

Public Consultation on TTIP Sustainability Impact Assessment

EPHA Contribution | June 2016





Public Consultation on TTIP Sustainability Impact Assessment: EPHA Contribution

EPHA Recommendations

1. Public health impact of TTIP

Recommendation 1: The Sustainability Impact Assessment (SIA) should include a comprehensive quantitative and qualitative assessment of the impact of TTIP on public health. If this cannot be done, then it should clearly state that no full impact assessment has been conducted on the social and economic public health impacts of TTIP. Having two small scale, qualitative health-related case studies cannot be considered a proper public health impact assessment.

2. Unhealthy commodities, the reduction of tariffs and the impact on Non-Communicable Diseases (NCDs)

Recommendation 2: The SIA should retain the language of 'unhealthy commodities' in this case study, which forms a crucial aspect of the SIA of TTIP in the absence of a more detailed quantitative and qualitative public health impact assessment.

Recommendation 3: The SIA should be strengthened by making greater reference to the impact of the processed food sector on health outcomes in narrative form.

Recommendation 4: The SIA should highlight the societal and economic impacts of NCDs more clearly in order to more accurately reflect the scale of the challenge, as well as the importance of ensuring that consumption of 'unhealthy commodities' does not rise due to TTIP.

Recommendation 5: The SIA should clearly state that the reduction in tariffs will (absent any other policy decisions) lead to a reduction in prices, which in turn will increase



demand and consumption of ‘unhealthy commodities’, leading to adverse health and economic outcomes. It is only the **extent** of the increased consumption that will depend on the elasticities of demand. The SIA should be clear that those negative impacts cannot be considered as mitigated by simply referring to the right to regulate.

Recommendation 6: The SIA should state the relative impact on health outcomes for the poorest populations and young people (the impact on health inequalities) more clearly.

Recommendation 7: The SIA should confirm that if any form of ISDS/ICS is included in TTIP, it must contain specific guarantees ensuring the full respect of the margin of appreciation of governments in the field of public health protection.

Recommendation 8: The SIA should note that right of governments to regulate within their territories to achieve legitimate policy objectives including protecting public health, free from fear of litigation, must be included as a broad horizontal reservation in the final text of the TTIP agreement to have the maximum impact on mitigating ‘regulatory chill’.

Recommendation 9: Based on EPHA’s assessment (see [the Annex to this submission](#)), in order to mitigate the negative health consequences of TTIP resulting from tariff reductions, the SIA should state that the final text of TTIP should commit Member States to maintain at least the same price levels for unhealthy commodities. EU tariffs on unhealthy commodities must not be removed unless they are compensated by other EU and national-level measures, such as EU proposals aiming at harmonising increased taxes or excise duties.

3.Exclusion of public healthcare services

Recommendation 10: The SIA analysis of the current situation in the US healthcare system should be expanded to highlight the relatively poor performance of the US health system compared to health systems in the EU, particularly with regard to cost-effectiveness.

Recommendation 11: The SIA should analyse the impact on TTIP of a general exemption for the 28 national health systems through a modelled approach.

Recommendation 12: The SIA should state that rather than an exemption in ISDS/ICS, excluding public services from the whole scope of application of TTIP (in a similar fashion to the exclusion for audio-visual services) would better protect ‘Services of General Interest’, including education, social, healthcare and water and sanitation, regardless of whether they are publicly or privately funded.



4. Pharmaceutical chapter and the impact on pricing and transparency

Recommendation 13: The SIA should note that cost savings for pharmaceutical firms may not translate into lower prices, particularly in the context of monopoly pricing as a result of low market competition for drugs in specific disease areas. The SIA should note that in order to ensure that cost-savings are translated into more affordable medicines, the final text of TTIP should include an explicit statement to that effect.

Recommendation 14: The SIA should note that unless the primary objective of regulatory cooperation in pharmaceuticals is explicitly stated to be improving patient outcomes, patient safety may be at risk when looking to achieve a trade benefit.

Recommendation 15: The SIA should compare the cost and return on investment from including a detailed pharmaceutical annex in TTIP with new structures, with the counterfactual scenario of: including only a brief commitment to closer working between regulators in TTIP without detailing these aspects, and allowing the European Medical Agency (EMA) and Food and Drug Administration (FDA) to make progress on this front using existing well-established mechanisms.



1.Introduction

EPHA welcomes the publication of the draft interim technical report and the public consultation on changes to be made prior to publication of the final interim technical report. We would also welcome the opportunity to engage in bilateral discussions on the areas covered by this submission, and the impact of TTIP on public health more broadly.

EPHA is Europe's leading NGO advocating for better health. We are a dynamic member-led organisation, made up of public health NGOs, patient groups, health professionals, and disease groups working together to improve health and strengthen the voice of public health in Europe. We have been campaigning to mitigate the negative public health impacts of TTIP, including the impact of reducing tariffs on the growing rates of non-communicable diseases (NCDs); the potential impact on public healthcare services; and the potential impact of the pharmaceutical chapter on affordability of medicines and transparency of clinical trials data.

This submission looks at each of these areas, noting EPHA's analysis and providing suggested changes to the Sustainability Impact Assessment (SIA) to ensure that the health impacts of TTIP are accurately reflected in the final report. The submission also includes areas where EPHA supports the approach taken by the SIA with regard to health, including the use of the term 'unhealthy commodities'.



2. The overall analysis of the public health impacts of TTIP should be strengthened

Recommendation 1: The SIA should include a comprehensive quantitative and qualitative assessment of the impact of TTIP on public health. If this cannot be done, then it should clearly state that no full impact assessment has been conducted on the social and economic public health impacts of TTIP. Having two small scale, qualitative health-related case studies cannot be considered a proper public health impact assessment.

The quantitative and qualitative analysis of the potential impacts of a trade agreement focuses on the economic, social, human rights, and environmental impacts. There is, however, a need for a more detailed analysis of the public health impacts. This is particularly the case given that health was identified as one of the core social elements of sustainability in the 'Handbook for trade sustainability impact assessment' (2nd edition), published in April 2016.¹ The attention given to this area in the SIA is scant, comprising only two small scale, qualitative case studies.

Trade negotiations are taking place in the context of a high and growing burden of chronic non-communicable diseases (NCDs), such as: cardiovascular disease (CVD); diabetes; certain cancers; chronic obstructive pulmonary disease (COPD); and rising levels of obesity.

The evidence shows that increased globalisation and free trade agreements are linked to a nutritional transition towards diets characterised by a high intake of cheap, energy-dense nutrition-poor ultra-processed foods, high in (saturated) fats, salt and added sugars (HFSS), and a low intake of products high in fibre such as fruit and vegetables, and whole grains.²

Accordingly, the SIA should ensure that these impacts are considered with regard to TTIP in a comprehensive manner, including the economic costs that arise, for example, from the impact on the workforce and higher healthcare costs. This quantitative assessment should complement a more robust qualitative assessment of the public health impacts of TTIP.

¹ European Commission. Handbook for trade sustainability impact assessment (2nd edition). Luxembourg: Publications Office of the European Union, 2016. Available at http://trade.ec.europa.eu/doclib/docs/2016/april/tradoc_154464.PDF (retrieved 6th June 2016)

² World Health Organization. Globalization, Diets and Non-Communicable Diseases. Switzerland, 2002. Available at <http://whqlibdoc.who.int/publications/9241590416.pdf> (retrieved 6th June 2016)



3. The term ‘unhealthy commodities’ in the case study on health should be retained

Recommendation 2: The SIA should retain the language of ‘unhealthy commodities’ in this case study, which forms a crucial aspect of the SIA of TTIP in the absence of a more detailed quantitative and qualitative public health impact assessment.

Despite not comprising a comprehensive assessment of the impact of TTIP on public health, EPHA welcomes the inclusion of this case study.

Collecting tobacco, alcohol and foods high in salt, saturated fat and added sugar under the umbrella of ‘unhealthy commodities’ is reasonable and evidence-based. The ‘reference’ for the current state of evidence for this case study should be officially published WHO positions. The WHO is the global normative and standard setting body for health with a fully democratic decision-making structure (through representation by the Ministries of Health of each member state, and decisions made through the process of ‘one country, one vote’). In its norm and standard setting roles, the WHO has always retained a high level of credibility. Any resistance by industry lobby groups to definitions and guidance published by the WHO is therefore clearly unfounded and should be rejected outright. This section cites WHO sources, but the [annex to this submission](#) includes a more detailed review of evidence in this area.

Evidence of the impact of **tobacco** consumption on health is now beyond contention, and so merits no further discussion here.³

Evidence of the impact of harmful use of **alcohol** on health is clear, causing 3.3 million deaths per year worldwide (5.9% of all deaths). Alcohol is also a causal factor in more than 200 disease and injury conditions and leads to death and disability relatively early in life: in the 20-39 age group approximately one quarter of all deaths are alcohol-attributable. The WHO also highlights that there is a causal relationship between harmful use of alcohol and a range of mental and behavioural disorders; other non-communicable diseases; injuries; and infectious diseases such as tuberculosis and HIV/AIDS. The harmful use of alcohol has also been established as leading to significant social and economic losses to individuals and society at large. The WHO notes that there is *substantial scientific knowledge* that ‘reducing demand through taxation and pricing mechanisms’ will reduce the burden from harmful use of alcohol.⁴

Evidence of the impact of what the WHO describes as an ‘**unhealthy diet**’ on health is also clear, noting ‘there is convincing evidence that the consumption of high levels of high-energy foods, such as processed foods that are high in fats and sugars, promotes

³ World Health Organization. Tobacco: Fact sheet. June, 2016. Available at: <http://www.who.int/mediacentre/factsheets/fs339/en/> (retrieved 6th June 2016)

⁴ World Health Organisation. Alcohol: Fact sheet. January, 2015. Available at: <http://www.who.int/mediacentre/factsheets/fs349/en/> (retrieved 6th June 2016)



obesity compared to low-energy foods such as fruits and vegetables'.⁵ More specifically, the WHO advises that for an adult, a healthy diet contains:⁶

- **Less than 10% of total energy intake from free sugars** which is equivalent to 50g (or around 12 level teaspoons) for a person of healthy body weight consuming approximately 2000 calories per day, but **ideally less than 5%** of total energy intake for additional health benefits.
- **Less than 30% of total energy intake from fats.** Unsaturated fats (e.g. found in fish, avocado, nuts, sunflower, canola and olive oils) are preferable to saturated fats (e.g. found in fatty meat, butter, palm and coconut oil, cream, cheese, ghee and lard). **Industrial trans-fats** (found in processed food, fast food, snack food, fried food, frozen pizza, pies, cookies, margarines and spreads) **are not part of a healthy diet.**
- **Less than 5g of salt** (equivalent to 1 teaspoon) per day and use iodised salt.

Accordingly, processed foods and beverages containing high levels of added sugars, salt, saturated fats, and any trans-fats, are de facto 'unhealthy' in that they have a negative impact on health. Reducing the cost of sugar for producers further reduces the prices for these goods, leading to increased consumption of 'unhealthy' levels of free sugars with reference to the WHO guidelines.

⁵ World Health Organization. Global Health Observatory data: Unhealthy diet. Available at: http://www.who.int/gho/ncd/risk_factors/unhealthy_diet_text/en/ (retrieved 6th June 2016)

⁶ World Health Organization. Healthy diet: Fact sheet. September 2015. Available at: <http://www.who.int/mediacentre/factsheets/fs394/en/> (retrieved 6th June 2016)



4. The case study on the impact of unhealthy commodities on health should be strengthened, particularly with regard to the reduction of tariffs and the impact on NCDs

Recommendation 3: The SIA should be strengthened by making greater reference to the impact of the processed food sector on health outcomes in narrative form.

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As the SIA rightly points out, ‘unhealthy commodities’ include not only tobacco and alcohol, but also foods and beverages that are high in added sugar, salt and fats. Whilst the SIA clearly states that the processed food sector has not been modelled to ensure accurate output, this case study should be strengthened by making greater reference to the impact of this sector on health outcomes in narrative form.

As noted in the previous section, the evidence clearly shows that all of these ‘unhealthy commodities’ contribute to increased rates of NCDs including: type 2 diabetes; high blood pressure and cardiovascular disease leading to heart attacks and strokes; respiratory diseases (such as asthma, COPD); liver disease; and most forms of cancer. These diseases have **major health consequences**, including both serious disability during life as well as early deaths. They also have **significant economic consequences**, including productivity losses from workforce absences and long-term unemployment, as well as the cost to health systems of managing patients with these conditions. Specific evidence for this includes:

NCDs account for 86% of deaths in the WHO European Region and 77% of the disease burden.⁷ NCDs affect more than 80% of people aged over 65 and represent a major challenge for health and social systems. 70 to 80% of health care budgets, an estimated €700 billion per year are spent on chronic diseases in the European Union.⁸⁹

The World Economic Forum and the Harvard School of Public Health predicts that NCDs will result in a cumulative loss in global economic output of \$47 trillion, or 5% of GDP, by 2030, principally through heart disease, stroke, alcohol misuse and depression in high- and upper-middle-income countries. The predicted cumulative losses of 5% of GDP would be even larger if the economic value and utility that people attribute to health were adequately captured.¹⁰

Further evidence is included in the annex to this submission, and EPHA and its members would be happy to supply the SIA team with the evidence on specific areas on request.

The SIA should highlight these impacts of NCDs more clearly in order to more accurately reflect the scale of the challenge, as well as the importance of ensuring that consumption of ‘unhealthy commodities’ falls rather than rises due to TTIP. Notably, this should include framing this issue as not only conflicting with the human right to health (Art. 12 ICESCR; Art. 11 ESC), but also as having negative effects on GDP growth (through impacts on labour) and requiring increased spending on health by states.

Additionally, the SIA should avoid using language such as “...*commodities are seen as some of the main risk factors for a global increase in chronic non-communicable diseases*” (p.123) (emphasis added), when these links are clearly established by high-quality evidence. These statements should be stated instead as objective facts with the evidence or WHO guidance clearly referenced.

⁷ WHO Europe (2014). Prevention and control of Non-Communicable diseases in the European Region: a progress report

⁸ <http://www.oecd.org/dataoecd/43/9/48245231.pdf>

⁹ The 2012 Ageing Report: Economic and budgetary projections for the 27 EU Member States (2010-2060), European Economy 212012. European Commission.

http://ec.europa.eu/economy_finance/publications/european_economy/2012/pdf/ee-2012-2_en.pdf

¹⁰ Bloom, David et al. (2011), ‘The Global Economic Burden of Non-Communicable Diseases’, World Economic Forum, Geneva, http://www3.weforum.org/docs/WEF_Harvard_HE_GlobalEconomicBurdenNonCommunicableDiseases_2011.pdf



The SIA rightly points out that the major challenge here is that the reduction in tariffs will (absent any other changes) lead to a reduction in prices, which in turn will increase demand for and consumption of ‘unhealthy commodities’, leading to the health and economic outcomes outlined above. Whilst **strength** of the effect depends on the relative price elasticities of demand of the commodities, it is nonetheless certain that this effect **will** take place, and this point could be made more clearly. This applies to all of the ‘unhealthy commodities’, and singling out tobacco as a relatively price inelastic good is misleading in this context. Furthermore, the use of tobacco as an example should also include the fact that a tax that increases tobacco prices by 10% decreases tobacco consumption by about 4% in high-income countries – leading to a huge improvement in health outcomes.¹¹ Therefore, the SIA should note that with regard to tobacco, as with all other ‘unhealthy commodities’, a fall in price **will** lead to an increase in consumption and negative health outcomes.

The SIA also points out that the impacts could spread through society in an asymmetric way, affecting the poorest most. However, the relative impact on health outcomes for the poorest populations and young people could be stated more clearly. Those on the lowest incomes are most sensitive to changes in prices for all commodities, including ‘unhealthy commodities’. As noted, the removal of tariffs (absent any other changes) **will** lead to a fall in price for these products and an increase in demand and consumption across all income levels. However, the increase in consumption will be highest in the poorest and in young people, leading to worse health outcomes in these groups. This will worsen health inequalities across the EU and USA, contrary to current EU policy.¹² This should be clearly stated in the SIA.

On the topic of mitigating actions, the SIA notes that:

“the potential impact of removing trade tariffs on “unhealthy commodities” on health can be mitigated by measures taken by (national) governments. Policies and regulations can, through taxation, increase the price of ‘unhealthy commodities’ and keep total consumption stable, balancing the possible increase in consumption as a result of trade liberalization” (p.127).

The SIA also notes that the concerns of civil society organisations with regard to ‘regulatory chill’ preventing regulators from taking such actions due to fears of legal action through the ISDS/ICS mechanism, and highlights that under the new ICS mechanism that has been proposed this will not be the case. This explicit support for the right of governments to regulate in the interests of public health (as laid out in the proposed Art. 2, para 1 of the ICS proposal) is to be welcomed. However, research indicates that the revised EU proposal for an Investment Protection Court (ICS) proposal would not prevent similar cases like Phillip Morris vs Uruguay¹³ being launched against EU governments and causing regulatory chill.¹⁴ There is no need for such an ISDS or ICS clause at all between two developed, democratic economies respecting the rule of law and this is why the best option for the public interest is not including any ISDS/ICS chapter in TTIP.

¹¹ World Health Organization. Tobacco: Fact sheet. June, 2016. Available at: <http://www.who.int/mediacentre/factsheets/fs339/en/> (retrieved 6th June 2016)

¹² http://ec.europa.eu/health/social_determinants/policy/index_en.htm

¹³ http://www.tobaccotactics.org/index.php/Philip_Morris_vs_the_Government_of_Uruguay

¹⁴ https://www.foeeurope.org/sites/default/files/eu-us_trade_deal/2016/icstest_web.pdf



However, in case ISDS/ICS is included, there is need for a wider public health protection in the investment chapter of TTIP. The TTIP agreement must ensure that it is the legally immutable right of the EU and Member States ('margin of appreciation') to propose and implement policies and measures to achieve public health protection and improvement as democratically legitimate, irrefutable public policy objectives. In contrast, panel members of investment arbitration courts are in no position to evaluate the relative necessity of a public health measure. In principle, it is desirable that international investors consider political and regulatory stability as a factor in their judgement of investment risk and due diligence assessments.

In addition to that, without this language being used explicitly throughout the TTIP agreement, the risk of 'regulatory chill' remains. Accordingly, the SIA should note that this right of governments to regulate within their territories to achieve legitimate policy objectives including protecting public health, free from fear of litigation, must be included as a broad horizontal reservation in the **final** text of the TTIP agreement. It must be noted however that referring to the right to regulate cannot be presented as a way to mitigate the identified risks for public health in TTIP.

Finally, the SIA should also balance the discussion on the 'legal' right of governments to raise taxes on 'unhealthy commodities' with the real world 'political' challenges in doing so (given that the SIA is looking at 'real world' impact). Whilst it is true that *'policies and regulations can, through taxation, increase the price of unhealthy commodities' (p.127)*, many governments in Europe are not willing or able to increase taxes on some or all of these goods. This renders the 'legal' right to do this inadequate for preventing the negative consequences to health. Reasons for this include ideological opposition to raising taxes within political parties, and pressure from industry directly and through industry-funded lobby groups. Prices in these jurisdictions will therefore fall, demand and consumption will rise, and the rates of chronic diseases, hospital admissions and deaths will rise together with the economic costs as outlined above.

This 'political economy' lens is an essential part of the analysis of the impact that these measures will have on health in the real world. Failure to include this leads to a partial analysis, as in the present case, where it is suggested that the impact of tariff reduction will be *negligible* because governments *can* raise taxes, when in practice the impact of tariff reduction may be *significant* because governments *may not* raise taxes. The SIA should also note that a provision in the final text of TTIP that commits Member States to maintain **at least** the same price levels for unhealthy commodities would mitigate against the risk of political inaction to some extent.



5. The SIA should model the impact of exclusion of public healthcare services from TTIP

Recommendation 10: The SIA analysis of the current situation in the US healthcare system should be expanded to highlight the relatively poor performance of the US health system compared to health systems in the EU, particularly with regard to cost-effectiveness.

Recommendation 11: The SIA should analyse the impact on TTIP of a general exemption for the 28 national health systems through a modelled approach.

Recommendation 12: The SIA should state that rather than an exemption in ISDS/ICS, excluding public services from the whole scope of application of TTIP (in a similar fashion to the exclusion for audio-visual services) would better protect 'Services of General Interest', including education, social, healthcare and water and sanitation, regardless of whether they are publicly or privately funded.

We welcome the inclusion of a specific case study on the impact of TTIP services liberalisation on public health services, particularly with reference to the entrance of US private healthcare providers on EU healthcare services and the potential for 'regulatory chill' that will prevent future government policy action to improve public health.

The analysis of the current situation in the US healthcare system should be expanded to highlight the weak relative performance of the US health system compared to health systems in the EU, particularly with regard to cost-effectiveness. A number of studies exist that demonstrate this, for example the Commonwealth Fund report 'Mirror, Mirror on the Wall: How the Performance of the US Health Care System Compares Internationally'.¹⁵ This report showed that the US health system is the most expensive in the world but consistently underperforms relative to other countries on most dimensions of performance. This would serve to highlight the concerns of civil society organisations of greater delivery of health services in the EU by US healthcare companies in terms of higher costs and worsening patient outcomes.

The SIA analysis notes that TTIP by itself will have minimal impact on domestic health services in the EU, due to this area being a Member State competence. Accordingly, we propose that health services are excluded completely from TTIP – as this analysis suggests that there will be minimal impact and Member States will remain free to allow US health service companies to enter their healthcare markets should they so choose. Excluding health services from TTIP in this way will therefore also prevent the 'regulatory chill' effect much more effectively than including trade in health services in TTIP then seeking to carve out an exemption in the ICS/ISDS chapter as is proposed by the SIA. The UK has already stated that it intends to seek to exempt the National Health Service (NHS – the UK health system) from TTIP, and so it appears to be very possible to do this for all countries through a blanket provision. The SIA should analyse the impact of doing so through a modelled approach.

¹⁵ Davis K, Stremikis K, Squires D et al. Mirror, Mirror on the Wall: How the Performance of the US Health Care System Compares Internationally. The Commonwealth Fund, 2014. Available at http://www.commonwealthfund.org/~media/files/publications/fund-report/2014/jun/1755_davis_mirror_mirror_2014.pdf (retrieved 6th June, 2016)



The trade in services is another area where we would argue that a 'political economy analysis' would show that whilst 'legally/technically' Member States remain able to exclude US healthcare companies should they so wish, in practice there may be political pressure to include them and open up tenders for services accordingly. This may lead to rising costs and worsening health outcomes in EU health systems in line with what has been observed, and difficulty in reversing these shifts. This also supports the proposal that trade in health services should be excluded entirely from TTIP.



6. Pharmaceutical chapter and the impact on pricing and transparency

Recommendation 13: The SIA should note that cost savings for pharmaceutical firms may not translate into lower prices, particularly in the context of monopoly pricing as a result of low market competition for drugs in specific disease areas. The SIA should note that in order to ensure that cost-savings are translated into more affordable medicines, the final text of TTIP should include an explicit statement to that effect.

Recommendation 14: The SIA should note that unless the primary objective of regulatory cooperation in pharmaceuticals is explicitly stated to be improving patient outcomes, patient safety may be at risk when looking to achieve a trade benefit.

Recommendation 15: The SIA should compare the cost and return on investment from including a detailed pharmaceutical annex in TTIP with new structures, with the counterfactual scenario of: including only a brief commitment to closer working between regulators in TTIP without detailing these aspects, and allowing the European Medicines Agency and Food and Drug Administration to make progress on this front using existing well-established mechanisms.

Pharmaceuticals are referred to both at '4.3.1. Case study: impact of TTIP on human health' and '8. Potential TTIP impact on the chemicals and pharmaceuticals sector'. The SIA notes that there are no tariffs in the pharmaceutical sector, and that:

“the EU and US already have a strong basis for regulatory cooperation in this field – both bilaterally and at the international levels ... and TTIP could further strengthen this cooperation which could lead to consumer (price) gains.”

Similarly, it notes that *“patient safety, innovation, and cost-effectiveness could be the result.” (p.128)*

Whilst we agree that cost-savings **could** lead to a fall in prices, without an explicit commitment in TTIP to do so it may be the case that these cost-savings are instead absorbed by the industry, leading to higher profits or higher marketing budgets – in short, not translated into benefits for patients. This is particularly the case in the context of the patented pharmaceutical industry where there is limited competition on specific drugs classes for specific disease areas. In the absence of a competitive market, monopoly pricing is already present, and so the decreased costs as a result of TTIP may just be absorbed into this.

Accordingly, the SIA should be strengthened by noting that the final text of TTIP should include an explicit statement in order to ensure that these cost-savings are translated into more affordable medicines. This is particularly important in the context of rising prices for medicines across the EU and the USA at the same time as a squeeze on healthcare budgets – highlighted by the European Council and WHO as a major public health issue.



Additionally, the SIA notes that ‘the shorter the timeframe needed to go through an authorisation process for a new medicine (on either side of the Atlantic), the faster the new EU (US) medical innovations can reach US (EU) consumers.’ This is true, but critically omits to mention that patient safety is of paramount importance in this area, and approvals processes must ensure that sufficient data has been collected on clinical-effectiveness (including side-effects) and cost-effectiveness before authorisation for use is given. Accordingly, the SIA should add that the primary objective of regulatory cooperation in this area must be improving patient outcomes, and therefore no aspects of this should jeopardise patient safety in order to achieve a trade benefit.

On intellectual Property (IP), the SIA notes that:

‘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.’

It also notes, however, that:

‘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.’

The SIA could link these areas by noting that in order to promote the goals of lower prices and higher levels of innovation, the ‘general principles on IP’ in the IPR chapter of TTIP should include a statement on the importance of appropriate limits on patent exclusivity for ensuring innovation and universal access to affordable medicines. This would protect against future shifts in IP in pharmaceuticals with negative outcomes on resource allocation (and ultimately patient care).

An area of concern with regard to pharmaceuticals that has not been picked up by the SIA is clinical trials transparency. The EU has made significant advances in this area in recent years, with the EMA policy on the publication of clinical trials data (October 2014) and the Clinical Trial Regulation (Regulation No 536/2014). These have ensured that pharmaceutical companies will be required to make all clinical data supporting the approval of their medicines freely available to the public. This represents a step-change for patient safety.

The recently released EU proposal for an annex on medicinal products (dated 24th May 2016) includes provisions to facilitate the exchange of confidential and trade secret information related to the authorisation of medicinal products. It provides that information shared between regulatory agencies that is not already in the public domain will not be disclosed by the other party. The SIA should include the impact on health if clinical trial data are not explicitly excluded from this section. If this progress on patient safety is to be maintained, it is critical that data on drug efficacy, side effects and complications are made public and subjected to further analysis by healthcare professionals and academics. Accordingly, the inclusion of clinical trials data in this section would risk undermining the progress made in the EU on this front, and prioritise the commercial interests of pharmaceutical companies ahead of public health.



Finally, the SIA notes in several places that the US and EU regulators already work together very closely, and have made good progress on strengthening the exchange of information as well as in other areas. In this context, the SIA should be strengthened by comparing the costs and benefits from including a detailed pharmaceutical annex in TTIP with additional structures, with the counterfactual scenario. The counterfactual scenario would be either excluding pharmaceuticals from TTIP, or only including only a brief commitment to closer working between regulators in TTIP without detailing these aspects, and allowing the EMA and FDA to make progress on this front using existing well-established mechanisms. This modelling would provide a clear illustration of the benefits and disadvantages of both approaches.

About EPHA

EPHA is a change agent – Europe's leading NGO advocating for better health. We are a dynamic member-led organisation, made up of public health NGOs, patient groups, health professionals, and disease groups working together to improve health and strengthen the voice of public health in Europe. EPHA is a member of, among others, the Social Platform, the Health and Environment Alliance (HEAL), the Transatlantic Consumer Dialogue (TACD) and the Better Regulation Watchdog.

EPHA's Transparency register number is 18941013532-08.



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