## Briefing

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# The Transatlantic Trade and Investment Partnership and the NHS Separating myth from fact

#### Who should read this briefing?

 This briefing will be of interest to all NHS organisations, and especially to those commissioning NHS services.

#### What this briefing is for

This briefing outlines the key issues raised by the current negotiations on the proposed trade pact
 – the Transatlantic Trade and Investment Partnership (TTIP) – between the European Union (EU)
 and the USA, and possible implications for the NHS.

#### Key points

- The trade agreement currently being negotiated between the EU and the USA has raised fears of increased 'privatisation' of NHS services.
- EU negotiators and the UK Government say that TTIP will not affect the right of member states to run their own health systems.
- Public debate on TTIP in the media is highly polarised and politicised.
- The wording of the trade pact has not yet been agreed, so it is impossible to predict exactly the impact on the NHS.
- The timetable is not defined, but negotiations are expected to continue for some time, possibly until 2016.
- The NHS European Office is monitoring developments to assess potential threats and benefits.
- We are engaging with key actors both in the EU and the UK, to push for robust safeguards for the NHS.





#### Background

Speculation has been rife recently about the possible impact on healthcare and a range of other public policy areas of the **Transatlantic Trade and Investment Partnership (TTIP)** agreement currently being negotiated between the EU and the USA. Concern about the NHS has focused on the fear that such an agreement could open the NHS 'market' to American companies, leading to widespread privatisation of services and possibly damaging consequences for patient care.

Supporters of the proposed agreement focus on the benefits to UK citizens and businesses of removing unnecessary trading barriers so that the UK can more easily export our products and expertise (such as in pharmaceuticals, innovative treatments and devices) to the USA, and in return be able to access the best they have to offer. A more integrated transatlantic marketplace could foster economic growth, create jobs and stimulate fruitful collaboration in leading-edge technologies, to the benefit of patients.

The aim of this briefing is to provide a factual analysis of a highly contentious and politicised debate. We aim to separate myth from fact and – given that the agreement has not been finalised – point to areas that may pose threats or opportunities for the NHS.

Our concern is to ensure that the NHS is protected from any potentially adverse consequences. To this end, the NHS European Office is following developments closely and engaging actively with key players in the European institutions, UK Government and wider health community to press for explicit safeguards in the agreement for areas that could impact on the NHS.

#### What is all the fuss about?

The proposed agreement has led to controversy, partly due to what it may contain and partly because of the confidential manner in which negotiations are being conducted. The European Commission has recognised the need to increase transparency and in October released the text of the EU's negotiating mandate, agreed by the member states.

However, since the detail of the negotiations is both complex and confidential, and as intelligence changes constantly during negotiations, it is impossible to predict with certainty what the final agreement will say. Opinions therefore vary between those who fear the agreement could have long-reaching, detrimental effects on public services and those who insist that is scaremongering and that safeguards are in place to ensure that will not happen.

#### Will TTIP cover healthcare services?

The organisation and provision of healthcare services is a national competence for the democraticallyelected governments of the EU's member states to determine. However, the free movement of goods and services is a matter for the EU's internal market, so information currently available suggests healthcare services will be within the overall scope of the TTIP agreement unless specifically excluded. This raises issues about the extent to which they should be covered by the trade pact, and implies a level of discretion for member states in making a political decision whether to press for certain kinds of services to be exempted. The precise wording of the final agreement will therefore be critical in deciding the extent to which publicly-funded healthcare services are covered.

#### What is TTIP?

TTIP is a planned trade pact being negotiated between the EU and the USA. If concluded it will become the world's largest free trade pact.

The aim is to liberalise trade and investment between the EU and USA by removing unnecessary barriers to market access and investment, making it easier for the EU and USA to trade goods and services freely. Both trading blocs believe this will be advantageous for business and citizens, create jobs and stimulate economic growth. There may be benefits from a greater convergence of standards and regulations on both sides of the Atlantic so that (for example) products and services don't have to meet two different sets of criteria before they can be traded. In the longer term, it may well act as the catalyst for global standards.

## Which elements of TTIP potentially pose threats/ opportunities?

Given the scenario already outlined, it is impossible to say what the implications will be until we see exactly what the final agreement says. However, we outline here certain areas that could pose potential threats or opportunities.

#### Commissioning of clinical services

The fear that TTIP will open the NHS market to American companies and lead to greater privatisation of clinical services has caused alarm in the healthcare community. Under existing domestic law on procurement and competition, NHS commissioners in England can already open clinical services to competition, if they wish. The current NHS commissioning model (the purchaser/provider split) has been the policy of successive UK governments, and was not enforced by the EU's rules on public procurement.

On the basis of the EU negotiating mandate for TTIP, and the wording of recent analogous trade agreements between the EU and Canada and Korea, it appears there is no intention to use TTIP to impose (rather than allow) liberalisation or privatisation of publicly-funded health services. Both the EU as a whole and individual member states can specify in the agreement areas where they reserve the right to adopt or maintain measures in respect of particular services, such as the provision of health services that receive public funding or state support. Provided that the wording in the agreement is sufficiently watertight, nothing envisaged in TTIP should change the current situation in the NHS regarding commissioning of publicly-funded health services.

Another issue for consideration is whether or not TTIP will contain a 'ratchet' clause whereby services that are 'privatised' cannot be returned to a public monopoly following a change of political direction. Again, the trade agreement with Canada explicitly excludes areas where policy is reserved to the EU or to national governments from such a clause.

## Reassurances regarding TTIP and publicly-funded health services

In July, the chief EU negotiator wrote to John Healey MP, chair of the All-Party Parliamentary Group on TTIP, with reassurances about the potential impact of TTIP on the NHS. The letter stated that "we are confident that the rights of EU member states to manage their health systems according to their various needs can be fully safeguarded". He also pointed to recent examples of bilateral agreements between the EU and other countries that specifically excluded publicly-funded health services from the scope of commitments, so that EU countries do not have to provide access to their markets for companies from the other party's country.

His reassurances were reiterated in a letter addressed to all MPs by Vince Cable MP, Secretary of State for Business, Innovation and Skills, in September.

The new President of the European Commission, Jean-Claude Juncker, assured the European Parliament in July: "The Commission would negotiate a reasonable and balanced trade agreement with the USA, in a spirit of mutual and reciprocal benefits and transparency." He promised he would not "sacrifice Europe's safety, health, social and data protection standards or our cultural diversity on the altar of free trade".

#### Action by the NHS European Office

We will scrutinise the wording of TTIP carefully and apply pressure through appropriate channels, with the aim of ensuring that the agreement does not have unintended adverse consequences for NHS services.

## Investor-to-State Dispute Settlement (ISDS)

#### What is ISDS?

The TTIP negotiations include provision for an Investor-to-State Dispute Settlement (ISDS) mechanism, which provides protection for investors from overseas against unfair treatment or discrimination on nationality grounds. This highly contentious arbitration settlement system allows corporations who consider their interests unfairly damaged by national or local laws to take governments before arbitration panels to settle disputes, instead of filing claims before regular courts. In order to succeed in their claim, they must prove their rights have been breached by (for example) expropriation without compensation, denial of justice or manifestly arbitrary treatment. The panel's decisions are usually binding and cannot be challenged in court, and can result in millions of pounds' worth of compensation for businesses who claim successfully.

The mechanism has been used by companies to challenge public health measures being introduced by governments – the most notorious current example being the case of the tobacco company Philip Morris who are challenging the Australian Government's introduction of plain packaging for cigarettes. This has led to concern that American companies could potentially sue a future UK government if they consider their interests damaged by domestic legislation.

It is important to remember, however, that ISDS works both ways: it is a means of ensuring that British companies who invest in the healthcare market abroad are not unfairly expropriated and have a means of redress. This is especially relevant when investing in countries who may not have mature domestic legal systems, meaning redress through national courts may not be possible. This is not, however, the case with the USA.

#### Could ISDS influence UK government policy?

Even if a company wins an ISDS case against a government and is awarded compensation, an ISDS tribunal cannot repeal or reverse legislation or require a change in government policy, such as by trying to reverse political decisions on the way health services are organised. The letter in July 2014 from the EU's chief negotiator to John Healey MP made this clear: "We can state with confidence that any ISDS provisions in TTIP could have no impact on the UK's sovereign right to make changes to the NHS. There is no reason to fear either for the NHS as it stands today or for changes to the NHS in future as a result of TTIP."

Concern, however, remains about potential 'policy freeze': might governments think twice about introducing certain kinds of legislation if they fear potential challenges under ISDS?

#### Does TTIP have to include ISDS?

The transatlantic trade deal does not have to include ISDS: there are several examples of countries who have successfully negotiated trade pacts without ISDS provision. There are calls from various quarters for ISDS to be excluded from TTIP.

Such has been the level of concern about ISDS that the European Commission launched a public consultation earlier this year, asking stakeholders for their views concerning the EU's negotiating position. We expect the Commission to respond by reporting the outcomes and publishing proposals soon.

If the final agreement includes ISDS, we would wish to see very strong safeguards built in so that this mechanism cannot be used to frustrate the public policy intentions of elected member state governments.

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## Healthcare products and innovation

We want the outcomes of the TTIP negotiations to maintain or improve UK standards of patient safety. For example, there is scope in the negotiations for greater harmonisation of technical standards, quality assured by independent bodies, which would reduce unnecessary duplication of tests (thereby saving time and money) and iron out unjustified contradictions and discrepancies. Areas that pose particular opportunities or threats are outlined here.

#### Medical devices

We welcome the opportunity offered by TTIP for the EU to improve the quality and safety of medical devices by aligning with the higher surveillance standards that apply in the USA. NHS patients could benefit from access to the best diagnostic devices and innovative technologies developed on both sides of the Atlantic, and UK companies would be more able to compete in the US market. TTIP could pave the way for further international standardisation of products and certification procedures, with overall benefits for patient safety.

#### Clinical trials

Recent European legislation has improved transparency on clinical trial data. A publicly-available summary of the results of a trial must be published within one year of its end, irrespective of the outcome. Only personal data and confidential commercial information will not be available online to the public. Care should be taken in the TTIP negotiations to maintain these improvements and ensure that 'commercial confidentiality' cannot be (ab)used to ignore certain trials or hide unfavourable results.

#### **Pharmaceuticals**

Currently, medicinal products that have received regulatory approval in the USA may not be approved in Europe, or vice-versa, nor is there consistency in (for example) information given to patients inside and on packaging. There could therefore be advantages in mutual recognition of standards in drug manufacture. There is a need to be vigilant that the TTIP wording does not lower standards for the approval of pharmaceuticals, and for member states to retain control of the assessment of new drugs, pricing and reimbursement of pharmaceuticals. US rules on direct advertising of prescription drugs to patients also differ from the law in many European countries – UK legislation is more stringent in this respect.

#### Intellectual property rights

The more stringent intellectual property rights in force in the USA could, if extended to the EU, affect the health sector negatively. Extending patent protection to interventions such as diagnostic, therapeutic and surgical procedures could limit and/or delay patient access to innovative treatments and medicines and to cheaper generic drugs.

#### Professional qualifications

It remains to be seen whether TTIP will extend into this area. Currently, EU law on automatic recognition of professional qualifications does not extend to qualifications obtained by non-EU citizens in non-EU countries, which have to be assessed on a case-by-case basis by regulatory bodies such as the General Medical Council and Nursing and Midwifery Council. However, the trade agreement between the EU and Canada contains provisions to enable a possible future system of mutual automatic recognition, the details of which would need to be agreed subsequently.

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#### Next steps

The timeframe for the deal is not defined as it depends on the progress made in negotiations. These are likely to continue throughout 2015, with the possibility of agreement in early 2016. However, this timescale could change. When agreement in principle is reached, the proposed text will have to be ratified unanimously by the European Council (the member states) and passed by the European Parliament, as well as by the member state parliaments.

The NHS European Office is following the negotiations closely. We respond to consultations and engage with key players such as the European Commission, UK government departments and members of the European Parliament to alert them to any potentially damaging consequences, or missed opportunities, for the NHS. We make representations both directly and by influencing the position of our European partner organisations.

We will take every opportunity to push for robust and explicit safeguards for publicly-funded health services.

#### Further information

NHS European Office's web pages on TTIP: www.nhsconfed.org/TTIP

European Commission's web pages on TTIP: http://ec.europa.eu/trade/policy/in-focus/ttip

The Department for Business, Innovation & Skills's web pages on TTIP:

www.gov.uk/government/collections/transatlantictrade-and-investment-partnership-ttip

If you would like more information on the issues covered in this briefing, please contact kate.ling@nhsconfed.org or visit www.nhsconfed.org/europe

#### The NHS European Office

The impact of the EU agenda on the NHS is constantly increasing, bringing with it both challenges and opportunities. The NHS European Office is the conduit for the NHS to engage with the EU agenda. Hosted by the NHS Confederation, we are the representative body for the range of NHS organisations in England on EU affairs. Our work includes:

- monitoring and influencing EU policy and legislation in the interest of the NHS
- facilitating access to EU funds for NHS bodies and their partner organisations
- supporting pan-European collaborations and sharing successful EU practices.

For more information on EU affairs of importance to the NHS and to get in touch with the NHS European Office, visit www.nhsconfed.org/europe or email european.office@nhsconfed.org

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