

THE ROLE OF PUBLIC HEALTH IN A RENEWED TRADE POLICY FOR A STRONGER EUROPE

**RESPONSE BY THE EUROPEAN PUBLIC HEALTH ALLIANCE
TO THE PUBLIC CONSULTATION ON EU TRADE POLICY**

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Introduction

The European Public Health Alliance (EPHA) is a member-led organisation made up of public health NGOs, patient groups, health professionals and disease groups. We work to improve health and strengthen the voice of public health in Europe.

EPHA is seriously concerned at how little attention has been paid to health by the European Commission in the consultation on future EU trade policy. A renewed trade policy for a stronger Europe hardly mentions health and lacks the basic coherence between international trade and public health. This approach contradicts the mandatory legal principle of Health in All Policies which requires having health considerations in all aspects of public policy, including EU trade policy (TFEU 168) and is particularly concerning given that it aims to learn lessons from the COVID19 crisis.

Therefore, EPHA considers that DG TRADE should seriously rethink its value-based trade approach and offers the following entry points in trade policy to make it more coherent with public health.

Question 1: How can trade policy help to improve the EU's resilience and build a model of open strategic autonomy?

We live in a complex and fast-paced world. Now more than ever, people are faced with navigating this constant state of flux, leading to multiple challenges to protect and promote health and health equity, particularly in the realm of the wider determinants of health. This is especially true when it comes to trade, where social and environmental protections which affect public health are key considerations of trade negotiations and final agreements. Trade negotiations between large global economic actors have considerable implications for current and future generations, the environments in which they live and the domestic policy-making process.

The EU's international trade policy for the 21st century should serve people's well-being, delivering overall societal benefits via enhanced trade collaboration. A pure GDP and economic focus makes the EU's trade position extremely fragile since, if people do not realise the trade benefits, it can erode societal support for international trade, undermining the democratic legitimacy and final approval of Free Trade Agreements (FTAs) via national parliaments.

Moreover, current developments in EU trade policy have also demonstrated the potential for a narrow-minded trade approach, which does not incorporate wider societal challenges, to damage the democratic legitimacy between the EU institutions. It is especially notable how the current trend has led to major disagreements between the Commission, Member States and the European Parliament, increasing scepticism towards the EU project and creating a further distance between the EU and ordinary Europeans. The societal resistance to the Transatlantic Trade and Investment Partnership (TTIP) as well as the Comprehensive Economic and Trade Agreement (CETA) offer good case studies in this regard.

Historically, when 'health' is referred to in a trade policy context the focus is on 'health & safety', e.g. SPS matters and health and safety in the workplace. However, **public health protection is much broader; it includes health promotion and prevention of health, as well as health care services**, such as universal access to healthcare, or ensuring affordable and effective medicines. Protection and promotion of health may entail regulatory intervention, including on products which can harm health.

However, despite the increased salience of the link between health and trade in the wake of COVID-19, there is still a limited understanding of what this means in terms of supply chains for medical products. What is missing in trade policy debates is a more comprehensive consideration of the complex interactions that exist between trade, investment and public health. This must go beyond considering whether goods, services and capital move freely across borders or the nationality of an asset. As EPHA demonstrates below in this submission, international trade policy can have fundamental implications for public health that goes beyond the ability of supply chains to produce and distribute medical goods; for example, the impacts on nutrition through increased consumption of unhealthy foods and beverages as a result of the removal of tariff and non-tariff barriers; or restrictions in access to medicines as a result

of cross-border flows of trade and investment¹ and provisions in trade agreements on intellectual property rights;² I or investor-to-state dispute settlements (ISDS) and regulatory cooperation, which can constrain governments and public bodies seeking to implement measures to protect and promote public health.³

What measures are needed to ensure trade policy is coherent with public health objectives?

Health promotion and disease prevention programmes focus on keeping people healthy. Health promotion programmes aim to engage and empower individuals and communities to choose healthy behaviours, and make changes that reduce the risk of developing chronic diseases and other morbidities. Defined by the World Health Organization⁴, health promotion is:

“The process of enabling people to increase control over, and to improve, their health. It moves beyond a focus on individual behavior towards a wide range of social and environmental interventions.”

Disease prevention differs from health promotion because it focuses on specific efforts aimed at reducing the development and severity of chronic diseases and other morbidities.

Health promotion and disease prevention programmes often address **social determinants of health**, which influence modifiable risk behaviours. According to the World Health Organization⁵, social determinants of health are the economic, social, cultural, and political conditions in which people are born, grow, and live that affect health status. Modifiable risk behaviours include tobacco use, poor eating habits, and excess alcohol consumption, which contribute to the development of chronic diseases.

Today’s main public health challenges are chronic diseases as well as overweight and obesity. A correlation between the rise in overweight and obesity and a country’s integration into globalised food supply chains has been observed.⁶⁷ For example, foreign direct investment (FDI) by transnational food companies has been identified as a particularly potent indicator of increased availability and accessibility of highly processed foods high in fat, sugar and salt (HFSS).⁸ Altering the local availability, nutritional quality and desirability of foods, affects population diets and increasingly raises concerns about the development of obesity

¹ See, for example, Baker, P. et al. (2016), ‘Trade and investment liberalization, food systems change and highly processed food consumption: a natural experiment contrasting the soft-drink markets of Peru and Bolivia’, *Globalization and Health*, 12 (24), pp. 1-13.

² Muzaka, V. (2011) *The Politics of Intellectual Property Rights and Access to Medicines* (Basingstoke: Palgrave Macmillan).

³ Gleeson, D. and Labonté, R. (2020), *Trade Agreements and Public Health: A Primer for Health Policy Makers, Researchers and Advocates* (London: Palgrave Macmillan); De Ville, F. and Siles-Brügge, G. (2017), ‘Why TTIP is a game-changer and its critics have a point’, *Journal of European Public Policy*, 24 (10), pp. 1491-1505.

⁴ <https://www.who.int/healthpromotion/en/>

⁵ https://www.who.int/social_determinants/thecommission/finalreport/key_concepts/en/

⁶ Boyd Swinburn et al. (2009) Increased food energy supply is more than sufficient to explain the US epidemic of obesity. *Am J Clin Nutr*. <https://academic.oup.com/ajcn/article/90/6/1453/4598059>

⁷ Yevgeniy Goryakin et al. (2015) The impact of economic, political and social globalization on overweight and obesity in the 56 low and middle income countries. *The Lancet*.

<https://www.sciencedirect.com/science/article/pii/S0277953615001744>

⁸ Corinna Hawkes (2005) The role of foreign direct investment in the nutrition transition. *Public Health Nutr*. <https://www.ncbi.nlm.nih.gov/pubmed/15975180>

and chronic diseases.^{9,10} The high prevalence of chronic diseases and overweight and obesity is largely the result of changes in the economic and social environment. It is widely recognised that these conditions undermine sustainable economic development.

Tackling them requires innovative policies and approaches 'correcting' their causes. Incorporating flexibility for the EU and its member states' policy interventions ('policy space') into trade agreements by highlighting public health – through the inclusion of a dedicated Chapter – could be desirable. It would highlight the need for 'experimental' interventions, which may be called for in a complex new health reality. Such experimental interventions should not be seen as 'trade nuisances' but be given time to prove their effectiveness.

Thus, trade should serve people; aligning trade policy objectives with public health policy objectives (policy coherence) could contribute to efficiently improving the EU's resilience and building a model of open strategic autonomy.

Question 2: What initiatives should the EU take – alone or with other trading partners - to support businesses, including SMEs, to assess risks as well as solidifying and diversifying supply chains?

EPHA reiterates its call expressed above that identifying health with supply chains diversification itself is not a value but economic interest trade category. The EU should move from an interest-based international trade policy to a value-based approach, which in the long-term is the most sustainable way to ensure Europe's leading position as a global trading partner.

A value-based trade policy cannot be neutral. Trade should also contribute to wider societal and public health goals. A consistent and [systematic public health risk register](#)¹¹ should be applied to current and future FTAs to ensure policy coherence with health. The scoring system could be used as either an independent assessment, by including it as a foundation for a Health Impact Assessment (HIA), or by using its analysis to further expand the current Sustainable Impact Assessment (SIA) to provide more analysis on public health risks.

EPHA has developed the following **scoring system** to assess the potential risks to public health arising from trade agreements. Each thematic area (e.g. food, access to medicines, antimicrobial resistance) considered is assigned a score from one to five to indicate the magnitude of the danger to public health from this area arising from a given deal. The scores can be assigned based on the various sources for the paper, and the organisation's assessment based on their work on international trade.

⁹ Corinna Hawkes (2006) Uneven dietary development: linking the policies and processes of globalization with the nutrition transition, obesity and diet-related chronic diseases. BioMed Central.

<https://www.odi.org/sites/odi.org.uk/files/odi-assets/publications-opinion-files/9580.pdf>

¹⁰ Sharon Friel et. Al. (2013). A new generation of trade policy: potential risks to diet-related health from the trans-pacific partnership agreement <https://www.ncbi.nlm.nih.gov/pubmed/24131595>

¹¹ <https://epha.org/wp-content/uploads/2018/09/trade-public-health-brexite.pdf>

The scoring criteria are as follows:

1. **VERY HIGH RISK:** public health measures and goals in this area would be faced with major obstacles, and could be significantly undermined, or prevented entirely in this scenario.
2. **HIGH RISK:** public health measures and goals in this area would be faced with considerable obstacles, and could be undermined, or jeopardised in this scenario.
3. **MEDIUM LEVEL RISK:** public health measures and goals in this area would be faced with some obstacles and could be undermined in some aspects in this scenario.
4. **LOW LEVEL RISK:** public health measures would face minor obstacles and be minimally affected in this scenario.
5. **VERY LOW-LEVEL RISK:** public health measures would face few or no obstacles and be largely unaffected in this scenario.

The main potential risks and some of the issues to be considered in developing a risk register are outlined below:

1. Unhealthy commodities: energy-dense, nutrient-poor foods, tobacco and alcohol

Trade and investment agreements can affect the relative price and availability of certain goods (including products such as processed foods high in fat, sugar or salt, sugar sweetened beverages, animal products, alcohol and tobacco) which are often still subject to high levels of protection (in the trade sense). Processed confectionery and snacks are particularly profitable because of their low production cost, long shelf-life and high retail value, creating incentives for industries to market and sell more of these products.

Trade and investment deals aim to reduce costs and barriers to supply, enabling greater imports from abroad, or an increase in the capacity for domestic production, based (at least partially) on capital from overseas. Increased affordability and availability of goods creates strong incentives for consumption, leading to knock-on impacts on the burden of Non-Communicable Diseases (NCDs), and population-level dietary habits, via a number of routes:

- Increased imports due to tariff reduction or elimination on these products, which are often more protected than other goods,
- Reduced tax revenues for government spending on health, due to tariff reduction,
- Increased foreign direct investment and integrated food supply chains,
- The EU also makes use of intellectual property measures, especially Geographical Indications, as a way to protect certain foods (including alcohol and HFSS foods) in foreign markets and enable them to be marketed as exclusive products - 270 spirit drinks alone are listed on the EU website as protected.
- Reduced costs and barriers to retail and marketing of energy-dense, nutrient-poor foods, on which most food marketing is focused.

Fundamentally, trade deals do not distinguish between products based on their health value, and governments often list goods as “offensive interests” – i.e. push for an advantageous arrangement in the negotiations for these particular goods due to the expected economic gains

in these sectors – regardless of their health impacts. For example, tobacco was an explicit offensive interest for the EU in its negotiations with Mercosur.

The example of alcohol shows the health harmful effects of reduced tariffs and increased imports through trade agreements. The CETA agreement will eliminate all import tariffs on spirit alcohols and wines. Indeed, both industry groups Spirits Canada and Spirits Europe see the potential for growth in Europe and Canada respectively. Spirits Canada have said that they expect to double their exports to Europe, targeting Eastern Europe in particular.

The relationship between trade and diets is of course a complex one, as many factors are involved in forming a country's dietary patterns and the resulting health impacts. Economic globalisation is only one of these factors, while social and political forms of globalisation may also have an impact on public health, entirely separately from trade. For example, the spread of “westernized”, more sedentary ways of working may impact on population health due to reduced physical activity. The impacts of economic globalisation (such as liberalising trade and investment) on the spread of NCDs may also be subject to a time-lag as the effects cannot be observed immediately, due to the long-term nature of these shifts in behaviour. Similarly, digital trade and online advertising of harmful products can profoundly affect population health.

However, it remains clear that trade and investment deals form part of national food and drink environments, as they play a role in determining what is available, how much, at what price, and what is marketed. In any trade negotiation there are risks that the availability of foods high in saturated fats, trans-fatty acids, free sugars or salt (i.e. energy dense and nutrient poor foods) will increase rapidly.

Although there is no clear direct link between tariff elimination in trade agreements and food prices, as many other factors affect the final price paid by consumers, it is interesting to note a widespread trend of a marked increase in the price of fruit and vegetables while prices for processed foods (often energy-dense and nutrient-poor) have either fallen or increased much more slowly. Linked to increasing liberalisation, this likely plays a part in worsening health outcomes.

Intellectual property rules can sometimes also be used to argue for compensation following the introduction of plain packaging measures, as “unjustifiable encumbrances on trademarks” as prohibited under the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS) Article 20. Tobacco companies, for instance, have argued that packaging measures indirectly expropriate trademarks and other rights, for example in the case of Philip Morris versus Uruguay.

2. Industry involvement

As mentioned above, corporate interests, including big tobacco, alcohol, food and pharmaceutical companies, along with other health-harmful industries (fossil fuels), have many opportunities to influence trade policy and will push for their greatest advantage, regardless of the public health impacts. The extent of industry influence of course depends on the process by which agreements are formed: for example, the UK Wine and Spirit Trade Association has offered to strike template agreements with its counterparts in other countries.

Deregulatory initiatives, including regulatory cooperation and Good Regulatory Practices (GRPs), and investment protection measures, as mentioned above, can give corporate actors multiple routes to change, delay, block or influence policy – with high-profile cases potentially leading to regulatory chill, and posing a threat to public health. And more broadly, these type of rules privilege a ‘trade/investment barrier reduction logic’ over other public interest objectives – which happens to also be the interest of industry.

3. Services of General Interest and Health Services

Services of General Interest, covering social services, healthcare, education and water, can also be threatened by trade deals, and especially by the newer measures. Incentives for liberalisation, including negative listing and the ratchet clause, constrict government space to legislate. Investment protection measures could also threaten government decisions to reverse the liberalisation of key public interest services.

Health services have been a particular target of business lobbyists, hoping to capitalise on increasing health expenditure driven by ageing populations in the EU, while the health sector suffers from fiscal pressures. For example, the Washington-based Alliance for Healthcare Competitiveness, an association representing private healthcare providers, repeatedly criticises state-owned and state supported models within the health sector, from hospitals to health insurers, seeing this as market distortion.

CETA includes a carve-out for publicly funded services, but this is insufficient as Services of General Interest are not always publicly funded, as in for example, in Belgium where the Belgian mutual health insurance providers are not publicly funded.

Annex 1 of CETA also has a general horizontal reservation with regard to public services, and the health sector specifically, but this is not adequate to prevent limits being placed on government policy space. The EU provisions for CETA simply state: *“The EU reserves the right to adopt or maintain any measure with regard to the supply of all health services which receive public funding or State support in any services, other than privately funded hospital, ambulance, and residential health facilities services other than hospital services.”*

Services *“supplied in the exercise of governmental authority”* is usually interpreted narrowly, meaning that any services which are supplied for any form of remuneration, such as healthcare, could be regarded as being supplied commercially, and therefore subject to competition rules. The EU is primarily concerned with locking in existing levels of services liberalisation, but new trade mechanisms such as Negative Listing and others can have the effect of favouring privatisation and market-based healthcare, by opening up outsourcing and procurement processes.

4. Access to medicines

New generation trade deals often push TRIPS+ rules, meaning that they go beyond the WTO baseline to include more stringent intellectual property rules. These tend to reinforce the power of patent-holders, restricting governments’ ability to take decisions on pricing and

reimbursement, by prioritising the rights of businesses to defend their intellectual property over patients' rights to high-quality and effective healthcare.

There have been also several investment dispute cases related to pharmaceuticals and patent disputes. For example, Eli Lilly, a US pharmaceutical corporation launched a case against Canada under the North American Free Trade Agreement (NAFTA), after it was not granted a new patent, due to lack of novelty. Although Eli Lilly eventually lost the case, the fact that investment protection under NAFTA could potentially undermine the sovereign right of governments to grant or refuse patents was a worrying signal. The extension of patent protection terms through such measures as Secondary Patents, Sui Generis Protections, Supplementary Protection Certificates (SPCs) and extended data exclusivity can significantly impact the affordability of medicines and sustainability of health systems. The EU remains non-committal on critical points including data exclusivity, enforcement and the use of SPCs.

The danger is that if these measures are included in multiple trade deals, they will be “locked in” as global norms – affecting both EU national governments and partner countries – making them harder to reform at national level in the interests of equitable access to medicines. Strict TRIPS measures in bilateral trade agreements also override moderating measures such as “research exemptions” (which allow testing and researching for a limited time before the end of a patent term), and other flexibilities which are permitted under the WTO TRIPS agreement.

Concerningly, a critical mass of bilateral agreements including TRIPS+ measures could even be used to justify an amendment of the WTO TRIPS agreement. This is despite the fact that the original WTO agreement was intended to be a ceiling for IP measures, setting the maximum level that could be asked, but it has increasingly become a floor, a threshold to go beyond, which clearly disadvantages developing countries. Trade agreements could also give industry a greater say in decisions around pricing and reimbursement, through the promotion of good regulatory practices.

Lastly, a lack of transparency, and increased emphasis on secrecy in order to protect the intellectual property of pharmaceutical companies, may reduce the safety and efficacy of medicines we take.

5. Antimicrobial Resistance (AMR) and food safety

AMR and food safety issues are often covered by SPS chapters, and problems can arise when agricultural markets are opened up, and more emphasis is put on a streamlined import/export process than on ensuring food safety and minimising AMR. This global public health threat can only be tackled efficiently if new SPS chapters facilitate the prudent use of antibiotics in agriculture.

In US and Canadian trade, AMR is a particular concern due to differing production standards. The EU has included a general article on cooperation to combat AMR as a proposal in TTIP and in the current agreement in principle with Mercosur but it is unclear that this language will be accepted. Whether or not such a clause is included, it is vital that the legally binding parts of the trade agreement – especially the SPS chapter – does not undermine efforts to tackle AMR.

6. Labelling schemes

Labelling schemes aiming to boost dietary health, such as the UK's traffic light labelling system or the nutriscore system used in France and Belgium for example, can be affected by TBT chapters. Nutrition labelling is clearly a trade issue.¹² The recent example of the US seeking to include a clause to prevent any warning symbol, shape or colour that "inappropriately denotes that a hazard exists from consumption of the food or non-alcoholic beverages" in the U.S.-Mexico-Canada Agreement (USMCA), replacing NAFTA may be extreme, and did not appear in the final text, but it is illustrative of how labelling schemes can be classified as barriers to free trade. The EU's standard text states that only information "*relevant for consumers or users of the product... or to indicate the product's conformity with the mandatory technical requirements*" should be required. These provisions, although not as explicit as the US's desired text, remain too vague to prevent challenges to health-related food labelling schemes. Further, it is important that these provisions also take account of changes in EU legislation to make sure that product requirements remain relevant in the future.

7. Procurement schemes

Procurement schemes aiming to favour healthy diets, i.e. by mandating a certain amount of fruit and vegetables, and limiting products exceeding certain values in fat, salt or sugar, can also be threatened by procurement chapters of trade deals, depending on the wording used.

The WTO has a Government Procurement Agreement, which is not signed by all members, and is relatively weak, so bilateral agreements often go beyond it, to grant greater access to procurement markets. Provisions to support local fresh food are particularly under threat, as this is seen as favouring domestic applicants, and therefore can be claimed to be discriminatory. The EU's internal market policy prevents EU Member States from favouring local production in their procurement processes, and the EU wants to export this limitation to its trade partners, in order to preserve a "level-playing field". In so doing, the EU can also rule out public procurement from supporting the purchase of seasonal or organic food, which may contribute to healthy diets.

Furthermore, the EU's proposal for public procurement in its negotiations with Mexico and Chile, currently refers only to allowing "environmental, social and labour considerations" to be taken into account in procurement procedures, if "*they are linked to the subject-matter of the contract*". This wording seems unlikely to be strong enough to prevent challenges to dietary health-promoting criteria for public procurement.

Similar criteria were used by EPHA in the development of the report ["Unhealthy Trades:](#)

¹² <https://www.obesityevidencehub.org.au/collections/prevention/nutrition-labelling-as-a-trade-policy-issue>

[the Side-Effects of the European Union’s Latin American Trade Agreements](#),¹³ which rated the risks to public health from the EU’s trade deals with Mexico, the Mercosur countries, and Chile against nine areas of trade with the following results:

No.	Area	Risk Level
1	Tobacco	1
2	Unhealthy food	2
3	Alcohol	3
4	Labelling schemes and regulatory cooperation	2
5	Antimicrobial Resistance (AMR) and animal health	3
6	Investment provisions	1
7	Intellectual property rights and access to medicines	1
8	Health impact assessments	1
9	Procurement	4

A detailed explanation on how each level of risk was determined can be found in the report.

Question 3: How should the multilateral trade framework (WTO) be strengthened to ensure stability, predictability and a rules-based environment for fair and sustainable trade and investment?

Unilateral focus on the WTO would not be sufficient to ensure policy coherence between trade and health. There are other instruments developed by the international health community, facilitated by the World Health Organization (WHO) which should be regarded when defining a multilateral trade framework and explicitly referenced in trade agreements in the way that other international conventions e.g. on labour rights/the environment are.

In this context, there are relevant international commitments such as the:

- Declaration of Alma Ata on primary healthcare of 1978;¹⁴ the World Declaration and Plan of Action for Nutrition of 1992;¹⁵
- Doha Declaration on the TRIPS Agreement and Public Health of 2001;¹⁶
- WHO Framework Convention on Tobacco Control of 2003;¹⁷
- Global Strategy on Diet, Physical Activity and Health of 2004;¹⁸
- International Health Regulations of 2005;¹⁹ the Global strategy to reduce harmful use of alcohol of 2010;²⁰

¹³<https://epha.org/unhealthy-trades-the-side-effects-of-the-european-unions-latin-american-trade-agreements-report/>

¹⁴ http://www.euro.who.int/__data/assets/pdf_file/0009/113877/E93944.pdf

¹⁵ http://www.who.int/nutrition/publications/policies/icn_worlddeclaration_planofaction1992/en/

¹⁶ https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

¹⁷ http://www.who.int/fctc/text_download/en/

¹⁸ http://www.who.int/dietphysicalactivity/strategy/eb11344/strategy_english_web.pdf?ua=1

¹⁹ <http://www.who.int/ihr/publications/9789241580496/en/>

²⁰ http://www.who.int/substance_abuse/activities/gsrhua/en/

- Political Declaration of the High-level Meeting of the General Assembly [of the United Nations] on the Prevention and Control of Non-communicable Diseases of 2011;²¹
- Global Action Plan for the Prevention and Control of NCDs 2013-2020 of 2013;²²
- Rome Declaration on Nutrition of 2014;²³
- Rome Framework for Action on Nutrition of 2014;²⁴
- Transforming Our World: the 2030 Agenda for Sustainable Development. (the outcome of the UN Summit on Sustainable Development of 2015).²⁵

Question 4: How can we use our broad network of existing FTAs or new FTAs to improve market access for EU exporters and investors, and promote international regulatory cooperation—particularly in relation to digital and green technologies and standards in order to maximise their potential?

EPHA reiterates that in the middle of a global health pandemic, a post-COVID19 EU trade policy must consider the impact on health in addition to digital and green technologies.

There is a need for policy coherence between public health and trade policies and technical discussions on regulatory cooperation is not an exception. Throughout these expert discussions, and also in any potential trade negotiations, the EU should hold to its binding obligations under Article 168 TFEU and Article 35 of the Charter, to ensure that health aspects are taken into account (Health in all policies).

Therefore, the European Commission's language regarding “*reduce administrative obstacles*” and “*slashing costs*” is concerning. This kind of language is predicated on the assumption that regulations are irritants to trade. However, regulations are not always arbitrary bureaucratic impediments to business, but often measures designed to protect health and well-being, and this must be acknowledged and upheld by the EU.

Appropriate impact assessment – including health impacts - of any regulatory cooperation, including the benefits of existing regulations, should be a precondition for any kind of cooperation between the EU and any partner. Before considering regulations as ‘trade irritants’ because of their costs, the benefits of these regulations and standards – including health benefits - should be measured and taken into consideration.

Regulatory cooperation in the health sector

1. Pharmaceuticals and medical devices

²¹ UN document A/66/L.1 http://www.un.org/ga/search/view_doc.asp?symbol=A/66/L.1

²² <http://www.who.int/nmh/publications/ncd-action-plan/en/>

²³ Second International Conference on Nutrition, Rome, 19-21 November 2014 <http://www.fao.org/3/a-m1542e.pdf>

²⁴ Second International Conference on Nutrition, Rome, 19-21 November 2014 <http://www.fao.org/3/a-mm215e.pdf>

²⁵ http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E

Concerns about the impact of trade on reforming the medical innovation model

The Doha Declaration on the WTO Agreement on Trade-Related Aspects of IPRs (TRIPs) and Public Health adopted on 14 November 2001 recognises concerns over the relationship between protection of Intellectual Property Rights (IPR) and the impact on medicine prices. The EU should continue to uphold this principle, and implement it in its trade negotiations.

There is an ongoing [European policy discussion](#)²⁶ both in the Council and the European Parliament about the suitability of the Intellectual Property-related incentives in medical innovation, questioning the current innovation model.^{27 28}

Regulatory cooperation around medicines should be considered in the context of this ongoing debate to reform the current medical innovation model.

The UN Secretary-General established [the High-Level Panel on Access to Medicines](#) to propose solutions for the incoherencies between international human rights, trade, intellectual property rights and public health objectives. Their report “Promoting innovation and Access to Health Technologies, published in September 2016, called for a new deal to close the health innovation and access gaps. The report points out that for decades, many international treaties and national constitutions have enshrined the fundamental right to health and the right to share in the benefits of scientific advancements. The misalignment between the right to health on the one hand, and intellectual property and trade on the other, fuel this tension.²⁹

The intention of the EU to avoid discussing Regulatory Cooperation or Good Regulatory Practices patents or intellectual property rights with the US recently is welcome, and EPHA would encourage the Commission to resist any pressure to do so.

For example, such pressure could be a legal text, such as was [incorporated into TPP](#) (in Chapter 26 on Transparency and Anti-Corruption, Annex A), notably Article 3e)³⁰ which prescribes a review mechanism that allows pharmaceutical companies to challenge decisions not to reimburse pharmaceuticals/medical device.

Regulatory cooperation on medicines and medical devices

Any cooperation on veterinary drugs must include clear protections against the spread and development of AMR. This cooperation must not undermine the prudent use of antibiotics in the veterinary, agriculture and aquaculture sectors. The European Commission should strive to achieve the adoption of successful best practices and legislation on AMR as a public health concern, and cooperate with international partners in this regard.

2. Antimicrobial Resistance and antibiotic research and development

In accordance with the [European One Health Action Plan against Antimicrobial Resistance \(AMR\)](#), EPHA would welcome strengthened ongoing collaboration on AMR within the

²⁶ <https://epha.org/dutch-pharma-policy-a-groundbreaking-presidency/>

²⁷ <https://epha.org/scientists-voice-concerns-about-adaptive-pathways/>

²⁸ <https://epha.org/scientists-voice-concerns-about-adaptive-pathways/>

²⁹ <http://www.unsgaccessmeds.org/final-report>

³⁰ <https://ustr.gov/sites/default/files/TPP-Final-Text-Transparency-and-Anti-corruption.pdf>

Transatlantic Task Force on Antimicrobial Resistance (TATFAR) which includes the EU, the US, Canada and Norway. Moreover, it is important that the EU promotes international regulatory convergence between the European Medicines Agency and other regulatory agencies such as the US Food and Drug Administration (FDA) on development plans for new antimicrobials.

One of the “pull” mechanisms to incentivise biomedical innovation concerning new antibiotics is the granting of additional monopoly protection through the extension of IP or related exclusivities. Transferrable IP rights is thought to overcome the risk of further incentivising antibiotic sales as companies receive the right to extend their monopoly protection for another product upon successful development of a new antibiotic. However, for antibiotic R&D, EPHA considers this measure inappropriate as it does not de-link development costs from the price of the new product. Therefore, it cannot be used to set conditions to make global access and conservation a requirement. This has resulted in limited antibiotic innovation and increased costs for patients. In addition, it does not address the principles of affordability, accessibility and conservation of new antibiotics.

EPHA calls upon the European Commission to continue to defend EU standards and EU policies on AMR in these trade negotiations, including encouraging partners to align themselves with the EU ban on the use of antibiotics as growth promoters in food-producing animals as well as enforcing this EU ban as a conditionality to all food imports. An AMR cooperation article could also be explored in trade agreements.

Conformity assessments

EPHA calls for the precautionary principle to be the central organising principle regarding conformity assessments for medicines and medical devices. Public health must remain the utmost concern in this rather than cost reduction. Reducing the cost of conformity assessments cannot be at the expense of consumer safety. The EU should guarantee the impartiality, independence and technical competence of conformity assessment bodies.

Question 5: With which partners and regions should the EU prioritise its engagement? In particular, how can we strengthen our trade and investment relationships with the neighbouring countries and Africa to our mutual benefit?

On the international scene, the EU should prioritise trade with countries who support the EU's values of diversity, tolerance, and who promote policies to tackle the climate emergency. Moreover, the link between the pure economic interest logic of trade and the interaction with human rights should be re-considered and violation of human rights would have implications on choosing our trading partners. Establishing a progressive FTA with like-minded countries will help the EU to set a high standard for FTAs in the future.

Question 6: How can trade policy support the European renewed industrial policy?

In order to contribute to the European renewed industrial policy, international trade should balance investment protection with the public interest. This would require systematically removing investment protection measures from FTAs.

The EU approach on investment protection maintains the privileges of foreign investors ahead of EU investors (and vice-versa). The Investment Court System (ICS) presents a dispute settlement option for foreign investors not normally available to citizens. Therefore, the proposal does not address the inherently discriminatory nature of the system.

The current provision of Fair and Equitable Treatment (FET) on standard of protection raises a number of issues; most importantly, it may infringe on states' de facto right-to-regulate. FET introduces a substantial degree of subjectivity to proceedings, and allows arbitrators (or 'judges') to rule against policies in the public interest. This can also be said to apply to indirect expropriation and other investment protection standards – which also allow for arbitrator discretion.

The Commission has repeatedly stated that the ICS will guarantee a state's regulatory sovereignty. To this end, we welcome that the ICS proposal includes "the right of the Parties to regulate within their territories through measures necessary to achieve legitimate policy objectives." However, the ICS proposal still lacks a clear, legally-binding provision establishing that claims against the public interest are explicitly out-of-bounds. A legally-binding provision will bolster the right-to-regulate, and prevent effects like 'regulatory chill' and 'regulatory snare'. However, this is an approach which is hard to design, so from a public health perspective it would be safest to abandon ICS/ISDS completely.

The proposal also clarifies obligations for judges and includes a code of conduct intended to address conflicts of interest. However, the proposal fails to establish clear rules against the corrosion of judgments by arbitrators' prior employment and engagements. We therefore call on the Commission to strengthen the code of conduct so as to uphold high ethical standards and ensure that it is enforceable in cases of breach and non-compliance.

The bilateral aspect of the ICS concept used by the EU in bilateral FTAs was a first step towards a multilateral system, to be established in the medium run, provided that such a system will respect the necessary conditions to protect the public interest and will replace bilateral investment dispute settlement mechanisms.

Question 7: What more can be done to help SMEs benefit from the opportunities of international trade and investment? Where do they have specific needs or particular challenges that could be addressed by trade and investment policy measures and support?

N/A

Question 8: How can trade policy facilitate the transition to a greener, fairer and more responsible economy at home and abroad? How can trade policy further promote the UN Sustainable Development Goals (SDGs)? How should implementation and enforcement support these objectives?

EPHA has developed some textual proposals in the form of a [model public health chapter](#),³¹ which should be incorporated into the legal text of trade agreements in order to ensure true coherence between the trade deal and public health objectives. **The model chapter is attached to EPHA's submission in the Annex.**

Several examples below illustrate where EU trade policy could contribute to health-related SDGs, but where its actions continue to be misaligned with that objective. The inclusion of a public health chapter based on the model provided above, would allow the EU to better assess the health risks, benefits and trade-offs, and allow it to design a trade agenda that maximises sustainability co-benefits.

Nutrition labelling

Mexico is one of the countries currently undergoing a nutrition transition which is resulting in rapidly increasing levels of overweight and obesity. One of the measures to stem this tide was the introduction of a front of pack nutrition labelling (FOPNL) system involving health warnings on processed foods and drinks.

During the 45th meeting of the Codex Alimentarius, Committee on Food Labelling, the EU submitted that health warnings should not be considered as FOPNL, under the ambiguous argument that this system did not improve "consumer's understanding of the nutritional value of their food". The aim of this position was to exclude systems such as the Mexican one from the scope of coverage of the Codex definition. Moreover, the EU, alongside the US and Canada, pressured Mexico to delay the introduction of its labelling system in the context of the WTO, undermining Mexico's legitimate and non-discriminatory efforts to protect the health of its population.

³¹ <https://epha.org/eu-model-chapter-shows-how-to-ensure-trade-public-health-coherence/>

One Health and Planetary Health.

'One Health' is a concept recognising that human health is closely connected to the health and well-being of animals and the environment. The [concept](#) of 'Planetary Health', and action which this inspires, is based on the understanding that human health and human civilisation depend on flourishing natural systems and the wise stewardship of those natural systems. Both concepts show the close interaction between public health, animal welfare and environmental objectives.

In its trade relations the EU needs to ensure that adequate and binding precautions are in place to prevent the advancement of supply chains which increase planetary health risks. A [recent study](#) has shown that at least 20% of soy exports and at least 17% of beef exports from Brazil to the EU may be contaminated with illegal deforestation and land-use change from the Cerrado and Amazon. Wide scale deforestation, biodiversity loss and destruction of natural habitats does not only impair the EU's efforts to tackle climate change, but also [creates the conditions that increase the risk](#) of spread of infectious zoonotic diseases, such as COVID-19.

In the negotiations on the EU-Mercosur Trade Agreement, such considerations should be at the centre of concerns, and should play a decisive role in decisions concerning the conclusion of the agreement and its provisions. The precautionary principle should take precedence in such grave matters of global concern.

Antimicrobial resistance

A set of significantly upgraded rules on farm antibiotics use will come into effect in the EU in 2022. Considering these higher standards of human and animal health protection, it would be illogical and unfair to expose European farmers to competition from producers complying with significantly lower antibiotics-use standards, and to expose the European population to a greater risk of acquiring antibiotic resistant bacteria through imported products.

Therefore, all imported animal-derived foods should be produced under equivalent antibiotics use standards to those in effect in the EU. Imported products should be accompanied by a credible certificate/declaration of not having been produced with methods involving the use of antibiotics as growth promoters, the routine use of antibiotics, and/or the use of antibiotics for preventive treatment of groups of animals. Products not carrying such assurances should be barred from entering the EU market, or face an equitable import levy.

Question 9: How can trade policy help to foster more responsible business conduct? What role should trade policy play in promoting transparent, responsible and sustainable supply chains?

The definitions of investment and FET are especially problematic from a responsible business conduct point of view. The definition of investment under FTAs is too loosely formulated to distinguish between those with positive and negative externalities. Because of the respective

benefits and costs they generate for host societies, EPHA argues that these two categories of foreign investment merit fundamentally different legal considerations. At the same time, the EU approach on investment protection does not address potential issues arising from unpredictable and abusive risks such as speculative investments, for example.

The EU should reflect about investor obligations in order to move towards a trade policy more aligned with wider societal challenges.³²

Question 10: How can digital trade rules benefit EU businesses, including SMEs? How could the digital transition, within the EU but also in developing country trade partners, be supported by trade policy, in particular when it comes to key digital technologies and major developments (e.g. block chain, artificial intelligence, big data flows)?

Given the rise of digital trade and service provision, as well as the increased online marketing of products because of COVID19, care must be taken to ensure that trade rules do not undermine the Commission's intentions to establish a safe and ethical framework for digitalisation in the health domain that protects population health, including via the Digital Services Act, ePrivacy measures and the approach to Artificial Intelligence. It will be important to ensure that national governments can continue to develop and implement progressive public health policies (e.g. such as on online advertising). At the same time the EU should ensure that trade rules do not create loopholes that might weaken EU data protection and privacy legislation.

The digital transition can and should support SMEs, including in the broader health and well-being domain, but this also means that the activities of big IT platforms must be controlled and restricted as "one size does not fit all" when it comes to people's health and care needs, including products and services that may be traded digitally.

This is particularly and acutely concerning at the moment, given the range and depth of medical information being collected as a result of the implementation of national measures to tackle COVID19.

Question 11: What are the biggest barriers and opportunities for European businesses engaging in digital trade in third countries or for consumers when engaging in e-commerce? How important are the international transfers of data for EU business activity?

Digital rules are relevant for healthcare services. Ensuring that similar high standards of data protection, patient safety and service quality will be adopted via trade agreements among trading partners represents a worthy aspiration. However, the inclusion of digital health in a

³² <https://www.iisd.org/itn/en/tag/investor-obligations/>

future EU trade agreement would be undesirable given European health systems' orientation towards striving for universal access to quality healthcare for all, which makes them less compatible with commercial imperatives.

While developments such as mHealth, Big Data and Artificial Intelligence hold many opportunities for improving individual and population health, the experience of the eCommerce sector – marked by major breaches of privacy and data security – demonstrates that prudence is of the utmost importance when it comes to gathering, storing, processing and analysing personal data in a global context.

As health data is particularly sensitive, the potential consequences of such breaches are very serious as they put patient safety at risk, threaten livelihoods and compromise quality access to healthcare for all in Europe. European health systems should not be infiltrated by the marketing objectives of private IT companies whose “personalised” health offers are available only for the few; rather, Europe's future digital health policy should be driven by the actual needs of European patients, healthcare professionals and citizens.

Question 12: In addition to existing instruments, such as trade defence, how should the EU address coercive, distortive and unfair trading practices by third countries? Should existing instruments be further improved or additional instruments be considered?

If a more value-based focus is pursued in future FTA: as suggested, this would require the further development of Trade Defence Instruments (TDIs) to better include distortive and coercive practices of third countries that do not respect EU standards regarding public health, to ensure that the agreed health standards in the FTA is followed by both parties.

This is vital since unfair practices can both distort competition by creating disadvantages for European companies in the third country as well as negatively affecting public health, for example through badly implemented labelling schemes.

Question 13: What other important topics not covered by the questions above should the Trade Policy Review address?

It is unfortunate that despite available evidence on the interaction between international trade and public health, trade provisions having health-harmful potential, described above, continue to feature in the EU's trade policy agenda. This is despite being at a time where more, rather than less, policy flexibility is called for to deal with the unprecedented challenges posed by the coronavirus – not least for public health.

The negative effects of Trade and Investment Agreements should be mitigated, and FTAs should be used to protect and improve public health and well-being. There are a number of instruments and measures implemented by institutions, or suggested by campaigners and civil

society organisations, to mitigate the negative effects of trade and investment agreements, or to use them to promote the public interest.

There is an ongoing debate within the broader trade movement on whether it is better to oppose trade agreements outright, or to try to protect and promote public health, for instance, within the trade agreements. While this debate is not within the scope of this submission, there are opportunities to explore this issue in more detail.

Below is a non-exhaustive list of measures and their advantages and disadvantages, on which NGOs or other interested organisations can advocate, to improve the coherence between trade and health.

1. Health in all Policies/ Mainstreaming health in trade deals

Within the EU, the Lisbon Treaty states that “A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities”. This treaty obligation is a key link between public health and trade issues, and can be used to argue for health to be mainstreamed throughout all parts of trade agreements.

2. Add public health chapters to trade deals

As suggested above this can address health relevant issues in FTAs.

3. Establish a more transparent and democratic process

Focusing on the need for public interest groups to be informed and involved, and to ensure that all actors are appropriately included in the negotiation process.

4. Make more outcome based regulatory cooperation

Make regulatory cooperation about promoting outcomes other than reduced trade/investment barriers.

5. Health/Sustainability impact assessments (H/SIA)

This would require all trade deals to be subject to a thorough health impact assessment process, publish the results and implement changes accordingly.

6. Carve-outs

Explicitly excluding certain health-relevant areas from the remit of a trade agreement. Campaigners achieved a tobacco carve-out in the Trans-Pacific Partnership, for example. Systematically removing livestock farming should be considered.

7. Interpretative declarations

These can be issued alongside the legal text of trade deals to guide how they should be used and interpreted.

8. International standards

Referring to other international agreements or standards (e.g. the Framework Convention on Tobacco Control, WHO agreements, the Paris Agreement or the SDGs), that both parties will have to uphold in order for the agreement to be valid

8. Conditionalities

This broad term essentially means only allowing trade/ based on certain standards, e.g. making parts of the deal conditional on having a target to reduce use of antibiotics to tackle AMR

9, Non-regression clause

Including a clause setting a “regulatory floor” below which standards cannot fall

ANNEX 1

A MODEL HEALTH CHAPTER IN EU TRADE AND INVESTMENT AGREEMENTS (developed by the European Public Health Alliance and the European Heart Network)³³

For inclusion in the Agreement's preamble

This Agreement is entered into to encourage and facilitate trade [and investment] between the Parties. The Parties acknowledge that enabling trade [and protection of investments] is not [a] goal[s] in themselves/itself, but constitute[s] a means to improve citizens' standards of living and their well-being.

The Parties acknowledge that this Agreement is entered into in a context where there is an imperative to ensure sustainable development, to protect the environment, to address complex public health challenges, and to protect consumers.

Nothing in this Agreement can encumber the Parties' basic right to regulate.

Nothing in this Agreement can oppose fundamental values and rights expressed in domestic and/or international law.

CHAPTER – TRADE AND PUBLIC HEALTH

Article 1

General

1. The Parties reaffirm their commitment to pursue public health promotion and protection, and are committed to promote the development of international trade [and investment] in such a way so as to contribute to achieving their respective national as well as global health and health-related objectives and targets.
2. The Parties recognise the value of global standards and agreements on public health as fundamental instruments to promote and achieve good health for all and stress the need to enhance the mutual supportiveness between trade and labour policies and rules.
3. Accordingly, the Parties recall the Declaration of Alma Ata on primary healthcare of 1978,³⁴ the World Declaration and Plan of Action for Nutrition of 1992,³⁵ the Doha Declaration on the TRIPS Agreement and Public Health of 2001,³⁶ the WHO Framework Convention on Tobacco Control of 2003,³⁷ the Global Strategy on Diet, Physical Activity and Health of 2004,³⁸ the International Health

³³ <https://epha.org/eu-model-chapter-shows-how-to-ensure-trade-public-health-coherence/>

³⁴ http://www.euro.who.int/__data/assets/pdf_file/0009/113877/E93944.pdf

³⁵ http://www.who.int/nutrition/publications/policies/icn_worlddeclaration_planofaction1992/en/

³⁶ https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

³⁷ http://www.who.int/fctc/text_download/en/

³⁸ http://www.who.int/dietphysicalactivity/strategy/eb11344/strategy_english_web.pdf?ua=1

Regulations of 2005,³⁹ the Global strategy to reduce harmful use of alcohol of 2010,⁴⁰ the Political Declaration of the High-level Meeting of the General Assembly [of the United Nations] on the Prevention and Control of Non-communicable Diseases of 2011,⁴¹ the Global action plan for the prevention and control of NCDs 2013-2020 of 2013,⁴² the Rome Declaration on Nutrition of 2014⁴³ and the Rome Framework for Action on Nutrition of 2014,⁴⁴ and the outcome of the UN Summit on Sustainable Development of 2015 entitled "Transforming Our World: the 2030 Agenda for Sustainable Development."⁴⁵

Article 2 *Objectives*

Through this chapter, the Parties aim to:

- a. ensure the positive contribution of this Agreement to public health;
- b. ensure policy coherence and uphold the Parties' public health promotion and protection objectives;
- c. formulate and implement policies that contribute to the achievement of universal healthcare coverage and public health goals;
- d. promote public consultation and participation in the discussion of public health issues arising under this Agreement.

Article 3 *Right to regulate and levels of protection*

1. The Parties recognise the right of each Party to determine its public health policies and priorities, to set and regulate its level of public health protection in line with the WHO Constitution and WHO definition of health promotion and prevention and to adopt or modify relevant policies and laws accordingly.
2. This Agreement does not and should not prevent the Parties from taking measures to protect public health and ensure access to affordable care [similarly to but not exclusively as the Alma Ata Declaration and Doha Declaration on the TRIPS Agreement and Public Health].
3. In the eventuality of a dispute, public health protection measures cannot be brought before the investment court [if an ICS chapter is included] by foreign investors unless they represent a violation of Article [X.X] on national treatment.

³⁹ <http://www.who.int/ihr/publications/9789241580496/en/>

⁴⁰ http://www.who.int/substance_abuse/activities/gsrhua/en/

⁴¹ UN document A/66/L.1 http://www.un.org/ga/search/view_doc.asp?symbol=A/66/L.1

⁴² <http://www.who.int/nmh/publications/ncd-action-plan/en/>

⁴³ Second International Conference on Nutrition, Rome, 19-21 November 2014 <http://www.fao.org/3/a-ml542e.pdf>

⁴⁴ Second International Conference on Nutrition, Rome, 19-21 November 2014 <http://www.fao.org/3/a-mm215e.pdf>

⁴⁵ http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E

Article 4 *Context and cooperation*

Non-Communicable Diseases

1. The Parties underline their commitment to the prevention and control of non-communicable diseases worldwide, and recognise the importance of international treaties, agreements, strategies and action plans in this area.

2. Accordingly, the Parties acknowledge that non-communicable diseases constitute a major obstacle to sustainable development, economic productivity, social development and equality as well as the sustainability of health care systems.

[3. To this end, the Parties aim to:

- a. formulate and implement population-level WHO best buy policies to prevent and reduce the level of exposure of individuals and populations to modifiable risk factors for non-communicable diseases namely, tobacco use, unhealthy diets, physical inactivity, and the harmful use of alcohol, and their determinants, to create and shape norms, environments and conditions for populations to lead long, productive lives in good health;
- b. exchange information and cooperate, as appropriate, as effective non-communicable disease prevention and control require policy coherence, leadership and multi-sectoral approaches for health at the government level, including, as appropriate, health in all policies and whole-of-government approaches across such sectors as health, education, energy, agriculture, sports, transport, communication, urban planning, environment, labour, employment, industry and trade, finance and social and economic development;
- c. promote worldwide implementation of multi-sectoral, cost-effective, population-level interventions in order to reduce the impact of the major non-communicable disease risk factors, namely tobacco use, unhealthy diet, physical inactivity and harmful use of alcohol, through the implementation of relevant international agreements and strategies, and education, legislative, regulatory and fiscal measures, without prejudice to the right of sovereign Nations to determine and establish their taxation policies;
- d. strengthen cooperation with relevant stakeholders free from conflicts of interest by acknowledging the contribution and important role played by civil society, academia, and where and as appropriate, the private sector, by acknowledging the contribution and important role played by all relevant stakeholders, in support of national efforts for non-communicable disease prevention and control, and recognise the need to further support the strengthening of coordination among these stakeholders in order to improve effectiveness of these efforts;
- e. cooperate internationally as the rising prevalence, morbidity and mortality of non-communicable diseases worldwide can be largely prevented and controlled through collective and multispectral action at local, national, regional, and global levels, and by raising the priority accorded to non-communicable diseases in development cooperation by enhancing such cooperation in this regard.]

Tobacco control

1. The Parties underline their commitment to implement the WHO Framework Convention on Tobacco Control (FCTC) of 2003.

2. Accordingly, the Parties reaffirm that the spread of the tobacco epidemic is a global problem with serious consequences for public health that calls for the widest possible international cooperation and the participation of all countries in an effective, appropriate and comprehensive international response.

[3. To this end, the Parties aim to:

a. implement effective domestic policies and measures to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke;

b. exchange information and cooperate, as appropriate, as tobacco control at all levels requires sufficient financial and technical resources commensurate with the current and projected need for tobacco control activities;

c. promote world-wide implementation of the Protocols and Guidelines developed in the framework of the FCTC;

d. strengthen cooperation with interested stakeholders, especially with non-governmental organisations and other members of civil society not affiliated with the tobacco industry, including health professional bodies, women's, youth, environmental and consumer groups, and academic and health care institutions in order to strengthen tobacco control efforts nationally and internationally;

e. cooperate internationally to eliminate all forms of illicit trade in cigarettes and other tobacco products, including smuggling, illicit manufacturing and counterfeiting.]

Food and nutrition

1. The Parties underline their commitment to eliminate hunger and to reduce all forms of malnutrition and the objectives for human development, food security, agriculture, rural development, health, nutrition and environment and sustainable development enunciated in a number of international conferences and documents.⁴⁶

2. Accordingly, the Parties reaffirm their commitments to the nutritional well-being of all people as a pre-condition for the development of societies and that it should be a key objective of progress in human development.

[3. To this end, the Parties aim to:

⁴⁶ The World Food Conference, 1974; the Alma Ata Conference on Primary Health Care, 1978; the World Conference on Agrarian Reform and Rural Development, 1979; the Convention on the Elimination of All Forms of Discrimination Against Women, 1979, especially articles 12 and 13; the Innocenti Declaration on the Protection, Promotion and Support of Breast feeding, 1990; the Montreal Policy Conference on Micronutrient Malnutrition, 1991; the Rio Declaration on Environment and Development, 1992. The Global Strategy on Diet, Physical Activity and Health of 2004, the Rome Declaration on Nutrition of 2014 and the Rome Framework for Action on Nutrition of 2014; outcome of the UN Summit on Sustainable Development of 2015 entitled "Transforming Our World: the 2030 Agenda for Sustainable Development.

- a. implement effective domestic policies and measures to ensure continued access by all people to sufficient supplies of safe foods for a nutritionally adequate diet;
- b. exchange information and cooperate, as appropriate to achieve and maintain nutritional well-being of all people;
- c. promote environmentally sound and socially sustainable development to contribute to improved nutrition and health;
- d. strengthen co-operation with interested stakeholders to encourage commitments to promote nutritional well-being;
- e. cooperate internationally to develop strategies to ensure better nutrition for all that are oriented towards economic growth with equity, ensuring social justice and protecting and promoting the well-being of all, particularly of vulnerable groups.]

Alcohol

1. The Parties underline their commitment to reduce harmful use of alcohol and recognise the importance of international rules and agreements in this area.
2. Accordingly, the Parties reaffirm that alcohol harm is a global problem with serious consequences for human rights and human capital, public health, sustainable development, social cohesion and economic productivity that calls for the widest possible international cooperation and the participation of all countries in an effective, appropriate and comprehensive international response.
- [3. To this end, the Parties aim to:

- a. formulate and implement population-level best buy interventions addressing the affordability, availability and marketing of alcohol;
- b. exchange information and cooperate, as appropriate, on preventing and reducing harmful use of alcohol;
- c. strengthen cooperation with stakeholders, as appropriate, to reduce the harmful use of alcohol, especially with civil society free from conflicts of interest, and sectors such as development, transport, justice, social welfare, fiscal policy, trade, agriculture policy, consumer policy, education and employment to enhance policy coherence;
- d. cooperate internationally to reduce the harmful use of alcohol by effective policy measures and by relevant infrastructure to successfully implement those measures. Cooperation should be oriented towards sustainable economic growth, reducing health inequalities and protecting the well-being of all, particularly of vulnerable groups.

Article 5

Other health threats

Antibiotic resistance

1. The Parties recognise that antibiotic resistance is a serious and transnational threat to human and animal health, sustainable food production, and development.

2. Accordingly, the Parties underline their commitment to take a broad, coordinated approach to address the root causes of antibiotic resistance across multiple sectors, especially human health, animal health and agriculture.⁴⁷

Communicable diseases and pandemics

1. The Parties [re]affirm their commitment to collaborate on communicable diseases and emerging pandemics in accordance with existing agreements including but not limited to the International Health Regulations (IHR).

Article 6

Access to affordable care

1. The Parties reaffirm their commitment to equitable access to quality health services and medicines.

2. The Parties reaffirm their commitment to the Doha Declaration on the WTO Agreement on Trade-Related Aspects of IPRs (TRIPS) and public health adopted on 14 November 2001.

3. Accordingly, the Parties recognise the relationship between protection of IPR and the impact on medicine prices and aim to promote research and innovation that delivers competitiveness and trade as well as increase patient access to affordable medicine.

Article 7

Horizontal issues

Upholding levels of protection

1. The Parties recognise that it is inappropriate to weaken or reduce the levels of protection afforded in domestic public health promotion and protection laws in order to encourage trade or investment.

2. A Party shall not waive or derogate from, or offer to waive or derogate from, its public health promotion and protection laws as an encouragement for, or in a manner affecting, trade or investment.

3. A Party shall not, through a sustained or recurring course of action or inaction, fail to effectively enforce its public health promotion and protection laws as an encouragement for, or in a manner affecting, trade or investment.

Transparency and public participation

1. Each Party, in accordance with Chapter ... [Transparency], shall ensure that any measures pursuing public health objectives that may affect trade or investment – or trade or investment measures that may affect the promotion and protection of public health are developed, introduced, implemented and reviewed in a transparent manner.

2. The Parties shall encourage timely communication to, and consultation of, all stakeholders. No class of stakeholders should be accorded privileged treatment. Particular effort should be made to seek input from public interest groups.

⁴⁷ Political declaration on antimicrobial resistance adopted at the high-level meeting of the UN General Assembly on antimicrobial resistance of 22 September 2016, A/RES/71/3, available at: <http://digitallibrary.un.org/record/842813?ln=en>

3. The Parties shall take into consideration public health organisations', patients' and public health experts' recommendations in order to ensure implementation of this Chapter of the Agreement.

[4. The dialogue on the public health promotion and protection should be conducted in the framework of relevant fora, platforms and advisory groups.]

5. The Parties shall consider the impacts on public health notably in the framework of ex-ante and ex-post impact assessments. The Parties shall take into account the available data and recommendations given by the stakeholders listed in paragraph 3.



EPHA (AISBL) is the European Platform bringing together public health organisations representing health professionals, patients groups, health promotion and disease specific NGOs, academic groupings and other health associations. The European Public Health Alliance has received funding under an operating grant from the European Union's Health Programme (2014-2020). The content of this email represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains. Transparency Register Number: 18941013532-08