	Relative change (in %)		
	Total	Income	Expenditure
Fourth quintile	0.1	0.5	-0.5
Fifth quintile	0.1	0.5	-0.5
At risk of poverty	0.0	0.5	-0.5
Socio-economic groups			
Manual workers	0.1	0.5	-0.5
Non-manual workers	0.1	0.5	-0.5
Self-employed	0.1	0.5	-0.5
Unemployed	-0.1	0.4	-0.5
Retired	-0.1	0.3	-0.4
Inactive	-0.1	0.4	-0.5
Geographic groups			
Densely populated	0.0	0.5	-0.5
Sparsely populated	0.0	0.5	-0.5

Source: E3MG model, the total effect is the sum of the income and expenditure effects.

Income inequality in the EU-28

The last quantitative social indicator that the E3MG model provides is the Gini coefficient. The Gini coefficient is a measure of the extent to which the income distribution deviates from a perfectly equal distribution.[142] Any increase in the Gini coefficient is to be interpreted as a step towards more income inequality.

In the baseline, the EU-28 has a Gini coefficient of 30.00. The impact of TTIP on the EU-28 Gini coefficient is less than a 0.07 percent increase, resulting in a final value of 30.02. In the moderate scenario, the expected increase is half that. These results also follow from Tables 4.6 and 4.7. The top income bracket (the fifth quintile) will face a larger increase in their real disposable income than the lowest income bracket (the first quintile). While in the ambitious scenario real disposable will increase for all income groups, the largest (positive) impact is to be expected for the richest 20% of the income distribution.

Nevertheless, with a 0.07 percent increase in the Gini coefficient in the ambitious scenario and no significant change in the less ambitious scenario, the effect of TTIP on income inequality is expected to be very marginal.

4.3. Assessment of social impact through the trade channel

Social effects resulting from the *trade* channel are the most direct effects of trade policy. The *trade* channel covers the human health effects and access to medical devices triggered by trade provisions on certain products. Tariff provisions can make some goods cheaper, which could have a positive or negative social effect. The choice to look at human health impacts via a few categories of food and drinks, as well as medical devices and medicines is taken in close consultation with civil society. Because it is difficult to separate the potential impact channels totally, there is also an element of regulatory cooperation already involved in this section.

4.3.1. Case study 1: impact of TTIP on human health

TTIP is both about tariff liberalization and about regulatory cooperation. Both these elements have a potential impact on the prices – and therefore – quantities of goods traded. That is why – next to the case study on how TTIP could influence public health systems – this case study focuses on how TTIP could impact public health through trade liberalization (e.g. cheaper

[142] In the E3MG model, this measure is ranked on a range from 0 (everyone earns the same income) to 100 (one individual earns all the income). Source of definition: http://data.worldbank.org/indicator/SI.POV.GINI.

products[143]) and through regulatory cooperation in the fields of pharmaceuticals and medical devices including intellectual property rights.

Trade between the EU-US in selected categories of consumption productsand its impact on health

Trade in alcohol, tobacco and sugars

This section will look at the current trade relations between the EU and the US for a number of consumption products; sugars, tobacco and alcohol. The EU imported 15 percent of its total extra-EU imports from the US in 2014. Weighted average trade tariffs for these products range from 0.6 percent for alcohol to 22 percent for tobacco in Europe and 0.1 percent for alcohol to 120 percent for tobacco in the US in 2014. The trade tariffs function indirectly on the one hand to (partly) protect consumers from consuming these goods and provide domestic producers market protection. On the other hand trade tariffs drive up domestic prices due to a lack of competition in products and/or resources. Next to trade tariffs, trade in above commodities is hampered by non-tariff barriers. According to the MIRAGE project, NTBs for alcohol and tobacco lead to an increase in prices of approximately 14 percent for US imports and 50 percent for EU imports.[144]

> **Box 4.3 General impact(s) of tariff liberalization**
> Tariff liberalization, as part of a Free-Trade Agreement, between two countries should lead to an increase in trade between the two countries in a number of sectors. An increase in trade has economically speaking (generally) a positive effect on total welfare in both countries, caused predominantly by a reduction in prices of products and greater coherence of regulations. There are however also negative effects. Tariff liberalization can for instance lead to the closing down or outsourcing of a sector in country A to country B, caused by comparative disadvantages, caused by higher input prices and/or social –and environmental regulatory differences.

Table 4.8 below give an overview of current tariff lines, import volumes, and the share of EU imports from the US compared to total imports for alcohol, tobacco and sugars.

Table 4.8 EU-US trade in selected consumption products, 2014

Importance of selected imported food and drinks from the US					
Product group code	**Imports from US (mln EUR)**	**Total extra-EU imports (mln EUR)**	**US in total extra-EU import (%)**	**Weighted average EU-tariff[145] (%)**	**Weighted average US-tariff (%)**
Sugars[146]	58,4	2373,2	2,5%	12,9%	8,3%
Alcohol[147]	1230,5	5248,1	23,4%	0,6%	0,1%
Tobacco[148]	276,3	2631,7	10,5%	22,1%	120,2%

Source: Import values is Eurostat data, Ecorys calculations. Tariff data is AHS, 2014.

The Table above shows that there is a high disparity between EU and US import tariffs on selected product groups. If import tariffs for the above product groups would fall to zero c.p. a

[143] We have selected a number of consumption products for this case study, after consultation with stakeholders in an earlier phase of the study. The exact impact on human health of consumption of these products is not necessarily comparable, as it predominantly depends on the level of consumption.
[144] IFO Institut, 2013, Dimensions and Effects of a Transatlantic Free Trade Agreement between the EU and US.
[145] Based on AHS, 2014. Weighted average EU and US tariffs for sectors at the HS 2-digit level; 02 for red meat, 17 for sugar, 22 for alcohol, 24 for tobacco.
[146] Sugar contains HS codes 1701, 1702, 1703, 1704.
[147] Alcohol contains HS codes 2202, 2203, 2204, 2205, 2207, 2208.
[148] Tobacco contains HS codes 2401, 2402, 2403.

decrease in costs for consumers could be an outcome in both the EU and US.[149] The table also gives an indication of the importance of imports from the US in total extra-EU imports.

The impact of selected consumption products on public health

The products introduced in this section impact human health in different ways, and to different degrees. As with any consumption product, excessive consumption of these products can lead to adverse health effects.. If these goods become more readily available and with lower prices than consumers are currently used to on the EU and US markets, as a result of lowering tariffs on these products in TTIP, consumers – subject to the law of demand – may be invited to consume more of these products. This potential adverse effect of TTIP on the targets of the UN Sustainable Development Goals (e.g. reduction of smoking, promotion of harmful use of alcohol, prevention of diseases, access to basic medication, etc.) is mentioned often by civil society.[150] Moreover, since the relatively more vulnerable groups of the population – those with relatively the lowest income levels – have the highest share of 'food costs' in their typical expenditure patterns (e.g. the poorest 20 percent of the EU population spends 19.2 percent of their income on food, while the top quintile spends 11.2 percent of income on food)[151], these effects could spread through society in an asymmetric way – implying that human health could be affected to different degrees for different population groups.

The study by Stuckler et al (2012) has shown, for instance that low-and middle income countries that signed an FTA with the US had an average increase of 63.4 percent in soft drink consumption per capita, much higher than the increase in consumption without the FTA. An increase of consumption of these products can not completely be attributed to an FTA , as for instance regulation can impact consumption levels in a similar way (for example the UK alcohol market deregulation). Middle-and-high income countries show a different development. In the observed countries economic growth occurs without an observed increase in consumption of these products, showcasing the importance of (national) policies –and regulations in mitigating future NCDs risks[152].

Trade between the EU-US in medical innovations – and devices and the impact on public health

Trade in medicines and medical innovations

The global health sector is one of the biggest sectors in the world, amounting up to 7 trillion USD according to the World Bank. Furthermore the sector is expected to grow by 4.4 percent between 2014 and 2017 due to changes in demography and increased demand from Asia.[153] The health sector is of importance to both the EU[154] and the US[155] who are together responsible for 70 percent of innovative new medicines and 80 percent of global sales in these medicines.[156] The healthcare sector is next to this a pull factor for R&D investments in the EU and US. The sector accounts for one fifth of global R&D investments and in Europe the healthcare sector ranks second, after automobiles, in corporate R&D spending[157], making it one of the drivers in the knowledge dependent economy of Europe.

Intellectual property (IP) is very important in the pharmaceutical industry and necessary for investments in R&D. Under TTIP IP revision is seen by proponents as an opportunity for the EU and US to harmonise certain key IP issues (such as some standards, protection and enforcement approaches). An aligned IP approach could incentivise the investment in new

---

149 c.p.: ceteris paribus; keeping all other things constant (such as a shift in import/export volumes or shift from/to products).

150 Health and Trade Network, Health and Trade: what hope for SDG3? 28 September 2015, feedback received from the Health and Trade Network during civil society consultation. This publication is also available online, at: https://healthandtradenetwork.wordpress.com/2015/09/28/health-and-trade-what-hope-for-sdg3/ [accessed 4 November 2015].

151 According to the statistics used by Cambridge Econometrics to calculate expenditure effects from price changes predicted by TTIP.

152 Stuckler et. al, 2012, Manufacturing epidemics: The role of global producers in increased consumption of "unhealthy commodities" including processed foods, alcohol, and tobacco. PLoS medicine, V9/I6.

153 ECIPE, 2015, The health of Nations: A transatlantic trade and investment agenda for better healthcare.

154 Health expenditures is for most European governments one of the largest areas of government expenditure (around 20%), often only expenditures on social protection are higher (Eurostat, 2012).

155 More then 40% of Europe's export goes to the US and almost 67% of Europe's import are sourced from the US. (ECIPE, 2015).

156 http://globalhealthprogress.org/qa/ttipqa#question-222, 11-09-2015.

157 EFPIA estimated that in 2012 €30 million was invested in R&D by pharmaceutical companies.

innovative medicines according to industry.[158] Opponents of IP legislation alignment however stress that such a development is one of the major risks to EU health systems.[159] One of the main fears brought forward is that alignment of IP rules between the EU and US could lead to longer periods of regulatory data protection (RDP) than is currently the case. In addition, research from Oxfam indicates that in recent years pharmaceutical companies moved from a focus on developing innovative new medicines towards extension of patent right to increase their rate of return on investments.[160] When we compare the EU and US IP systems, we find that the US has a regime of 12 years for biologics, but 5 + 3 years for new chemical entities (e.g. small molecules), while the EU has 8 + 2 + 1 years for both biologics and new chemical entities – so there is not much difference between the EU and US in terms of the time periods when medicine monopolies are allowed. The EU, in its negotiating proposals, does not intend to harmonise this small difference in regulatory regimes in TTIP and hence does not aim to introduce changes to the current legislation.

Barriers to trade

The EU and US have for decades been the main health sector trading hubs, driven mainly by trade in medical devices, advanced medical technology and pharmaceuticals. As a result of this long trade relation there is close alignment between the trade blocs. Trade between the two hubs is however not optimal. The existing trade import tariffs on medical devices limits trade and market access opportunities for especially SMEs[161] and poses obstacles to a further reduction in healthcare costs.

Trade between companies in the pharmaceutical and the medical device industry is further hampered by regulations, regulatory practices and the general environment for protection of innovation. There is for example no clarity regarding defining of prior user rights; handling of patent applications; and/or how patentability is determined[162]. Another example of a trade barrier, according to the sector, relates to duplicative clinical testing/product approval procedures, leading to higher R&D costs, hence higher prices and slower access of medicines in (the) overseas market.[163] The EU and US already have a strong basis for regulatory cooperation in this field – both bilaterally and at the international levels at the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the International Medical Device Regulators' Forum (IMDRF) and TTIP could further strengthen this cooperation which could lead to consumer (price) gains. See Box 4.4 for a short example of the international cooperation towards a harmonized electronic submission system for drugs, and devices.

Box 4.4 Cooperation on a Harmonised Electronic Submission System for Drug, Devices

The International Medical Device Regulators' Forum (IMDRF) has in the last years focused on medical device harmonisation efforts, in the context of RPS. The IMDRF was launched in 2012 as the regulators-only successor to the Global Harmonization Task Force (GHTF), which disbanded in December 2012 after its device regulatory members decided to split off and form their own juncture without the involvement of industry. At present, organisations involved in the IMDRF include the **US Food and Drug Administration (FDA)**, Australia's Therapeutic Goods Administration (TGA), Brazil's National Health Surveillance Agency (ANVISA), Health Canada, the **European Union (EU)**, Japan's Pharmaceuticals and Medical Devices Agency (PMDA), Russian Ministry of Health and the affiliate organisations; the Pan American Health Organization (PAHO) and the Asian Harmonization Working Party (AHWP). Regulators have stated that IMDRF would maintain the regulatory workload previously discussed under the GHTF. Trautman, US FDA regulator, said: *"there is much for the medical device industry to anticipate coming out of IMDRF. No longer is the focus of global regulators just on regulatory harmonization. Instead, they are increasingly looking to a "regulatory convergence" in which additional parts of the regulatory ecosystem (e.g. the technical documents, standards, practices and scientific principles among them)*

158 http://www.lilly-europe.eu/global/img/PDF/Branch-of-TTIP-position-paper.pdf.
159 Feedback from Civil Society during the 9th of July workshop on the case studies for the TSIA in Brussels.
160 Oxfam Novib, 2014. Trading away access to medicines "Revisited".
161 For SMEs a 1 or 2% trade barrier can already be a huge obstacle for trade due to associated administrative burden (ECIPE, 2015).
162 LSE, 2015. TTIP: International trade, law, health systems and public health.
163 http://globalhealthprogress.org/qa/ttipqa#question-222, 11-09-2015.

are voluntarily adopted by multiple countries. The process of convergence represents an important form of regulatory cooperation which in turn makes possible additional, enhanced forms of cooperation and collaboration between regulatory authorities."

A hot potatoe within the IMDRF – and the medical devices sector – was the global Unique Device Identification (UDI) system. A UDI is a labeling or marking standard by which regulators can keep track of a product-a sort of track-and-trace method for medical devices that allows anyone to determine from where a product originated and other information about a device. In addition, a UDI system is able to provide other benefits, such as allowing for the creation of a device registry to track the safety and efficacy of various products. Clearly, UDI would allow regulators to get more information about origins and other information about products, enabling them to better uphold and increase consumer health and safety protections. These constitute significant consumer benefits. The creation of UDI has been historically complicated by several regulators' attempts to put together their own systems, which have been in progress for many years. Indeed, national regulatory agencies have been drafting and publishing their own regulations, which could potentially lead to regulatory divergences. On the 17th of April 2013, the IMDRF issued a major guideline regarding UDI. This guidance provides "non-binding rules for use in the regulation of medical devices." The IMDRF explained that *"this guidance provides a framework for those regulatory authorities that intend to develop their own UDI systems - such that, when implemented, it achieves a globally harmonized approach to UDI." "It is expected that the regulatory authorities will follow the guidance when developing their own UDI requirements."* Furthermore, the hope, IMDRF said, is that *"UDI systems around the globe will be highly interoperable, allowing for the exchange of data on devices as they move throughout various regulatory systems and supply chains."*

The UDI example, provides a clear point in case how harmonisation can be stimulated globally – providing a global benchmark – while national regulatory authorities remain in charge of drafting their own UDI requirements.

Source: Regulatory Affairs Professional Society (RAPS) website, 19.11.2015.

The two tables below give an overview of current trade tariffs between the EU-US; import volumes; and the share of EU imports from the US compared to total imports for the pharmaceutical industry and medical device sectors.

Table 4.9 EU-US trade in selected sectors, 2014

Importance of selected imported medical devices from the US					
Product group code	**Imports from US (mln EUR)**	**Total extra-EU imports (mln EUR)**	**US in total extra-EU import (%)**	**Weighted average EU-tariff[164] (%)**	**Weighted average US-tariff (%)**
Pharmaceutical industry (30)[165]	21.449,7	53.954,0	39,8%	0.0%	0.0%
Other medical apparatus (902229)	5,3	13,3	39,8%	2.1%	0.8%
X-ray tubes (902230)	80,5	129,0	62,4%	2.1%	0.9%
Medical parts and accessories (902290)	352,5	749,8	47,0%	2.1%	0.9%

Source: Import values is Eurostat data, Ecorys calculations. Tariff data is AHS, 2014.

Table 4.9 shows that there is a disparity between EU and US import tariffs on selected sectors and product groups, excluding pharmaceuticals where no tariff exist. If import tariffs for above

[164] Based on AHS, 2014. Weighted average EU and US tariffs for sectors at the HS 2-digit level; 02 for red meat, 17 for sugar, 22 for alcohol, 24 for tobacco.

[165] There are no EU import tariffs on pharmaceuticals and very few on US import.

product groups would be reduced to zero c.p.[166] – indirectly – a decrease in costs for consumers could be the outcome in both the EU and US. The removal of tariffs (specifically small tariffs) are expected to especially benefit SMEs, because – especially for them – they reduce costs disproportionately.

Table 4.9 also gives an indication of the importance of US export to the EU for selected product groups. The last column shows, for instance, the strong connection between the EU-US in the pharmaceutical industry (40 percent of all extra-EU imports come from the US) and the medical devices sub-groups (with the US share in total extra-EU imports ranging between 40 percent for other medical apparatus to 63 percent for X-ray tubes).

Impact of TTIP on trade in selected public health related sectors

This section describes the identified main extra additional economic impacts (increased exports – or other effects) that can be expected and attributed to TTIP.

Expected impact of TTIP on public health with respect to selected consumption products

The situation for this group of products is assessed by comparing the expected trade world with TTIP to the baseline trade forecasts without TTIP. In this way we can identify the potential impact of the Transatlantic Trade and Investment Partnership.

We expect, as stated before in the section on tariff liberalisation, that the removal of the trade tariffs on most of the identified categories of consumption products will lead to a decrease in price for these goods.[167] An exemption is spirits, for which tariffs on both sides of the Atlantic are zero already. For those consumption products that will become cheaper, the expected impact of such a price decrease is difficult to predict, since this would depend on the price elasticity of demand. For instance, in the case of tobacco: will a European consumer currently smoking start to smoke more if cigarettes become cheaper? Will EU consumers who do not smoke now start smoking? In the cigarettes example, we know cigarettes to be very price inelastic (i.e. the cigarette smokers are very price insensitive) and thus consumers are expected not to change the quantity of cigarettes they smoke very much. In the longer run, new consumers might prefer the lower priced goods, however, leading to an increase in smoking. It is important to note that these categories of food and drinks may only serve as an input for a final retail good (e.g. sugars) or face additional levies and excise duties that are more important in the determination of the price than import tariffs (e.g. tobacco).

Having described this direct tariff effect, the question that then follows is whether this is a desirable development from the perspective of the EU and EU Member State regulators and whether they can act upon this undesirable development. Currently regulators and EU Member State governments are actively trying to reduce consumption of certain types of commodities by putting high(er) taxes on these commodities and/or by dis-incentivising consumption through non-regulatory measures. The current European retail price for tobacco is for instance around 75 to 87 percent higher than global market prices due to taxes in place to discourage consumption of tobacco. In addition, governments increasingly put national regulatory barriers in place to reduce consumption of tobacco, for instance through prohibiting smoking in public places. So the potential impact of removing trade tariffs on the selected consumption products on health can be mitigated by measures taken by (national) governments. Policies and regulations can, through taxation, increase the price of thesecommodities and keep total consumption stable, balancing the possible increase in consumption as a result of trade liberalization.

Civil society fears, however, that through Investor Protection and (at least the 'old' version of) ISDS, (public health) regulators could be put off from responding in a regulatory manner to this price decrease (i.e. the argument of 'regulatory chill'). While under the pre-TTIP, pre-CETA Investor Protection and ISDS rules, this concern would certainly be worth debating, under the latest EU negotiating proposal on Investor Protection and Investment Court System (ICS) things

[166] c.p.: ceteris paribus; keeping all other things constant (such as a shift in import/export volumes or shift from/to products).

[167] EPHA, 2015, EPHA contribution – public health concerns on food and agriculture in TTIP.

look different.[168] This new EU proposal is different from earlier ongoing practices in that it strengthens the right to regulate in a dedicated new article, a new system for resolving disputes – the Investment Court System – is proposed, and an appeal mechanism is envisaged. Especially the first innovation matters from the perspective of human health. Article 2 (Investment and regulatory measures/objectives) sub 1 reads: *"The provisions of this section shall not affect the right of the Parties to regulate within their territories through measures necessary to achieve legitimate policy objectives, such as the protection of public health, safety, environment or public morals, social or consumer protection or promotion and protection of cultural diversity."*[169] One can for example look at tobacco policy, in which case Article 2 of the investment chapter states that governments can still draft and implement strong tobacco control legislation, without potential litigation by the tobacco industry.

Expected impact of TTIP on trade on the medical device sector

Economic impacts on the pharmaceutical and medical device industry and public health are compared to the baseline trade and the expected impact based on the goals of EU negotiators as set out in the respective position papers.

> **EU negotiating aims regarding medical devicesand devices**
> Medical devices are a vital part of both the EU and US medical systems. Currently sometimes duplicative testing is needed. Under TTIP the EU negotiators plan to remove these duplicative audit requirements to reduce costs and speed up the take-up of new innovations two-ways across the Atlantic. The main goals are to achieve convergence of the Unique Device Identification (UDI) (traceability) systems, provide for common electronic data submission forms (Regulated Product Submission) and recognise audit results of each other's Quality Management Systems (QMS).

Expected economic impact of TTIP on trade in the medical devices sector

Tariff liberalisation in the field of medical devicesis not expected to lead to significant changes due to current existing low tariff rates. Having said that, given the existence of complex global value chains, where raw materials, parts and components and final products are traded heavily – implying that some part or component may be crossing international borders multiple times – also low levels of tariff may have a significant impact since they are counted multiple times. A larger impact of TTIP on medical devices could come from the following regulatory elements, also highlighted in the EU's position paper on medical devices:

- Mutual recognition of manufacturer's quality management systems (QMS) audits;
- Further convergence of systems of identifying and tracing medical devices (UDI – see Box above);
- Convergence of models for marketing submissions (Regulated Product Submission).170

If the EU and US can further align their UDI in TTIP – flanked by the international discussions at the IMDRF – and if EU and US could mutually recognise QMS audits, producers and hence consumers are expected to financially benefit because – without affecting protection levels for consumer health, the price for medical devices could be lowered. We expect that TTIP could have a positive economic impact on the medical devices sector if these negotiating ambitions are achieved.[171]

Expected (regulatory) cooperation through TTIP and its impact on medical innovations

TTIP will affect trade between EU and US pharmaceutical if regulatory cooperation in the field of non-tariff barriers is achieved.

---

168 On the 12th of November, the EU sent its new proposal on Investor Protection and Investment Court System to the US.

169 http://trade.ec.europa.eu/doclib/docs/2015/september/tradoc_153807.pdf.

170 EU position paper on medical devices. DG Trade website, downloaded 18th of November 2015.

171 Note: Increased competition could lead to local negative impacts and local unemployment in sub-sectors. If such impacts are expected due to EU trade liberalization the EU can prolong tariffs to reduce short-term effects and allow companies to slowly phase out from a market.

EU negotiating aims regarding medical innovation (pharmaceutical sector)
The main goal of the EU negotiators with respect to pharmaceuticals in TTIP is related to strengthening the already ongoing bilateral and multilateral level talks (e.g. via ICH), with a particular focus on establishing bilateral commitments that would facilitate pharmaceutical products authorisation processes and increase agencies' resources for inspections and exchange of confidential information, as well as fostering additional harmonisation of technical requirements in new areas like biosimilars, paediatrics, generics and terminology. Finally the EU and US aim to reinforce joint approaches on scientific advice and evaluation of quality by design applications.[172]

'Facilitating pharmaceutical products authorization processes' is a very important goal and currently a significant non-tariff measure because there are unnecessary duplications and best practices could be shared more than is currently the case in the bilateral and multilateral dialogues. Therefore, the aims in pharmaceuticals include reducing unnecessary duplications (also with respect to clinical trials) and building on best practices for regulatory practices. If the negotiations are breaking significant ground on these two goals, patient safety, innovation, and cost-effectiveness could be the result. For example, the shorter the timeframe needed to go through an authorization process for a new medicine (on either side of the Atlantic) the faster, new EU (US) medical innovations can reach US (EU) consumers. At a macro-level that means that the rate of medical innovation is sped up by allowing innovations from elsewhere (read: the US) to reach the EU market faster than is currently the case. This does require a degree of focus of regulator's resources – but that is also a clear negotiating aim.

The second important NTM regarding medical innovation has to do with Intellectual Property protection, on which the EP said the following in 2013: *"IP is one of the driving forces of innovation and creation and a pillar of the knowledge-based economy and TTIP should include strong protection of precisely and clearly defined areas of IP..."*. Based on this and discussions with stakeholders we expect that TTIP will lead to increased cooperation between the EU and US regarding IP. But from the EU position paper on IPR, it is clear that in TTIP the IPR chapter is expected to be a limited one, focusing on a few core issues only:[173]

- Listing of international IP agreements to which both sides are committed (i.e. information exchange);
- Listing general principles that stress the importance of IP as a tool for innovation, growth and jobs, as well as a number of high-standard agreed principles on key topics (envisaged in a preamble);
- Binding commitments on a limited number of significant IP issues (details in the EU position paper);
- Cooperation on areas of common interest.

Civil society is concerned – in particular – about the length of patents and whether this length could be increased as a consequence of TTIP, making medicines more expensive for more extended periods of time, and delaying the introduction of cheaper generic medicines to uphold the *human right to health*.[174] They state: *"IP provisions will lead to a lock up of technology and stifle independent innovation, leading ultimately not to job creation but to stagnating employment"* [175]. Indeed, from an economic viewpoint, granting longer periods of monopoly power could lead to lower levels of innovation, higher prices and lower levels of medicine production than optimal for society. On the other hand, without the option of recovering R&D investment costs no pharmaceutical company would invest in the future in developing new drugs because there would be no chance to earn back the investment.[176]

Hence we looked carefully into this concern. We first of all find that the duration of patent protection is 20 years in both the EU and US so there would be no rationale for regulatory

[172] EU position paper on pharmaceuticals. DG Trade website, downloaded 19th of November 2015.
[173] The EU position paper on IPR. DG Trade website, downloaded 19th of November 2015.
[174] A concern that came to the fore during the September 21st, 2015 workshop with civil society in Brussels as part of this TSIA.
[175] http://www.europarl.europa.eu/RegData/bibliotheque/briefing/2014/140760/LDM_BRI(2014)140760_REV1_EN.pdf.
[176] Berden, K. and C. van Marrewijk (2007) 'On the static and dynamic costs of trade restrictions'. The Journal of Development Economics, 2007.

alignment in TTIP of something that is already aligned. Second, we do not come across evidence – from the accessible texts – that the EU and US seek to extend the exclusivity time on pharmaceutical products. There is, however, already the provision (not in TTIP) that the terms of a pharmaceutical patent could be extended by a supplementary protection certificate (SPC). An SPC is meant to compensate for the time needed to obtain marketing authorisation of pharmaceutical products, and could extend the patenting period by up to five years. All EU Member States already have the SPC option and the US has a very similar system to the EU. Hence it is unlikely this issue will be addressed in the IPR Chapter of TTIP. Nonetheless, it would be worthwhile to examine whether the time period on SPCs could not be shortened in case TTIP would be successful in terms of creating shorter timeframes needed to go through an authorization process and introducing a new product on the EU (US) markets.

Conclusions

This topic was selected to investigate the potential effects of combined tariff and regulatory cooperation elements in TTIP for human health. We looked at impacts of TTIP for a number of food and drinks categories and medical innovations and devices. Regarding food and drinks products we found that tariff liberalisation could lead to increased consumption of these commodities since this may have a price reducing effect. This potential negative effect would be disproportionately higher for the lower income strata of the population (as food is a larger share of their expenditure).

However, we also find that the proposed provisions in TTIP regarding the states' right to regulate in the public interest (e.g. in the area of human health) sufficiently safeguard EU Member States' freedom to address this negative tariff effect on human health, if they wish to do so, in order to meet their human rights obligations. With respect to *medical innovation and medical devices* we found that the impact of removing the tariff on medical devices because of TTIP could be positive because hospital equipment would get cheaper, reducing health care costs. We also found that the potential impact of regulatory cooperation – for medical devices this means removing duplicative testing requirements (e.g. mutual recognition of quality audits) and speeding up the take-up of new innovations in medicines (e.g. through convergence on RPS) – could be still more substantial. TTIP could flank and strengthen the ongoing EU-US dialogue at the ICH and IMDRF. This work is helping to simplify trade in medical devices while improving patient safety (e.g. regarding UDI). Finally, there is no evidence that the EU would intend to harmonise the IP regime for medicines with the US, which – some fear – could lead to longer exclusivity for patent rights.

4.4. Assessment of social impact through the rules-setting channel

Having looked at the social impacts through the economic and trade channels, we turn to the potential effects through the channel of rules-setting. In Chapter 3 we have seen that the bulk of the economic positive effects can be attributed to the processes of regulatory co-operation and regulatory coherence of non-tariff measures in goods. It is also clear that – in contrast to tariffs – there is a clear rationale for having certain rules and regulations in place, e.g. to ensure consumer safety, social protection, environmental protection, etc. As such, the economic gains presented in Chapter 3 are a potential positive effect of TTIP, but only if they do not come at the expense of what the rules and regulations were created for in the first place. The most important issues raised in the social dimension are the impact of TTIP – through rules-setting – on ILO Fundamental Labour Conventions and the potential social impact of TTIP on public healthcare services. Both issues were prioritised in workshops with civil society over the summer of 2015 and they are covered in this section.

4.4.1. Case study 2: impact of TTIP on ILO Fundamental Conventions

The ILO has identified a number of labour rights, called the core labour standards that should apply, irrespective of the stage of economic development of the country. These four core labour standards, codified in eight Conventions (the "Fundamental Conventions"), constitute the social 'floor' of the world of work and deal with the freedom of association and collective bargaining, the elimination of child labour, forced labour and discrimination.[177] All EU Member States have ratified and implement all eight of the fundamental Conventions, whereas the US has ratified just two, and tends to follow the letter of the other conventions to different degrees.

[177] The International Labour Organization's Fundamental Conventions http://www.ilo.org/wcmsp5/groups/public/---ed_norm/---declaration/documents/publication/wcms_095895.pdf.