Protecting noncommunicable disease prevention policy in trade and investment agreements

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Protecting and promoting regulatory action for noncommunicable disease prevention in future Trade and Investment Agreements

Abstract
Preventing noncommunicable diseases (NCDs) is a global priority, and the World Health Organization has identified reductions in tobacco use, consumption of alcohol and unhealthy foods as a priority. However, regulation has been strongly opposed by affected industries, including through invoking legally binding Trade and Investment Agreements (TIAs). This multidisciplinary analysis presents a short ‘primer’ on NCD prevention policy and TIAs, and key opportunities for safeguarding public health policy space. In doing so, we help public health policy actors to take advantage of a critical window that has opened for public health engagement in the trade policy space. Specific opportunities to effectively protect and even enhance public health in TIAs that are identified in this analysis include: exceptions for public health measures; commitments to good regulatory practice that balance the importance of transparency and cooperation with the need for governments to limit the influence of vested interests; and an overarching reference point and expectation regarding the importance of public health in TIA Preambles. In addition, excluding Investor-State Dispute Settlement mechanisms and limiting the scope and definition of key provisions related to investor protection could reduce the risk of an investment dispute. By synthesising the multidisciplinary literature to highlight these specific opportunities for a public health policy audience, this analysis supports more strategic and informed engagement between the health and trade policy sectors. Our analysis also highlights the need for multidisciplinary insights and cooperation, including legal, public health and economic expertise, and improved transparency in trade policy making, in ensuring a high level of health protection in TIAs.

Background
Preventing noncommunicable diseases (NCDs) is a global priority, with three quarters of deaths worldwide (42 million annually) attributed to NCDs (1). The direct economic costs of diabetes alone were estimated to be $USD 760 billion in 2019 (2), and in 2011 it was estimated that, without concerted action to prevent and control NCDs, the loss to the global economy would exceed $USD 47 trillion by 2025 (3). As the high personal, economic and social burden of NCDs continues to increase, there is growing consensus that effective prevention requires the regulation of the tobacco, alcohol and food industries, as the consumption of tobacco, alcohol and unhealthy food are major NCD risk factors. The World Health Organization has recommended a range of “Best Buy” policy actions for NCD prevention, which include taxation, marketing restrictions and labelling of harmful products (4). Full implementation of these actions globally, particularly in low and middle income countries, could generate a return on investment of up to US$ 230 billion by 2030, due to health care savings and productivity gains (5).

In response, governments have committed to regulate the tobacco, alcohol and food industries and impose marketing restrictions, strengthen labelling requirements and introduce pricing policies (6). However, such regulation has been strongly opposed by affected industry actors (7-9). The strategies deployed to avoid or delay the regulation of commercial practices have included invoking legally binding Trade and Investment Agreements (TIAs) (10, 11). Recent high profile disputes have drawn attention to the potential for TIAs to constrain governments in their efforts to prevent NCDs. In particular, the tobacco giant Philip Morris challenged (unsuccessfully) the innovative tobacco packaging legislations that the governments of Australia
and Uruguay had adopted (7, 10, 12-14). As a result of these prominent disputes, public health actors are becoming increasingly cognizant of TIAs as potential barriers to robust NCD prevention measures, through constraining policy space (the “freedom, scope, and mechanisms that governments have to choose, design, and implement public policies to fulfill their aims” (15)).

Public health and trade objectives are not mutually exclusive, although they are often (and oversimplistically) perceived as such. TIAs typically contain clauses (text) to clarify that nothing in a given agreement prevents parties from addressing public health and human rights concerns (9, 16). However, the scope and content of these clauses, and thus the protection they afford health policy, vary. The public health community can play an important role in supporting improved trade and health policy making by engaging with new TIA negotiations, to highlight how these agreements can protect, or even enhance, policy space for NCD prevention. Globally, changes in the (increasingly intertwined) trade and investment policy space have opened a critical window for public health engagement (17). In particular, many governments are negotiating and renegotiating TIAs in response to domestic developments (e.g. the United Kingdom following its departure from the European Union (EU), and India and Brazil following termination of several investment treaties (18)).

However, opportunities to support health-promoting trade policy have yet to be summarised systematically. Such analysis is potentially very useful to public health advocates and policymakers, who often lament the lack of accessible information on opportunities for health protection. Instead, such information tends to be available primarily through specialist academic journals spanning multiple disciplines that may not be readily accessible to health policy actors.

TIAs are international legal agreements designed to achieve (primarily) economic policy objectives and are as such mainly subject to legal, policy and economic analyses. This contribution presents a short ‘primer’ regarding the relationship between NCD prevention policy and TIAs, and identifies mechanisms to assist in safeguarding public health policies. We draw on legal, economic and public health literature to first describe the ways in which TIAs may constrain the ability of governments to enact best-practice NCD prevention policy, and second to identify specific opportunities for health policy actors to influence TIAs, to better protect and promote NCD prevention policy.

What are trade and investment agreements?

TIAs encompass Trade Agreements; these can be multilateral (i.e. including (nearly) all parties, namely the Agreements of the World Trade Organization [WTO]), plurilateral (many parties), bilateral (two parties), or regional (with membership limited to a specified region), Investment Agreements, (mainly bilateral), and combined Trade and Investment Agreements (mainly bilateral or regional). Even though individual agreements vary, they are generally based on a core set of provisions and principles. Agreements are negotiated between countries (the parties), signed, and then implemented and administered, and enforced through agreed dispute settlement procedures including binding arbitration. The WTO includes a dispute settlement mechanism, the International Centre for Settlement of Investment Disputes (ICSID) offers arbitration of investment disputes, and processes for dispute settlement are written into agreements.
National governments participate in TIAs primarily to achieve economic policy objectives. In particular, TIAs: 1) reduce barriers to flows of trade and investment and 2) create a predictable regulatory environment for trade and investment. By signing a TIA, a government commits to ensuring that their domestic policy measures are consistent with specific provisions of the Agreement, which are often subject to binding dispute settlement mechanisms. However, TIAs also include recognition that there are necessary restrictions on trade – including policies implemented for public health purposes (19). Public health measures that are non-discriminatory and designed to achieve a legitimate public health objective without imposing unnecessary restrictions on trade are permissible under TIAs (see Box 1 for key terms).

Box 1: Overview of key terms at the interface of TIAs and NCD prevention

Dispute settlement mechanisms are the formal structured process that addresses disputes that arise between two or more parties to a TIA. Disputes can also be raised by investors against parties (national governments), under Investor-State Dispute Settlement (ISDS) mechanisms. Dispute settlement is mediated by courts, tribunals or other adjudicatory bodies and decisions are bindings on parties to the agreement.

Exceptions to the commitments contained in agreements are permitted in TIAs, based on the recognition that trade and investment are made in a context in which governments also pursue other public interest objectives. These exceptions must, however be legitimate and necessary.

Expropriation refers to situations in which property is taken for public use or benefit, by the state; indirect expropriation can occur where new regulations undermine the ability of an investor to fully take advantage of its investments.

Fair and Equitable Treatment (FET) is frequently invoked in investment disputes and refers to the standard set by international law for the treatment due by each State regarding the property of foreign nationals. FET is determined by reference to specific circumstances of application (in contrast to the ‘national treatment’ clauses in trade agreements, for example, FET does not depend on reference to treatment accorded to other investors).

Increasing economic efficiency refers to improving the allocation of resources to increase economic welfare, and in this context relates to minimising trade diversion, the impact of regulatory diversity on international trade and other market distortions.

Legitimacy refers to whether a domestic measure pursues legitimate public interest objectives and can effectively contribute to these objectives. Arbitrary discrimination and disguised restrictions on trade are not legitimate public interest objectives.

Legitimate expectations form part of the FET standard and relate to due process. It is intended to ensure the consistent application of the law in light of the representations that a host State has made and can justify the reliance of a particular investor on these representations. The extent to which such expectations have been established influences the application of exceptions, and the interpretation of investor rights.

Necessity (sometimes referred to as proportionality) requires a consideration of the extent to which a measure unduly restricts trade or investment and, in particular, whether an equally effective alternative measure could achieve the objective(s) pursued whilst being less restrictive of trade or investment.
**Non-discrimination** has two elements in the WTO: treating all parties (other countries) without discrimination (the ‘most favoured nation’ principle) (though bilateral and regional TIAs are conditional violations of the ‘most favoured nation’ principle), and treating all ‘like’ goods, services and nationals (regardless of domestic or international origin) equally once they have entered the country paying any taxes required and meeting local standards (national treatment).

**Predictability** refers to the creation of certainty and confidence regarding the trade- and investment-related policy environment. For example, that trade barriers or requirements for investors will not be raised arbitrarily and that the rights of investors in the host country are protected.

### How TIAs can constrain policy for NCD prevention

Industry actors and governments have invoked commitments within TIAs in order to delay or avoid the implementation of NCD prevention measures. This is most evident in formal disputes regarding health policy measures under TIA dispute settlement mechanisms. However, the informal challenges, for example, when specific trade concerns are raised in committees of the WTO, occur more frequently and have also contributed to changes and delays in implementation of the NCD prevention policies that have been challenged (20).

Formal disputes and informal challenges to NCD prevention measures may also contribute to wider changes in policy, implementation delays, or the abandonment of a policy altogether (‘regulatory chill’) (21, 22). Governments are sometimes reluctant to adopt novel measures when 1) a dispute has occurred elsewhere or 2) when there is the threat of a dispute. For example, the government of New Zealand reported delaying the introduction of its tobacco plain packaging legislation whilst awaiting the outcome of the disputes regarding the Australian regulation (22). This is problematic because the threat of a dispute does not necessarily relate to the likelihood of success of the dispute (8). Therefore, the tobacco, alcohol and food industries may feel emboldened to strategically pressure governments to change course, even where their chances of success are small. It is therefore not surprising that, over the past 20 years, there has been an increase in investor-state disputes but a decreased success rate, which “may be a result of a rise in strategic litigation by investors whose aim is not only to obtain compensation but also to deter governments’ regulatory ambitions” (23).

Table 1 summarises the key commitments in TIAs that can be used to constrain public health policy for NCD prevention, drawing on legal, economic and public health analyses. Two of the most widely cited clauses include commitments to provide compensation for indirect expropriation, which can occur where a government policy detrimentally impacts on an investment, and investor-state dispute settlement (ISDS) mechanisms (Box 1). Other clauses that may also constrain NCD prevention policy include commitments to limit technical barriers to trade and commitments to extend protections for intellectual property rights, as well as commitments to Good Regulatory Practice (GRP) and ‘fair and equitable treatment’. These provisions are all designed to achieve the objectives of TIAs, as outlined above. However, attention to health implications in the drafting of TIAs, as we describe below, can influence the extent to which such provisions can be used to challenge NCD prevention policies.
### Table 1. Specific TIA commitments that may be used to challenge NCD prevention measures

| TIA Commitment                        | Summary of relevant features                                                                 | Examples of potential use to constrain policy for NCD prevention                                                                 |
|---------------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| Limits to technical barriers to trade | Limits on the introduction of new regulations, including food, alcohol, and tobacco regulations, to ensure that they do not introduce ‘unnecessary’ trade costs because, for example, the objective could be achieved through other means. These typically accompany rules requiring members to share information about new regulations and provide opportunities for stakeholders to comment before their adoption.(20) Justifying such measures as ‘necessary’, despite their impact on traded goods, can include onerous evidence requirements (24, 25). | Can be invoked to challenge new regulations. For example, partners argue that the measure should be watered down or that an alternative should be pursued. |
| Increased protections for intellectual property rights | Commitments to protection of intellectual property rights, particularly trademarks (7, 26, 27). | Can be invoked to challenge NCD policies that affect labelling, packaging and advertising, particularly those that affect the use of trademarks. |
| Limits to indirect expropriation       | Limits to states’ ability to introduce new regulations that undermine the ability of the investor to fully take advantage of its investment as anticipated (27). | Can be invoked to challenge NCD policies that affect the value of an international businesses’ investments - including, in some cases, future anticipated profits. |
| Fair and equitable treatment (FET) commitments | Protections against ‘unfair’ treatment as a result of a regulation being introduced. This includes protections against the introduction of measures that are deemed arbitrary, discriminatory, and unreasonable (27, 28). | Can be invoked to argue that a new NCD policy is discriminatory, because, for example, the measure affects certain products of investment but not others. |
| ‘Good regulatory practice’ (GRP) provisions | Requirements concerning the development of new policies, including requirements for ‘transparency’ and stakeholder consultation. Can also include commitments to allow stakeholders from both parties to participate in policy development (29, 30). | Provide new opportunities for industry actors with a conflict of interest to request that they participate in policy development processes and lobby against the introduction of effective NCD policies. |

### Ways in which TIAs could protect and enhance policy for NCD prevention

Analyses from the legal, public health and economic literature indicate that careful drafting of TIAs to explicitly articulate commitments to public health can assist governments to effectively pursue public health objectives and contribute to expectations by parties regarding evidence based health policy (24, 31). This can help reconcile the trade obligations of States with their public health obligations (9). In particular, it provides explicit recognition that States may need
to impose barriers to trade to protect and promote the human right to health (10, 32). In this section, we briefly discuss four relevant mechanisms.

**Exceptions for public health measures**

General exceptions typically state that nothing in a given Agreement should prevent a Party from adopting measures necessary to protect public health (often as part of a list of other legitimate public interest measures), provided they are non-discriminatory and do not constitute an unnecessary restriction on trade. Exceptions are thus important to provide policy space for NCD prevention measures that apply to traded goods or services, or to the products of investment.

The application of these exceptions is usually explicitly premised on compliance with legal principles underpinning trade agreements. Two key principles in this context are non-discrimination and necessity (33, 34). With respect to trade agreements, and integrated TIAs, establishing the ‘necessity’ of a measure, in relation to whether it can benefit from an exception, relies on a clear framing and explanation of the contribution a measure makes to its objectives. Critical to this is the evidence supporting its effectiveness, and determining that the measure is not unduly trade restrictive (including that there are no viable alternatives that are less trade-distorting) (25, 26, 31).

**Limiting the risk of investor disputes regarding NCD prevention measures**

The wording of provisions related to investor protection is an important consideration in safeguarding policy space for NCD prevention measures, because of the impact that such measures may have on investors in the tobacco, food and alcohol industries. Public health measures can be protected through exclusion of ISDS commitments from TIAs, as was done in the Australia-US Free Trade Agreement (35). Another potential option is to ‘carve out’ (exclude) specific measures from ISDS; this has been done for tobacco control measures in at least three recent agreements (35). Other options include ruling out indirect expropriation as the basis for an ISDS claim, as in the United States–Mexico–Canada Agreement, or excepting public health measures from the expropriation chapter, as in the US–South Korea FTA (25). ‘Fair and equitable treatment’ provisions are a common basis for ISDS claims, and are broadly recognised as excessively ambiguous (36). As such, clear definitions of ‘fair and equitable treatment’ including qualifications to limit its application – can help to safeguard public health policies (24).

Another similar approach is to include in TIAs a clear definition of indirect expropriation that limits its application to public health measures. For example, in the EU–Canada Comprehensive Economic and Trade Agreement (CETA) and the EU – Singapore Trade Agreement, detail on the definition of indirect expropriation is provided as follows: “The determination of whether a measure constitutes an indirect expropriation requires a case-by-case, fact-based inquiry .... For greater certainty, except in ... rare circumstances ... non-discriminatory measure or series of measures by a Party that are designed and applied to protect legitimate public objectives such as public health, safety and the environment, do not constitute indirect expropriation” (28). This clause thus effectively disallows a claim of indirect expropriation in relation to a legitimate, non-discriminatory and necessary public health measure.

**The value of TIA Preambles**

The inclusion of statements in TIA preambles recognising the importance of public health as a whole-of-government objective creates an expectation regarding government action (and prioritisation) in relation to future public health measures. As such, it can serve as an aid to interpretation of contentious provisions, even though these statements are not legally binding
For example, the Preamble of the 2018 Peru-Australia Free Trade Agreement recognises the “right to regulate and ...to set legislative and regulatory priorities...and protect legitimate public welfare objectives, such as public health...”. Governments can enhance the effectiveness of such statements in the preamble of TIAs, by ensuring that they avoid creating any expectation for investors in other contexts (e.g. contractual or otherwise) that the regulatory environment regarding public health will not change (37).

**Good Regulatory Practice commitments that allow for the management of conflicts of interest**

GRP provisions allowing governments the flexibility to determine appropriate stakeholder engagement to minimise conflicts of interest are important to support evidence-based, best practice public health policy. One option is to exclude the GRP chapter from dispute settlement, which reduces the implications of different interpretations of these commitments, as was done in the TPP regulatory coherence chapter (29). Alternatively, qualifications to GRP clauses that make reference to “appropriate” consultation or engagement could support the management of conflicts of interests and promote effective NCD prevention policies (38).

**Opportunities for the health sector to promote robust NCD prevention measures in the context of TIAs**

The literature reviewed indicates that the health sector can protect the policy space that governments have to implement robust NCD prevention policy measures in the context of TIAs in two ways: through health policy design and engagement with the trade sector.

First, health policy measures for NCD prevention can be strategically designed to minimise the risk of violating TIA commitments; effectively maximising public health opportunities by understanding the constraints presented by TIAs (39). In particular, taking account of key TIA principles such as necessity and non-discrimination in the articulation of the objectives and substance of a health measure, documenting the evidence base indicating the necessity of the measure, and adhering to good regulatory practice while minimising the influence of conflicts of interest (25, 40). Reference to international instruments, such as the World Health Organization’s Framework Convention on Tobacco Control (FCTC), can also strengthen policy measures for NCD prevention in a trade and investment context (12, 13, 16). The FCTC has been used repeatedly as a reference point by tribunals “who reliably uphold non-discriminatory [tobacco control measures] on public health grounds” (41). In addition, it has been specifically cited as providing an evidentiary basis for tobacco policy measures in formal disputes and other challenges under TIAs, supporting the necessity of such measures (13).

Health policy design considerations are particularly relevant to safeguarding NCD prevention policy in the context of TIA commitments on technical barriers to trade. There is usually no specific health ‘exception’ to commitments on technical barriers to trade, under which concerns have been raised regarding tobacco, alcohol and diet-related NCD prevention policy measures. However, these TIA provisions contain explicit recognition of health as a ‘legitimate objective’ for which technical measures can be adopted (e.g. see article 2.2 of the WTO Technical Barriers to Trade Agreement, which is often adopted into newer TIAs in its entirety). As an example of the implications of these provisions for public health, analysis of the unsuccessful dispute regarding Australia’s plain packaging under the WTO Technical Barriers to Trade Agreement shows that recognition of the public health objective of the measure (as a legitimate objective) was critical. Subsequent to that, the issues were the necessity of the measure and whether there were other less trade-restrictive alternatives to achieve the objective (12). For example,
objectives for labelling policy measures that focus on their direct effect in informing consumers, rather than their long term contribution to health indicators, such as the prevalence of obesity or NCDs (42).

Second, cross-governmental engagement by the health sector during negotiation can draw attention to potential constraints on health policy that may arise from TIAs. A core tenet of trade policy is the need for complementary and mitigating policies to address unintended consequences and maximise benefits; when TIAs place constraints on health policy, they render the health sector unable to take such action. However, public health actors often do not contribute to TIA negotiations, either through lack of knowledge or interest or as a result of their deliberate exclusion (43, 44). With an awareness of key provisions to raise for consideration, familiarity with health protections in agreements to date, and by drawing on legal and economic expertise relevant to trade, the health sector can support policy space for NCD prevention in the drafting of TIAs. At the national level, engagement by the health sector can occur through formal consultation, submissions and direct lobbying during the process of TIA negotiation and drafting (44, 45). For example, health actors’ use of formal and informal mechanisms to raise awareness of the importance of protecting access to medicines and tobacco control was important to the inclusion of safeguards in Australia’s negotiating agenda for the Trans-Pacific Partnership (45).

In order to maximise opportunities for cross-sectoral engagement, experience to date indicates that capacity building will be needed for both trade and health policy makers to facilitate constructive participation by public health actors (9, 24, 46). For example, strengthened capacity of government and non-government health sector actors contributed to removal of proposed intellectual property and investment measures in the Regional Comprehensive Economic Partnership that could have limited access to medicines (47). The literature shows that there is a need for greater transparency in trade negotiations and the development of formal opportunities for engagement of the health sector in these negotiations. On the health side, capacity building can provide a clear understanding of the health sector ‘asks’ regarding specific inclusions in TIAs, to inform negotiation, and capacity for robust analyses of the implications of proposed TIA text (44). On the trade side, interpretation of the potential constraints arising from TIAs for NCD prevention policy can be heavily influenced by industry (48). As such, capacity building can provide alternative interpretations regarding the need for health policy measures within TIA commitments (46). Further to this, engagement by global health policy actors can also provide normative support for national health policy in a trade and investment context, including through providing technical support and an evidentiary basis for defense of NCD prevention policy measures (13, 27, 46).

Conclusion

This analysis has highlighted specific opportunities to effectively protect and even enhance public health in TIAs, including: exceptions for public health measures, commitments to GRP that balance the importance of transparency and cooperation with the need for governments to limit the influence of vested interests, and an overarching reference point and expectation regarding the importance of public health in TIA Preambles. In addition, excluding ISDS mechanisms and limiting the scope and definition of FET and indirect expropriation within commitments to investor protection could reduce the risk of an investment dispute. By synthesising the literature to highlight these specific opportunities for a public health policy audience, this analysis has the potential to support more strategic and informed engagement.
with the trade and investment policy space and therefore promote more effective NCD prevention policy.

This analysis also highlights that ensuring a high level of health protection in TIAs will require multidisciplinary insights and cooperation. First, the development of specific proposals for health safeguards to inform TIA negotiations must draw on legal and economic expertise. In particular, insights from trade and investment lawyers can support the strategic design of health policy measures that regulate commercial activities, to better anticipate potential legal challenges under TIAs and limit their chances of success. Second, awareness of the links between trade and health among policy makers will be critical to provide opportunities for trade and health engagement. On the trade side, recognition of the importance of considering health in the design of trade measures can increase both formal and informal opportunities for engagement with the health sector during negotiation. On the health side, improved understanding of the key avenues for promoting better health can support constructive engagement with relevant experts from law, economics and public health policy to develop feasible and effective proposals to inform the negotiations. These strategies will be most effective where they are supported by transparent policy processes and governance structures that ensure those with relevant expertise can contribute to policy discussions on trade and health.

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