Glossary on free trade agreements and health part 2: new trade rules and new urgencies in the context of COVID-19

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ABSTRACT
Part 1 of this glossary provided a brief background on the rise of regional/bilateral free trade agreements (FTAs) and described the health implications of new trade obligations that figure prominently in current and recent trade negotiations, focusing on those provisions that build on previous agreements of the World Trade Organization (WTO). This approach continues into part 2 of the glossary, which also considers components of FTAs that have no precedent within WTO treaties. Following a broader discussion of how the current political context and the COVID-19 pandemic shape the contemporary trade environment, part 2 considers the main areas of trade and health policy incoherence as well as recommendations to address them.

INTRODUCTION
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TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS
The WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS) establishes the minimum standards of protection for different forms of intellectual property. TRIPS grants a monopoly on a patented product to the holder of the intellectual property rights for 20 years. A primary public health concern with TRIPS is that this leads to monopoly pricing and higher costs of pharmaceuticals. Although a TRIPS flexibility allows for compulsory licensing (ie, when someone else is allowed to produce a patented product without the consent of the patent owner), the rules surrounding this flexibility are incredibly complex, limiting its use in practice.

Contemporary FTAs have progressively expanded and extended the protection of intellectual property through a number of health-relevant ‘TRIPS-Plus’ protections. These provisions often include patent term adjustments and data protection for new pharmaceutical products which can negatively affect access to medicines by delaying generic competition and raising drug costs. Included in the recent agreement between the USA, Mexico and Canada (USMCA), for example, are provisions that would extend patent terms beyond the 20-year TRIPS protection (ie, Art. 20.44 and Art. 20.46). The USMCA also includes a provision that allows for the protection of clinical data (Art. 20.48), which is expected to limit or delay generic competition by preventing regulators from using originally submitted clinical trial data to assess an application from a generic company.

Further, the original agreed text of both the Trans-Pacific Partnership (TPP) agreement and the USMCA included language that would grant extended periods of market exclusivity for biologic drugs (ie, medicines produced from living cells and other biological materials via biotechnology processes, which include many new cancer and immunotherapy drugs). While such language was eventually removed in the final version of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) and in the Protocol Amendment to the USMCA, efforts to ‘ratchet up’ intellectual property protections in FTAs appear to persist.

TRADE IN SERVICES
The General Agreement on Trade in Services (GATS) came into force with the establishment of the WTO and was the first (and remains the only) multilateral trade agreement to liberalise services trade. It governs trade in several sectors of great importance to public health such as healthcare, education, and water and sanitation services. Trade in services can also affect the availability and affordability of harmful commodities like tobacco, alcohol and unhealthy foods through, for example, the liberalisation of marketing and advertising services.

One of the most important differences between obligations set out in GATS and those in FTAs is that while the former requires countries to make specific commitments about which services they...
would like to liberalise (a practice known as positive listing), the latter require countries to specify which services they would like to exempt from liberalisation obligations (ie, negative listing). In negative listing, countries can only exclude services that are already currently available, rendering any future (new) service or service sector automatically open to liberalised market forces. Negative listing also introduces a high degree of complexity, raising the risk that negotiators may unintentionally fail to exclude certain services they do not intend to liberalise. Finally, once a service is committed, trade provisions may prevent governments from bringing it back under public provision, even if this is desired for the purpose of protecting the public’s health.

The growing importance of e-commerce raises new concerns with protection of personal health data. Both the CPTPP and the USMCA, for example, prohibit localisation policies that would require that digital data (including personal health data) be stored within its country of origin. Localised data storage is considered important in terms of privacy protection since rules governing privacy vary considerably across countries. Government-collected data may be excluded from this provision, as it is in the CPTPP and, unless governments choose to exempt from other countries in the agreement, and emphasise that commercial considerations (efficiency, cost) should be the main criterion for awarding contracts. This could lead to firms in countries moving more into health services commerce, such as personalised healthcare, the prospect of these firms ‘harvesting’ non-excluded health records of persons from other countries for commercial use is not only possible but likely.

**GOVERNMENT PROCUREMENT**

Government procurement provisions within the WTO trading system are located in the Agreement on Government Procurement (GPA). The GPA is a plurilateral agreement which means that some, but not all, WTO members are signatories. At the heart of the WTO GPA are legally binding rules that require signatories to establish open, fair and transparent conditions of competition in government procurement processes for certain areas they have agreed are covered.

Several contemporary FTAs contain government procurement chapters which, in some cases, bind countries to procurement measures that they have not agreed to as part of the WTO GPA. One area these chapters have been found to hold implications for is pharmaceuticals. All ratifying countries of the CPTPP, for example, appear to have committed to allow suppliers from other parties to the agreement to bid for pharmaceutical government procurement contracts. Because the CPTPP allows countries to specify how much of a particular country’s pharmaceutical procurement is covered, and over what time period it can be liberalised, it is difficult to draw conclusions about whether liberalisation in this area will assist in lowering or raising drug costs.

Additionally, many FTAs require that new public contracts beyond a certain threshold must be open to competitive bidding from other countries in the agreement, and emphasise that commercial considerations (efficiency, cost) should be the main criteria for awarding contracts. This could lead to firms in countries with lower labour standards winning contracts, putting downward pressure on labour standards.

Opening government procurement to foreign bidders may also limit a crucial tool used by governments to create demand for locally produced goods and services, often under conditions that promote equity, social justice and environmental sustainability. Exceptions, however, can be written into FTAs to permit government procurement under certain conditions that are beneficial to public health. In the USA-Korea Free Trade Agreement, for example, exemptions from government procurement rules are made in the area of domestic content requirements and ‘human feeding programs’. These types of exemptions might be used by governments to preferentially purchase domestic produce for public institutions, like school food programmes, to meet public health nutrition goals.

**NEW TRADE RULES: FTA PROVISIONS WHICH HAVE NO PRECEDENT WITHIN WTO TREATIES**

FTAs import many of their provisions from existing WTO agreements, but also introduce components that have no precedent within WTO treaties. In public health research, three particular topic areas have received attention which have limited WTO precedent: regulatory coherence, provisions related to labour standards and provisions related to environmental standards.

**Regulatory coherence**

Under the WTO trading system, baselines for regulatory practices are largely defined through sanitary and phytosanitary measures and technical barriers to trade provisions. A unique feature of recent FTAs is the inclusion of separate chapters outlining further regulatory mechanisms outside of these established obligations. Individual regulatory chapters, for example, can be found in many of the contemporary FTAs described in part 1 of this glossary.

These provisions can present opportunities for improved regulatory governance, but they can also increase the demands on domestic policy makers and create greater opportunities for private sector input into the design of new regulations. Such concerns have negative health implications in relation to trade in harmful commodities (eg, tobacco, alcohol and unhealthy foods) and drug pricing.

The CPTPP and the USMCA have the most ambitious chapters in terms of institutionalising regulatory coherence practices. Several provisions within the CPTPP, for example, are likely to increase the burden on domestic regulatory systems. The agreement stipulates that within 1 year after entry into force, each Party must ‘make publicly available the scope of its covered regulatory measures’ (Art. 25.3). Other provisions require countries to create processes to facilitate interagency consultation and coordination (Art. 25.4, ¶1), and review its covered regulatory measures to determine if they should be modified, streamlined, expanded, or repealed’ (Art. 25.5, ¶6). The chapter also requires that countries shall provide opportunities for interested persons of the Parties to provide input on matters relevant to enhancing regulatory coherence’ (¶25.8), which could potentially permit industry manipulation of domestic regulatory systems.

While modelled on the CPTPP, regulatory commitments within the USMCA are more prescriptive and forceful (eg, Parties ‘shall’ rather than ‘should’ abide by the chapter’s different provisions). Further, while the CPTPP allows participating countries to determine which regulatory measures will be covered by the regulatory coherence chapter, the USMCA essentially places all regulatory measures within its domain. Finally, unlike the CPTPP, the regulatory practices chapter of the USMCA is enforceable through state-to-state dispute settlement, at least to address a sustained or recurring course of action or inaction that is inconsistent with a provision of this Chapter’ (Art. 28.20).

The regulatory chapters in both the CPTPP and the USMCA contain text that acknowledges each country’s right to pursue its own public policy objectives (including health, safety and environmental goals) (USMCA 28.2 ¶3a) and ‘identify its regulatory
priorities and establish and implement regulatory measures to address these priorities, at the levels that the Party considers appropriate” (CPTPP Art. 25.2, ¶2h). However, the language surrounding this text is aspirational and could make it difficult for countries to do so.6,17 The USMCA, for example, requires that regulations be published before they are finalised to allow for comments from ‘any interested person, regardless of domicile’ (Art. 28.9). Article 28.14 specifically obliges countries to ensure opportunities for ‘any interested persons’ to make ‘written suggestions for the issuance, modification, or repeal of a regulation’ if, among other reasons, it has become more burdensome than necessary to achieve its objective ‘(for example, with respect to its impact on trade)’. This essentially provides a mechanism through which regulated industries can petition governments to deregulate.6

Labour
Labour provisions in FTAs have become more commonplace and comprehensive in recent years. In 1995, only three FTAs contained labour provisions; as of 2016, 77 FTAs include labour provisions, covering 136 economies.18 Public health research has long established that labour standards can impact health through a range of labour market pathways (related, eg, to wages, working conditions and economic security),19 while politicians often suggest that writing these standards into trade agreements is vital to protect against negative social consequences of trade.20

The two leading proponents of labour provisions within FTAs are the USA and the European Union (EU). At the heart of each approach is reference to the labour standards of the International Labour Organization (ILO). Contemporary FTAs in which the USA is the lead negotiating party make reference to the ILO 1998 Declaration and allow for the possibility of trade sanctions when commitments are violated. Although in the run-up to ratifying a USA-led FTA, lower labour standards may be improved in some countries, from a public health perspective, there are a number of criticisms related to the US approach.6,20,21

First, the labour standards countries must uphold are in reference to the ILO Declaration, which are distinct from the ILO’s Core Conventions. The main distinguishing feature is that whereas the former refers to recognised principles ‘that should (somehow) be respected’, the latter entails a legal obligation to implement these rules along with reporting requirements.22 Essentially, reference to the ILO Declaration in a labour chapter merely reaffirms countries’ existing membership in the ILO, without providing any incentive or obligation to ratify and implement the eight corresponding Core Conventions (of which, the USA has only ratified two). Further, implementation obligations in USA-led FTAs are largely ornamental, offering little in terms of concrete improvements for employment or working conditions.6,20,21 A central labour provision in the (then USA-led) TPP and retained in the CPTPP, for example, states that each signatory country ‘shall adopt and maintain statutes and regulations…governing acceptable conditions of work with respect to minimum wages, hours of work, and occupational safety and health’ (Art. 19.3.2). A footnote to this provision establishes that the acceptability of these working conditions is to be determined by each individual country which, in practice, means that there is no floor below which regulations should not fall. While the US approach to labour regulations allows for sanctions should a labour obligation be violated, this is only true if failure to do so affects trade and investment, not compliance with the laws per se.21

FTAs in which the EU is the lead negotiating party refer to the more binding ILO Core Conventions. While there has yet to be a public health analysis of the EU approach to labour provisions within FTAs, critical analysis by international trade scholars indicates that EU-style FTAs nonetheless fail to bind partner countries to ILO ratification procedures. Instead, FTAs rely on cooperative mechanisms that are meant to oversee the implementation of labour provisions but that are regarded to be ill designed and largely ineffective.23 Finally, FTAs, regardless of being USA-led or EU-led, generally neglect other important labour rights, notably those pertaining to social protection policies which can provide a means of mediating the health impact of trade-related job loss,24 for example, through unemployment insurance.

Environment
From the 1990s, the number of environmental provisions in FTAs has increased considerably.25 As with labour provisions, the USA and EU are major proponents of environmental provisions within FTAs, again with politicians celebrating their inclusion as an indication of trade treaties becoming more socially conscious. Public health evaluations to date, however, have found environmental provisions in contemporary FTAs, like labour provisions, to be extremely weak.6,21,26

Recent FTAs, like the CPTPP and the USMCA, refer to several multilateral environmental agreements (MEAs). Provisions that stipulate the terms related to their implementation and enforcement, however, have been called into question. In the CPTPP, for example, only one of the seven referenced MEAs is directly enforceable. Further, countries are not obliged to ratify any MEA that they have not already ratified, only to uphold their existing commitments; and any failure to do so is not subject to dispute settlement or even consultations. In the USMCA, the failure of countries to abide by certain environmental accords is subject to dispute, but only if existing standards are lowered to gain a trade or investment advantage.27 In both instances, this means that a country can destroy environmental commons at will, so long as it has not lowered standards specifically to gain a trade or investment advantage. Finally, environmental chapters in several FTAs are extraordinarily silent on climate change and fossil fuel emissions. In the CPTPP, for example, countries agree only to cooperate in transition towards a low-emissions economy (Art. 20.15).

CURRENT POLITICAL CONTEXT FACILITATING AND SHAPING THE CONTEMPORARY TRADE ENVIRONMENT AND NEW URGENCIES IN THE CONTEXT OF COVID-19
Even before the COVID-19 pandemic, global trade’s contribution to gross domestic product had still not returned to its zenith (60.9%) reached in 2008.27 The election of Donald Trump in 2016, and his administration’s prompt withdrawal from the TPP and promise to renegotiate the North American Free Trade Agreement, raised concerns that the WTO multilateral era was ending, and a new protectionist era of ‘Buy America’ could dampen international trade. Certainly since 2018, growth in global trade volumes has slowed, while trade tensions between the USA and China, which some describe as a trade war,28 have increased uncertainty about how important international trade will continue to be as a driver of economic growth. Already, trade politics had shifted decisively from the WTO to bilateral or regional FTAs. Negotiations in such non-multilateral space continue, often involving the USA with its ability to dominate when the other Parties are fewer and economically weaker. The Trump administration’s ‘America First’ policy is widely seen as undermining international (multilateral) trade law,29 including

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US refusal to appoint new members to the WTO Appellate Body, effectively preventing enforcement of dispute panel rulings, including those that it has recently lost.30 An interim appeal arrangement was agreed on by the EU and 19 other WTO member states in late April 2020 to retain some functioning of the WTO dispute system until the US impasse is resolved.31 Alternatively, smaller regional and bilateral negotiations may support innovation in ways that multilateralism has not. The Peru-Australia Free Trade Agreement referenced in part 1, for example, excludes investor disputes for any measure taken to protect public health.1 Taking an optimistic view, this innovation, once shown to be politically feasible in one agreement, may diffuse in new negotiations. Much will depend on the economic assumptions or ideological persuasions of trade policy makers and their governments.32

The COVID-19 pandemic has added substantially to trade uncertainty. The WTO forecasts a decline in trade of 13%–32% by the end of 2020, with any 2021 recovery dependent on when the pandemic risk ends and what policies governments might use to re-energise their national economies.33 This is predicted alongside a 40% drop in global foreign direct investment flows.34 There is emerging consensus that global supply chains are likely to shrink (especially for critical health goods), some ‘re-shoring’ of outsourced production may occur, investment in developing country economies will decline, and the global economy as a whole risks entering a prolonged recession or even depression. The health-negative impacts of economic decline will be experienced worst by poorer populations living in vulnerable conditions, which the economic impacts of public health lockdowns have already demonstrated.35

At the same time, health-relevant provisions in FTAs assume new significance in the context of COVID-19. Concerns have been raised, for example, that government lockdown measures may lead to a rush of investor-state dispute settlement (ISDS) claims.36 Indeed, using Italy as a case study, a legal analysis suggests that almost all government pandemic-mitigation measures may be vulnerable to an ISDS challenge,37 leading to calls for an intergovernmental agreement to a moratorium on all such claims.38 Further, many FTA provisions can endanger governments’ ability to address non-communicable diseases (NCDs), like heart disease, obesity or cancer, which are major risk factors for suffering far worse COVID-19 outcomes.39 For example, provisions related to intellectual property rights, and biologics in particular, could affect the availability and accessibility of drugs to treat NCDs. The threat of ISDS claims, along with FTA provisions which create new administrative burdens, may deter governments from pursuing the most effective strategies towards preventing and managing NCDs.

As governments struggle to balance health goals alongside economic ones, the pandemic has also provided commercial producers with a new pretext to influence trade policies. Alcohol producers in high-income countries, for example, have been petitioning their governments to pursue tariff-free arrangements in trade negotiations, with these measures being framed as essential to countries’ economic recovery.40

Efforts to return to a pre-COVID-19 economy based on increased consumption and production must contend with the pre-existing ‘existential’ health crises of climate change and ecological overshoot. Both are driven by unsustainable and hugely inequitable levels of consumption to which past global trade has contributed.41 With the International Monetary Fund Director urging governments to scrap subsidies to fossil fuels, and to tax carbon and stimulate post-COVID-19 demand in ‘green’ sectors,42 pressure for a paradigmatic pivot to a postindustrial green economy is growing. The EU has announced the world’s so far most ambitious post-COVID-19 green recovery plan, with legally binding targets and mandatory requirements that government procurements must follow environmental sustainability criteria.43 44 Others urge inclusion of labour rights and income equity criteria as well. Such provisions could affect how other countries with an EU trade agreement bid for contracts or influence their own economic and trade policies going forward. Whether such shifts succeed is still far from assured, and the positive role new trade agreements might play by discouraging trade in carbon-intensive goods or encouraging it in green technologies could be offset by challenges from recalcitrant states or investors under existing (and especially older) international investment agreement provisions. And without binding clarity on the Paris Agreement’s ‘common but differential responsibilities’ that include measures leading to a massive redistribution of financial and ecological capital from the global 1% to the rest, there will be little chance of an ecologically sustainable future that is also an equitable one.

What, then, should a trade policy fit for future purpose, one that is both environmentally sustainable and economically just, look like?

OVERCOMING GOVERNANCE PROBLEMS LEADING TO TRADE AND HEALTH POLICY INCOHERENCE

One of the underlying conditions for policy incoherence between trade and health remains the dominance of neoliberal ideas in shaping how governments and policy makers see the purpose of trade agreements. Through this lens, or policy framing, government officials emphasise economic growth via market solutions and private enterprise, and envisage most public regulation as intrusive on producers’ economic rights.45 Although governments often invite interested parties to identify their ‘asks’ or concerns in the run-up to new treaty negotiations, the dominant trade policy framing largely excludes attention to health or its social determinants.46 Once initiated, processes of trade negotiations skew favourably towards industry actors.45

In the USA, for example, domestic industry committees enable 600 corporate stakeholders to view and comment on sections of negotiating text confidentially, a privilege available to only a very small number of approved non-government organisations.46 Some countries have introduced mechanisms for greater health and trade collaboration, such as Thailand’s International Trade and Health Programme to strengthen health officials’ capacity on trade-related matters and generate evidence-based policy decisions such as health impact assessments.47 In most countries, however, access to text is often not publicly released until a treaty is signed, few governments implement robust health impact assessments of treaty text, and health/trade researchers often have to rely on ‘leaked’ negotiating texts or earlier trade or investment agreements in their efforts to influence treaty outcomes.

Expanding consultation with health experts and other civil society stakeholders during the negotiation process could reduce the potential for inadvertent policy incoherence. Collaboration between public health specialists and economists, who are often asked to evaluate (both ex-ante and ex-post) the impact of trade agreements, could also prove beneficial. Further, limitations in health exceptions to treaty obligations under WTO rules48 could be overcome by carefully worded carve-outs for any non-discriminatory public health, environmental or social protection measure introduced by a Party to an agreement. Such an optional carve-out for tobacco control measures from ISDS rules

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was agreed to in the CPTPP and for any public health measure in the Peru-Australia Free Trade Agreement. New FTAs could more simply exclude ISDS entirely, or at least adopt more procedurally just and transparent rules. Public health carve-outs should also extend beyond simply ISDS rules. Intellectual property rights, in turn, should not expand beyond those already provided for under the WTO TRIPS Agreement. More radically, perhaps, new treaties should give explicit and enforceable prioritisation to normative commitments governments have made under international health, environmental, labour rights and human rights treaties, including the requirement for ratification of these ‘public good’ treaties prior to the new FTA entering into force.

Fundamentally, trade policy needs to return to the original intent of the WTO, and its founding Marrakesh Agreement, the preamble to which states that:

…the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world’s resources in accordance with the objective of sustainable development. 49

An enduring public health concern has been that trade and its enforceable rules have long ceased being the means to achieve the goal of trade as announced in the unenforceable preamble. Rather, trade and investment liberalisation have become the ends in themselves. The COVID-19 pandemic puts in plain sight, and gives new urgency to, many of the health risks associated with FTA provisions. The resulting slowdown in trade gives trade policy makers an opportunity for a reset in which trade treaty measures are designed to achieve their putative public good ends, and not merely to increase international commercial and financial exchange or aggregate economic growth.

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