

HEALTH IN A GLOBALIZED WORLD

WHAT EVERY PUBLIC HEALTH PROFESSIONAL SHOULD KNOW

ABOUT TRADE POLICY

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INTRODUCTION

International trade is hardly a new phenomenon. Though the means have become more sophisticated and the volume has increased dramatically, the idea behind international trade – the movement of goods and services across international borders – remains the same. In fact, trade is so ingrained in today’s societies that all of us encounter it several times a day without even realizing it. The availability of fresh fruit in winter and access to all manner of consumer and industrial products – plant seeds, clothing, autos, and more – are all the result of trade activity.

Thus, it is no surprise that public health and international trade frequently overlap. In fact, the emergence of international health – or the cooperation between countries to address health issues – was the result of trade concerns. Recognition of these links led to the first International Sanitary Conference in Europe in 1851, which began an international discourse on the intersection of trade and health that continues and evolves today. While the interaction between international trade and health is complex, several fundamental concepts, processes, and institutions provide a foundation.

TRADE AS A HEALTH DETERMINANT

International trade and trade policy influence society’s ability to become and remain healthy in a variety of ways (Figure 1). Government procurement of medical products is shaped by trade rules on tariffs, intellectual property, sanitary standards and technical requirements (referred to in trade as technical barriers) and the procurement process itself. The increasing movement of health professionals, foreign investment in the construction and management of hospitals and medical centers, and medical tourism opportunities are just a few examples of how trade influences public health.

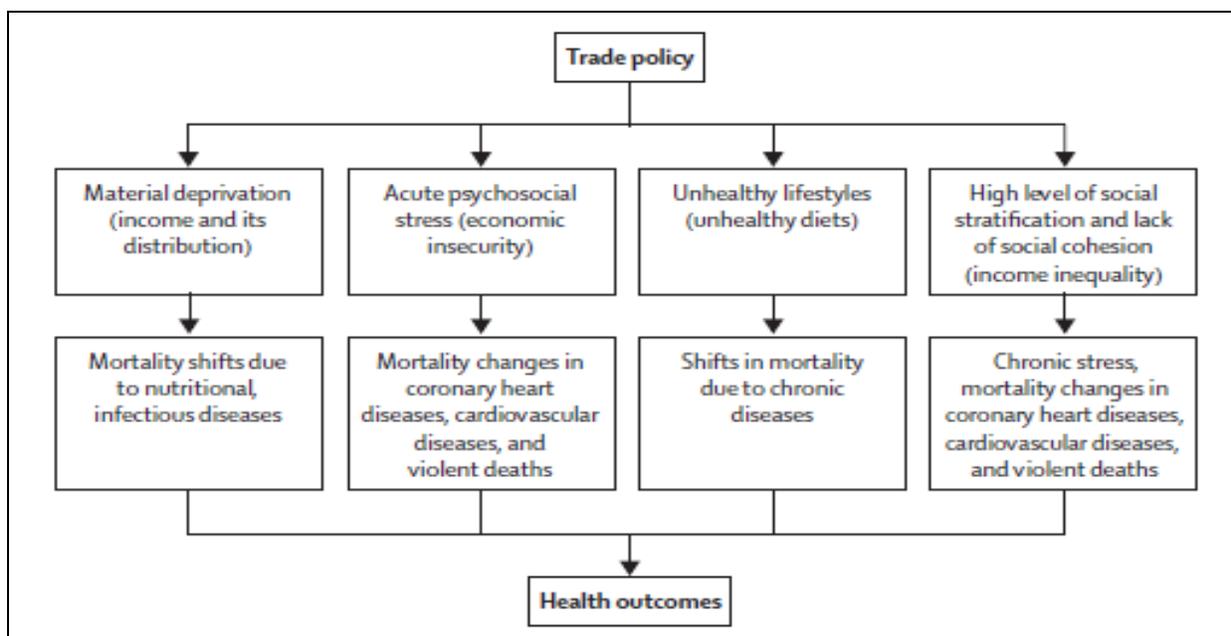


Figure 1. Effect of trade policy on the social determinants of health¹

The links between international trade and public health have been recognized for centuries. In the fourteenth century, the Black Death (bubonic plague) followed heavily-used trade and travel routes, just as the H1N1 (e.g., swine flu) virus used travel routes to spread to more than 200 countries by January

2010.² The first International Sanitary Conference in 1851 and 13 subsequent conferences largely targeted containment of infectious disease outbreaks at port cities, which are hubs for growing international commerce and potential sites for the spread of disease across borders. International health organizations, such as the World Health Organization (WHO), evolved from these early efforts in which trade was recognized as an indirect determinant of health and began to address this topic as early as the 1800s. The WHO has maintained this view and incorporated it into the WHO Work Program and several treaties, including the recently revised International Health Regulations (2005) and the Framework Convention on Tobacco Control.

Widespread understanding of the subject, however, is hindered by the lack of empirical evidence that demonstrates fully how public health intersects with trade policy. This limitation, including issues such as lack of a common research methodology, is finally gaining attention at the global level. A 2007 WHO report on intellectual property and health observed the need for systematic and sustained research and monitoring to assess the impact of intellectual property policies on public health.³ The WHO Executive Board has echoed the call for research and methodologies to understand the intersection of trade and health and has noted the need for experts on both trade and health.⁴

Box 1. Where to find public health in WTO treaties

- 1947 GATT Art. 20(b)
- 1947 GATT Art. 34(1)(a)
- 1994 GATS Art. 14(b)
- 1994 TRIPS Art. 8
- 1994 TRIPS Art. 27(2)-(3)

Trade negotiations, rules and laws are complex, requiring consideration of a variety of variables. Their formation is frequently the product of specific political and economic interests, often with limited understanding or attention to the unintended ramifications related to public health issues. The reason is simple: trade ministers and other trade stakeholders typically focus on and understand best the economic aspects of trade policy. Public health does not automatically factor into their approach to trade debates, particularly as negotiators often possess limited public health expertise. Public health professionals do not usually find themselves on the inside of trade negotiations; a significant limitation often cited by public health experts.⁵

This primer attempts to introduce public health professionals to the basic trade documents and issues that affect public health. It provides a starting point for future action and investigation at a global level, but does not address domestic trade issues. Furthermore, it does not take a position on whether the trade rules are good or bad – the primer’s purpose is to inform and educate.

THE BASICS: INTERNATIONAL TRADE 101

Although international trade is a complex subject, a basic understanding of how international trade works and where it intersects with public health is important for public health professionals, particularly those in global public health. Knowledge of the rules and agreements that govern the trade of goods, services and intellectual property (IP) across international borders provides a foundation on which to build a more sophisticated understanding of the intersection of trade and health. Similarly, familiarity with the organizations that administer the principal multilateral agreements will enable public health professionals to contribute to the discussion of trade issues that affect their work.

Box 2. Defining Trade

International trade is the exchange of goods, services, and intellectual property across an international border. It can involve both the private and public sectors or the national government, which shapes the regulatory environment based on the international rules.

DISSECTING INTERNATIONAL TRADE

The current volume of internationally traded goods and services is unprecedented (see Figure 2). In 2010, global merchandise exports were valued at US\$15.2 trillion and commercial services at US\$3.7 trillion,ⁱ with an increasing contribution being seen from developing countries, which exceeded 45 percent by 2010.⁶ Since 2000, there has been a trend toward economic expansion among developing countries; by 2007, the growth rate in the least-developed countries (LDCs), which have the lowest socioeconomic indicators, fully matched the rate for all developing countries.

At the global level, national governments are represented at the intergovernmental organization, the World Trade Organization (WTO), based in Geneva, Switzerland. The WTO administers the treaties and the global standards by which governments regulate domestic and foreign businesses as they engage in trade across borders. These treaties and standards apply to both the public and private sectors and guide government-to-government interactions on trade matters, including trade disputes.

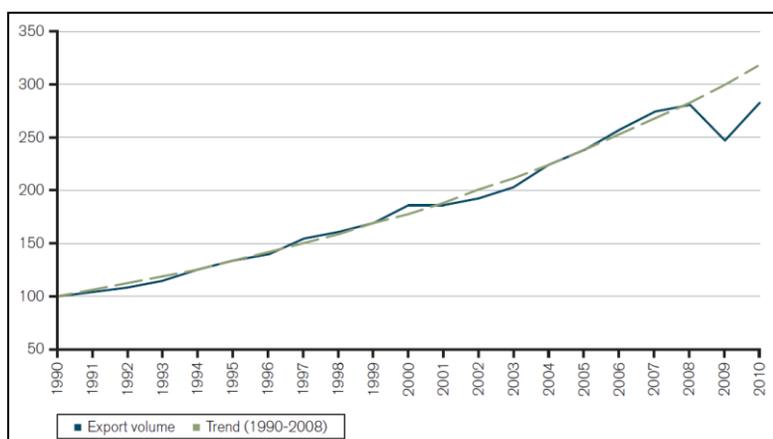


Figure 2. Volume of world merchandise trade, 1990-2010

ⁱ Unless otherwise noted, all monetary values are in U.S. dollars.

WHAT CAN BE TRADED?

There are three things that can be traded, which are governed by the WTO treaties and standards: (1) goods, (2) services and (3) intellectual property. While many other things can be traded, such as securities and other financial instruments, there are only three items governed by the WTO system. Goods were the first recognized category in international trade agreements and include anything that you can physically put your hands on: clothing, metals, office and telecommunication equipment, chemicals, medicines, automobiles, electronics, fuels, and agricultural products, to name just a small

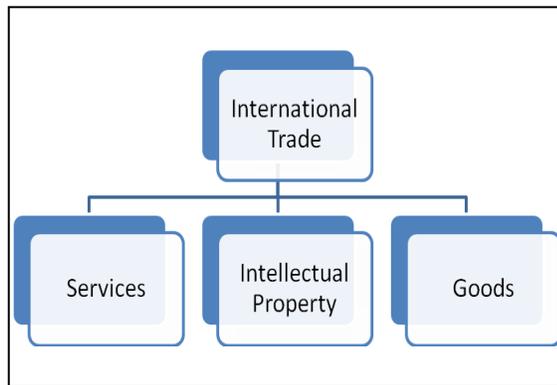


Figure 3. Types of international trade

fraction of the thousands of goods that cross international borders every day. Goods can be finished, raw or partially completed. In the case of health-related trade, raw materials to manufacture a drug are considered 'goods'.

Trade in services, a rapidly growing segment of international trade, includes such sectors as health services, law, communications, construction, education, energy, finance, and tourism. Some services may fall under more than one sector; for example family planning education can be treated as both education and health services.

Intellectual property is a form of property that can be an intangible or attached to a physical item such as a CD of music or words in a book. IP includes copyrights, trademarks and patents. Examples of IP transactions include collecting royalties for the authorized sale of goods that embody or contain intellectual property and licensing protected technology. IP rights, including the right to reproduce or distribute, are attached to the intangible results of the creative process, such as a song or poem. In some cases, the IP-protected item may be attached to a physical object – e.g., a song may be contained on a compact disc, which is traded as a good. Adding to the complexity, IP rights on the intangible item may not automatically transfer with the sale of the tangible product.

WHAT ARE THE BASIC INTERNATIONAL TRADE PRINCIPLES AND MEASURES?

Trade agreements outline or establish guidelines on what national laws and regulations can or must do. All WTO agreements incorporate basic trade principles and measures.⁷ These principles, which were first articulated in the 1947 General Agreement on Tariffs and Trade (GATT), guide negotiations among members and help shape international trade standards.

MOST-FAVORED NATION PRINCIPLE. The name of this principle may be counterintuitive – it essentially prohibits WTO members from playing favorites among WTO trading partners.⁸ All WTO members must be given the same treatment with regard to trade measures, such as tariffs (i.e., taxes) and non-tariff barriers. If a country wishes to grant a special benefit to a trading partner who is a member of the WTO, it must extend the same benefit to all other WTO members. In a sense, it means that all WTO members are most-favored.

NATIONAL TREATMENT PRINCIPLE. Under the national treatment principle, all goods or services being traded within a country must receive the same treatment when it comes to competitive opportunities.⁹ National treatment only applies once a product has entered the domestic market. Therefore, customs duties assessed on imports do not violate this principle as they are not yet being sold in the domestic market. These customs charges are often passed onto consumers, increasing the price they pay for imported products.

Box 3. Development of International Trade Rules

1500s	Trade under colonialism, substantial quantities of spices shipped
1947	GATT goes into effect
1960	European Free Trade Association is established
1993	European Union forms, allowing free trade between its members
1985	US-Israel Free Trade Agreement (first U.S. FTA) takes effect
1994	Uruguay Round leads to the updated GATT and the newly created GATS, TRIPS, and WTO; also, North American Free Trade Agreement takes effect
2006	DR-CAFTA takes effect

TARIFFS. Also known as customs duties, tariffs are taxes imposed by governments on the importer when goods enter a country. They may be imposed for a variety of reasons, mainly as a means to protect local industries, raise revenue, influence competition or cost, or retaliate against another country for violating trade rules. Using pharmaceuticals as an example, tariffs tend to raise the price of medicines where they have been imposed. As such, a 2008 U.N. Millennium Development Goals (MDGs) Working Group report recommends – and is supported by many civil society and international organizations, including WHO – eliminating duties on medicines that are considered essential.^{10,11}

NON-TARIFF BARRIERS. Non-tariff barriers (NTBs) include all other trade measures imposed by governments in an effort to restrict or prohibit imports. These include quota subsidies, inspection regulations, and customs formalities, which effectively reduce the quantity and variety of goods imported into a country, including essential drugs and medical supplies.¹² While NTBs can be necessary to protect public health, as tariffs have declined in the last 20 or so years, their use has increased and can be a barrier to trade.

SUBSIDIES. Subsidies are measures by which governments provide tax credits, direct payments, or other monetary support to a local industry. Subsidies allow the local industry to price its products at a competitive level in relation to imported goods. Domestic subsidies are sanctioned by the WTO, which considers export subsidies and price distortion illegitimate.

PREFERENCES. Preferences are special trade advantages given by governments to trading partners to promote export growth and development, such as tariff preferences. They are often granted by developed countries to LDCs.

THE ROLE OF INTERNATIONAL ORGANIZATIONS IN TRADE

There are two main international organizations that influence public health outcomes – the World Trade Organization (WTO) and the World Health Organization (WHO). As evidenced by the growing body of interest and inquiry related to the intersection of international trade and public health, collaboration between the two organizations is becoming increasingly important.¹³ This section outlines the essential structures and functions of WTO, their impact on public health, and how these intersect with WHO's increasing role in international trade.

WHAT IS THE WORLD TRADE ORGANIZATION?

Established in 1995, the WTO emerged from the recognized need to formalize and institutionalize international trade rules. The organization succeeded the General Agreement on Trade and Tariffs (GATT), which had been the governing body for international trade since 1944. Today, the WTO provides the basic legal framework for international commerce, establishing and upholding the basic guidelines for how countries can engage in international trade. These basic guidelines, known as multilateral or international agreements, harmonize rules across countries and create a standard approach to trade.

ORIGINS OF THE WTO. Ideas regarding an organization to govern international trade first emerged during the Bretton Woods Conference in 1944, during which 44 nations gathered to establish a series of rules for a new international monetary system. Though an International Trade Organization (ITO) was proposed during the conference, an agreement on a formal entity was never reached – although a charter was successfully negotiated, it was never approved. This left the General Agreement on Tariffs and Trade (GATT) – signed in 1947 as a means of lowering tariffs – as the only multilateral mechanism to handle international trade relations.

After nearly 50 years of enforcement, the GATT was succeeded by the World Trade Organization (WTO), which was created following the Uruguay Round (1986-1994) of trade negotiations. With 123 original members, the WTO began administering the updated GATT (GATT 1994), the newly created General Agreement on Trade in Services (GATS), and Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

THE WTO TODAY. The WTO is currently comprised of 153 Members and serves as a forum for intergovernmental dialogue and negotiation on international trade.¹⁴ Members are responsible for determining membership rules, including who can serve as an observer, and they agree to be bound by the agreements administered by the WTO. During the accession process, applicants engage in a process to bring national laws into compliance with WTO's international standards requirements. WTO membership focuses on the application of a common set of trading rules, a means to resolve disputes, and the establishment of a “level playing field” on which to trade by the integration of the international rules into national practice.

The organization structure includes three principle components: (1) ministerial conferences; (2) the General Council; and (3) the Secretariat (Figure 3). In addition to Member states, numerous international intergovernmental organizations have been granted observer status for one or more of WTO's councils or committees.¹⁵

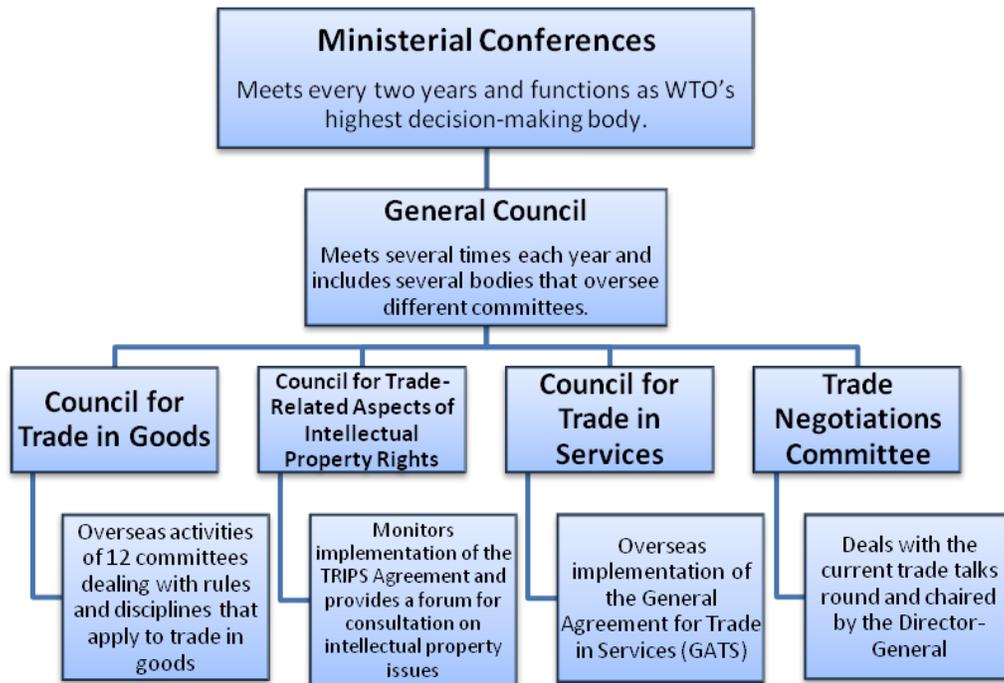


Figure 4. WTO Organogram

- ❖ **MINISTERIAL CONFERENCES.** Meets every two years and functions as WTO's highest decision-making body.
- ❖ **GENERAL COUNCIL.** Meets several times each year and includes several bodies that oversee different committees. These include (a) Council for Trade in Goods; (b) Council for Trade-Related Aspects of Intellectual Property Rights; (c) Council for Trade in Services; and (d) Trade Negotiations Committee.
- ❖ **SECRETARIAT.** The organization is the Secretariat for 26 international trade agreements.¹⁶

The WTO is relatively small, particularly in comparison to the World Health Organization. WTO operates on roughly one-eighth the budget and a total staff of 560 and has no regional or country offices.

WTO's Role in International Trade

The WTO is the only intergovernmental organization dealing with international trade rules. Many of today's international trade agreements have resulted from negotiations among members of the WTO and have provided internationally accepted standards that guide nations in addressing international trade under their domestic laws.¹⁷ The WTO outlines the minimum requirements and principles, but allows members some flexibility to edit and adapt agreements to fit their local context.¹⁸ This mutually reinforcing relationship also extends into the spheres of transparency, as members are required to inform the WTO about relevant rules and laws, and in-turn, submit to WTO-conducted reviews.

The WTO serves several basic functions, often working in conjunction with other international organizations, such as the WHO and the International Labor Organization (ILO). WTO functions include:

- (1) Administering trade agreements;
- (2) Providing a forum for trade negotiations;
- (3) Adjudicates trade disputes;
- (4) Monitoring national trade policies; and
- (5) Providing technical assistance and training for developing countries.¹⁹

As with any international institution, the WTO receives both support and criticism. Trade is recognized by many as an essential catalyst for economic growth and poverty alleviation. In this light, supporters of the WTO view the organization's rules as enabling for global economic output and increasing living standards. On the other hand some experts have raised concerns regarding WTO's inclusiveness, particularly in the decision-making process.²⁰ Such concerns point to the continuing power differential between economically developed and developing countries in trade negotiations, which some advocates claim results in a system wherein trade decisions favor developed country interests, particularly commercial interests, rather than the interests of development, human rights, health, safety and the environment.^{21,22} An often cited example is the use of export subsidies by developed countries, which critics claim distort the ability of developing countries to enter the same markets as companies from developed countries. Export subsidies are often illegal because of their potential for price distortion, which can unfairly cause an imbalance in trade for some countries.²³

THE DOHA DEVELOPMENT ROUND. The WTO hosts ongoing trade negotiation rounds, which are periods of multilateral trade negotiations on a predetermined set of trade issues. The current trade negotiation round – the Doha Round – began in November 2001 following the Ministerial Conference in Doha, Qatar. Since the GATT, only eight rounds of multilateral trade negotiations have taken place – one of the most important being the Uruguay Round, which saw the establishment of the WTO at its conclusion (see Table 1).

Geneva Tariff Conference	1947
Annecy Tariff Conference	1949
Torquay Tariff Conference	1950-51
Geneva Tariff Conference	1955-59
Dillon Round	1960-61
Kennedy Round	1963-67
Tokyo Round	1973-79
Uruguay Round	1986-94
Doha Round	2001-

The Doha Round commenced after trade ministers agreed to the Doha Ministerial Declaration, which outlined a series of trade topics, including agriculture, services and intellectual property. In addition, the Doha Round – dubbed the Doha Development Round – has a specific focus on development, particularly in the context of trade concerns facing developing countries.²⁴ Several of these concerns relate directly to preserving public health, which the Doha Development Round attempts to uphold. The Doha Declaration reaffirmed the importance of public health considerations in trade policies, and specifically reiterated WTO member rights when addressing access to essential medicines issues.²⁵ Despite some progress, talks persistent differences still exist between many developed and developing nations over agricultural subsidies, industrial tariffs, and non-tariff barriers that apply to medical technologies, services, and trade remedies.

OTHER THAN WTO AGREEMENTS, ARE THERE OTHER TRADE INSTRUMENTS?

In addition to the WTO's rules and agreements, there are numerous secondary arrangements organized on a regional, plurilateral, and bilateral basis. Non-member countries do not have to recognize WTO rules in the course of trade activities. However, they may participate in regional or bilateral arrangements that include WTO members and are modeled on the WTO rules and international standards.

The number of these non-WTO arrangements is growing and can take a variety of different forms, including plurilateral, regional, and bilateral trade agreements and unilateral positions taken by just one

country. The resulting agreements apply only to trade between those states that are signatories to the treaty.

- ❖ **Plurilateral trade agreements** are negotiated and signed by some WTO member countries to target a single global issue. Examples include the Pharmaceutical Tariff Elimination Agreement and the Agreement on Government Procurement. If all of the WTO members sign the agreements are considered multilateral.
- ❖ **Regional trade agreements (RTAs)** are negotiated and signed by countries belonging to a particular region, either an informal, geographic construct or a formal political organization. The number and geographic reach of RTAs are steadily increasing, and there are several prominent examples, including the European Union, South African Development Community (SADC), Mercosur, Gulf Cooperating Council (GCC), Association of Southeast Asian Nations (ASEAN) and Economic Community of West African States (ECOWAS). The WTO maintains an online database of all 202 RTAs currently in force.²⁶ Many regional trade agreements include provisions on services, investments, technical barriers to trade, and competition rules.²⁷
- ❖ **Bilateral trade agreements** are negotiated between two countries and specify trade conditions between only the two contracting countries. Many such agreements come in the form of free trade agreements, which have increased during recent years, particularly those involving the United States.²⁸
- ❖ **Unilateral trade policy and legal positions** are individual country positions on trade that WTO members can take as long as the position is not in violation of any of its international obligations or the country is willing to face retaliation if there is a violation.

Box 4. WTO committees and councils involved in TRM

- Agriculture
- Market access
- Sanitary and phytosanitary measures
- Safeguards
- Antidumping
- Rules of origin
- Subsidies and countervailing measures
- Import licensing
- Customs valuation
- Technical barriers to trade
- Trade in financial services
- Investment measures
- Balance of payments
- Goods
- Services
- TRIPS

OVERSIGHT MECHANISMS OF INTERNATIONAL TRADE

Review or oversight of international trade occurs at the multilateral, bilateral, and national levels. National oversight is handled officially by government agencies and courts and unofficially by watchdog organizations and citizens. The multilateral trade environment, on the other hand, is slightly more complex, regulated through several review and dispute resolution processes that ensure the smooth operation of WTO agreements. These processes, all of which offer entry points for participation by public health professionals, include trade policy reviews (TPR), transitional review mechanisms, and dispute settlement.

TRADE POLICY REVIEWS (TPR). The WTO conducts multilateral trade policy reviews. Member states participate on a voluntary basis in each TPR, which is also a means of influencing policy. Reviews are available online at <http://www.wto.org>.

TRANSITIONAL REVIEW MECHANISM (TRM). In TRM reviews of compliance to WTO commitments, members may submit questions in advance, including questions submitted by a member's citizens. Public health professionals can participate in this process. The frequency of review is based on a member's share of world trade – countries with large shares of world trade, such as China and the United States are

reviewed annually. Reviews take into account the economic environment, trade and investment regimes, trade policies and practices, and trade policies by sector. Other circumstances, such as market behavior and structure, fair trading, product safety, credit contracts, and consumer finance are also considered.

DISPUTE SETTLEMENT. The WTO is unique in its authority to hear disputes, make determinations, and impose remedies and sanctions for member violations. Dispute cases are categorized by subject – health is not a subject, but categories related to health issues include bottled water, food items and cigarettes. Member countries, generally through their trade representatives, raise cases for resolution or to correct violation of a trade rules. Countries occasionally may accept potential retaliations rather than correct measures that violate a WTO trade rule. Retaliation, which conflicts with most favored nation treatment, can include such actions as imposing quantity limits on products from the country against which a dispute has been settled.

WHAT IS WHO'S ROLE IN TRADE?

WHO's core mandate, as articulated in its constitution, is to protect and promote the mental, physical, and social well-being of the world's population. The organization fulfills three recognizable and discrete roles in (1) setting global norms and standards in public health; (2) directing and coordinating among various actors; and (3) researching and monitoring public health issues, such as disease eradication efforts.²⁹ Though WHO has no authority or formal role in regulating or administering international trade, it can and has undertaken a role in collaborating and participating in trade matters.

Much of WHO's engagement in international trade began shortly after the Doha Declaration under then Director-General Gro Harlem Brundtland. Under Brundtland's leadership, WHO assumed a more prominent role identifying actual and potential links between trade (including WTO agreements) and health. Many of these links were first comprehensively described in a 2002 joint WHO-WTO report entitled *WTO Agreements and Public Health*.³⁰

Since then, WHO has sponsored studies, developed training tools and materials, held workshops and increased its collaboration with other international organizations and technical support to Member States. In 2006, the World Health Assembly (WHA) – the decision-making body of the WHO that meets annually and includes member-appointed delegates – issued to its members and to the WHO Director-General a call to action for greater cooperation between the health and trade sectors.¹ The goal of this call was to ensure that trade policies are formulated in a way that best addresses the problems faced by the health sector, including in such areas as infectious diseases, food safety, tobacco, environment, access to medicines, health services, food security and nutrition, and emerging issues such as biotechnology.

Though WHO does not maintain a department devoted exclusively to trade, it undertakes trade-related activities under a number of its departments and programs, including:

- ❖ Immunization, Vaccines, and Biologicals;
- ❖ Medicines Policy, Essential Drugs and Traditional Medicine;
- ❖ Ethics, Equity, Trade and Human Rights;
- ❖ Public Health, Innovation and Intellectual Property; and
- ❖ The Tobacco Free Initiative.³¹

WHO is also now more involved, formally and informally, with relevant trade proceedings at WTO. For example, WHO holds ad hoc observer status to the WTO Councils on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Trade in Services; serves as a member of the Committees on Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPM); and attends Special Sessions of the Council on Trade in Services as an observer, upon invitation.

THE BASIC PUBLIC HEALTH-RELATED TRADE AGREEMENTS: CONTENT AND KEY ISSUES

Though there are more than 20 WTO agreements, five are critical to public health (Table 2). Of these five agreements, three – GATT, GATS and TRIPS – cover the main trade categories of goods, services and intellectual property (IP), respectively. Two other agreements address regulations that impose requirements on products and services: the Agreements on Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPM), which deal with health products and safety regulations.

WTO agreements place an obligation of transparency on all signatories: a country must publish or otherwise make available information relating to all trade measures in a format that is easy to access, free, and in English (the language of international trade). It must also notify the WTO of any new laws or regulations that may affect existing commitments. This type of transparency helps to promote good governance and minimize information asymmetry. However, finding information about the local laws, regulations, or rules related to a nation’s health system can be a daunting task.

Table 2. Selected Trade Agreements and Health Topics

Issue	Trade Agreement	Health Topic
Women’s health	GATS	Brain drain
Children’s health	SPS, TBT	Safety standards on products, such fire retardation for toys
HIV/AIDS	TRIPS	Access to drugs and patents
Infectious diseases	GATT	Reduced tariffs on essential medicines
Health systems	GATT	Medical products public procurement

THE GENERAL AGREEMENT ON TARIFFS AND TRADE (GATT)

Since 1947, GATT has become one of the most significant legal texts for international trade, defining in many ways the key international trade principles and mechanisms that govern international trade today. The main purpose of the 1947 GATT and its revisions in 1994 is the “substantial reduction of tariffs and other trade barriers and the elimination of preferences, on a reciprocal and mutually advantageous basis.” While GATT is an agreement governing trade in goods, it also defines key international trade principles and mechanisms, including subsidies, preferences, and non-tariff barriers.

The key trade principles in GATT, such as most-favored nation principle, tariffs, and subsidies (see section “The Basics: International Trade 101”), are generally applicable to all goods and specifically to those that are imported. Goods can be imported in two ways: by the government via public procurement and by the private sector through private international trade transactions. In the case of health goods, items such as hospital beds, uniforms, essential medicines, vaccines, computers, X-ray equipment, test kits, API, bed nets, reagents, syringes and baby warmers would all fall under GATT’s jurisdiction. In addition, a country’s own regulations on particular goods can determine whether GATT provisions are applicable. For example, an essential medicine may or may not be subject to a tariff reduction – it is necessary to check the national rules to verify the tariff status for the drug. This relationship between GATT and national law and regulation is the basis of the link between GATT and health.

Box 5. The Doha Round Highlighted Issue: Waiver Extension

The WTO General Council will make a determination on a proposal to extend the ten-year waiver that allows developing countries to provide preferential tariff treatment to products of LDCs without being required to extend the same tariff treatment to other WTO members. This promotion of South-South trade (i.e., between developing countries) could be applied to, for example, raw materials and generic drugs. Given that trade between developing countries has grown significantly over the past nine years, the adoption of this proposal would have a significant impact in encouraging trade between developing countries.

GATT also contains provisions that allow for national legislation to reconcile potential conflicts between trade and health. For example, Article XX (b) states that “nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures ... necessary to protect human, animal, or plant life or health.” Article XXIV (1) (a) cites the Agreement’s aim to raise the “standards of living and the progressive development of the economies of all contracting parties.” GATT reiterates the importance of raising health standards in the least-developed countries. Reconciling health and trade issues has been demonstrated in both the Doha Declaration and the International Health Regulations, which permit a country to block trade for the benefit of health in the event of an internationally significant disease outbreak, as defined in the Regulations.³²

THE GENERAL AGREEMENT ON TRADE IN SERVICES (GATS)

During the Uruguay Round of negotiations, WTO members recognized the increasing trade in services – particularly in health, education, telecommunications and insurance – and the need for an international agreement. GATS entered into force in 1995, providing a standardized framework to govern service-related trade. Several health-related sectors and sub-sectors that may be liberalized under GATS include specialized and general health personnel, nursing services, ambulance services, and physiotherapeutic and paramedical services by medical and dental laboratories.

GATS addresses issues that arise when a nation opens its borders to services provided by citizens of another country. Under the agreement types of traded services are delineated as four different modes:³³

MODE 1: CROSS-BORDER SUPPLY – e.g., telemedicine; outsourcing of medical records transcription; audio, visual and data communications; consultancies; and web conferences.

MODE 2: CONSUMPTION ABROAD – e.g., a patient entering another country seeking health care, medical tourism or studying a health profession abroad.

MODE 3: FOREIGN COMMERCIAL PRESENCE – e.g., a commercial organization establishing a presence in a country other than its home country or foreign investors investing in a local entity (such as a hospital or health insurance company) or in health-related products (such as insecticide-treated bed nets).

MODE 4: MOVEMENT OF NATURAL PERSONS – e.g., health professionals moving from one country to another to work in health.

Box 6. Examples of services liberalized in the 50 commitments of record

- Medical labs
- Veterinary services
- Dentists
- Hospitals
- Physiotherapy
- Paramedical services
- Nursing
- Midwives

Mode 4 is arguably the most complex, involving migration of trained professionals, commitments across multiple modes or sectors, and return of government-funded investment in personnel. Research on such movement often explores the impact of immigration on non-migrants, however, the barriers and implications of emigration are increasingly being explored.³⁴ More specifically, the health workforce is increasingly transitory, often migrating from low-resource settings to countries with a more robust formal labor market (known commonly as ‘brain drain’). This complex movement of persons, however, has implications for both sending countries (e.g., health and financial costs, as many emigrants received training that was at least partially government-funded) and receiving countries (e.g., professionals working abroad often send a portion of their earnings home to their families in the form of remittances), prompting WHO member states to adopt a Global Code of Practice on the International Recruitment of Health Personnel.^{35,36}

COMMITMENTS. GATS neither requires members to open any sector to foreign competition nor prohibits government or private monopolies. GATS allows each nation to decide which sectors to open to trade and foreign competition, i.e., which commitments it chooses to make. A nation must provide details for each commitment related to the mode of services, the type of services included and whether it will be a full, partial, or unbound commitment.³⁷ A full commitment denotes all health services are liberalized; partial denotes that just nursing services are liberalized; and an unbound commitment means a commitment has yet to be made. Furthermore, a country may specify the sectors in which it intends to treat foreign service providers differently than it treats national service providers.³⁸

Health-related factors that could cause a government to make commitments under GATS include the nature of the country’s health system, infrastructure needs, private sector presence and the degree to which certain sectors are the topic of negotiations. Commitments may encourage more international suppliers and investors to enter the domestic market, which can strengthen the local economy. With this cross-border flow of services, the local public health sector may benefit from increased skills and expertise.³⁹ Furthermore, trade in services in other sectors may have an impact on health; for example, commitments in a country’s financial sector may affect health insurance (Box 7).⁴⁰

Box 7. Emerging Issues Related to GATS

In the Special Session of the Council for Trade in Services, some members have identified the removal of limitations relating to non-portability of insurance schemes under Modes 1 and 2 as objectives for the market access negotiations in this sector.⁴⁰ In addition, GATS rules not yet conclusively negotiated include emergency safeguards, subsidies, government procurement, and the optional carve-outs for essential health services or primary health services.

THE CARVE-OUT FOR GOVERNMENTAL SERVICES. GATS applies in principle to all but two service sectors, one relevant to health and the other to air traffic rights. The health-related carve-out exempts services that are supplied by governments and that are not available through commercial or other providers.⁴¹ This exception has a deeply felt impact, given the number of countries where the government is a major, if not the only, supplier of health services.

THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

A significant number of products crossing international borders everyday have intellectual property (IP) rights attached to them. These IP rights are largely in the form of copyrights, trademarks and patents, which are associated with a creative process – from jotting down a poem to inventing a life-saving medicine or vaccine based on years of research and development. IP is an intangible property right that can be owned by a person or *entity*, such as a community-based organization, a corporation, or even a government. National laws define what can be considered IP, how ownership is established, what rights an owner has, and how this kind of property is protected against unauthorized usage. As IP status is

determined by national law only, the establishment of a right of record is done on a country-by-country basis.

TRIPS, which entered into effect in January 1995, establishes minimum standards for national intellectual property legislation as it relates to international trade (i.e. IP that is exclusively traded domestically is not subject to TRIPS). TRIPS works in conjunction with and supplements earlier international agreements on IP, including the Universal Copyright Convention (UCC) the Berne Convention for copyrights, the Madrid System for trademarks and the Patent Cooperation Treaty (PCT) for patents. Like other WTO agreements, a country must enact national legislation that is adapted to its own interests but does not conflict with TRIPS.

TRIPS respects national autonomy over public health issues and strives to find an appropriate balance between the needs of the public and the rights of IP holders.⁴² Article 8 allows a nation to take measures necessary to protect public health. Article 27 provides authority for nations to limit patents related to public health – for example, WTO may exclude from patentability certain diagnostic, therapeutic, or surgical methods that are essential public health interventions. The enforcement mechanisms mandated in TRIPS are designed to ensure that nations are able to carry out public health and safety laws.⁴³ Given growing concerns that TRIPS patent rules may limit access to essential life-saving drugs in developing countries in certain circumstances, the 2001 WTO Ministerial Conference in Doha reiterated the importance of public health. The Doha Declaration elevated health above basic IP concerns, affirming that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.”⁴⁴

COPYRIGHTS. Copyrights are used to protect creative expressions, but not ideas, procedures, methods of operation or mathematical concepts.⁴⁵ Creativity may bring to mind songs, art and books, but it also includes the creation of, for example, databases and software. The expression must be original and fixed – a poem must be written down or a song recorded – to receive copyright protection. Barring certain exceptions, a copyright allows the holder the exclusive rights of reproduction, adaptation, publication, performance, and display. The copyright holder can license these rights to others without giving them up; for example, a software developer allows people to license programs if they agree to the terms of usage.



TRADEMARKS. A trademark distinguishes one person or organization’s goods or services from those of others. Trademarks include words, symbols, logos or phrases. For example, the Global Health Council’s logo constitutes a trademark. The holder of a trademark has the right to prevent others from using the mark (or a similar one) in a manner that would cause confusion for consumers regarding the origin or sponsorship of a good or service.



PATENTS. Patented products surround us in our everyday lives, from cell phone technology to disposable water bottles. A patent is used to protect technological information in products and processes by granting the patent holder the exclusive right, typically for 20 years, to make, use and sell an invention. In exchange for the period of exclusivity, the underlying social contract is that the knowledge from the innovation process becomes part of the public record. To receive a patent, the product creator must apply for a patent, which requires disclosure of the details of the creative process, including drawings, diagrams, and research data. The application becomes part of the public record unless the applicant requests that the application not become public.⁴⁶ The incentive of patent protection has been particularly challenging when addressing neglected or orphan diseases, as the return on investment may be limited.

Other IP issues

In addition to copyrights, trademarks and patents, there are other protection mechanisms, such as geographical indicators (a product name that denotes the region of production, e.g. Parmesan cheese) and industrial designs (aspects of a product's aesthetics that are not simply utilitarian in nature).

Box 8. Counterfeits: a key TRIPS issue

Counterfeit health products and pharmaceuticals have the potential for wide-reaching and devastating results. Counterfeit medicines sold with markings of a well-known drug have been known to cause the deaths of unsuspecting victims. IMPACT and ACTA are two noteworthy efforts aimed at combating trade and manufacture of counterfeit drugs.

IMPACT, short for International Medical Products Anti-Counterfeiting Taskforce, a task force initiated by the WHO attempted to bring together stakeholders to address the problem. The Anti-Counterfeiting Trade Agreement (ACTA) is a proposed international agreement, the aim of which is to enhance the some elements of enforcement standards to strengthen international cooperation to combat counterfeits of all types.

Furthermore, traditional medicines, biotechnology, genetic materials and discoveries, medical devices, and technology transfer may also be protected, depending on decisions a country makes as to its domestic laws and as long as these are in compliance with TRIPS.⁴⁷

COMPULSORY LICENSES. Under TRIPS Article 31, government authorities may license the use of protected IP to a third party, regardless of consent from the rights holder.⁴⁸ TRIPS also stipulates a negotiation period between a member state and the rights holder unless in the case “of a national emergency or other circumstances of extreme urgency.” CLs are most well-known to public health for their use in trying to achieve greater access to essential medicines, notably for HIV/AIDS drugs.^{49,50} Access to patents has evolved into a debate over economic incentives versus access to essential medicines. Those arguing for the former note that the financial benefits from patents are needed to ensure further research and development for new medicines

and vaccines; those arguing for the latter suggest that the market exclusivity granted by patents restricts knowledge and delays the creation of generic medicines desperately needed throughout the world. More countries began to invoke this claim between 2003 and 2005, which saw a marked increase in CL episodes, roughly two-thirds of which were for HIV/AIDS drugs.⁵¹ Since 2006, researchers have noted a substantial decline in the use of CLs.⁵²

PROTECTION OF DATA SUBMITTED FOR REGISTRATION OF PHARMACEUTICALS. TRIPS Article 39(3) requires that member states establish protections for test data submitted in conjunction with patent applications. In order to bring a new product to market, pharmaceutical companies must first submit data demonstrating the safety, quality and efficacy of the product to a regulatory authority. Art. 39(3) is construed by some member states to extend exclusivity to the same test data used in an application for marketing approval. An entity other than the originator may file for authorization but do so with permission of the originator and with the data. As a result, competing drug manufacturers are unable to gain access to the relevant test data for reproduction of the product, which, according to some, impedes entrance of generic drugs into the marketplace during the exclusivity period.⁵³ Conversely, proponents of data exclusivity point to the significant investments made by product originators to generate the data to support their argument that originators should be awarded a period when a regulatory authority cannot rely on such data to register generics.⁵⁴

EXHAUSTION AND PARALLEL IMPORTS. The Doha Declaration reaffirms members' rights to establish their own systems regulating parallel importing, which is the importation of a patented product into a country without that patent holder's consent. TRIPS states that once a product has been marketed with the patent holder's consent in one country, the patent holder cannot prohibit the resale of that product. This is known as the principle of exhaustion; the patent holder's rights in a market have been exhausted through the initial sale of the product.

Box 9. The emergence of human rights as a trade issue

There is a growing body of literature that explores the relationship between human rights and trade, especially in the realm of public health. For example, in 2009 the U.N. Special Rapporteur to the UN Commission on Human Rights released a thematic report that analyzed TRIPS and the right to health with emphasis on the access to medicines. This report suggests that the obligations imposed on countries that have adopted human rights conventions should also be applied to corporations. Moreover, the report proposes an expansion of the role of private companies beyond their legal mandate of enhancing shareholder value by adding the responsibility of fulfilling a social function within a viable business model. While morally compelling to some, the legal validity of these views has been questioned while also buopening the door to discussion of the roles and responsibilities of corporations. At the same time, others have argued that the U.N Special Rapporteur overstepped the bounds of his mandate, offering a viewpoint unsupported by current human rights law. Regardless, the ensuing debate will undoubtedly be of great interest to public health professionals.

THE TECHNICAL BARRIERS TO TRADE AND SANITARY AND PHYTOSANITARY MEASURES AGREEMENTS

WTO Members have negotiated two notable agreements that hold that public health is a valid reason for instituting trade restrictions.⁵⁵ These are the Technical Barriers to Trade (TBT) Agreement and the Sanitary and Phytosanitary Measures (SPS) Agreement.

In addition to WTO agreements, other international agreements permit limitations on trade for the protection of public health. For example, the Codex Alimentarius sets standards for food safety and moving food across borders in international commerce. Adhering to these standards helps ensure better access to markets for exporting nations.

Box 10. Food security as an emerging international trade issue

Every public health professional understands the importance of nutrition, including both the quantity and quality of foods consumed. For countries that rely on imports for a significant portion of their food supply, the removal of barriers is essential, as is the importance of maintaining measures to protect food safety. As transporting foods across borders becomes easier, greater importance is placed on ensuring food safety: “With respect to the ever-increasing global market ... the advantages of having universally uniform food standards for the protection of consumers are self-evident.” Both the TBT and the SPS, often in conjunction with the Codex Alimentarius, work to define the international standards that will provide the needed safety.

Concern over food security is apparent in the Doha Round debates over agricultural subsidies and in recent efforts to block the export of foods during the 2008-2009 price escalation. Agricultural exports are a mainstay for many countries and a path towards improved economies at household and national levels. Trade-distorting subsidies on basic commodities, such as corn, wheat or sugar, can have a greater impact on developing country economies compared to countries with large economies.

TBT AGREEMENT. The TBT was developed in the Uruguay Round and aims to prevent tariffs and non-tariff barriers that unnecessarily restrict trade. Though it allows for trade restrictions for “legitimate reasons” – protection of human health or safety, animal or plant life or health, environment, and national security interests; and prevention of deceptive practices – it prohibits unnecessary technical restrictions that act as obstacles to trade. Although the Agreement encourages the use of international standards, signatories may deviate from them if their application would be “ineffective” or “inappropriate” in fulfilling the legitimate objective in question.⁵⁶

One example of a TBT agreement involved a negotiation between Peru and the European Commission (EC) in 2001. Claiming violation of the TBT, Peru requested consultation with the EC concerning an EC regulation that prevented Peruvian exporters from using the term “sardines” on

product packaging. Peru’s argument was that such use fell within the food safety standards of the Codex Alimentarius. This regulation, Peru claimed, constituted an unjustifiable barrier to trade. However, the Panel found that the regulation was a “technical regulation,” as defined by the TBT and the EC was within its rights to set the relevant standard, as described at: <http://www.worldtradelaw.net/reports/wtopanels/ec-sardines%28panel%29.pdf>.

SPS AGREEMENT. The SPS limits a member’s ability to set policies concerning food safety and plant and animal health. The Agreement requires that any restrictions are based on scientific justification. Although the precautionary principle allows members to err on the side of caution when facing a potential threat that lacks scientific certainty, if such restrictions are not based on some rationale they can be set aside in a dispute resolution process under WTO rules.

As an example, in 1996, the trade disputes arose between the EC and Canada and the United States when the EC prohibited importation of meat and meat products that had been treated with certain hormones

were governed by the SPS. The original WTO Dispute Resolution Panel that reviewed the case found the EC's trade measures were a violation of the SPS. However, the Appellate Body reversed the findings and found that concern over the presence of these hormones in the beef was rational and thus the prohibition was not found to be in violation of trade rules.

INFORMING TRADE POLICY

Trade policy is formulated in the same manner as other national policies, with the goal of creating a positive scenario and mitigating adverse consequences. National governments control trade policy, though there are roles for other actors, including trade associations, civil society, religious organizations, and corporations. Public health professionals, whether in the public or private sector, have a natural role in working to reduce or eliminate the negative effects of trade policies on health. In the end, trade policy benefits from an iterative process with input from all stakeholders.

WHAT ARE THE STEPS?

The steps outlined in the WHA on international trade and health (Resolution WHA 59.26) are a starting point for Member States when considering health in trade policy. They include:

- (1) to provide support to Member States, at their request ... to frame coherent policies to address the relationship between trade and health;
- (2) to build the capacity to understand the implications of international trade and trade agreements for health; and
- (3) to continue collaborating with the competent international organizations in order to support policy coherence between trade and health sectors at regional and global levels, including generating and sharing evidence on the relationship between trade and health.

The WHO approach can serve as the framework for the public health community to engage in trade policy formulation and can be adopted or adapted depending on the mission, scope and capacity of each public health professional or organization.⁵⁷ The following are key areas and potential activities for public health professionals to engage in international trade policy.

1. GATHER, UNDERSTAND AND SHARE EVIDENCE

- Identify and develop competence gathering and understanding the variety of trade data and their sources, including the *Manual on Statistics on International Trade in Services*, to inform the policy development process;⁵⁸
- Subscribe to listservs and information sources related to international trade and public health; and
- Consider taking on international trade and public health as a field of research.

2. COLLABORATE AND BUILD CAPACITY

- Join existing NGOs and civil society organizations, networks, and collaborations engage in trade and public health issues;
- Share informational materials with others in your community;
- Encourage the local public health association or government to host a seminar;
- Enroll in a graduate course, seminar, or workshop related to international trade and public health;
- Find ways to build knowledge, such as talking with knowledgeable people (e.g., law school or public health professors, and WTO or WHO technical advisors); and

- Identify people who are dually trained in trade and health and engage other professionals to grow the understanding of trade and public health within your professional community.

3. PARTICIPATE AND INFORM THE POLICY PROCESS

- Assist in the work of NGOs and civil society organizations that focus on trade issues, such as conducting trade and analysis, serving on national trade advisory committees, commenting on proposed agreements, and organizing information and briefings for Ministerial meetings;
- Participate in community and public forums on trade and public health organized by governments or international organizations, including the WTO;
- Ensure that the health ministry is part of the trade delegation and policy formulation process;
- Urge policy-makers to take positions in support of health within your country and at the multilateral, regional, and bilateral levels.
- Find out where countries stand on trade matters and whether they are WTO members;
- Engage legislators (and legislative staff) who play a role in drafting or regulating trade agreements; and
- Identify key agencies and ministries – in the United States, the U.S. Trade Representative and the International Trade Administration under the Department of Commerce are key players in developing and negotiating trade policy.

CONCLUSION

Despite the fact that the protection of public health has been recognized as an exception to trade rules for more than 60 years, challenges to finding coherence between trade and health policy remain. The participation of public health professionals is critical to ensure that health is protected in trade policy and agreements. Similarly, trade professionals need to engage on health issues to understand better the epidemiologic, medical, economic and social implications of limitations on health services, products and innovations. The interdisciplinary nature of global health requires multi-sectoral input.

Trade in goods, services and intellectual property covers a broad range of health-related topics – from distribution of medication to workforce management to developing new and innovative approaches to care. A standard set of rules that levels the playing field for developing countries can facilitate their ability to participate and compete in the international trade arena. A major benefit of WTO agreements is that they are negotiated between and enforced by member countries – providing a common foundation on which both WTO members and non-member countries can build.

The views and experiences of civil society advocates and public health professionals can bring an influential and practical perspective to national and international policy formulation. The complex relationship between the public and private sectors varies by country, as does the level of acceptance of civil society engagement. Countries in which civil society is not fully integrated into the political system may benefit from the external influence of the WTO and its members, similar to the dynamic in the World Health Assembly, where ministers of health interact with each other and the WHO staff.

To incorporate global health perspectives more fully into international health, there is a need for bi-directional education between the trade and health communities. Further, there needs to be a willingness to work together in a constructive manner to identify and achieve common goals. Of course, this is possible, but it requires commitment from both communities to promote dialogue and to learn from each other.

ADDITIONAL RESOURCES

“Trade and Health” Lancet Series (Launched January 21, 2009) – www.thelancet.com

Global Health Council Trade and Health Series (Launched January 27, 2010) - www.globalhealth.org

Fact Sheets

- Trade and Health: 101, January 2010
- WHO/WTO Roles and Responsibilities, January 2010
- Food Security, Trade and Health, January 2010
- Counterfeit and Substandard Drugs in Low Income Countries, January 2010
- Global Health Implications of Intellectual Property and TRIPS, March 2010
- Trade and Health Workforce Migration, March 2010
- International Trade in Medical Products, April 2010

Other Publications by the Global Health Council

- Understanding Private Sector Involvement in Health Systems, Research Brief, DATE
- The Impact of Tariff and Non-Tariff Barriers on Access to Essential Drugs for the Poorest People, Policy Brief, DATE

International Organizations

World Trade Organization – www.wto.org

World Health Organization: Trade, Foreign Policy, Diplomacy and Health - <http://www.who.int/trade/en/>

World Intellectual Property Organization – www.wipo.int

United Nations Conference on Trade and Development – www.unctad.org

U.S. Government Offices and Agencies

Office of the United States Trade Representative (USTR) - www.ustr.gov

Food and Drug Administration – www.fda.gov

GLOSSARY

Bound	To be obligated by the terms of the agreement
Collective Request	A request by several countries submitted to a GATS signatory requesting market access in a specific sector or sub-sector
Concession	A tariff reduction, tariff binding, or other agreement to reduce import restrictions; usually accorded pursuant to negotiation in return for concessions by other parties
Good	Something that has economic utility or satisfies an economic want
Liberalize	In trade, to remove barriers for greater access to markets
Measure	A law, regulation, rule, or procedure; a decision, administrative action, etc., whether taken by a central, regional or local authority
Medical Tourism	A term applied to the practice of patients shopping across borders for health interventions that may not be available as readily in their home country
Treatment	Lowest tariff rates it applies to any other country
National Treatment	Trade principle that affords individuals and firms of foreign countries the same competitive opportunities, including market access, as are available to domestic parties
Negotiating Proposal	A proposal regarding the structure and content of a proposed negotiation
Non-tariff Barriers	Measures other than tariffs imposed by governments which restrict imports with or without the intent to do so
Precautionary Principle	The principle stating that defensive measures should be taken if there is a potential threat to human health, even if the scientific evidence for such precautions are not fully established
Protectionism	An economic policy characterized by higher tariffs, the application of regulatory requirements to non-nationals in a manner different from nationals, or subsidies and other measures that limit trade
Preferences	Special trade advantages (e.g. tariff preferences) given by governments to trading partners in order to promote export growth and development; often granted by developed countries to LDCs
Safeguards	The General Agreement on Tariffs and Trade (GATT) permits two forms of multilateral safeguards: (a) a country's right to impose temporary import controls or other trade restrictions to prevent commercial injury to domestic industry, and (b) the corresponding right of exporters not to be deprived arbitrarily of access to markets
Secretariat	The international body that oversees the administration of an international agreement
Tariff	A tax assessed by a government in accordance with its tariff schedule on goods as they enter (or leave) a country; may be imposed to protect domestic industries from imported goods and/or to generate revenue
Treaty	An agreement between two or more nation states

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