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 Trade and Health 2

## Bridging the divide: global governance of trade and health

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The main institutions responsible for governing international trade and health—the World Trade Organization (WTO), which replaced the General Agreement on Tariffs and Trade (GATT) in 1995, and WHO—were established after World War 2. For many decades the two institutions operated in isolation, with little cooperation between them. The growth and expansion of world trade over the past half century amid economic globalisation, and the increased importance of health issues to the functioning of a more interconnected world, brings the two domains closer together on a broad range of issues. Foremost is the capacity of each to govern their respective domains, and their ability to cooperate in tackling issues that lie at the intersection of trade and health. This paper discusses how the governance of these two areas relate to one another, and how well existing institutions work together.

### Introduction

At WHO's 59th World Health Assembly, member states urged their governments to ensure that trade and health interests are appropriately balanced and coordinated, and that their relevant ministries work constructively to address aspects of international trade related to international health.<sup>1</sup> Responsibility for achieving this balance lies with the many and diverse institutions that govern trade and health policy. In this paper we assess the global governance of trade and health and focus on the organisations, institutional mechanisms, formal and informal rules, and decision-making processes that collectively manage trade and health issues. We discuss which institutions have the authority and capability to take action on trade and health matters, who participates in and who is excluded from making decisions, and who sets the agenda and defines policy. At present, there are challenges to strengthen the representation of health interests within international trade governance and to ensure trade issues are managed appropriately by health organisations. These deficits need to be addressed before a balanced and coordinated trade and health agenda can be achieved.

### Global trading system

After World War 2, new institutions were created to support international economic cooperation. The General Agreement on Trade and Tariffs (GATT) was established in 1947 and presided over trade negotiations for 50 years. The World Trade Organization (WTO) was established in 1995 as the GATT's successor to formalise and expand international trade rules. The WTO's agreements are the main legal framework for international commerce.

WTO substantially changed the global trading system. The functions of the GATT were extended and binding rules for all countries were made and guarded by strict enforcement provisions (panel). The reach of the trade agenda expanded to include new issues such as internationally-traded services (eg, banking, telecommunications, tourism, professional services etc), intellectual property, and investment. Trade negotiations

now impinge on areas traditionally within the domain of domestic regulation, including immigration control, environmental protection, and public health.

The WTO has a highly structured institutional framework. Foremost are the ministerial conferences—six have been held since 1996—that make decisions on matters related to multilateral trade agreements. The general council that acts on behalf of the ministerial conference undertakes the day-to-day operations. It also meets as the dispute settlement body and trade policy review body to manage disputes and monitor national trade policies, respectively. Below the general council are the councils for trade in goods, trade in services, and trade-related aspects of intellectual property rights (TRIPS), plus various committees that report directly to the general council. The work of these three councils is further divided into committees and working parties.

In view of the extended reach of the WTO, questions have intensified about its legitimacy and capacity to fairly balance the interests of diverse stakeholders. Criticism from member states, academics, and civil society organisations came to a head at the Seattle Ministerial Conference in 1999, and continuing gridlock in negotiations under the Doha Round has renewed concerns about the governance of the trading system.

In principle, the WTO decisions are agreed by all member states, who each have one vote. In practice, most decisions are made by consensus, achieved “if no member, present at the meeting when the decision is formally taken, formally objects to the proposed decision”.<sup>2</sup> The consensus details are usually decided in closed, informal meetings at which most agendas are set and deals made. These meetings include small group discussions in Geneva (Switzerland) and national capitals, informal gatherings of ministers, and bilateral meetings between some countries. A longstanding concern is that the major trading partners of the four major (quad) countries (European Union, USA, Japan, and Canada) dominate the restricted bilateral meetings—most notably the so-called green room discussions that are limited to 20–40 delegates. Many countries have

expressed frustration about being excluded and then having decisions presented without being allowed the chance to substantially change them. Recent efforts have been made to include representatives of country coalitions in small-group discussions and to report proceedings to the full membership.

Despite attempts to change decision-making procedures, barriers to participation persist. The ability to shape trade and health agreements crucially depends on the capacity of countries to meaningfully participate. Many low-income and middle-income countries do not have resources to sufficiently monitor or influence negotiations. The average delegation from low-income countries is two staff. By contrast, the European Union sends over 140 staff<sup>3</sup> in addition to capital-based trade officials. The breadth and complexity of the WTO's agenda (involving more than 60 committees) means many countries find engaging in negotiations difficult. Consequently, the priorities of countries with the greatest resources remain dominant.

Disparities between high-income and low-income countries are further shown by differences between the international institutions that deal with trade and public health. As paper 1 described,<sup>4</sup> trade governance is formalised and demanding, whereas global health governance has little structure, a greater diversity of contributors and perspectives, and weaker legal obligations. WHO has limited access to the WTO meetings at which trade issues that could directly affect health are discussed. Thus, WHO has observer status in the committees on sanitary and phytosanitary measures and technical barriers to trade, and ad-hoc observer status in the TRIPS and trade in services councils. Observer status allows WHO to contribute to discussions but not be officially involved in making decisions. Since 2000, there has been political deadlock over the issue of observer status, and several WTO bodies have granted this status ad hoc to international organisations, such as WHO, in the interim. Importantly, there are few trade issues deemed to directly affect health, and thus representation by WHO is restricted. Moreover, the restricted sharing of information between health and trade communities, and the scarcity of substantive monitoring and assessment of trade policies from a public-health perspective, remain barriers to coordinated action between the WTO and WHO.

The dispute settlement process in the WTO is central to the rules-based trading system. When a member government believes another member is in violation of a WTO agreement, a complaint can be filed under the dispute settlement understanding. Between 1995 and 2005, 332 cases were brought to court.

Strict enforcement provisions are integral to the WTO's functioning, and consequently intense debates have arisen over whether or not the dispute settlement process adequately balances commercial and health interests. Sufficient trade restrictions are needed to protect the life

#### Panel: Key functions of the WTO

- Provision of a forum for negotiations between WTO members about their multilateral trade relations in matters dealt with under WTO agreements
- Administration of multilateral trade agreements
- Promotion of the transparency of WTO members' trade policies and actions regarding the implementation of WTO obligations, through regular monitoring and surveillance
- Provision of a process for WTO members to mediate and settle trade disputes
- Working in cooperation with relevant international organisations to achieve greater coherence in global economic policy making

and health of people, animals, and plants. But, health provisions need to be appropriately applied so that abuse of the system cannot occur for protectionist reasons. Concerns have been raised about the degree to which action to protect health can be taken before there is complete scientific proof of a risk. Under environmental agreements, the precautionary principle supports action without full scientific evidence if there is risk of substantial adverse health outcomes. However, debate continues in the WTO about the legal status of the principle, the necessary level of scientific evidence, and the use of international standards and risk assessments.

According to the sanitary and phytosanitary agreement, trade restrictions must be based on scientific evidence. Although exemptions are allowed when evidence is insufficient (article 5.7),<sup>5</sup> a precautionary principle that allows restrictions has not been written into the agreement, which would be inconsistent with the rest of member states' obligations.<sup>6</sup> An example is the ruling in March, 2008, against the European Union's ban on the import of hormone-treated beef from the USA on the grounds of inadequate scientific-risk assessment.<sup>7</sup> The challenge is to create a mechanism for initiating precautionary measures to protect health, which ensures actions are necessary, effective, and do not cause undue conflict between members.<sup>8</sup>

Regional and bilateral trade agreements are an increasingly important part of trade and health governance. From 1990 to 2007, the number of such agreements notified to the GATT or the WTO increased from 20 to 159.<sup>9</sup> At present, over 250 regional and bilateral trade agreements govern more than 30% of world trade.<sup>10</sup> A primary concern is that regional and bilateral trade agreements can include provisions that go beyond the WTO's provisions. In many cases, these stricter rules have little flexibility to protect health—eg, the USA and European countries have pushed for stricter intellectual property rights than those under the TRIPS agreement. Since 2001, every trade agreement signed or under negotiation by the USA has increased the terms and scope of intellectual property right protection of

pharmaceuticals, including patent terms beyond the 20 years provided for under the WTO. These so-called TRIPS-plus standards are widely criticised for eroding the hard-fought flexibilities recognised by the Doha Declaration.<sup>11</sup> Agreed in 2001, the Doha Declaration reaffirmed the flexibilities available to countries under the TRIPS Agreement to support public-health concerns, and clarified their rights to use compulsory licences to access generic drugs.

Protection of knowledge and genetic resources is another area in which regional and bilateral trade agreements could affect health. Several agreements ease restrictions on patenting life forms and the protection of plant varieties. Under US free-trade agreements, the Dominican Republic, Peru, and Columbia will no longer be able to reject patent applications when a company does not indicate a plant's origin or show proof of consent for its use from a local community.<sup>10</sup> Under the economic partnership agreements, which are being negotiated between the EU and African, Caribbean, and Pacific countries, there are concerns that proposed provisions of intellectual property rights will reduce the ability of farmers to save and share seeds—techniques that have enabled communities to select the strongest varieties to improve production.<sup>12,13</sup>

Nationally, a long-standing concern is the low status that health policy receives compared with the status of commercial interests in the setting of trade policy. In the US trade policy advisory committee system (a key consultation mechanism of the US trade representative with the private sector and civil society organisations), a health representative was only added to two of the 16 advisory committees.<sup>14</sup> Moreover, these committees consisted of 20 and 33 private sector representatives, respectively. Despite a legal requirement that the committees reflect a balance of views, 93% of the 742 advisors represented commercial interests.<sup>15</sup> Privileged access to government policy makers means that businesses have dominated the formulation of negotiating positions and have, in turn, exerted their influence over the WTO's agenda. Many businesses—including pharmaceutical, services (eg, financial and telecommunications), and agricultural sectors—have devoted vast resources to lobbying governments and, in some cases, basing permanent representatives in Geneva to monitor WTO proceedings.

In low-income and middle-income countries, the absence of health representation in trade policy is similarly pronounced. Securing favourable market access for exports has usually outweighed public-health priorities—even when benefits are likely to be short lived and eroded as tariffs decrease. For example, the Peruvian and Columbian Governments agreed to a free trade agreement with the USA that contained various TRIPS-plus standards, despite warnings by public-health authorities of potentially disastrous effects from increased drug costs.<sup>11</sup> Generally, public-interest groups exert less

weight in setting priorities, and shaping the international trade agenda than do industry lobbyists.

### Public-health engagement with trade issues

Engagement by health organisations in world trade policy occurs in many ways although most formal links are with WHO. From 1948 until the 1990s, these links were narrowly circumscribed, mainly defined by provisions of the International Sanitary Regulations (renamed the International Health Regulations in 1969). The original purpose of the International Health Regulations—dating from the 19th century—was to set out the responsibilities of member states for managing diseases and other health risks spread through international trade and travel. Until the revision of the International Health Regulations in 2005, regulations covered only a few acute and potentially epidemic diseases. Specific measures to be taken, such as disease surveillance and reporting, regulation of ports of entry, and quarantine, represented trading interests of major trading states.

In addition to the International Health Regulations, trade in food products has been governed by the *codex alimentarius* commission, which was created in 1963 by the Food and Agriculture Organization and WHO to develop food standards, guidelines, and related texts. The purposes of the Joint Food and Agriculture Organization/WHO food standards programme are to protect the health of consumers, ensure fairness in food trade, and to promote the coordination of food standards by international governmental and non-governmental organisations. For member states, article 20 of the GATT allows governments to act on trade to protect the life or health of people, animals, or plants—provided that there is no discrimination or use of the agreement to disguise protectionism.

For many decades, the governance of trade and health issues used these two regulatory instruments that were considered to largely deal with technical and fairly uncontroversial matters. However, expansion of the world trading system meant that health determinants and outcomes could be affected by trade in several ways. Further, the creation of the WTO required new forms of engagement by the public-health community such as participation in trade-related meetings, monitoring of trade negotiations and agreements, and interaction with trade lawyers. Moreover, this expanded trade and health agenda has encompassed different interests, values, and goals and as a result, there are now challenging policy issues to address.

The complexity of the trade policy environment was evident when concerns were expressed over the potential effect of the TRIPS agreement on access to drugs. The publication of WHO's report<sup>16</sup>—*Globalization and Access to Drugs, Implications of the WTO/TRIPs Agreement* in 1997—by the action programme on essential drugs was ostensibly a defence of public-health principles over trade principles. Alongside the report was a proposed resolution

to the World Health Assembly on a revised drugs strategy that called on member states to “ensure that public health rather than commercial interests have primacy in pharmaceutical and health policies and to review their options under the Agreement on Trade Related Aspects of Intellectual Property Rights to safeguard access to essential drugs.”<sup>17</sup> Both the report and resolution were strongly criticised by the pharmaceutical industry and US government,<sup>18</sup> instigating a further year of consultation and heated debate. These initial disputes prompted WHO to strengthen engagement with trade issues, and to show “needed leadership”.<sup>19</sup>

In 2000, a small programme on globalisation, trade, and health was established to strengthen knowledge, develop analytical methods, and produce training materials for supporting member states in addressing trade and health issues. The programme’s first major report—WTO agreements and public health—was a broad study of how specific trade agreements relate to drugs and intellectual property rights, food safety, tobacco, and other issues “subject to passionate debate”.<sup>20</sup> The study was jointly published by WHO and the WTO, with their respective heads advising that “health and trade policy-makers can benefit from closer cooperation to ensure coherence between their different areas of responsibilities”.<sup>20</sup> The price of this study, according to critics, has been compromise. Rather than confronting difficult issues or advising ministries of health on how to protect health amid trade liberalisation, the study was cautiously worded and largely descriptive. Although the remit of the globalisation, trade, and health programme has been to “achieve greater policy coherence between trade and health policy so that international trade and trade rules maximise health benefits and minimise health risks, especially for poor and vulnerable populations”,<sup>21</sup> the real challenge has been to ensure health policy is appropriately represented.

Initially, the globalisation, trade, and health programme was located centrally within the Director-General’s office, indicating a desire for closer collaboration. The then Director-General, Gro Harlem Brundtland, stated, “We need WTO as an effective and fair forum for negotiating trade rules and resolving disputes.”<sup>22</sup> The unclear priority given to trade issues within WHO has been reflected in the changing location of the programme. Under the late Lee Jong-wook, the programme was relocated to a new department of Ethics, Trade, Human Rights and Health Law where it produced legal reviews of the GATT, the agreement on technical barriers to trade, and agreement on sanitary and phytosanitary standards. In 2007, lead by Margaret Chan, the programme was incorporated into the new department for ethics, equity, trade, and human rights—created by merging the department for ethics, trade, human rights, and law with the department for equity, poverty, and social determinants of health. The programme has been responsible for Chan’s initiative

on global health diplomacy, including the “especially challenging area”<sup>23</sup> of trade and health.

Throughout, the programme has been strongly reliant on extra-budgetary funds and, with few WHO staff, on external consultants to provide technical expertise. Without enough core funding the programme is vulnerable to donor preferences, which generally favour funding of infectious diseases over politically sensitive areas such as trade. Indeed, the uncertain status of the programme throughout this time has been invariably affected by political pressures from the US Government and powerful businesses seeking to circumscribe the organisation’s involvement in trade issues—notably in relation to the framework convention on tobacco control and access to essential medicines. According to non-government organisations, WHO’s financial dependence on major donors, amid the proliferation of other global health initiatives, has led the organisation to act with some caution. Additionally, beginning under Brundtland, individuals from the pharmaceutical industry have been recruited to prominent positions within the organisation.<sup>24</sup> WHO’s perceived support for the use of industry-discounted rather than generic drugs, and its failure to support countries such as Thailand, India, and South Africa who seek to uphold TRIPS flexibilities, such as compulsory licences,<sup>25,26</sup> are regarded as examples of reticence to offend specific interests.

The issue of access to essential medicines is used as a measure to assess WHO’s institutional capacity and willingness to engage with trade issues. In 2003, the commission on intellectual property rights, innovation, and public health was created and located within the Director-General’s office. The commission was welcomed as a political compromise between a proposal made by Kenya and Brazil for a global mechanism to provide financial support for research driven by public-health needs and industry support for market-driven solutions. The commission’s work concluded in 2006 after several years of debate of the issues, although specific recommendations on ways forward were not agreed. Public-health advocates continue to call for WHO to take an assertive stance. As Rodrigo Estrela of Brazil’s UN mission in Geneva states, “Developed countries used to say IP rights were not an issue for WHO, but instead for WTO...WHO has work to do in this area, including supporting measures contained in TRIPS regarding flexibilities.”<sup>27</sup>

The difficulty in the management of trade and health issues was evident in the revision process of the International Health Regulations. The revision was eventually achieved in 2005 after the outbreak of severe acute respiratory syndrome (SARS) in 2003, focused attention of major financial contributors to global health. Although trade has remained central to the purpose of International Health Regulations, “to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are



commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade,”<sup>28</sup> its measures now show the broader scope and scale of international trade. The International Health Regulations (2005) represent what can be achieved when shared goals exist between the trade and health communities. However, WHO faces much challenge when there is little commonality between these goals. As Ford and Piédagnel write, “In the face of rising infectious diseases such as AIDS, tuberculosis, and malaria, and the increasing marginalisation of health problems that do not affect the developed world, the importance of an international, independent organisation that is brave, aggressive, and vocal in its defence of global public health has never been more important.”<sup>25</sup>

### Protection and promotion of health in a global trading system

There is substantial potential for the global trading system to benefit societies worldwide. However, the breakdown and present impasse in multilateral trade negotiations suggests dysfunction in the present governance of trade, arising from widely held dissatisfaction with existing institutions. Weak representation of health concerns within trade governance is a key part of this dissatisfaction. For the global trading system to be sustainable, it has to operate in a fair and ethical way that is sensitive to both social and environmental needs. How then, can the public-health community play a more effective part in the governance of trade and health?

Worldwide, the lack of coherence in global health governance is a major hindrance to more effective representation. The patchwork of institutional mandates, activities, authority, and resources that characterise global health initiatives show that there is no agreed plan or strategic vision to tackle the broad determinants of health, including trade.<sup>29</sup> Concerted leadership on trade and health issues within the public-health community is needed.

If WHO is to take a lead role, the involvement of WHO with the WTO Secretariat and its members should be substantively enhanced to enable more meaningful participation. WHO should become a permanent observer of the WTO’s general council, and dispute settlement panels should have equal participation of trade and health experts in appropriate cases. Furthermore, cooperation agreements by the International Monetary Fund and World Bank with the WTO have provided useful platforms for the expansion of activities and programmes to cover many trade issues.<sup>30</sup> Fostering similar links between health and trade would help with sharing of information and analysis, the monitoring and assessment of policies, and would encourage greater transparency in discussions. Of crucial importance is building incentives for collaboration into such cooperation agreements, in the form of funding and other resources.

Gaining leverage for achieving improved health representation in the WTO should initially focus on obvious areas of shared interest. An example is infectious disease outbreaks, which have the potential to adversely affect global economic activity. The SARS outbreak in 2002–03, and the perceived potential for pandemic influenza to inflict substantial damage on international commerce, has prompted unprecedented outbreak preparation by major corporations and leading economies. Thus, although the health community has so far focused on showing how trade affects health, the importance of protecting health for trade reasons has not been clearly articulated.

To enable stronger representation by health interests, there is a need by WHO and its member states to commit sufficient resources for this purpose. Although extra-budgetary funds can be substantial, they remain subject to the whims of major donors. Their reluctance to expand WHO’s role might be attributable to the organisation’s lack of strategies to tackle health and trade issues, but could also be because of the perceived threat to vested economic interests. Therefore, regular-budget funds need to be forthcoming to strengthen the organisation’s capacity to engage more actively in trade and health issues. Similarly, WHO has inadequate technical expertise to analyse and advocate on trade and health matters, and the management of these issues is often fragmented, which sometimes results in competition between programmes. WHO needs to shift efforts from building their knowledge base to supporting member states to effectively participate in the governance of trade issues. Besides building analytical capacity within member states—which requires corresponding resources—WHO has to show political leadership in resisting powerful political and economic interests. So far, WHO’s role has been reactive. With improved resources and high-level support, WHO could be more proactive and timely in representing health interests in trade negotiations regionally, nationally, and worldwide.

Adjustments within global institutions extend to their relations with national governments. Ministries of health are especially disadvantaged by existing institutional configurations, and need support to understand the technical aspects of trade agreements and to act to protect their health interests. To improve the analytical capacity that governments need to participate meaningfully in trade negotiations, WHO should work with ministries of health to strengthen what David Fidler calls “trade epidemiology”.<sup>31</sup> This term refers to the application of public-health principles and methods in the formulation and implementation of trade policy through activities such as building an evidence base for policy, monitoring, and reporting on the health effects of trade agreements; integration of public-health expertise into negotiations of new agreements and arrangements; and enabling health

institutions a right of reply during the so-called cooling off periods for trade agreements. The WTO's trade policy review mechanism, which regularly reviews and reports on the national trade policies of member states, might be a model to follow. WHO could adopt a similar process or partner with the WTO to provide health input into the process for the trade policy review mechanism. Adoption of a similar practice would fit with the WHO framework for country analysis, which would provide consistent, comparable information about trade policies and the effect of trade development. WHO could also assist in the provision of training on the health-related implications of trade agreements, not only to ministries of health but also to ministries of finance, foreign affairs, trade, and commerce, as documented in Uganda.<sup>32</sup>

Furthermore, WHO could support collaborative links between national governments of like-minded, pro-health coalitions. Low-income and middle-income countries, particularly, need to be coordinated in their work within WHO and the WTO. As on other trade issues, coalitions have increased their capacity, technical expertise, and negotiating power,<sup>33</sup> which could improve sharing of information between countries and delegates who manage different areas. This approach would strengthen the ability of individual governments to monitor the complex and broad range of trade issues involved, and encourage shared positions that form the basis of lobbying and negotiations.

Furthermore, alliance building should be pursued between stakeholders within countries. In a national government, ministries of trade, finance, and foreign affairs will rightfully remain the lead agencies in trade negotiations. The challenge for health ministries is to keep abreast of and contribute to national policy-making processes. Many governments recognise the importance of improving coherence across different sectors through, for example, interministerial committees. Strengthened parliamentary engagement and oversight in setting trade policies could be encouraged so that broader welfare considerations, including health, will be considered. In 2001, the ministries of health and trade in the Philippines launched President Gloria Macapagal-Arroyo's GMA 50 initiative that focused on providing cheaper essential medicines through parallel importation.<sup>32</sup> In Kenya, civil society organisations targeted parliamentarians to successfully prevent changes in legislation for intellectual property rights that would have harmed access to affordable drugs.<sup>34</sup> In view of the little formal access of public-interest groups to policy making, health ministries could push for wider stakeholder consultation. Health interests could be actively represented in the design of revised legislation, and allowed to voice concerns and reservations with draft legislation through activities such as public workshops, public debates, and engagement with the media.

Outside governmental institutions, informal mechanisms can have a crucial role in trade and health governance. Although civil society organisations are not formally represented in negotiations at the WTO, they make an essential contribution by providing technical and practical assistance to low-income and middle-income countries, and by mobilising public opinion to regulate the behaviour of powerful states and corporate interests. Civil society organisations have arguably been most effective in upholding public-health protections when drawing on worldwide norms such as the international human rights framework and the work of the UN Special Rapporteur on the right to health. Civil society organisations have been able to position access to essential medicines, for example, as a moral rather than economic issue resulting in the WTO Declaration on TRIPS and Public Health.<sup>35</sup>

In conclusion, there are many opportunities for trade and health to be mutually strengthened. The complexity of the issues and powerful vested interests involved, and the need for clear political leadership, has hindered the public-health community from having a meaningful role in issues for which trade and health intersect. These challenges must be overcome through a strategic and coordinated approach that would contribute not only to improved protection and promotion of health, but also to the creation of a more sustainable form of economic globalisation.

#### Conflict of interest statement

We declare that we have no conflict of interest.

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