EPHA submission on the public health related case studies of the draft final Technical report (trade SIA TTIP)

Suggested recommendations for the trade SIA on TTIP

1. **As case studies cannot be considered as a proper public health impact assessment, a comprehensive study should be carried out on the qualitative and quantitative assessment of the potential public health impacts of TTIP,** given the burden of mortality, morbidity and economic loss that TTIP is likely to cause

2. As long as there are no guarantees and recommendations to governments and the EU on how to mitigate the **negative public health impacts of reduction of tariffs on unhealthy commodities** (tobacco, alcohol and foods high in fat, salt and sugar and low in essential vitamins and other components important for a healthy diet), **existing tariffs on unhealthy commodities should be maintained**.

3. **There is a need for an assessment of the costs of Regulatory Cooperation and Good Regulatory practices for European and national level**, including the implications for public interest decision making, missing from the current Report.

4. The most preferable option would be to have **a full carve-out of services of general interest (SGEI)** from TTIP in the same way that audio-visual services have been excluded in the negotiating mandate for TTIP. [1] **TTIP is problematic because it limits the freedom of governments to make policy decisions on they wish to organise services of general interests relevant for public health** (social, healthcare, education, water) by giving incentives for further liberalisation and making it financially more difficult to reverse such a decision.

5. TTIP **shall not contain provisions having the potential to undermine affordability of medicines and transparency of clinical trials** (IP related monopolies and exclusivities for medicines, pharmaceutical pricing and reimbursement, trade secret protection).

This joint submission reflects upon the public health related case studies (**4.3.1. Case study 1:** *Case study 1_ impact of TTIP on Human health* and **4.4.2. Case study 3:** *Impact of TTIP services liberalisation on public health services*) of the draft final Technical Report (the Report).

Our Recommendations should be read alongside of the comments and recommendations made by the previous submissions of the European Public Health Alliance (EPHA) submitted on 15 October 2015 and on June 2016), the European Heart Network (EHN), submitted 3 June 2016, the European Association for the Study of the Liver (EASL), submitted June 2016, the European Alcohol Policy Alliance (Eurocare), submitted June 2016 and the Independent Order of Good Templars (IOGT) International, submitted June 2016.

[1] Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America 11103/13 DCL 1, 17 June 2013 http://data.consilium.europa.eu/doc/document/ST-11103-2013-DCL-1/en/pdf

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We welcome the inclusion of public health specific case studies into the trade SIA on TTIP which we consider a step to the right direction. However, given the significance of the potential public health impacts of TTIP, these small case studies are too limited and arrived too late in the process to give sound evidence on the projected health impacts. **The current assessment lacks in depths analysis and cannot be considered as a basis for addressing the potential negative public health impacts of TTIP.**

- *"In the cigarettes example, we know cigarettes to be very price inelastic and thus consumers are expected not to change the quantity of cigarettes they smoke very much" (case study 1)* is true that tobacco is price inelastic but it is not true that tax increases do not lead to a decrease in smoking.[2] See also the WHO recommendation saying that increasing the price of tobacco through higher taxes is the single most effective way to encourage tobacco users to quit and prevent children from starting to smoke.[3]

- *''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'" (case study 1)* However, given the current state of the EU policy climate and the discussions on the regulatory cooperation chapter in TTIP, we are not confident that the necessary regulatory action will be forthcoming to counterbalance the adverse impact of the rise in consumption from the reduced tariffs on alcohol, tobacco, foods and beverages that are high in fat, salt and sugar (unhealthy commodities). In the past two years, the EU Commission has opposed sub-national action on Minimum Unit Pricing for alcohol in Scotland in the CJCEU and asked Finland to repeal its so-called ice cream tax.

- *"We do not come across evidence – from the accessible texts – that the EU and US seek to extend the exclusivity [4][5] time on pharmaceutical products." (Case study 1)* However, the study does not assess the potential impacts on the price of medicines, as a result of closer regulatory cooperation with the U.S. – a country with the highest per capita medicines spend in the world. The U.S. and the EU take different approaches to pharmaceutical IP, though the ultimate result is the same – long periods of market exclusivity for new medicines which are sold at high prices. This leads to significant profits for the manufacturer, high costs for healthcare systems, and can result in limiting access to medicines for patients or increased out of pocket payments. This is unacceptable in the context of high prices limiting equitable access to medicines in both the EU[6] and the U.S. [7] The report does not state that affordability of medicines should be taken into account in the process of regulatory cooperation, which is projected to save resources and to lower costs for pharmaceutical firms and administrations. These lower costs will not necessarily lead to lower prices for consumers in the context of the branded pharmaceutical sector, instead potentially being absorbed into increased profits or marketing budgets. Furthermore, the study does not mention other elements relevant in TTIP such as pharmaceutical pricing and reimbursement and trade secret protection.

- *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*

[2] http://www.tobaccoinaustralia.org.au/13-1-price-elasticity-of-demand-for-tobacco-produc
[3] http://www.who.int/tobacco/mpower/raise_taxes/en/
[4] http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-balance-pharmaceutical-system/
[5] http://www.unsgaccessmeds.org/final-report/
[6] http://hepcoalition.org/news/press-releases/article/hepatitis-c-gilead-patent-on-sofosbuvir-partially-maintained-following-mdm
[7] Jackevicius CA et al. Generic atorvastatin and health care costs. New England Journal of Medicine 2012; 366(3):201-204. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3319770/ (accessed 8th June 2016)

legislation, without potential litigation by the tobacco industry (case study 3). However, this does not mean that regulatory chill is no longer an issue. it is true that Article 2 emphasises the right of governments to regulate to achieve legitimate policy objectives but it is not true that it precludes litigation by, for instance, tobacco companies, as stated in the Report. It may make it more difficult for these companies to win – but the threat of litigation remains and will continue to cause "regulatory chill". The study also omit to add that there is an global binding treaty on tobacco (Framework Convention on Tobacco Control (FCTC) but there is no such a legally binding tool in the policy fields of alcohol or unhealthy food which may be an issue for policy actions.

- *"There are no provisions in TTIP that would require EU governments to privatize public services or to bring them back into public domain once they were privatized. if CETA were to be the benchmark for TTIP on how to treat and protect public services, no major impact on EU Member States' health care systems is to be expected (...) If public health services are carved out from Investor Protection – i.e. investors cannot claim any compensation for public authorities' decisions to carry out changes in public healthcare systems – then the risk for 'regulatory chill' would be further reduced, if not completely removed". (case study 3)* The study omits to recognise that TTIP may limit the freedom of governments to organise public services by creating financially significant barriers to reverse such decision. The study mention CETA as a benchmark which contains a controversial 'ratchet clause' which limits the reservations made by the Parties, as it applies CETA's provision – including ICS - to all measures which go against liberalisation. Services of General Interests – including privately funded services – are not carved out from TTIP therefore Investment protection/ ICS rules and the "regulatory chill' is still relevant.

- *"When looking at the various ways in which regulatory co-operation is pursued – ranging from information exchange, using international agreements together, mutual recognition agreements of conformity assessments or of test results, to mutual recognition of functionally equivalent technical requirements or harmonised technical regulations – there is no tool where TTIP is meant to 'legislate'." (case study 3)* The Report does not address the fundamental concerns of public health groups that trade deals are not the appropriate tools to influence or decide on principles of law-making for the public interest. The EU proposals would institutionalize a higher level of regulatory cooperation and good regulatory practices for the future, creating a mechanism to narrow the gap between European and American regulations, which could have lower level of protection ('lowering standards' or 'race to the bottom') as an outcome. [8]

Conclusions

While trade liberalisation initiated by TTIP has the potential to support public health by supporting economic growth, higher incomes and greater employment opportunities, this can be undermined by the unintended side-effects of the trade deal. **TTIP can be incoherent with key public health policy goals and could undermine the battle against the growing burden of Non-Communicable Diseases and obesity and could not contribute to universal access to affordable medicines**

We firmly believe that **international trade deals can be beneficial to public health** on the condition that negotiations establish appropriate regard to the public interest and set the right conditions to ensure protection and continuous improvement of public health and rights, and access to quality health services and affordable medicines. There is every reason to believe that following the above mentioned recommendations would get a much better deal for Europe that would be capable of winning support, and set a genuinely progressive blueprint for future trade deals with other parts of the world.

[8] Europe's Regulations at Risk The Environmental Costs of the TTIP, Boston University
https://www.bu.edu/pardeeschool/files/2016/04/ACKERMAN.final .pdf