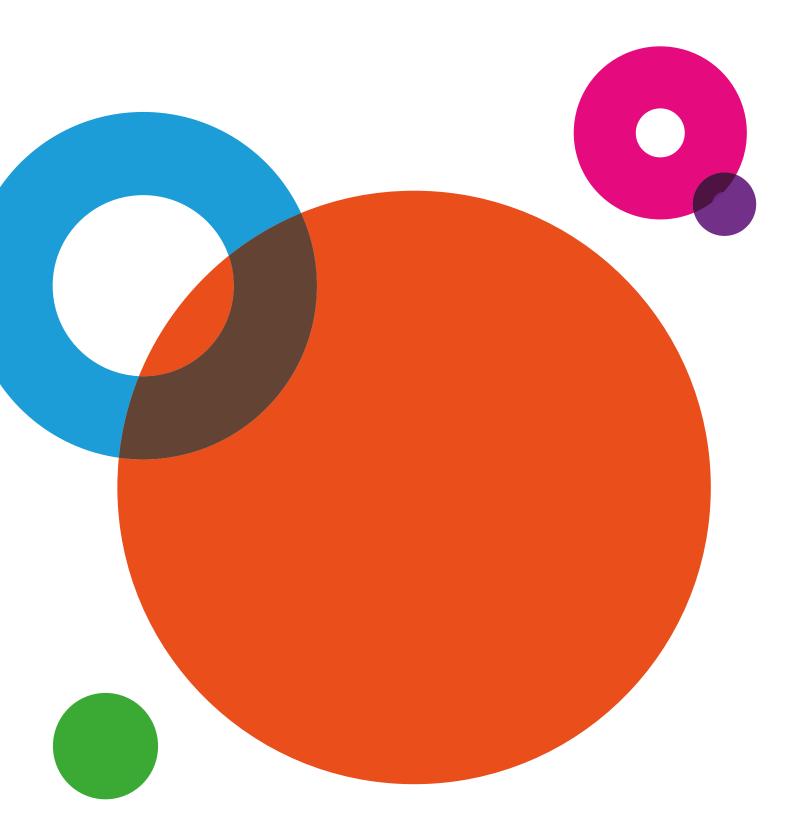


The NHS and future free trade agreements



Introduction

The health of the NHS, like all public services in the UK, depends on the overall economic health of the nation. Future trade deals should aim to create an economic climate that will support population health, by improving the wider determinants of mental and physical health such as employment, good housing, education and nutrition. This virtuous circle is not only desirable in itself but will also reduce costs longer term.

The NHS Confederation argues strongly that trade agreements between the UK and third countries should protect patients and the public from provisions that could increase healthcare costs or lower standards, or place additional burdens on services and budgets in health and social care which are already severely challenged. Nor should such provisions inhibit the ability of future governments to promote population health, for example through regulation. The interests of patients should not be compromised in exchange for short-term commercial advantages.

Trade agreements also offer opportunities to capitalise on the UK's reputation as a world leader in clinical care and governance, healthcare education, medical and scientific research, and development of innovative treatments, products and services. This paper suggests what elements of future trade deals could support exporting the 'NHS brand', while maintaining and improving domestic provision of high-quality healthcare in the four UK countries.

Key points

- Health issues are often not high on the agenda (or on the agenda at all) in trade negotiations. Trade agreements should not result in lowering standards or increasing costs for patients and the health and social care system.
- The impact of trade deals should be assessed to ensure that **commercial** advantage is not prioritised at the expense of human and economic health.
- There should be parliamentary and public scrutiny of trade negotiations.
- Free trade agreements (FTAs) will not, of themselves, change the
 fundamental principles of the NHS in the UK free care provided to all on
 the basis of need at the point of use and funded through general taxation
 and should do nothing to weaken or undermine that principle.
- The NHS depends on a highly complex and sophisticated supply chain which relies on thousands of companies, many of which are based outside the UK. Some NHS services are already provided by independent providers, including American-owned companies. We expect some competition to continue when commissioning service provision in England, albeit with a greater emphasis on delivering services collaboratively for the benefit of local populations.
- Operating on World Trade Organisation (WTO) terms will not force the NHS to open services to foreign providers: it will be for the **UK government** to decide what services to offer, or not, in a future deal.
- An early priority should be to negotiate a trade agreement with the EU, to promote continuity and minimise potential disruption and costs after the UK is no longer an EU member.

Protecting the NHS: Our asks

The give and take of trade negotiations entails both risk and opportunity. In order to protect the NHS, when negotiating free trade agreements (FTAs) the government should consider:

- excluding publicly-funded healthcare services from the scope of the FTA
- where they are within scope, explicitly exempting healthcare services from liberalisation commitments
- positive rather than negative listing of commitments
- ensuring that **trade agreements contain an explicit recognition that governments have the right** to enact policies, legislation and regulation with the objective of protecting and promoting public health and safety
- not including investor dispute settlement procedures, or if they are included, agreeing a fair and transparent a system that recognises the right of governments to promote public health and safety, including through regulation
- maintaining high regulatory standards and refusing to countenance any provision which weakens protection for patients
- maintaining early access for NHS patients to generic medicines by resisting extension of intellectual property rights
- resisting provisions that could increase the cost of medicines by changing pricing and reimbursement systems
- exploiting opportunities to promote and sell NHS services abroad.

Will the NHS be covered by future trade deals between the UK and third countries?

What would trading 'on WTO terms' mean for the NHS?

After exiting the EU, the UK would, if operating on World Trade Organisation (WTO) General Agreement on Trade in Services (GATS) terms, be free to make its own trade agreements, rather than being part of the EU trading bloc.

The GATS applies in principle to all service sectors, and therefore covers health services, but there is an important exception under Article 1(3) excluding "services supplied in the exercise of governmental authority... neither on a commercial basis nor in competition with other suppliers".

It would be unwise to conclude that NHS services are covered by this exception, as it is unclear how narrowly the definition of "services supplied in the exercise of government authority" would be interpreted. Some of the services commissioned on behalf of the NHS in England are competitively tendered.

However (and most importantly) operating as an independent WTO member would not oblige the UK to open healthcare services to foreign providers. It will be up to the government of the day to decide which services should fall within the scope of the agreement, and any exceptions or "reservations".

Each WTO member is required to have a schedule of specific commitments which identifies the services for which the member guarantees market access and national treatment for all other members, and any limitations that may be attached.

In addition, in their free trade agreements with specific countries WTO members can, if they wish, go beyond the commitments they have made to all other members and offer greater access to foreign companies.

The impact on the NHS of the UK trading on WTO terms would therefore depend on what decisions the UK government makes in future regarding national commitments or reservations in FTAs.

What assurances has the government given?

The government has stated in their recent *Preparing for our future UK trade policy* white paper, that they will "continue to ensure that decisions about public services are made by UK governments, including the devolved administrations, not our trade partners".

Current EU trade agreements with third countries, such as the Comprehensive and Economic Trade Agreement (CETA), state: "The EU reserves the right to adopt or maintain any measure with regard to the supply of all health services which receive state support or funding in any form, and are not considered to be privately funded". The UK has carried over this wording into the recent agreement with South Korea and we would hope that such clauses would form part and parcel of any future FTA between the UK and a third country, however powerful.

How might potential services liberalisation in FTA provisions affect NHS services?

The NHS is a public service, free at the point of use and funded by general taxation. This does not preclude some publicly funded NHS services being provided by independent sector providers. As a result of domestic policy decisions by successive UK governments many NHS services are already delivered by private (including voluntary) sector providers – about 20 per cent of total NHS spend, if one includes core services such as GP services, dentists and community pharmacies.

NHS commissioners (CCGs and NHS England) in England may choose to invite competitive bids for local services, within the framework of requirements set out in a number of different regulations. It is for commissioners to decide what services to provide and how best to secure them in the interests of patients.

Commissioners in England must advertise if, taking into account considerations such as efficiency, effectiveness, economy and the need to provide services in an integrated way, they deem there is more than one "capable provider". Services tendered vary widely (for example MRI scans, endoscopy, cataract surgery, mental health services). In practice the great majority of contracts have been awarded without competitive tendering, for example because there is no realistic local market.

Trade deals will not force the NHS to provide preferential access to foreign companies: foreign companies, including those from the USA, are already eligible to bid for NHS clinical contracts in England, provided they meet UK requirements. Being part of the EU trade bloc has not led to large numbers of contracts awarded to EU-owned companies.

"Operating as an independent World Trade Organisation member would not oblige the UK to open healthcare services to foreign providers. It will be up to the government of the day to decide which services should fall within the scope of the agreement, and any exceptions."

How might a future UK government protect the NHS in future trade agreements?

Consider excluding healthcare services from the scope of the FTA or from liberalisation commitments

After leaving the EU the UK will, if operating on WTO terms, need to agree what services it wishes to commit for provision by foreign providers (currently the UK is covered by the EU's commitments). The UK could decide to entirely exclude certain public services, for example publicly funded health services, from the scope of the trade agreement. Or if these services are within scope, to explicitly exclude them from scheduled commitments.

Excluding state-funded public services from the UK's trade offer would maintain the status quo, ensure stability and would allow for review once the UK's trading relationships globally are known, rather than locking in commitments at a premature and uncertain stage.

This would not prevent NHS organisations commissioning providers of public services from inviting bids from overseas suppliers, but would mean they would not be obliged to do so.

Positive rather than negative listing of commitments

We would prefer FTAs to schedule positive rather than negative lists of commitments (that is to list which services are open for liberalisation, rather than those which are not).

(NB the USA negotiating mandate explicitly prefers the "narrowest possible" list of exceptions, under negative listing).

Mainstream the right to regulate to protect human health

Future FTAs should include clauses to the effect that the parties retain the right to regulate in the interests of public health and safety - that protection of human health should be "mainstreamed" in all trade deals. This broadly replicates the safeguards and exceptions for public health contained in EU trade deals such as CETA, the agreement with Canada (and the UK could go beyond them if we so wished).

Ensure healthcare is "not for sale": Accountability

Health is often not high on the agenda when trade deals are being negotiated. It should not be sidelined or sacrificed to short-term commercial advantage. When conducting impact assessments of potential costs and benefits, government should take into account the longer-term impact of trade that could have detrimental impacts on public health, for example policies on food standards or pricing that may result in people needing more health or social care leading to increased pressure and expenditure on services in the long run, or job losses leading to higher expenditure on welfare benefits or mental health services.

Trade agreements could provide an opportunity to reduce health inequalities by maintaining or improving current high EU standards, for example in relation to food safety, food labelling, advertising and pricing of unhealthy commodities (sugar, alcohol, tobacco), the environment and animal welfare.

Negotiations on trade deals should be conducted with the greatest transparency possible (without jeopardising the UK's negotiating objectives). Agreements should be subject to parliamentary and public scrutiny, and should respect maximum autonomy for the UK's constituent nations in areas where they have devolved policy and operational competence, such as health.

Strike a fair balance between public protection and investor protection

Where services are open to competition from international providers, investor protection provisions (procedures whereby investors [companies] can seek redress where they feel they have suffered detriment because of the actions of a state) may be included in trade agreements. Such provisions are controversial because even where there are clear caveats as described below, the possibility of a potentially costly legal challenge can deter governments from taking action, for example to discourage consumption of unhealthy products.

The Confederation would prefer to resist inclusion of investor protection provisions as unnecessary in FTAs between countries with robust legal systems, where cases could be settled in domestic courts. However, if investor protection provisions are included, a system should be agreed which is transparent, equitable and gives due regard to a fair balance between the right and duty of governments to legislate in the interest of public health, and the right of investors to safeguard their investments and be treated fairly.

Such a dispute resolution mechanism should contain very clear safeguards about the primacy of human and animal health over commercial considerations, and maintain policy space for national and devolved governments to promote public health, including through regulation.

"Health is often not high on the agenda when trade deals are being negotiated. The interests of patients should not be compromised in exchange for short-term commercial advantage."

What specific risks might there be for the UK in a future trade deal with the USA?

The United States, in its summary of specific negotiating objectives for USA/UK trade negotiations, is transparent about what it would like to see from a trade deal once the UK is no longer bound by common EU rules.

Public procurement

In relation to government procurement, the USA's stated objective is to "increase opportunities for US firms to sell US products and services to the UK", mirroring existing USA government procurement practices. It would clearly press for as much access as possible to UK public procurement markets, specifying that where any services are excepted this should be "on a negative list basis of the narrowest possible exceptions with the least possible impact on NHS firms".

The primary consideration for the NHS is always to provide the best possible quality of service for patients while obtaining value for money. NHS services in England (not Scotland, Wales or Northern Ireland) already operate on a competitive tendering basis where they deem this appropriate, and can invite bids from USA-owned companies if they so wish. In practice local commissioners do not invite bids for the majority of NHS services as they are considered unsuitable for competitive tendering: it is not cost-effective or in the best interests of patients to go through an expensive and time-consuming procurement process in the absence of a realistic market. Such decisions could be challenged, should the UK choose in an FTA explicitly to open healthcare services to market access by USA companies.

It is debatable how successful the UK would be in extracting reciprocal commitments from the USA given the USA's stated objective of excluding sub-federal (state and local governments) from commitments, and favouring preferential local arrangements ("Buy America").

Sanitary and phytosanitary measures (SPS), and technical barriers to trade (TBT)

Regarding trade in goods, the USA singles out "non-tariff barriers that discriminate against US agricultural goods". On sanitary and phytosanitary measures (SPS), it refers repeatedly to the obligation to adopt "science-based" SPS regulation (standards, for example, on food, based on scientific evidence of risk), as opposed to the EU's "precautionary principle" which is more cautious (excluding products where risk cannot be definitively ruled out).

The objectives contain strong wording about "unwarranted barriers" and "unjustified... restrictions or... requirements". Particularly concerning regarding the UK's right to regulate are the USA's intentions to "require the UK to publish drafts of regulations, allow stakeholders in other countries to provide comments on these drafts, and require authorities to... explain how the final measure achieves the stated objectives".

Similar wording is employed in the section of the summary of USA negotiating objectives concerning technical barriers to trade (TBT), requiring the UK to publish and justify proposed standards, technical regulations and conformity assessment procedures.

The USA also seeks to restrict the UK's freedom to decide what to require of other third countries in trade agreements, by aspiring to obtain a commitment from the UK not to require third countries with whom the UK concludes deals to align with "non-science based" restrictions and requirements. This is clearly an attempt to prevent the UK maintaining EU standards based on the precautionary principle and requiring its trading partners to adhere to the same standards, with which the USA could not comply.

Public health bodies in the UK have expressed concern that this could lead to lower standards, for example, of food hygiene, than current EU standards.

Pharmaceuticals

Regarding pricing, the USA objectives seek to "ensure that government regulatory reimbursement regimes are transparent, provide procedural fairness, are non-discriminatory, and provide full market access for US products". Currently the UK has a voluntary pricing and access scheme (VPAS), an agreement between the Department of Health and Social Care (DHSC), NHS England and the Association of the British Pharmaceutical Industry (ABPI) which covers policy for patient access and pricing of branded medicines in the UK and runs until the end of 2023. Under the scheme, NHS expenditure on branded medicines is capped, ensuring predictability of expenditure for the NHS on the entire branded medicines bill.

One can assume that such a scheme would not meet the USA's objectives, which if achieved would result in higher prices for medicines and pass on costs to both patients and the NHS.

The USA objectives seek provisions on protection of intellectual property rights that reflect current USA legal standards, which are generally more favourable to rights holders than EU standards. Longer patents, extended data exclusivity rights and stringent enforcement measures against perceived infringements would favour companies who develop and market branded medicines. This could delay patient access to cheaper generic medicines, with knock-on impacts (supply and cost pressures) for health and social care services.

The WTO TRIPS (trade-related aspects of IPR) agreement allowing (in certain circumstances) generic versions of medicines still under patent can be obstructed by clauses in FTAs restricting the use of TRIPS flexibilities to emergencies only, affecting patient/health system access to cheaper generic medicines.

"The primary consideration for the NHS is always to provide the best possible quality of service for patients whilst obtaining value for money."

A free trade agreement with the EU – What are the priorities for the NHS?

Maintaining continuity and compatibility

Our most significant trading partner is the EU, not only because of the volume of trade in both goods and services but because the UK (unlike other third countries with whom the EU may conclude future agreements) is already in full regulatory alignment with the 27 EU Member States in respect of both tariff and non-tariff barriers. Leaving the EU's single market and its "four freedoms" (free movement of people, goods, services and capital) means that in order to minimise barriers to trade in services, a top priority for the UK will be to conclude a favourable agreement with the EU that maintains as far as possible continuity of co-operation, regulation and supply, entailing compatibility between the UK and EU's respective regulatory frameworks.

For example, the supply of medicines and medical devices to the NHS relies not only on physical logistics but also on equivalence in regulatory standards. Failure to agree suitable systems of mutual recognition could result in the NHS experiencing delays and/or increased costs.

Mutual recognition of qualifications is extremely helpful in encouraging mobility of healthcare professionals and medical researchers, who (even under a liberal migration regime) must still meet requirements demonstrating equivalence for professional registration. For the NHS, such a system has proved beneficial in facilitating inward and outward exchange of expertise, alleviating skills shortages and speeding up recruitment to unfilled posts. It also attracts top class scientists and innovators to collaborate with hospitals and universities in the UK in developing groundbreaking new treatments.

Shared access to data

Current mutual recognition arrangements include access to a shared EU-wide database whereby regulators can exchange warnings about healthcare professionals who have been struck off or sanctioned in one or more MS and may be seeking to practise elsewhere, risking patient safety. This is one of a range of EU-level databases and networks from which the UK could be excluded unless specific provisions are made in an FTA to allow continued access.

These include databases enabling researchers and clinicians to share confidential information on clinical trials; membership of European Reference Networks (ERNs) for collaboration on tackling rare diseases; access to surveillance and warning systems flagging and enabling action against health security threats such as potential epidemics or adverse reactions to medicines and medical devices; ePrescriptions and eDispensing allowing patients to access medication across borders; and a pilot electronic Patient Summary enabling secure transmission of patient data across borders.

Cross-border healthcare

The EU single market also underpins the provision of cross-border healthcare services: under EU legislation a citizen of one EU Member State (MS) has the right to access treatment in another Member State on the same basis as a national of that state. For example, emergency treatment using the European Health Insurance card (EHIC) if a tourist is taken ill on holiday, and longer-term healthcare arrangements for expats resident in another MS. We would expect a negotiated withdrawal agreement between the UK and EU to include arrangements for reciprocal healthcare as part of the "citizens' rights" package, but in the absence of such an agreement, bilateral reciprocal arrangements would need to be agreed between the UK and individual MS. We regard such arrangements to protect patients as a priority in any future FTA with the EU.

Are there opportunities or benefits for the NHS from a future trade deal?

Procurement

Under current EU procurement rules, transposed domestically into the Public Contracts Regulations 2015, contracts worth over 750,000 euros must be advertised across the EU wherever there is a realistic possibility of interest from cross-border suppliers. Commissioners cannot discriminate in their treatment of EU and local bidders.

Exemptions from the requirement to tender exist for services such as A&E that can only be provided by one provider.

In addition to EU procurement rules, there are also specific domestic procurement regulations applying to the NHS in England (such as Section 75 of the Health and Social Care Act 2012).

Leaving the EU will release commissioners from compliance with the EU's procurement rules and give the UK more flexibility in deciding what services to commit (or not) to trading partners under the WTO GPA regime. The UK could decide to exclude healthcare services completely, or certain kinds of services (for example clinical services) from procurement requirements; or alternatively, to use FTAs to go further than the GPA and liberalise public procurement.

The UK will leave the EU as a United Kingdom and trade deals will be negotiated on behalf of the entire country. However, health is a devolved matter and the devolved nations will want to have the policy space to exercise as much control as possible over the way in which healthcare services are provided within their jurisdiction, as they do now.

Offensive interests – making the most of FTAs for the NHS

Future trade agreements provide opportunities to capitalise on the UK's strength as a world leader in medical and scientific research, innovation and life sciences, health education and training, clinical governance and associated consultancy, IT and support services. Leaving the EU makes it easier for the UK to strike deals with other countries that go beyond their existing deals with the EU, if they have them.

NHS organisations already have contracts to supply education and training, clinical services, consultancy and digital healthcare in third countries. For example, there are excellent collaborations between some royal colleges and teaching hospitals to deliver high quality training abroad. Ambitious FTAs with third countries could facilitate greater export of UK healthcare-related services by reducing barriers such as recognition of qualifications (especially in countries where educational curricula are closely aligned with those of the UK) and regulatory standards.

The focus of our offensive interests will depend on the relative strength of our negotiating partner in the relevant sector(s) and what they want from us in return – the USA is also strong in many of the areas cited above, which is why the UK's global strategy in promoting our healthcare exports currently targets other markets (China, India, Middle East, SE Asia) in addition to "wealthy" markets such as the Middle East, medium-income countries such as the Philippines, Malaysia and Vietnam which are investing in healthcare and moving towards universal health coverage may well be interested in adapting the NHS model.

About the NHS Confederation

The NHS Confederation is the membership body that brings together and speaks on behalf of all organisations that plan, commission and provide NHS services.

Our members are drawn from every part of the health and care system and join 560+ organisations connected to the NHS Confederation.

We have three roles:

- to be an influential system leader
- to represent our members with politicians, national bodies, the unions and in Europe
- and to support our members to continually improve care for patients and the public.
- All of our work is underpinned and driven by our vision of an empowered, healthy population supported by world-class health and care services; and our values of voice, openness, integrity, challenge, empowerment.

The NHS Confederation's European Office provides your link between European and international policy and the NHS. Visit **www.nhsconfed.org/europe** Twitter: Follow us **@NHSConfed_EU**



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