TTIP, international trade and cardiovascular health – a European Heart Network paper

February 2015

Introduction

The aim of this paper is to consider the impact that international trade policies can have on cardiovascular diseases, especially heart disease and stroke, and related risk factors. The paper has a special focus on the Transatlantic Trade and Investment Partnership (TTIP).

Cardiovascular disease (CVD) – the main forms of which are coronary heart disease and stroke – is the main cause of death in the EU, accounting for over 1.9 million deaths each year. CVD is also a major cause of disability and a significant economic burden across the EU, estimated to cost the EU economy almost 196 billion euros (2009 figures) every year; 106 billion euros are the cost to the health care systems in the EU and 90 billion euros due to production losses and informal care costs.¹

Leading risk factors are tobacco use, high blood pressure, overweight and obesity, physical inactivity, diabetes, unhealthy diets and harmful use of alcohol. It is often said that CVD is a lifestyle disease. Whilst it is true that the risk factors are linked to lifestyles it is equally true that these risk factors are so widely prevalent that it is appropriate to refer to CVD as a societal disease.

Societies are shaped by policies – policies have an impact on people’s lives and lifestyles. Policies are shaped at several levels: local, national and international.

About the European Heart Network

The European Heart Network (EHN) is a Brussels-based alliance of heart foundations and other like-minded non-governmental organisations throughout Europe. EHN has members in 25 countries in Europe. EHN plays a leading role in the prevention and reduction of cardiovascular diseases, in particular heart disease and stroke, through advocacy, networking, capacity-building and patient support, so that they are no longer a major cause of premature death and disability throughout Europe.

Summary

At the heart of international trade is the belief that they will have a positive economic benefit. Theoretically, with greater prosperity comes greater health. It seems that economic gain can be expected from TTIP but also that projections of net economic benefit should be treated with caution.

TTIP may impact on health in several ways. Impacts relate to tariff reductions and can emanate from extended regulatory cooperation. Intellectual property, technical barriers to trade (TBT) and an investor-state dispute settlement (ISDS) provision may also have an impact on health.

There appear to be limited health-related benefits accruing from TTIP in relation to trade in goods. On the other hand, applying the overall logic of trade agreements, it is to be expected that a reduction in tariffs will result in an increase in trade of goods and a reduction in prices. A proportion of such goods is likely to be high in sugar, salt and saturated fats.

Quality medicine at affordable prices is vital for patients with cardiovascular diseases. There are differences between EU and US patentability standards that could impact on how pharmaceuticals are regulated in the EU. It is estimated that pharmaceutical costs represent 1.5% of European GDP, therefore any increase in intellectual property protection arising from the TTIP might have a tangible impact on healthcare costs. This may offset potential positive impacts from innovation stemming from pharmaceutical companies’ R&D investments.

The primary objective of an extended regulatory cooperation is facilitation of trade. Promotion of public interests, such as public health, is an underlying principle but measures to protect and promote public health can be considered obstacles to trade. A strong reliance on “cost-effective” regulations aiming to quantify in monetary terms the costs and benefits of regulatory options does not necessarily take into account the non-monetary value of human health and lives, nor the future cost to society if no regulatory action is taken. In addition, the establishment of complex regulatory cooperation mechanisms may have a negative impact on regulatory interventions considered effective in addressing CVD and other chronic diseases.

TTIP measures on TBT aims at removal of unnecessary barriers to trade arising from differences in the content and application of technical regulations, standards and conformity assessment procedures. But what constitutes technical barriers to some, constitutes protection of health to others. Lately, a record-breaking number of new trade concerns, mostly dealing with issues such as the protection of health and the environment, has been raised before the WTO’s TBT Committee. These trade concerns include nutrition labelling – in particular proposals relating to health and nutrition such as the so-called ‘traffic-light’ nutrition labelling. They also include plain packaging for tobacco.

While no sovereign state, in principle, can lose its right to regulate in the public interest under any trade or investment agreement, the fear of being sued before an arbitration tribunal may lead to a so-called ‘regulatory chill’, i.e. a decision by governments not to introduce a measure to protect public health, such as plain packaging for tobacco, because the financial risks involved in ISDS – in terms of both arbitration costs and the amount of damages awarded – are significant.
For TTIP to have a positive, or at least neutral, effect on public health – also beyond the EU and the US – EHN recommends that:

- In the preamble to the TTIP, it is:
  - stated that nothing in the TTIP can encumber the parties’ basic right to regulate (although this may go without saying).
  - stipulated that though TTIP is entered into to encourage and facilitate trade and investment between the parties, the parties acknowledge that facilitation of trade and protection of investments are not goals in themselves but constitute a means to improve people’s standards of living and their health and well-being, and to protect the environment and consumers.
  - acknowledged that TTIP is entered into in a context where there is a need to address the high and growing burden of chronic non-communicable diseases as well as obesity.

- Where necessary, TTIP must recognise the importance of leaving policy space to the parties enabling them to respond to health challenges in innovative ways; such innovative ways may denote that a full evidence base is not yet available and that this fact does not render them either illegitimate or unnecessarily trade-restrictive.

- Regulatory cooperation mechanisms are transparent, democratic and with strong accountability. The Chapter on regulatory cooperation must contain provisions guaranteeing parliamentary oversight and access for public interest stakeholders, including public health experts, to the various bodies and mechanisms to provide input at all stages and levels.

- TTIP does not include investment protection in the form of ISDS.

As long as negotiations are on-going, EHN recommends that negotiators (in the EU and the US) consult extensively on their text proposals in a transparent way. In particular, text proposals on measures which can have an impact on public health, including intellectual property rights, services and public procurement, must be assessed by experts.

**Trade, Prosperity and Health**

At the heart of international trade is the belief that they will have a positive economic benefit. Theoretically, with greater prosperity comes greater health.

**Economic assessments**

There have been several assessments of the economic benefits of trade. The initial economic assessment of an ambitious and comprehensive TTIP, published on the European Commission’s website (DG TRADE) in March 2013, suggested that it could bring significant economic gains as a whole for the EU (119 billion euros a year) – with 80% of the gain coming from reducing non-tariff barriers – “cutting costs imposed by bureaucracy and regulations” – and from liberalising trade in services and public procurement.

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[2](http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf)
However, a report published a year later (March 2014), whilst confirming the findings of previous studies on economic gain, concluded that projected gains could be offset by revenue losses and costs resulting from short term growth in unemployment. The study argued that 80% of total benefits from TTIP could be “overly optimistic”. Of relevance to the public health debate, the study also challenged the estimated gains due to the removal of non-tariff barriers (NTBs).³

It seems that economic gain can be expected from TTIP but that it is difficult to assess the size of the gain and how it may benefit society as a whole.⁴

EHN concludes that projections of net economic benefit should be treated with caution.

**Health Impacts**

TTIP may impact on health in several ways. Impacts relate to tariff reductions and can emanate from extended regulatory cooperation. Intellectual property, technical barriers to trade (TBT) and an investor-state dispute settlement (ISDS) provision may also have an impact on health.

**Cardiovascular Diseases (CVD)**

CVD remains the main cause of death in the EU and represents a major cause of disability. Over the past 30 years death rates from coronary heart disease (CHD) and stroke have fallen remarkably – by more than 50% in several European countries.⁵ Around 50-75% of the fall in CHD, the single most common cause of death in the EU, has been explained by risk factor improvements.⁶ The greatest benefits appear to have come from reductions in mean cholesterol concentrations, smoking prevalence and blood pressure levels.⁷ The remaining 25-50% of the fall is attributed to medical and surgical treatments.

Where death rates can go down they can also go up. If societies provide environments that are supportive of healthy lifestyles, e.g. a non-smoking culture, availability of healthy foods at affordable prices, measures to dissuade high intakes of alcohol and encouragement of regular physical activity, avoidable death and disease from CVD and several other major chronic diseases can be prevented. For example, sustained public policies to reduce intake of salt and saturated fats as well as reducing smoking and increasing physical activity could result in a reduction in mortality from CHD of about one third. But changes in societies can also put people’s health at risk. The last decades have seen phenomenal increases in prevalence of overweight and obesity referred to as “one of the greatest public health

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challenges of the 21st century”. Overweight and obesity increase risk of developing CVD as well as other major chronic diseases such as diabetes.

EHN submits that public policy interventions aimed at reducing deaths and disability from CVD and other major chronic diseases through targeting risk factors (e.g. tobacco use; unhealthy food) are legitimate measures. The EU and its Member States must retain policy space to test innovative approaches and measures. Innovative measures may still not have a fully-developed evidence base, but this must not render them illegitimate.

Tariff reductions and trade in goods

There appear to be limited health-related benefits accruing from TTIP in relation to trade in goods.⁹

On the other hand, applying the overall logic of trade agreements, it is to be expected that a reduction in tariffs will result in an increase in trade of goods and a reduction in prices. A proportion of such goods are likely to be high in sugar, salt and saturated fats.

Considering that such products are problematic in terms of cardiovascular diseases¹⁰ as well as several other major chronic diseases, and overweight and obesity, TTIP could have the impact of exacerbating the situation by facilitating a reduction in the market price for such goods and an increase in consumption.

Public policy measures such as taxation and minimum pricing can be used to counter the potential public health consequences of tariff reductions, and EHN emphasises the importance of ensuring that TTIP in no way impedes the right of the EU and/or its Member States to implement them.

 Intellectual property

Quality medicine at affordable prices is vital for patients with cardiovascular diseases. The exact number of people living with CVD in the EU is not known but it is estimated that more than 10 million people live with CVD, making it one of the largest communities of patients in Europe.¹¹ The cost of CVD medication in the EU amounts to over 30 billion euros per year.¹²

An EU-funded study CardioScape¹³, published in 2014, provided a snapshot of funds invested in CVD research in the EU. It found that at least 876 million euros was awarded for CVD research project grants under competitive open funding schemes in the EU over a three-year period (2010 – 2012) – or on average 292 million euros per year. Major funders are the

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⁸ http://www.euro.who.int/en/health-topics/noncommunicable-diseases/obesity/obesity
¹¹ EHN Charter for European CVD patients - http://www.ehnheart.org/patients/charter.html
¹³ http://www.cardioscape.eu/Final-Conference
EU, Government agencies and charities – with two thirds of the 876 million euros coming from national governments and charities. Whereas it was not possible to include information about industry funding for CVD research and development in the CardioScape project, EFPIA (European Federation of Pharmaceutical Industries and Associations) estimates that, in 2012, pharmaceutical companies’ total investment in research and development (R&D) in Europe was just over 29 million euros.\(^\text{14}\)

There are differences between EU and US patentability standards that could impact on how pharmaceuticals are regulated in the EU. It is estimated that pharmaceutical costs represent 1.5% of European GDP, therefore any increase in intellectual property protection arising from the TTIP might have a tangible impact on healthcare costs.\(^\text{15}\) This may offset potential positive impacts from innovation stemming from pharmaceutical companies’ R&D investments.

EHN calls for a very careful weighing up of the level of protection of industry investment in R&D and patients’ access to quality medicine at affordable prices.

**Regulatory cooperation**

Elimination, reduction and prevention of unnecessary regulatory barriers are expected to provide the biggest benefit of the TTIP. To that end it is proposed that TTIP be a “living agreement” with mechanisms and structures in place that extend regulatory cooperation in the future between the US and the EU. This part of TTIP is unique compared to existing international trade agreements.

According to the EU position paper on “Trade Cross-cutting disciplines and Institutional provisions”\(^\text{16}\), the purpose is to develop and implement efficient, cost-effective, and more compatible regulations for goods and services, including early consultations on significant regulations, use of impact assessments, periodic review of existing regulatory measures, and application of good regulatory practices. It is stated that basic principles underlying the regulatory provision in TTIP include:

1. The importance of regulatory action to achieve public policy objectives, including the protection of safety, public health, the environment, consumers and investors, at a level that each party considers appropriate.
2. TTIP provisions shall not affect the ultimate sovereign right of either party to regulate in pursuit of its public policy objectives and shall not be used as a means of lowering the levels of protection provided by either party.

On face value, the objective and the underlying principles are straight forward.

However, the primary objective of regulatory cooperation remains facilitation of trade. Promotion of public interests, such as public health, is an underlying principle but measures to protect and promote public health can be considered obstacles to trade; moreover a strong

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reliance on “cost-effective” regulations aiming to quantify in monetary terms the costs and benefits of regulatory options does not necessarily take into account the non-monetary value of human health and lives, nor the future cost to society if no regulatory action is taken.

Standards and approaches to regulating on the two sides of the Atlantic are not the same. Lowering of standards and protection is not on the table during the negotiation of TTIP, according to policy makers. But with a “living agreement” it is necessary to look beyond the TTIP agreement itself and look into what may happen in respect of future standards, review of existing standards, and mutual recognition of standards in the framework of a potentially complex regulatory cooperation system with different levels of bodies, groups and mechanisms.

Early consultations between the EU and the US, including potentially further impact assessment with extended stakeholder consultations earlier in the legislative process, may lead to delays in or even abandonment of regulation. To be able to engage with an additional layer of consultation and impact assessment, over and above existing EU impact assessment requirements, necessitates considerable resources. There is a resource asymmetry between business stakeholders and public interest stakeholders. Unless this asymmetry is addressed robustly in the framework of the regulatory cooperation system, it is likely to give an advantage to business stakeholders over public interest stakeholders with a potential negative impact on public health. This is of concern as much regulatory intervention to help promote public health collides with the interests of business stakeholders who invest vastly in avoiding or delaying it.17

Whilst recognising the usefulness of eliminating redundant regulatory barriers and that the establishment of regulatory cooperation mechanisms can be helpful in this, EHN is concerned that a complex regulatory cooperation system with additional layers of administrative hurdles may have a negative impact on regulatory interventions considered effective in addressing CVD and other chronic diseases. It is imperative that public health stakeholders are fully involved in regulatory cooperation mechanisms at all stages and levels.

Technical barriers to trade

The OECD (Organisation for Economic Cooperation and Development) defines technical barriers to trade (TBT) to be technical regulations, minimum standards and certification systems for health, safety and environmental protection and to enhance the availability of information about products, which may result in the development of TBTs.18

Members of the WTO (World Trade Organisation) are bound by its agreement on TBT.19 The aim in the TTIP is to achieve a TBT+ Chapter where the EU and the US go beyond existing commitments in the WTO Agreement on TBT.20 TBT will be an essential element of the regulatory cooperation between the EU and the US (see above).

The TBT+ is guided by principles such as:

17 http://tobaccocontrol.bmj.com/content/early/2014/08/10/tobaccocontrol-2014-051822.full?g=w_tc_open_tab
19 http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm
- “...measures should aim at removal of unnecessary barriers to trade arising from differences in the content and application of technical regulations, standards and conformity assessment procedures.”
- “...while the need for a high level of protection remains, measures should aim for methods of regulation, standardisation and conformity assessment that are not more trade-restrictive than necessary to achieve the relevant public interest objective, while taking into account the need to give preference to internationally harmonized methods.”

The Office of the United States Trade representative, in a paper from March 2014, noted “...Achieving our TBT objective in T-TIP would mean going beyond existing commitments by setting us on a path of increased transparency and openness in the development of standard and technical regulation to ensure that U.S. bodies are permitted to test and certify products sold in Europe, promote EU recognition of international standards used to support global trade by U.S. exporters and producers, and establish an ongoing mechanism to discuss TBT concerns. Not only would our companies be more competitive, innovative, and efficient as a result, but T-TIP could set a positive example to other countries around the world.”

But what constitutes technical barriers to some, constitutes protection of health to others. Lately (November 2014), a record-breaking number of new trade concerns, mostly dealing with issues such as the protection of health and the environment, has been raised before the WTO’s TBT Committee. These trade concerns include nutrition labelling – in particular proposals relating to health and nutrition such as the so-called ‘traffic-light’ nutrition labelling. They also include tobacco with four measures on plain packaging being discussed.22

In the EU and US, as in the rest of the world, non-communicable diseases (NCDs) and obesity are of an epidemic proportion. The WHO (World Health Organization) has set out a range of actions to be implemented within its Global Action Plan for the Prevention and Control of Non-Communicable Diseases action plan.23 Actions include initiatives to fully implement the FCTC (Framework Convention on Tobacco Control) and reducing salt levels, eliminating industrially produced trans-fatty acids, decreasing saturated fats and limiting free sugars. Plain packaging of tobacco is recommended in the Guidelines to the FCTC (implementation of FCTC Article 11)24 and clear and understandable nutrition labelling is recommended in the WHO European Food and Nutrition Action Plan (2015-2020). Several countries are implementing these recommendations.25

Whereas it is perfectly legitimate for governments to seek to create regulatory conditions that help companies to become more effective, competitive and innovative, and to that end seek common standards and measures to facilitate trade, it is even more legitimate for governments to help stem the tide of NCDs and obesity, including engaging in innovative labelling initiatives and other measures generally considered effective in reducing tobacco use, intake of foods high in fat, salt and sugar, and harmful use of alcohol.

22 http://www.wto.org/english/news_e/news14_e/tbt_04nov14_e.htm
23 http://apps.who.int/iris/bitstream/10665/94384/1/9789241506236_eng.pdf?ua=1
24 http://www.who.int/fctc/guidelines/article_11.pdf?ua=1
25 http://www.euro.who.int/__data/assets/pdf_file/0008/253727/64wd14e_FoodNutAP_140426.pdf?ua=1
EHN emphasises that great care must be taken to avoid that the TBT Chapter in TTIP restricts policy space for the EU and its Member States restricting their options to adopt measures with the aim of reducing consumption of certain products. No provision in the TTIP should inadvertently increase the standard of proof with regard to evidence of effectiveness.

Investor-to-State Investment Dispute (ISDS)

ISDS is an instrument of public international law that grants an investor the right to use dispute settlement proceedings against a foreign government (‘host state’) and it provides foreign investors with a substantive legal protection (including the right to ‘fair and equitable treatment’ and the right not to be directly or indirectly expropriated without full compensation). ISDS is not unique to the TTIP; it has been around for several decades where it has been included in bilateral and international investment treaties. However, ISDS is currently much debated. One reason for this is probably that while ISDS was used relatively infrequently until the 1990s, investors have since come to rely steadily on this system and, in 2012, 58 cases were filed – the highest number ever.  

A main concern about ISDS is the extent to which a ‘host state’ may see its policy space restricted, i.e. jeopardise its right to regulate to protect public health. Two governments, Australia and Uruguay, have been sued before arbitration tribunals under ISDS clauses because of measures they have taken regarding the packaging and labelling of tobacco products to protect health. These cases are still on-going.

While no sovereign state, in principle, can lose its right to regulate in the public interest under any trade or investment agreement, the fear of being sued before an arbitration tribunal may lead to a so-called ‘regulatory chill’, i.e. a decision by governments not to introduce a measure to protect public health, such as plain packaging for tobacco, because the financial risks involved in ISDS – in terms of both arbitration costs and the amount of damages awarded – are significant.

In the context of TTIP, the EU ran a consultation on ISDS, the results of which are yet to be published. In its consultation, EU is proposing “to strengthen the balance between investment protection and the right to regulate, through clarifying and improving the substantive investment protection provisions while at the same time preserving the right of States to take measures for legitimate public policy objectives.”

It is often claimed that investors may not be given effective access to justice, e.g. denied access to appeal or due process, leaving them without any effective legal remedy, and that ISDS is necessary to allow legitimate claims to be pursued. However, protection against misuse or abuse of governmental powers is a standard feature of domestic law. At least in advanced legal systems, the standard would generally not fall below what is offered in international investment law.

EHN acknowledges that the EU has accepted the criticism of the ISDS mechanism and has made an appreciable effort to counter it. Nevertheless, we remain concerned about a

potential ‘regulatory chill’ effect caused by the significant financial risks involved in ISDS. Considering moreover that the vast majority of EU Member States do not have bilateral investment treaties with the US, and that both the EU and the US must be considered to have advanced legal systems, EHN recommends that the EU negotiate a TTIP without ISDS. EHN suggests that it is unlikely that a TTIP without an ISDS mechanism will have a major negative impact on foreign investment from the US into the EU.

**Conclusions and Recommendations**

EHN recognises that TTIP does not appear in a vacuum. The EU and its 28 Member States are members of the WTO and bound by its agreements (on TBT etc.). The EU and its Member States are also parties to a plethora of bilateral trade and investment agreements and treaties.

The EU suggests that, *far beyond the positive effects on bilateral trade, the TTIP offers a unique chance to give a new momentum to the development and implementation of international regulations and standards (multilateral or otherwise plurilateral). This should reduce the risk of countries resorting to unilateral and purely national solutions, leading to regulatory segmentation that could have an adverse effect on international trade and investment.*

This unique chance of influencing international trade and investment agreements must be seized to emphasise that trade agreements are a means to an end – not an end themselves. Offering potential economic gain, TTIP – as other trade and investment agreements – must recognise that the goal is to improve people’s standards of living and their health and well-being. It is all well and good to strive for international regulations and standards; but as long as no international standards are agreed or universally recognised, countries must remain free to define such standards in accordance with their own appreciation of what is necessary in the public interest, e.g. public health. In no way can trade facilitation be above public health.

For TTIP to have a positive, or at least neutral, effect on public health – also beyond the EU and the US – EHN recommends that:

- In the **preamble** to the TTIP, it is:
  - stated that nothing in the TTIP can encumber the parties’ basic right to regulate (although this may go without saying).
  - stipulated that though TTIP is entered into to encourage and facilitate trade and investment between the parties, the parties acknowledge that facilitation of trade and protection of investments are not goals in themselves but constitute a means to improve people’s standards of living and their health and well-being, and to protect the environment and consumers.
  - acknowledged that TTIP is entered into in a context where there is a need to address the high and growing burden of chronic non-communicable diseases as well as obesity.

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- Where necessary, TTIP must recognise the importance of leaving policy space to the parties enabling them to respond to health challenges in innovative ways; such innovative ways may denote that a full evidence base is not yet available and that this fact does not render them either illegitimate or unnecessarily trade-restrictive.

- Regulatory cooperation mechanisms are transparent, democratic and with strong accountability. The Chapter on regulatory cooperation must contain provisions guaranteeing parliamentary oversight and access for public interest stakeholders, including public health experts, to the various bodies and mechanisms to provide input at all stages and levels.

- TTIP does not include investment protection in the form of ISDS.

As long as negotiations are on-going, EHN recommends that negotiators (in the EU and the US) consult extensively on their text proposals in a transparent way. In particular, text proposals on measures which can have an impact on public health, including intellectual property rights, services and public procurement, must be assessed by experts.