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Bridging the divide: The global governance of trade and health

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Summary

The main institutions responsible for governing international trade and health, the World Health Organization and General Agreement on Tariffs and Trade (GATT), replaced by the World Trade Organization (WTO) in 1995, were established after the Second World War. The two domains largely operated separately for many decades within their respective domains. 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. This has given rise to a number of institutional challenges. Foremost is the capacity of these institutions to govern their domains effectively, not only in carrying out their functional roles, but ensuring good governance. Where trade and health issues come together, how well do existing institutions work together? Fundamental questions have been raised on both counts.

Bridging the divide: The global governance of trade and health

Introduction

At WHO's 59th World Health Assembly (WHA), member states urged their governments to ensure that trade and health interests are appropriately balanced and coordinated, and relevant ministries work constructively to address public health-related aspects of international trade.[1] At the heart of achieving this balance are the institutions responsible for governing trade and health policy. Numerous and diverse in their constituencies, and often unfamiliar with other sectors, these institutions are responsible for fulfilling this aspiration of a balanced and coordinated trade and health agenda.

This paper assesses the global governance of trade and health, broadly concerned with the organisations, institutional mechanisms, formal and informal rules, and decision making processes that collectively manage trade and health issues. What institutions have the authority and capabilities to take action on such issues? Who participates in, and who is excluded from, decision-making? Who sets the agenda and defines policy goals? As presently configured, there are clear challenges for strengthening the representation of health interests within the governance of international trade, as well as ensuring trade issues are dealt with appropriately within health institutions. Concerted attention to these deficits will be needed before a balanced and coordinated trade and health agenda can be achieved.

The global trading system: Shaping the rules of the game

After the Second World War, 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 over the next

fifty years. The World Trade Organisation (WTO) was established in 1995 as the GATT's successor to formalise and expand international trade rules. Today, the WTO's agreements are the central legal framework for international commerce.

The WTO dramatically changed the global trading system. The functions of the GATT were extended and binding disciplines on all countries were established, guarded by strict enforcement provisions (Box 1). The reach of the trade agenda expanded 'behind the border' and included new issues such as services, intellectual property and investment. Trade negotiations now impinge directly on areas traditionally within the domain of domestic regulation including immigration control, environmental protection and public health.

Box 1: Key functions of the WTO

- Providing a forum for negotiations among WTO members concerning their multilateral trade relations in matters dealt with under WTO agreements;
- Administering multilateral trade agreements;
- Promoting the transparency of WTO members' trade policies and actions regarding the implementation of WTO obligations, through regular monitoring and surveillance;
- Providing 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.

The WTO is a highly structured institutional framework. Foremost are Ministerial Conferences, six since 1996, which take decisions on matters related to any of the multilateral trade agreements. Everyday operations are conducted by the General Council which acts on behalf of the Ministerial Conference. It also meets as the Dispute Settlement Body (DSB) and Trade Policy Review Body to handle 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.

Given the expanded reach of the WTO, questions have intensified about its legitimacy and capacity to fairly balance the interests of diverse stakeholders. Criticism from member states, scholars and civil society organisations (CSOs) dramatically came to a head at the Seattle Ministerial Conference in 1999. More recently, ongoing gridlock in negotiations under the Doha Round has renewed concerns about the governance of the trading system.

How multilateral trade agreements are negotiated

In principle, WTO decisions are voted on by all member states, each having one vote. In practice, virtually all decisions are taken by consensus, achieved "if no member, present at the meeting when the decision is formally taken, formally objects to the proposed decision."[2] The content of such consensus is traditionally hammered out in closed, informal meetings where much of the real agenda setting and deal making takes place. These include small-group retreats in Geneva and national capitals, informal gatherings of ministers, and "bilateral meetings" between select countries. One common concern is that the major trading partners of the "Quad" (EU, US, Japan and Canada) dominate these restricted meetings, most notably the "green room" discussions, which involve a limited number of delegations (between 20 and 40). Many countries have expressed frustration about being excluded and then having decisions presented *fait accompli*. Recent efforts have been made to include representatives of country coalitions in small group discussions and to report proceedings back to the full membership.

Despite attempts to tinker with decision-making procedures, barriers to participation persist. The ability to shape agreements crucially depends on the capacity of countries to meaningfully participate. Many low and middle-income countries (LMICs) lack the resources to sufficiently monitor, let alone influence, negotiations. The average size of least-developed country delegations is two professional staff. In contrast, the EU sends over 140 staff,[3] in addition to capital-based trade officials. The breadth and complexity of the WTO's agenda (involving more than 60 committees) means many countries face real difficulties engaging in negotiations. Consequently, the priorities of countries with the greatest capacity remain dominant.

The disparities between rich and poor are also mirrored by differences between the international institutions that deal with trade and public health. As Paper 1 described, trade governance is highly formalised and demanding, whereas global health governance exhibits little structural coherence, a greater diversity of actors and perspectives, and weaker legal obligations. WHO also has limited access to WTO proceedings as an observer in areas where there are considered to be direct health implications from trade. On this basis, WHO has observer status in the Committees on Sanitary and Phytosanitary (SPS) Measures and Technical Barriers to Trade, and ad hoc observer status in the TRIPS and Trade in Services Councils. Observer status allows WHO to follow, and provide inputs into, discussions but not be officially involved in decision-making.[4] Importantly, the issues deemed to have direct health implications, and thus permitted representation by WHO, remain restricted. Moreover, the limited sharing of information between the health and trade communities, and the lack of substantive monitoring and evaluation of trade policies from a public health perspective, pose significant barriers to meaningful participation.

Settling Trade Disputes

The dispute settlement process in the WTO is a central pillar of 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 (DSU). Between 1995 and 2005, 332 cases were brought, with the decisions taken creating legal precedent.

As strict enforcement provisions have become an integral part of the WTO's functioning, intense debates have followed about whether the DSB adequately balances commercial and health interests. Sufficient trade restrictions are required to protect the life and health of human, animals and plants. At the same time, health provisions need to be appropriately applied so as not to be open to abuse 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 the notion of action without full scientific evidence, given the risk of significant adverse impact. However, debate remains in the WTO about the legal status of the principle, as well as the necessary level of scientific evidence and the use of international standards and risk assessments.

Under the SPS Agreement, trade restrictions must be based on clear scientific evidence. Although qualified exemptions are allowed where evidence is insufficient (Article 5.7), a precautionary principle has not been written into the Agreement that allows restrictions, which would otherwise be inconsistent with the rest of member states' obligations under the Agreement.[5] This is illustrated by the long-awaited ruling in March 2008 against the EU on the import of hormone-treated beef from the US on

the grounds of lack of inadequate scientific risk assessment.[6] Overall, creating a mechanism for initiating precautionary measures to protect health, which ensures such actions are necessary, effective and do not cause undue conflict among members, remains a clear challenge.[7]

Negotiating Trade Beyond the WTO

Regional and bilateral trade agreements (RTAs) form an increasingly important part of the governance of trade and health. From 1990 to 2007, the number of RTAs notified to the GATT/WTO increased from 20 to 159.[8] Today, over 250 RTAs govern more than 30 per cent of world trade.[9]

A primary concern is that RTAs can include additional provisions that go beyond the WTO. In many cases, these stricter rules have limited the flexibilities available to protect health. For example, the US and European countries have pushed for stricter intellectual property rights (IPRs) than exists under the TRIPS Agreement. Since 2001 every trade agreement signed or under negotiation by the US has increased the terms and scope of IPR protection of pharmaceuticals, including patent terms beyond the twenty years provided for under the WTO.[10] These so-called 'TRIPS-plus' standards have been criticised for eroding the hard fought flexibilities recognised by the Doha Declaration.[11]

The protection of knowledge and genetic resources is another area where RTAs have potentially significant health implications. Several agreements ease limitations on the patenting of life forms and protection of plant varieties. Under US free trade agreements, the Dominican Republic, Peru and Columbia will no longer be able to reject patent applications because a firm fails to indicate a plant's origin or show proof of consent for its use from a local community.[9] Under the Economic

Partnership Agreements (EPA) being negotiated between the EU and African, Caribbean and Pacific (ACP) countries, there are concerns that proposed IPR provisions will reduce the ability of farmers to save and share seeds, techniques that have enabled communities to select the strongest varieties to improve production.[1213]

Setting National Trade Priorities

At the national level, a long-standing concern has been the relatively low status health policy receives alongside commercial interests in the setting of trade policy. For example, in the US Trade Policy Advisory Committee system (a key mechanism of consultation of the US Trade Representative with the private sector and CSOs), a health representative was only recently added to two of the sixteen advisory committees. These committees were respectively composed of 20 and 33 private sector representatives. Despite a legal requirement that the committees reflect a balance of views, 93 per cent of the 742 advisors represent commercial interests.[14] Enjoying privileged access to government policymakers, businesses have unsurprisingly dominated the formulation of negotiating positions and have, in turn, exerted similar influence over the WTO agenda. Many, including the pharmaceutical, services and agricultural sectors, have devoted vast resources to lobbying governments and, in some cases, basing permanent representatives in Geneva to monitor WTO proceedings.

In LMICs, the absence of health representation in trade policy is similarly marked. Securing favourable market access for exports has usually outweighed public health priorities (even when benefits are likely to be short-lived and eroded over time as tariffs progressively decrease). For example, the Peruvian and Columbian governments agreed to an FTA with the US that contained a broad range of TRIPS-

plus standards, despite warnings by public health authorities of potentially disastrous effects from increased drug costs.[11] In general, public interest groups exert less weight in setting priorities, and shaping the international trade agenda.

Public health engagement with trade issues: A big enough voice?

Engagement by health organisations in trade policy at the global level occurs in a multitude of ways, with the most formal links focused on WHO. From 1948 until the 1990s, these links were narrowly circumscribed, mainly defined by the provisions of the International Sanitary Regulations (renamed the International Health Regulations (IHR) in 1969). The original purpose of the IHR, dating from the nineteenth century, is to set out the responsibilities of member states in dealing with diseases and other health risks spread through international trade and travel. Until the revision of the IHR in 2005, the regulations covered only a handful of acute and potentially epidemic diseases. Specific measures to be taken, such as disease surveillance and reporting, regulation of ports of entry, and quarantine, reflected the trading interests of major trading states.

In addition to the IHR, the food trade has been additionally governed by the Codex Alimentarius Commission, created in 1963 by the Food and Agriculture Organisation (FAO) and WHO to develop food standards, guidelines and related texts. The purposes of the Joint FAO/WHO Food Standards Programme are to protect the health of consumers and ensure fairness in the food trade, and to promote the coordination of food standards by international governmental and nongovernmental organisations. For member states, Article 20 of the General Agreement on Tariffs and Trade (GATT) allows governments to act on trade in order to protect human, animal

or plant life or health, provided they do not discriminate or use this as disguised protectionism.

The governance of trade and health issues remained focused on these two regulatory instruments for many decades, seen as largely dealing with technical matters and thus relatively uncontroversial. However, the expansion of the world trading system, as described above, heralded a new environment where health determinants and outcomes could be influenced by trade in many more ways. The creation of the WTO required new forms of engagement by the public health community. Moreover, this expanded trade and health agenda has encompassed different interests, values and goals, thus representing a more politically challenging set of policy issues to address.

This more difficult policy environment was immediately signaled by concerns expressed over the potential impact of the TRIPS Agreement on access to medicines. The publication of the WHO report, *Globalization and Access to Drugs, Implications of the WTO/TRIPs Agreement* in 1997 by the Action Programme on Essential Drugs was ostensibly a defense of public health principles over trade. Alongside the report was a proposed resolution to the WHA on a Revised Drugs Strategy which 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."[15] Both the report and resolution were strongly criticised by the pharmaceutical industry and US government,[16] instigating a further year of consultation and heated debate.

These initial wrangles prompted a realisation of the need for WHO to strengthen its engagement with trade issues, and to demonstrate "needed

leadership."[17] In 2000, a small programme on Globalisation, Trade and Health (GTH) was established to strengthen knowledge, develop analytical tools and produce training materials for supporting member states in addressing trade and health issues. Its first major report, *WTO agreements and public health*, was a wide-ranging study of how specific trade agreements relate to drugs and IPRs, food safety, tobacco and other issues "subject to passionate debate". Significantly, the study was jointly published by WHO and 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".[18] The price, 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 remained carefully worded and largely descriptive.

While the remit of the GTH 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," in practice, ensuring health policy is appropriately represented has been the real challenge. Initially, the programme was located centrally within the Director-General's office, a reflection of then Director-General Gro Harlem Brundtland's desire for closer collaboration: "We need WTO as an effective and fair forum for negotiating trade rules and resolving disputes."[19]

The unclear priority given to trade issues within WHO has been reflected in the changing location of the GTH. Formed in 2000 within the Department of Health in Sustainable Development, in 2002 it was moved to the Strategy Unit within the Director-General's Office (DGO). This was seen as reflecting high-level support for its work by Brundtland. However, under the late Lee Jong-wook, it was moved out of

the DGO to a new Department of Ethics, Trade, Human Rights and Health Law (ETH) where it produced legal reviews of the General Agreement on Trade and Services (GATS), Agreement on Technical Barriers to Trade (TBT) and Agreement on Sanitary and Phytosanitary Standards (SPS). In 2007, under Margaret Chan, the programme was then incorporated into the new department on Ethics, Equity, Trade and Human Rights, created by merging the departments, for Ethics, Trade, Human Rights and Law and for Equity, Poverty, Social Determinants of Health. The programme has been responsible for Chan's new initiative on global health diplomacy, including the "especially challenging area" of trade and health.[20] Throughout, the programme has been strongly reliant on extrabudgetary funds (EBFs) and, with few WHO staff, on external consultants to provide technical expertise. Without substantial core funding, GTH has been vulnerable to donor preferences which generally favour funding of infectious diseases over politically sensitive issue areas such as trade. Indeed, the uncertain status of GTH throughout this period has been invariably influenced by political pressures asserted by the US government and powerful corporate interests seeking to circumscribe the organisation's involvement in trade issues, notably in relation to the FCTC and access to medicines. According to NGOs, the financial dependence of WHO on major donors, amid the proliferation of other global health initiatives, led the organisation to act with a degree of caution. In addition, beginning under Brundtland, individuals from the pharmaceutical industry had been recruited to prominent positions within the organization.[21] The organisation's support for using industry discounted, rather than generic drugs, and its failure to speak out definitively in support of countries such as Thailand, India and South Africa seeking to uphold TRIPS flexibilities,[22,23] have been seen as examples of this reticence to offend certain interests.

The issue of access to medicines has remained a barometer for assessing WHO's institutional capacity and willingness to engage with trade issues. The creation of the Commission on Intellectual Property Rights, Innovation and Public Health in 2003, and location within the DGO, has been welcomed as a political compromise between a proposal by Kenya and Brazil for a global mechanism to provide financial support for public health needs-driven research; and industry support for market-driven solutions. Whether the Commission will be able to put forth any specific recommendations, after several years of prolonged debate, remains uncertain. Public health advocates continue to look to WHO to play a more assertive role. 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."[24]

The trickiness of dealing with trade and health issues was also evident in the revision of the IHR. After a prolonged process of delay, this was achieved in 2005 only after the SARS outbreak in 2003 focused the minds of donors. While trade has remained central to its purpose, "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,"[25] its measures now reflect the broader scope and scale of international trade today. The IHR (2005) represent what can be achieved when there are shared goals between the trade and health communities. Where commonalities are less evident, however, WHO faces greater challenges. As Ford and Piédagnel write,

> In the face of rising infectious diseases such as AIDS, TB, 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.[22]

Restacking the deck: Protecting and promoting health within a global trading system

There is significant potential for the global trading system to bring widespread benefits to societies worldwide. However, the breakdown and current impasse in multilateral trade negotiations signals dysfunction in the current governance of trade, arising from widely held dissatisfactions with existing institutions. The weak representation of health concerns within trade governance has been an important part of this disgruntlement. If the global trading system is to be sustainable, it must operate in a fair and ethical way which includes sensitivity to social and environmental needs. How then can the public health community play a more effective role in the governance of trade and health?

At the global level, 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 characterising global health initiatives reflects the absence of an agreed plan or strategic vision to tackle the broad determinants of health including trade.[26] Concerted efforts to designate clear leadership on trade and health issues within the public health community are needed.

If WHO is to take a lead role, the involvement of WHO with the WTO Secretariat and its members could be substantively enhanced. WHO should become a permanent observer of the WTO's general council, and DSB panels should involve equal participation of trade and health experts in appropriate cases. Also, cooperation

agreements by the IMF and World Bank with the WTO have provided useful platforms for the expansion of activities and programmes at a managerial and staff level to cover many trade issues.[27] Fostering similar linkages on health and trade issues would facilitate the sharing of information and analysis, the monitoring and evaluation of policies, and allow greater transparency in discussions. Of critical importance are the building of incentives for collaboration into such 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. One example is infectious disease outbreaks which have the potential to adversely impact on global economic activity. The SARS outbreak in 2002-2003, and the perceived potential for pandemic influenza to inflict substantial damage on international commerce, has prompted unprecedented attention by major corporations and leading economies to outbreak preparedness. Thus, while the health community has so far focused on demonstrating how trade affects health, the importance of protecting health to trade concerns has been less clearly articulated.

Within WHO, to fulfil such hopes, commitment by WHO and its member states of sufficient resources to fund such efforts is needed. While EBFs offer potentially substantial resources, they remain subject to the whims of major donors. Their reluctance to expand WHO's role may be due to the lack of clear indicators or interventions to tackle health and trade issues, but also to perceived threats to vested economic interests. Core resources from regular budget funds, to strengthen the organisation's capacity to engage more actively in trade and health issues, must therefore be forthcoming. Similarly, appropriate technical expertise in WHO to analyse and advocate on trade and health matters remains inadequate. Moreover,

different issues are tackled by different parts of the organisation, resulting in fragmentation and even competition among programmes. WHO must also expand its efforts to shift, from building the knowledge base, to supporting member states to effectively participate in the governance of trade issues. As well as building analytical capacity within member states, which requires corresponding resources, WHO must demonstrate political leadership in resisting powerful political and economic interests. To date, WHO's role has been reactive, with efforts focused on informing and building capacity within ministries of health to analyse the health implications of trade agreements already adopted. With appropriate resources and high-level support, WHO could fulfil a more proactive and timely role in representing health interests in trade negotiations at the global, regional and national levels.

Adjustments among global institutions extend to their relationships with national level actors. Ministries of health are especially disadvantaged by existing institutional configurations, and must be supported in their efforts to understand the technical aspects of trade agreements, and enabled to act accordingly to protect their health interests. To improve the analytical capacity that governments require to participate meaningfully in trade negotiations, WHO should work with ministries of health to strengthen what David Fidler calls 'trade epidemiology.'[28] This is the application of public health principles and methods in the formulation and implementation of trade policy through such activities as building an evidence-base for policy, monitoring and reporting on the health impacts of specific trade agreements; integrating public health expertise into negotiations of new agreements and arrangements; and enabling health interests a right to reply during the 'cooling off' periods for trade agreements. The WTO's Trade Policy Review Mechanism (TPRM), which regularly reviews and reports on the national trade policies of

member states, may be a model to follow. WHO could adopt a similar process or partner with the WTO to provide health input into the TRPM process. In the former, this would fit with the WHO Framework for Country Analysis, which would provide consistent, comparable information on trade policies and the impact of trade development. WHO could also play a major role in providing training on the health-related implications of trade agreements, not only to ministries of health, but also ministries of finance, foreign affairs, trade and commerce as documented in Uganda.[29]

Collaborative links across national governments could also be supported by WHO in the form of like-minded, pro-health coalitions. LMICs, in particular, need to work in a more coordinated fashion within both WHO and the WTO. As on other trade issues, coalitions have increased their capacity, technical expertise and negotiating power.[30] This could involve greater sharing of information among countries and, at an individual country level, among delegates who cover different areas. This approach would strengthen the capacity of individual governments to monitor the complex and broad range of trade issues involved, and encourage collective positions that form the basis of lobbying and negotiations.

Alliance building should also be pursued among stakeholders at the country level. Within national governments, 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 feed meaningfully into, national policy-making processes. Many governments recognise the importance of achieving greater coherence across different sectors through, for example, inter-ministerial committees. Greater parliamentary engagement and oversight in setting trade policies might also be encouraged so that broader welfare considerations, including health, will be taken into account. For example, in 2001, the ministries of health and trade in the

Philippines launched President Macapagal-Arroya's GMA 50 initiative focused on providing cheaper medicines through parallel importation.[29] In Kenya, CSOs targeted parliamentarians to successfully prevent changes in IPR legislation that would have harmed access to affordable medicines.[31] Given limited 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 an initial offer, and effectively allowed to voice concerns and reservations with draft language. This should not be part of a one-time effort, but a continuing series of activities such as public workshops, public debates, and engagement with the media.

Outside governmental institutions, informal mechanisms can play a crucial role in trade and health governance. Although CSOs are not formally represented in negotiations at the WTO, they make a critical contribution by providing technical and practical assistance to LMICs, and mobilising public opinion to regulate the behaviour of powerful states and corporate interests. CSOs have arguably been most effective in upholding public health protections when drawing on globally shared norms such as the international human rights framework and the work of the UN Special Rapporteur on the right to health. CSOs have been able to frame access to medicines, for example, as a moral rather than economic issue resulting in the WTO Declaration on TRIPS and Public Health.[32]

In conclusion, there are ample opportunities for trade and health to be mutually strengthened. The complexity of the technical issues involved, powerful vested interests at play, and need for clear political leadership, has hindered the public health community from playing a more meaningful role where trade and health issues intersect. These challenges must be overcome through a more strategic and coordinated approach that would contribute, not only to improved protection and

promotion of health, but to the creation of a more sustainable form of economic globalisation.

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