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TRADE, INVESTMENT AND PUBLIC HEALTH AN EPHA GUIDE AND RISK ASSESSMENT TOOL

EXECUTIVE SUMMARY

This document is intended for public health professionals, as an introduction to trade and investment policy and its relevance to public health. It also offers a tool for public health organisations to assess the risk level for public health arising from trade agreements.

The document lays out the structures of the international multilateral trading system, namely those of the **World Trade Organization (WTO)**, which is the international body that sets the rules for global trade between nations. Its key principles emphasise non-discrimination between trading partners, and between domestic and imported goods. Its agreements cover trade in goods and services, rules for "technical barriers to trade" and for food safety measures, intellectual property rights, government procurement and state-state dispute settlement, among others. The health relevant aspects of each agreement are highlighted.

Negotiations at the WTO have been stalled for a number of years, and so many nations have turned to bilateral free trade agreement (FTA) negotiations to increase their liberalisation and economic ties to partners. This **new generation of FTAs** has introduced a range of new elements and focus on "non-tariff barriers" i.e. differing behind-the border regulations between trading partners.

The EU has been pursuing FTAs since 2006, and has a clear governance structure for their negotiation, approval and assessment. New measures included in FTAs, such as regulatory cooperation and so-called "good regulatory practices", can promote and entrench deregulatory approaches. Investment protection measures allow companies to seek damages from governments if they feel investment protections have been breached. This can induce "regulatory chill" whereby other states/governments are discouraged from taking similar legislative actions for fear of cases being brought.



Other measures such as negative listing (where all items are affected except those listed) and the ratchet clause promote liberalisation, putting limits on governments' space to regulate. Lastly, the so-called science- or risk-based approach is often included in FTAs, and in WTO agreements, side-lining the precautionary principle which puts health first where the scientific evidence about a potential risk is unclear.

As trade and investment agreements increasingly focus on "non-tariff barriers" their potential impacts on public health increase. Trade agreements can affect the price and availability of high fat, salt or sugar (HFSS) food and drink, alcohol or tobacco via increased imports, increased investment, intellectual property measures and marketing. The tobacco, alcohol, food and pharmaceutical industries are frequently involved in the process of making trade policy, which can increase the chance of trade deals undermining public health. Health services can be threatened via clauses promoting increased liberalisation and preventing renationalisation. Access to medicines can be threatened through the inclusion of more stringent intellectual property measures. Lastly, the document considers a number of measures and instruments which have been proposed to improve trade agreements and mitigate their effects on public health, with their various advantages and disadvantages.



Glossary of terms

AMR – Antimicrobial Resistance, when microorganisms such as bacteria, viruses, fungi and parasites become resistant to the medications used to cure the infections they cause, rendering the treatment ineffective. (WHO, 2017a).

BIT -Bilateral Investment Treaty.

CETA – Comprehensive Economic and Trade Agreement, the EU's trade and investment agreement with Canada.

CJEU – Court of Justice of the European Union.

DAG – Domestic Advisory Group.

DALYs - Disability Adjusted Life Years, the number of years lost due to ill-health, disability or early death. (WHO, 2018)

EMA - European Medicines Agency.

FCTC - Framework Convention on Tobacco Control.

FTA – A Free Trade Agreement.

GATS – General Agreement on Trade and Services.

GATTS – General Agreement on Trade and Tariffs.

GI - Geographical Indications, a sign used on products that have a specific geographical origin and possess qualities or a reputation that are due to that origin. (European Commission, 2013a)

HFSS - High in Fat, Sugar or Salt.

ISDS - Investor State Dispute Settlement.

ICS - Investment Court System.

MFN - Most Favoured Nation.

MIC - Multilateral Investment Court.

NAFTA – The North American Free Trade Agreement, signed between the USA, Canada and Mexico.

NCDs - Non-communicable Diseases.

NHS - UK National Health Service.

OECD – Organisation for Economic Cooperation and Development.

Precautionary Principle – A part of EU law which may be invoked to protect the environment and/or public health when a phenomenon, product or process may have a dangerous effect, identified by a scientific and objective evaluation, even if this evaluation does not allow the risk to be determined with sufficient certainty. (Eur-LEX 2016).

(S)IA – (Sustainability) Impact Assessment.

SDGs – The United Nations Sustainable Development Goals.

SPCs - Supplementary Protection Certificates, an intellectual property right that serve as an extension to a patent, applying to specific pharmaceutical and plant protection products. (European Commission, 2018).

SPS – Sanitary and Phytosanitary Measures, a trade agreement chapter covering measures to protect humans, animals and plants from diseases, pests or contaminants. (WTO, 2018a).



TBT – Technical barriers to trade, a trade agreement chapter covering a wide range of regulations, standards and assessment procedures to ensure they are non-discriminatory and do not create unnecessary barriers to trade. (WTO 2018b).

TRIPS – Trade Related Aspects of Intellectual Property Rights.

TSD – Trade and Sustainable development chapters.

TTIP – Transatlantic Trade and Investment Partnership, the EU's incomplete trade and investment agreement with the United States of America.

WHO – The World Health Organization.

WTO – The World Trade Organization.



PART I: Trade and Investment

This section will look at the multilateral trading system (i.e the World Trade Organization, its history and treaties) before moving on to cover the new generation of bilateral free trade and investment agreements, explaining the innovative mechanisms and clauses popularised through the current generation of deals.

The multilateral trading system

The General Agreement on Tariffs and Trade (GATT) was signed in 1947, with the aim of reducing or eliminating trade barriers such as tariffs and quotas, and thereby promoting international trade. (WTO 2018b) There are two key obligations under the GATT: The Most Favoured Nation (MFN) and national treatment principles. MFN means that every time a country lowers a trade barrier or opens up a market, it has to do so for the same goods or services from all of its trading partners, unless through a Free Trade Agreement (FTA) or customs union. (WTO 2018c) National treatment means that imported and locally-produced goods should be treated equally with respect to domestic taxation and regulation, once foreign goods have entered the market. (WTO 2018c)

The GATT was the forerunner of the World Trade Organization (WTO), borne out of the Uruguay round of GATT negotiations between 1986-1994 and which deals with the rules of trade between nations. It has 164 member countries and is based in Geneva. The core of the WTO is a number of agreements negotiated and signed by most

of the world's trading nations. (WTO 2018d) **Key WTO agreements** include the General Agreement on Trade in Services (GATS);
Technical Barriers to Trade (TBT) agreement;
Trade-Related aspects of Intellectual Property (TRIPS); the Sanitary and Phytosanitary (SPS) Measures Agreement; Government Procurement and others.

The WTO's various agreements represent the "multilateral" trade approach whereby all, or many, states negotiate one set of rules to apply as the basis of the global trading system. There are some WTO agreements that are plurilateral, meaning that not all WTO members are party to them, including for example the Government Procurement Agreement. Separate bilateral or plurilateral agreements can then be negotiated between two, or more, parties to further deepen liberalisation on a reciprocal basis between them, provided they abide by certain rules and are notified to the WTO. (WTO 2018e)

The GATT includes Article XX which guarantees Members' right to take measures to restrict imports and exports, when those measures are necessary to protect the health of humans, animals and plants. (WHO/WTO 2002) However, this article has only once been used successfully to protect public health, in the case of the French ban on asbestos, which is still being contested. This suggests that the article is generally interpreted rather narrowly. (Zeigler 2009) In the case of measures covered by specific agreements (such as the technical barriers to trade, or sanitary and phyto-sanitary agreements – see below) these take



precedence over the GATT.

The WTO has been at deadlock since the mid-late 2000s, failing to progress past the Doha round, which began in 2001, and which was effectively abandoned at the 2015 meeting of WTO ministers in Nairobi. These negotiations covered about 20 areas of trade, including services, agricultural goods tariffs, the removal of agricultural and farm subsidies, geographical indications and the environment – many of which are highly complex and/ or highly sensitive in nature. (WTO 2018f) WTO talks are still ongoing in other areas, for example on e-commerce and fishing subsidies. During this deadlock, bilateral trade agreements have multiplied. (Pakpahan 2012)

Between 2001 and 2017, 200 regional trade agreements were notified to the WTO, more than doubling the existing number to that point (87 to 287). (WTO 2018g) This new generation of bilateral trade agreements will be examined in more detail below. Threats to the multilateral trading system have also multiplied recently, for example from the current US administration, which is blocking appointments to the WTO's appellate body, which hears and tries to resolve disputes between members (see dispute settlement, below). (The Economic Times 2018)

There are five aspects of the WTO system which are particularly key for health:

- The Technical Barriers to Trade Agreement (TBT)
- 2. The Sanitary and Phyto-sanitary Agreement (SPS)

- 3. Trade-Related aspects of Intellectual Property Rights Agreement (TRIPS)
- 4. WTO dispute settlement
- The General Agreement on Trade and Services (GATS)

1. Technical Barriers to Trade:

The TBT agreement aims to ensure that technical regulations, standards and conformity assessment procedures are not discriminatory and do not create unnecessary obstacles to trade. It also recognises members' right to implement measures to achieve legitimate policy objectives such as the protection of human health or the environment.

Key points:

- The agreement is designed to address packaging and labelling requirements and requires that they be non-discriminatory and no more trade-restrictive than necessary (PAHO 2016)
- Most Favoured Nation and National Treatment obligations are extended but no specific standards are mentioned.
- The key addition of the TBT agreement is the "least restrictiveness" clause which states that '[...] technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create.' (WTO 1995)
- States are required to notify the WTO
 of any planned measures, and to take
 comments from other members into
 account in their policy development. This
 isn't necessarily a constraint.
- Encourages mutual recognition both of



standards, known as "equivalence", and conformity assessment but hasn't made much progress.

2. Sanitary and Phyto-sanitary Standards:

The SPS agreement sets out the basic rules for food safety and animal and plant health standards. It allows countries to set their own standards, but also enshrines the Science-based Approach, rather than the Precautionary Principle.

Key points:

- More onerous than TBT
- Requires members to base measures on internationally-recognised standards where possible
- Members can maintain a higher level of protection 'only to the extent necessary' to achieve the objective and 'if there is a scientific justification [...] based on' a 'risk assessment' (WTO 2018h)
- Precautionary measures are allowed on a 'provisional' basis while more scientific information is sought
- As with TBT there are notification requirements and changes in measures must also be reported.
- Encourages equivalence but hasn't made much progress.

3. Trade-Related Aspects of Intellectual Property (TRIPS)

The WTO TRIPS agreement attempts to harmonize the different systems for protecting intellectual property around the globe regardless of the development level of different countries, establishing minimum levels of IPR. This can often be

seen as problematic from a public interest perspective. It is based on the basic WTO principles of MFN and National Treatment, covering copyright, trademarks, geographic indications, patents and so on. (WTO 2018i)

TRIPS is particularly relevant for pharmaceuticals, and food and alcohol products protected by geographic indications. Protection for non-wine or spirit products is only provided where wider use would be misleading and excludes generic names (e.g. cheddar). (Ungphakorn 2018) TRIPS allows for members to "adopt measures necessary to protect public health and nutrition."

The WTO Doha Declaration on the TRIPS Agreement and Public Health was agreed by WTO members in 2001 and frames the implementation of IP requirements in a health policy context, explicitly acknowledging the concerns around the link between patents and medicine prices. (Doha 2001) It stresses the need for the TRIPS Agreement to be part of the wider national and international action to address public health challenges experienced by developing and least-developed countries. The Declaration identified and further clarified specific options open for governments to address public health needs, also termed 'flexibilities', such as voluntary and compulsory licences. The importance of such flexibilities was highlighted more recently by their inclusion in the Sustainable Development Goals. (WTO 2018i)

4. Dispute settlement

Resolving trade disputes between WTO



members is one if its key activities, allowing the rules of the global trading system to be enforced. The system allows only state-to-state dispute settlement – Member States can bring cases to the WTO against each other, when they consider that the action of another state is breaking WTO agreements, or failing to live up to its obligations under them. The preferred method for resolution is for the two countries to discuss their problems and settle the case themselves. (WTO 2018k)

The process begins with an initial panel stage, which may be followed by an appeal to the Appellate Body, where decisions are adopted unless there is "negative consensus" i.e. there is a majority against the decision. (WTO 2018I)

There are many examples of health-related cases being brought to the WTO: for example, Ukraine filed a dispute against Australia on its plain packaging requirements on tobacco, referring to TRIPS, and TBT measures. (WTO 2012) They later withdrew, but other countries took on the case. Although nations must bring disputes to the WTO, and companies are not allowed to do so, companies have given financial support to governments which bring such cases and could of course pressure them to do so. (The Conversation 2017)

An important but much less well-known case is Australia vs Thailand. Since 2010, members of the WTO, including Australia, have opposed Thailand's proposal for graphic warnings on alcohol containers. This case highlights the willingness of WTO members

to question the autonomy of other countries to pursue their public health goals and use dispute settlement to advance the protection of its own alcohol industry at the expense of public health policies abroad. (O'Brien 2012)

Many disputes are related to the SPS agreement. The US has challenged the EU's ban on beef treated with hormones as not science-based, resulting in a memorandum of understanding between the two, agreed in 2009, some 13 years after the complaint was raised. The MoU gave the US a larger zerotariff quota for "high-quality" (hormone-free) beef sales in the EU. The WTO process can result in trade sanctions under the agreement, if possible targeting the relevant sector. However, sanctions cannot be retroactive i.e. if a country is found in violation, it can eliminate the measure or come to an agreement with the opposite party, without any other consequence.

5. The General Agreement on Trade and Services (GATS)

The GATS agreement provides the rules for international trade in services, aiming to fulfil the same aims as the GATT but for services, establishing the principles of MFN and non-discrimination to promote trade. The GATS excludes "services supplied in the exercise of governmental authority" covering services supplied neither on a commercial basis nor in competition with other suppliers. The MFN principle is subject to important exemptions for services, while National Treatment is only granted in services for specifically designated sectors. (WTO 2018m)



However, GATS exceptions and exclusions regarding health are narrow and likely to be interpreted restrictively, and therefore are very unlikely to shield public health measures from the force of the treaty.

The GATS is a broad agreement, and some have argued that it seeks to deliberately affect "behind-the-border" regulatory activities of governments, such as advertising prohibitions and restrictions, or alcohol monopolies. Moreover, it applies equally to cases that are non-discriminatory – meaning that it is possible to violate the agreement even when measures are applied equally to foreign and domestic suppliers. (Grieshaber, Jernigan 2001)

The new generation of FTAs

With negotiations at the global level blocked, many countries have negotiated deals directly with partners. The European Union (EU) launched its "Global Europe" strategy in 2006, and since then has pursued a number of FTAs with various countries. (Pakpahan 2012)

The first of the new generation of FTAs is widely considered to be the deal signed between the EU and South Korea on the 6th October 2010, but the most significant and high-profile have been the incomplete Transatlantic Trade and Investment Partnership (TTIP) with the United States, and the Comprehensive Economic and Trade Agreement (CETA) with Canada. TTIP negotiations began in 2013 and are currently frozen. CETA negotiations began in 2009, and

the deal was provisionally applied from the 21 September 2017, but still awaits ratification by several EU Member States.

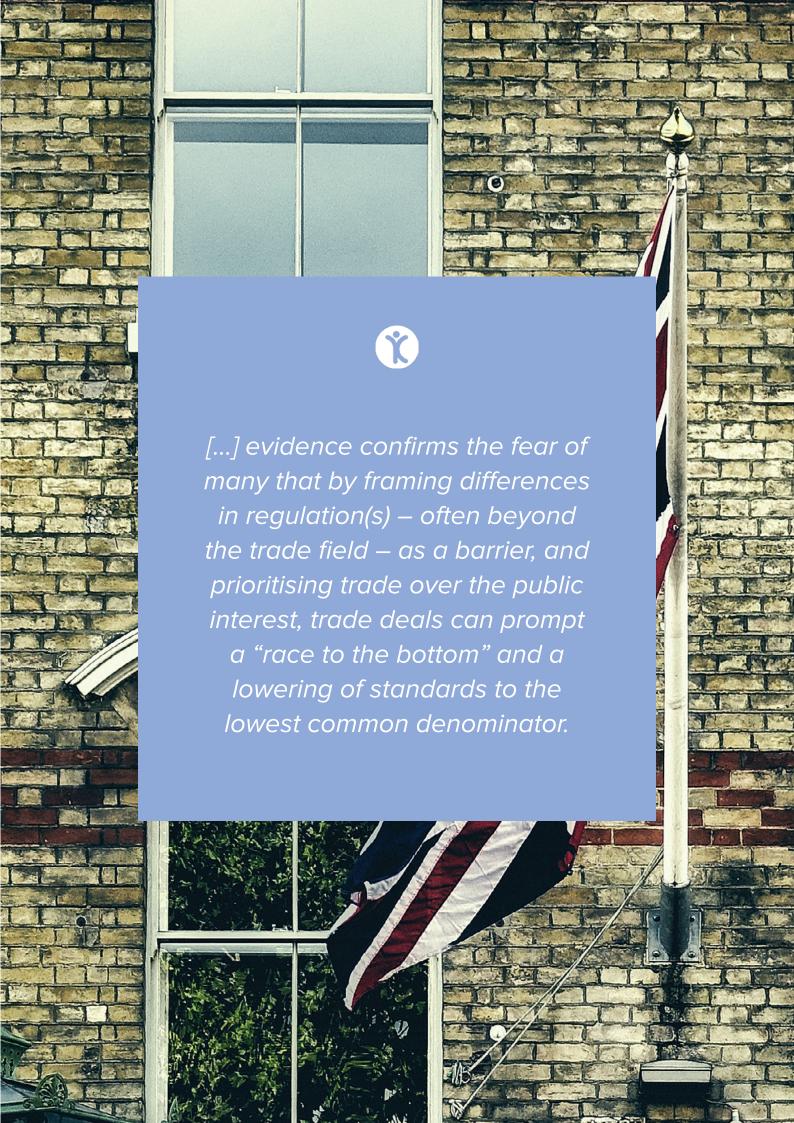
There are several key questions:

1. How are they negotiated?

Within the EU, trade or commercial policy is one of the few areas where the EU has "exclusive competence", meaning the EU alone (and not Member States) is able to agree deals concerning these areas. (EUR-Lex 2016a) However, the European Court of Justice (CJEU) has found investment issues, particularly portfolio investment, to be mixed competences, meaning that trade deals which include investment issues must also be ratified by all EU Member State parliaments. (CJEU 2017)

European investment protection measures have been subject to a number of legal challenges at the European Court of Justice. First, the CJEU ruled (in relation to the EU-Singapore agreement) that certain investment issues are a mixed competence, meaning that any trade deals relating to those issues must also be ratified at Member State level (this was also the case for CETA). The CJEU's Achmea judgement may also hint that the court sees separate investor protection courts as incompatible with EU law, although consensus among Member States and the European Parliament seems to be in favour of investor protection courts like the Investment Court System (ICS). Lastly, Belgium has submitted a request for a CJEU opinion on whether the ICS, as included in CETA, is compatible with EU law. All this means





that the legality and politics of investment protection is still very much a live issue. Trade deals are negotiated by the European Commission on behalf of the Council of the EU (CotEU - the forum for EU national governments to come together to determine policy in a certain area). The Council gives the Commission a mandate for negotiation, laying out what it expects to gain, and what it would be willing to concede. The Commission negotiates on this basis, often over many years, before returning to the Council for approval. The European Parliament (EP) also formally gets a yes-no vote on the final deal, although it can wield its influence earlier as well, by adopting resolutions, own-initiative reports and so on, to try and affect the direction of negotiations by indicating its level of support or approach on an issue. For example, during the CETA and failed TTIP negotiations, the Parliament adopted a resolution to promote their view, and push the Commission to take a different approach in negotiations. It is also stated in the treaties that the Commission must regularly report to the Council's Trade Policy Committee and the European Parliament's International Trade (INTA) Committee. (EC 2018)

Finally, both institutions (the EP and CotEU) must approve the deal, along with the other party, for it to take effect. As stated above, "mixed" deals, which also concern EU Member State responsibilities must be approved by all EU national parliaments, before coming fully into force. The deals, however, can be provisionally applied once approved at EU level, meaning clauses related to EU-exclusive competences will

apply, as is the case currently with CETA. In 2015, the EU published a new strategy for trade and investment: "Trade for All: Towards a more responsible trade and investment policy" as a direct response to the debate around TTIP, moving towards basing EU trade policy on three key principles: effectiveness, transparency and values. The practical implications of this are debatable, but it does provide a (non-binding) standard to which to hold the EU.

2. How do they work?

The new generation of trade deals has gone beyond the traditional focus on eliminating tariffs. Although tariff elimination is included, since tariffs on many goods are already low at WTO and on bilateral levels, the principal area of economic benefit for the EU from trade deals is thought to emanate from reducing "non-tariff barriers" – caused both by potentially discriminatory measures but also in situations where legislation, standards and regulation differ between the two parties, complicating the sale and marketing of goods, as manufacturers must adhere to two separate systems. Although tariffs are still considered, non-tariff barriers in areas such as TBT are often emphasised. In TTIP, for example, the economic benefits from tackling TBTs were estimated at around €70bn¹. (De Ville, Siles-Brugge 2015) However, this does not consider the economic benefits that may derive from these regulations and the health benefits they bring, and which may far outweigh the projected gains from deregulation. It is hard to estimate the financial benefits of regulations, but misleading to only consider their costs. (ETUI



2015)

FTAs typically comprise of a number of thematic chapters, including but not limited to Trade-in-Goods, Competition, TRIPs, SPS, TBT, Investment, Trade in Services, Trade and Sustainable Development, and Transparency.

3. How are they assessed?

EU trade agreements are assessed at several stages:

- At inception, an impact assessment and an impact assessment report are completed before negotiations begin to describe the likely economic, environmental, social and human rights impacts of the deals. (EC 2018a)
- A so-called Sustainability Impact Assessment (SIA) (itself made up of several stages, from inception to final report) which provides the Commission with an in-depth analysis of the potential economic, social, human rights and environmental impacts of ongoing negotiations. These are supposed to help steer the negotiations, (EC 2018b) but in reality, this can often be difficult as negotiations are pursued with more vigour than the SIA and completed before the final SIA report. For example, the EU-Mexico deal reached a political conclusion in April 2018, with the final SIA expected later that year.
- Lastly, the European Commission conducts an ex-post evaluation to assess whether the deal was justified and is working as expected. (EC 2018c)

The EU also has a handbook containing

guidance on how to conduct SIAs. The second edition was published in 2016 and refers to public health. (EC 2016) There is no specific Health Impact Assessment at EU level, and health is at best partially covered in SIAs.

4. What new elements do they include?

Non-tariff barriers: governments' policy space and the right to regulate

As outlined above, "non-tariff barriers" refer to divergent regulation between negotiating parties, and the new generation of trade deals often aim to eliminate these differences. However, evidence confirms the fear of many that by framing differences in regulation(s) – often beyond the trade field – as a barrier, and prioritising trade over the public interest, trade deals can prompt a "race to the bottom" and a lowering of standards to the lowest common denominator. Governments use a number of technical measures for health and health services regulation, such as labelling, licensing, granting permissions and recognition of qualifications.

Targeting non-tariff barriers also often leads (or threatens) to restrict governments' policy space (although the formal right to regulate may remain, it may be restricted). There are three main new elements that can have the effect of restricting government policy space:

- Regulatory Cooperation and so-called "Good Regulatory Practices";
- Investment Protection Mechanisms:
- the Ratchet Clause and Negative Listing.



a. Regulatory Cooperation and "Good Regulatory Practices"

Regulatory cooperation is a broad concept, which can be understood to include regulatory convergence, as defined by the Organisation for Economic Cooperation and Development (OECD). (OECD 2012)

Within trade agreements it tends to consist of horizontal, cross-cutting promises to cooperate on future law-making, institutionalising higher levels of cooperation between the partners. In TTIP, the EU proposal on regulatory cooperation aimed to broaden its scope to shaping future regulation beyond the specific provisions included in the agreement, creating a mechanism to bring EU and US regulations closer together over time, intended to lead to increased liberalisation, and economic integration, but which could lead to lower levels of protection – the so-called "race to the bottom." (Ackerman 2016)

This is not an inevitable outcome, but the deregulatory motivation for including this mechanism and the involvement of industry in negotiations and such processes should raise alarm bells. Many proponents see regulatory cooperation as a good way to reduce regulations which are simply trade irritants or barriers, and thereby increase the economic benefits of the deal.

As part of regulatory cooperation, working groups and committees are often established to allow the parties to engage in that cooperation, and attempt to resolve market

access issues. Under the EU-Korea FTA for example, there are working groups on pharmaceutical products and medical devices, and on chemicals, along with committees on SPS and trade in goods, made up of government officials from both sides. (EC 2011)

Similarly Good Regulatory Practices (GRPs), also known as regulatory coherence, first included by the EU in TTIP, are a form of soft law that tend to promote deregulatory approaches and voices by privileging the elimination of trade barriers over other policy objectives. (De Ville, Siles-Brugge 2017) For example, the draft Transparency chapter of the EU negotiation with the Mercosur trading bloc (consisting of Brazil, Argentina, Uruguay and Paraguay) sets the chapter's objective as "promoting a transparent and predictable regulatory environment and efficient procedures for economic operators," mandating many opportunities for business interests to influence policy, as well as including a review and appeal article which specifies that each party should establish procedures for "prompt review and, where warranted, correction of an administrative decision" (EC 2017) Both regulatory cooperation and GRPs may block or weaken vital health, or other public interest laws.

In practice, both regulatory cooperation and GRPs mean that trade deals have an impact much more widely than trade policy, as they can influence or set principles of law-making for a wide range of areas. It is true that these provisions are not subject to investor-state or state-to-state dispute settlement



provisions (see below), so governments cannot be challenged by businesses or other government parties to the agreement, over failure to follow these provisions. It has also been claimed that the proposals are voluntary, but this is not reflected in a satisfactory manner in the language of the legally binding parts of the text.

b. Investment Protection Mechanisms

Investor-state dispute mechanisms are generally considered to be the most controversial part of investment agreements as they allow foreign investors to sue governments for damages through investorstate dispute settlement provisions. TTIP and CETA brought investment protection measures to public attention, although they have long been included in investment treaties. Investor State Dispute Settlement (ISDS), as proposed by the US in TTIP and included in many Bilateral Investment Treaties (BITs) between nations, provides a mechanism independent of state judicial systems for foreign investors to take legal action against governments when they feel investment protection obligations have been breached by a government decision or legislation. Such rights include the right to be protected against direct or indirect expropriation, whereby a government takes control of property which requires the payment of compensation, (Allen & Overy 2012) or the obligation of a government to provide foreign investors with "fair and equitable treatment." (Kalicki, Medeiros 2007) This is in contrast to WTO dispute settlement. which is only on a state-to-state basis and therefore investors are not able to directly

challenge governments. Another difference is that the WTO can authorise retaliation by the aggrieved Member State, whereas investment protection and arbitration can only result in direct financial compensation to an investor.

ISDS mechanisms are premised on a model of commercial arbitration and were originally put in place to reassure investors that they would have access to justice in countries where the legal system could be biased or unreliable. Traditional investment treaties were between less developed (importing) and more developed states (exporting) and the judiciaries of these lesser developed states often suffered from (perceived or actual) corruption or bias. Investment protection was therefore a means to promote or increase investment from more developed states in developing ones.

However, ISDS can undermine democratic policy development, induce regulatory chill, whereby other governments are discouraged from taking similar action, and discriminate against local investors. (EPHA 2015) The scope of investment protection can be important for health promotion, in particular, in areas with strong global industries, such as alcohol, tobacco, food and soft-drinks industries. Companies can afford to fund lengthy and costly arbitration to attempt to stop, or undermine precedent-setting policies, even when their case is weak. For some, they can't afford not to.

Therefore, there are many examples of corporate interests using ISDS to slow or prevent the passage of health regulation



that would affect their business, regardless of the functioning of the justice system. For example, Philip Morris International (PMI) sued Uruguay and Australia for their antitobacco legislation, mandated under the Framework Convention for Tobacco Control. These cases were eventually rejected, and the governments of Uruguay and Australia were awarded their legal costs, (Carless 2016) but PMI were successful in delaying the legislation, causing regulatory chill in New Zealand which reportedly shelved its plans for plain packaging of tobacco following the PMI case against Australia. (Kelsey 2017)

Another issue is that the principle of exhaustion of domestic remedies – whereby a case must proceed all the way through a domestic court system before going to an international court or arbitration – is often not included. This, in effect, grants foreign investors a privileged route to compensation for damages as legal remedy, unencumbered by domestic legal process.

Following the opposition to ISDS in Europe, the EU proposed the Investor Court System (ICS) as an alternative, aiming to address the lack of transparency and potential conflict of interests for arbitrators. It did not change the fact that foreign investors would still have access to their own private court, a right denied to ordinary citizens and domestic businesses, and could result in the institutionalisation of arbitration, rather than eliminating the need for it. (EPHA 2015a)

However, ICS did succeed in reframing investor protection, and by targeting other

significant trade policy-makers (Germany and Socialist and Democrat MEPs in the European Parliament), rather than the general public, were able to remove obstacles to its ratification, if not its public acceptability. (Siles-Brugge 2018) The EU has since pushed this deal in its negotiations, including it in the deal with Canada. Meanwhile, it has also proposed a Multilateral Investment Court (MIC), to fulfil a similar role at the multilateral level, which it is pursuing at the UN level. If the EU is successful with this initiative, it could result in investor-state dispute mechanisms being locked in at the global level.

As mentioned above, there have been a number of legal challenges regarding investment policy at the European Court of Justice, one of which is still ongoing. Clearly the legality and politics of investment protection is still very much a live issue.

c. Negative Listing and the Ratchet Clause

These innovations were first introduced in TTIP and represented a departure from previous norms. They concern liberalisation of services within trade and investment agreements focussed on eliminating restrictions on market access (such as quotas or equity caps) and ensuring the application of National Treatment to foreign service providers and investors. The Negative Listing approach reverses the logic of selective liberalisation and means that all services will be subject to market liberalisation unless an explicit exception is made in the text. (EPHA2016)

The Ratchet Clause, included in TTIP and



CETA negotiations, has a similar aim to incentivise further liberalisation, by making it difficult to reverse decisions to open up certain sectors. Essentially the clause included in TTIP meant that regulations could only be amended in a way that leads to more liberalisation and not less. The clause – particularly when combined with the possibility for private companies to sue European governments under the investor protection provisions – therefore represents a considerable legal obstacle to returning privatised services to state operation, including potentially health services. (EPHA2016)

Science-based Approach or the Precautionary Principle?

Although the principle of being Science-based is one of the key parts of the WTO SPS agreement, recent bilateral deals have served to reinforce this approach (which is favoured by the US), over the EU's Precautionary Principle. Simply put, the Precautionary Principle puts the onus on proving that something is not harmful before it can be sold or traded, whereas the Science or Risk-based Approach insists that products must be allowed to be sold/traded until they can be concretely proven to pose a threat to human health or the environment.

For example, in the EU's ongoing negotiations with the Mercosur trade bloc the clause proposed by the EU only refers to precautionary measures taken to prevent environmental degradation despite the fact that in the EU application of the Precautionary Principle is much wider, covering health

and consumer protection along with environmental issues. Furthermore, the Precautionary Principle is only included in the Trade and Sustainable Development chapter which is not subject to dispute settlement, meaning that violations of the provisions cannot lead to sanctions. What's worse is that binding parts of the agreement favour a risk-assessment based model where restrictions must be based on scientific evidence for harm, requiring "scientific justification" to be provided for any SPS measure. (Bilaterals.org 2017)

Therefore, we can see that even the EU trade body fails to fully and adequately include the Precautionary Principle in its trade agreements, leading to risks for human health, despite the fact that the EU is its main proponent.

Transparency Measures and Advisory Groups

The EU has responded to pressure from campaigners by moving towards a more transparent approach: publishing more documents, and including businesses, trade unions and NGOs in its trade work more systematically. A TTIP Advisory Group was established when negotiations were ongoing, and recently a general Trade Advisory Group was established. However, it is important to critically assess the type of transparency and involvement being offered to civil society organisations: is it simply window-dressing or is there a genuine attempt at a more participative or inclusive approach? For instance, TTIP Advisory Group members had access to negotiating texts and were able to



give concrete input on live issues, whereas the newer Trade Advisory Group is general to the point of being unhelpful.

Another example concerns what is published. Although the European Commission promised to publish all documents in its *Trade for All* strategy, it failed to do so during the negotiations with Japan. It may also choose to publish its own proposed texts, but not consolidated texts, which show proposals from both parties, and what has been agreed by the two sides.

Some have observed a difference between the European Commission's interpretation of transparency and civil society's expectations. For the European Commission, they consider they primarily owe transparency to the other institutions, and also see it as a useful tool to bust anti-trade myths, without harming their negotiating position. Trade campaigners on the other hand primarily want a more participative democratic process, in which people are represented, either directly, or through civil society organisations. (Borderlex 2017) Therefore, it is important to look at the proposed transparency measures, the motivation for proposing them, and to see whether they fit expectations of transparency.

Trade and Sustainable Development Chapters

The EU has pioneered the inclusion of Trade and Sustainable Development chapters in its trade deals to make the link between trade and labour and environmental issues. However, these chapters are generally weak; are non-binding (i.e. there are no sanctions if measures are not followed); and have not

to date acknowledged the key relevance of health to truly sustainable development. Groups known as Domestic Advisory Groups (DAGs), composed of civil society organisations, have also been established under EU trade deals to advise on issues related to these chapters.

Part II Trade and Public Health: potential impacts and relationships

This section will look at the pathways by which trade can impact public health and offers a model for assessing the risks from each area which can be applied to any trade deal as needed. European officials and policymakers often claim that trade policy is neutral, as if it does not affect health at all. This is not true, however, and even if it were, neutrality

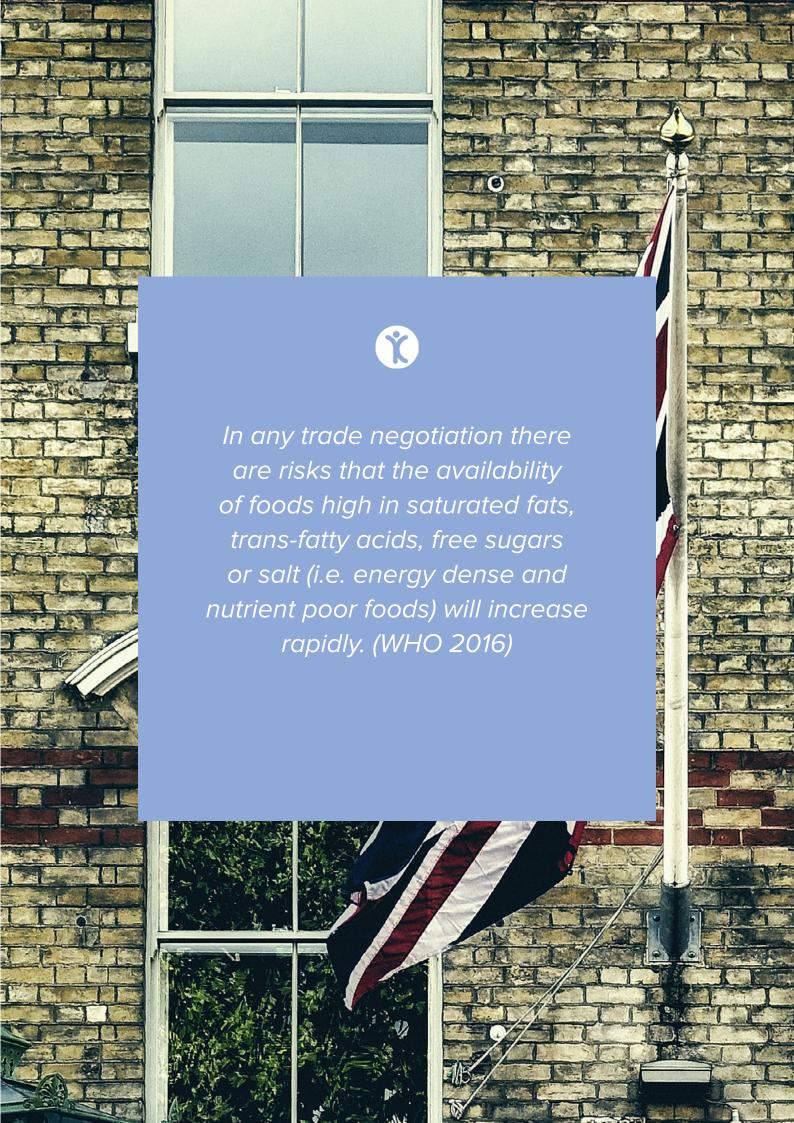


EPHA'S MODEL FOR A TRADE-HEALTH RISK REGISTER

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.

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 minorly 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.

is insufficient – trade deals should be health coherent and health promoting, not simply not health-harmful.

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, sugarsweetened 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. (Thow, Hawkes 2009)

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. (EC 2012)
- Reduced costs and barriers to retail and marketing of energy-dense, nutrient-poor foods, on which most food marketing is focused. (EHN 2017)

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 is an explicit offensive interest for the EU in its negotiations with Mercosur. (CotEU 2017)

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. (Khan et al 2015)

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 "westerntype" 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. (Goryakin et al 2015)

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. (WHO 2016)

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. (Wiggins, Keats 2015)

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 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. (Tobacco Tactics 2017)

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. (WSTA 2017)

Deregulatory initiatives, including regulatory cooperation and 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.

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. 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. (Fritz 2015)

CETA includes a carve-out for publicly funded services, but this is insufficient as Services of General Interest are not always publicly funded. For example, the Belgian mutualités are mutual health insurance providers but 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 form, and are therefore not considered to be privately funded. [...] The EU reserves the right to adopt or maintain any measure with regard to all privately funded health services, other than privately funded hospital, ambulance, and residential health facilities services other than hospital services." (CotEU 2016)

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. (Krajewski 2016) 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 several investment

dispute cases related to pharmaceuticals and patent disputes. For example, Eli Lilly, a US pharmaceutical corporation launched a case against Canada under NAFTA, after it was not granted a new patent, due to lack of novelty. (Public Citizen 2013) 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, (Knowww 2017), 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. (HAI, EPHA 2017)

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), (Wikipedia undated) and other flexibilities which are permitted under the WTO TRIPS agreement.



Worryingly, 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. (Public Citizen, HAI Commons Network 2016)

5. Antimicrobial Resistance (AMR) and food safety

AMR and food safety issues are often covered by SPS chapters, and problems can come when agricultural markets are opened up, and more emphasis is put on a streamlined import/export process than on ensuring food safety and minimising Antimicrobial Resistance. In trade with the US and Canada, 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 negotiations 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, can be affected by TBT chapters. The recent example of the US including 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 NAFTA (its deal with Mexico and Canada) (Ahmed et al 2018) may be extreme, 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 text, remain too vague to prevent challenges to health-related food labelling schemes.

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

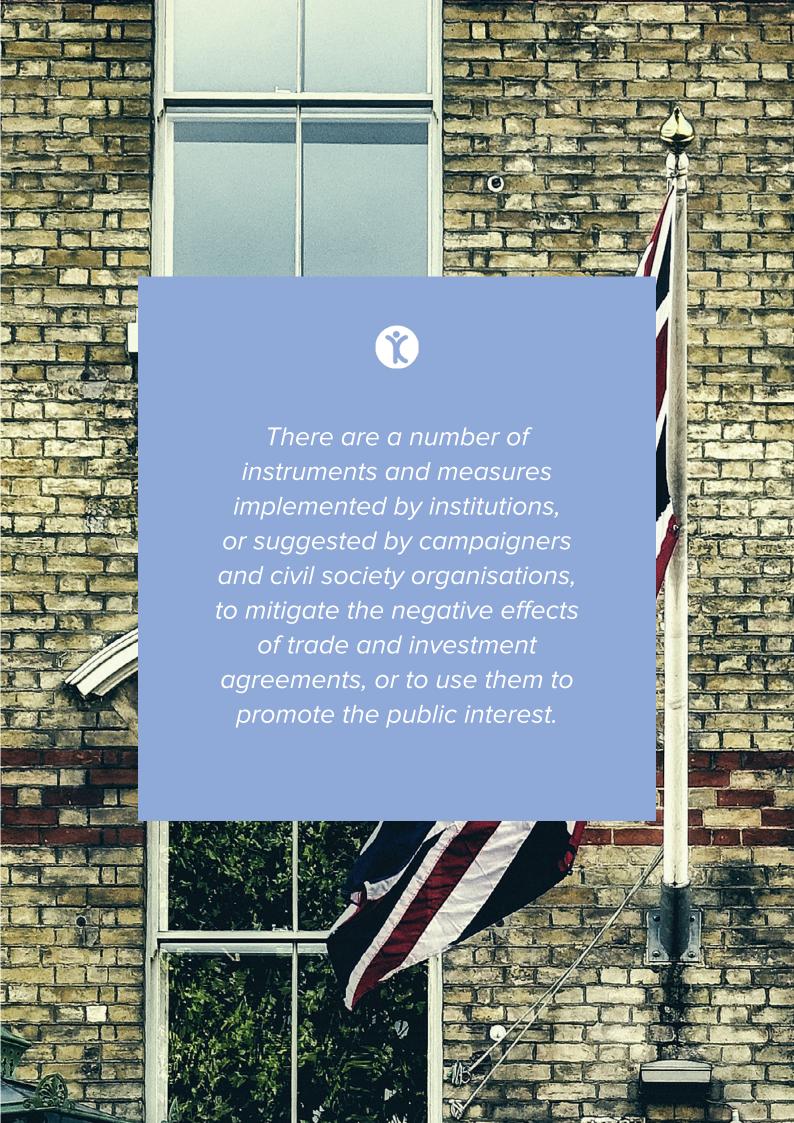
considerations" to be taken into account in procurement procedures, if "they are linked to the subject-matter of the contract" (EU-Mexico 2016). This wording seems unlikely to be strong enough to prevent challenges to dietary health-promoting criteria for public procurement.

These criteria were used by EPHA in the development of the report "Unhealthy Trades: the Side-Effects of the European Union's Latin American Trade Agreements," (EPHA 2018), which rated the risks to public health from the EU's trade deals with Mexico, the Mercusor 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.





Part III Mitigating the Negative Effects of Trade and Investment Agreements, and using them 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 deals. While this debate is not within the scope of this briefing, the suggested reading list offers opportunities to explore this issue in more detail. Regardless of this debate, the EU is set on entering into trade negotiations, as will the UK post-Brexit, and therefore it is important to build understanding in these areas.

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

POSITIVES

DRAWBACKS

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 deals.

- If done thoroughly, the most consistent approach
- Has the advantage of not separating health from other issues and emphasising the links between trade and various aspects of public health.
- Hard to cover all issues, and retain total coherence
- There will always be trade-offs/ compromises – can trade deals be truly "neutral"?

ADD PUBLIC HEALTH CHAPTERS TO TRADE DEALS

To address health relevant issues

- Gives public health visibility, ensures inclusion in agreements
- Could be weak, or not legally enforceable, making it little more than window-dressing



POSITIVES

DRAWBACKS

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.

- Could give NGOs/CSOs more influence
- Raise the public profile of trade issues, and how they impact health
- More collaborative approach

- Business representatives will also be involved
- Could just be window-dressing, rather than have any actual influence

HEALTH/SUSTAINABILITY IMPACT ASSESSMENTS (H/SIA)

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

- A key tool to show (in)coherence with health policy, enforcing a health in all policies approach
- If the need to revise the deal on the basis of HIA is made mandatory, could have significant effect
- Can still be ignored, or deprioritised. For instance, the European Commission is obliged to conduct sustainability impact assessments but for the deals with Mexico and Mercosur the process has been far behind the negotiations, and so there is no clear way for the outcomes of the final SIAs to change the deals.
- Need to have binding impacts

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.

- Clear and simple
- Has been achieved

- Quite low ambition just defensively guarding the status quo
- Depends on where in the text it is, as to whether it is binding or not.
- Usually specific to a particular product a carve out for tobacco does not address health problems related to alcohol, food etc.



POSITIVES

DRAWBACKS

INTERPRETATIVE DECLARATIONS:

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

- May help protect public health measures from successful legal challenges
- These are legal instruments

- CETA was accompanied by a joint interpretative declaration which included mention of public health, but this did not offer any legally secure improvements or solutions to the legal text, and also cannot stop legal challenges being brought in the first place, only guide their interpretation.

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

- Can create a common understanding, and help to improve standards in partner countries, prompting a race to the top rather than the opposite.
- These are often referred to in Trade and Sustainable Development (TSD)chapters, and are therefore not subject to any dispute settlement, so there is no effective accountability mechanisms, and parties can take years to implement the provisions
- TSD chapters may offer a one size fits all approach, and not be tailored to specific needs of partners

LEGAL CHALLENGES:

in the EU, as mentioned above, aspects of trade policy have been referred to the European Court of Justice and the Court's judgements have had a significant impact on EU trade policy

- Provides an objective/separate accountability mechanism
- Can set precedent.

- Requires the highest court to have the power to interpret trade law.



POSITIVES

DRAWBACKS

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

- Could be an effective way to leverage trade deals to protect health and improve standards
- -Needs to be approved by the opposite party, making it an uphill battle.
- Can only really apply to imports.

NON-REGRESSION CLAUSE

including a clause setting a "regulatory floor" below which standards cannot fall (this has beer suggested by Michel Barnier in the context of Brexit) (Oroschakoff 2018)

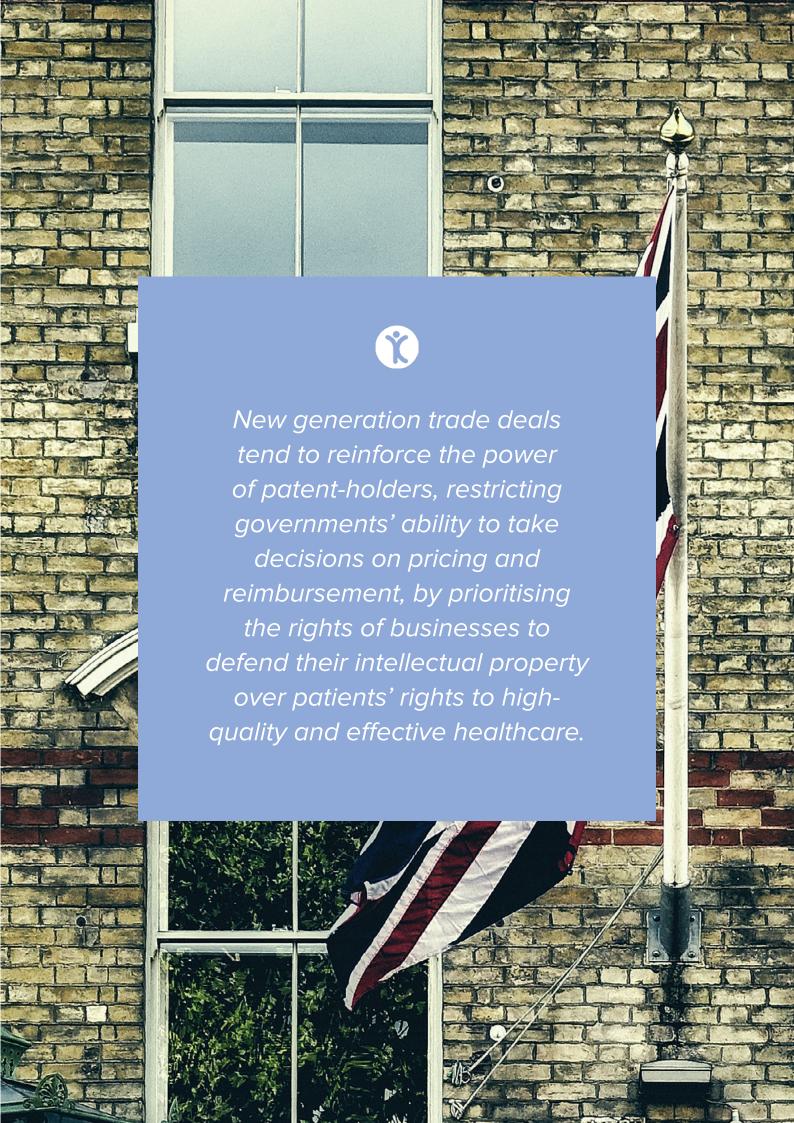
- Prevents the race to the bottom, could facilitate a race to the top instead.
- Only really works if two parties already share many standards (as currently is the case between the UK and the EU)

PUSHING FOR AN ALTERNATIVE/PROGRESSIVE TRADE POLICY

providing an alternative model for trade which can advance the public interest. This has been attempted by many European and national organisations (see further reading)

- Pushing for a more holistic and sustainable change
- Pushing back against the mantra of trade liberalisation.
- Could build a positive trade policy that promotes public health, rather than simply protecting public health in trade agreements
- Likely to be viewed sceptically by policymakers, without evidence.
- Will often require sustained advocacy and campaigning to get this approach onto the political agenda.





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