

Trade and Health:

Towards building a National Strategy

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Preface

Globalization and the rise of international trade of goods and services in terms of volume and speed influence human health. This influence can be both positive and negative. Our work on “trade and health” is all about harnessing and maximizing opportunities to promote public health and minimizing the risks and threats.

WHO and its Member States are very conscious of these opportunities and challenges. In 2006 the World Health Assembly adopted a resolution (WHA 59.26) on international trade and health and urged Member States to take advantage of the potential opportunities, and address the potential challenges, that trade and trade agreements may have for health. There are a number of additional WHO resolutions and decisions that involve the international trade and health interface. These deal with subjects such as tobacco control, the HIV/AIDS epidemic, intellectual property, international migration of health personnel, medical tourism as well as nutrition and alcohol policies. WHO’s work on international health regulations (IHR), which addresses health and trade issues, epitomizes the significance that we attach to helping the international community to prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide.

At the global level, WHO works closely with relevant organizations such as the World Trade Organization, the World Intellectual Property Organization as well as the United Nations Conference on Trade and Development. We work with the Food and Agriculture Organization of the United Nations to develop and promote international food standards through the Codex Alimentarius to protect the health of consumers and ensure fair trade practices. The WHO Framework Convention of Tobacco Control (FCTC) was the first international treaty negotiated under the auspices of WHO to tackle the globalization of the tobacco epidemic. These are just a few examples of WHO’s involvement in trade and health related issues at global level.

Coherence between trade and health policies at the country level is the key to effectively manage the interface between trade and health. This requires going beyond the confines of sectoral policies to embrace new collaborations. The first step towards policy coherence is the development of a good understanding of the issues, based on the analysis of the situation from both a health and trade perspective. WHO has for a long-time identified this as an area, which needs to be facilitated through technical cooperation and provision of assistance through offering reliable empirical evidence and a menu of viable policy options.

This publication is part of WHO’s response to help develop a better understanding of the issues involved in the interface of trade and health, generally and with reference to specific issues. We have produced a number of important publications on trade in health services, intellectual property and public health, and health impact of trade liberalization. Our latest publication is a product of the trilateral cooperation between WHO, WTO and WIPO, titled “Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade”.¹ On tobacco and trade, WHO has published “Confronting the tobacco epidemic in a new era of trade and investment liberalization” in 2012.²

This publication was initiated some years ago as part of a programme to support WHO Member States to systematically assess their trade and health situation. The project was originally conceived as two parts: the first, a background document on key issues in trade and health and the second, an assessment tool to facilitate the development of national strategies on issues at the trade and health interface. We are now pleased to make available online this background document.

1 Available at: http://www.who.int/phi/PAMTI_WHO-WIPO-WTO.pdf?ua=1

2 Available at: http://www.who.int/tobacco/publications/industry/trade/confronting_tob_epidemic/en/ (Given this comprehensive monograph, we decided not to include a chapter on tobacco in this publication).

There are a number of acknowledgements in order here: first and foremost I would like to appreciate a former colleague of mine at WHO, Nick Drager who very effectively directed the trade and health area of work for many years as well as his collaborator Matthias Helble. I also would like to acknowledge all the contributors of the chapters. Thank you all for being generous with your time.

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Last but not the least, I am grateful to my colleague Peter Beyer who led this project through the last mile and made this publication possible.

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Contents

Preface	III
Trade and health – the linkages	1
Richard Smith, Chantal Blouin, Nick Drager	
1.1 The growing challenge of trade and health	1
1.2 Overview of the relationship between trade and health	2
1.3 Overview of this book	5
Policy coherence in trade and health	7
Chantal Blouin, Nick Drager	
2.1 Towards policy coherence: definitions and frameworks	7
2.2 Achieving policy coherence: key recommendations	9
2.3 Achieving policy coherence: the wider political context	16
Capacity building in trade and health	19
Alka Bhatia	
3.1 Introduction	19
3.2 Trade capacity building	19
3.3 Aid for Trade	22
3.4 Integrated Framework for Trade-Related Assistance for Least Developed Countries	25
3.5 Conclusion	32
Macroeconomic aspects of trade and health	35
Richard Smith, Chantal Blouin	
4.1 Introduction	35
4.2 Trade, growth and health	37
4.3 Distributional impacts of trade on income	37
4.4 Trade, government revenue and health care spending	39
4.5 Economic stability and health	39
4.6 Sources of information, key indicators and their interpretation	40
Implementing trade commitments with a public health perspective	45
David P. Fidler	
5.1 Introduction	45
5.2 National implementation of international legal commitments: general considerations	45
5.3 National implementation of international legal commitments: specific considerations related to trade and health	46
5.4 Conclusions	54
Regional trade agreements and health services	56
Mina Mashayekhi, Elisabeth Tuerk	
6.1 Introduction	56
6.2 Services trade liberalization and cooperation in preferential trade agreements	63
6.3 Health services: specific experiences in selected RTAs	67
6.4 Conclusions	74

Trade in health services	76
Pierre Sauvé, Chantal Blouin, Aniket Bhushan, Olivier Cattaneo	
7.1 Introduction	76
7.2 Trade in health-related services: characterizing the current environment	76
7.3 Evidence of the impact of trade in health services on health systems	81
7.4 Conducting a trade-related regulatory audit	86
7.5 Conclusion	90
Trade liberalization, food, nutrition and health	92
Corinna Hawkes, Delia Grace, Anne Marie Thow	
8.1 Introduction	92
8.2 Policy measures that liberalize food trade	94
8.3 Step 1: Assessment of impact of food trade liberalization on nodes in the food supply chain	96
8.4 Step 2: Assessment of implications for food safety, availability, price and marketing	98
8.5 Step 3: Nutrition and health implications	103
8.6 Step 4: Implications of trade agreements for policy space to address food-related health	105
8.7 Opportunities for using trade policy to improve nutrition and health	107
8.8 Moving forward	107
Trade in medicines	117
Frederick Abbott	
9.1 Introduction	117
9.2 Trade, TRIPS and TRIPS-plus	118
9.4 Ownership	123
9.5 Trade policy instruments	124
9.6 Innovation and intellectual property rights	126
9.7 Access and intellectual property rights	129
9.8 The need for a cost-benefit analysis of both pharmaceuticals and intellectual property scope	134
9.9 Data sources, indicators and interpretation	135
9.10 Conclusion	136
9.11 Further reading	139
Contributors	141

Chapter 1

Trade and health – the linkages

Richard Smith, Chantal Blouin, Nick Drager

1.1 The growing challenge of trade and health

The view of health as predominantly a national concern is increasingly being challenged as the international dimensions of health grow in number and importance. According to one commentator

[o]ver 1 million people travel to Asia each year to receive health care, contributing some US\$2 billion to the region's economy. Over 50% of doctors trained in Ghana emigrate. Cuba is a regional hub for tele-radiology services. Private companies from India, Singapore and elsewhere invested more than US\$1 billion [in 2007] establishing hospitals or other ventures abroad (1; *see also* 2).

The severe acute respiratory syndrome (SARS) outbreak of 2003 resulted in a loss of some US\$100 billion in global gross domestic product, and a potential pandemic influenza outbreak could create far greater economic as well as health losses (3, *see also* 4). The financial crisis and recession of the late 2000s had negative impacts on health and the affordability of health care (5). Food price rises have increased malnutrition, yet at the same time record levels of type 2 diabetes (which is associated with being overweight) are being observed in developed and developing countries alike. The reader could no doubt add extensively to this list of challenges currently facing health policy-makers.

As the global movements of goods, services, capital, people and ideas grow, what will the impact on health systems and population health be? What will the implications of increased economic liberalization in other sectors be on the health sector and on population health? What impact do health issues, such as infectious disease or obesity, have on non-health sectors? How well placed are health policy-makers to address these questions?

This book is designed to guide the systematic analysis of such questions, considering the core evidence concerning key aspects of international trade and health, and the linkages between them. It aims to help policy-makers and decision-makers address the challenges posed by global health issues and to incorporate such issues into national health-related processes.

In order to further assist policy-makers and others in dealing with this daunting agenda, an important component of this process will be the preparation of national and regional strategy papers on trade and health, whereby national policy-makers can assess the opportunities and risks associated with international trade and trade rules, and with greater cross-border flows of goods, services and capital. These national and regional strategy papers should position governments, especially developing-country governments, to adopt a clear plan to harness the benefits associated with trade in order to promote health and to prevent or mitigate any negative impacts of international trade on health. It should also facilitate the participation of health authorities in the trade policy-making process, to ensure that a health perspective is integrated in the adoption of new rules and new trade policies at the national and regional level. Finally, a national strategy paper should enable policy-makers in developing countries to access resources for building trade capacity, as they would be in a better position to identify the needs and gaps where training or research is necessary. The situation analysis provided by the above-mentioned assessment tool would feed into the development of a national or regional strategy paper.

This chapter provides an introduction to the scope of the issues facing health policy-makers concerning trade and health. Section 1.2 provides an overview of the relationship between trade and health, and

the role of globalization as a key factor in this relationship. Finally, section 1.3 outlines the content of the remaining chapters of the book.

1.2 Overview of the relationship between trade and health

Increased cross-border flows in goods, services, people and capital — whether health related or of wider relevance — will affect health through a number of ways, including the cross-border spread of infectious disease, the advertising of unhealthy lifestyles and the migration of health professionals. Health, and the health sector, will be affected by general changes in trade liberalization, international agreements and international institutions, as well as by changes specific to health (6). One development affecting health and the health sector is increased trade in services. Indeed, perhaps the main reason that the health sector has been relatively unaffected by globalization directly is because it is predominantly a service-oriented sector, and historically trade liberalization has focused upon the movement of goods, and to a lesser degree people, as goods can be stored and therefore transported. However, this has changed as a result of a number of factors, including advances in technology, making e-commerce and web-based medicine a technical possibility; easier travel and fewer border restrictions, making feasible the temporary cross-border movement of patients and health professionals; and the rise of transnational corporations, making the ownership and management of health care facilities more fluid (2).

Trade agreements too will have implications for health and the health sector, whether they are bilateral, linked to the World Trade Organization (WTO), or involve regional trading systems such as the European Union, the Association of Southeast Asian Nations (ASEAN), the Southern African Development Community (SADC) and the North American Free Trade Agreement (NAFTA). For instance, the General Agreement on Trade in Services (GATS), finalized in 1994 during the Uruguay Round of WTO negotiations, aims to liberalize trade in services, including health services. Similarly, the WTO's 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) mandates patent protection for pharmaceuticals, which has the potential to provide greater incentives to invent new medicines but is also likely to increase the prices of those new medicines and therefore reduce their accessibility especially for the poor. In terms of non-WTO trade agreements, ASEAN has been promoting the development of agreements covering the migration of health-care workers, and there are many concerns about recent bilateral trade treaties — particularly between the United States of America and Europe and various developing countries — that include provisions going beyond WTO rules and offering even greater patent protection for, e.g. pharmaceuticals (7, 8).

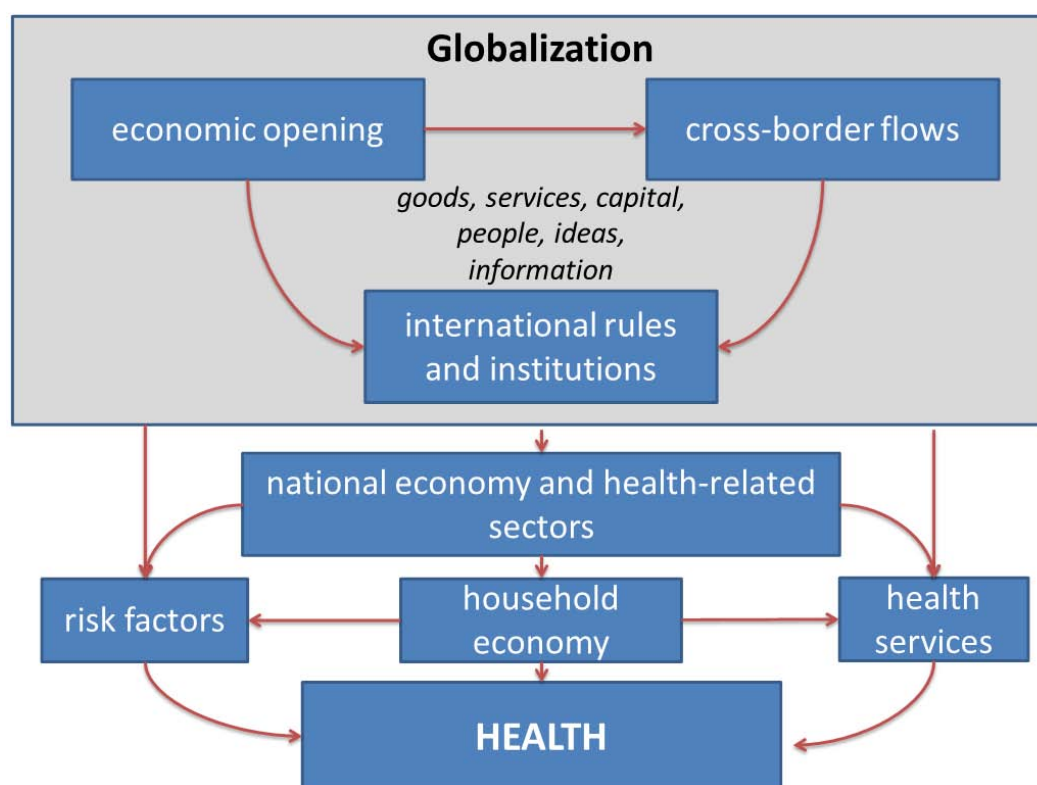
Historically trade and health have operated as separate policy spheres, but developments such as those just mentioned mean that the two policy sectors are increasingly interrelated. Although some issues have produced closer cooperation between the two sectors, others have exposed tensions between the goals of (a) protecting health and (b) promoting trade in goods, services and investment capital. These developments in trade liberalization have thus raised concerns that changing trade patterns are outpacing the ability of governments, and especially health policy-makers, to adjust to and manage them effectively (9). This situation may be further complicated in the case of conflicts or misunderstandings between trade and health officials, which furthers the confusion of how to estimate the potential benefits and risks associated with trade liberalization. When national ministries of trade (and perhaps finance and foreign affairs) make trade commitments, they often do so in isolation from health ministries, yet such trade commitments have an impact on health, of which trade ministers may have limited knowledge. Conversely, ministries of health typically have very limited knowledge of trade issues. A critical factor in trade and health is therefore to address this asymmetry of information by enabling ministries of health to make informed and comprehensive presentations to ministries of trade regarding the likely impact of trade agreements on health issues.

The limited exception to the liberalization of trade and removal of non-tariff barriers is the implementation of the WHO Framework Convention on Tobacco Control (WHO FCTC), ratified by 179 countries. These

countries now have binding obligations in terms of imposition of non-tariff barriers such as Pictorial Health Warnings on all tobacco products. The Parties to WHO-FCTC have also negotiated the Protocol to Eliminate Illicit Trade in Tobacco Products (ITP) that is pending ratification by the requisite number of parties to come into force.¹ ITP imposes a number of non-tariff barriers/trade restrictions on the tobacco trade.

In order to begin to develop a national or regional strategy to deal with these multifarious trade and health issues, it is helpful to systematically frame those issues first and then map out the linkages between them, in order to create a priority order for consideration, and to assist in the development of a framework for gathering and interpreting relevant information. The purpose of this section is to explore the implications of international trade on health and the health sector, and thus to assist in the formulation of an informed policy on international health and trade. This framing is illustrated in Figure 1.1

Figure 1.1 Globalization, trade and health



The figure aims to summarize the main determinants and linkages between trade and health. The lower half of the figure represents the individual country under consideration, while the upper half represents the aspects of globalization that have an impact upon the country. The three arrows between the two halves indicate the major linkages. This is a deliberately simplified picture to provide a concise frame of reference as background to the issues discussed in this book. A more comprehensive exposition of the various linkages between trade and health is provided elsewhere (10,11).

¹ For more details of the ITP please refer to the website of the convention: <http://www.who.int/fctc/protocol/en/>

Taking the lower half of the figure first (within-country issues), the standard influences on health are illustrated: **risk factors**, including genetic predisposition to disease, environmental influences on health, the incidence of infectious disease and other factors; **household economy**, including factors associated with human capital and the investment in health by individuals and households; **the health sector**, including the impact of goods and services consumed principally to improve health; and **the national economy**, representing the meta-influences of government structures and general economic well-being. The range of interlinkages between these factors is also illustrated.

In the upper half (globalization issues), the influences of factors outside the national economy are illustrated. For example, there are a wide variety of international influences upon risk factors for health, including elevated exposure to infectious disease flowing from increased cross-border travel; increased marketing of unhealthy products; and increased environmental degradation as a result of industrialization. Many of these factors may be associated with negative externalities. For example, an illness contracted by one person while on a business trip can result in risk of transmission of that illness to many others upon return to that person's home country. In addition, many of the risk factors at least to some extent have public good attributes (or perhaps more accurately, "public bad" attributes). For example, the negative effects from environmental pollution affect everyone and an individual cannot easily be excluded from these negative effects by making different personal choices (except, perhaps, by departing the country or region). These global externality and public good aspects of, and impacts on, health are not considered further here, but are covered in detail elsewhere (12).

Trade also affects health through influences upon the national economy. There is an extensive literature concerning the relationship between health and wealth (13, 14). Thus, to the extent that trade influences economic growth, and growth is associated with improved health, then trade will be expected to influence health through this route. Finally, trade will affect health through the direct distribution and provision of health-related goods and services as well as the increased transfer of health-related knowledge (6). Also in the upper half of the figure, we see the importance of international trade agreements.

Although simple, this figure therefore encapsulates the major elements of the relationship between trade and health, and the major linkages between them. In order to develop a trade and health strategy, it is important to understand current and pending international trade agreements as well as the way that these international agreements have been or are likely to be implemented within a country (Chapter 5).

The blue arrows indicate the linkages between elements at the global or national level, which have been the subject of other literature. However, of concern here are the red arrows, which indicate the need to consider three specific forms of linkages between the global trade environment and the domestic environment. First, trade will bring associated changes in risk factors for disease. These will include both communicable diseases, through the greater cross-border flows of people and goods that are associated with such diseases (for example poultry and avian influenza, cattle and bovine spongiform encephalopathy); and noncommunicable diseases, for instance as a result of changes in the patterns of food consumption brought about by changes in income, life style and the food industry through greater trade (Chapter 9), or trade in hazardous or harmful substances (Chapter 8). Second, trade will have an impact upon the domestic economy through changes in income and the distribution of that income, as well as influencing the levels of tax receipts and the form of tax receipts. This will influence the household economy and also the ability of government to be engaged in public finance and the provision of health care (Chapter 4). Finally, health will also be impacted by direct trade in health-related goods and services, such as pharmaceuticals and associated technologies, health-care workers, patients and so forth (Chapters 7 and 10). Clearly such imports and exports will generate a variety of opportunities and risks for the health sector directly and thus have implications for the breadth and depth of health-care provision.

As outlined in the following section, the chapters in this book are designed to provide background information on the key aspects of trade in health in order to guide policy-makers in elaborating a national response to trade and health-related issues, including the development of a national strategy paper on trade and health.

1.3 Overview of this book

The present chapter sets the scene for the remainder of the book by providing background information, including reflections on the challenges presented by trade and health, and an overview of the relationship between trade and health. Chapter 2 expands on the need for policy coherence in addressing the challenges and makes recommendations on how to achieve such policy coherence, focusing particularly on the importance of developing a national strategy paper on trade and health. Chapter 3 reviews recent initiatives in trade and health capacity building, focusing on two key multilateral initiatives: Aid for Trade and the Enhanced Integrated Framework for Trade-Related Technical Assistance to Least Developed Countries.

The next three chapters consider the relationship between general trade and health, through channels related to the general economic climate of a country and the impact of general trade on risk factors for disease. Chapter 4 examines the indirect and broader, macroeconomic impacts of general trade on health, addressing issues such as how trade policy impacts social determinants of health, including poverty or inequality; the effect of trade reforms on public revenues and ability of the government to make health expenditures; and how trade policy influences economic stability, including the effects stability issues might have on health. Chapter 5 offers technical advice, from a public health perspective, on the implementation of trade treaties in national legislation. Chapter 6 focuses on regional (preferential) trade agreements, which have increased significantly in number in recent years. The chapter reviews the level of commitments undertaken by governments in five different regional trade agreements, considering the main motivations behind the negotiation of services trade within regional trade agreements, the importance of reciprocity and discrimination in trade policy with respect to such agreements, and the distinct approaches adopted between such agreements with respect to scope, structure and modalities for liberalization.

The book concludes with three chapters on sector-specific intersections between health and trade. Chapter 7 deals with trade in health services, distinguishing between the four Modes of supply of services as they are classified in most trade agreements: (1) e-commerce, (2) cross-border movement of patients, (3) foreign investment in health services, and (4) the cross-border movement of health professionals. Chapter 8 considers how international trade in foodstuffs may affect population health, through its impact on nutrition and food safety. Finally, Chapter 9 examines the impacts of trade agreements and trade flows on medicines and associated technologies, especially aspects related to intellectual property protection.

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Chapter 2

Policy coherence in trade and health

Chantal Blouin, Nick Drager

2.1 Towards policy coherence: definitions and frameworks

Policy formulation on trade and health will in some cases uncover tensions between the various policy objectives of national governments. For instance, the objective of promoting medical tourism may clash with the objective of providing health services in rural areas, given that medical tourism could potentially exacerbate shortages of health professionals in those regions as medical professionals from rural areas move to urban areas to respond to the increasing demand for health care from foreign based patients. This chapter discusses the overarching frameworks that can guide policy coherence, and proposes five steps that policy-makers can adopt to move towards trade policies that contribute to the achievement of national health objectives. These five recommendations are based on a research project that documented policy processes adopted at the national level to address trade and health policy issues (1, 2).¹

At the most basic level, policy coherence refers to the idea that policy actors are engaged in an effort to achieve common goals. One of the actors most involved in exploring the concept of policy coherence has been the Organisation for Economic Co-operation and Development (OECD), which has examined how the policies of its members can support (or undermine) efforts towards the achievement of development objectives (3 4). For instance, they have highlighted how trade barriers maintained by OECD countries against the products of developing countries can undermine the impact of development aid provided by those same donor countries. The definition of policy coherence proposed by this work programme is a process through which governments make efforts to design policies that take account of the interests of other policy communities, minimize conflicts, maximize synergies and avoid unintended incoherence. A degree of incoherence may sometimes be inevitable, but trade-offs should be transparent and appropriate measures taken to mitigate negative impacts (4).

If we define policy coherence as efforts to achieve common goals then the key question becomes, what goals are we trying to achieve? Indeed, an overarching framework is necessary to guide the process of policy coherence. In policy coherence for development, the OECD countries identify the Millennium Development Goals (MDGs) and recommend that the MDGs guide the coherence effort. The MDGs include health targets such as the reduction of infant and maternal mortality, as well as targets of poverty reduction, itself a key social determinant of health. These goals can be useful tools to measure progress and to mobilize people for policy change at the national and international levels. While they are helpful, they may not be sufficient to provide a framework for guidance when considering the overarching question of policy coherence.

The concept of human development is another framework that can guide policy-makers. Developed by economist Amartya Sen and used by such United Nations agencies as the United Nations Development Programme (UNDP), this approach sees development as the enhancement of human freedoms: freedom from want, fear, and discrimination, and freedom of participation, expression and association. In this lens, economic development (economic growth, increased income or industrialization) is not seen as the only element of the development of a country, but contributes importantly to “the general capability of a person to live more freely” (5). The lack of basic health-care facilities and the inability to obtain medicines for treatable diseases are denials of human freedoms that a human development approach would seek to

¹ The research project Trade and Health Policy Coherence for Human Development received funding from the Canadian International Development Agency, the International Development Research Centre and the Department of Foreign Affairs and International Trade of Canada. The main results of the projects were published in Blouin, Heymann and Drager (1) and Blouin (2).

address. Policy coherence would mean ensuring that all policies contribute to the expansion of freedoms that people enjoy.

What distinguishes a human development approach from a human rights approach to policy coherence? One of the key differences is the focus on accountability that is embedded in a human rights approach.

To have a particular right is to have a claim on other people or institutions that they should help or collaborate in ensuring access to some freedom. This insistence on a claim on others takes us beyond the idea of human development. In the human development perspective, social progress of the valued kind is taken to be a very good thing . . . but the normative connection between laudable goals and reasons for action does not yield specific duties on the part of other individuals, collectivities or social institutions to bring about human development . . . (6).

As this accountability for achieving social progress usually lies with the nation state, the human rights approach is especially relevant for policy-makers grappling with policy coherence. Indeed, most national governments have formal commitments and existing obligations to the right to health, either through the inclusion of the right to health in national constitutions or by having ratified international human rights treaties such as the International Covenant on Economic, Social and Cultural Rights. With the appointment by the United Nations Commission on Human Rights of a Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (resolution 2002/31),² there has been growing interest in the policy implications of the right to health. A number of documents analysing how to approach trade policy with a view to achieving the right to health have been prepared by the Special Rapporteur (7).

A paper by Hunt and MacNaughton proposed guidelines on how to carry out health impact assessments of public policies, including trade policies, from a human rights perspective (8). The following excerpts highlight the basic principles that should guide a right to health approach in assessing the coherence of trade policy with the overarching goal of achieving human rights.

1. **Explicit human rights framework.** A rights-based approach to impact assessment must be explicitly based on a human rights normative framework. The right-to-health approach developed here is based on ICESCR [International Covenant on Economic, Social and Cultural Rights] Article 12 and the Committee's General Comment 14 defining the normative content of Article 12 [Committee on Economic, Social and Cultural Rights]. In selecting the appropriate human rights normative framework, States should look to the specific human rights treaties that they have ratified as well as international consensus documents pertaining to the particular subject of the policy.

2. **Progressive realization.** A rights-based approach also demands that the State take deliberate steps to progressively realize the right to health as expeditiously and effectively as possible. Impact assessment provides States with the methodology to do so. Integrated into policy-making processes, rights-based impact assessment aids the State in selecting, from among policy alternatives, those policies that will most expeditiously and effectively realize the right to health. Rights-based impact assessment will also ensure that the State is aware when a proposal is likely to impede the right to health, and thus, can take measures to mitigate or compensate for such impacts, avoiding any measures that might be considered retrogressive or otherwise in violation of legal obligations.

3. **Equality and non-discrimination.** Rights-based impact assessment means that the principles of equality and non-discrimination must be considered at all stages and in all aspects of the impact assessment. For example, the principle of non-discrimination requires States to consider the likely impacts of proposals on different groups to ensure that a policy does not adversely affect a protected group. To do such analysis will require disaggregated information on potential impacts. Furthermore, people must be able to hold the

² The first Special Rapporteur was Paul Hunt (New Zealand), 2002–2008, succeeded by Anand Gover (India) in August 2008.

State accountable for any illegal discrimination in the assessment process. The principle of equality requires States to consider alternatives that could be more effective in promoting equality, including devoting more resources to areas with the greatest potential to benefit poor people. It also means that all people must be encouraged to participate in the impact assessment.

4. Participation. Rights-based impact assessment requires participation by all stakeholders. To ensure meaningful participation requires providing all stakeholders with information on the proposed policy and promoting the free exchange of ideas concerning the proposal. Effective participation also means that the people affected are heard, have the opportunity to influence decision-making and feel empowered by taking part in the decision-making; in sum, it means that they are able to exercise their rights to take part in the conduct of public affairs. This will require the State to encourage participation by both women and men, and by marginalized people, including people living in poverty, and to ensure that their voices are heard. It also requires the impact assessment process to be transparent and accessible to all.

5. Information. Rights-based impact assessment also requires the State to provide information on the proposed policy and on the process of such assessment for all stakeholders. All parties potentially affected by the policy must be fully informed in order to meaningfully participate in the impact assessment and to effectively hold the State accountable. The right to information also means that States must respect the freedom of everyone to seek and receive information, to freely discuss the proposal and to propose options for avoiding or minimizing adverse impacts on rights and alternatives that could enhance rights.

6. Accountability. A rights-based approach also demands accountability. Thus, States must ensure that stakeholders are advised of the rights and obligations relevant to a rights-based impact assessment process and of mechanisms of accountability that are available to them. These mechanisms must be accessible, transparent and effective. People must be able to hold duty-bearers accountable for the process of the impact assessment should it fail to respect their human rights.

7. Interdependence of rights. A rights-based approach also recognizes the interdependence of rights – the fact that the enjoyment of some rights is dependent on or contributes to the enjoyment of others. It also recognizes that impact assessments aimed at progressively realizing the right to health and thereby reducing poverty (and vice versa) must reflect the interdependence of all human rights; economic, social, cultural, political and civil. As poverty is defined in terms of all these rights, a rights-based approach must encompass them all.

2.2 Achieving policy coherence: key recommendations

Why do some national governments fail to adopt trade policies that are coherent with their health objectives? Trade and health policies are influenced by the nature of the political process, and it follows that “technical analysis of the economic and health aspects is necessary, but not sufficient” (9). One important theoretical contribution to understanding why some policy options are adopted, and others blocked, comes from the political economy, which stresses the distributional consequences of public policies and the dilemmas of collective action (10). This well-established approach highlights how dispersion and concentration of the benefits and costs associated with policies will influence the incentives for collective action. When the benefits of a policy change are large and concentrated among a small group of actors, the group has a strong incentive for acting collectively to support the proposed policy change, and therefore more likely to have an influence on the policy-making process. On the other hand, diffused interests (where minor advantages are expected for a large number of individuals) generally have less influence over the policy process, given difficulties encountered in organizing large groups of individuals.

Social scientists have found this theoretical approach very useful in explaining the formulation of trade policy (11), and have recently expanded this approach to explain other aspects of economic foreign policy, such as policies regarding international finance and exchange rates, along with foreign investments. In the case of trade policy as it relates to health, the theory would predict that the policy preferences of small groups of actors that stand to reap large benefits would prevail. If these actors are large pharmaceutical companies or large (semi) governmental agencies involved in health insurance or investment in health facilities, their stakes in standards of protection for intellectual property or decisions about liberalization in health services or insurance are high and the number of actors relatively small; hence, the strong incentives for these actors to be politically active making it relatively easy for them to associate into a single, effective organization. In comparison, groups of unified patients or consumers tend to be less organized and consequently have less influence.

Given these dynamics, achieving policy coherence is therefore not simply a question of adopting the procedural measures suggested in the recommendations below. The focus here is on some steps that policy-makers in national governments can take to facilitate the adoption of trade policies that contribute to, rather than hinder the achievements of national health objectives.

Recommendation 1. Build common understanding through dialogue and joint fact-finding

Policy-makers and analysts from the health and trade sectors tend to have different academic backgrounds and may hold beliefs and values that may not coincide. Therefore formal, as well as informal exchanges of dialogue between trade and health officials at the national, regional and global levels are required. In addition to fostering dialogue, one effective way to develop common understanding is to undertake joint fact-finding exercises. Each party can learn from having to work together on identifying a research agenda or a work programme that will explore the potential benefits and risks related to the policy under scrutiny. Such joint fact-finding may not result in all parties sharing the same views and interests, but it can clarify the trade-offs that are at stake and the possible policy responses to offset negative impacts.

The case of protection of intellectual property rights in regional trade agreements in Central America illustrates the above point. Some bilateral and regional trade agreements, such as the Dominican Republic-Central America-United States Free Trade Agreement (CAFTA-DR), have led to intellectual property protection for pharmaceutical products beyond that required by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Trade negotiations are usually based on the mutual exchange of market access concessions; for instance, country A agrees to open its market to the sugar exports of country B in exchange for better access to the telecommunications market of country B. In the case of CAFTA-DR, the United States requested strengthened intellectual property protection in exchange for better access to its markets.

More dialogue and joint fact-finding would give trade officials a better understanding of the implications of agreeing to strengthened patent protection. It would also mean that health officials would be better equipped to engage in discussions about the economic benefits and costs to their countries of receiving better access to United States markets. Once officials have a better understanding of the potential benefits and risks involved they are able to design an alternative approach or other complementary domestic measures. For instance, the results of a study conducted by the Costa Rican Ministry of Trade suggested that the short-term impact of increased patent protection would be limited, especially when weighed against the potential benefits of access to United States markets. However, this fact-finding exercise was not conducted in collaboration with actors from the health sector.

Box 2.1 Building common understanding

Comments from Anabel Gonzalez, former trade negotiator for Costa Rica

To promote policy coherence is not to promote inaction, either on the health front or in the trade arena, or to engage in fruitless confrontations, but rather to promote greater understanding of the linkages between trade and health, leading to greater interaction between policy-makers and practitioners in these two areas. This must be done at both the technical level and the political level. Increased coherence requires building the knowledge base on trade and health linkages, particularly among trade and health practitioners and, in a broader sense, among the general public. From the perspective of a trade negotiator, this information is vital in order to participate in trade negotiations. The information, of course, must be based on sound analysis and research. Regional and international bodies have a role in generating and disseminating such knowledge, though differences between countries or groups of countries should also be taken into consideration. Mechanisms for addressing specific questions or concerns in a timely fashion are part of an appropriate response.

It must be remembered that a lot of the existing information appears to be geared towards the challenges and risks implied whilst little seems to be dedicated, so far, to the opportunities and benefits that arise from the interaction between trade and health. This dimension should also be more thoroughly explored and recognized so that countries may incorporate relevant elements in their national strategies, for instance in terms of investment attraction, promotion of competitiveness and tourism development. Developing countries in particular should aim less at presenting defensive positions in trade negotiations and more at using those negotiations as opportunities for advancing their offensive interests, including in the trade and health areas.

Although strengthening the technical basis for discussion and decision-making, through information, dialogue, capacity building and monitoring, will significantly improve policy coherence, ultimately decisions on trade and health policies are of a political nature (12). This is particularly the case when there are conflicting views as regards priorities and objectives.

Recommendation 2. Ensure health ministries play a leading role

Several cases involving interaction between trade and health policy-makers highlight the importance of close collaboration between the ministries of health and trade in order to ensure policy coherence. The ministry of health can play a leading role in this collaboration.

Box 2.2 Leadership of the health ministry in Malaysia

Comments from Nik Noraihan Thani, Deputy Undersecretary, MOH, Malaysia (13)

For an effective and coherent trade and health policy, it is imperative that health and trade officials, nongovernmental organizations (NGOs) and the private sector come together and use various opportunities to build a collaborative relationship. Toward this end, the Malaysian Ministry of Health conducts annual dialogues between relevant stakeholders. Members of the annual dialogue involve three major groups: NGOs, professional bodies and industrial groups, covering a total of about 90 organizations.

Another important factor is leadership and capacity building. A committed group of key officials and leaders knowledgeable about the issues and willing to share information on future policy decisions is the most important element to achieve better trade and health policy coherence. Trade and health concerns may at times be in conflict, so a strong and committed leadership should be able to address such concerns in a constructive way and view them as opportunities for finding common ground. The Ministry of Health is a relatively new player in the area of trade and health but recognizes the opportunities that lie ahead, and seeks to address the concerns that arise. Toward this end, the Ministry of Health has established a Steering Committee on Trade and Health chaired by the Secretary-General of Health. Several subcommittees, known as expert groups, have been formed to address specific concerns about trade in health, such as on pharmaceuticals, food safety, health care services, medical devices and tobacco control. These expert groups bring together academic experts, civil society and ministry representatives to discuss key health and trade issues, and will advise the Steering Committee accordingly. The Ministry of Health also established a contact or focal point for trade officials to make it easier for them to seek the views of the Ministry of Health.

In contrast, Latin American countries such as Argentina, the Dominican Republic, Guatemala and Mexico provide examples of situations in which ministries of health have had little involvement in trade negotiations or the implementation of trade agreements. Given this lack of involvement, national legislation implementing the TRIPS Agreement in Latin America has not taken full advantage of the flexibilities embedded in the Agreement to ensure accessibility to pharmaceutical drugs. The lack of leadership by the health authorities may have resulted from their limited knowledge of trade rules on access to medicines, and their relatively low level of influence outside their specific field of competence. Historically, ministries of health have been marginalized in two ways: first, they have been excluded from foreign policy; and second, they have been disconnected from other policy areas within domestic policy-making. Consequently, health ministry officials have often been in more frequent contact with their counterparts abroad than with officials in the ministries of trade or foreign affairs at home. Ensuring that ministries of health take a proactive role in trade and health policy-making therefore requires a reversal of long-held practices.

The case of Thailand is another example of how the leadership of the health ministry, working together with trade officials, can be a key determinant of policy coherence. Trade officials in Thailand have recognized the role that the Ministry of Health has been playing over recent years, in terms of building a better understanding of, and accumulating evidence with respect to, the implications of trade agreements on the national health systems. As a result, trade officials naturally turned to the Ministry of Health when they needed evidence on the costs of increasing intellectual property protection, in the context of trade negotiations with the United States.

Recommendation 3. Create and facilitate institutional mechanisms of collaboration

To achieve coherence, institutional mechanisms often need to be created to ensure collaboration between organizations. In several countries a national inter-ministerial committee plays this role, fostering coherence across the large number of issues that are affected by trade policy: procurement, environmental policies, public services and so on. In some countries, the public health authorities are members of this committee. Some countries prefer a special mechanism devoted to trade and health coordination (14). Indeed, institutional mechanisms can take many forms, and can be more or less formal in nature.

While some mechanisms include the private sector and representatives from civil society, others include only government officials. Institutional mechanisms aim to create incentives for collaboration, and, with time, to build trust between actors not accustomed to working together. For instance, in Thailand, the Ministry of Commerce was the only institution involved in the trade negotiations until 1995–1996. In 1997 however, the structure for international trade negotiations in Thailand was reformed and many more stakeholders became involved, including representatives of all concerned ministries, the private sector, academia and civil society. The Ministry of Commerce is still the central agency, and is responsible for the secretariat of the National Committee on International Trade Policy, but the new infrastructure provides an umbrella for capacity development and for the networking of all stakeholders. Thus, in 1998, the Ministry of Public Health established a Ministerial Committee on Health Impact from International Trade. The regular meetings resulted in a better understanding among stakeholders, as well as clearer national positions for the national negotiation team.

The Trade Policy Staff Committee of the United States is another example of an institutional mechanism that allows cross-sectoral collaboration and trust building over time. The Committee is an interagency structure responsible for formulating trade policy as it relates to food standards, and for resolving agency questions or policy divergence. The United States Trade Representative coordinates the group of eight agencies, but the mechanism guarantees an appropriate voice for all relevant government players in the health and trade sectors. The United States food safety agencies provide technical and policy expertise and guidance, but do not serve in a trade promotion role. Rather, they see their role as ensuring that health protection is not compromised by trade priorities.

Recommendation 4. Engage stakeholders

Bringing a wide range of governmental and nongovernmental actors into the policy process is critical to ensuring policy coherence. This is an effective way to ensure that divergent views and interests are included in an explicit and transparent manner in the balancing act of policy-making, especially if stakeholders are engaged and consulted early in the process. The case of patent legislation in Sri Lanka highlights the importance of engaging with civil society to achieve coherence. In the context of bilateral trade negotiations with the United States in 2003, new patent legislation was adopted without broad consultation. Perhaps as a result, the new law did not allow for compulsory licensing or parallel importing, which are important tools to ensure affordable access to pharmaceuticals (15). Several Sri Lankan activists and legal advocates challenged the bill in the Supreme Court; the court agreed that the constitution prevented the government from introducing legislative measures that would knowingly increase inequality, or deny people equal access to health services. When the time came to revise the bill, government officials consulted a variety of stakeholders and civil society organizations, which unanimously supported a new draft of the legislation that allowed for compulsory licensing and parallel imports (16).

There are several examples of positive contributions made by public consultation in the formulation of trade policy relevant to health. In the case of the offers made by Pakistan during the GATS negotiations as they related to health services, the Pakistan Ministry of Health was consulted and in turn engaged in discussions with various associations representing health professionals. In reaction to comments received during these discussions, Pakistan made an offer on professional services in the health sector that included a public service “carve-out”, i.e. excluding health services provided by public institutions from the scope of Pakistan’s GATS obligations. The objective of this exclusion was to ensure future regulatory flexibility to improve accessibility to health services, whether through subsidies, universal service obligations or other measures.

Recommendation 5. Get the evidence right

Trade and health officials need detailed information to be able to make informed choices about how to balance divergent interests and views. In Thailand, the Ministry of Public Health developed estimates of the economic costs of the “TRIPS-plus” provision proposed in the Thailand-United States Free Trade Agreement (17). In the case of the bilateral negotiations with the United States, the main recommendation of the Thai Ministry of Health was to prefer intellectual property provisions with no TRIPS-plus provisions, but the Ministry also offered an alternative position that attempted to minimize the negative impacts of TRIPS-plus provisions should they be adopted (Box 2.3).

Box 2.3 Evidence to inform negotiation: the case of intellectual property protection in Thailand

Comments from Suwit Wibulpolprasert, Ministry of Public Health, Thailand

In its negotiations of bilateral free trade agreements with industrial countries such as the United States and European countries, Thailand has received requests to further strengthen the protection of intellectual property rights. These requests go beyond what is required in the TRIPS Agreement of WTO, and are therefore often referred to as “TRIPS-plus”. If accepted, these requests would allow a three-to-five-year market exclusivity of non-patented innovative drugs. TRIPS-plus elements in trade agreements can also contain other provisions making it more difficult for companies producing generic drugs to enter the market or to use the flexibilities existing in the TRIPS Agreement to ensure the affordability of new drugs.

Concerns about the negative impact of the free trade agreements have led to strong civic movements against such agreements in Thailand. The movements have led the Cabinet to establish a working group to monitor and assess the effects of free trade agreements. This working group is supported by the Fiscal Policy Institute, a research arm of the Ministry of Finance. The Institute contacted the Ministry of Public Health’s International Health Policy Programme to carry out studies on the possible effects of TRIPS-plus on the health care system in Thailand and propose possible options for negotiations within six months, which was in time for the formulation of the Thai position for the Thailand-United States Free Trade Agreement.

The trade negotiators, the Department of Intellectual Property of the Ministry of Commerce, requested that the results be presented to them by the researchers, leading to clarifications and a better understanding of the findings. The results were also presented to the Minister of Health and to the National Health Security Office, the main payer of pharmaceuticals in Thailand. The adviser of the research project was then included in the trade negotiating team as a representative of the Ministry of Public Health. The negotiations of the Thailand-United States Free Trade Agreement were delayed by the political turmoil in early 2006 in Thailand. The results of the research have been key in stimulating public debates about free trade agreements and increasing the likelihood that the final outcome of the negotiations takes into account national public health objectives. It also had the additional effect of pushing the public authorities to consider a more rational use of pharmaceuticals and central purchasing to reduce pharmaceutical expenditure.

The ability to monitor the impact of trade policies following their adoption is also crucial to being able to prepare an appropriate response. For example, Thailand has seen a large increase in the number of foreign patients coming to receive medical care. The Ministry of Health monitored the impact of medical travel and found that the increased demand for doctors and nurses to care for foreign patients has led to an internal brain drain from the rural public sector to the urban private sector. Thanks to this monitoring capacity, the Ministry could adopt a policy for scaling up the training of doctors and nurses under a special curriculum to facilitate rural distribution (18). In some cases, in order to pool limited resources, a regional rather than a national approach to collecting the information can be used. For example, the secretariat of the Common Market for Eastern and Southern Africa (COMESA), in partnership with officials in each member country, coordinated comprehensive assessments of the state of trade in services (including health services) in this region, in preparation for economic partnership agreements with the European Union and GATS negotiations (Box 2.4). This regional approach is also relevant for other elements of the policy process discussed here, such as the need to create institutional mechanisms for collaboration. Many low-income countries may not have the resources to create a distinct unit or committee to deal with trade and health, and regional collaboration may be the best way to ensure internal coherence.

International organizations such as the World Health Organization and the World Trade Organization also have an important role to play in developing the evidence relevant to trade and health policy and making it accessible to policy-makers. Their technical assistance and capacity-building activities need to be coordinated and strengthened to ensure that trade and health officials receive appropriate information so they can engage in national policy discussions.

The need for evidence-based policy-making goes beyond the direct impact of trade reforms on health. For example, insecticides to fight malaria, such as dichlorodiphenyltrichloroethane (DDT), may, if they are used as pesticides in agricultural production and thus enter the food chain, cause environmental and health problems that could jeopardize export opportunities. This is an example of a situation where trade and health policy-makers need to work together in order to ensure beneficial outcomes.

Given the strong link between poverty and poor health, officials also need better information on the impact of trade reforms on poverty and inequity. Overall, trade openness tends to be associated with poverty reduction (19). However, the relationship between trade and poverty varies from one country to another, depending on such factors as the nature of the reforms at stake and initial conditions. Moreover, the impact on poor people will also vary according to several factors, including their skill level, gender and geographic location (for example urban or rural). Therefore, aggregate information may not reveal enough to be useful for policy-makers. Detailed information about the poverty impact of planned or ongoing reforms is usually not available, despite it being crucial to ensuring coherence.

Box 2.4 Trade in health services in COMESA: looking beyond the movement of health personnel

Comments from Chawe Mpande-Chuulu, former COMESA official (20)

In most Member States of the Common Market for Eastern and Southern Africa (COMESA), as in many countries in sub-Saharan Africa, the health sector is constituted by an overburdened public sector and a weak and unregulated private sector. The discussion on trade in health services in the COMESA region is primarily dominated by the brain drain issue, i.e. the loss of qualified personnel to more developed countries. The focus on the brain drain (under MODE 4) leads to a failure to look at the other modes of supply, i.e. MODE 1 (cross-border delivery), MODE 2 and MODE 3 (commercial presence). The majority of Member States have highly skilled and qualified health personnel who are essential for successful trade in services in the other modes of supply, apart from MODE 4.

Most of the impediments to trade in these areas have less to do with external factors and more to do with the domestic regulatory environment. For MODE 1, the impediments include the lack of dynamic telecommunications infrastructure to facilitate cross-border exchanges. In MODE 2, the lack of portability of insurance coverage is the key obstacle for both imports and exports of services. Regarding foreign investment (MODE 3), the key impediments are a lack of robust and coherent private sector policies for the provision of health services, with governments still wanting to be dominant players even when they cannot meet basic universal service obligations, compounded by the lack of specific investment incentives in the health sector and access to financing.

Regulatory authorities need to better understand the benefits and costs that could accrue from all modes of trade in health services and then decide which mode of trade should be promoted. Member States need to look at their education and health services domestic regulatory environment more critically and consider:

- the regulatory environment for private provision of health education services
- the investment incentives for the private provision of health education services
- the regulatory environment for the private provision of health services
- the investment incentives for the private provision of health services.

2.3 Achieving policy coherence: the wider political context

Five recommendations have been presented above on measures that can help ensure coherence between health and trade policy. Application of the measures can ensure that trade reforms will, at the very least, not worsen health outcomes or the social conditions that lead to ill health. However, even a strong ministry of health, whose officials are armed with good information, that is actively involved in an inter-ministerial committee on trade, and that is building common ground and is supported by a broad coalition of stakeholders, cannot guarantee a particular outcome. For instance, during bilateral trade negotiations with the United States, the Government of Peru agreed to several TRIPS-plus provisions, despite opposition from a wide variety of civil society groups (such as public health actors and human rights groups), underpinned by studies on the short-term impact of strong patent protection on access to drugs, and despite a visit and press release from the United Nations Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (7). This is a reminder that trade policy-making is embedded in a larger complex political process, and that the recommendations here are necessary, but not sufficient, conditions for policy coherence.

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Chapter 3

Capacity building in trade and health

Alka Bhatia

3.1 Introduction

Globalization has led to greater interdependence, across countries and within countries, resulting in an increased emphasis on strengthening multilateral cooperation for sustainable development. This is underscored further in the global Post 2015 Sustainable Development Goals agenda, which will be the guiding framework over the next fifteen years. To achieve meaningful results, however, this cooperation needs to be replicated within each country when framing policies on economic and social development are being drafted. One obvious area of such collaboration is between the trade and health sector. This area of collaboration has been recognized in the World Health Assembly resolution on trade and health (WHA59.26), which, among other things, calls for developing capacity at the national level to analyse potential opportunities and challenges related to trade in the health sector. Given the growing relevance of health issues in international trade, it is important that health officials are sensitized to the implications that trade may have for health. Creating this sensitivity requires greater awareness regarding the interface between trade and health, and greater policy coordination and coherence amongst trade and health officials. There is a need to build capacity¹ in developing and least developed countries to identify relevant issues and draw up cogent action plans that leverage opportunities in this area (1).

In doing so, the capacity building initiatives being carried out by the World Trade Organization (WTO) and other organizations must be considered.

This chapter provides an overview of such multilateral initiatives, including Aid for Trade and the Enhanced Integrated Framework for Trade-Related Technical Assistance to Least Developed Countries. The intention is to provide an accessible overview for use by policy-makers and other stakeholders working in the trade and health sectors when drafting funding requests for capacity building.

3.2 Trade capacity building

Trade capacity building is an integral part of all WTO activities and those of its partner organizations, including the United Nations Conference on Trade and Development (UNCTAD) and the International Trade Centre (an organization based in Geneva and jointly supported by WTO and UNCTAD). WTO collaborates with the Bretton Woods institutions in pursuance of its coherence mandate, enshrined in the Declaration on the Contribution of the World Trade Organization to Achieving Greater Coherence in Global Economic Policymaking (2). This collaboration was extended to other international organizations, including the World Intellectual Property Organization (WIPO), the United Nations Development Programme (UNDP) and the World Health Organization (WHO), through initiatives such as the Integrated Framework for Trade-Related Technical Assistance to Least Developed Countries and the Standards and Trade Development Facility. This reflects growing awareness within the international community of the synergies between all issues related to development.

¹ Capacity building denotes the assistance rendered to entities, in the present context to developing countries, to upgrade performance. UNDP has defined capacity building as the creation of an enabling environment with appropriate policy and legal frameworks, including institutional development and human resources development, recognizing that it is a long-term, continuing process requiring maximum participation by all stakeholders (1)

² WT/MIN(11)/W/2 (1 Dec. 2011).

The importance of technical assistance and capacity-building initiatives was underscored in the Doha Ministerial Declaration (3), by which ministers confirmed that “technical cooperation and capacity building are core elements of the development dimension of the multilateral trading system”. Ministers also endorsed the New Strategy for WTO Technical Cooperation for Capacity Building, Growth and Integration and instructed the WTO secretariat, in coordination with other relevant agencies, to support domestic efforts for the incorporation of trade into national plans for economic development and strategies for poverty reduction. At the sixth WTO Ministerial Conference (Hong Kong, 2005) ministers reiterated the significance of technical assistance and capacity building by outlining concrete measures to enhance them through a revamping of the existing Integrated Framework for Trade-Related Technical Assistance to Least Developed Countries and a new initiative on Aid for Trade (4). At the eighth WTO Ministerial Conference (Geneva, 2011) ministers noted the progress achieved on Aid for Trade and reiterated their commitment to provide funds so as to enable the secretariat to continue to provide required technical assistance and capacity building.² The ninth WTO Ministerial Conference (Bali, 2013) noted the outcomes of the 4th Global Aid for Trade Review (Geneva, July 2013) and reiterated the continuing need for aid for trade support to developing countries, especially Least Developed Countries (LDCs). Ministers have directed that a new work programme on aid for trade should be shaped by the post 2015-global development agenda.

In addition to its Annual Technical Assistance Plan, WTO also carries out trade capacity building in collaboration with other international organizations under the aegis of established programmes such as the Enhanced Integrated Framework, the Joint Integrated Technical Assistance Programme, the Standards and Trade Development Facility and the Aid for Trade initiative. The focus of the present chapter, however, is on the Enhanced Integrated Framework and Aid for Trade, as these are an on-going initiative focusing on a broader view of development, which is relevant for trade and health policy-makers. Box 3.1 gives a brief description of other joint initiatives of relevance to capacity building in trade and health.

The rationale for the Aid for Trade initiative and the Integrated Framework process stems from the desire to strengthen the capacities of developing and least developed countries to take advantage of more open markets and to harness the multilateral trading system in support of their economic growth and development. Given the emphasis that is presently placed on harmonization of technical assistance and a holistic view of development, these initiatives provide an opportunity for health officials to articulate their needs in respect of the trade and health sectors and to access financial assistance under relevant projects.

Box 3.1 Initiatives supporting capacity building in trade and health

Standards and Trade Development Facility

In the sanitary and phytosanitary standards area, the Standards and Trade Development Facility (STDF) was established in 2002 to facilitate collaboration between beneficiary countries and organizations such as WTO, WHO, the World Bank, the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (OIE) in enhancing the expertise and capacity of developing countries to implement sanitary and phytosanitary standards. As a coordinating and financing mechanism that is housed within and administered by WTO, STDF has now become an integral part of the Aid for Trade initiative and reports regularly to the WTO Committee on Sanitary and Phytosanitary Measures. It acts as the coordinator for all technical cooperation related to sanitary and phytosanitary standards, in addition to mobilizing funds from bilateral donors, international organizations and the private sector. In January 2012, STDF adopted a new Medium Term Strategy for the period of 2012–2016, with a stated goal “to contribute to sustainable economic growth, poverty reduction, food security and environmental protection in developing countries” (5).

Paris Declaration on Aid Effectiveness

Increasing activity in the aid field has raised the number of duplicative efforts and instances of aid programmes working at cross-purposes, thus limiting their value and effectiveness. Acknowledging this reality, the OECD in 2005 endorsed the Paris Declaration on Aid Effectiveness (Paris Declaration), which outlined a set of principles to “continue to increase efforts in harmonization, alignment and managing aid for results with a set of monitorable actions and indicators” (6). With the objective of increasing the impact of aid in reducing poverty and inequality, 56 commitments were adopted, organized around the following five principles: ownership, alignment, harmonization, managing for results and mutual accountability. The declaration sets forth 12 indicators to monitor progress in aid effectiveness and also endorses the use of mechanisms to ensure accountability in aid efforts. The principles set forth in the Paris Declaration now guide and inform all capacity-building initiatives, including the Integrated Framework and Aid for Trade. In 2008, ministers of developing and donor countries endorsed the Accra Agenda for Action, affirming their commitment to accelerate and deepen implementation of the Paris Declaration (7). An independent global evaluation of the effectiveness of the Paris Declaration, issued in 2011, concluded that although the overall burden of aid management had not yet been reduced as hoped, the global aid situation was far more transparent than 20 or 25 years earlier and the Paris Declaration had “strengthened agreed norms and standards of better practice and partnership” (8).

3.3 Aid for Trade

3.3.1 *Aid for Trade: impetus and beginnings*

Trade, and thus the rules-based multilateral trading system, is recognized as an important mean of supporting and promoting development through facilitating the integration of the weaker economies into the global economy. However, it is acknowledged that the relatively less developed countries are unable to take advantage of a more open trading system due to a number of factors, including supply-side constraints, poor infrastructure and other difficulties associated with adjusting to an increasingly globalized world economy. This reality was recognized by Group of Seven (G-7) ministers in February 2005 when they directed the World Bank and the International Monetary Fund to propose mechanisms to assist developing countries in dealing with trade liberalization. This call was further strengthened by an agreement of Heads of State at the 31st Group of Eight (G-8) Summit (Gleneagles, Scotland, July 2005), to increase aid to developing countries aimed at building their physical, human and institutional capacity to trade. At the sixth WTO Ministerial Conference (Hong Kong, December 2005), trade ministers mandated a new WTO work programme on Aid for Trade.

3.3.2 *What then is Aid for Trade?*

In paragraph 57 of the 2005 Hong Kong Ministerial Declaration, ministers noted that:

Aid for Trade should aim to build the supply-side capacity and trade-related infrastructure that [developing countries and particularly least developed countries] need to implement and benefit from WTO agreements and more broadly to expand their trade.

The purpose of Aid for Trade is thus to increase the capacity of developing and least developed countries to share in the benefits of increased global trade, with a view toward promoting growth, development, poverty reduction, the achievement of the Millennium Development Goals (MDGs) and other development objectives. The Aid for Trade initiative is guided by the Paris Declaration on Aid Effectiveness (see Box 3.1) and aims to promote the effective participation of developing and least developed countries in the multilateral trading system. Aid for Trade is broad in scope and consists of five principal elements:³

- providing technical assistance to trade officials and other stakeholders;
- promoting trade development (such as the promotion of investment);
- improving trade-related infrastructure;
- building productive capacity;
- providing adjustment assistance (9).

3.3.3 *Role of WTO: mobilizing, monitoring and evaluating*

WTO plays a key role in monitoring and evaluating progress on Aid for Trade, through periodic global reviews in the Committee on Trade and Development and an annual General Council debate on Aid for Trade. Monitoring and evaluation takes place on three levels:

- a global review of Aid for Trade flows using the OECD Development Assistance Committee database to assess whether additional resources are being delivered, to identify where gaps lie, to highlight where improvements should be made and to increase transparency on pledges and disbursements;
- evaluations of the Aid for Trade activities of national, regional and multilateral donors, based on donor self-assessments;

³ As outlined in the recommendations of the task force on Aid for Trade set up by the Director-General of WTO (WT/AFT/1, dated 27 July 2006) (9).

- country and region-based monitoring and evaluation to provide a more focused country-specific perspective on whether trade needs are being met, financial resources are being provided and Aid for Trade is being effective on the ground.

It is critical to Aid for Trade that there be coherence between the various capacity-building initiatives being undertaken by multilateral institutions, bilateral donors and nongovernmental organizations. Aid for Trade requires WTO to collaborate with a range of national, regional and international actors, including those in the private sector, to increase flows of technical and financial assistance through existing channels and to work with developing and least developed countries to assist them in identifying their trade-related needs that could be met by additional Aid for Trade.

In 2012, the WTO Committee on Trade and Development held a workshop on Aid for Trade and Services, noting that trade in services has been relatively neglected in the literature despite its substantial contribution to global trade. The secretariat's Background Note to the workshop suggested that Aid for Trade could help to address a number of supply-side and trade-related infrastructure constraints that may adversely affect services sectors in certain developing countries, including (a) lack of access to export financing, (b) poor telecommunications infrastructure, (c) weak domestic legal environment for business, and (d) limited educational infrastructure and consequent scarcity of trained staff (10).

3.3.4 Aid for Trade flows

One of the important aspects of the monitoring and evaluating function is to assess changes in the level of resources being made available and to identify the areas where gaps exist and improvements are required. Accordingly, WTO, in partnership with OECD, established a joint monitoring system based on data on global flows of development aid and on feedback from donor and partner countries. Aid for Trade flows are profiled using the OECD Creditor Reporting System, which is the closest approximation to the categories identified under Aid for Trade.⁴ Some donors have developed their own methodologies for identifying Aid for Trade expenditures.

Between 2002 and 2005, donors committed on average US\$ 21 billion per year to the aid categories most closely associated with Aid for Trade. This figure comprises US\$ 11.2 billion to build economic infrastructure; US\$ 8.9 billion to promote productive capacities (including US\$ 2 billion for trade development); and US\$ 0.6 billion for increasing the understanding and implementation of trade policy and regulations (11). The largest aid providers by volume are Japan and the United States. Other important bilateral donors are France, Germany, the Netherlands and the United Kingdom. Large multilateral and regional institutions, for example the World Bank and the regional development banks, provide around 50% of their sector programmes via Aid for Trade.

In the same period (2002–2005), the largest allocation of Aid for Trade was received by Asia (51%, mainly for economic infrastructure) while Africa received 30%, Latin America and the Caribbean 7%, Europe 5% and Oceania 1%. Most Aid for Trade went to lower middle-income countries (36%), followed by the least developed countries (25%).

The level of aid commitments rose significantly by 2009, increasing by 60% over the baseline years of 2002–2005, according to a joint WTO/OECD publication (12). Aid to sub-Saharan Africa and the Americas increased by 40% and almost 60%, respectively, while aid to other areas decreased: Europe by 34%, Asia by 18%, and Oceania by 28%. These regional trends reflect increasing donations to low income countries and simultaneous decreases in aid to middle income countries. In 2010, Aid for Trade commitments were exceptionally high at \$48 billion. However there was a shift in aid for trade flows in 2011 and 2012, as it declined with decreasing support for infrastructure, particularly in Africa. While funding for least developed countries (LDCs) decreased, they did not bear the brunt of the decline. The flows indicate a shift in funding towards private sector development and value chain promotion. Aid dedicated to building productive capacity with a trade development objective almost doubled from 2007 (\$2.6 bn) to 2011 (\$5.4bn).

⁴ Categories include: trade policy and regulations; trade development; trade-related infrastructure; building productive capacity; trade-related adjustment; and other trade-related needs.

In 2011, aid-for-trade commitments were made to 146 countries, with Africa registering a drop of 29 percent, while Asia received 5 percent less compared to 2010. For Latin America and the Caribbean, flows remained at 2010 levels. Within this region however Central America and the Caribbean were the major beneficiaries as flows almost doubled (a 93 percent increase) compared to the 2002–2005 baseline (13).

Donors and beneficiaries are increasingly prioritizing Aid for Trade in their programmes. Indeed, a spectrum of organizations, including intergovernmental and private sector organizations, are developing Aid for Trade strategies to enable them to better participate in the initiative. The overall trend seems to be one of positive growth in Aid for Trade.

3.3.5 Demand-driven process

To sustain and enhance the rising trend in Aid for Trade, it is essential that it be demand-driven. Beneficiary countries need to centralize trade development as a key element in their economic development strategies. Donor support is more assured when political commitment is demonstrated through prioritization of trade in national development plans, including: poverty reduction strategy papers; appropriate political backing to carry through action plans; and preparedness to actively partner in the conception, design and implementation of prioritized projects.

One of the foremost issues identified in various diagnostic studies is the lack of adequate capacity in terms of skilled human resources. Moreover, many developing countries currently lack appropriate and sufficient tools to effectively manage their own capacity development processes. Also apparent is a lack of awareness of the far-reaching impacts that trade rules and negotiations may have on the health sector. This could be one immediate area where assistance is required in training and awareness raising among health professionals, specifically with respect to trade rules in the area of sanitary and phytosanitary measures, technical barriers to trade, trade related intellectual property rights and the regulation of health services. Through Aid for Trade the trade and health assessment tool could assist countries in assessing their needs and capacities as a basis for drawing up concrete action plans and projects that could attract funding and technical assistance. The new holistic approach related to access to health services and health outcomes evidenced in the new sustainable development agenda provides further impetus for enhancing the capacities and undertaking a needs analysis of the trade and health sector. The ultimate objective is to capacitate developing countries to contribute to an open global trading system in which their national development flourishes and the multilateral trading system is leveraged to increase economic efficiency and promote good governance.

The Aid for Trade initiative supports countries in carrying out needs assessments, identifying their priorities (for example in the trade and health sector), discovering policy gaps and considering solutions to bridge those gaps. Solutions may take the form of technical assistance and hands-on training regarding the implications of trade-related provisions for the health sector. Countries may require investment in infrastructure for establishing testing laboratories, training personnel in reforming the regulatory environment, and facilitating greater policy coherence on issues pertaining to trade in health services (14). Improved knowledge of the challenges and opportunities that trade agreements can bring to the health sector may enable policy-makers to better frame appropriate policy responses, including negotiating strategies in international trade negotiations.

In keeping with the rationale of the Aid for Trade initiative, any projects that are conceived need to demonstrate that they address national priorities. Projects envisaged in the trade and health sectors would therefore typically involve collaboration between the ministries of trade, health, development planning, and finance, as appropriate. For accessing any funds under Aid for Trade, the ministry of trade would normally be the nodal agency, though this may vary from country to country. While the nodal ministry is responsible for drawing up a comprehensive strategy on trade and development, the input outlining the priorities of other ministries, including health, should inform this strategy.

3.3.6 *Summing up*

The Aid for Trade initiative has established a framework for bringing together all stakeholders, including beneficiary countries, donors, the private sector, regional development banks and multilateral institutions, to work towards a common goal. It is essentially a demand-driven process, with the onus on the beneficiary country to demonstrate a need, establish priorities and submit bankable projects to achieve the desired outcomes. The underlying theme of coherence underlines the importance of exploring synergies between aid programmes in health and trade. The upcoming global Post 2015 Sustainable Development Goals Agenda also recognizes the value of development aid as well as aid for trade to address outstanding issues and tackling new frontiers in the area of communicable and non-communicable diseases. Stemming from the experience of implementing the MDGs, there is now more than ever a realization of the need for an appropriate financing mechanism for achieving sustainable development, which may call for building innovative mechanisms within the Aid for Trade agenda by leveraging not only public resources but also private sources of finance and effective domestic resource mobilization.

In this context, both trade and health policy-makers need to focus on the need for a mutually supportive relationship in the trade and health sectors. Such a focus would support their ability to overcome the difficulties they face in adapting the new aid architecture to trade and health. From analysing priorities to implementation, all development partners need to collaborate in order to make best use of the additional funding available for better trade and health outcomes. The assessment tool being developed for health policy officials would be of great assistance in setting the priorities in the trade and health sector and identifying the capacity and infrastructure gaps where additional financial resources are required. Access to these resources would be facilitated through the Aid for Trade initiative.

3.4 Integrated Framework for Trade-Related Assistance for Least Developed Countries

3.4.1 *What is the Integrated Framework?*

The first WTO Ministerial Conference in 1996 recognized that the least developed countries faced difficulties in integrating into the global economy. This recognition led to the adoption of the WTO Plan of Action for Least Developed Countries. Following this, WTO convened a high-level meeting in October 1997 to deliberate on the specific needs of the least developed countries and to formulate a programme to strengthen their trade capacities, including supply-side and market access capacities. The Integrated Framework for Trade-Related Technical Assistance to Least Developed Countries was a product of those deliberations.

The Integrated Framework, whose Executive Secretariat is housed within the WTO, is supported by eight multilateral institutions, namely the International Monetary Fund, the International Trade Centre, UNCTAD, UNDP, the World Bank and WTO, with UNIDO and UNWTO as observers; and 23 donors. The objective of the programme is to join efforts with least developed countries and donors to address the trade development needs of those countries. These range widely in scope, from increasing macroeconomic stability to developing trade policy and trade administration capacity, and from addressing supply-side constraints and meeting international standards to developing infrastructure (15). The Integrated Framework was envisaged as an initiative to integrate least developed countries into the global trading system by mainstreaming trade into national development plans, including poverty reduction strategy papers. The Integrated Framework also serves to assist in coordinating the delivery of trade-related technical assistance in response to needs identified by the least developed countries. It is built on the principles of country ownership and partnership and is designed to deliver harmonized trade-related technical assistance.

3.4.2 From Integrated Framework to Enhanced Integrated Framework

Evaluations of the functioning of the Integrated Framework carried out over the period 2003–2004 concluded that while the Integrated Framework provided a good basis for least developed countries to enhance their trade capacities, the anticipated results had not been fully achieved (16, 17). This was due to such factors as inadequate provision of financial and human resources to the least developed countries, weak country ownership and scant response by donors to the priorities identified in diagnostic trade integration studies (see section 3.4.6). The Development Committee of the World Bank and International Monetary Fund, at its meeting in September 2005, recommended that the Integrated Framework be enhanced and provided with additional resources. The Integrated Framework Steering Committee established a task force to develop proposals for such an enhancement. It was agreed that the enhanced Integrated Framework should cover three specific elements:

- increased, additional, predictable financial resources to implement action matrices;
- strengthened in-country capacities to manage, implement and monitor the Integrated Framework process;
- enhanced Integrated Framework governance.

At the sixth WTO Ministerial Conference in Hong Kong (2005), trade ministers endorsed the establishment of a task force to make recommendations on institutional issues, including staffing of the Executive Secretariat, defining the in-country approach and programming issues, and launching the replenishment process (4).

The task force acknowledged the importance of trade liberalization for improving economic conditions in the least developed countries and achieving the Millennium Development Goal of halving poverty by 2015 (18). The task force also made recommendations focused on four broad areas:

- the need for stronger ownership of the Integrated Framework by the least developed countries and the donors, which could only be achieved by building and strengthening capacity in the least developed countries;
- the need to fill the gap between the diagnostic trade integration study and the submission of bankable projects, and the need to convert action matrices related to the study into living documents that could be updated regularly to reflect changing needs;
- the necessity of a responsive management and implementation structure in order to assure the successful functioning of the Integrated Framework; and
- most importantly, the need for adequate and predictable funding in order to meet the objectives of the Integrated Framework.

There was also broad consensus during the task force deliberations that the private sector should be included at all stages in the work of the Integrated Framework at the country level, including the diagnosis stage.

The EIF presently supports 47 LDCs and two recently graduated countries through a multi-donor trust fund, the EIF Trust Fund, with contributions from 23 donors. A high-level pledging event in 2007 set a funding target of US\$ 250 million over five years.⁵

⁵ <https://www.enhancedif.org/en/about> (Last accessed on 27 January 2014).

The mid-term evaluation of the programme in 2012 has concluded that the EIF is extremely relevant to the trade and economic priorities of LDCs as it supports trade mainstreaming into national development strategies, contributes to strengthening capacities for trade-related strategies and plans and ensures a coordinated delivery of prioritized trade-related assistance. Additional areas identified include strengthening linkages to related donor programming and enhancing customisation of projects at country level for greater impact. Consequently the EIF Steering Committee extended the programme mandate up to 31 December 2015, with an additional operational period for project implementation running through to 31 December 2017.⁶

3.4.3 Integrated Framework governance structure

The Integrated Framework governance structure is established at two levels: international and national. Tables 3.1 and 3.2 show the principal components or bodies of the governance structure, along with their composition and functions, at the international and national levels respectively.

Table 3.1 Integrated Framework structure at the international level

Body	Composition	Functions
Integrated Framework Steering Committee	Six core agencies, all donors and all least developed countries	Provides broad policy direction and reviews work of Integrated Framework Board
Integrated Framework Board	Six core agencies and three representatives each from the donors and least developed countries	Key decision-making body Responsible for overall management of process, including oversight of the Trust Fund
Integrated Framework Executive Secretariat	Headed by an Executive Director, who is also an ex officio member of the Board	Responsible for providing support to least developed countries Assists the Integrated Framework governing bodies by providing administrative and secretarial support Coordinates and monitors the Integrated Framework process and engages in outreach activities
Trust Fund	Multidonor trust fund managed initially by UNDP, then by the United Nations Office for Project Services	Provides funds for (1) the diagnostic trade integration study and for strengthening in-country Integration Framework implementation capacity, and (2) projects identified in the action matrices

⁶ Ibid.

Table 3.2 Integrated Framework structure at national level

Body	Composition	Functions
National steering committee	Members of government, in particular from trade, finance and development ministries; members of the national committee that drafts the poverty reduction strategy paper; representatives of civil society and private sector	<p>Monitors overall Integrated Framework process and activities, including trade mainstreaming into poverty reduction strategy papers and other development plans</p> <p>Ensures effective coordination among government institutions, private sector, civil society and other stakeholders</p> <p>Approves tier 2 projects, in consultation with donor facilitator and Executive Secretariat (see further down for the differentiation of tier 1 and tier 2 projects)</p> <p>Participates in appraisal and approval process of tier 1 projects</p> <p>Ensures that trade-related issues are included and receive due attention in donor conferences, such as consultative group meetings and round-table meetings</p>
Focal point	Appointed by government; usually a high-level civil servant, either from the ministry of trade or from another core ministry, the prime minister's office, or the national poverty reduction strategy paper committee	<p>Oversees functioning of the national implementation unit and advises country government on the unit's staffing and operations</p> <p>Chairs tier 1 and tier 2 appraisal committees and invites other representatives to participate in these committees</p> <p>Works with relevant bodies to ensure that trade-related technical assistance projects are mainstreamed into poverty reduction strategy paper</p> <p>Leads preparation of diagnostic trade integration study</p> <p>Reports to country government and Executive Secretariat on progress of Integrated Framework</p>
National implementation unit	Country government decides on modalities of the national implementation unit, including staffing requirements and venue of office; for example, members of core ministries could be seconded, or national consultants hired by national steering committee	<p>Supervised by Integrated Framework focal point</p> <p>Works with relevant ministries and trade-related institutions to ensure coordination at all stages of Integrated Framework process</p> <p>Works with Executive Secretariat, donor facilitator and Integrated Framework agencies in preparation of the diagnostic trade integration study and formulation and appraisal of tier 1 and tier 2 project proposals</p> <p>Monitors implementation of tier 1 and tier 2 projects under national steering committee and reports on progress to Executive Secretariat</p> <p>Works with all relevant partners on the inclusion of trade integration strategies and priorities in poverty reduction strategy papers or national development plans</p>
Donor facilitator	In principle, this role should be undertaken by the most active donor in the field of trade-related technical assistance in the country with assistance if needed; full commitment of donor facilitator to role is essential	<p>Assists country government in enlisting and coordinating donor responses to the action matrices produced, including liaison with donors to ensure effectiveness, complementarity and harmonization of interventions</p> <p>Supports national implementation unit and focal point in the conduct of their responsibilities</p> <p>Assists national implementation unit to formulate and appraise tier 1 and tier 2 projects</p> <p>Facilitates country government's contacts with donors to ensure that all relevant information regarding Integrated Framework and its implementation is transmitted to stakeholders</p> <p>Informs stakeholders, including donors, on the progress and results of implementation of the Integrated Framework</p> <p>Assists local authorities in understanding the Integrated Framework process in the country</p>

Source: World Trade Organization (19).

3.4.4 *Process for implementation of the enhanced Integrated Framework*

The implementation of the enhanced Integrated Framework consists of three broad stages:

1. preparatory activities, which typically include an official request from the country to participate in the Integrated Framework process, a technical review of the request, the establishment of the national Integrated Framework steering committee, and identification of a donor facilitator;
2. a diagnostic phase, which following approval of the request, results in the elaboration of a diagnostic trade integration study;
3. follow-up activities that start with the translation of the findings of the diagnostic phase into the elaboration and validation of an action plan, which serves as a basis for trade-related technical assistance delivery.

Even though assistance in the preparatory phase to the beneficiary country has traditionally been rendered by the six implementing agencies (International Monetary Fund, International Trade Centre, UNCTAD, UNDP, World Bank and WTO), in accordance with their areas of competence, it is not necessarily limited to those agencies. The process is also open to other agencies or donors that may be identified by the beneficiary.

Given the increasing importance of trade in foodstuffs, health services and pharmaceuticals, it is vital that health officials assist in addressing product quality challenges, such as a lack of standards for foodstuffs, the absence of appropriate testing and certification laboratories, or the opening up of health services and regulations pertaining to pharmaceuticals. Opportunities for health officials to collaborate in the national mechanism set up under the Integrated Framework are available through the national steering committee and the national implementation unit. The focal point under the Integrated Framework could be contacted by national health officials to ensure their participation in the national steering committee and the national implementation unit.

3.4.5 *Funding and access to resources*

An Integrated Framework Trust Fund was created in 2001 to finance the diagnostic studies and the implementation of priority actions. Contributions to this fund are made voluntarily by 23 multilateral and bilateral donors. The Trust Fund was initially managed by UNDP but was transferred to the United Nations Office for Project Services to ensure increased, additional, and predictable financial resources to implement the action matrices, though UNDP will continue to manage all on-going activities under the Integrated Framework until their natural conclusion.

Under the enhanced Integrated Framework, the tier 1 financing arrangement funds the core activities with the objective of supporting greater in-country capacity and ownership. A sum of around US\$ 77 million was made available for tier 1 from the enhanced Integrated Framework Trust Fund, with the funding ceiling per country set at US\$ 2 million. Activities eligible for funding include preparatory work, the diagnostic trade integration study, updates of the study and support for national implementation arrangements. All participating least developed countries are eligible for tier 1 funds.

The tier 2 financing arrangement funds the priority activities identified in each country's diagnostic trade integration study and its action matrix. The spending from tier 2 is related to such activities as actual project implementation and feasibility studies; larger infrastructure projects require funding from other mechanisms. Some examples of tier 2 funding include:

- assistance in implementing WTO or other trade policy commitments;
- project preparatory activities;
- capacity-building activities for key trade support institutions;
- preparation of sector wide approaches for priority sectors identified in the diagnostic trade integration study
- assistance for WTO accession.

Following the recommendations of the task force for enhancement of the Integrated Framework, it was agreed that an amount of US\$ 400 million over five years would be sufficient to meet the costs associated with domestic capacity building (tier 1). This included some activities identified in the action matrices (tier 2), and the costs of the Executive Secretariat. The size of the enhanced Integrated Framework Trust Fund was envisioned to be about US\$ 240 million, with the remaining US\$ 160 million to be met through funding from in-country donors. The amount of funding currently available totals US\$ 100 million, and pledges of US\$ 182 million are to be disbursed over a five year period.

Given the well-defined governance and funding structure under the Integrated Framework, it is clear that health officials need to be associated with the national steering committee and the national implementation unit. An assessment tool could assist the task of mapping out priorities in the trade and health sector and identifying the capacity gaps that need to be filled. Concrete projects for domestic capacity building in the area of trade and health could be financed under tier 1 of the Integrated Framework Trust Fund. Twinning with related donor programmes in health as well as customisation as per country needs is also possible under the programme. To obtain the requisite funding, it is necessary to demonstrate, through domestic and inter-ministerial coordination, a real need and a project with tangible benefits.

3.4.6 *Diagnostic trade integration study*

Perhaps the most significant part of the Integrated Framework process is the preparation of the diagnostic trade integration study, as it generally embodies the following:

1. a comprehensive assessment of the country's macroeconomic environment;
2. structure and pattern of trade and investment;
3. institutional and regulatory framework;
4. trade and poverty linkages;
5. business environment, standards, trade facilitation, export competitiveness; and
6. infrastructure constraints.

Based on this assessment, which has normally been led either by the World Bank or UNDP along with the beneficiary country, an action plan (or matrix) is drawn up reflecting the priorities identified in the diagnostic study. Care should be taken to align the action plan with the country's national development plan and poverty reduction strategy paper. The action plan is then executed by the beneficiary country with technical assistance from the international development community.

A total of 58 projects and 37 Diagnostic Trade Integration Studies (DTIS) and DTIS updates were ongoing in 43 countries in 2012–2013.⁷ Some of the completed studies were reviewed to assess the number of cases where trade and health issues had been prioritized. It was discovered that, even though health issues are an important component of what is conceived as development, they are often not specified directly in the diagnostic trade integration study as a key priority. Thus, efforts should be made to develop a broad strategy for enhancing competitiveness and protecting human, plant and animal health as well as “attaining health for all at all ages”.

For instance, a number of diagnostic trade integration studies, as in the case of Uganda and Zambia, identify the need for better coordination between the trade ministry and other ministries, including the ministry of health, along with improved standard-setting procedures and the initiation of legal and regulatory reform (20, 21). In other cases, as in Vanuatu, which has a high literacy rate and some positive health indicators, emphasis is placed on improving access to health services and education (22). The diagnostic trade integration study of the United Republic of Tanzania notes that the country is likely to continue to be highly aid dependent, and addressing its macroeconomic issues would require balancing aid and public expenditure between the social, infrastructure and productive sectors (23). It is nonetheless acknowledged that higher spending on social sectors would help meet some of the Millennium Development Goals (health, education and access to water). Senegal also attaches considerable importance to improving social and human capital indicators, both for promoting export growth and for its long-term development (24).

From the foregoing, it is clear that linkages between trade and health are often neglected at the national level, and diagnostic trade integration studies are thus an important aspect of the national development strategies of least developed countries. To assist in making this linkage, coordination between trade, health and development officials at the country level is imperative, as the issues identified should not only be a part of the national development plans or poverty reduction strategy papers, but should also draw the attention of donors and international organizations to supportive action they might take in that area.

Under the Integrated Framework, the diagnostic trade integration study offers a valuable opportunity for health officials to influence the process and prioritize trade and health issues, and to seek assistance for capacity building. Health officials can use the aforementioned trade and health assessment tool to help them in this endeavour by identifying their current capacity and gaps in that capacity. For example, a least developed country may identify that cross-border delivery of health services through use of information and communication technologies, such as telemedicine, could alleviate its human resource constraints and help increase efficiency in the health care sector. Resources for this initiative could be accessed under the Integrated Framework after a concrete plan to achieve the objective is ratified by the Integrated Framework national steering committee.

The trade and health assessment tool and the diagnostic trade integration study can thus play complementary roles. The assessment tool can identify gaps in national capacity as they pertain to trade in health products and services whilst the diagnostic trade integration study can build on this information to guide policy-makers in the development of a national strategy on trade and health.

This self-assessment is the first step towards mobilizing resources following the development of a concrete action plan to address these needs. Donors need to be presented with evidence of tangible plans, country ownership and commitment. Moreover, a rational and consistent national development strategy, which prioritizes trade and health issues and which also figures in the country's poverty reduction strategy paper, is the appropriate way forward to ensure capacity building in the area of trade and health.

3.4.7 Mainstreaming trade and health issues in national development plans: the way forward

An integrated policy oversight body would facilitate an efficient use of the various assistance mechanisms that are now available to developing and least developed countries. Pursuant to the principles expressed in the Paris Declaration, the increasing emphasis on ownership, harmonization and alignment of aid initiatives should be adopted at both the country and regional levels. The needs assessment on trade and health

⁷ www.enhancedif.org/en/publication/2013-12/ (Last accessed on 27 July 2015)

issues may be conducted by countries, bearing in mind the fact that assistance under the Aid for Trade and the Integrated Framework initiatives is predicated on a demand-driven process, founded on political commitment and full ownership by the beneficiary country. The needs assessments should result from a prioritization process developed through stakeholder consultation and should have the endorsement of donors as well as development partners. Concrete projects for capacity building in trade and health issues, as reflected in national priorities, merit full consideration under trade capacity-building initiatives.

Thus, systematic information sharing between health and trade ministries and cooperative efforts while employing the diagnostic tools are essential. This is an opportune moment for strengthening partnership between WHO and WTO in capacity-building initiatives that would advance trade and health.

3.5 Conclusion

The trade and health sectors, both at the country and global levels, seek to alleviate poverty, increase economic growth, enhance health for all and thereby promote sustainable human development (25). This common objective calls for consistent policy approaches that are mutually supportive. Trade rules touch upon virtually all aspects of public policy, which makes it incumbent upon policy-makers to minimize conflicts between different sectors and explore synergies to enhance development and growth. Areas of immediate concern to policy-makers in developing and least developed countries include the alarming incidence of epidemics such as HIV/AIDS H1N1 (influenza), Ebola virus, the difficulty in containing food-borne diseases which are transmitted across national borders through freer trade, and the possible opening up of trade in health services. This calls for greater coordination of policies, and also may entail structural adjustments.

Underpinning all of this, however, is the great need for capacity to undertake an analysis and assessment of a country's own requirements, priorities and the gaps that may exist in giving adequate attention to health policy issues in trade rules. The technical assistance and capacity-building initiatives in the area of trade are premised on a more holistic conception of development and thus afford an opportunity to health policy officials and stakeholders to access these initiatives to address the gaps in the trade and health sector. The two main initiatives that respond to capacity-building needs are Aid for Trade, which is available to all developing and least developed countries; and the Integrated Framework, which is limited to least developed countries. The trade and health assessment tool developed by WHO would be a valuable complement to the diagnostic trade integration study and the action matrices in the Integrated Framework, and the needs assessment and gap identification process required to be conducted under Aid for Trade. Employed together, these instruments can prove useful in charting the needs for capacity building and national and regional priorities for a cogent trade and health strategy.

To access resources under the Integrated Framework, health officials in least developed countries could use the instruments mentioned above in order to: (1) take stock of the prevailing domestic regulatory environment as it affects trade in health products, including pharmaceuticals and services; (2) provide guidance in plotting capacity gaps and needs; and (3) assist understanding of the offensive and defensive interests in the trade and health sector. In addition, the information generated can help policy-makers formulate concrete action plans, such as educating health officials on the interface between the trade and health sectors; assess the need for setting up necessary infrastructure, such as testing laboratories; develop the regulatory framework to safeguard public health from trade in harmful products; and enhance capacities to participate in health services negotiations. Equipped with this knowledge, health officials and their counterparts in trade ministries are better positioned to provide evidence of a demonstrable need for additional resources to international organizations and donors.

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Chapter 4

Macroeconomic aspects of trade and health

Richard Smith, Chantal Blouin

4.1 Introduction

Most countries are undertaking trade reforms to increase the openness of their economy to international trade. This is typically done through a reduction in tariffs and quotas, but can also be accomplished by a reduction in other non-tariff barriers that limit the ease of entry of foreign goods and (especially more recently) services into a country. Clearly the pace, extent and impact of trade reforms vary, often in response to initial levels of openness, and depends on whether trade reforms are part of a wider domestic reform agenda or a conditional part of borrowing from international financial institutions such as the International Monetary Fund or the World Bank.

4.1.1 *Importance of the trade–health relationship*

Trade liberalization will inevitably impact human health. It is well known that medical care is only one of many important determinants of human health, with other (perhaps more fundamental) determinants including employment, nutrition, environmental factors, social capital and education. Through these and other factors, there is considerable evidence of the link between health and wealth, with poverty and income inequality being associated with poorer health (1). As the *raison d'être* of trade is to increase both wealth and the availability of goods, changing trade patterns can influence both income (buying power) and its distribution, and thus have an impact upon health.

Trade liberalization will also have an impact on the health sector, not only with respect to direct trade in health-related goods and services, but also as a consequence of liberalization more broadly. For instance, trade liberalization can affect overall public expenditures by allowing governments to purchase less expensive foreign goods and services, which will in turn affect the amount of money available to fund public health care.

However, although there is generally a positive relationship between trade liberalization and national income (2–4), there is increasing recognition, including amongst international financial institutions such as the World Bank, that trade liberalization in the absence of other policies will not necessarily lead to higher growth (5). Thus, although trade liberalization generally is advantageous, the crucial factor in how advantageous and to whom it is, is “how countries manage the process of integrating into the global economies” (6).

For example, trade liberalization often triggers employment creation and destruction within and across sectors, as firms adjust to the new competitive environment (7). In order to ensure that the movement of labour is as smooth as possible and to avoid excessive unemployment, effective labour market policies will be required. Trade can only explain a small fraction of the general increase in wage inequality observed in both developed and developing countries in recent decades. The lion's share of this increase in inequality stems from the strong association between technological change and higher demand for skilled labour (“skill-biased technical change”) (5, 8–11).

There is still a lack of sound empirical evidence demonstrating how trade liberalization links directly and indirectly to health. Even though the positive link between increased trade, poverty reduction and economic growth is widely accepted, evidence regarding the impact of trade liberalization on the social determinants of health varies from one national context to another. Hence, adapting trade liberalization

to national conditions is important in ensuring desired outcomes (12, 13). This requires consideration of “flanking” policies that may be undertaken to mitigate adverse consequences, and the design of trade policies that reduce the potential health risks associated with freer trade whilst maximizing the positive impact of trade liberalization on the social determinants of health.

4.1.2 Trade and health policy

As the World Commission on the Social Dimensions of Globalization noted, in a competitive international economy there is greater vulnerability to sudden change than in protected national markets (14). Therefore, policy-makers should continually review and update national systems of social protection that can stabilize incomes, distribute the gains of globalization to groups that would otherwise be excluded and support the development of new capabilities.

It is critical to distinguish social protection schemes between low-income countries and middle-income countries. Low-income countries have very limited financial resources available to fund social protection schemes and limited capacity to raise such funds, given that a large part of their economy is informal or based on subsistence agriculture. Given these limited resources, social protection should focus on interventions that contribute to long-term poverty reduction and that have multiplier effects (15), such as health insurance schemes that protect against unexpected (and often catastrophic) medical expenses (16–18).

Middle-income countries have a wider range of instruments available to them to reduce economic insecurity, so a key policy issue becomes whether social protection should be universal or targeted to particular groups. Targeted programmes may be very attractive in terms of reducing the fiscal implications of social protection (19–21), however, evaluative and policy studies offer powerful arguments in favour of universality. For instance, targeted coverage is exclusionary and reinforces existing social stratification and stigmatization. Additionally, macroeconomic shocks are a rude reminder that in times of systemic crisis, there is little that separates middle-income from lower-middle-income groups, and finally, the targeted programmes often involve greater administrative costs and are prone to “leakage” on many levels.

In summary, trade policies adopted by national governments can affect health and health systems through a very diverse set of channels and intermediate variables. However, these causal linkages can be difficult to track and monitor. Moreover, in many political systems, health authorities are not in a position to directly affect trade policy decisions at the national level. Nevertheless, their existing knowledge of the determinants of population health and their jurisdiction over social and health policies place health policy-makers in a privileged position to ensure that, in an increasingly global economic environment, domestic policies and regulations are designed to maximize the potential of, and to minimize the risks presented by, trade liberalization.

There are many national and international information sources that discuss trade and the general macroeconomy, such as public expenditure reviews and trade policy reviews. However, the key issue facing health policy-makers is how to interpret this information with respect to the health sector. What information needs to be extracted? How might this information be interpreted? What health and trade policies should be adopted in light of the information?

This chapter provides an overview of the complex relationships between trade and health focusing on general macroeconomic factors such as the growth and distribution of national income, rather than on direct trade in health-related goods and services (which are covered elsewhere). The aim is to acquaint health policy-makers with some fundamental facts, concepts and evidence concerning the influence of macroeconomic factors on population health and the health sector. The chapter thus creates a basis for later chapters that deal with more specific trade and health issues.

4.2 Trade, growth and health

Macroeconomic policy is concerned with gross domestic product (GDP), which measures the value of all goods and services produced in a country during a given time period. An increase in GDP represents economic growth. International trade is a key factor leading to economic growth through specialization, given that specialization allows each country to exploit its comparative advantage in particular areas. Differences between countries in their technology, labour skills, climate, institutions and other factors mean that their production functions across different goods and services differ (22). The law of comparative advantage states that each country specializes in the production of goods and services that best suit its relative endowment of skills and resources and trades these for other goods and services from countries that are relatively more efficient at producing those goods and services. Specialization and international trade thus changes relative prices and allows countries to produce and consume more than they would under a system of autarky. Trade liberalization increases competition, which leads not only to lower prices but also increased selection. Overall, those countries that engage in trade will see increasing GDP, lower prices, a wider selection of available goods and services, higher employment and higher government revenues (due to higher income and the ability to tax that income) (23–25).

General analyses suggest that “wealthier countries are healthier countries” (26, 27). The relevant factors in this relationship are generally improved nutrition, sanitation, water and education (1, 28–34). The direction of causation is subject to some debate, although it is widely accepted that a “virtuous circle” exists between increasing wealth and health such that both directions of causation are valid (35).

Important in the context of this chapter is that it has been well documented that open economies grow more rapidly than restricted ones, and thus the health gains from higher growth will accrue more quickly in those countries that engage more in international trade (5, 24, 36–39).

Trade liberalization implies adjustment and so is likely to have distributional impacts. Evidence supports the proposition that trade liberalization will be poverty-alleviating in the long run and on average. However, trade reform is not always the most important determinant of poverty reduction (37).

4.3 Distributional impacts of trade on income

It is important to remember that macroeconomics relates to *aggregate* populations and incomes, and not individuals. In many cases, changes in macroeconomic policy, of the sort indicated above, may be beneficial overall but will have distributional impacts, especially during the adjustment period, meaning that some individuals will experience economic benefit while others may suffer economic loss. Most macroeconomic indicators do not account for these distribution impacts, and are focused instead on the aggregate of total income, trade volume, employment, and so on, rather than the composition of that total.

Lowering tariffs (taxes on imports) may generally benefit consumers who can then purchase imported goods at lower prices, but may also create losses in competing domestic firms and reduce import tax revenue. Losses to domestic firms can, in turn, negatively impact the employees and other stakeholders of the firms, such as via lost jobs, reduced wages (40), or reduced revenue from both corporate and personal income taxes. For these reasons, countries are often careful in opening sectors to international competition. However, recent evidence suggests that, overall, trade liberalization benefits domestic producers by both lowering the prices and increasing the variety of imports used as inputs in production (41), suggesting that these gains more than offset the negative effects just described.

Depending on the economic geography of a country, some regions might benefit more than others from liberalized trade. For instance, it might be the case that export goods are produced in urban areas. Increased income from trade accruing to these urban areas may benefit those areas and surrounding rural areas (through higher demand due to rising incomes), but may not reach areas farther away. However, if managed wisely by the government, the new income opportunities could thus, in principle, benefit the entire population.

Thus, although in aggregate trade liberalization may generate economic benefits for a country, it is also likely to require adjustment at various levels, including at the individual level. This adjustment process might cause a feeling of increased economic insecurity with implications for psychological well-being. Some experts suggest that economic insecurity also increases the demand for more generous social insurance that compensates individuals for a riskier environment (42–44).

Despite these distributional caveats, evidence shows that the gains from trade liberalization should outweigh the adjustment costs and lead to net welfare gains (Box 4.1).

Box 4.1 Distributional impacts of CAFTA-DR

The Dominican Republic-Central America-United States Free Trade Agreement (CAFTA-DR) is an agreement involving the United States of America, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and the Dominican Republic. Given unilateral trade liberalization undertaken in the 1990s, Central American countries, in general, were already relatively open when the US-CAFTA process began in 2004. However a handful of sensitive agricultural commodities, such as maize, beans, dairy products and poultry, still had significant levels of protection. These levels of protection were reduced or eliminated as a result of CAFTA-DR, which gradually entered into force for its member countries over the period 2006–2009.

While the majority of Central Americans are expected to benefit from CAFTA-DR in the medium to long term, primarily through lower domestic prices for sensitive commodities, the reduction or elimination of existing tariff protection on those commodities could adversely affect a small share of the population living in rural areas of Central America.

CAFTA-DR includes a range of provisions to deal with liberalization of trade in sensitive goods, such as grace periods for initiating liberalization, extended tariff phase-out periods (in some cases as long as 20 years following entry into force), interim quotas and phase-downs of quota rates, as well as special safeguards. However, it has been proposed that governments go further and create targeted programmes to help households that would be faced with significant income losses. In fact, targeted compensation may be preferable to long transition periods. Although slow phase-out of tariffs gives producers extended periods to make economic adjustments, it also deprives consumers of the benefits of liberalization associated with lower prices for the same extended time period. A shorter time frame for removal of trade barriers, coupled with well-targeted transfers, could enhance household welfare in the short term on the consumption side while providing reasonable support to producers to make the economic transition.

Source: World Bank (9).

4.4 Trade, government revenue and health care spending

Trade affects government income and hence the ability to finance or provide public services, including those related to health. Trade directly affects government revenue via taxes (tariffs) imposed on imports to the country. However, trade can also indirectly affect government revenue via income taxes paid by local businesses and their employees. Trade effects on indirect taxes can result in net contributions to government income, such as where gains in tax revenue traceable to increased export income exceed losses in tax revenue due to increased imports, or net detraction (i.e., where trade-related losses in tax revenue exceed gains). Understanding the potential impact of trade on the different type of taxes is important because certain types of tax income are relatively easy to collect (such as tariffs) while other types may be harder to collect (such as consumption taxes, income tax and value-added tax) (45).

In some developing countries, tariffs are an important source of public revenue and thus contribute to the capacity of these countries to adopt policies that affect the various determinants of health. The contribution of tariff revenues to total government revenues ranges from less than 1% for members of the Organisation for Economic Co-operation and Development (OECD) to around 80% in Guinea, with typical examples of Cameroon at 28% and India at 18% (46).

The concern is that trade liberalization changes the tax revenue structure, reducing the proportion of government income from easy-to-collect sources such as tariffs. Although theoretically governments should be able to shift tax bases from tariffs to domestic taxes, such as sales or income taxes, in practice developing countries, especially low-income countries, find this difficult, due to the informal nature of their economies, which often have large subsistence sectors (45). For instance, high-income countries are usually able to recover 100% of the lost tariff revenues, whilst middle-income countries accrue around 40–60%, whereas low-income countries can only gather around 30% (47).

Evidence also suggests that tariff revenues decline following trade liberalization given that trade liberalization is concerned with reducing or eliminating barriers to trade, such as tariffs. Most developing countries, especially low-income countries, have not yet been able to replace tariffs with other types of revenues, and have thus witnessed a general decline of their public revenues (48–50). In this case, reduced import tariffs have resulted in a decline of government income available to pursue public policies, whether related to health care, education, water, sanitation or social safety nets.

On the other hand, lower import prices might benefit the public provision of health care, as inputs into health services become cheaper and more available. Furthermore, consumers are likely to benefit from lower prices thus enabling them to spend more on health care, education and other beneficial services.

Finally, it is important to note that lower tariffs on imports are not necessarily correlated with lower total revenue (51). This is because trade liberalization can increase the volume of international trade such that the base expansion may exceed the rate reduction and hence yield higher revenues, at least where tariffs are reduced rather than eliminated. For instance, halving import tariffs may be entirely offset if trade doubles. This appears to have been the case in a few countries at the early stage of implementation of World Bank trade reform programmes (52). Import tariffs can also have complex structures. Lower average duty rates are not necessarily the result of across-the-board rate reductions. For example, high duty rates may be lowered, while low duty rates may be raised. Interestingly, the impact of liberalization on tariffs may also be an argument for increased multilateral, rather than bilateral, trade negotiations, as the latter often involve more severe tariff concessions than the former.

4.5 Economic stability and health

Human health is promoted by *stable* economic growth. Economic instability can be manifested in volatile markets, external shocks and financial crises, and can result in destabilizing effects, such as rapid changes in employment. These events will affect the adequacy of financial preparedness for ill health by the household and the (public and private) health sector, and generate investor reluctance (including within the health

sector itself). They might also translate into economic insecurity, which is closely linked to increased stress-related illness (53).

The empirical evidence suggests that there is no link between trade liberalization and economic stability. Rather, studies find that the institutional quality of a country determines to what extent it is able to cope with economic shocks and is thus an important determinant of its economic stability (54). For example, the impact of the Asian crisis in the late 1990s was felt particularly severely by some countries, revealing institutional gaps in social protection and other areas. (Compared with the OECD average of 12.7%, East Asia spent 1% of GDP on social protection.) In the aftermath of the Asian crisis, it was thus recommended by the World Bank that higher-quality institutional structures be put in place to help households manage the risks of income shocks (55).

4.6 Sources of information, key indicators and their interpretation

Trade increases national income, which improves health directly by increasing consumer purchasing power. Through increased government revenues, provisions for a wide-reaching and better health care can be established. In addition, trade can improve health more indirectly through effects on education, consumer values and consumption patterns. However, this is in the aggregate and over the long term. In the short term or for specific groups, there are likely to be detrimental effects. Key indicators should therefore be monitored to track the implementation of trade policy and its impact on health and the health sector, and the data gathered should inform negotiations with trade policy-makers and the design of proactive and responsive health policy.

A range of readily accessible indicators from national data sources may be used to monitor and analyse the issues highlighted in this chapter. Collecting and interpreting these indicators will guide policy-makers towards identifying and understanding the linkages between the general economic and health environment and the changes engendered by trade reforms over time. In this latter respect, these indicators would be best subjected to a time series analysis with one or more health indicators as dependent variable(s) and the indicators discussed here as independent variables. Existing indicators of relevance include:

- GDP per capita
- the ratio of trade to GDP
- the ratio of imports to exports
- the unemployment rate
- the Gini coefficient¹ (general distributional concerns)
- tax revenue as a proportion of GDP
- tariff revenue as a proportion of overall tax revenue
- average and sectoral tariff rates
- the inflation rate.

Indicators such as these could be combined to provide useful information. For example, stable and equitable economic growth (and trade liberalization) would be indicated by high and sustained (little annual variance) increases in GDP, low overall unemployment and a low Gini coefficient. Trade liberalization promotes *sustained* economic growth (first indicator) and should go hand in hand with promoting *equitable* economic growth (latter two indicators).

The assessment of the direct and indirect impacts of trade on health can be made before the adoption of a major trade policy change, or it can be conducted afterwards in order to monitor the changes associated with the new trade environment. An assessment tool (see section 1.1 of Chapter 1) could be used to compile

¹ The Gini coefficient is a commonly used measure of inequality of wealth, with a coefficient of 1 indicating large wealth disparities and a coefficient of zero indicating evenly distributed wealth.

information about trade and health issues in a country, forming a basis for analysis of the trade reforms under consideration.

When attempting to compile these data, what main sources could officials use to easily find the necessary information? First, the trade policy reviews prepared by the WTO Secretariat can serve as good starting points for the description of national trade policies and their macroeconomic context. The objective of these reviews is to increase transparency by describing each WTO Member's trade policies and practices, and trade policy-making institutions.² Trade policy reviews can also be useful for gathering information about the impacts of trade on health. For instance, the sections reviewing recent trade trends in specific sectors can provide information on health care services or the policies relating to patents and pharmaceutical drugs.³ However, for now, these reviews generally do not contain information about the distributional impacts of trade policies or the importance of tariff revenues.⁴ Therefore, other sources have to be used to conduct a national assessment of trade and health.

Another important source of information is the diagnostic trade integration study (DTIS), prepared by the World Bank in the context of the enhanced Integrated Framework for Trade-Related Technical Assistance to Least Developed Countries (see Chapter 3). These country studies evaluate internal and external constraints on a country's integration into the world economy, and recommend areas where technical assistance and policy actions can help the country overcome these barriers. In recent years, the World Bank has applied the DTIS methodology beyond the Integrated Framework and has been using it in its dialogue with other client countries.⁵

The DTIS usually includes a section on trade and poverty where one or several policy options or scenarios are examined in terms of their impact on poverty reduction. For instance, the DTIS for Uganda highlights how increases in tariff levels, due to regional harmonization of protection, led to higher prices of goods, which was of particular significance for food and beverages. Because these items represent a large part of the expenditure of poor households, the higher tariff levels had an adverse impact on poverty. When available, the DTIS can thus be useful to understand the distributional impacts of trade policy. Other potential sources of information are the poverty reduction strategy papers prepared in many developing countries.

In addition to these reports, a number of indicators can be used and monitored to track the implementation and impact of trade policy on health, and from this inform negotiations with trade policy-makers and the design of proactive and responsive health policy. A range of readily accessible indicators from national data sources may be used for this purpose. Collecting and interpreting these indicators will guide policy-makers towards identifying and understanding the linkages between the general economic and health environment and the changes engendered by trade reforms over time.

² See http://www.wto.org/english/tratop_e/tpr_e/tpr_e.htm

³ See, for example, trade policy review for Malaysia: http://www.wto.org/english/tratop_e/tpr_e/tp325_e.htm

⁴ Trade policy reviews can also be useful for gathering information about the direct impact of trade on health. For instance, the sections reviewing recent trade trends in specific sectors can provide information on health care services or the policies related to patents and pharmaceutical drugs.

⁵ For available DTIS, see <http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/TRADE/0,,contentMDK:20615178~menuPK:1574524~pagePK:148956~piPK:216618~theSitePK:239071,00.html>

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Chapter 5

Implementing trade commitments with a public health perspective

David P. Fidler

5.1 Introduction

This chapter focuses on the importance of implementing trade commitments in a manner that remains sensitive to public health objectives. The discussion is divided into two levels of analysis. First, the chapter discusses the general considerations which countries face when implementing treaty commitments. Second, it considers specific issues that arise with respect to trade and health. Finally, the chapter concludes with some guiding principles applicable to the national implementation of commitments in trade treaties from a public health perspective.

5.2 National implementation of international legal commitments: general considerations

Domestic law is no excuse for a country's failure to comply with its international legal commitments. The international legal commitments of concern here arise from treaties, which are written agreements between two or more States (Vienna Convention on the Law of Treaties, Art. 2). Treaties are only binding for those States that affirmatively agree to be bound by them. Thus, a binding treaty commitment under international law represents an informed and voluntary sovereign act of a State that desires to bind itself to the obligations in the treaty (1).

Upon a treaty's entry into force, the parties to the treaty are legally bound under international law to fulfil the treaty's obligations (Vienna Convention on the Law of Treaties, Art. 26). The international law regulating treaties provides that a party to a treaty may not invoke the provisions of its internal law as justification for its failure to perform a duty under the treaty (Vienna Convention on the Law of Treaties, Art. 27). These rules highlight the responsibility of parties to ensure that the obligations found in the treaty are implemented within national policy and law. Treaties sometimes re-emphasize this responsibility by including specific obligations on implementation of treaty provisions into national legislation.

The responsibility to ensure that national law and policy allow the implementation of international legal obligations requires parties to develop strategies to implement treaty obligations. The constitutional framework within a State largely determines how a State implements its treaty obligations. Some systems of constitutional law give ratified treaties direct legal status in national law, such as the provision in the Constitution of the United States of America that makes ratified treaties supreme over earlier conflicting federal statutes or earlier or future state law. However, even in the U.S., some treaties are considered "non-self-executing", meaning that the U.S. Congress must implement them through legislation and that their provisions may be enforced only through these implementing statutes.¹ Other constitutional arrangements, such as the British approach, require the legislative body to transform the international legal commitments into formal statutory law.

After identifying the appropriate constitutional pathway for treaty implementation, the first step in thinking about implementing treaty obligations involves determining whether any new national law is needed to make a treaty obligation effective. This step requires the detailed comparison of obligations in the treaty with substantive and procedural aspects of existing national law. Often existing national law suffices to

¹ Renkel v. United States, 456 F.3d 640, 643 (6th Cir. 2006).

provide a basis on which to implement the requirements of a treaty. Where the adoption of a new national law is necessary, then the nature of the change required and the impact of the change on existing national law and policy, it is important to identify these in as much detail as possible.

The need to implement a treaty obligation sometimes reveals a conflict that States must resolve. In brief, a conflict is a situation in which simultaneous compliance with two different legal obligations is not possible. A broader definition not only includes the “obligation versus obligation” context but also incorporates situations where the implementation of a discretionary right accorded by one legal rule would produce a breach of a mandatory obligation imposed by another legal rule. This type of conflict should be taken into consideration when analysing the impact of treaty implementation on national law.

Conflicts can exist between obligations created by two or more treaties (for example, between a trade treaty and a human rights treaty) or between obligations found in a new treaty and in existing national law. Most legal systems have default rules that apply to resolve such conflicts, such as the “later-in-time” rule in the United States under which, in the case of a conflict between a treaty provision and a federal statutory provision, the one that was enacted later in time prevails. The application of such rules can produce situations in which a country is no longer in compliance with its international legal obligations if the national law trumps the conflicting treaty rule. It is important to understand whether the implementation of a treaty would cause a conflict, and how such a conflict might be handled, under a policy-maker’s own system of law.

If conflicts do not arise from treaty implementation, and if new statutory law is required to implement a treaty effectively, then a country faces the task of adopting new national law to make effective its international legal obligations. Again, how new statutory law is adopted is a matter generally governed by constitutional law.

Finally, parties must monitor how the treaty is implemented internationally and within their respective national legal systems. Of particular importance is how the treaty is interpreted and applied, perhaps through decisions of international or national courts. Interpretations of treaties, and the national law implementing them, might have legal consequences that affect how countries continue to abide by their treaty commitments.

5.3 National implementation of international legal commitments: specific considerations related to trade and health

Much of the existing body of international trade law, such as the agreements under the auspices of the WTO, was negotiated and adopted without much input from public health experts and officials. Within the public health community, concerns have been raised that the acceptance and implementation of international trade treaties adversely affect the mission of public health by reducing the “policy space” that public health agencies have to protect population and individual health. This line of reasoning asserts that implementation of trade treaties harms the ability of governments to protect the public’s health from disease risks heightened by the globalization of markets, trade and commerce. Table 5.1 contains an illustrative list of public health interventions and the trade treaty concerns they might trigger.

Table 5.1 List of possible health intervention categories and issues under international trade treaties

Category	Examples	Trade treaty issue(s)
Fiscal measures to increase cost of products to encourage reduced consumption or use	Tariffs	Most-favoured-nation principle Bound commitments (i.e. caps) on tariff rates Transparency and due process requirements
	Domestic taxes	National treatment principle Transparency and due process requirements
Quantitative restrictions on imports that pose a risk to health, whether goods or services	Import bans	Prohibition on quantitative restrictions on import of goods Market access specific commitments with respect to imports of services Most-favoured-nation principle National treatment principle Risk assessment and scientific evidence (for food safety measures) Harmonization requirement (for food safety measures)
	Quotas	Prohibition on quantitative restrictions on import of goods Market access specific commitments with respect to imports of services Most-favoured-nation principle National treatment principle
Regulation of content and performance of goods to protect against disease risks	Required or prohibited ingredients or components	Risk assessment and scientific evidence (for food safety measures) Harmonization requirement (for food safety measures) Most-favoured-nation principle National treatment principle Prohibition on quantitative restrictions on imports of goods Transparency and due process requirements
	Technical regulations or standards (not involving food safety)	Most-favoured-nation principle National treatment principle Harmonization requirement Transparency and due process requirements Procedural requirements on how regulations and standards are adopted and applied
Regulation of product information	Labelling requirements	Risk assessment and scientific evidence (for food safety measures) Harmonization requirement (for food safety measures) For non-food safety issues, obligations that apply to use of technical regulations and standards (see above)
	Advertising restrictions	If construed as a measure affecting trade in goods, the measure would have to comply with the most-favoured-nation principle, national treatment principle and transparency requirement This type of measure also affects the provision of a service (advertising), requiring analysis of General Agreement on Trade in Services (GATS) or service provisions in regional or bilateral trade agreements Under GATS, advertising restrictions could be affected by specific commitments for both market access and national treatment, if any Under regional or bilateral trade agreements, market access and national treatment commitments, if any, would also be of concern

Category	Examples	Trade treaty issue(s)
Measures to increase access to products	Compulsory licensing	Permitted under conditions established in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) but sometimes more restricted under regional or bilateral trade agreements
	Parallel importing	Permitted under TRIPS Agreement but sometimes restricted under regional or bilateral trade agreements
	Subsidies (i.e. government payments to producers to reduce market price)	Subsidies that support exports or that adversely affect trade in like products face difficulties under treaty provisions on subsidies
Quantitative limitations on provision of services	Economic needs test	Under GATS, quantitative limitations fall under market access, so the issue is whether the WTO Member has made market access commitments that preclude the use of quantitative limitations Under regional or bilateral trade agreements, the issue would be the nature of market access commitments and whether those commitments would affect the quantitative limitation in question
Measures favouring domestic services and service suppliers	Discrimination in favour of domestic service suppliers on price and contract length	Under GATS, national treatment principle only if WTO Member has made specific national treatment commitment for the service sector in question Under regional or bilateral trade agreement, the issue would be whether the scope of any national treatment principle would apply to the measure in question
Regulation criteria for provision of services	Qualification and licensing requirements and technical standards	Under GATS, such measures must be no more burdensome than necessary to ensure the quality of the service as delineated in specific rules negotiated in the Council for Trade in Services (to date, only rules on domestic regulation of accounting services have been adopted) Regional or bilateral trade agreements may regulate such measures more directly through actual rules in the treaties
Health-based justifications for violating a principle of a trade treaty (e.g. general exceptions for products not related to food safety)	Import ban on a product or service that poses danger to human health if used or consumed (e.g. violates prohibition on use of quantitative restrictions in trade in goods)	Measure must rationally relate to the objective of protecting human health Measure must be the least trade-restrictive measure possible to achieve the level of health protection sought Measure must not be applied in a manner that constitutes a disguised restriction on trade or arbitrary or unjustified discrimination

Worries about public health's permanent loss of policy space to trade interests have, however, evolved into strategies to produce better policy coherence between trade and health. The policy coherence agenda recognizes potential problems between trade liberalization and health protection but acknowledges that governments retain significant policy discretion and choice in how trade commitments are implemented and how they might affect national public health strategies. The production of a strategy paper on trade and health based on a national needs assessment should facilitate more informed and systematic efforts at producing policy coherence.

In the national strategy paper, issues concerning the implementation of commitments found in trade treaties will cluster around the substantive areas of trade law involved, such as the international law on trade in products and trade in services. The following sections undertake a thematic analysis of implementation issues within the policy coherence agenda.

5.3.1 *Macroeconomic and trade environment*

Trade and trade liberalization are important to the achievement of national and international economic growth. For the foreseeable future, therefore, policy-makers and public health authorities will have to consider the impact of treaty commitments as they make health policy decisions.

Recent developments in international trade law are making the situation for public health more complex, heightening the difficulties of achieving policy coherence. In addition to the trade negotiations taking place, albeit without much progress, in the WTO's Doha Development Round, many countries are pursuing regional and bilateral trade agreements, many of which include more aggressive provisions on liberalizing trade in products and services and on protecting intellectual property rights than the corresponding provisions under the relevant WTO agreements. Thus, from a macroeconomic perspective, the national strategy on trade and health must consider not only the WTO agreements but also the increasing number of regional and bilateral trade agreements (see Chapter 6)

Trying to adopt a harmonized public health approach to the implications of trade agreements becomes more difficult as the number and types of agreements multiply. This difficulty appears throughout the process of negotiating, debating and implementing trade agreements because, generally speaking, most public health authorities in countries, especially developing countries, do not have the capacity to participate in and monitor every development in international trade. From the trade negotiator's perspective, trying to apply harmonized public health principles and criteria consistently across numerous negotiations and agreements might seem too burdensome, given the perceived political and economic exigencies of getting agreements finalized.

Even in this difficult environment, the protection of health as a national policy objective actually fares better than other objectives in terms of its relationship with trade liberalization and trade treaties. Trade treaties on products and services expressly recognize that the protection of health is an important government function and that measures protecting health, if applied properly, will trump trade interests (see, for example, GATT Art. XX(b)).

The WTO Dispute Settlement Body (DSB) has enunciated a set of principles that underscore WTO's recognition of the importance of health as a political and social objective. In various cases, the DSB has ruled that (a) the protection of health is a national objective of vital importance; (b) WTO Members are free to select the level of health protection they believe appropriate for their populations; (c) health effects should be included in the case-by-case analysis of whether products or services are alike; and (d) trade restrictive measures to protect human health are permissible under the WTO agreements so long as there are no less restrictive alternative measures that could reasonably be expected to achieve the health policy objectives in question (2, p. 184)

In this respect, public health has a much stronger profile in international trade law than the protection of human rights, which is not recognized as a legitimate reason for restricting trade. In short, in implementing trade treaties, it is possible for national policy-makers and legislators to build coherence between trade and health.

5.3.2 Trade in products

The three main categories of trade in products that are relevant to human health are products that are potentially harmful to health, such as tobacco or weapons; foodstuffs (Chapter 8); and health-specific products, such as medicines or medical devices.

In terms of ensuring that national implementation of trade commitments concerning trade in products is done in a manner consistent with public health objectives, the first step is to locate the category of trade in products in which a given commitment falls. If the product is one that is consumed as food, then implementation of commitments will involve different treaty obligations than those arising from commitments related to trade in non-food products. Trade in health products may involve intellectual property rights not relevant to health concerns about trade in foodstuffs (although intellectual property rights may apply to food and beverages as well). Selecting the right category or categories identifies the set of trade treaty obligations potentially affecting public health action against disease risks.

Parties to trade treaties might find little dissonance between treaty commitments and existing national policy and law, but coherence in “law on the books” should not obscure problems that may arise from a lack of regulatory capacity to deal with the increased speed and volume of traded products and services. A robust legal power to protect public health, even under trade treaty commitments, does not ensure actual technical and human regulatory capacity to protect the public from health threats moving in international commerce.

General commitments applied to trade in products in international trade law

Regardless of the category into which a traded product falls, a few obligations typically appear in most trade treaties. These obligations include:

- caps on tariffs (sometimes called “tariff bindings”);
- prohibitions on national measures that treat an imported product from any country more favourably than a like product imported from a country that is a party to the treaty (most-favoured-nation principle);
- prohibitions on national measures that treat a domestic product more favourably than a like product imported from a country that is a party to the treaty (national treatment principle);
- prohibitions on national measures that impose quantitative restrictions (for example quotas or import bans) on products imported from a country that is a party to the treaty; and
- requirements that all national measures affecting trade be transparent in promulgation and application and that countries provide due process to entities that seek to complain about the application of trade measures.

The DSB has found certain national health measures in violation of some of these general rules. The rulings in *US–Gasoline* (3) and *EC–Asbestos* (4) each held that the respondent WTO Member had violated the national treatment principle in the General Agreement on Tariffs and Trade (GATT). In *Brazil–Tyres*, the DSB held that Brazil violated the prohibition on quantitative restrictions when it applied an import ban on retreaded automobile tyres for health-related purposes (5).²

These cases do not mean that these general principles on trade in products in GATT and other trade treaties pose significant threats to the policy options of national public health authorities. Robust public health action against disease threats does not require discrimination against imported products. Where imported products pose health risks that exceed those associated with similar domestic products, the most-favoured-nation and national treatment principles are flexible enough to allow restrictions in such circumstances and therefore do not pose serious problems for public health. Further, as the Appellate Body held in *EC–Asbestos* (4), WTO Members can factor in health risks when evaluating whether two products are like products for purposes of the national treatment principle.

² For an index of WTO disputes issues, see http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm?id=G14#selected_subject

Health protection exception to obligations under trade treaties

Treaties covering trade in products typically provide exceptions that allow flexibility where the measure in question is necessary to protect human health. To make use of these exceptions, a party generally has to show that:

- the measure rationally relates to the protection of health;
- is the least trade-restrictive measure possible to achieve the level of health protection sought (the necessity test); and
- is not applied in a manner that constitutes arbitrary or unjustified discrimination or a disguised restriction on trade.

For example, in *Brazil–Tyres*, the DSB held that Brazil's import ban on retreaded tyres violated the prohibition on quantitative restrictions in GATT but was necessary to protect human health. The DSB nevertheless struck down the import ban because Brazil applied it in an unjustified manner because it imported significant amounts of used tyres that posed essentially the same health threat as the retreaded tyres. The inconsistency in Brazil's trade measures had no public health justification.

Implementation of trade treaties into national law should be done in such a way as to ensure the ability to use the health-related exceptions typically found in those treaties. As can be seen from *Brazil–Tyres*, it is important to implement the law in a manner consistent with those treaties (5).

Trade in foodstuffs and commitments on sanitary and phytosanitary (SPS) measures

Trade treaties that contain specific rules on food safety, such as the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), typically apply the general principles found in treaties on trade in products (such as "most-favoured nation" or the "necessity test"), as well as specific requirements that address health risks associated with foodstuffs, including beverages. Under the SPS Agreement, trade restrictions may be imposed in order to protect human, animal or plant life or health, but these measures must be based on: (1) adequate assessments of health risk, (2) scientific principles and sufficient scientific evidence, and (3) recognized international SPS standards (including those of the Codex Alimentarius).

From the perspective of national implementation, these science-based requirements may generate more need to change existing substantive and procedural law than the most-favoured-nation or national treatment principles. When adopted in the SPS Agreement, for example, the science-based provisions were novel obligations that had not appeared in GATT. Thus, the entry into force of the SPS Agreement in 1995 created the potential for more systematic change in national law and policy, with respect to SPS measures.

As a general matter, the requirement for a scientific basis in order to impose SPS measures supplements GATT obligations that health-protective measures be necessary and applied in a non-arbitrary manner. The SPS Agreement provides that members may provisionally adopt sanitary or phytosanitary measures where scientific evidence is not sufficient, provided that they seek additional information, so as to allow an objective review of the temporary measure, within a reasonable period of time (SPS Agreement, Art. 5.7). Certain preferential trade treaties, particularly those to which the European Union is a party, also recognize that scientific evidence may not be clear in all cases, and therefore allow public health measures to be implemented in a precautionary manner until scientific evidence develops on the issue in question. National implementation of SPS provisions in trade treaties should ensure that national policy and law allows precautionary measures to be taken.

Trade in health "bads" and in health-specific products: technical regulations and standards for products

Health "bads" are products which can result in harm to health when used. Tobacco is an example of a public health "bad" because no use or consumption of tobacco occurs without some harm to health. Many

products contain ingredients or components (for example toxic chemicals) that may harm health if not properly secured or made safe in the product and its use. On the other hand, health-specific products are designed to improve or contribute to health (for example pharmaceuticals).

The general obligations of trade treaties apply to both health-specific products and health “bads”. These obligations include the technical product regulations and standards of the WTO Agreement on Technical Barriers to Trade (TBT Agreement). The TBT Agreement recognizes the protection of health as a legitimate goal that can be pursued through such regulations and standards, but requires that any measures be applied in a non-discriminatory manner, be harmonized where possible on the basis of recognized international standards, be transparent, and be the least trade-restrictive measures possible to achieve the level of health protection sought. Most of these obligations are similar to the rules applied generally to trade in products and to the provisions in the SPS Agreement.

Treaty provisions on technical product regulations and standards may prove challenging to implement into national legislation because of the sheer scope of the provisions’ coverage and the complexity of the process of making and applying such regulations and standards. The scope of application of the TBT Agreement is enormous, with provisions that potentially touch on a broad spectrum of existing national laws and policies.

The *US-Clove Cigarette* (6) case demonstrates the importance of the TBT Agreement to health policy. In this case, the DSB held that a U.S. law banning importation of variously flavoured cigarettes violated the national treatment provision of the TBT Agreement because the U.S. continued to permit sales of domestically manufactured menthol-flavoured cigarettes. Unlike GATT, the TBT Agreement does not contain any exception to which the U.S. could appeal to justify a violation of the national treatment principle. Various WTO Members have also filed pending claims under the TBT Agreement against Australia’s imposition of plain-packaging requirements for all tobacco products.

Health-specific products and intellectual property rights

Perhaps the most contentious area in the relationship between trade and health arises with treaty provisions governing intellectual property (IP) rights. In the WTO, IP rights fall under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). Regional and bilateral trade agreements also often include protections for IP rights. IP provisions directly relate to trade in health-specific products, such as pharmaceuticals or medical devices, which are the results of innovative research and development. IP rights also arise in other contexts, as seen in the claims WTO members have made under the TRIPS Agreement that Australia’s plain-packaging requirements infringe on trademark rights (7).

The general rules on trade in products, described above, apply to trade in health-specific products. For example, the most-favoured-nation provision and the national treatment provision apply to imports of pharmaceutical products. The TRIPS Agreement provides additional rules. However, the importance of TRIPS as the primary agreement covering IP rights is to some extent being eroded by the rise of so-called “TRIPS-plus” provisions, which are being included in regional and bilateral trade agreements (see Chapter 10)

Treaties that address IP rights typically establish minimum levels of protection, such as the minimum duration of 20 years for patent rights contained in the TRIPS Agreement. The minimum levels of patent protection required by the TRIPS Agreement apply “in all fields of technology”, notably pharmaceuticals (although least developed countries currently have until 2016 to implement patent protection for pharmaceutical products, a period which may be further extended and benefit from a general exception to implement TRIPS until 2021 – see Chapter 10 for more detailed information). The public health concern with establishing minimum levels of patent protection for pharmaceutical products is that patent protection, by design, increases prices as an incentive to invest in inventive activities. However, these higher prices will generally limit access to medicines and other important health products, once they are developed.

The TRIPS Agreement includes safeguards that provide broad discretion to all WTO Members to allow for both parallel importing and compulsory licensing, provided certain requirements are met (see Article

31 of the TRIPS Agreement for a list of requirements). However, some developed countries or regions — especially the United States, the European Free Trade Area (EFTA)³, and the European Union — have negotiated regional and bilateral trade treaties that include provisions with higher levels of protection for IP rights than those required by the TRIPS Agreement. These higher levels of protection (therefore often called “TRIPS-plus” provisions) in regional and bilateral agreements could have even wider impact than meets the eye because the most-favoured-nation provision in the TRIPS Agreement requires WTO Members to accord each other the best treatment they give to any other country with respect to IP protection.

Unlike GATT and the General Agreement on Trade in Services (GATS), the TRIPS Agreement does not contain a provision that exempts regional and bilateral trade agreements from the application of the most-favoured-nation principle, a distinction that may be quite important in this context. The result is that national implementation of TRIPS-plus provisions cannot be confined to the States that are parties to the regional or bilateral agreement in question. Instead, national implementation must accord TRIPS-plus treatment to all WTO Members under the most-favoured-nation principle.

Whether or not a WTO Member has agreed to TRIPS-plus provisions, national implementation should be pursued in such a way as to maximize utilization of any public health safeguards available in the treaties (such as the provision on “limited exceptions” to patent rights in Article 30 of the TRIPS Agreement, and the compulsory licence provision of Article 31 of that Agreement). Even where treaty flexibilities exist, practical opposition to integrating such safeguards firmly into national law and using these flexibilities may deter some countries from taking full advantage of the safeguards in their national policies and laws. Such domestic opposition often connects to external pressure that countries face to include TRIPS-plus provisions in negotiating regional and bilateral trade agreements.

5.3.3 Trade in services

Public health considerations also arise with respect to commitments countries make in trade treaties concerning the liberalization of trade in services. As with trade in products, countries face two levels of implementation issues. The first level involves the GATS, while the second concerns regional or bilateral treaties that address the liberalization of trade in services. As with trade in products, the regional and bilateral services agreements sometimes have more aggressive liberalization provisions than GATS.

GATS, discussed further in Chapter 7, contains general obligations with respect to trade in services as well as specific commitments on market access and national treatment that WTO Members chose to undertake in their individual Schedules of commitments (see GATS Part III). GATS imposes the most-favoured-nation principle as a general obligation, but, as with trade in products, this principle appears to be compatible with robust public health measures. For service sectors in which a WTO Member has agreed to additional, specific commitments in its Schedule, any modification or withdrawal of those commitments (such as the grant of a national monopoly) obligates that Member to provide compensation to WTO Members that have been injured as a result (see GATS Art. XXI). Some commentators have expressed concern that the compensation requirement might adversely affect a country’s ability to address its public health needs. Other general obligations in GATS are mainly procedural in nature and do not raise serious public health concerns.

Unlike GATT, the general obligations of GATS do not prohibit the use of quantitative restrictions or contain national treatment provisions. Instead, the national treatment provisions of GATS apply only to the specific commitments undertaken by WTO Members in their Schedules pursuant to Parts III and IV of GATS (see GATS Art. XVII, entitled “National Treatment”). GATS permits WTO Members to design the scope of their market access and national treatment commitments, should they decide to make such commitments (see GATS Part III).

From a national implementation perspective, the specific commitments are more important than the general obligations because GATS provides disincentives to the modification or withdrawal of specific commitments. These include the requirement to notify the GATS Council at least three months prior to modification or withdrawal, the prohibition on modification or withdrawal during the first three years after the specific commitment’s entry into force, and the requirement that other Members injured by the

³ EFTA includes Switzerland, Norway, Iceland and Lichtenstein.

modification or withdrawal be compensated (see GATS Article XXI). Importantly, few WTO Members have made significant specific commitments in areas directly related to health services, and some have stated that they will not entertain any requests to liberalize trade in health services during the Doha Development Round, the completion date of which is currently uncertain.

However, the most important step from a public health perspective is not the implementation of the specific commitments but whether such commitments should be made in the first place. Thus, attention should be focused foremost on the national and diplomatic processes through which decisions are reached regarding these specific commitments.

As with trade in products, regional and bilateral trade treaties may contain provisions that liberalize trade in services more aggressively than GATS.⁴ National implementation of these agreements may, therefore, be more extensive and complicated than implementation of GATS, particularly in terms of deeper market access obligations and broader national treatment coverage. However, provisions in regional and bilateral agreements that liberalize trade in services may not be applicable to the entire WTO membership because GATS includes an exemption from the most-favoured-nation principle when such agreements satisfy certain criteria (see GATS Article V).

5.4 Conclusions

The current macro-political climate favouring the pursuit of trade liberalization (whether in WTO or in regional and bilateral settings), means that public health officials will continue to confront questions of treaty implementation for the foreseeable future. As implementation issues arise, policy-makers should endeavour to:

- understand the source of the international legal obligations to be implemented (i.e., does the commitment come from a WTO agreement or a regional or bilateral agreement?);
- analyse the substance of the commitment, with particular attention to whether it affects existing or planned public health policies, strategies and authorities;
- identify any conflicts that may exist between the trade treaty commitment and national law, and the constitutionally appropriate way to resolve such conflicts;
- understand the full range of public health actions that can legitimately be undertaken in compliance with the commitment and ensure implementation policies and legislation take full advantage of these flexibilities;
- anticipate how national implementation of trade treaty commitments may adversely affect public health while building implementation policies and legislation aimed at mitigating such adverse effects;
- engage in pre-emptive action by closely monitoring ongoing trade negotiations, both within WTO and in regional and bilateral contexts by providing input to negotiators; and
- share information and collaborate with public health experts in other governments to develop a transnational understanding of the best and worst practices with respect to the implementation of treaty commitments.

⁴ See WTO, Dataset of service commitments in regional trade agreements (RTAs), http://www.wto.org/english/tratop_e/serv_e/dataset_e/dataset_e.htm.

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Chapter 6

Regional trade agreements and health services

Mina Mashayekhi, Elisabeth Tuerk

6.1 Introduction

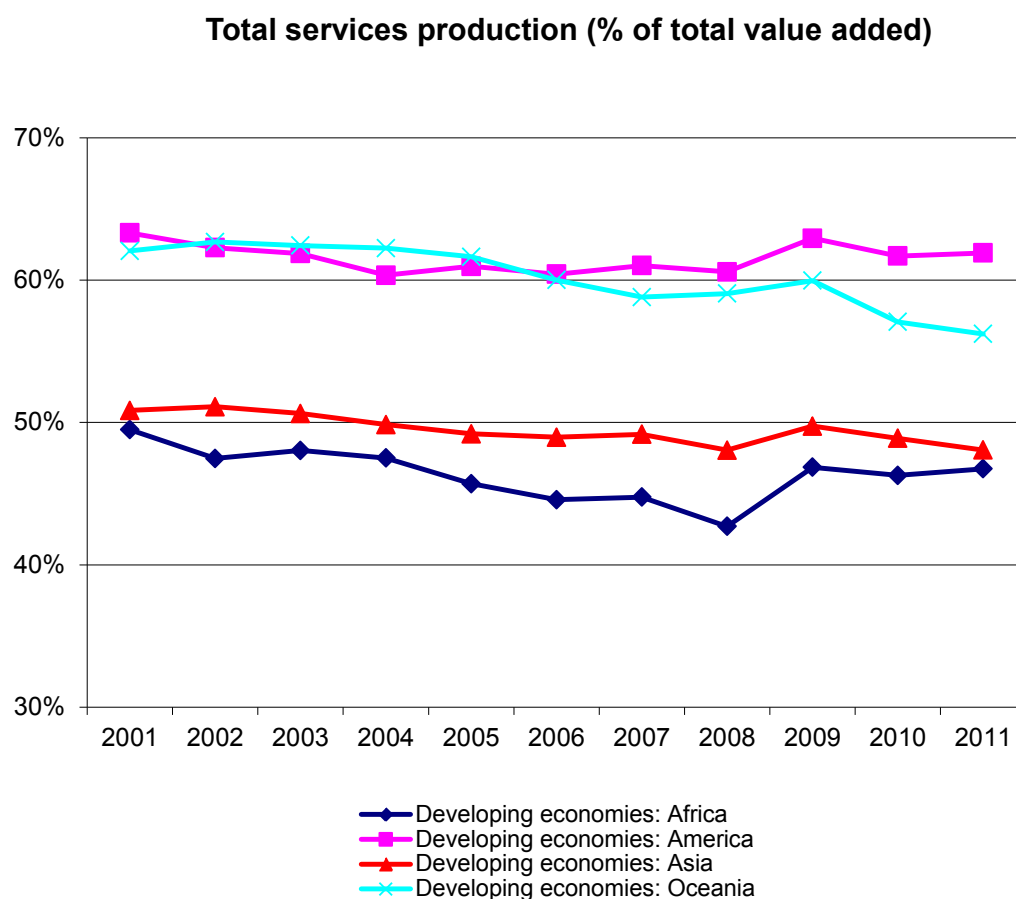
Regional trade agreements (RTAs)¹ have proliferated worldwide, particularly over the last decade. Existing RTAs are being reinvigorated and expanded, and new ones are being negotiated. RTAs are a defining feature of today's international trade policy landscape. They exist on sub-regional, regional and inter-regional scales. They are negotiated and concluded on a North–North, North–South and South–South basis, including between regions. Many of these RTAs include provisions on services, health care, intellectual property protection, investment and temporary movement of labour.

Progressive liberalization of services has also been pursued at the multilateral level under the WTO Doha Round. Nevertheless, services did not receive priority attention, with progress conditioned to advancements in agriculture and non-agricultural market access negotiations. This remains the case despite the outcome of the recent WTO Ninth Ministerial Conference, including the trade facilitation agreement and the ministerial decision on operationalization of the waiver concerning preferential treatment to services and services suppliers of least developed countries. Within this framework, plurilateral, and regional initiatives have intensified. Negotiations for a plurilateral trade in services agreement (TISA) were launched by 23 WTO members representing 70% of the global services trade. TISA intends to build upon the General Agreement on Trade in Services (GATS) to promote subsequent multilateralization and participation of new members and capture autonomous and preferential liberalization (1).

The services sector contributes importantly to production in developing countries as well as global and regional value chains. As a percentage of total value added, services represent more than half of the GDP in Latin America and developing countries in Oceania and almost half in Africa and in developing countries in Asia (see Figure 6.1). The services production in developing countries has grown more than 10% between 2002 and 2011 and, as a percentage of the global services production, is less than 20% in developing Asia, less than 10% in Latin America and around 2% in Africa (see Figure 6.2). Services exports in developing countries in Asia represent 25% of global services exports while services exports in Latin America and in Africa represent less than 4% of global values (see Figure 6.3).

¹ The term “preferential trade agreements” (PTAs) is utilized by some sources in place of “regional trade agreements” (RTAs). This chapter, however, follows the convention of the World Trade Organization (WTO) as stated at www.wto.org/English/tratop_e/region_e/region_e.htm, which defines RTAs as involving reciprocal concessions and PTAs as involving unilateral concessions.

Figure 6.1 Evolution of services production as a percentage of total value added

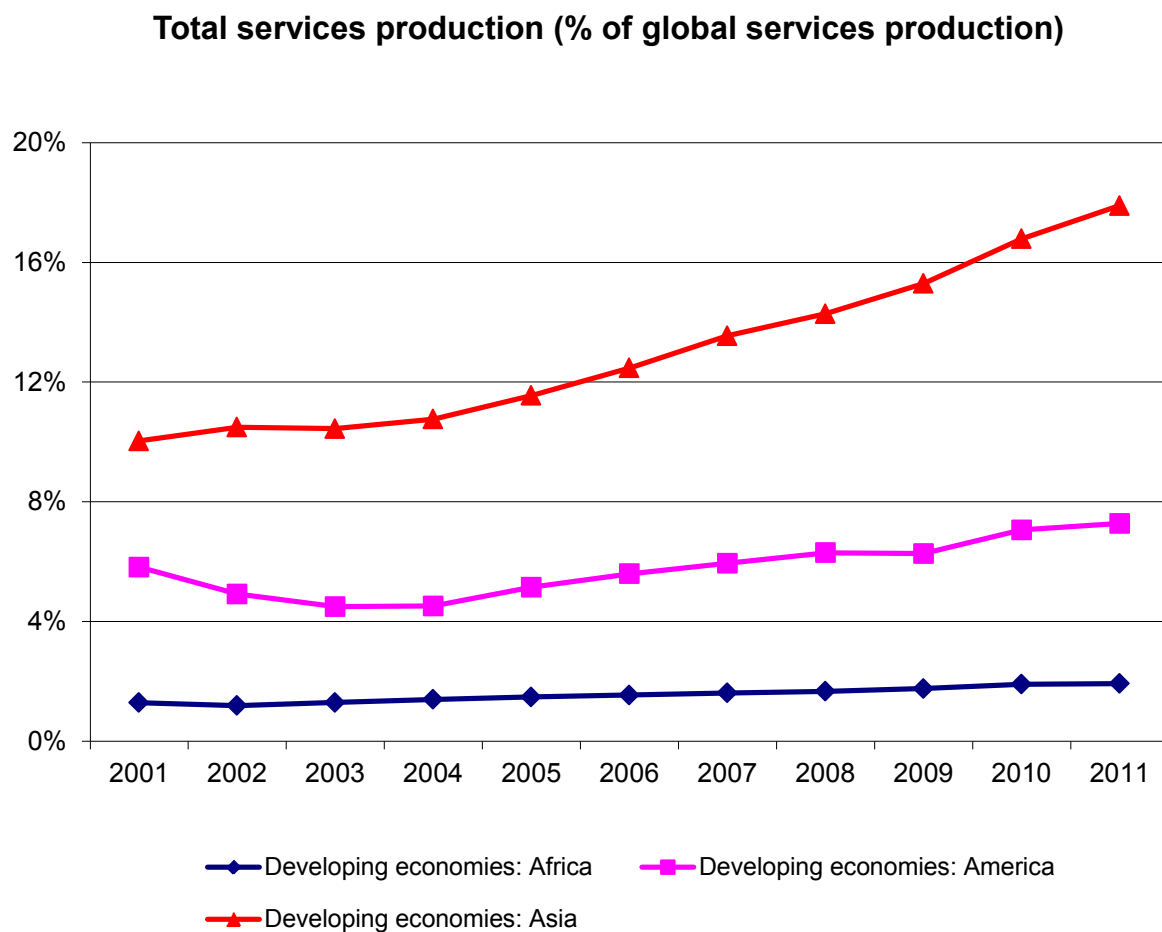


Source: UNCTADStat, consulted on 13 February 2014.

Total services production of (% total value added)	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Developing Africa	49.5%	47.5%	48.0%	47.5%	45.7%	44.6%	44.8%	42.7%	46.9%	46.3%	46.8%
Developing America	63.3%	62.3%	61.9%	60.3%	61.0%	60.4%	61.0%	60.6%	62.9%	61.7%	61.9%
Developing Asia	50.8%	51.1%	50.6%	49.9%	49.2%	49.0%	49.2%	48.1%	49.7%	48.9%	48.1%
Developing Oceania	62.1%	62.7%	62.4%	62.3%	61.6%	60.0%	58.8%	59.1%	60.0%	57.1%	56.2%

Source: UNCTADStat, consulted on 2014-02-13.

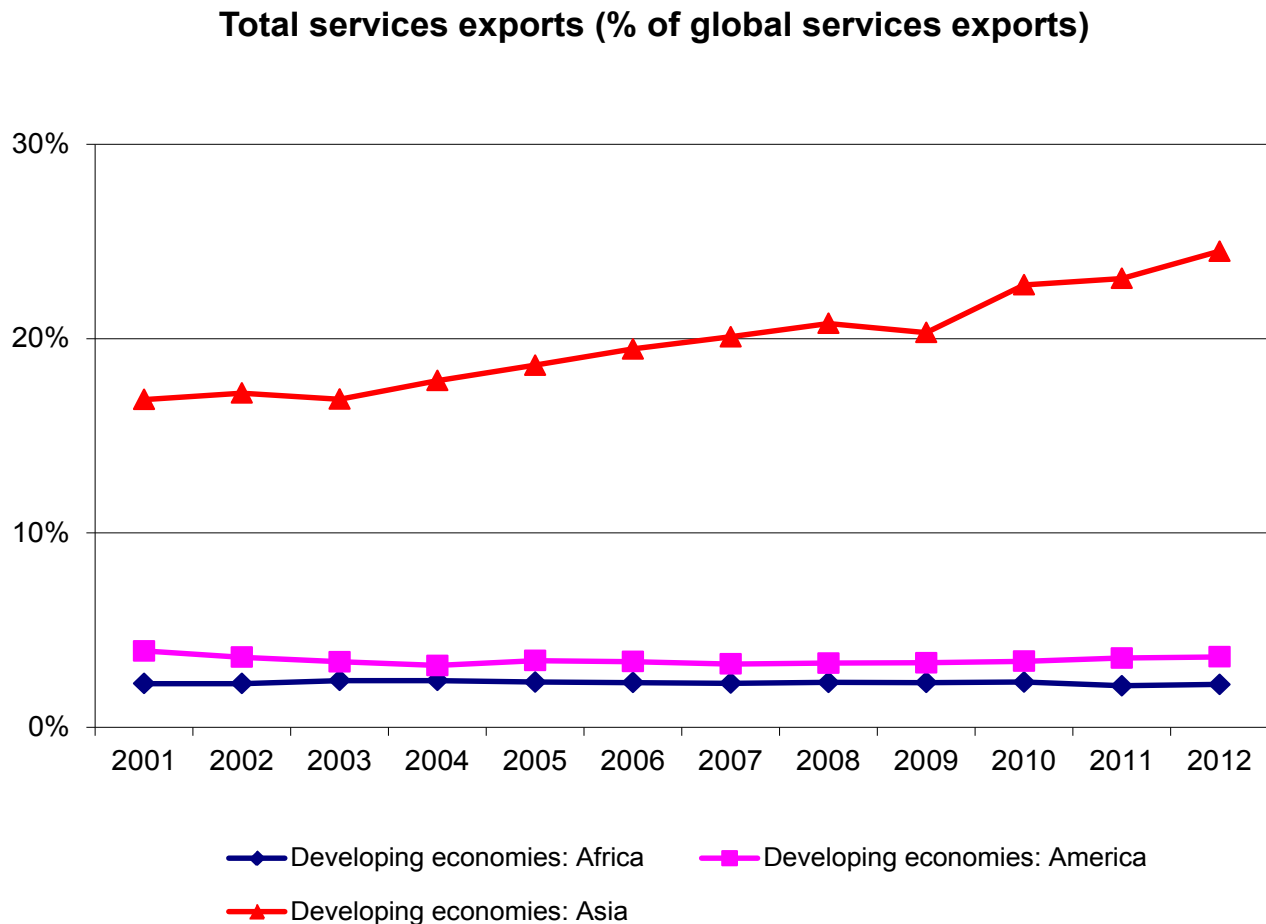
Figure 6.2 Evolution of services production as a percentage of global services production



Total services production (% of global services production)	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Developing Africa	1.3%	1.2%	1.3%	1.4%	1.5%	1.5%	1.6%	1.7%	1.8%	1.9%	1.9%
Developing America	5.8%	4.9%	4.5%	4.5%	5.1%	5.6%	5.9%	6.3%	6.3%	7.1%	7.3%
Developing Asia	10.0%	10.5%	10.4%	10.8%	11.6%	12.5%	13.5%	14.3%	15.3%	16.8%	17.9%

Source: UNCTADStat, consulted on 13 February 2014.

Figure 6.3 Evolution of services exports as a percentage of global services exports

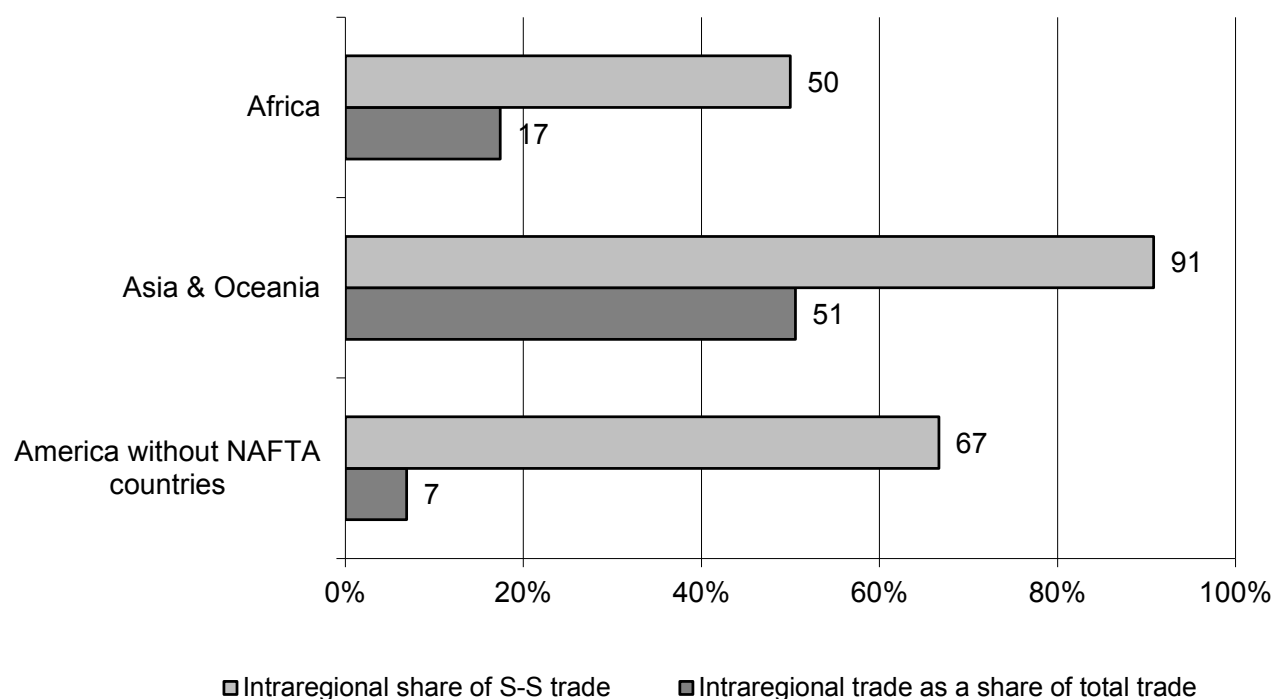


Total services exports (% of global services exports)	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Developing Africa	2.2%	2.2%	2.4%	2.4%	2.3%	2.3%	2.3%	2.3%	2.3%	2.3%	2.1%	2.2%
Developing America	3.9%	3.6%	3.4%	3.2%	3.4%	3.4%	3.3%	3.3%	3.3%	3.4%	3.6%	3.6%
Developing Asia	16.9%	17.2%	16.9%	17.8%	18.6%	19.5%	20.1%	20.8%	20.3%	22.8%	23.1%	24.5%

Source: UNCTADStat, consulted on 13 February 2014.

The trend for services in RTAs is occurring in parallel with a trend of increasing intra-regional trade in services. Among developed countries, around 80% of services trade is taking place within the region. Intra-regional trade is also important in the South–South context. In fact, it accounts for most of the South–South services trade of developing countries in Asia & Oceania and in America (without NAFTA countries) and half of it in Africa, as illustrated in Figure 6.4. Intra-regional services trade is particularly significant in Asia and Oceania, where it accounts for more than half of total services trade. However, interregional trade in services remains below 20% in other developing country regions (2, 3).

Figure 6.4 Importance of intraregional trade as part of South–South services trade

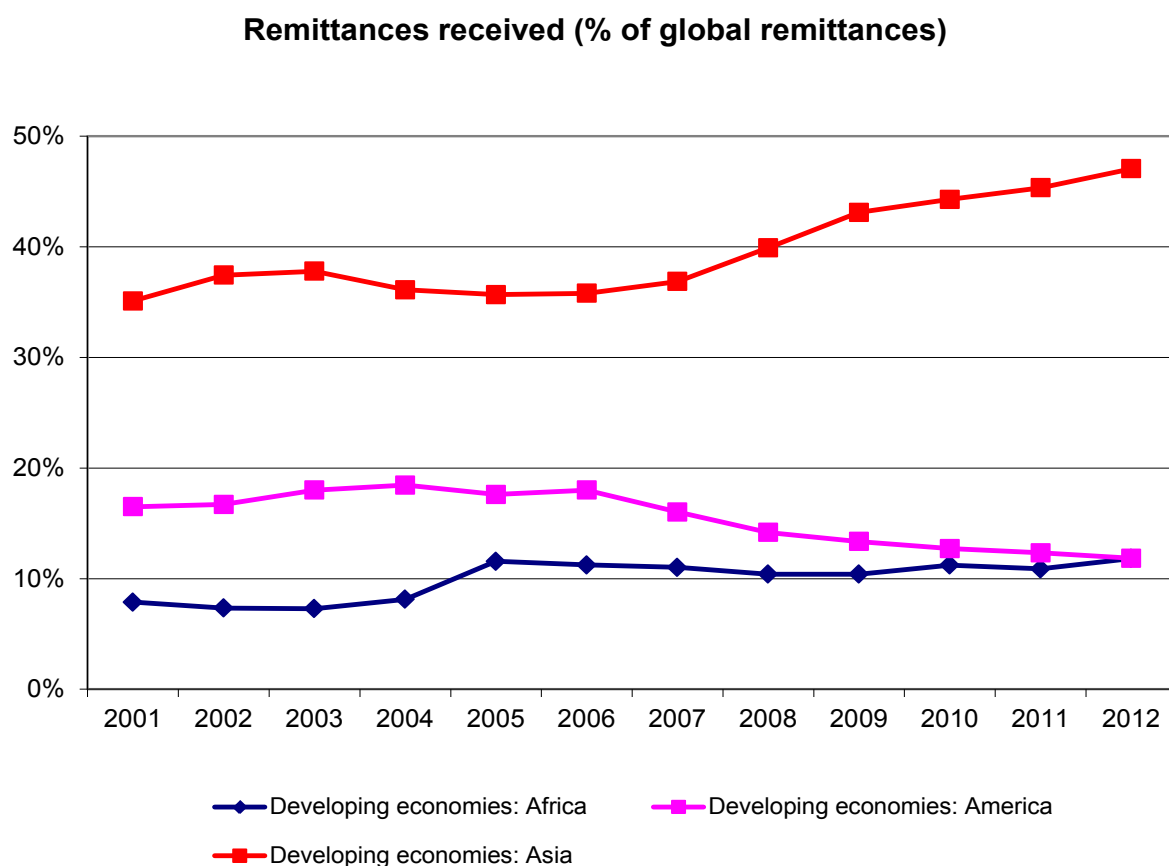
Developing countries' regional trade in services in 2007

Total remittances received (% of global remittances)	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Developing Africa	7.9%	7.3%	7.3%	8.1%	11.6%	11.2%	11.0%	10.4%	10.4%	11.2%	10.9%	11.8%
Developing America	16.5%	16.7%	18.0%	18.5%	17.6%	18.0%	16.0%	14.2%	13.4%	12.7%	12.3%	11.8%
Developing Asia	35.1%	37.4%	37.8%	36.1%	35.7%	35.8%	36.9%	39.9%	43.1%	44.3%	45.3%	47.1%

Source: UNCTADStat, consulted on 13 February 2014.

Differences between developing regions can also be found in inflows of remittances. Developing Asian countries received 47% of global remittances inflows in 2012 and African and Latin American countries received 12% each (see Figure 6.5). Remittances inflows have grown more than 15% in developing Asian countries and in Africa between 2003 and 2012, while growing 9% in Latin America in the same period.

Figure 6.5 Evolution of remittances inflows as a percentage of global inflows of remittances



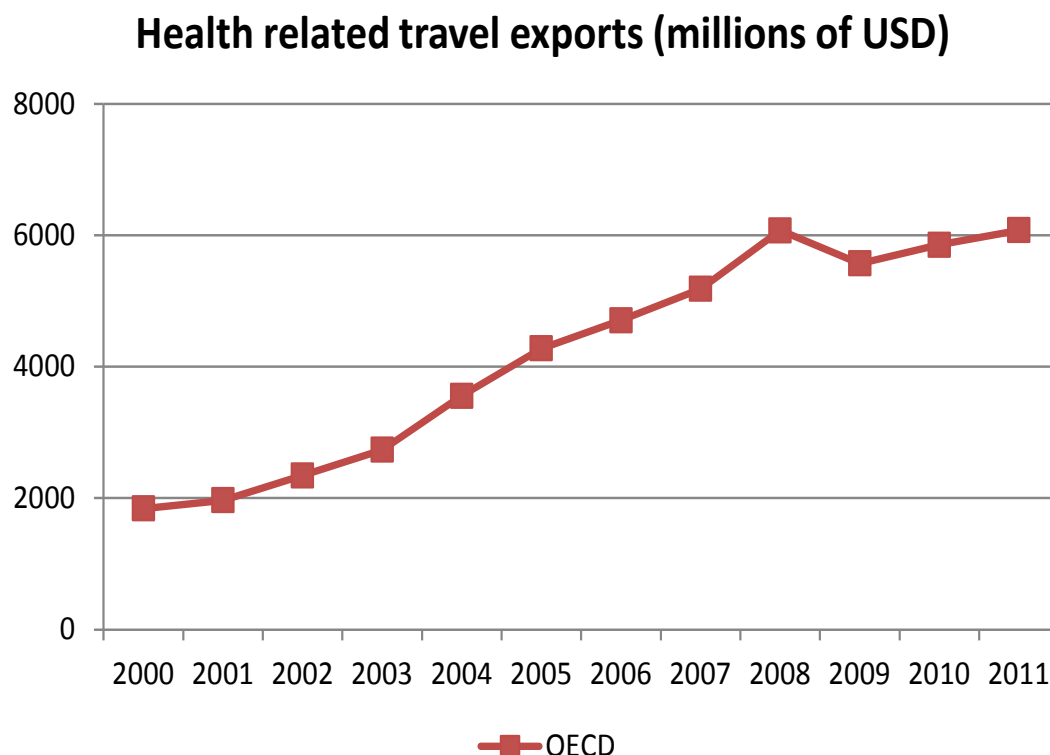
Total FDI received (% of global FDI)	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Developing Africa	2.4%	2.3%	3.0%	2.4%	3.1%	2.5%	2.6%	3.2%	4.4%	3.1%	2.9%	3.7%
Developing America	9.7%	9.3%	8.0%	13.1%	7.9%	6.6%	8.6%	11.6%	12.3%	13.5%	15.1%	18.1%
Developing Asia	14.7%	15.3%	21.1%	22.7%	22.7%	20.0%	18.2%	21.8%	26.7%	28.4%	26.4%	30.1%

Source: UNCTADStat, consulted on 13 February 2014.

Global foreign direct investment (FDI) flows amounted to 1.4 trillion USD between 2009 and 2011, 69% of which were directed at services and 31% at the infrastructure services sector (ISS) in particular (1).

For developing countries, much of regional trade reflects trade in commercial services such as freight transportation, tourism, construction and business services. However, the scope (and therefore volume) of traded services is expanding rapidly as countries progressively privatize and liberalize those services traditionally performed as a government function (3), such as health services. In OECD countries, where data are available, it is possible to confirm that health exports, measured by exports of health related travel, have reached more than US\$ 6000 million in 2011 and have grown 11% between 2002 and 2011 (see Figure 6.6).

Figure 6.6 OECD exports of health related travel in millions of USD



Health related travel exports	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
OECD	1841	1967	2345	2736	3555	4278	4706	5184	6073	5571	5855	6076

Source: UNCTAD calculations based on OECD statistics, consulted on 13 February 2014.

Given the growth of RTAs, and their implications for health and health care, health policy-makers need to pay attention to the respective negotiation and implementation processes with a view to achieving coherence between trade and health policy objectives. While regional liberalization of health services through RTAs may generate pro-development outcomes, such benefits are not automatic, and liberalization needs to be properly paced and sequenced within the development of an adequate regulatory, institutional and policy framework.

This chapter outlines the current scope of services trade, and especially health services trade, within the principal current RTAs. Section 2 considers the main motivations behind the negotiation of services RTAs, the importance of reciprocity and discrimination in trade policy with respect to RTAs and the distinct approaches adopted between RTAs with respect to scope, structure and modalities for liberalization, all of which are relevant for health services trade. Section 3 then considers the extent and manner in which a selection of specific RTAs covers and liberalizes trade in health-related services, before concluding in section 4.

6.2 Services trade liberalization and cooperation in preferential trade agreements

By extending their coverage to services, RTAs are expected to generate even more intra-regional services trade. However, while estimates indicate that a significant share of services trade already occurs regionally, the contribution of RTAs in generating such trade remains to be assessed. RTAs are expected to strengthen domestic services sectors, such as by increasing exports, allowing for economies of scale, and facilitating knowledge transfer from one country to another. Any increased volume of services exports may in turn accelerate learning curves and allow for increased investments in equipment, infrastructure, and other productive assets.

Countries have different motivations for negotiating services RTAs. Central among them are the desire to increase national services exports, stimulate regional growth and develop regional supply capacities. Other considerations motivating the negotiation of services in RTAs include the following:

- Services and trade in services are seen as important for growth and development, and it is expected that increased regional services trade will help strengthen supply capacities and competitiveness in domestic services sectors and attract investment (4).
- Services liberalization is considered to be more easily negotiated at the regional level, as opposed to the multilateral level, as RTAs often include countries with geographic proximity, cultural ties, and similar levels of economic development; moreover, RTAs involve a more limited number of participants than multilateral negotiations, facilitating agreement.
- RTAs allow experimentation with new provisions and approaches on a relatively smaller scale; they can thus serve as a “laboratory” before pursuing similar approaches at the multilateral level.
- Along these lines, RTAs are considered to have the potential to promote liberalization of the temporary movement of services suppliers, including through regulatory cooperation on mutual recognition (for example via harmonization) of professional qualifications and provisions for labour mobility.
- Similarly, RTAs can include cooperative mechanisms aimed at promoting shared regional infrastructure, policy and regulatory cooperation, and skills sharing and capacity building.
- RTAs are often concluded for reasons other than purely economic ones with strategic, cultural, social and political considerations figuring prominently.

However, pro-development outcomes are not guaranteed by services trade liberalization at either the multilateral level or at the regional level as certain preconditions must be in place in order to generate benefits. Most important among these is that liberalization be adequately paced and sequenced, and preceded by proper regulatory, institutional and policy frameworks (5). As proper pacing and sequencing between domestic reform and international commitments is central for benefits to materialize, there is a need for support to strengthen regulatory and institutional capacities in developing countries to ultimately allow them to benefit from services trade liberalization.

Additional complexities arise from the multiplicity of forums where services trade liberalization is negotiated. The interplay between multilateral and regional services liberalization processes creates challenges as regards the pacing and sequencing of the different liberalization processes. Indeed, trade liberalization may be classified into types based upon whether it is mandated through negotiated liberalization commitments on a reciprocal basis or a unilateral basis, and whether it is discriminatory or non-discriminatory, as illustrated in Table 6.1.

Table 6.1 Different types of trade liberalization

Status	Reciprocal	Unilateral
Discriminatory	Regional trade agreements (RTAs), bilateral agreements (free trade agreements)	Preferential trade agreements (PTAs)
Non-discriminatory (most-favoured-nation)	Multilateral agreements	Autonomous liberalization

6.2.1 Reciprocity and discrimination in RTAs

Article V ("Economic Integration") of the General Agreement on Trade in Services (GATS) determines the conditions under which services RTAs are allowed to exist and operate (3). It establishes an exception to the most-favoured-nation principle. In order to fall within the exception, two key requirements must be met: first, services RTAs must have "substantial sectoral coverage" in terms of "number of sectors, volume of trade affected and modes of supply"² (no "a priori exclusion of any mode of supply" is allowed); and second, RTAs must provide for "the absence or elimination of substantially all discrimination" in terms of national treatment (GATS Article XVII) through "elimination of existing discriminatory measures, and/or . . . prohibition of new or more discriminatory measures". This level of liberalization must be achieved "on the basis of a reasonable time-frame". Moreover, RTAs must be designed to facilitate trade between Member States and must not raise the overall level of barriers to services trade against third countries.

Unlike Article XXIV of the General Agreement on Tariffs and Trade (GATT), GATS Article V contains special and differential treatment to aid developing countries. First, developing countries are to be afforded flexibility as to the two key conditions noted above, in accordance with the level of development of the countries concerned (GATS Art. V:3(a)). Second, developing country RTAs may allow "more favourable treatment" to be provided to "juridical persons owned or controlled by natural persons of the parties" in respect of the requirement to engage in "substantive business operations" in the territory of a party to an agreement (GATS Art. V:3(b)). Various interpretations have been put forward as to what constitutes "flexibility" and "more favourable treatment" in Article V:3(b).

World Trade Organization (WTO) negotiations under the Doha Work Programme on RTA rules are aimed at "clarifying and improving" rules on RTAs, including Article V, while taking into account the "developmental aspects of [regional] trade agreements". The outcome may affect regional negotiations and the terms of agreements. A transparency mechanism for RTAs was adopted in December 2006. It seeks to improve procedures for early announcement, notification, examination and reporting of both goods and services RTAs. As of July 2013, 575 notifications of RTAs had been received by the WTO, 379 of which were in force and 129 had been notified under article V of GATS. Of RTAs notified since 1985, some 60% of those formed by developed countries and 55% of those formed by developing countries contain services (1). WTO maintains a database of both RTAs, which involve reciprocal concessions, and preferential trade agreements (PTAs), which WTO defines as involving unilateral concessions.³

In addition to the need to manage the interface between multilateral and regional services trade liberalization, there is a need to properly pace and sequence South–South and North–South liberalization. This issue has gained increasing attention in the context of European Union and United States negotiations with regional blocks of developing countries. Given the nascent state of the services sector in developing countries, the implications of North–South market liberalization in these sectors should be carefully assessed (3). Unlike in the case of trade in goods, unilateral preference schemes (i.e. PTAs) usually do not cover services.

² GATS Article I defines four "modes of supply", i.e. four ways in which services can be "traded" internationally. They include "the supply of a service: (a) from the territory of one Member into the territory of any other Member; (b) in the territory of one Member to the service consumer of any other Member; (c) by a service supplier of one Member, through commercial presence in the territory of any other Member; (d) by a service supplier of one Member, through presence of natural persons of a Member in the territory of any other Member".

³ www.wto.org/English/tratop_e/region_e/region_e.htm

Different RTAs adopt different approaches to services liberalization. It is therefore necessary when assessing the extent to which RTAs have effectively liberalized trade in services – including health services – to examine both the services regime (framework agreement) and the commitments under it. The framework agreement can go beyond liberalization in the sense of market access and national treatment, and also include provisions on investment, integration of labour markets, government procurement, and reciprocal recognition of foreign licences (such as a license to practice medicine) and qualifications. Furthermore, numerous RTAs include sectoral initiatives for specific services sectors (6), though these cover mostly financial services, transport (air, maritime and land), telecommunications, professional services and mode 4 trade (movement of natural persons). The last two, professional and mode 4, are clearly relevant for health services.

6.2.2 Scope, structure, modalities, commitments and regulatory cooperation

RTAs vary as to scope, structure, modalities for liberalization, depth of commitments, and regulatory cooperation, all of which are relevant to health services trade (3, 7).

RTA scope (sectoral and modal coverage)

RTAs tend to provide for universal sectoral coverage, although sensitive sectors such as air and maritime transport and audiovisual services may frequently be excluded.⁴ In addition, some RTAs may establish specific rules for certain services sectors (for example financial, telecommunications). While some RTAs exclude “public services”, it seems that no RTA generally excludes health services from its sectoral coverage (8). In fact, the Association of Southeast Asian Nations (ASEAN) has identified health services as one of its twelve priority sectors;⁵ the Southern African Development Community (SADC), on the other hand, does not include health services among the six priority sectors identified for liberalization.⁶

RTA structure

The “four modes” for delivering services defined in GATS Article I.2 have become a part of many RTAs, including those of the Common Market for Eastern and Southern Africa (COMESA), SADC, ASEAN, the Andean Community, and Mercosur. However, other RTAs provide for separate treatment of investment (for example the North American Free Trade Agreement (NAFTA)) and movement of persons (NAFTA, Australia-Thailand Free Trade Agreement) (6, 7, 9).

RTA liberalization modalities

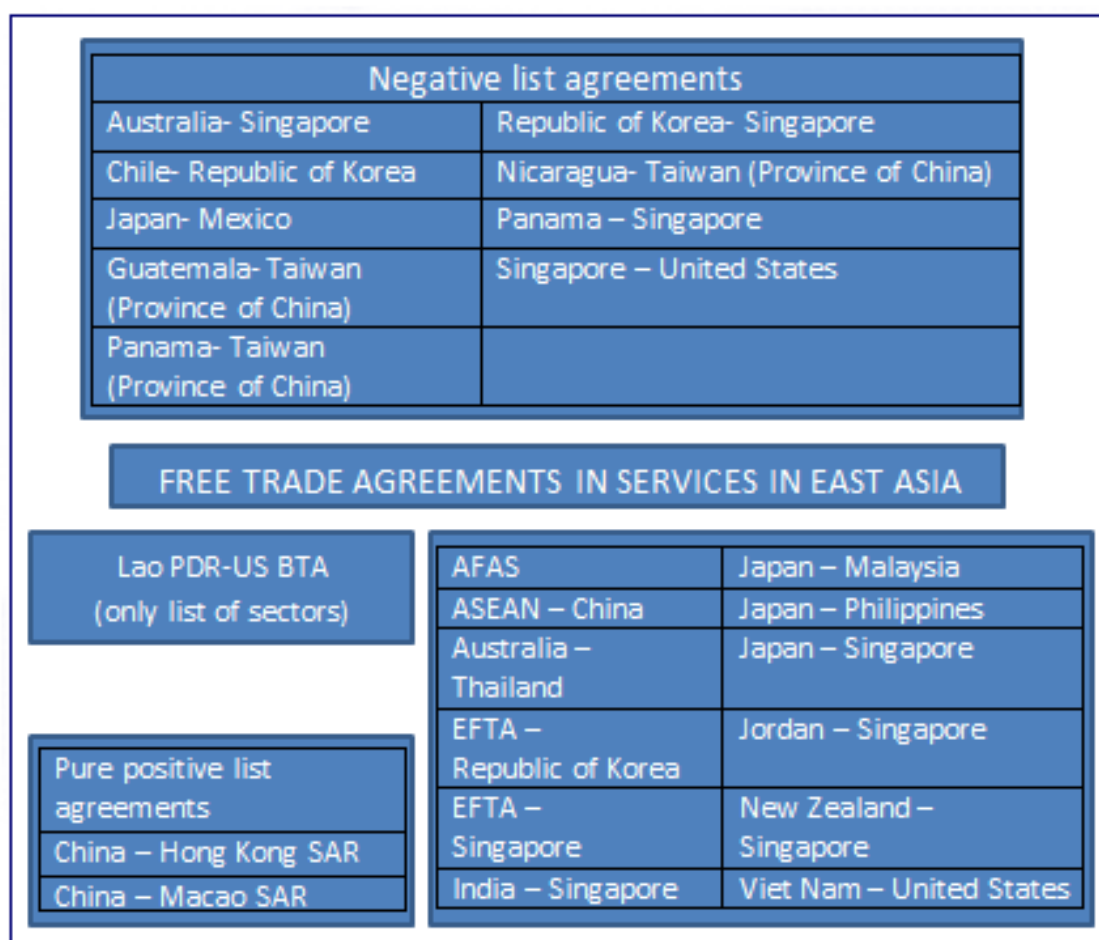
RTAs tend to follow either a negative or a positive list approach.⁷ The negative list approach begins with a general rule that all RTA obligations apply across all sectors, but allows countries to exclude certain sectors and modes of supply by specifically enumerating them in a list of exceptions. Restrictions that are not initially eliminated may be subject to negotiated elimination, sometimes combined with a so-called “ratchet mechanism”, which automatically integrates further liberalization into the agreement (10). Under the positive list approach, in contrast, countries affirmatively list those sectors and modes of supply in which they would like to commit to liberalization. In theory, both approaches can provide the same level of liberalization. The positive list approach, however, provides greater flexibility in designing the scope and pace of liberalization commitments and it is considered to be the preferred choice for developing countries, particularly when it comes to North–South but also South–South liberalization (3). The positive list approach was adopted in the EU–Chile, ASEAN, Mercosur, Central American Common Market, Japan–Singapore and United States–Jordan agreements. The negative list approach has been adopted in a number of NAFTA-type RTAs, as well as in the agreement between Canada and the Caribbean Community and Common Market (CARICOM). In discussions on whether or not to cover services in economic partnership agreements between the European Union and the African, Caribbean and Pacific Group of States (ACP), the choice between positive and negative listing received great attention. Figure 6.7 provides an illustration of negative and positive listing approaches taken in the East Asian region.

⁴ Note however, that some RTAs, particularly in the Latin American area, do include detailed rules on maritime transport.

⁵ See *ASEAN economic community blueprint* 21 & 36 (<http://www.asean.org/archive/5187-10.pdf>).

⁶ The six SADC priority sectors whose liberalization has been under negotiation since 2011 are: communication; construction; energy; financial; tourism; and transport. See <http://www.sadc.int/themes/economic-development/trade-services/>

⁷ Some refer to GATS as reflecting a hybrid approach, which combines aspects from positive listing (choosing sectors and modes that will be subject to liberalization commitments) and negative listing (choosing sectors and modes to exclude from liberalization commitments).

Figure 6.7 Classification of East Asian free trade agreements by scheduling approach

Source: Fink and Molinuevo 2007 (7).

Depth of RTA commitments

RTA liberalization tends to be more extensive than that required under GATS. Although analyses so far have not focused specifically on health services, initial analysis of professional services suggests that countries with GATS-plus commitments nevertheless tend to maintain greater restrictions on medical and dental (and legal) services (11).

RTA regulatory cooperation

Regarding regulatory issues, RTAs tend to contain provisions on domestic regulation, such as qualification requirements. Frequently, however, they refer to the respective WTO legal framework. Domestic regulations determine the level of liberalization, as such requirements often constitute important market entry barriers to services trade. For example, a country's provisions regarding physician licensing determine the ease with which physicians from one country can treat patients in another country. Harmonization and mutual recognition of professional qualifications are pursued under some RTAs, including Mercosur, NAFTA (accountancy, architecture, engineering), CARICOM and ASEAN (nurses), but often merely obligate parties to "endeavour to ensure" that licensing requirements are minimally burdensome. The benefits of regulatory cooperation may be particularly great for sectors where trade is impeded by differences in qualification requirements, licences and standards or by visa-related issues (3).

6.3 Health services: specific experiences in selected RTAs

This section considers some health services provisions of selected RTAs. The analysis is not intended to be comprehensive, nor does it address liberalization in related areas such as financial services.⁸

6.3.1 Andean Community

The Andean Community, established by the 1969 Cartagena Agreement, aims to promote the balanced and harmonious development of its Member countries through integration and economic and social cooperation. Its current Members are Bolivia, Colombia, Ecuador and Peru.

In 1998 the countries of the Andean Community adopted decision 439,⁹ which sets out the regime for the liberalization of services trade. The Andean Community Members opted for a negative list, with a standstill obligation and an inventory of restrictive measures that eventually are to be removed through further negotiations. In 2006, the Andean Community Members adopted decision 659 and identified sectors (professional, financial, transport and some audiovisual services) that would be subject to deeper integration through liberalization or regulatory harmonization.¹⁰ As is the case with many RTAs, services integration in the Andean Community is more extensive than liberalization at the multilateral level (i.e. GATS) (3).

In addition to the general regime for liberalization of services trade, the Andean Community has adopted regulations in specific services sectors (for example professional, telecommunications, tourism, and transport). The Andean Community legal framework also contains a special regime for investment-related issues and for issues related to mode 4 services trade (for example an Andean passport system was created by decision 504). The mode 4 regime also contains specific health-related initiatives (including an Andean system for the migration of health workers).

In their schedules,¹¹ Andean Community Members can lodge reservations¹² for market access and national treatment so as to exempt existing measures. Few reservations have been inscribed into national services schedules (for example Bolivia has inscribed 46 measures, Colombia 75, Ecuador 74 and Peru 20). Given the negative list character of the services regime of the Andean Community and the limited reservations, the services framework of the Community implies significant liberalization.

Box 6.1 outlines examples of services-related reservations made by members of the Andean Community. Bolivia, Colombia and Ecuador have inscribed reservations pertaining directly to health services and have also inscribed reservations for professional services that may be indirectly health-related. Many of the reservations appear to address issues related to labour market regulation and domestic employment, mostly referring to administrative or registration requirements. Although these reservations may be helpful to the extent that a well-functioning labour market contributes to a robust health system, most schedules appear to lack specific reservations that could promote robust health systems more directly. One of Ecuador's horizontal (i.e. broadly applicable) reservations refers to "public services", but it requires only that foreign companies providing public services establish themselves in accordance with certain domestic laws and regulations making the link to health policy objectives indirect.

Concerns have been voiced about the adequacy of the liberalization process, particularly by Bolivia, which has been granted preferential treatment (such as the opportunity to request deferred implementation periods) under decision 659.

⁸ Both the scheduling and counting of commitments and reservations are subject to numerous choices, according to different interpretations of the respective agreement's texts, lists of commitments and reservations, and the specific language therein. For methodological difficulties regarding the recording of numbers, nature and sectoral incidence of reservations across agreements; see United Nations Conference on Trade and Development (11).

⁹ Services trade liberalization is mandated by Article 79 of the Cartagena Agreement.

¹⁰ Liberalization in the financial and some audiovisual services sector has been suspended by decisions 694, 696, 718 and 772. See <http://www.comunidadandina.org/Documentos.aspx#>

¹¹ "Schedules" are documents attached to a treaty in which additional information or party commitments or reservations are provided.

¹² "Reservations" are unilateral statements made by a party when signing or acceding to a treaty whereby the party purports to exclude (or modify the legal effect of) certain provisions of the treaty; in lay terms, reservations are exceptions to a treaty. See Vienna Convention on the Law of Treaties, Article 2(d).

Box 6.1 Health-related reservations in Andean Community schedules

Measures for which Andean Community countries have included reservations in their services schedules include:

- nationality requirements (nursing and social services, Bolivia; nurse management and teaching, Colombia);
- preferential rights for domestic professionals in terms of public or private employment (health professional services, health teaching, pharmacies and laboratory services, Bolivia);
- economic need / labour market test (recruitment of foreign doctors is limited to meeting local shortages, Colombia);
- higher registration/inscription fees for foreigners for membership in professional bodies (dental laboratory service providers, Bolivia; medical and dental services, Ecuador);
- limitations for foreign professionals engaged in scientific, teaching or sanitary functions, to exercise other functions (doctors, Colombia; odontologists, Bolivia);
- requirement of specific legal form (private health services companies should be organized according to what Ecuador defines as “sociedad anónima”);
- time limits for foreign workers (one year for foreign doctors in scientific or teaching missions, Colombia; six consecutive months in one year for nurses, Ecuador).

Source: Decisión 510. - Adopción del Inventario de Medidas Restrictivas del Comercio de Servicios (2001), Gaceta Oficial del Acuerdo de Cartagena, N. 734, Lima, Peru.

6.3.2 Mercosur

In 1991, Mercosur countries (Argentina, Brazil, Paraguay and Uruguay) signed the Treaty of Asunción, according to which they pursue regional integration to accelerate economic development and social justice. In 1997 Members of Mercosur adopted the Montevideo Protocol, which sets out a framework agreement on trade in services with a positive list approach to liberalization. The Montevideo Protocol obligates Member States to enter into successive annual rounds of negotiations in order to extend liberalization to different services sectors and modes of trade. In 1998 the Protocol was complemented by four annexes, and Members launched the first annual negotiation round. As a result of this and subsequent negotiations, new commitments have been progressively incorporated into national schedules under the Protocol and now go beyond what is required by GATS. The Protocol has been ratified by Argentina, Brazil and Uruguay, and entered into force in 2005. Mercosur uses a mixed GATS-type approach that allows for the scheduling (i.e. the promising by inscription in a “schedule” attached to the treaty) of market access and national treatment commitments, as well as the scheduling of conditions and limitations attached to these commitments.

Mercosur contains specific regimes for particular services sectors (professional, telecommunications, tourism, financial and transport) and modes (mode 4 and investment). Efforts are also being developed to create a regulatory framework (good practices, technical regulations and others) envisioning the harmonisation of the organization and provision of health services. Moreover, although the Montevideo Protocol does not specifically address health-related services, its treatment of professional services (Article XI) would govern some health-related services. Overall, the Mercosur region is characterized by a low degree of regulatory harmonization. While national health systems differ considerably, selected regional cooperation initiatives have taken place (for example a standard card allowing patients to receive health care services in one country can be used to receive health care from an analogous health services provider in another Mercosur country).

Through the annual rounds of negotiations, Mercosur Members entered into a considerable number of liberalization commitments, which exhibit a certain pattern across Members and sectors, as illustrated in Box 6.2. For example, under professional services, member countries committed 11 subsectors each (with Argentina and Uruguay providing additional disaggregation), of which several relate to health.¹³ In addition, under health and social services, each of these four countries committed three subsectors (hospital, other human health and social services), with Paraguay also committing “other health services”.

Box 6.2 Health-related conditions and limitations in Mercosur schedules

Mercosur schedules exhibit a certain pattern of commitments across Members and sectors.

Argentina liberalizes psychology services in mode 1 (cross-border supply of services) and in mode 4 (movement of natural persons) and keeps the other health-related professional services subsectors (for example medical, dental, veterinary, pharmacy services) “unbound in mode 1 and in mode 4 (for “lack of regulation” and for lack of technical feasibility in mode 1, and with the typical cross-reference to the horizontal section in mode 4; fully liberalizes mode 2 (consumption abroad); attaches conditions to the liberalization of mode 3 (commercial presence). A largely similar pattern also emerges for the three subsectors of health services.

Brazil has a regime in which commitments in health-related professional services and three subsectors of health services are either liberalized or unbound for lack of technical feasibility in mode 1; fully liberalized in mode 2; liberalized in mode 3 for veterinary, pharmacy and psychology services, with a limitation regarding foreign equity ownership for the remaining health, social and health-related professional services; and are liberalized according to horizontal commitments in mode 4 (with an additional market access restriction for medical and dental services that can only be provided by foreign professionals if they are invited by the government). In medical and dental services, either for mode 1 or 2, it is forbidden to prescribe treatment, medication or other procedures without direct examination of the patient, except in cases of emergency.

Paraguay keeps medical and dental services, veterinary services and services provided by midwives, nurses, physiotherapists and paramedical personnel unbound for all 4 modes; for the three subsectors of health services inscribed, modes 1 and 4 are unbound (mode 1 for lack of technical feasibility) and mode 2 is fully open. In mode 3, hospital services and other human health services are unbound while social services are liberalized. “Other health services” are fully open across all four modes.

Uruguay keeps veterinary services open while all other subsectors of health-related professional services and remaining health and social services are unbound, in several cases due to lack of technical feasibility, in mode 1; mode 2 is fully liberalized; mode 4 is unbound. Mode 3 is unbound for all subsectors of health and social services and open for most health-related professional services. Pharmacy services in mode 3 are subjected to several conditions that include restrictions to ownership, distance to other pharmacies and number of pharmacies.

¹³ Countries committed medical and dental services; veterinary services; deliveries and related services, nursing services, physiotherapeutic and paramedical services. Argentina and Brazil also committed to psychology and pharmacy services and Uruguay to pharmacy services. Although Paraguay and Uruguay do not make explicit reference to psychology services, as Paraguay does not make explicit reference to pharmacy services, these countries are also committing to other health professional services.

Similarly to the Andean Community situation, none of the four Mercosur Members analysed included a public services “carve-out” in its schedule; similarly, there are no provisions addressing health-related subsidies. At the same time, the commitments reflect careful drafting, with schedules leaving adequate flexibility for domestic policy-makers. Particularly for mode 1 (the cross-border provision of health services) countries have left it unbound, or unbound for lack of technical feasibility, or specifically mention that the mode is unbound for the lack of regulatory frameworks (in the case of Argentina, for certain professional services). All the countries analysed tend to fully liberalize mode 2 for health services, possibly aiming to capitalize on health tourism services. In sum, the schedules appear to reflect Members’ desire for flexibility — as provided by the positive list approach — to carefully pick and choose commitments in these sectors and modes where liberalization promises to be beneficial to them.

6.3.3 CAFTA-DR

The free trade agreement between the United States and Central American countries was concluded in December 2003 after 12 months of negotiation involving Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and the United States. The Dominican Republic became an additional party in August 2004, creating the Dominican Republic-Central America-United States Free Trade Agreement (CAFTA-DR).

CAFTA-DR adopts the model typically used in free trade agreements to which the United States is a party. That is, it seeks to achieve comprehensive trade liberalization through numerous chapters on agriculture, sanitary and phytosanitary measures, technical barriers to trade, trade remedies, government procurement, investment, trade in services, financial services, telecommunications services, electronic commerce, intellectual property, labour and the environment.

The services chapter is also typical, with provisions on national treatment, most-favoured-nation treatment, market access, local presence, transparency and domestic regulation. The services chapter (Chapter 11) also contains a provision on mutual recognition (partly modeled on GATS), as well as an annex on professional services (Annex 11.9), focusing on the development of professional licensing standards. While the services chapter also contains a provision on domestic regulation, this provision is largely modeled on GATS and stops short of harmonizing regulatory standards.

While CAFTA-DR’s provisions on intellectual property rights (Chapter 15) have given rise to intensive policy debates about their potential health impacts, liberalization of health-related services has gone almost unnoticed.

Reservations with respect to both services (Chapter 11) and investment (Chapter 10) are set out in a single list. Reservations for both chapters are scheduled under two annexes: Annex I allows the scheduling of reservations for *existing measures* related to national treatment, most-favoured-nation, local presence, performance requirements, nationality of senior management or members of boards of directors, and market access; Annex II allows the scheduling of reservations for *future measures* related to these areas.

Among all services sectors, professional services stand out with the highest number of reservations, particularly for Annex I (for example 46 in the case of Costa Rica, 7 for El Salvador and 9 for Honduras). Professional services are followed by financial services, with a particular focus on banking services (with reservations under annex III).

Several of the entries in Annex I also relate to health, with Costa Rica and the Dominican Republic listing several health-specific reservations, as outlined in Box 6.3. Guatemala and Nicaragua do not specify any health-specific reservations (although there is a reciprocity requirement for professional services in Nicaragua that may impact health services providers). El Salvador, has one health-specific reservation (a detailed authorization regime for temporary and permanent work) and Honduras imposes higher registration fees in professional bodies for non Central American veterinarians, for foreign microbiologists and foreign clinical chemists.

The United States contains one health-specific reservation, however, another reservation effectively carves out all existing sub-federal measures (i.e. laws of a state or locality of the United States, as opposed to the laws of the United States federal government) in all sectors from the application of the agreement.¹⁴

Several of the reservations made to CAFTA-DR appear to be targeted towards the organization of the labour market, particularly for those countries having few reservations. Some of the reservations inscribed by Costa Rica and the Dominican Republic, in turn, appear to be directly influenced by health policy objectives (for example Costa Rica requires all physicians and surgeons, dental surgeons, microbiologists, pharmacists, nurses and nutritionists to perform the equivalent of one-year continuous, remunerated “social service”. This reservation allows Costa Rican nationals to be given certain types of preference (see box 6.3)).

More importantly, however, most CAFTA-DR countries¹⁵ include some sort of public services carve-out in their lists of reservations on Annex II. The United States, for example, reserves the “right to adopt or maintain any measure with respect to the provision of . . . the following services to the extent they are social services established or maintained for a public purpose: income security or insurance, social security or insurance, social welfare, public education, public training, health, and child care”.¹⁶ Costa Rica specifically includes a carve-out for water services. Honduras also adds on Annex II a reservation regarding the obligatory membership in a professional association of chemists or pharmacists. These reservations point to conscious decision-making regarding the potential health implications of opening up health-related services sectors.

Finally, the schedules of CAFTA-DR exhibit certain differences across countries. The lists of reservations of Costa Rica and the Dominican Republic stand out for their high level of detail in health-specific measures. This raises the question of whether these differences in schedules reflect differences in the countries’ health systems and respective measures pursuing health policy objectives, or are due to differing technical and negotiating capabilities and resources deployed in the negotiating process.

¹⁴ More specifically, this reservation applies to all sectors, to all five possible obligations concerned and refers to “all existing non-conforming measures of all states of the US, the District of Columbia, and Puerto Rico”.

¹⁵ Costa Rica, the Dominican Republic, El Salvador, Honduras, Nicaragua and the United States.

¹⁶ This text is quoted from the United States schedule; similar language can be found in the schedules of the other five countries.

Box 6.3 Health-related reservations in CAFTA-DR schedules: examples from Costa Rica and the Dominican Republic

Both Costa Rica and the Dominican Republic include numerous health-specific reservations in their schedules.

Costa Rica's health-specific reservations relate to:

- its laws for health-related professional bodies (for example those of pharmacists, physicians and surgeons, veterinarians, nurses, dental surgeons, medical and surgical technicians, optometrists, psychologists and chiropractors), including reciprocity requirements for membership in most of these professional bodies;
- residency requirements (pharmacists, physicians and surgeons, veterinarians, dental surgeons, medical and surgical technicians, and nurses);
- obligatory (although it can be waived for temporary professional practice), remunerated "social service" (one continuous year); the slots for such services are allocated by lottery with certain preferences given to nationals (doctors, dental surgeons, microbiologists, pharmacists, nurses, and nutritionists).

The Dominican Republic's health-specific reservations:

- allow foreign nationals that graduated from foreign universities to practice in the Dominican Republic if all of the following criteria are present: (a) there is a reciprocal agreement between the relevant governments allowing professionals to practice in both countries (b) the service is not offered or is insufficient in the Dominican Republic and (c) the foreigner has the degree certified for equivalency by the appropriate agency within the Dominican Republic;
- allow foreign health professionals to practice in the Dominican Republic on a non-profit basis, if authorized by the Dominican Ministry of Health (SESPAS), and in some cases on a for-profit, temporary basis;
- impose residency requirements for the practice of psychology;
- require pharmacies, drug stores and industrial pharmaceutical laboratories to be at least 500 metres from each other.

6.3.4 SADC

Regional cooperation of the Southern African Development Community (SADC) was formalized in 1992 through the Windhoek Treaty, which aims to promote a genuine and equitable regional integration. As of 2012, Members of SADC include Angola, Botswana, Democratic Republic of the Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, United Republic of Tanzania, Zambia and Zimbabwe. Since 1996, SADC countries have embarked on a process of trade negotiations aimed at gradually liberalizing their markets and eventually creating a common market with a common currency.¹⁷

In 2009, SADC ministers of trade adopted a framework Protocol on Trade in Services, which was signed by the Heads of State in August 2012. The protocol adopts a positive list approach, which will be implemented through follow-up negotiations. Six sectors have been earmarked for priority liberalization: communication, construction, energy, finance, tourism and transport. The list of sectors subject to liberalization negotiations can be expanded in the future.

The SADC Protocol on Trade in Services pursues services integration with a view to: achieving the harmonious, balanced and equitable development of the region; ensuring progress and the well-being of

¹⁷ <http://www.sadc.int/about-sadc/integration-milestones/>. All SADC countries except the Seychelles became WTO Members between 1995 and 1997.

the people of southern Africa through poverty alleviation, with the ultimate objective of its eradication; and achieving sustainable development and meeting the challenges of globalization.

The protocol places great emphasis on achieving coherence and generating synergies with other SADC services protocols, including the SADC Protocol on Health. The SADC Protocol on Health offers examples of specifically health-related cooperation, including by aiming to: coordinate regional efforts on epidemic preparedness, mapping, prevention, control and where possible the eradication of communicable and non-communicable diseases; facilitate the establishment of a mechanism for the referral of patients for tertiary care; promote and coordinate laboratory services; and collaborate with other relevant SADC sectors. The activities have been set in motion, with implementation plans and several projects, including the development of a health implementation plan and a project on reversing the “brain drain” in the health sector from the SADC region to other countries. Under this project, the SADC secretariat has mobilized resources for the development of policy guidelines to attract and retain health care professionals in the public sector.

6.3.5 ASEAN

ASEAN Members (Brunei Darussalam, Cambodia, Indonesia, Lao People’s Democratic Republic, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam) aim towards an ASEAN Economic Community by 2015. In 1995, ASEAN Members signed the ASEAN Framework Agreement on Trade in Services. The agreement adopts a positive list approach, and the long-term objective of eliminating restrictions on trade in services is to be achieved through negotiating rounds. By 2012 eight packages of commitments had been signed,¹⁸ including some coverage of health care services. These commitments are generally of a GATS-plus nature (apart from mode 4, which is mostly at GATS level). Liberalization commitments are complemented by mutual recognition arrangements¹⁹ and cooperative mechanisms.

Health services have been addressed by numerous initiatives. At the ninth ASEAN Summit in Bali, health care was identified as one of 11 priority sectors for integration (12); at the tenth ASEAN Summit, health care (together with the e-ASEAN initiative) was identified as a priority sector for advanced liberalization under the ASEAN Framework Agreement for the Integration of Priority Sectors (13). The liberalization of such priority sectors is advanced through the “ASEAN minus X” formula, which allows some countries to move forward and enter into agreements, even if others are not yet ready to commit. The ASEAN Framework Agreement on Services establishes that liberalization is to be complemented by mutual recognition arrangements,²⁰ and by 2009, arrangements had been signed with respect to nursing,²¹ the practice of medicine²² and the practice of dental medicine.²³

Upon closer scrutiny of the mutual recognition arrangements, it is revealed that they lack real and concrete mutual recognition and might not meaningfully facilitate the movements of health professionals. For example, nurses must have at least three years of work experience in the country of origin, a requirement that effectively only facilitates the movement of experienced nurses (14).²⁴ Similarly, medical and dental practitioners must have at least five continuous years of work experience in their country of origin. Moreover, the absence of complete liberalization affects not only the movement of health care professionals, but also that of patients: Despite the importance of health care tourism in the region, further integration to promote the portability of health insurance is lacking (13).

¹⁸ *Protocol to implement the eighth package of commitments under the ASEAN Framework Agreement on Services*, 28 October 2010 (<http://www.asean.org/news/item/protocol-to-implement-the-eighth-package-of-commitments-under-the-asean-framework-agreement-on-services>).

¹⁹ Mutual recognition arrangements facilitate the recognition by one country of professional qualifications obtained in another country. Mutual recognition focuses on professional services such as engineering, accountancy, architecture, surveying, medical and dental practitioners and nursing.

²⁰ The agreement encourages Members to enter into further agreements to recognize education or experience obtained, requirements met or licences granted in another ASEAN country.

²¹ *ASEAN mutual recognition arrangement on nursing services*, 8 December 2006 (<http://www.asean.org/news/item/asean-mutual-recognition-arrangement-on-nursing-services>).

²² *ASEAN mutual recognition arrangement on medical practitioners*, 26 February 2009 (<http://www.asean.org/news/item/asean-mutual-recognition-arrangement-on-medical-practitioners-2>).

²³ *ASEAN mutual recognition arrangement on dental practitioners*, 26 February 2009 (<http://www.asean.org/news/item/asean-mutual-recognition-arrangement-on-dental-practitioners-2>).

²⁴ Interestingly, this requirement does not exist in any of the domestic laws and regulations of ASEAN countries.

The ASEAN process is also interesting from a coherence perspective. Meetings of ASEAN health ministers or senior officials regularly refer to trade liberalization initiatives. In 2000, for example, the Declaration on Healthy ASEAN 2020 called upon ASEAN to strengthen the national and collective ASEAN capacity on issues of “health implications of globalization and trade liberalization”. In 2005, senior officials reiterated the importance of urgently addressing the health impact of trade liberalization (including with regard to the movement of service providers) and called for consultations with the respective services and investment bodies (12). In 2012 ASEAN health ministers agreed that, in order to reduce tobacco consumption and associated non-communicable diseases, tobacco must be withdrawn from the list of products scheduled to be liberalized by 2015 within the ASEAN Free Trade Area.

6.4 Conclusions

An increasing number of RTAs cover services, including health-related services. Hence, health policy-makers need to pay attention to the respective negotiation and implementation processes, with a view to achieving coherence between trade and health policy objectives. RTAs pursue different approaches to the liberalization of services and the attendant cooperative mechanisms, and frequently serve as laboratories for innovative solutions. While regional liberalization of health and other services can generate pro-development outcomes, such benefits are not automatic. Instead, liberalization needs to be properly paced and sequenced with the development of adequate regulatory, institutional and policy frameworks.

At a broader level, there is a need to manage the interface between regional and multilateral services trade liberalization and to properly design the relationship between South–South and North–South liberalization. Given the nascent stage of the services sectors in developing countries, the implications for those sectors of North–South reciprocal market openings in services need to be carefully assessed.

Cooperative mechanisms can offer an important contribution to making regional trade liberalization of services contribute to development, particularly in the areas of health care and social services. A type of cooperation that is essential from a development perspective is one which aims to enhance regulatory development and institution building (for example financing, technical assistance, regular information exchange and meetings, and partnerships between institutions and other collaborative projects). Cooperation can also cover infrastructure services or support institution building or supply capacity building. Cooperation in this area is important because improved infrastructure is a central requirement for the efficient delivery of health care services.

Effective cooperation should be implemented over a sustained period of time prior to liberalization. Although North–South RTAs often provide for cooperative mechanisms, the effectiveness of these mechanisms continues to be at the forefront of regional discussions in developing regions.

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Chapter 7

Trade in health services

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7.1 Introduction

This chapter outlines the current trends and issues with regard to trade in health (and health-related) services, giving particular attention to domestic regulation in the context of this trading environment.¹ Given that existing literature already provides substantial coverage of certain aspects of trade in health services, as well as a comprehensive and widely available framework specifically focused upon health services trade (1), this chapter's added value lies primarily in its focused consideration of regulatory issues. The chapter starts with a brief review of the key characteristics of the trade policy environment within which the interface between services, trade and health has been approached (2, 3). This is followed by an overview of possible benefits and risks to national health systems associated with the liberalization of trade in health services. The chapter then focuses on how to conduct a trade-related regulatory audit with a view to better understanding how domestic regulation related to health services can affect international trade in health services, how international trade agreements can affect domestic regulatory space in the health sector, and how to design more coherent policies in the areas of trade and health. It also incorporates a series of specific case studies.

7.2 Trade in health-related services: characterizing the current environment

Trade agreements in recent decades have increasingly incorporated services, including health services, commonly classified² as being supplied through four Modes:

1. cross-border supply (through remote supply, that is, by suppliers that are not present in the receiving country), such as telemedicine or e-health services;
2. consumption abroad, when domestic consumers (patients) travel to a foreign country to receive health services;
3. commercial presence, when a foreign service provider (for example a hospital chain) establishes a presence in a host country for purposes of supplying health-related services;
4. movement of natural persons, when health care professionals (for example medical doctors or nurses) from one country supply their services abroad on a temporary basis.

Consistent with the provisions of many current trade treaties, countries are allowed to make legally binding commitments pertaining to trade and investment in health services and to formulate such commitments in accordance with domestic health policy objectives. These treaties include the World Trade Organization's (WTO) General Agreement on Trade in Services (GATS), the vast majority of recently concluded preferential trade agreements (PTAs) concluded at the bilateral and regional levels, as well as the burgeoning number of bilateral and regional investment treaties covering cross-border investments in services.

¹ Health (and health-related) services will be referred to simply as "health services" throughout this chapter. The World Trade Organization's General Agreement on Trade in Services divides all services into 12 categories, of which four contain health and health-related services (business, communication, financial and health-related and social services). The definition of health services used in this chapter comprises all services, in the four categories, pertaining to health care.

² These four Modes of supplying services are defined in Article I of the General Agreement on Trade in Services (GATS). See Chapter 6.

It is worthy to note from the outset that trade and investment agreements typically do not cover “services supplied in the exercise of governmental authority” (GATS Article I). Under GATS (and most PTAs), services that fall under the “exercise of governmental authority” are defined as services “supplied neither on a commercial basis, nor in competition with one or more service suppliers” in the domestic market. This implies that countries have carved out a regulatory space that shields domestic regulatory measures from the reach of trade and investment provisions in sectors characterized by significant public good attributes such as in the fields of *public* health, *public* education or national defense. In addition, the GATS allows WTO Members to attach limitations to their commitments in order to preserve the right to implement measures inconsistent with full market access or national treatment obligations. Much the same leeway is afforded to PTA signatories.

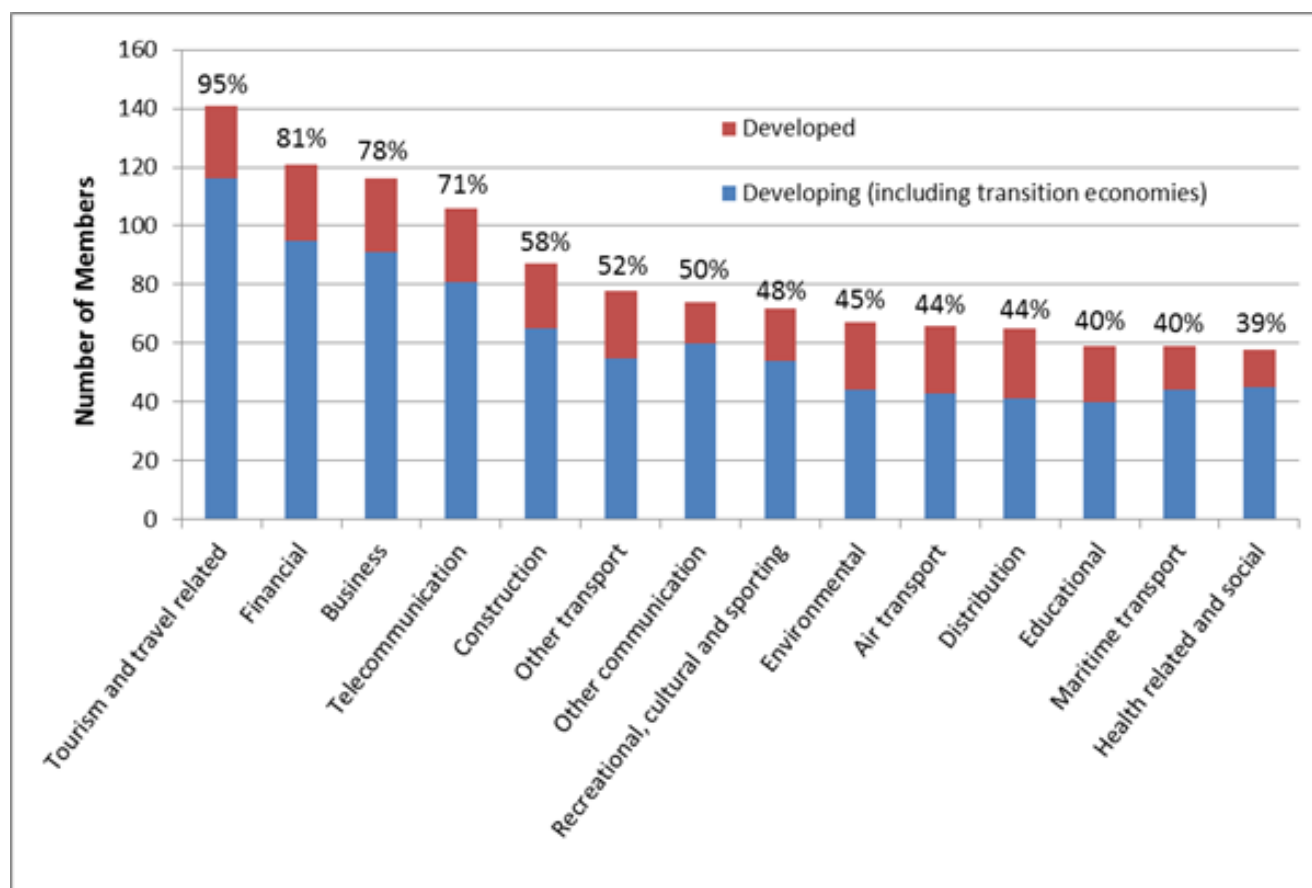
However, the notion of “services supplied in the exercise of governmental authority” is seldom defined in trade and investment agreements. In part, this reflects the fact that countries differ markedly in their collective preferences and the degree to which the responsibility of service provision is entrusted to the public sector. The above discussion is of potentially great significance in considering whether, how and to what extent domestic regulatory conduct in the health sector can be affected by trade and investment agreements.

It is also noteworthy that relatively few WTO Members have made commitments with respect to health and social services, compared to the number of Members having made commitments in other service sectors. Figure 7.1 reveals how, alongside education with which it shares several policy sensitivities, the health sector ranks among the least committed of all major service sectors covered by the GATS. The data in Table 7.1 confirm such trends, showing that only 56 of the WTO’s 160 Members have to date scheduled commitments in health services, just over a third of the membership (35%), representing the lowest coverage ratio of all sectors and connoting a keen desire for the preservation of policy space in the formulation of health care policies. Such a trend is also broadly seen at the PTA level despite the greater overall level of market opening achieved in the health field under the latter agreements.

Moreover, even where WTO Members do undertake commitments, it should be kept in mind that such commitments do not necessarily entail full market access, but can be limited in scope and retain existing restrictive practices. Conversely, WTO Members can engage in trade in health services even if they have not made any commitments under GATS.

To date, low-income economies have limited scope for trading health services, due to the combination of acute resource constraints (particularly human resources) in health care and poor health care infrastructure. Thus, commitments pertaining to trade and investment in health services have been undertaken predominantly by middle-income and developed countries. However, regardless of development levels, very few countries have to date assigned a significant role to trade and investment policy in managing or shaping the development of the health sector (4–7).

Figure 7.1 Sectoral distribution of market access commitments under the GATS



Note: Figure 7.1 lists the service sectors in accordance with the classification system used under the GATS. Such a classification does not correspond to the definition of health services used in this chapter (see Footnote 1).

Source: WTO-World Bank I-TIP Services database, June 2015.

<http://i-tip.wto.org/services/ComparativeReports.aspx> (accessed on 31 January 2014)

Table 7.1 Sectoral distribution of scheduled commitments under the GATS

Service Sector	Number of WTO Members Scheduling Commitments	Share of WTO Members with Commitments in the sector (% out of 149*)
Business services	116	77.9
Communication services	113	75.8
Construction and related engineering services	87	58.4
Distribution services	65	43.6
Educational services	59	39.6
Environmental services	67	45.0
Financial services	121	81.2
Health related and social services	58	38.9
Tourism and travel related services	141	94.6
Recreational, sporting and cultural services	72	48.3
Transport services	97	65.1
Other services	10	6.7

*The European Union commitments reflected as one schedule in this table are those of the EC-12.

Source: WTO-World Bank I-TIP Services database, June 2015.

Despite the above caveats, the overall level of negotiating activity and policy engagement in health services trade and investment is growing, due to several factors. On the demand side, demographic change (particularly population ageing) is occurring in both developed and developing countries, and the resulting increase in demand for the services of health care professionals must contend with pressures to contain health budgets and the scope trade offers to alleviate such costs in some instances. On the supply side, new technologies are facilitating the remote supply of an increasing range of health services (including to isolated populations in developing countries). In addition, there has been a continued liberalization of cross-border investment in health-related services, indeed the emergence of multinational health care firms, several of which originate in developing countries. Moreover, the sector continues to witness significant doses of cross-border mobility of health care professionals. As with many other sectors, progress in addressing trade and investment in health services has also tended to proceed more extensively under PTAs than at the WTO level. This can be seen in Table 7.2, which calculates implicit margins of preference across major service sectors flowing from the greater liberalization achieved under preferential agreements relative to the GATS and the latest negotiating offers made in the Doha Round (8). On an index scale that runs from 0 to 100, the level of liberalization achieved in health services in the most liberal PTA (34) is more than four times that observed in the GATS (9). This implies relatively high derived preference margins in the sector, reaching 76% in the PTA that has achieved the greatest degree of market opening in the health sector. It bears recalling, however, that such preference margins originate in a sector that shows, as under the WTO, the lowest absolute level of preferential liberalization.

**Table 7.2 Implicit margins of preference in services trade:
comparing the level of services trade liberalization across sectors**

Sectors	GATS	DDA Offers (0 to 100)	PTAs	GATS/PTAs (%)	DDA/PTAs (%)	Preference Margin
Professional	30	39	67	45	58	42-55
Computer	55	74	93	59	80	20-41
Postal/Courier	14	20	53	26	38	62-74
Telecoms	51	58	80	64	73	28-36
Audiovisual	17	20	50	34	40	60-66
Construction	40	46	75	53	61	39-47
Distribution	32	41	76	42	54	46-58
Education	18	25	57	32	44	56-68
Environmental	20	30	62	32	48	52-68
Financial	36	40	53	68	75	25-32
Health	8	11	34	24	32	68-76
Tourism	51	61	83	61	73	27-39
Maritime	12	23	57	21	40	60-79
Rail	14	20	52	27	38	62-73
Road	16	18	56	29	32	68-71
Aux. Transport	21	24	58	36	41	59-64

Source: Sauvé and Shingal (2011).

A growing number of developing countries, particularly middle- and higher-income developing countries, today regard health services, especially those that can be combined with tourism-related activities, as a potentially significant source of foreign exchange earnings, foreign investment and skills upgrading, which ultimately might contribute to economic growth and development. Several such countries are devoting significant policy attention to building health-related export clusters, with some having developed targeted trade and investment promotion strategies in the sector.

Although the health sector received the fewest overall commitments (market access and national treatment) in the Uruguay Round of multilateral trade negotiations (1986–1994) and in subsequent negotiations regarding accession to the WTO, the increasing profile of trade in health services reflects the importance of appropriate domestic regulation combined with effective institutional and enforcement capacities.

7.3 Evidence of the impact of trade in health services on health systems

The literature devoted to cross-border trade and investment in health services (2, 3, 9) has drawn useful attention to the potential opportunities and risks associated with each of the four Modes of trading health services internationally. Such opportunities and risks should be considered when designing policies at the interface of trade and health.

7.3.1 Mode 1 trade in services

Mode 1 trade covers cross-border supply, i.e. where service suppliers and consumers are located in different countries. Technological progress, and in particular advances in the area of information technology, have vastly increased the scope for remotely supplying services that were previously not tradable across borders. The most palpable examples of such services in the health field include the electronic delivery of medical services, such as diagnostics and medical transcription (see Box 7.1) but such trade has also scaled up remarkably in its technological sophistication to include remotely performed surgeries through the use of advanced robotics (10).

There are a number of potential benefits of Mode 1 trade in health services. First, it can allow services to reach geographically remote populations that may not be adequately served by existing health services. Second, Mode 1 trade may offer significant scope for cost savings in some cases. Third, Mode 1 trade (such as web-based medicine) may provide new export opportunities for both developing and developed countries.

A potential risk of remotely supplied services includes the possible reallocation of resources away from rural health care (and/or away from primary care) and towards export-oriented, specialized health services targeting higher income population segments (11).

Box 7.1 Offshore medical transcription services in the Philippines

Medical transcription is the process of writing down (or encoding electronically) the oral dictation of health professionals regarding patient treatment, diagnosis, etc. Outsourcing from the United States has been the main driver of the global medical transcription business. Since the entry into force of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA", which requires businesses to safeguard private medical data), the demand for medical transcription services in the United States has expanded rapidly, growing at an estimated 20% per year, coupled with a 10% per year decline in the number of transcriptionists in the United States .

The first large medical transcription company, Outsource Transcription Philippines, was founded in the late 1990s. As the third-largest English-speaking nation in the world, with a large workforce, 94% literacy rate and a strategic location with an ideal 12-hour time difference from the east coast of the United States, the Philippines possesses key inherent advantages as a "first-choice [medical transcription] outsourcing destination" for advanced country institutions (Business World Philippines). Medical transcription is one of the five subsectors identified by the Philippines Department of Trade and Industry in its campaign to promote the country as a global hub for outsourced information technology (IT)-enabled services (12). The government of the Philippines has lent strong support to the medical transcription industry by implementing an e-commerce law, adopting the Data Privacy Act (2012) and setting up the Information Technology and Electronic Commerce Council. The government has also aided in developing and expanding the IT infrastructure of the country. These efforts have borne fruit as medical transcription outsourcing to the Philippines has over the past decade experienced the fastest growth among all outsourcing sectors in the Philippines.

Despite this growth, the Philippines' market share is still quite small compared to the potential market size. Prospects for further rapid growth remain bright, given the anticipated surge in outsourcing as hospitals in developed countries have yet to convert records into electronic formats as is increasingly required by law, and in light of future reforms that are expected to promote greater use of IT in health care management. Furthermore, the vast majority of companies exporting these services from the Philippines are owned by investors from the OECD area. Hence the expectation is that, as the benefits of outsourcing are more fully understood, the Philippines will be well positioned to benefit from outsourcing of other aspects of health-related administrative operations. Privacy concerns have so far not inhibited outsourcing from the United States to the Philippines. Patient information is protected through service contracts between importing hospitals in the United States and exporting transcription companies in the Philippines.

7.3.2 Mode 2 trade in services

Mode 2 trade (consumption of services abroad) occurs when natural persons travel across international borders to receive health services. These health services encompass a broad array of medical treatment received abroad, such as surgery or medical screening, as well as spa and massage services or visits to practitioners of holistic or alternative medicine.

The principal potential benefit of Mode 2 trade in health services lies in its potential to improve the health care system in the exporting country (receiving foreign patients) and alleviating health care budgets in the importing country (by sending patients abroad for lower cost medical interventions so long as the quality of care can be certified as equivalent to that practiced in the home country). In the exporting country, Mode 2 trade might contribute to the development of the health care sector by generating additional investment in health care facilities and technological upgrading. Such trade can also increase both business revenues and government tax receipts, provide needed foreign exchange, and can typically create positive synergies with tourism-related activities. People and entities in importing countries may gain as well, mostly in the form of lower health care costs and the concomitant increase in the ability of patients to access health care.

According to one estimate, the United States health care system could save up to US\$ 1.4 billion annually if only one in ten patients were to go abroad for a limited set of 15 highly tradable, low-risk treatments (13). However, a significant limitation to medical travel is that of insurance portability across borders (see Box 7.2). In addition, some critics of “medical tourism” question whether the quality of health services procured abroad would be adequate, or whether the risk of substandard care procured abroad might actually increase costs to the importing country, for example if patients return home disabled or in need of corrective treatment. Recourse to mutual recognition procedures and the certification of quality standards thus assume crucial importance in the context of this Mode of service supply.

Box 7.2 Medical travel and the portability of medical insurance coverage

One of the most significant barriers to health services exports under Mode 2 (medical travel) is the lack of portability of health insurance overseas. Even where opportunities for cost savings exist, the absence of an insurance framework that covers treatments received overseas limits the potential gains that can arise from medical travel. Two of the most obvious concerns insurers have about extending coverage overseas are the quality of treatment in foreign hospitals and the potential for higher costs arising from possible follow-up treatments.

The first concern is increasingly allayed by quality signaling through accreditation, the presence of a growing number of health care professionals at hospitals in developing countries that have been trained in developed countries, and international collaboration agreements between reputable medical establishments. The second concern, (the cost of follow-up treatments) can be addressed through increased collaboration among global networks of hospitals and medical facilities and by limiting the list of treatments eligible for coverage overseas.

However, there may be further reasons that prevent insurers from extending coverage abroad: insurers may face high costs of monitoring care received overseas; where coverage is provided by public health schemes, institutional impediments might be significant. For instance, allowing participation of foreign providers in government-controlled schemes would require changes to social security laws. Despite these impediments, promising examples of cross-border health insurance coverage can be cited. For instance, Tricare covers both emergency and non-emergency care for both active-duty and retired United States military personnel and their families, for treatment received while stationed overseas. Some multinational corporations and international organizations such as the World Bank also offer plans that reimburse employees for both emergency and non-emergency care received abroad. These plans treat overseas providers as “out of network”, which results in higher out-of-pocket employee co-payment.

The potential risks of Mode 2 trade are similar to those noted above for cross-border supply (Mode 1). The development of Mode 2 trade activities geared towards foreign consumers of health care services may attract scarce human resources away from health care institutions that serve the local population. It might also increase local prices due to the rise in demand and thus reduce access for the local population; and public investment might be reallocated to provide high-quality health to foreign patients, to the detriment of the health care needs of poorer segments of the host country population. These negative effects might be mitigated in the medium- to long-term by a supply-side response, such as an increase in foreign direct investment or the expansion of education and training of health care professionals.

Several countries are actively seeking to attract a greater number of medical travellers and health-related tourists. Three of the top six destinations for medical travel in the world today can be found in the Association of Southeast Asian Nations (ASEAN) region: Malaysia, Singapore and Thailand. Much of this trade involves patients from other ASEAN countries. Similarly, Cuba is a long-standing hub for foreign patients from countries in South and North America and the Caribbean, whilst Jordan has long been referred to as the “medical centre of the Arab world” (14) (see Box 7.3), though its position as regional leader has in recent years been increasingly challenged by new suppliers established in the Arabic peninsula (e.g. Dubai in the United Arab Emirates, and Qatar).

Box 7.3 Health and medical tourism: the case of Jordan

Due to the high quality of medical services provided, Arab patients started visiting Jordan for medical treatment as early as the 1970s. In the 1990s, Jordan began to consciously promote its health services exports. In 1998, the Ministry of Health established an office at the Queen Alia Airport to facilitate the entry of foreign patients (15).

While Jordan has invested in upgrading and modernizing its public hospitals and medical schools, it is Jordan’s private sector hospitals that dominate the market for medical travel. The private sector accounts for 54% of the hospitals in the country and 46% of available beds. Jordan’s private hospitals are state of the art and many have links with renowned hospitals and medical centres in Europe and North America.

The Jordanian experience highlights the importance of public–private collaboration. A special directorate, established by the government in partnership with the private sector, lays out the vision and strategy for promoting medical travel to Jordan. The vast majority of foreign patients in Jordan come from the Arab world, mainly Bahrain, Libya, Saudi Arabia, Sudan, Syrian Arab Republic, West Bank and Gaza Strip, Yemen and others. The majority of patients seek treatment in cardiology, neurology, bone disease and other internal diseases.

Medical travel to Jordan further highlights the importance of bilateral relationships and protocols between sending and receiving countries. As in the case of Cuba and a few Asian health service exporters, some of the patients coming to Jordan enjoy the coverage of home country medical insurance funds. For instance, a protocol was signed between Jordan and the Algerian Social Security Fund, with the terms of payment for treatment in Jordan linked to the Algerian social security system. Jordan has medical cooperation protocols with several other countries, while private sector hospitals have their own agreements with governments and private clients in foreign countries (15).

While the Jordanian Ministry of Health plays a limited role in trade policy formulation, it is notable that the Ministry is represented at the Jordan Investment Board and actively functions on the board in matters related to the health sector. Success in the promotion of medical travel has prompted Jordan to create incentives for national and foreign private investment in the health sector.

However, Jordan is facing stiff competition in the medical travel sector from countries in the Gulf region, such as the United Arab Emirates, as well as from Lebanon and Tunisia. There has been a large recent inflow of foreign patients into Lebanon, with the majority coming from Gulf countries. The American University of Beirut Medical Center attracts a large share of foreign patients to the country. The Lebanese Ministry of Health has established a joint commission to promote “medical tourism” and an independent company was designated to promote medical travel on behalf of participating hospitals.

7.3.3 Mode 3 trade in services

Mode 3 trade occurs when a foreign service provider establishes a commercial presence in a host country. This mode of supplying services accounts for more than half of world trade in services and makes up the predominant share of legally binding commitments scheduled under the GATS and PTAs. Cross-border investment activity is further subject to rules emanating from the increasingly dense network of international investment agreements (IIAs). The most popular form of such treaties remains bilateral investment treaties (BITs), of which there are today close to 3200 worldwide, but some investment agreements are regional in scope and others are embedded in PTAs, such as Chapter 11 of the North American Free Trade Agreement (NAFTA).

An IIA sets substantive standards that benefit private investors from other parties to the treaty. The main purposes of IIAs are commercial in nature and aim to secure a stable and predictable environment for foreign investors by protecting them from various kinds of state actions, such as discrimination and confiscation (the taking of property without adequate and prompt compensation), with a view to encouraging foreign investment. Mode 3 trade in health services can thus generate additional foreign direct investment, contribute to upgrading health care infrastructure, create jobs, encourage the transfer of know-how and medical expertise to local providers and practitioners, and provide a broader array of specialized medical services than those available locally.

The potential risks of Mode 3 trade include the possibility of increasing inequity with respect to access to health care, notably the risk of witnessing the emergence or reinforcement of a two-tiered health care system. Such a system may arise from an internal “brain drain”, i.e. if health care professionals are tempted to accept positions with higher-paying foreign health care ventures. As noted earlier, trade and investment treaties covering investment in services typically carve-out public services, including public health services, as a result of express provisions in the treaties themselves. Several issues have been raised concerning the scope of such excluded activities.³ Responding to such concerns, the most recent generation of IIAs and PTAs feature provisions that more clearly define what is and what is not actionable under such agreements and spell out in greater detail how domestic regulations enacted in pursuit of legitimate public policy objectives are immune from legal action taken by foreign investors.

7.3.4 Mode 4 trade in services

Trade in services via the temporary movement of natural persons (Mode 4 trade) may help developing countries exploit their comparative advantage in semi-skilled and unskilled labour and, for some developing countries, in more highly skilled labour as well. This is an increasingly important component of services exports for many developing countries, which send abroad a variety of service providers, from nurses, teachers and domestic workers to medical doctors, architects, engineers and IT specialists. These individuals may work abroad either as intra-corporate transferees (i.e. secondments) or as independent contractors (professionals) on a temporary basis, usually ranging from three months to five years. Mode 4 trade remains somewhat limited due to a number of stringent regulatory barriers imposed by recipient countries that seek to protect domestic labour markets. Policy restrictions also respond to the fear that temporary admission may lead to overstays or even permanent illegal migration. Such barriers include immigration rules, work visa requirements, discriminatory treatment of foreign providers and the non-recognition of foreign qualifications. Virtually all countries impose quantitative restrictions (i.e. quotas) on temporary work-related admission and such quotas rarely satisfy the demand for entry.

It is vital to appreciate how Mode 4 trade involves the *temporary* movement of service suppliers, as distinguished from immigration policy, which governs more permanent forms of labour movements. This distinction matters as measures governing permanent immigration lie outside the scope of trade and investment agreements. Simply put, temporary admission to work does not create any right or pathway to permanent residence, nor any right to enter the host country labour market. These are important and often misunderstood distinctions in the public policy debate over Mode 4 trade that bear emphasizing.

³ Exclusions typically do not give governments the right to confiscate foreign investments or to breach certain other obligations when pursuing public health objectives.

A potential benefit of the movement of health care professionals via Mode 4 trade is the promotion of knowledge spillovers, that is, the dissemination of clinical knowledge and skills among professionals. Conversely, a potential drawback of Mode 4 trade is that temporary mobility may encourage movement of a more permanent nature, such that health care professionals needed domestically, and often trained at considerable local cost, depart from their home country (the so-called “brain drain” problem).

7.4 Conducting a trade-related regulatory audit

Many service sectors are highly regulated in order to promote policy objectives such as consumer protection, equitable and universal access to health or education, environmental protection, or, in the case of financial services, financial and macro-economic stability. In general, such general purpose regulation is fully allowed under the GATS and PTAs and may be particularly important for developing countries given the need to buttress nascent regulatory regimes and institutions.

There are two main ways in which services trade liberalization can intersect with domestic regulation. First, in making regulations, governments should consider the impact of such regulation on the country’s international trading position. Second, the process of liberalizing services trade may require the implementation of new regulations at the national level, for example, to ensure that the expected benefits of liberalization are realized or that important policy objectives continue to be achieved within the new market structure. Transparency and the involvement of relevant stakeholders are important when designing, implementing and enforcing regulations (see Box 7.4).

Box 7.4 The importance of transparency in services trade

Transparency of domestic regulations is critical to the effective implementation of any trade or investment agreement. Transparency assumes particular importance in services trade. This is because many service sectors are subject to extensive regulation given the high incidence of market failure (for instance, asymmetries of information underlying professional licensing regimes in the medical and many other regulated professions). Greater transparency is also necessary to ensure that domestic regulations do not discriminate overtly, burden business unduly or inhibit competition.

The GATS, like the vast majority of PTAs covering services, require Members to ensure sufficient transparency of their trade regimes. Article III of the GATS ensures that Members publish promptly all measures *affecting* trade in services. Moreover, there is an obligation to notify the WTO’s Council for Trade in Services at least annually of all regulatory changes that significantly affect trade in sectors where specific commitments have been made. Members are also required to establish “enquiry points”, whereby they designate (and provide contact information for) individuals or offices that are available to answer questions related to national services trade policy and domestic regulatory requirements.

Moreover, while the GATS, PTAs and IIAs covering services allow Members to maintain measures inconsistent with full market access or national treatment, Members must do so in a transparent manner by listing, under the GATS, any limitations on market access under Article XVI or on national treatment under Article XVII in sectors, subsectors and Modes of supply where they undertake legally binding commitments. They must also transparently list all exceptions to the principle of most favoured nation (MFN) treatment under Annex II of the GATS. PTAs and IIAs, the majority of which today proceed on a so-called “negative list” approach, require parties to list any non-conforming to (i.e. exceptions from) full treaty privileges in reservation lists appended to the relevant agreements.

Liberalization of services markets often necessitates regulatory reform, which in turn involves consideration of a number of questions, including:

- **Purpose:** What is the purpose of the regulation, e.g. protecting consumers or the environment, promoting competition, or ensuring universal access to a service?
- **Design:** Will the proposed regulation be effective in achieving its stated objective? If so, is it the most efficient way to achieve the objective? Factors to consider may include whether the regulation is reasonable, objective in its application and transparent, proportional to the objective being pursued, and linked to international standards.
- **Implementation:** How will the regulation be implemented? Are there transparent and impartial procedures for implementing the regulation? Can persons or entities affected by the regulation provide input prior to its adoption? Do persons or entities adversely affected by the regulation have any recourse? Do the relevant government agencies have the requisite skills, financial resources and political legitimacy to implement the regulation?
- **Evaluation:** Has the regulation been effective? Have the expected outcomes been achieved? What costs have been incurred in implementing the regulation? Are these costs reasonable relative to the outcome? Which challenges had to be overcome?

Different countries may consider certain questions to be more pressing than others, or may wish to take other factors into consideration. This can be a challenging process, in particular for developing countries with limited administrative capacity and many countries requiring significant training and technical assistance regarding the implementation of regulations following market opening.

Neither the GATS and nor PTAs prescribe the type of regulations that governments should enact in any given sector. Instead, they allow countries to formulate their own regulations subject to the general requirements that those regulations be non-discriminatory, proportional and transparent (see Box 7.4 above). In addition, such regulations should not constitute “disguised restrictions” to trade and investment.

GATS Article VI (and its PTA equivalents) addressing the issue of non-discriminatory domestic regulation requires that, in those sectors or sub-sectors where specific commitments have been undertaken, all measures be “administered in a reasonable, objective and impartial manner”. In addition, countries must provide for the prompt judicial or administrative review of administrative decisions affecting trade in services. (Article VI.2)

GATS Article VI also lays down specific rules on domestic regulation pertaining to qualification requirements and procedures, technical standards and licensing requirements. The Agreement stipulates that domestic regulations should not be devised in a way that nullifies or impairs the benefits that other treaty members should reasonably expect in light of a country’s market-opening commitments. That is, a commitment to open a market to foreign service providers will be of little commercial value if the qualification requirements or procedures applied make it all but impossible for the foreign providers to deliver the services in question, even if they are technically qualified to do so. Trade and investment agreements encourage countries to regulate in a manner that, whenever feasible, is least restrictive to trade and investment (i.e. minimizes the adverse effect on cross-border activity).

7.4.1 *Important questions during negotiation of trade services*

The process of negotiating services trade is both time consuming and information intensive. Questions that may arise during the negotiation process include the following:

- What are the policy objectives of the regulatory measure in question?
- How transparent is the regulatory measure and the process that was used to adopt it?

- When was the policy measure, law or regulation enacted?
- When was the measure last invoked?
- Is the measure periodically reviewed?
- Is the policy objective pursued by the measure in question still consistent with overall government policy?
- Is the government satisfied that the policy objective is being achieved by the measure in question, and has it developed a credible means of coming to such a determination through tested impact assessment methodologies?
- Can the policy objective be achieved through other means or in a manner that might lessen the measure's restrictive impact on trade or investment?

7.4.2 *Performing the regulatory audit*

Through exploration of the above questions, the negotiation process may generate positive policy spillovers by informing domestic regulatory conduct and design. Governments may be interested in engaging in a trade-related regulatory audit in order to:

- ensure that key policy objectives are met in the most efficient manner (that is, in a manner that is least wasteful and distorting to trade and investment);
- identify antiquated or inefficient regulations and adopt international best practices;
- encourage, where feasible, the adoption of market access-friendly regulations;
- build trust within the government through whole-of-government dialogue and enhanced inter-agency coordination;
- deepen dialogue between key government stakeholders (both regional and local), producers and consumers.

One useful starting point for engaging in such an audit is to prepare a list of domestic regulations that, but for country reservations (exceptions), would not conform to treaty obligations (e.g. national treatment, market access and most-favoured-nation treatment). This list should include a comprehensive description of:

- the sector to which the non-conforming measure applies;
 - the level of government that enacted or applied the non-conforming measure (e.g., local, regional or national);
 - the legal citation of the non-conforming law or regulation in question;
 - a concise description of how the measure fails to conform.
- Box 7.5 offers examples of non-conforming measures under NAFTA

Box 7.5 Listing nonconforming measures: examples from NAFTA

(i) Canada

Example 1

Sector: Social services

Type of reservation: National Treatment (Articles 1102, 1202); Most-Favoured-Nation Treatment (Article 1203); Local Presence (Article 1205); Senior Management and Boards of Directors (Article 1107)

Level of government: All

Description: Cross-Border Services and Investment. Canada reserves the right to adopt or maintain any measure with respect to the provision of public law enforcement and correctional services, and the following services to the extent that they are social services established or maintained for a public purpose: income security or insurance, social security or insurance, social welfare, public education, public training, *health*, and child care. [emphasis added]

Example 2

Sector: Business services

Subsector: Trademark agents

Industry classification: SIC 999 – Other Services, Not Elsewhere Classified (limited to trade-mark agency)

Type of reservation: National Treatment (Article 1202); Most-Favoured-Nation Treatment (Article 1203); Local Presence (Article 1205)

Level of government: Federal

Citation: Trade-Marks Act, R.S.C. 1985, c. T-13; Trade-Marks Regulations, C.R.C. 1978, c. 1559

Description: Cross-Border Services. To represent persons in the presentation and prosecution of applications for trade-marks or in other business before the Trade-Mark Office, a trade-mark agent must be resident in Canada and registered by the Trade-Mark Office. A registered trade-mark agent who is not resident in Canada must appoint a registered trade-mark agent who is resident in Canada as an associate to prosecute an application for a trade-mark. Trade-mark agents who are resident, and are registered (in good standing), in a Commonwealth country or the United States may be added to the register of trade-mark agents.

Phase-out: Citizenship and permanent residency requirements are subject to removal within two years of the date of entry into force of this Agreement in accordance with Article 1210(3).

(ii) Mexico

Sector: Professional, technical and specialized services

Subsector: Medical doctors

Industry classification: CMAP 9231 – Private Medical, Odontological and Veterinary Services (limited to medical and odontological services)

Level of government: Federal

Citation: Ley Federal del Trabajo, Capítulo I

Description: Cross-Border Services. Only Mexican nationals licensed as doctors in the territory of Mexico may provide in-house medical services in Mexican enterprises.

Phase-out: None

Trade-related regulatory audits may be used to:

- identify regulations in need of reform in order to harness the benefits and mitigate the negative impacts of trade liberalization;
- provide a comprehensive overview of the trade and investment-restrictive components of a country's regulatory regime;
- assess the continued need for trade or investment-restrictive regulations;
- identify measures that may be offered during negotiations for scheduling (i.e. incorporation) into trade agreements;
- provide a complete inventory of existing discriminatory measures, which may help to anticipate partner country negotiating requests.

7.5 Conclusion

This chapter has provided a brief overview of the key elements of trade and investment regulation in health services, including some of the main opportunities and risks arising from such trade, illustrated by various country case studies. The chapter examined selected aspects related to regulation of the domestic health sector within the context of increased liberalization of international trade in services, highlighting both the policy space and the various benefits and challenges of liberalizing trade in health services in Modes 1 through 4. A brief discussion then followed of key aspects related to the conduct of a trade-related audit of domestic regulation in the services sector and some of the benefits of such an audit.

The chapter has made clear that, for a variety of reasons, governments of both developed and developing countries have generally adopted a policy stance imbued with significant regulatory precaution in approaching the relationship between trade and investment liberalization and domestic health care reforms. At the same time, many countries, particularly in the developing world, have been actively promoting trade and cross-border investment in health services. While such promotion efforts have chiefly taken the form of unilateral domestic reforms, international negotiations conducted along preferential lines and other treaties increasingly feature discussions of – and liberalization commitments on – cross-border trade and investment in health services.

By and large, governments opting to make binding international commitments on trade and investment in health services enjoy considerable latitude in deciding on the nature, pace and extent of market opening. International agreements generally include obligations to maintain transparency and to progressively lift discriminatory and anti-competitive measures. Yet governments must fully grasp, in advance, the likely effects of their policy choices. In addition, they should possess or develop sufficient technical expertise at the interface of trade and health policy to allow for the effective implementation of trade and investment policies that engage the health sector. A trade-related regulatory audit in the health sector may be of considerable use in this regard. Such an audit may allow governments to understand their own regulatory regimes, identify gaps in domestic regulation and regulatory implementation capacities, and also anticipate the negotiating requests of trading partners. All of this can help a government assess the country's readiness to engage in legally binding commitments relating to the health sector and the benefits (and downside risks) of assigning a more central role to trade and investment policy and international negotiations in the conduct of health care policy.

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Chapter 8

Trade liberalization, food, nutrition and health

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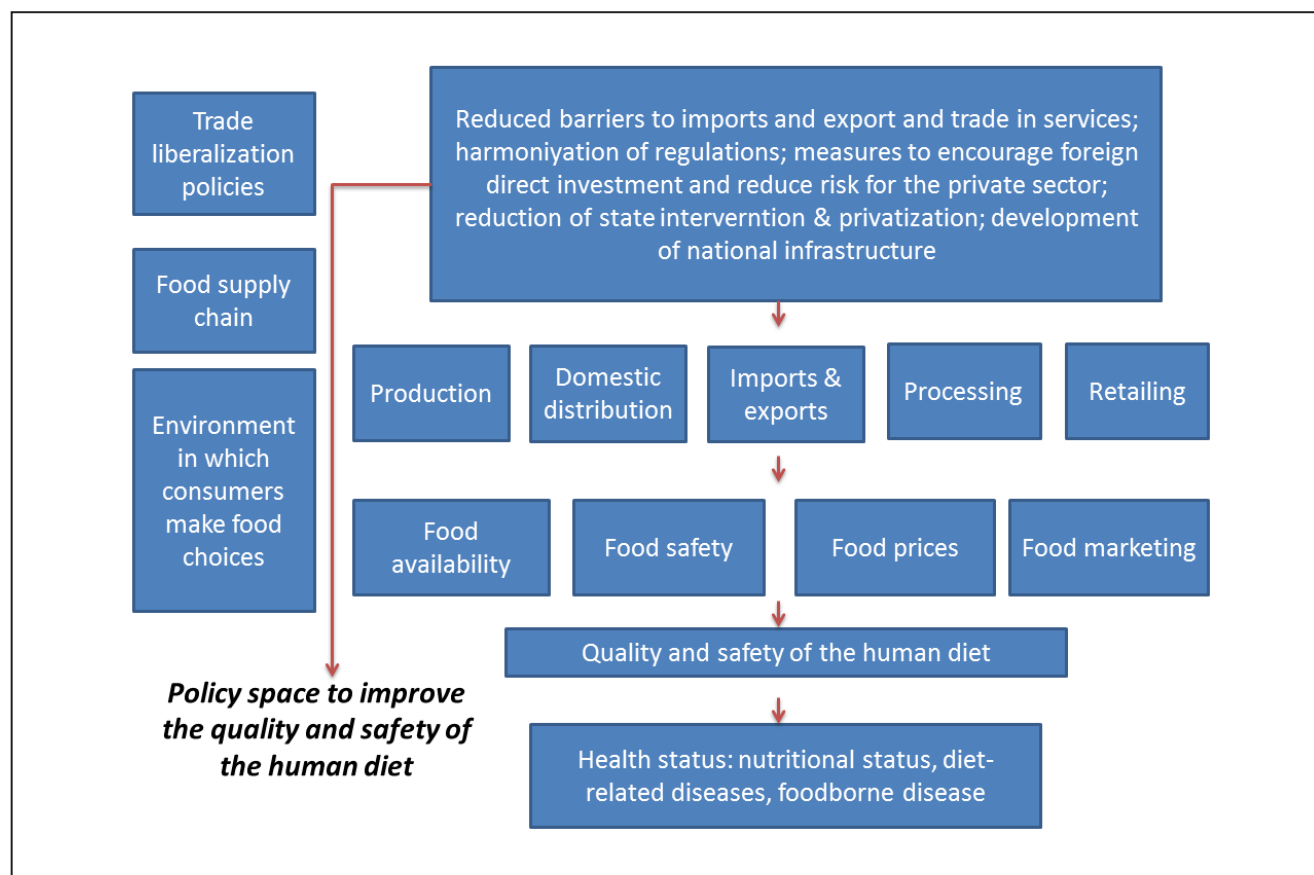
8.1 Introduction

By its very nature, liberalizing food trade facilitates trade in food products and services across national borders. Measures included in trade agreements also enhance the ability of the large-scale private agro-food industry to conduct business transnationally and expand in countries previously dominated by small-scale production and retail. Through these processes, trade liberalization has the potential to influence food-related nutrition and health issues. The pathways of impact are broadly conceptualized in Figure 8.1. Measures designed to liberalize trade influence the entire food supply chain. Changes along the food supply chain then influence the environment in which consumers make food choices i.e., the availability of foodstuffs (amount, type and nutritional quality), the safety of that food, what it costs, and how it is marketed. These factors, established as important components of national and household food security, influence the choices people make about the food they eat. These affect the diets of consumers and, therefore the prevalence of foodborne diseases, undernutrition, and obesity and diet-related non-communicable diseases (DR-NCDs).

In addition to these links, there are a range of indirect effects through which trade liberalization could affect human nutrition and health. These include the effects on household incomes, and the inadvertent entry of emerging human, animal, and plant diseases.

There is no precedent of countries undertaking impact assessments trying to predict the effect of policies designed to liberalize trade, or entire trade agreements, on food-related health. Following an overview of the different measures taken to liberalize food trade, this chapter goes through the four basic steps that can be taken to conduct such an assessment: (1) an assessment of the types of impacts trade liberalization could have, on a selected sub-set of key nodes in the food supply chain; (2) an assessment of the subsequent impact on food safety, food availability, food prices and food marketing; (3) an assessment on the food-related health outcomes themselves, namely foodborne diseases, undernutrition, and obesity and DR-NCDs; (4) an assessment of the implications of trade agreements on the policy space required to address these health conditions. In practice, the assessed impacts will vary widely between policies and national and local contexts; this chapter generically highlights potential impacts and provides examples of reported impacts where available. The chapter ends by raising some possible opportunities for using trade policy to improve nutrition and health.

Figure 8.1 Conceptual framework of the linkages between trade liberalization and food-related health



Sources. Adapted from Hawkes (5), Thow (6), Friel et al. (7)

8.2 Policy measures that liberalize food trade

Trade in foodstuffs can be liberalized through a range of measures, including those which:

- reduce financial and regulatory barriers to food imports and exports across national borders, such as the reduction of tariffs and the removal of quotas and export taxes;
- harmonize, remove, or increase the transparency of national food-related regulations, such as sanitary and phytosanitary measures, and food labelling regulations;
- encourage foreign direct investment in the agro-food industry, such as removing limits on the percentage of domestic companies that can be owned by foreign businesses, implementing protection for investors, protecting intellectual property rights and providing provisions for dispute settlement;
- reduce financial and technical barriers to the trade in services used by the agri-food industry, such as banking, telecommunications and real estate;
- decrease government support to domestic food production and state-managed entities, such as through the privatization of state-marketing boards, removal of domestic agricultural subsidies, and equal treatment of foreign and domestic food businesses in public procurement;
- support the development of infrastructure and capacity for trade and investment, by providing transportation routes and storage facilities, more efficient port facilities and the establishment and funding of export promotion agencies.

These measures have been advanced through three main mechanisms: international, regional and bilateral trade agreements, international investment agreements, and national investment in infrastructure. The growth in trade agreements has been particularly notable since the 1990s. The completion of the Uruguay Round of multilateral trade talks in 1994 marked a new era in food trade, with the founding of the World Trade Organization (WTO), its multilateral Agreement on Agriculture and a range of other agreements (Box 8.1). Though multilateral agreements have proved critical in the trade liberalization of foodstuffs, since the 2000s regional and bilateral trade agreements, such as the Central American Free Trade Agreement and the Trans-Pacific Strategic Economic Partnership Agreement, have grown in importance and scale.

Box 8.1. WTO multilateral trade agreements relevant to the trade of food and agricultural products (implemented 1995).

Uruguay Round Agreement on Agriculture. Pledges signatory countries to reduce tariffs (market access provisions), export subsidies (export competition provisions) and domestic agricultural support (domestic support provisions). The agreement focused on reducing subsidies for agricultural production in high income countries.

Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). Sets out rules for national measures that aim to reduce hazards to animal, plant and human health, including food safety regulations; it incorporates by reference the food safety guidelines and recommendations established by the Joint FAO/WHO Codex Alimentarius Commission. It recognizes that countries have a legitimate interest to protect human health from unsafe food, but upholds the principle that these measures should distort trade as little as possible.

Technical Barriers to Trade Agreement (TBT). Establishes obligations to ensure that national mandatory regulations, voluntary standards and conformity assessment procedures – including those affecting food – do not create unnecessary obstacles to trade. They are designed to ensure that technical regulations that apply to imported as well as domestic products are non-discriminatory and not unnecessarily trade restrictive, while also permitting countries the policy space to develop appropriate regulation to achieve domestic policy objectives based on scientific evidence.

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Imposes obligations on countries to provide minimum protection to a range of intellectual property rights, including on food products (e.g. patents on seeds, geographical indications of commercial identification).

Dispute Settlement. The WTO's procedure for resolving trade disputes.

General Agreement on Trade in Services (GATS). Contains measures designed to liberalize trade in services, such as cross border trade in telecommunications services and advertising.

Agreement on Trade-Related Investment Measures (TRIMs). Prohibits trade-related investment measures, such as local content requirements, that are inconsistent with basic WTO agreement provisions on non-discrimination and fair treatment of foreign investors. They aim to ensure compensation for expropriation of an investment (e.g. direct taking of a title or property) or for other measures having an equivalent effect (e.g. destroying the economic value of an investment) to ensure fair and equitable treatment.

8.3 Step 1: Assessment of impact of food trade liberalization on nodes in the food supply chain

8.3.1 Agricultural production

Trade liberalization can in theory have profound influence on the evolution of a country's agricultural sector. Liberalization can affect incentives for the amount of food produced, what is produced, the way it is produced, and who produces it. On the other hand, impacts may be weak; the effects depend on the specific trade reforms implemented in and between countries and existing policy infrastructures. Examples of possible effects include:

- *Lower barriers to imports* can increase competition from lower-priced imports thus reducing incentives for domestic production. On the other hand, lower costs of imported agricultural inputs can increase production incentives, such as through the introduction of more intensive production methods.
- *Introduction of food safety standards* can create barriers to market access for small-scale producers. It also can facilitate access to export markets.
- *Rules on intellectual property* can affect access to seeds and plant varieties.
- *Policies limiting domestic support (e.g. subsidies) for the agricultural sector* can reduce production incentives for the previously supported foods.
- *Policies that increase the ability of foreign investors to buy and use agricultural land* can increase global production and generate money for host countries. There is often controversy over displacement of local people and sharing of benefits (8).
- *Lower barriers to exporting to other countries* can encourage conversion to higher-value crops destined for international trade (9). Evidence suggests that trade reforms tend to benefit farmers producing export crops, but generally have negative impacts on farmers producing import-competing foodstuffs (10).

8.3.2 Domestic food distribution

The functions of state food marketing boards, or “parastatals”, include providing a support price to farmers, supplying (and sometimes subsidizing) agricultural inputs, procuring staples on government account, holding public stocks, and distributing these stocks through public distribution systems or open market operations to hold the price line for consumers (11). Their removal implies a greater role for the private sector in the food supply, which in turn has many implications for the way food is distributed within countries, including the regulation of food safety. Investment in transportation infrastructure also has important implications for domestic food distribution.

8.3.3 Food imports and exports

Consistent with trade theory, agreements which liberalize trade lead to higher imports and exports. Participating in a regional trade agreement, for example, significantly increases the degree of agro-food trade. According to the OECD, the share of global agro-food trade between countries with regional trade agreements rose from 20% to 40% between 1998 and 2009 (12).

Between 1980/1 and 2006, world agricultural trade rose from US\$ 243 billion (1); to US\$ 945 billion (13). Between 1970 and 2001, gross world food imports, measured in terms of calorie equivalents, rose by almost 60% (2). The share of agricultural production that is exported increased from 19% in 1971 to 40% in 2003.¹ Cereals remain the most widely traded commodity, but international trade in “high value” products has increased. The amount of fruit (excluding wine) and vegetable imports into Western Europe increased from

¹ Calculation based on statistics of the Food and Agriculture Organization of the United Nations (FAO) for agricultural exports.

17 million tons to 44 million tons between 1980 and 2007, and into least developed countries from 4 million tons to 22 million tons.² Trade in processed agricultural products more than doubled between 1995 to 2008 from more than USD 211 billion to almost half a trillion US dollars, faster than the rate of agricultural goods overall (14). Traded processed commodities include sugar and vegetable oils; by-products of processing used as food ingredients by food manufacturers (e.g. whey, potato starch, mechanically recovered meat); and highly processed foods like baked goods. Exports from high-income OECD countries – responsible for the vast majority of trade in processed products – more than doubled, increasing from USD 169 billion in 1995 to USD 363 billion in 2008. Exports from low-and middle- income countries increased even more, tripling and even quadrupling their exports during this time (14).

8.3.4. Food processing

As already indicated, food processing takes a whole range of forms, from basic packing to local flour production, to large scale sugar and edible oil processing and the complex manufacturing of ready-to-eat foods. Most food processing companies are small- and medium-sized enterprises, but large companies have become more significant in the era of trade liberalization.

Trade liberalization influences food processing, and processors, in a range of ways. Trade in services alters the business environment for processors. Food-related regulations, notably food safety and labelling standards, influence the burden of compliance. One of the most important influencers has been Foreign Direct Investment (FDI). FDI into processing and manufacturing foods for the host market grew significantly from the 1980s till the 2010s, mainly from high income countries (4). FDI from companies in the United States into food processing grew from US\$ 9 billion in 1980 to US\$ 38.2 billion in 2000 (15). Between 1990 and 2009, FDI in the food, beverage (and tobacco) sectors of high-income countries increased 11-fold; investment in these sectors in low and middle income economies increased fourfold and is projected to continue to rise (16). The beverage sector accounts for most of the food-related FDI originating in the United States; while the processed food industry is one of the top 10 sectors attracting FDI in India.

The use of FDI in the processed foods market reflects the economic advantage of FDI over imports and exports: it enables companies to locate closer to their customer base, and circumvent the still relatively high tariffs on processed foods (17); tailor their products to consumer preferences in the country and comply more easily with national regulations and standards.

8.3.5 Retailing

FDI has also been directed to supermarkets and other forms of modern retailing, such as “convenience store” formats. FDI from United States-based supermarket chains grew to nearly US\$ 13 billion in 1999, up from around US\$ 4 billion in 1990 (18) indicating dramatic rates of growth. In China, for example, the supermarket sector is growing at a rate of 30–40% sales growth per year (19). As a result, supermarkets have emerged as bigger players in the food system (20, 21). The number of food service outlets has also increased significantly as a result of FDI: United States-based food companies invested US\$ 5.7 billion in overseas eating and drinking establishments in 1998 (18).

Despite the growth in modern retailing, most perishable products in African and Asian developing countries continued to be accessed through traditional or informal value chains (22). Even in more developed countries, wet markets are often preferred: in Malaysia, for example, where supermarkets are commonplace, traditional markets remain the preferred place for buying fresh meat (23). Wet markets persist because of their ability to provide foods with attributes valued by customers including: accessibility; affordability; local products; and, a trust relation with sellers (24).

8.3.6. Supply chain organization

Measures designed to liberalize trade have had the effect of changing the way food supply chains are structured and organized. For example, although most food is still produced for national consumption within national borders, food supply chains increasingly extend beyond national borders. Trade patterns have become more complex, with foodstuffs and ingredients moving around the globe in an often

² FAOSTAT food balance sheets: <http://faostat.fao.org/site/354/default.aspx>.

complicated and dynamic web of interactions. Trade liberalization can also have the effect of creating greater unity between diverse production systems between countries in terms of crops, livestock and fish varieties grown and produced, producer characteristics, regulatory frameworks, and technical expertise (25).

Concentration and control by large companies have become more prevalent as a result of changing trade policies. Companies are more easily able to undergo vertical integration, so exerting influence over the length of the supply chain. They are also more easily able to horizontally integrate through mergers, acquisitions and joint ventures, so becoming larger. The degree of transnationalization (measured by foreign assets and foreign sales) of the world's largest transnational food companies (TNCs) has been increasing since at least the early 1990s. Between 1990 and 2001, the foreign sales of TNCs within the world's largest 100 TNCs rose from US\$ 88.8 billion to US\$ 234.1 billion, with total foreign assets rising from US\$ 34.0 billion to US\$ 257.7 billion (4, 26). The food retail market is also becoming more concentrated through the process of mergers and acquisitions. In 2004, Wal-Mart was estimated to have 6.1% of the global grocery market, with the French company Carrefour at 2.3% (20, 21).

However, in many countries supermarkets and integrated agri-business are growing from a small base, so even double-digit growth would not achieve significant market penetration in the near term. There is also persistent opposition to "supermarketization" and globalization in some countries: India continues to see strong opposition to the entry of foreign supermarkets from domestic retailers and political parties, who believe it will cause mass job losses in a sector that is mostly dominated by small, family-run shops.

8.4 Step 2: Assessment of implications for food safety, availability, price and marketing

The effects of the liberalization of food trade on food safety, availability (volume and variety), prices, quality and marketing are not straightforward, and depend on the nature of implementing legislation and other contextual factors (27).

8.4.1 Food safety risks

The implications of trade liberalization on food safety are both negative and positive. On the negative side, increased food trade may introduce new safety hazards, revive previously controlled risks, and spread contaminated food widely (28, 29). This is especially noticeable when the hazard is not found in the importing country: for example, the parasite *Cyclospora cyetanensis* is not indigenous to the United States and several major outbreaks have been traced to produce imported from Latin America (30). More unusually, trade may lead to the identification a hitherto unsuspected food safety problems in domestic markets, for example, in Abidjan the problem of chemicals in traditionally smoked fish was not discovered until fish was exported to diaspora populations in France (31).

Although most food imported into low-income countries can be reliably considered of higher sanitary quality than food in the domestic markets, low-income countries may also be more vulnerable to illegal imports of unsafe food. A study in Tanzania found that, despite the national import prohibition of Chinese milk products and unlabeled milk powder in Tanzania, 6% of milk powder samples were contaminated with melamine (32). Another risk introduced by more trade is that the increased complexity of the food supply makes the source of food safety risks more difficult to trace (33).

The increasing dominance of private sector actors at specific nodes in the supply chain has important implications for food safety. The privatization of parastatals has the effect of changing the competitive dynamics of the informal versus formal marketing sectors. This may lead to challenges in managing food safety by the national authorities, as has been shown in the case of the dairy sector. Dairy production in low and middle income countries has increasingly shifted from a formal sector heavily supported by development agencies and the public sector to a largely autonomous informal sector, with associated increasing difficulties of inspection and regulation (34).

Consumer demand for meat and other livestock products has created incentives for greater private investment in the intensification of animal production, which brings corresponding changes in the nature of food safety risks. Positive implications can arise when large private food companies with complex supply chains put structures into place to reduce risk, such as the adoption of “private standards” (which may be voluntary or legally-mandated) (35). These standards may raise the regulatory bar for food safety in countries where regulation is weak or lacking and may also prevent dumping of sub-standard food in developing country markets (36). There are potential spillover health benefits of participating in export markets. One study in Kenya found farmers who were given training and monitored for compliance used safer chemicals and had fewer reported health problems. However, the results are not consistent – another study found no benefits for producers involved in seafood for export in Brazil (37).

Even though large-scale, intensive, export-oriented or compliant agriculture is focused on ensuring biosecurity, there are clear linkages between intensification and disease emergence (38). Around 75% of new human diseases emerge from animals. Although most new diseases emerge from wildlife, intensive, industrial livestock systems appear to present more risk than extensive, traditional systems (39). Another adverse trend in veterinary public health is the result of increasing privatization of animal health services with negative implications for disease reporting and management (40).

There have also been important evolutions in public regulation of food safety of imported products, especially perishable animal and plant products which are most associated with foodborne disease. The SPS Agreement is reported to have increased the use of scientific risk assessment in the formulation of food safety measures (41). The requirement to adhere to the SPS Agreement presents an opportunity for developing countries to upgrade national food safety programmes with assistance from international and bilateral agencies (42, 43). For example, countries are adopting the hazard analysis and critical control point (HACCP) system – the international system recommended by Codex – as a foundation for control of biological, chemical and physical hazards in food (28). The SPS Agreement has also provided a forum for negotiating the reduction of food safety risks. Between 1995 and 2004, WTO Members made 330 complaints about food safety, plant and animal health regulations and other issues to the SPS Committee (44). The main items of concern were bovine spongiform encephalopathy (BSE), toxins, heavy metals, and foodborne microbial pathogens.

Nevertheless, concerns have been raised that adherence to internationally agreed standards may represent a reduction in the stringency of national food safety standards in high-income countries (45). And in low-income countries it is reported that “importing” models of food safety management systems from high-income countries may lead to ill-suited systems with counter-productive implications for food safety risks (46). There is also evidence that countries with similar SPS regulations tend to trade with each other, suggesting that the spread of food safety standards is restricted to specific countries rather than globally (47). Indeed, an assessment of progress in the implementation of the SPS agreement indicated there had been relatively slow progress in harmonizing regulations, although transparency had increased (48).

8.4.2 Food availability (amount, type and quality)

It is hard to estimate the net impacts of trade liberalization on food availability since, as noted by McCorrison et al. (49, p. 54), “it may be only one part of a package of economic reforms introduced by developing countries and there may be specific characteristics of the environment in which these reforms were undertaken that will determine [food] availability”. The most direct potential effect is through the changing balance of imports, exports and domestic food production. For example, domestic production of a particular foodstuff may decline – but be compensated for by an increase of imports. Exports may increase, but so may domestic production.

Global food availability increased significantly in the era of trade liberalization, but with significant variation between countries and foods. A comparative study of the effect of trade reform on food security by the Food and Agriculture Organization of the United Nations (FAO) found significant differences in the effects on food availability between countries. For example, in China per capita supplies of the principal nutrients

grew significantly in the post-reform period. In contrast, rates of change were very modest in Malawi, and declined in the United Republic of Tanzania (10).

The evidence is clear, however, that trade liberalization tends to increase the overall amount of food, feed and raw materials imported into a country (50). Analysis suggests that imports have moved countries with insufficient domestic food production towards food adequacy (51) and that national food availability increases when countries shift to net-importing status (52). Cross-country studies also indicate that food trade associated with more diverse food supply in middle and high-income countries (although not low-income countries, 53).

Imports also alter the relative availability of different foods. For example, trade can be directly associated with changes in national availability of different types of vegetable oils (Box 8.2). The implementation of free trade agreements in Central America and Mexico have been found to be associated with changes in the availability of meat, dairy products, processed foods, temperate (imported) fruits and/or animal food (54, 55, 43). Taking the case of Central America during a period of liberalization in the 1990s, imports of processed cheese slices grew by over three thousand percent – making a product available that had previously not been sold in these countries (54). In Pacific Island countries, imports (or in this case “dumping”) of high-fat meats led directly to an increasing availability, while the availability of traditional root crops declined (56).

Trade liberalization has an effect on availability of foods to consumers not just by direct imports and exports of those foods, but by influencing domestic manufacturing. The increase of imports of ingredients used by the processed food industry has facilitated the domestic production of processed foods. For example, there has been a rapid increase of exports of whey from cheese-producing countries into middle-income countries for use as a food ingredient (57). Increased imports of lower-cost animal feed (in many cases, from developed countries with subsidized production) have increased the availability of feed in developing countries. This has facilitated increased animal production at a lower cost, leading to increased availability (54, 5).

Processes extending beyond imports and exports can also explain changes in food availability. For example, FDI liberalization through trade agreements with the United States has been shown to significantly increase the availability of soft drinks within the signatory country (58). Exports of processed foods from the United States have been shown to be growing fastest in countries where modern grocery retailing is growing the fastest, suggesting that the growth of supermarkets also facilitates the growth of processed food markets (59).

Box 8.2. Trade liberalization and the availability and prices of vegetable oils

Higher imports have driven increased domestic supply (defined by FAO as “[p]roduction + imports – exports + changes in stocks”³) of vegetable oils in low- and middle-income countries (Table 8.1). The most traded oils are palm oil and soybean oil, which have become the world’s most consumed edible oils. A handful of key countries are responsible for most of the exports, notably Argentina, Brazil, Indonesia, Malaysia and the United States. There has also been an overall trend towards the decline in world vegetable oil prices, driven by lower costs of production in key exporting countries (2, 60).

Both the increase in imports and the decline in prices have been directly facilitated by trade liberalization: policies were implemented in exporting countries to facilitate exports (for example reduction of export tariffs), while importing countries reduced barriers to imports (for example reduction of import tariffs) (61). These changes have enabled greater consumption of vegetable oils in importing countries. Increases of consumption have been particularly notable in major importing countries such as China and India (62).

Table 8.1 Domestic supply and import quantity of vegetable oils, 1980 and 2003

	Country group	1980	2003	% increase 1980–2003
Domestic supply (million tonnes)	Developed countries	20.6	37.9	84.0
	Developed countries	20.8	65.1	213.0
Import quantity (million tonnes)	Developed countries	7.1	21.2	198.6
	Developed countries	6.0	28.6	376.7
Calories available (per capita per day)	Developed countries	310.9	421.7	35.6
	Developed countries	132.6	239.1	80.3
Imports as proportion of domestic supply (%)	Developed countries	34.5	55.9	62.3
	Developed countries	28.8	43.9	52.3

Source: FAOSTAT archived food balance sheets: <http://faostat.fao.org/site/354/default.aspx>.

³ See faostat.fao.org/site/375/default.aspx (last visited 9 July 2012).

8.4.3 Food prices

Agricultural trade liberalization plays a critical role in influencing food prices (49). Understanding price transmission – whether changes in the prices of agricultural commodities and food ingredients are passed onto consumers – is critical in understanding the effect of trade liberalization. Prices are important because they affect incentives for food production and consumption. If the domestic price is considerably lower than the international price, for example, then the country has the incentive to continue domestic production and increase exports. If, on the other hand, domestic prices are higher than international prices, reducing barriers to trade might increase imports of the food.

In theory, lowering barriers to imports decreases the average price of agricultural commodities. This places domestic producers under competitive pressure but can have the effect of lowering food retail prices if they are transmitted through the food supply chain. Domestic firms using lower cost imported ingredients for manufacturing (for example food processing firms) also benefit from the reduced cost of those commodities and may pass the lower prices to their consumers. Several other aspects of trade liberalization may lead to lower food retail prices. For example the privatization of state marketing boards could decrease food prices if marketing board functions are performed more efficiently by the private sector; easing the burden of food-related regulations may lead to lower production costs.

At the same time, reducing import barriers increases the exposure of domestic agricultural prices to the volatility of the world market. And if changes in the food supply chain lead to a powerful transnational gaining monopolistic market power, prices could rise (63, 64). The removal of subsidies and other protections covering agricultural sectors may also lead to higher international agricultural commodity prices, as would the increased burden of new regulations.

In practice, the effect of trade liberalization has been variable (10), but there is some evidence of a price lowering effect for specific foods. Analysis indicates that international trade has the effect of lowering the relative cost of energy-dense foods and diets (65). The case of vegetable oils is outlined in Box 8.2. The lower cost of poultry in countries around the world can also be attributed in part to the lower cost of imported feed (66).

Supermarkets have also been found to charge lower prices for processed foods relative to informal retail (64). For example, in South Africa, efficiencies in procurement mean that the prices of staple foods and packaged foods produced by large manufacturers are lower in supermarkets than in traditional retail outlets (57). Notably, however, it has been found that healthier foods, which are more readily available in supermarkets than in small shops, typically cost between 10% and 60% more in supermarkets than less healthy foods when compared on a weight basis. Moreover, in most developing countries highly nutritious perishable foods sold in supermarkets are more expensive than food sold in informal markets, as informal markets benefit from considerable pricing advantages (22).

The effect of trade liberalization on the prices of highly processed foods is also complex. Brands sold by leading TNCs are often more expensive than brands produced by domestic companies and unbranded equivalents. The snack food market presents a good example; locally produced unbranded snacks tend to be much cheaper than “premium” brands. Yet higher income consumers are willing to pay for these brands, especially given the “value” added to them through convenience, advertising and promotion. Another important dynamic here is the niche marketing strategy pursued by the processed foods industry. The same company develops a range of products, some of which are targeted at lower income consumers, others, at higher income consumers. This has the effect of increasing volume sales while also increasing sales of high-margin products. Prices also change over time as the market develops (66).

8.4.4 Food marketing

There are many varied mechanisms through which the process of trade liberalization can affect the marketing of food to consumers, including how food is marketed at point of sale, how it is advertised and promoted, and how it is labelled. The potential effects are of most relevance to processed, packaged foods.

Increased trade in advertising and other telecommunications services facilitates the commercial promotion of highly processed foods. The ability to advertise and promote is a major pull factor for inward investment by large TNCs into developing countries. Processed foods are commonly advertised and marketed all over the world, using a wide range of communications channels and marketing (67). Estimates from Asia suggest that food makes up a significant proportion of child-targeted advertising, ranging from 25% in the Republic of Korea to 70% in Malaysia (68). Studies in Latin America suggest a high proportion of advertising during children's programming are for processed foods, such as sweetened beverages, candy, sugar-sweetened cereals and chips.

During the 1990s, domestic advertising expenditures by the two leading soft drink and fast food companies declined in the United States but increased elsewhere, reflecting the recognition by those companies of the increased growth potential in newer markets (67). The United States, however, remains the world largest market for advertisers. The total amount spent on advertising by leading food companies in 2009 was \$1.79 billion.

8.5 Step 3: Nutrition and health implications

The changes in food safety, availability, prices and marketing brought about by trade liberalization have implications for three major health concerns: (1) foodborne diseases, (2) undernutrition and (3) obesity and DR-NCDs. Less direct implications include the introduction of new animal diseases which cause economic losses. For example, African swine fever is an important disease often introduced through food products and has resulted in millions of dollars of costs to affected economies (69).

8.5.1 Foodborne diseases

Foodborne diseases are a leading global public health concern, affecting billions of adults and children every year, especially in low- and middle-income countries (70). Diarrhoeal diseases (the leading cause of sickness and death among children under the age of five in developing countries) are often transmitted by unsafe food. The core cause of foodborne disease is contamination with microbiological or chemical hazards, or unconventional agents. Microbiological contaminants include bacteria (for example *Escherichia coli*, *Listeria*, *Salmonella* and *Campylobacter*), viruses (for example calicivirus and norovirus), and parasites (for example trematodes and *Cryptosporida* spp). Chemical contaminants include natural toxicants (for example mycotoxins) and environmental hazards (for example mercury and dioxins). Ingestion of chemicals introduced during food production, such as pesticides, antibiotics and growth promoters, can also pose health risks. Further risks include unconventional agents such as bovine spongiform encephalopathy (BSE).

In high-income countries, imported foods have been linked to outbreaks of foodborne diseases. For example, in the United States, there have been many well-documented cases of foodborne diseases associated with imported cheese made from unpasteurized milk (71). However the number of cases linked to imported food remains small: between 2005 and 2010, there were 39 outbreaks of disease traced back to imported foods in the United States, 45% of which foods came from Asia (72). This represents just 0.7% of the 5500 total outbreaks of food borne disease in this period (73). Although the average annual number of foodborne illnesses associated with fresh produce more than doubled between 1973–1987 and 1988–1991 with increases continuing through the 1990s, there is also no evidence that rising imports have been responsible for this increase⁴ (28). Greater contamination of domestic produce, better surveillance, and an increased overall volume of food consumption are thought to have contributed to the increase in reported incidents, although it is also possible that absence of traceability of imported food has led to underreporting. The US Centers for Disease Control estimates 48 million cases of foodborne diseases occur annually in the United States, but only around 30,000 cases per year were reported as outbreaks and in only 58% of outbreaks was the source traced. The 39 reported outbreaks are not only a small proportion of the total reported outbreaks, but an even smaller proportion of all cases of foodborne disease.

⁴ The average annual number of foodborne illnesses associated with fresh produce more than doubled between 1973–1987 and 1988–1991, a trend that continued into the late 1990s

Informal trade – much less amenable to regulation – may also be a more important cause of foodborne diseases of exotic origin. It seems likely that a significant proportion of import-associated foodborne diseases in high income countries arises as a result of non-commercial or illegal importation of perishable foods rather than commercial food imports. For example, in many cases unsafe cheese entering the United States comes from Mexico and enters the country for personal consumption without undergoing sanitary inspection (74). In the UK, around 12,000 tons of meat are illegally imported each year, from countries which typically have much higher levels of hazards in meat than in the UK (75). Recent studies have shown presence of pathogens in illegal meat imports (76).

In low- and middle-income countries, there is likewise little evidence that a lead reason for the spread of foodborne diseases is trade liberalization. Most poor countries are net food importers, and imported food is typically of higher sanitary quality than food in the domestic markets. Yet there is also little evidence that control of foodborne disease in low and middle-income countries has been aided by the increased attention to food safety regulation arising from trade liberalization. Most food sold in the domestic markets of poor countries is still not subject to effective food safety management. International processes established to implement the SPS Agreement, such as the WTO SPS Committee, for example, are largely utilized by high-income countries (77).

8.5.2 Undernutrition

According to the FAO, during 2011–2013 over 840 million people were unable to meet the daily nutritional requirements for a healthy life (78). The aggregate global burden of undernutrition is estimated to have caused over 3 million child deaths in 2011 (79). Despite steady improvements, stunting prevalence in children under five affected at least 165 million children in 2011 (79).

Although there is evidence on the impact of trade liberalization on food availability, and prices (see sections 8.4.2 and 8.4.3), there is little written evidence of the direct impact of trade liberalization on the prevalence of undernutrition in countries and communities. Indicators that there may be impacts come from the relationship between food availability and indicators of undernutrition. At the national level, there is some evidence from across countries that national availability and prices are linked to national levels of undernourishment. Cross-country studies using data from the 1990s indicate a direct relationship with national food availability of rates of undernourishment (80). Smith and Haddad (81) show that increased national food availability has consistently been one factor associated with declines of stunting since the 1970s. Food supply diversity in middle and high- (not low-) income countries is also associated with lower rates of several measures of undernutrition (53). On prices, there is evidence from the food price crisis of 2006–2008 which showed that high food prices increased undernutrition, especially in young children (82, 83).

Nevertheless, the particular impact of these national-level trends is likely to play out very differently among different groups. For example, trade liberalization may influence household nutrition among farming families by affected their incentives to produce for the market, or, through a pathway not discussed in this chapter, their income stream. This impact is likely to be very different to low-income consumers in urban areas, which itself may be very different from high-income households. The impact of trade liberalization on undernutrition is thus likely to emerge in different ways depending on the specific role played by trade on food availability and prices, the household context, and the role played by food relative to other immediate determinants in influencing undernutrition.

8.5.3 Obesity and diet-related non-communicable diseases

Non-communicable diseases are a serious global public health problem. According to the World Health Organization (WHO), NCDs are the largest cause of death in the world, killing more than 36 million people each year. Nearly 80% of NCDs deaths (29 million) occur in low- and middle-income countries. More than nine million of all deaths attributed to NCDs occur before the age of 70; 82% of these “premature” deaths occurred in low- and middle-income countries (84). The global prevalence of the leading NCDs is projected to increase substantially over the next two decades. A related problem is the rising number of people who are overweight or obese. WHO predicts that by 2015, approximately 2.3 billion adults will be overweight and more than 700 million will be obese (85).

Poor diet is a leading risk factor for obesity and DR-NCDs. The scientific evidence shows that diets high in fats (especially saturated fats and trans fatty acids), free sugars and salt, and low in fruits, vegetables, pulses (legumes), whole grains and nuts, pose significant risks for NCDs (86). Changes in food availability outlined in section 8.4.2 have facilitated a shift away from diets high in cereals and complex carbohydrates towards energy-dense, nutrient-poor diets with greater amounts of meat, fats, sweeteners and processed foods (87). Table 8.1 shows the increasing availability of vegetable oils, which are now used in large quantities in home-cooked foods, in restaurant foods, and as saturated and trans-fats in processed foods. Lower-middle-income countries experienced particularly rapid rates of growth in sales of packaged foods between 1996 and 2002 (Table 8.2). Food marketing used to promote these foods has also grown in scale and intensity, as have the stores that sell them.

Of all the food-related health conditions linked to trade liberalization, the association with NCDs appears to be the most evident. Analysis of the available data suggests that trade agreements and liberalization are associated with increased intake of soft drinks and fast food (88, 89). Island communities which are very reliant on imports present a particular case in point. Evidence from the Pacific Islands, for example, shows that trade has been a key factor in their epidemic of NCDs (90). Analysis points to a correlation between imports and expenditure on unhealthy foods (91).

Table 8.2 Annual average growth in retail sales of packaged foods, 1996–2002

Country group	Per capita retail sales of packaged foods 2002 (US\$)	Total retail growth of packaged foods 1996–2002 (%)	Per capita growth of packaged foods (%)
High-income	979	3.2	2.5
Upper-middle-income	298	8.1	6.7
Lower-middle-income	143	28.8	28.1
Low-income	63	12.9	11.9

Source: Euromonitor International.

8.6 Step 4: Implications of trade agreements for policy space to address food-related health

Trade policy has the potential to limit the “freedom, scope, and mechanisms that governments have to choose, design, and implement public policies to fulfil their aims” (92), because they may conflict with the aims of trade liberalization, such as the encouragement of private investment. For example:

- *Agreements on technical regulations such as the SPS, TBT and equivalent clauses in regional and bilateral trade agreements.* Technical regulations are legitimate from a trade perspective if they do not discriminate between imported and domestically produced foods. However, they may still be contested on the basis of lack of strong scientific evidence. For example, a proposal by the government of Thailand to introduce traffic light labelling on packaged foods was queried in the WTO TBT Committee on the basis of the limited evidence base for traffic light labelling (16). Trade agreements may also influence the process of developing regulations. For example, the recently concluded Korea–US Free Trade Agreement, which include provisions that allow persons [a national or an enterprise] of the other party to participate in development of standards and technical regulations (93).
- *WTO Agreement on Agriculture.* To enhance food security, many countries subsidize – or have proposed subsidizing – the production of staple foods, traditional fruits, vegetables and tubers (94). This form of subsidy could be perceived as being inconsistent with the WTO Agreement on Agriculture, which provides that governments should reduce domestic agricultural subsidies (Box 8.1). WTO member governments have already committed to progressive reductions in subsidies on a multilateral level, which are being gradually implemented.

- *Agreements on Investor Protection.* New bilateral and regional trade agreements are more extensive in their investor protections relative to the WTO TRIMS Agreement. In some cases they include an Investor State Dispute Settlement (ISDS) mechanism, which was previously only found in Investment Treaties. An ISDS mechanism gives private investors the right to bring disputes against states directly; in WTO forums, only states, not private entities, can bring disputes against other states. For example, Philip Morris Asia used the ISDS mechanism in the Australia–Hong Kong Special Administrative Region Investment Agreement to challenge a tobacco “plain packaging” policy on the grounds that the measure expropriated trademarks and undermined good will indirectly (95). Researchers have thus raised concerns that this limits policy space for policies designed to reduce markets for certain types of foods (for example, highly processed foods, which are commonly the subject of foreign direct investment) (16). For example, investors might claim that restrictions on advertising, or on the levels of fats, sugars and salt permissible in energy-dense foods and beverages, constitute indirect expropriation because they reduce the value of an investment.

To date, trade agreements have typically contained clauses to ensure that they do not interfere with legitimate (i.e. not disguised trade barriers) to protect human health. The Agreements of the WTO generally have latitude to enable countries to implement measures that are supported by evidence to demonstrate that they are reasonable to achieve legitimate public health outcomes (96). In particular, Article XX(b) of the General Agreement on Tariffs and Trade clarifies that a country may implement measures to protect health so long as they are not applied in a manner that would constitute arbitrary or unjustifiable discrimination between countries or a disguised restriction on trade. Despite commitments in the Agreement on Agriculture to reduce subsidies, analysis suggests that there is space for subsidies to achieve legitimate public health measures under the Agreement on Agriculture (95) and in 2013, a multilateral decision on food security at the 9th WTO Ministerial Meeting Bali permitted subsidies for *traditional* staple crops (97).

Investment treaties usually also allow latitude for public health measures. For example, the United States Model Bilateral Investment Treaty provides that “except in rare circumstances, non-discriminatory regulatory action by a Party that is designed and applied to protect legitimate public welfare objectives, such as public health, safety, and the environment, does not constitute indirect expropriations”. A similar clause is reiterated by the UN Conference on Trade and Development in its explanation of what comprises expropriation (98).

There is, however, very little latitude for trade bans. WTO provisions require that foodstuffs produced domestically and in other countries should be treated equally, so bans can only be justified if the country can prove the import cannot be substituted by a foodstuff produced domestically. For example, in 2007 in response to concern over the impact of fatty meat on health and the “dumping” of perceived “low quality” food on the market, the Government of Samoa banned turkey tail imports (99). In relation to international trade, Samoa received a request from the United States for further information about the ban and as a result of acceding to the WTO in 2012, the ban was lifted and a 300% import duty was set for two years followed by a 100% import duty. There are also concerns that the next generation of trade agreements – such as the Transatlantic Trade and Investment Partnership – will significantly extend earlier trade agreements and allow greater protection for investors, and less latitude for governments to implement regulations (1016).

In addition, even though policy space may exist, governments – particularly developing country governments – face challenges in understanding and utilizing this policy space (102). There are two main challenges:

- *Engagement with the public health sector.* Health policy makers and those in an advisory capacity are rarely included in formal discussions of trade and investment policy decisions, and only sometimes are able to participate informally. The health sector may also show little interest in such discussions, not understanding their potential implications. The lack of understanding of the reciprocal benefit to each of the two sectors is often the reason for this lack of engagement

- *Limited capacity in the public sector in low- and middle- income countries for developing trade-compliant nutrition policy options and for defending these options.* Addressing nutrition and NCDs require complex multisectoral approaches. In addition, scientific evidence for such approaches is often contested by private sector interest. The burden of proof to initiate or defend such regulation in international arbitration is resource intensive; the *threat* of challenge and/or query on the scientific evidence base thus presents a deterrent to the introduction of nutrition and health-promoting policies and, therefore, to “regulatory freeze.”

8.7. Opportunities for using trade policy to improve nutrition and health

There are a number of specific opportunities for utilizing policy space within the current trade and investment architecture to improve nutrition and health. For example, the formal participation of the principal nutritionist in Samoa’s accession committee to WTO demonstrates that strengthening engagement between health and trade is possible (103). In this instance, participation from the nutrition sector enabled development of an ongoing strategy to mitigate the effect of the removal of the ban on turkey tails, and to ensure that policy space was enshrined for an alternative health policy approach i.e. the implementation of a high sales tax (104). Similarly, the Bali decision on food security represents an opportunity to enhance trade-related food policy space to support both food security and NCDs prevention (105). Countries can now consider opportunities to subsidize relatively healthy traditional staple foods as part of strategies for both food security and NCDs prevention.

A comprehensive and multi-pronged approach to nutrition policy may be another strategy for countries to maintain policy space for nutrition and strengthen their position in the event of a dispute. Based on analysis of previous health-related WTO panel decisions, von Tigerstrom (96) argues that using several different types of regulations would increase the defensibility of nutrition policies. National governments can also strengthen the defensibility of nutrition policy measures by specifically noting their commitment to health and nutrition in investment policy strategies (16). This would help to manage the legitimate expectations of investors, to minimize the possibility that subsequent regulation cannot be construed as indirect expropriation.

With respect to preventing DR-NCDs, one opportunity is afforded by inclusion of technical measures related to NCDs prevention in the Codex Alimentarius. The Codex Alimentarius Commission was asked by WHO in 2005 to consider its role in NCDs prevention in relation to the Global Strategy on Diet, Physical Activity and Health. Potential measures include making guidelines on nutrition labelling and food composition more health-friendly. For example, Codex now includes nutrient reference values for nutrients associated with NCDs: saturated fatty acids and sodium, and recommends mandatory nutrition labeling (101).

Finally, there is an opportunity for improving policy coherence between trade and nutrition in the forum of Aid for Trade, which represents a growing component of global aid commitments (102). Aid for Trade includes strategic investments to improve internal and cross-border transport as well as storage, technology and infrastructure, in addition to agricultural development. For example, targeting fruit and vegetable production using Aid for Trade funds could help to increase availability and contribute to improved health and food security (103).

8.8 Moving forward

In November 2014, the Rome Declaration on Nutrition, adopted at the Second International Conference on Nutrition, acknowledged that:

“trade is a key element in achieving food security and nutrition and that trade policies are to be conducive to fostering food security and nutrition for all, through a fair and market- oriented world trade system, and reaffirm the need to refrain from unilateral measures not in accordance with international law, including the Charter of the United Nations, and which endanger food security and nutrition, as stated in the 1996 Rome Declaration.”

The Framework for Action for implementing the Rome Declaration included recommendations to:

- strengthen local food production and processing, especially by smallholder and family farmers, giving special attention to women's empowerment, while recognizing that efficient and effective trade is key to achieving nutrition objectives" (R9);
- encourage governments, United Nations agencies, programmes and funds, the World Trade Organization and other international organizations to identify opportunities to achieve global food and nutrition targets, through trade and investment policies (R17), and
- improve the availability and access of the food supply through appropriate trade agreements and policies and endeavor to ensure that such agreements and policies do not have a negative impact on the right to adequate food in other countries (R18).

These recommendations provide a framework for governments to make commitments to assess the food-related nutrition and health impacts of trade and trade policy and to identify trade as an opportunity to improve nutrition. As this chapter has shown, assessing the impact of trade liberalization on nutrition and food-related health is not straightforward. The impacts depend on if and how the effects are transmitted throughout food supply chains, how this then affects food environments, and then nutrition and health. Diagnosing health related outcomes thus requires tracing those changes, and the incentives which influence them. There will inevitably be trade-offs identified as part of this process. For example, in the case of food safety, standards may raise the regulatory bar for food safety in countries where regulation is weak or lacking. But they may also give private companies considerable negotiating power with governments when developing food safety regulations, which may create barriers to market access for small-scale producers. A rigorous analytical approach to diagnosis will go some way to enabling national governments to determine the potential effects of trade liberalization on food-related health and inform their policy making in this area.

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Chapter 9

Trade in medicines

Frederick Abbott

Annual worldwide spending on medicines is anticipated to exceed \$1.2 trillion by 2016 (1). Developing countries, and particularly so-called emerging markets, will account for a substantial portion of the growth in spending on medicines. A good part of global market demand will be satisfied by medicines that, in whole or in part, are developed and manufactured in countries other than where they are ultimately used by patients (2). Governments and patient populations are affected by trading rules affecting medicines development, production and trade, in terms of access to treatments and affordability. This chapter addresses those rules.

9.1 Introduction

A government has two primary interests with respect to trade in medicines. The first is the interest in protecting and promoting public health, which involves (among other things) providing citizens with the range of products necessary to prevent, diagnose and treat disease. The second is the interest in promoting economic welfare, including development and employment. These two interests are often complementary, although they may, in some circumstances, conflict. One of the most difficult tasks for policy-makers and regulators in the field of public health is to find the right balance between public health and commercial interests.

It is not surprising that trade in medicines (and related supplies) has been the subject of intensive international dialogue over the past several decades. The debate began in earnest in the 1970s when, on one side, multinational pharmaceutical producers based in developed countries expressed growing concern over alleged misappropriation of their patented technology by enterprises based in developing countries. At the same time, developing countries expressed deepening concern over the imbalance between developed and developing countries with regard to technological capacity and ownership of technology. This dialogue played out in a series of negotiations at the United Nations Conference on Trade and Development (UNCTAD), the World Intellectual Property Organization (WIPO) and ultimately at meetings of the General Agreement on Tariffs and Trade (GATT) during the Uruguay Round of trade negotiations, which culminated in 1995 in the entry into force of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

The debate concerning TRIPS and the impact of patent and other intellectual property (IP) protection on access to medicines is considered below. However, there are three other aspects of pharmaceutical trade that affect access to medicines, and these aspects also demand attention.

First, production, distribution and trade in pharmaceuticals and related supplies are subject to government regulatory control at a number of levels (2, p. 47- 52). Countries maintain substantially different regulatory standards to assure the safety and efficacy of the pharmaceutical supply chain. There can be good reasons why governments adopt different standards, such as to take account of differences in local environment likely to affect the condition of medicines as they are stored, distributed and used. However, in some cases differential regulation may unnecessarily hinder the cross-border movement of pharmaceuticals, particularly among regions that share public health interests and trade policy objectives.

Second, attention to assuring affordable access to existing medicines and related supplies should not disguise the fact that innovation is fundamentally important in making progress against disease burdens via the creation of new medicines. It is important that policy-makers consider the health of both current

and future populations. Future populations, for example, could benefit immensely from a vaccine against HIV infection, as such a vaccine could eventually allow public health workers to entirely avoid most of the problems associated with providing a continuous supply of antiretroviral treatment. It is therefore critical to encourage the research and development of future products while ensuring access to those that already exist. There is considerable debate about how best to encourage research and development, however, and using a patent system is not the only option (3).

Third, while the ultimate objective of government policy with respect to trade in medicines and related supplies is to promote and protect public health, the pharmaceutical industry may be an important part of the national economy, providing employment and affecting the balance of trade. Governments may choose to promote the development and maintenance of a strong local pharmaceutical industry as a part of national economic development policy. It is important to keep in focus the link between industrial policy and public health objectives as a strong local pharmaceutical industry does not automatically assure that local public health needs are properly addressed (4).

This chapter assesses the role of the pharmaceutical industry in economic development and discusses means to ensure adequate access to existing medicines. There is no generally accepted model for creating an optimal balance between commercial interests and public health interests, or between the health of current and future populations. All countries, at whatever stage of development and with whatever population characteristics, struggle to provide the best possible health care for their citizens. Some have developed more effective programmes than others. But, because countries differ widely in the availability of financial resources and in patterns of disease (based, among other things, on nutrition, working conditions, climate and geography), there is no single model that will create the best solution for every country. However, there are trade and regulatory tools that governments can use to promote particular policies that should be well suited to conditions within the country. The objective here is to identify those tools and how they may be effectively used.

The remainder of this chapter is split into seven principal sections. It begins by outlining the core aspects of TRIPS and TRIPS-plus provisions relevant to trade and access to medicine, providing the central legislative background to the issue of trade and medicines, before considering six elements of analysis: (1) assessment of what is being traded; (2) ownership of medicines and pharmaceutical trade; (3) trade policy instruments; (4) innovation and intellectual property; (5) access and intellectual property; and (6) the relationship between pharmaceuticals and intellectual property scope. As mentioned in Chapter 1, an assessment tool could be used to compile information related to trade and medicines at the national level, in order to inform policy development on the matter.

9.2 Trade, TRIPS and TRIPS-plus

9.2.1 TRIPS

The TRIPS Agreement requires WTO Members to grant patents in all fields of technology. This means that all WTO Members will eventually be required to make patent protection available for pharmaceutical subject matter inventions. Developing countries that did not provide pharmaceutical patent protection when the TRIPS Agreement entered into force in 1995 had the option of delaying protection for a 10-year period (TRIPS Art. 65), but this transition arrangement ended on January 1, 2005,¹ and developing countries that have newly acceded to the WTO have not been accorded new transitional extensions (5).

¹ Developing countries that took advantage of this option, such as India, were not obligated by the TRIPS Agreement to provide immediate means for processing and granting patent applications, but only for receiving such applications so they could later be either granted or rejected (this is the so-called “mailbox” provision; see TRIPS Art. 70.8). When the transition period ended, the mailbox applications would be examined, and if patents were granted the terms would commence from the initial mailbox filing date (i.e., for whatever remainder of the 20-year term). The transition arrangement included a complex obligation to grant “exclusive marketing rights” (EMRs) for a maximum of five years based on local filing of a patent application, local regulatory marketing approval, and the grant of a corresponding foreign patent and foreign marketing approval (TRIPS Art. 70.9).

Least-developed country (LDC) Members of the WTO were initially accorded an 11-year transition period to implement the TRIPS Agreement (Article 66.1). This transition period has been extended twice, first until 1 July 2013,² later until 1 July 2021.³ In parallel, LDCs benefit from a specific transition period that authorizes them not to adopt or enforce pharmaceutical patent protection and data protection,⁴ nor to extend exclusive marketing rights (EMRs),⁵ until 1 January 2016. Because the general extension until 1 July 2021 for TRIPS implementation by LDCs does not prevent them from “rolling back” existing IP protections that may have been granted,⁶ it appears that a renewal of the specific pharmaceutical-related extension that will otherwise expire on 1 January 2016 is not needed to authorize LDCs to continue to disapply pharmaceutical patent protection, data protection and the EMRs (Article 70.9) provision of TRIPS. Nonetheless, LDCs might decide to seek such a specific extension to avoid any doubts on this issue.

The early experience of developing countries with implementation of the TRIPS Agreement was problematic. South Africa confronted challenges by developed-country governments and multinational pharmaceutical enterprises following adoption of public health legislation in 1997. South Africa prevailed, but by the end of this episode the TRIPS Agreement was widely perceived as an obstacle to addressing public health problems. Members of WTO reacted to this by recognizing the importance of allowing governments to pursue flexible policies with respect to the protection of public health, which recognition was expressed in the 2001 Doha Declaration on the TRIPS Agreement and Public Health.⁷ The Doha Declaration was followed in 2003 by the adoption of a “waiver decision”⁸ that facilitated the export of pharmaceutical products under compulsory licence. In 2005 the General Council of the WTO adopted a Protocol Amending the TRIPS Agreement⁹ which, once accepted by a sufficient number of Members, will formally transform the 2003 waiver into a part of the TRIPS Agreement.¹⁰ As of 2014, the Protocol had not yet been accepted by a sufficient number of Members to bring it into force, but the waiver decision remains in effect.

Despite the Doha Declaration and associated events, the political situation with respect to access to medicines has remained difficult. Throughout 2007–2008 Brazil and Thailand came under pressure from multinational industries and supporting governments for having issued compulsory licenses. India has seen its 2005 pharmaceutical patent law, and subsequent administrative and judicial decisions applying it, harshly criticized by the multinational pharmaceutical industry as well as right-holder groups such as the US Chamber of Commerce. India’s grant in 2011 of a compulsory license on an important anti-cancer drug benefitted a substantial group of patients needing treatment, but this grant also garnered significant criticism from right-holder interest groups. While India’s patent law, patent office and court decisions are consistent with the TRIPS Agreement, foreign industry groups argue they reflect problematic policy. India, on its side, has reaffirmed a strong stance in favour of protecting the public health of its population despite the criticism from foreign industry groups.

9.2.2 From TRIPS to TRIPS-plus

“TRIPS-plus” is a non-technical term that is used to refer to intellectual property rules that extend the scope of covered subject matter or provide higher levels of protection than is required by the TRIPS Agreement. While TRIPS-plus is often used in reference to bilateral and regional free trade (and economic partnership) agreements (FTAs and EPAs), TRIPS-plus rules are also part of multilateral agreements, and may be found in national legislation.

TRIPS-plus provisions have raised concerns among a number of affected stakeholder groups, including in the area of information technologies, but for present purposes refer to provisions that affect the

² Decision of the Council for TRIPS of 29 November 2005, IP/C/40, 30 Nov. 2005.

³ Decision of the Council for TRIPS of 11 June 2013, IP/C/64, 12 June 2013.

⁴ Decision of the Council for TRIPS of 27 June 2002, IP/C/25, 1 July 2002.

⁵ General Council, Decision of 8 July 2002, WT/L/478, 12 July 2002.

⁶ The terms of the extension until 1 July 2013 expressly precluded LDCs from making changes to their laws and regulations that resulted in a lesser degree of consistency with TRIPS (i.e. “rolling back”). The extension until 1 July 2021 does not include such an express preclusion.

⁷ WT/MIN(01)/DEC/2.

⁸ WT/L/540 and Corr.1.

⁹ WT/L/641.

¹⁰ The amendment will technically apply only to the Members that have accepted it, although the waiver decision will continue to apply to other Members.

scope or duration of intellectual property protection for pharmaceuticals and related products. Patents establish rights to exclude third parties from making, using, selling, offering for sale and importing (for these purposes) medicines for a limited term.¹¹ They provide the basis for pricing at above “competitive market” prices, and in doing so limit affordability and access to newer treatments. Requirements to provide periods of marketing exclusivity based on submission of data to regulatory authorities likewise limit the introduction of generic medicines. Other forms of intellectual property, such as trademark and copyright, may also influence affordability and access. When TRIPS-plus requirements are introduced regarding these forms of intellectual property, they enhance the ability of patent and other IP right holders to limit competition. From the standpoint of affordability and access to medicines, TRIPS-plus rules must be approached with caution. Patents, in particular, are thought to encourage innovation and the development of new medicines, and this is not to suggest that patent protection as such is detrimental from a public health standpoint. The policy objective is to properly balance the innovation-encouraging aspects of patent protection with the need for access and affordability. The proper balance may be different for different countries and regions.

What types of innovation justify the award of patent-based marketing exclusivity? Because pharmaceutical companies often use minor changes in technology (such as changes in recommended dosage or route of administration, or slight changes in chemical structure that produce similar results in the body) to promote newer medicines to both doctors and patients, a patent on a minor change may effectively extend the marketing exclusivity enjoyed by the patent holder in a given therapeutic class. The older less expensive product will remain off patent. However, to the extent that doctors and patients can be persuaded to select the expensive new medicine instead of the old, patents on minor changes can and do facilitate the maintenance of originator as opposed to generic pricing.

One of the most important TRIPS-plus issues associated with bilateral and regional trade agreements involves the treatment of clinical data submitted in connection with government approval of pharmaceutical products. Article 39.3 of the TRIPS Agreement requires WTO Members to protect against “unfair commercial use” of undisclosed clinical data submitted to the government with respect to new chemical entities in the pharmaceutical sector. WTO rules leave substantial discretion to Members regarding how to implement this obligation (2, p. 63- 67). Some developed country WTO Members are dissatisfied with this level of discretion and seek to negotiate stronger “marketing exclusivity” requirements in bilateral or regional agreements.

Such TRIPS-plus marketing exclusivity requirements potentially have serious consequences with respect to the introduction of generic products in national markets. In the first place, the introduction of a fixed term of marketing exclusivity is nowhere mandated in the TRIPS Agreement, but a number of bilateral or regional agreements, notably those to which the United States or the European Free Trade Association¹² are parties, incorporate minimum terms that may sometimes be extended based on submission of supplementary clinical data. In some ongoing regional trade agreement negotiations demands are being made to provide extended periods of marketing exclusivity for originator biological medicines that may substantially delay the introduction of generic biologicals. Second, Article 39.3 of the TRIPS Agreement could be understood to mean that a government is obligated to protect only such regulatory data that has been submitted to it in the course of the drug approval process (2, p. 65). A number of bilateral and regional agreements, however, impose an obligation to grant marketing exclusivity based on submission of data in *foreign* countries, or to grant marketing exclusivity on the basis of an approval granted in a foreign country. Third, a number of bilateral and regional agreements subtly extend the scope of products to which marketing exclusivity applies from “new chemical entities” to “previously unapproved products”. This means that products that may be older and already generic in a foreign country must be treated as a new product if previously unapproved in the country where approval is sought.

The net result of all these requirements may be to significantly reduce the prospects for registration of generic versions of originator pharmaceutical products. At the same time, policy-makers should take into

¹¹ To be clear, as confirmed by the Doha Declaration, the patent right to block importation does not prevent a country from authorizing parallel importation of patented medicines.

¹² The European Free Trade Association (EFTA) comprises Iceland, Lichtenstein, Norway, and Switzerland.

account that there should be some incentive to register originator products for the local market, whether that incentive is directed towards the originator or a generic provider. If the generic provider is unable to locally provide the clinical data that was relied on for an initial registration abroad, there needs to be some local mechanism for assuring that drug regulatory approval is based on sound criteria.

Another aspect of the commitments in bilateral and regional agreements relates to so-called “patent linkage”, that is, the linking of drug regulatory authority (DRA) approval with patent status (2, p. 171- 173). In the absence of patent linkage requirements, a DRA generally would not consider the patent status of a medicine when regulatory approval is sought. Patent linkage provisions, however, may facilitate blocking of regulatory approval by the patent holder. Patent linkage may take a variety of forms. The particular choice of form may have a significant impact on the extent to which linkage facilitates the blocking of market entry of generic products. In one of its stronger forms, a linkage provision could prohibit a DRA from approving generic medicines where a patent has been listed (notified to the authority) with respect to the originator medicine. In a somewhat weaker form, a linkage mechanism might require notice to the patent holder upon submission of an application to the DRA by a generic company, and the patent holder would then have the opportunity to initiate a patent infringement action in court. Because courts in some jurisdictions grant preliminary injunctions without close examination of the validity of the patents on which the requests are based, even this seemingly less intrusive form of linkage may be quite problematic from an access standpoint. Such preliminary injunctions may remain in effect throughout the duration of the court case. As a practical matter, almost any form of linkage will adversely affect the ability of generic producers to enter the market, although a system limited to requiring originators to list relevant patents when applying for marketing authorization (without requiring notice to the originator when generic approval is sought) might be useful in promoting transparency for third parties regarding potential patent claims.

Another problem raised by linkage provisions in a number of bilateral and regional agreements is that, by their express terms, they may appear to preclude the grant of a compulsory licence unless the patent holder gives its consent. That is, because a drug may not be put on the market without DRA approval, if the drug regulatory authority is prohibited from approving a drug during the term of a corresponding patent, effective use of a compulsory license on the patent might remain blocked by the regulatory restriction. In a number of agreements, this potential conflict was addressed by the negotiation of “side letters” that were intended to permit the parties to avoid the blocking of compulsory licensing. However, the legal status of these letters is uncertain, and in any case such letters typically include their own conditions. Some agreements expressly incorporate into the intellectual property chapter itself the type of exception necessary to permit the registration of medicines for which compulsory licences have been granted.

A number of bilateral and regional trade agreements include chapters on the protection of investments and investors, and include intellectual property among the subject matter of protection. Including intellectual property in a chapter on investments is controversial because intellectual property protection (such as provided by patent) is often secured based on activities undertaken outside a host state, and does not represent local investment. Traditionally the protection of investments by a host state under international law was directed toward property purchased and/or developed within the host state. In addition, intellectual property rights can and are legislatively or judicially changed in scope or duration from time to time, and these changes do not bear relationship to local investments of capital by the right-holders. It is therefore not clear that intellectual property should be treated the same as other investment property.

In some bilateral or regional agreements, there is a specific provision indicating that a compulsory license issued in conformity with the TRIPS Agreement does not constitute the taking of an investment. While this suggests that compulsory licensing may not be the subject of investment chapter dispute, this may be somewhat deceptive because an investor may bring a claim on grounds that a compulsory license did not conform to the TRIPS Agreement requirements. If nothing else, this will require a government to spend resources defending against such a claim.

In some cases, bilateral or regional agreements provide a mechanism for third-party arbitration of investment disputes, which allow private parties to initiate claims against host governments. In this context,

diplomatic relations between the country parties to the agreement may not be an important factor at the dispute settlement phase. Private investors may be as aggressive as they wish. The government must be prepared to address those investors. Canada has been brought to dispute settlement under the NAFTA by Eli Lilly, an originator pharmaceutical company, on grounds that a certain judicial doctrine interpreting Canada's patent law constitutes an unlawful taking of Eli Lilly's patent rights. This represents a very substantial intrusion into the judicial processes of Canada, and is contrary to the respect traditionally shown to courts interpreting national law. The risks to the authority of national courts around the world from this type of investment chapter arbitration should not be underestimated.

So-called "non-violation complaints" are an arcane subject, more or less specific to international trade law. The essence of a non-violation complaint is that the complained-against party has not violated the terms of the agreement, but has nullified or impaired some benefit that the complaining party legitimately expected to receive when it entered into the agreement. The WTO dispute settlement system generally permits the filing of non-violation complaints (see, for example, GATT Article XXIII(1)(b)). This practice evolved based on the complex relationships between tariffs, subsidies and other measures that affect trade in goods.¹³ But, up until now, it has not permitted such complaints in the field of TRIPS. Article 64 of the TRIPS Agreement specifically imposed a five-year moratorium on non-violation complaints, which period has been repeatedly extended (see for example WT/L/783). By authorizing non-violation complaints with respect to intellectual property in a bilateral or regional trade agreement, however, a country opens itself up to a wide range of claims that it may not have expected to defend (6). It is difficult to know what the other party to a bilateral or regional agreement thought it would gain as an intellectual property-related benefit of the agreement, and what might therefore form the basis for a non-violation complaint.

A number of bilateral and regional trade agreements include enforcement provisions in the intellectual property chapter. These commitments often go beyond those that are required by the TRIPS Agreement. A government must exercise caution to avoid adopting potentially onerous penalties on generic pharmaceutical producers, as such penalties might have a "chilling effect" on the drug supply. One interesting feature of a number of bilateral and regional trade agreements is a provision that authorizes claims by intellectual property rights holder interest groups, such as pharmaceutical industry associations. If such interest groups are authorized to initiate patent infringement claims on behalf of their members, this may increase the number of claims that are brought, as local association representatives may find it easier than foreign patent holders to file and manage litigation claims.

9.3 What is being traded

The subject matter of this chapter is medicines, although there will be associated products, such as syringes, that are used to administer or are otherwise closely related to the chemical or biological material. From a public health standpoint, medicines are most commonly grouped by therapeutic class. From a trade standpoint, however, perhaps the most significant distinction is between originator medicines on the one hand, and generic medicines on the other. This is because the economics of the originator and generic pharmaceutical sectors are very different and may be characterized by substantially different development, marketing and distribution approaches (7). It is also important from a trade standpoint to distinguish between the active pharmaceutical ingredients (APIs) and the final formulated products into which the APIs are incorporated. An important part of world pharmaceutical trade involves the export and import of APIs which are used as inputs by local producers who manufacture and package finished products (8). A relatively small number of countries are substantial producers of APIs, while many countries have some local formulation capacity.

Most of the products on the World Health Organization (WHO) Model List of Essential Medicines are unpatented or no longer patented and are therefore available as generics. Often these are proven low-cost treatments, including, for example, common penicillins and cephalosporins, anti-inflammatories and

¹³ For example, a subsidy that is permitted under GATT rules may be used to defeat the domestic effect of lowering a tariff which would otherwise encourage competition from imports. Even though the subsidy is GATT compliant, the expectations of the exporting country that negotiated for the lower tariff are nullified or impaired.

palliatives (such as aspirin, ibuprofen and codeine). Such medicines (and their components) tend to be available from a wide range of suppliers on the international market at reasonable prices, and they are often formulated from APIs and excipients (inactive ingredients) into finished products within the national market.

However, there are a small number of medicines on the WHO Model List of Essential Medicines, particularly within certain therapeutic classes such as antiretroviral therapy, for which the drugs are relatively new and for which the patents have not yet expired. For these medicines, there may be a limited number of suppliers (and comparatively high prices) on the international market. As a consequence of the pre-1995 invention of most first-line antiretroviral treatments and the operation of TRIPS Agreement transition rules, most first-line antiretrovirals were not patented in many countries and should remain available from generic suppliers based in countries such as India. However, the international supply situation for newer second- and third-line antiretrovirals is more problematic because the relevant patents have not yet expired, meaning that prices may remain high for a number of years.

Characteristics of the local environment will necessarily shape the demand for drugs. The extent to which HIV/AIDS is present among the national population, other things being equal, will determine the level of demand for antiretrovirals in the country. Climate and geography may affect the type of formulation used or preferred for the local environment. Most countries share prevalence of coronary disease, diabetes, cancer and other so-called Type I diseases,¹⁴ and demand for treatment for such diseases is high in most countries, even if the supply (or access) situation is widely different depending upon economic and other factors.

9.4 Ownership

As indicated earlier, governments have two principal interests with respect to the national pharmaceutical sector: assuring that citizens have adequate access to safe and effective medicines, and developing and maintaining a well-functioning domestic pharmaceutical industry. In principle, the public health interest and the commercial interest may be perfectly complementary: a well-functioning domestic pharmaceutical industry may be able to supply safe and effective medicines at competitive prices, while at the same time boosting national employment and improving the balance of trade by substituting domestically produced pharmaceuticals for imports, or even by exporting domestically produced pharmaceuticals. A well-functioning domestic pharmaceutical manufacturing industry may also contribute to productive research and development, generating revenues and improving the balance of trade through licenses with manufacturers in other countries.

In addition to promoting employment and improvement in the balance of trade, a well-functioning domestic pharmaceutical manufacturing industry may help to protect public health security and ensure that local health needs are adequately addressed. While in ordinary circumstances a country may be well-served by relying on imports of pharmaceutical products, in times of international public health stress such reliance may prove problematic. Foreign sources of supply may elect to divert products based on their own public health needs or based upon ability to pay. Thus, for example, in response to the threat of an avian influenza epidemic, a number of countries announced their intention to reverse engineer the antiviral medicine considered most efficacious in treating the virus and to produce it locally, in order to ensure that national needs were met.

However, while public health security may weigh in favour of maintaining an adequate capacity to manufacture pharmaceutical products in times of urgency, as a general proposition very few countries are in a position to be self-sufficient in the development and production of the entire range of pharmaceutical therapies. Moreover, from the standpoint of effective allocation of global resources, it would probably not be welfare-enhancing for each country to attempt to reach pharmaceutical self-sufficiency. For many types of products and services, the global community may be better off if production is concentrated in those

¹⁴A Type I disease is one that is present in large numbers in both rich and poor countries, such as influenza or tobacco-related diseases. A Type II disease is one that occurs in both rich and poor countries, but that is more prevalent in poor countries, such as HIV/AIDS. A Type III disease is one that overwhelmingly or exclusively occurs in developing countries, such as trypanosomiasis. Type II and Type III diseases may be collectively referred to as “neglected diseases”. See (9, p.19).

countries that are more efficient in producing them. There may be countervailing reasons why countries want to retain greater self-sufficiency in certain sectors. For example, a certain level of agricultural self-sufficiency may be important to assure public welfare in times of war or natural calamity. In light of the various interests in the medicines sector: health, economic, and security considerations, each country must find its own appropriate balance between domestic production and reliance on imports.

The question whether local ownership or control in the pharmaceutical manufacturing sector is important to a country is difficult to answer. Local ownership may imply that profits from businesses are more likely to be reinvested within the country, though this is not necessarily the case. Similarly, local owners may be more responsive to addressing local conditions and to addressing concerns expressed by the government, and less likely to close manufacturing facilities in response to short-term fluctuations in economic conditions because of their direct connection to the community. If lower-income countries maintain adequate infrastructure to allow efficient production of pharmaceuticals, locally owned and operated pharmaceutical facilities may emerge as lowest-cost suppliers. Yet, a subsidiary of a foreign-owned multinational company might be substantially similar to a locally owned pharmaceutical manufacturer from a public health economic and social standpoint. Also, distinctions between “local” and “foreign” businesses may not be so easy to define, as shareholders, lenders, managers, employees and other stakeholders may have ties to multiple jurisdictions, and as joint venture relationships in one form or another (including product development agreements, licensing, intermediate manufacturing, etc.) are important elements of the pharmaceutical industry.

9.5 Trade policy instruments

The price and general availability of medicines is substantially affected by the level of competition on the national market including competition from imports. A number of countries impose trade restrictions on the import of medicines, sometimes to provide protection to local producers who might otherwise not be able to compete effectively (2, p. 77-78, 191-197). Although the tariff rates generally imposed on imports of medicines (including inputs and finished products) are generally low in both developed and developing countries, they tend to be somewhat higher in developing countries, and (perhaps surprisingly) somewhat higher still in least developed countries. Also, while tariffs rate policy can be used to encourage the development of local industry, at least as a temporary measure, not all countries have effectively integrated their tariff policies with their industrial development policies, leading paradoxically to tariffs that discourage local industry. Perhaps most important, if tariff rate policy is used to temporarily promote local industry, such policy must be offset with measures assuring that access is not restricted for patients needing medicines.

Governments employ a number of trade policy instruments to regulate pharmaceutical products and related supplies, which can often act as trade barriers. Governments first focused on tariffs and quotas, which are therefore sometimes referred to as “first-generation” trade barriers. Governments may also employ technical standards and other regulatory requirements, which are sometimes referred to as “second-generation” trade barriers. The original General Agreement on Tariffs and Trade (GATT) adopted in 1947 (the predecessor to WTO) was for several decades primarily concerned with reducing tariffs. In the 1970s, during the Tokyo Round of GATT negotiations, attention turned toward reducing the trade-distorting impact of unjustifiable regulatory measures. Refinement of the Tokyo Round agreements addressing regulatory measures was undertaken during the Uruguay Round of trade negotiations (1986–1993), at the conclusion of which the agreements were extended to all WTO Members. During those negotiations, some diplomats began to refer to gaps in intellectual property rights protection as “third-generation” trade barriers.

There are several reasons why quotas are in general disfavoured by WTO rules. First, quotas are a rigid form of protection. Even a foreign company that might be able to overcome a tariff-based competitive disadvantage cannot overcome a quota. Thus, quotas leave domestic producers without the threat of lawful competition at any price. Second, quotas are not transparent — and therefore enhance the risk of

corruption. Although importers can normally determine the tariff rate of a given good, they may not be able to determine, at the time of planning and investing in manufacture, the extent to which a quota for a particular good has been or will be filled. Not only does this create uncertainty, it also places in the customs authorities a substantial amount of power to manipulate the system for entry of goods into the country. Third, quotas present problems of allocation because, in theory, one major importer might rapidly occupy a country's full quota, leaving no room for import competition. WTO rules provide that, in situations in which quotas are used, a system for geographical allocation among WTO Members should be implemented. Fourth, quotas require complex and therefore expensive systems of licensing and recordkeeping, and are thus wasteful of scarce resources.

One of the great challenges of international trade regulation is to distinguish between measures adopted by governments to achieve legitimate public policy objectives, and measures adopted for the purpose of shielding the domestic market from foreign competition. An important premise underlying the WTO system is that, all else being equal, opening national markets to competition from foreign-sourced goods and services (while obtaining reciprocal access to the foreign market) is beneficial because this promotes the efficient allocation of global resources, which should benefit all WTO Member countries. At the same time, few if any governments fully embrace this premise. For example, many governments have long protected domestic agricultural markets on grounds of food security. Similarly, governments recognize that abrupt changes to trade regulations can have a disruptive impact on national employment (and other factors involving the domestic allocation of resources), and typically seek to build in transitional arrangements when adjusting trade policy. The WTO Agreement on Safeguards allows the temporary implementation of trade barriers, including quotas, where rapidly rising imports threaten to cause serious injury to domestic industry.

As noted earlier, governments may have legitimate policy reasons for seeking to develop and maintain local pharmaceutical production, as well as promote local research and development. In some circumstances this may be difficult to accomplish unless domestic producers are temporarily afforded some form of advantage over more highly capitalized and technologically advanced foreign competitors. A difficult question is how to promote local industry without inhibiting access to medicines.

Because of WTO national treatment rules, governments are generally prohibited from providing express preferences to local producers. However, there is an exception to the national treatment rule (Article III:8 of GATT) that permits preferential treatment in the area of government procurement, so long as it is not done for purposes of commercial resale. A government that purchases pharmaceuticals for use in a national health programme may be able to grant preferences under this exception. If a WTO Member is party to the "plurilateral" (optional for WTO Members) Agreement on Government Procurement, it may have accepted non-discrimination commitments in this area, but even then exceptions exist, including threshold purchase values as well as any exceptions contained in a given country's specific schedule of commitments.

Governments often provide direct or indirect financial support to the national pharmaceutical industry through subsidies to research institutions that provide essential inputs into the development of new products or production processes. The use of subsidies for specific industries is restricted by the WTO Agreement on Subsidies and Countervailing Measures, but governments nevertheless find ways of providing support for the development of local industry.

National governments sometimes grant preferences to local producers through the adoption of local manufacturing or regulatory compliance standards that are different from the standards under which originator versions of the products initially were approved by foreign regulators. For example, DRAs may require stability data from the testing of drugs that are unique to the local environment, and that import drug suppliers might generally be unable to supply without incurring substantial additional costs. Such an apparently neutral requirement may in practice act as a substantial trade barrier.

It is certainly to be expected that national governments require pharmaceutical importers to seek approval for and register their products. Health regulatory authorities may also require importers to properly store their products and to provide suitable arrangements for recalling products that cause difficulties.

One of the principal purposes of a regional trade agreement is to establish tariff or quota preferences among member countries, as permitted by GATT Art. XXIV. Because regulatory barriers may also restrict cross-border trade, regional trade agreements may also seek to facilitate the removal of regulatory barriers, such as by harmonizing national regulations or providing for mutual recognition of regulatory approvals. The reduction or removal of regulatory barriers is particularly important with respect to the pharmaceutical sector because regulation of the safety and efficacy of pharmaceutical products plays a substantial role in the marketing of such products, and reducing barriers on a regional basis may facilitate the establishment of production facilities that can efficiently supply regional requirements.

In addition to regional trade agreements, countries may benefit from agreements such as the United States Generalized System of Preferences (GSP), which unilaterally grants preferential access to the United States market, for the purpose of promoting economic growth in the developing world. The GSP is not a regional trade agreement because reciprocal market access is not necessarily provided by beneficiary countries to the United States.

9.6 Innovation and intellectual property rights

The structure of the innovation environment in virtually all countries involves a mix of public and private sector activity. The extent of investment in research and development in the pharmaceutical sector, and the medical supplies sector more broadly, varies widely among countries. Research and development in the pharmaceutical sector generally requires significant investment, which many developing countries cannot easily afford. For this reason, among others, public and private research institutions in these countries may find it necessary to enter into joint venture agreements with foreign research institutions, including private enterprises.

There are two principal means by which government policy-makers provide incentives for the development of new medicines and related technologies. The first is to subsidize research and development, either directly or indirectly. With a direct subsidy, the government finances purchases of research materials, laboratories and equipment, pays employee salaries, and so forth. Alternative versions of direct subsidies can involve the pre-invention award of grant money to researchers (a model employed by the United States National Institutes of Health), or the post-invention award of a prize to a successful inventor (such as the system of prizes provided in the former Union of Soviet Socialist Republics (10, p.U-42). In an indirect payment, the government may provide loan guarantees or tax incentives to the researcher.

Governments or other entities may also coordinate subsidies at the international level. For example, they may commit funds in advance that will be used to purchase output flowing from the inventive activity, thereby reducing market-based risk by providing potential producers with a guaranteed market. These so-called “advance market commitments” are a type of post-invention award and have been used recently to successfully develop a new pneumococcal vaccine that has already been deployed in the developing world.¹⁵

International coordination can also utilize a pre-invention subsidy model. WHO is coordinating discussions on the creation of a global framework for the financing of research and development for products that would meet the health needs of developing countries (11). One of the many options under consideration is a biomedical research and development treaty that would pool funds from national governments to be used to address priority health needs, particularly the needs of developing countries.

The second principal means by which governments provide incentives for the development of new medicines and related technologies is to provide private parties with a legal mechanism that can establish a more favourable market position than would otherwise exist. This can take either the form of a patent that authorizes the inventor to exclude others from the marketplace for a limited time, or through the grant of marketing exclusivity, which performs a similar function more directly. Almost all governments use both subsidies and market-based rewards as means to encourage invention in the field of pharmaceuticals.

¹⁵ See www.gavialliance.org/funding/pneumococcal-amc/

One of the broad trends in public research and development over the past two decades has been to offer incentives to researchers making use of public funding, such as permitting researchers to take title to patents issued based upon their research, or at least to allocate a share of patent-based income to those researchers. An example is the United States Patent and Trademark Law Amendments Act (Bayh-Dole Act) of 1980, which permits recipients of federal funding to own patents arising from their research. In recent years a number of countries (including Brazil, the Philippines and South Africa) have adopted similar legislation, in some cases adapting the legislation to their national circumstances (2, p. 33). Singapore, which has engaged in intensive national efforts to promote research and development in the pharmaceutical sector, provides mechanisms for researchers to share in the profits deriving from the exploitation of publicly funded inventions.

While the broad trend appears to favour allowing researchers to financially benefit more directly from publicly funded research, such incentive solutions are not without their problems. The most common criticism of Bayh-Dole style legislation is that the public, which initially funded the relevant research, must generally pay higher prices if resulting medicines inventions are patented by the private sector, in essence “paying twice” for the same research. Others reply that critics underestimate the extent of investment and the risk taken in moving potential new treatments from the basic research phase to marketing approval and manufacture, and argue that eliminating Bayh-Dole type incentives would make it even more difficult to introduce new medicines.

In any event, there is general agreement that Bayh-Dole style legislation should ensure that the public shares fairly in the outcome of any research and development that it sponsored. This might, for example, be accomplished by reserving to the government a right to grant nonexclusive licences to additional suppliers if the needs of the public are not being adequately met. In fact, the United States Bayh-Dole legislation includes a provision allowing the funding agency to withhold the grant of a patent in “exceptional circumstances” and also grants the government so-called “march-in” rights, allowing it to issue nonexclusive licences following a patent grant if the needs of the public are not being adequately met. In more than thirty years, however, march-in rights have never been successfully utilized, despite recent efforts by access-oriented groups demanding that the United States National Institutes of Health (NIH) make use of them.

The NIH, which administers funding for pharmaceutical research, has taken the position that high prices do not constitute a lack of availability or improper exploitation, and that action to moderate prices must be addressed by specific U.S. congressional action. The NIH has taken the position that if drugs are available – even if they are unaffordable for many patients – that patents are being sufficiently used, and it is up to Congress or state health authorities to find ways to pay for them. In order to avoid this type of result, Bayh-Dole legislation adopted by developing countries should probably include specific reference to price moderation as an objective of a march-in system.

One of the most significant changes brought about by the WTO TRIPS Agreement was to impose upon WTO Member governments a requirement to provide patent protection in the field of pharmaceuticals, as well as to impose a minimum 20-year duration of the patent term. The TRIPS Agreement also required governments to prevent the unfair commercial use of undisclosed regulatory data on new chemical entities in the pharmaceutical sector, and some countries have implemented that obligation by granting pharmaceutical originators a period of marketing exclusivity which, at least until recently, has generally run concurrently with the patent term.¹⁶

Yet, the distinction between patents and marketing exclusivity based on submissions to regulatory authorities may be unappreciated. Patents are often challenged in courts for having been improvidently granted. There may have been an inconsequential modification of a previously known substance that did not satisfy the inventive step requirement, or there may have been prior art that anticipated the claimed invention. There are a variety of grounds on which patents may be challenged and found wanting. Pharmaceutical patent holders are therefore worried about the strength of protection they may have. Marketing exclusivity based on regulatory submission is different. Such exclusivity typically cannot

¹⁶ The introduction of a 12-year term of marketing exclusivity for biologic drugs in the United States, for example, may result in periods of marketing exclusivity that extend beyond the term of patent protection.

be challenged by third parties on grounds of failure to make sufficient contribution to science. It is an exclusivity based on the fact of the regulator's approval of marketing. Because such exclusivity is far less vulnerable to third-party challenge than the patent,¹⁷ it is in high demand from originator pharmaceutical companies. This is why, for example, biological originator companies have pressed so hard for extended duration regulatory marketing exclusivity – and successfully lobbied for a 12-year term in the United States. They are worried that their patents might be vulnerable. It is the same reason why the United States has been pressing to include a 12-year term of marketing exclusivity for biologic medicines in the Trans-Pacific Partnership (TPP) negotiations. And, it is for this reason that the largest retired persons group in the United States (the American Association of Retired Persons or AARP) has openly objected to this negotiating objective; because the AARP believes that the biologics industry in the United States is trying to lock in extended high prices for new treatments – to which it objects – by including the marketing exclusivity provision in an international agreement.

Governments need to adopt intellectual property policies that balance their national interest in promoting the discovery of new medicines with the interest of their citizens in having access to them once they are brought to market. The way that this balance is best formulated may be quite different among countries. Some countries have a large capacity for innovation in the medicines sector and substantial national income. The economies of these countries can tolerate risky investments in attempts to find new cures for disease, and can more easily pay for higher-priced patented medicines. Some other countries have limited capacity for innovation in the medicines sector and have more scarce budgetary resources. The economies of these countries cannot afford risky investments in developing new medicines, and can ill afford higher-priced patented medicines. Nevertheless, people in these countries can often benefit from new medicines developed elsewhere. The national interest in intellectual property policy of countries in such different circumstances is not the same. It should not be surprising if government policy-makers in different circumstances come to different conclusions about what policy measures on intellectual property rights are best.

It is today generally believed that the development of a new pharmaceutical treatment, from basic research to production, is a very costly process, although the true cost of that process is a matter of some debate (2, p. 107-108). The development of a new pharmaceutical therapy may have positive public health implications, both locally and for the worldwide public. It may also allow the industry to earn substantial profits. How the costs and benefits of innovation are shared is a sensitive public policy question. To the extent that the results of innovative efforts are priced out of the reach of large numbers of consumers, the public health benefit from the innovation is obviously limited. But, if the return on investment in innovation is too tightly limited, this may cause investment in research and development to shift to other fields, leaving some disease conditions without treatments.

It is important to bear in mind that investment in the development of new pharmaceutical products carries high risk, and that those who are investing capital at high risk will typically require a higher-than-ordinary return. One way to reduce the required return on investment is to lower the level of development risk. There are potential mechanisms for lowering the level of risk in pharmaceutical development, including providing advance market commitments (which guarantee a certain level of sales), and improving early detection mechanisms that avoid continued development of products that ultimately will fail. Each of these mechanisms has a cost, which may end up being passed on in the form of higher costs to governments or patients.

Medicine innovation is not limited to the laboratory setting. The global community is paying increasing attention to traditional medicines, including by identifying the elements of traditional medicines that give rise to therapeutic effects. Countries at all levels of development may be repositories of traditional medicinal knowledge that can form a basis for new product development.

¹⁷ This does not mean that the grant of regulatory approval, and associated grant of marketing exclusivity, can never be challenged. But such challenges are not common, and the pathways to initiate and pursue such challenges are not well established.

9.7 Access and intellectual property rights

Some of the most vigorous debates in multilateral diplomacy since the inception of the GATT Uruguay Round of negotiations in 1986 have concerned the impact of pharmaceutical patents on access to medicines, particularly in resource-poor settings. The entry into force of the WTO TRIPS Agreement on 1 January 1995 resulted in a dramatic change in the legal obligations imposed upon WTO Members, namely, to eventually provide pharmaceutical product patent protection within their territories, as highlighted earlier. The subsequent Doha Declaration on the TRIPS Agreement and Public Health of 14 November 2001 in principle established a supportive environment for the use by developing countries of flexibilities and safeguards, almost all of which were already an integral part of the original TRIPS Agreement. It is therefore important to evaluate the extent to which WTO Members have taken advantage of these opportunities and to consider where bilateral and regional agreements incorporate obligations greater than those included in the TRIPS Agreement (“TRIPS-plus” provisions).

The extent to which a country maintains flexibility to adopt intellectual property policies depends to a substantial extent upon the international obligations it maintains. National legislative and executive authorities may elect to act inconsistently with international obligations when they consider it necessary. Although international legal obligations therefore do not preclude the exercise of flexibilities, a country that chooses to act inconsistently with its international obligations will incur liability which, under WTO rules, may take the form of trade concessions that are withdrawn by the injured party. As a consequence of the TRIPS Agreement, portions of some WIPO Conventions (most notably the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works) are enforceable through WTO dispute settlement.

Some of the most difficult issues in patent law relate to the types of pharmaceutical product inventions for which patents may be granted. The types of pharmaceutical inventions on which patents are granted may be expressly stated in a country’s patent legislation, and they may also be defined by judicial decision. Broadly speaking, patents can be categorized into “product” and “process” patents. A product includes a chemical compound, such as a pharmaceutical. A process of manufacture is a way of making a product. Pharmaceutical patents are today granted in what might be described as a third category, namely, “method of use” (also called “method of treatment”). In countries where this is allowed, a method of use or treatment patent may be granted on a previously patented chemical compound during the term of the original product patent, and even when the original product patent has expired. Of the countries that allow such method of use patents for pharmaceuticals, some have limited them to the first discovered therapeutic area, precluding the issuance of so-called “second medical indication” patents. The European Patent Convention expressly prohibits second medical indication patents, although the European Patent Office has overcome this prohibition by granting such patents when the claim is recited in the form of a “Swiss claim” (that is, “the use of compound X in the manufacture of a treatment for disease Y”). The India Patents Act prohibits the grant of patents on new uses of known compounds, as does the Andean Community¹⁸ via its Decision 486.

Some national patent offices grant patents with respect to new dosages (for example, 200 milligrams twice daily), routes of administration (for example, through a transdermal patch) and patient populations (for example, for the treatment of children under 6 years of age). This permits pharmaceutical originator companies to maintain limited patent protection related to a single chemical compound beyond the 20-year term prescribed by the TRIPS Agreement. However, as noted above, the product as originally patented will fall into the public domain following the original 20-year term, and any “evergreening” patents will be limited in scope to the specific new, industrially applicable, and non-obvious invention claimed therein.

It is therefore important to encourage pharmacists and doctors to avoid dispensing higher-priced patented compounds by instead prescribing dosages or routes of administration that are no longer covered by patent. Pharmaceutical companies, of course, have an interest in employing marketing practices that discourage doctors from doing so. This is not to suggest that incremental innovation in pharmaceutical products does not confer patient benefits, but that policy-makers, doctors and patients should consider

¹⁸ The Andean Community is comprised of the Plurinational State of Bolivia, Colombia, Ecuador, and Peru.

whether that incremental innovation justifies what in some cases may constitute a very large price premium on the product. National governments may, for example, wish to enact laws that encourage or require generic substitution when feasible. Because such “generic substitution” laws normally only apply to identical dosage forms, chemical entities, and routes of administration, governments additionally may wish to consider policies that encourage appropriate substitution of alternate treatments that may not be identical products per se, but rather are considered therapeutically “substitutable” products. Also, cost controls may be accomplished at least in part through pharmaceutical benefit or insurance plans limiting reimbursement based on an assessment of whether new patented treatments do, in fact, confer a meaningful benefit. Just as pharmaceutical companies have an interest in charging higher prices to maximize profits, government insurance schemes and private insurance companies typically have an incentive to reduce expenses, including to keep premiums within the reach of consumers. Private pharmaceutical benefit plans are usually part of a competitive market.

Another approach adopted by some governments has been to expressly limit the extent to which additional patents may be granted with respect to different forms of the same chemical entity or compound. Notable in this regard is Section 3(d) of the India Patents Act, which prohibits the granting of patents on new forms of known substances unless the patent applicant is able to show a significant improvement in efficacy. In 2013, the Supreme Court of India affirmed the denial of a patent applied for by Novartis on a form of imatinib mesylate (Gleevec or Glivec) because the applicant failed to show a significant enhancement in therapeutic efficacy.

Patents are typically granted by a national patent office, which may operate under the authority of a larger ministry, such as the ministry of commerce. In some countries, such as Brazil, the public health regulatory authority (for Brazil, ANVISA) reviews pharmaceutical patent applications with respect to the criteria of patentability, and must give its approval before a patent may be issued by the national patent office (for Brazil, INPI).

The patent offices of some countries do not perform a substantive examination of patent applications prior to the grant of patents, but merely register patents based upon properly completed paperwork and appropriate fees. The system in these countries is therefore known as a “registration system”, as opposed to an “examination system”. As a consequence, provided that procedural requirements are met and fees are paid, an applicant may obtain a patent on virtually anything. Registration systems impose substantial burdens on potential competitors that might wish to enter the market, but must first challenge patents that have been issued without examination. The public ultimately bears the economic cost of market access restrictions imposed by the patents. For countries that want to introduce an examination system, but do not have the resources to adequately assess the range of potential pharmaceutical inventions, some use might be made of the substantive examination conducted by an International Preliminary Examining Authority under the Patent Cooperation Treaty (PCT) system. However, the PCT has advantages and disadvantages, and it is important for the government to consider the way the PCT will be implemented, if it is used (13).

A number of countries permit third-party challenges to patent applications that have been filed but not yet approved. This is referred to as “pre-grant opposition” and it is typically conducted as a patent office administrative procedure. The advantage of pre-grant opposition is that competitors and the public may avoid bearing the burden of market access restrictions based upon improvidently granted patents. Alternately, or sometimes in addition, many countries permit challenges at the patent office immediately following the grant of a patent and for some period of time thereafter. This is referred to as “post-grant opposition” and is also conducted as a patent office administrative procedure, sometimes with recourse to a judicial body on appeal. A patent may be affirmed, revoked or its claims modified as a result of post-grant opposition. One of the main advantages of both pre- and post-grant opposition is that it typically may be initiated by any person with an interest to do so, and is not limited to a party against whom an infringement action has or may be initiated. In this regard, opposition proceedings are distinguished from ordinary judicial proceedings seeking invalidation of patents. In ordinary judicial proceedings, patent invalidity is often initiated as a defence to alleged patent infringement (although judicial invalidation proceedings may in some cases also be initiated as a stand-alone matter). Both pre-grant and post-grant opposition

procedures are adopted in recognition that patent offices and examiners are frequently overburdened, and may grant patents on inventions that do not, in fact, meet the criteria of patentability. Administrative proceedings leverage the knowledge and interest of private third parties to remedy improvidently granted patents and thereby reduce the strain that would otherwise be placed on the courts. They may often be a more cost-effective way than ordinary civil litigation to test the validity of patents.

Frequently, products that are “on patent” in one country are unpatented or otherwise “off patent” in other countries. In part this can be explained by the fact that rarely will pharmaceutical companies choose to incur the substantial costs of obtaining and maintaining a patent in all of the world’s markets, particularly in light of the relatively small markets in some countries.

Even if a particular medicine, such as an antiretroviral, is patented in a given country, the government has the option by the terms of Article 31 of the TRIPS Agreement to issue a compulsory licence either to manufacture locally or to permit importation. If there is insufficient capacity within the country to produce the medicine, under the WTO “waiver decision” described earlier, the government or a private party may request that another country issue a compulsory license for export.¹⁹ Also as discussed earlier, least developed WTO Member countries are permitted not to enforce pharmaceutical patent protection until 2016 (or later, based on a general extension of the requirement for TRIPS compliance until 2021). These countries may undertake domestic manufacture or importation, at least with respect to the TRIPS Agreement, without formally issuing a compulsory licence. A number of countries are not yet Members of the WTO and so do not have obligations under the TRIPS Agreement (although they may be party to other international agreements that include intellectual property-related obligations).

Compulsory licensing can be a core component of a country’s patent law that is useful in ameliorating the potentially harsh short-term consequences of patents on public health. Even if a compulsory licence is not ultimately issued, a government can use the threat of compulsory licensing during price negotiations with patent holders. The patent holder knows that if agreement is not reached, the government may grant a compulsory licence to itself or its contractors (a so-called “government use” licence), or to a private party for commercial exploitation. Governments may find that the possibility of a compulsory licence is sufficient to moderate prices. In a growing number of cases, compulsory licences for pharmaceutical products have in fact been issued.

Compulsory licensing tends to be controversial at the international level because the home country of the patent holder has an interest in earning income from exploitation of the patent and may not be particularly interested in the hardships within the country granting the compulsory licence. The exporting country views the compulsory licence as a loss of income, while the country granting the compulsory licence may view it as the solution to an important public health problem. A country granting a compulsory licence that affects foreign patent holders must therefore be prepared to respond to some level of criticism from trade officials of the exporting country, even if its actions in granting a compulsory licence are entirely lawful under international trade and intellectual property rules.

Policy-makers should be aware that under Article 31 of the TRIPS Agreement, patent holders must receive “adequate remuneration” in the circumstances of the case, generally in the form of a royalty, if a compulsory licence is granted. The appropriate amount of the royalty may be the subject of debate, although there are guidelines that may be helpful in some circumstances (14).

Article 31 leaves open to governments to determine the grounds that justify the granting of a compulsory licence. It does, however, impose a number of requirements relating to the grant of a compulsory licence, including the obligation to first make reasonable efforts to negotiate a voluntary licence with the patent holder (but see the exceptions below), and to consider licences on their individual merits. Article 31 also requires that the licence be non-exclusive and, as noted above, that adequate remuneration be paid to the right holder.

¹⁹ Least developed countries are understood to lack adequate manufacturing capacity.

The obligation to negotiate may be dispensed within the case of national emergency or other circumstances of extreme urgency, or for public non-commercial use. It should be emphasized that the existence of a national emergency is *not* a requirement for the grant of a compulsory license, but merely relates to the requirement of prior negotiation (2, p. 73). The Doha Declaration²⁰ re-emphasized that governments may grant compulsory licences on grounds of their own choosing²¹ and that governments have discretion to determine what constitutes a national emergency.²² The Doha Declaration also specifically noted that HIV/AIDS, malaria, tuberculosis and other epidemics may constitute national emergencies.²³

Governments may also opt for parallel importation, which refers to the importation of drugs under patent in the importing country that have been lawfully placed on the market outside the country. The TRIPS Agreement leaves to WTO Members the choice of permitting parallel importation of patented medicines, which flexibility was confirmed by paragraph 5(d) of the Doha Declaration. Parallel importation may help a country to lower the cost of patented medicines because it allows for the purchase and importation of the lowest-priced version of the same medicine from anywhere in the world.

The basic concept of parallel importation is somewhat controversial, and was deliberately left unaddressed in the TRIPS Agreement (see Art. 6). Governments may address parallel importation in different ways, and are not required to treat each form of intellectual property in the same way. Proponents of “international exhaustion” regimes argue that patent rights should be considered exhausted (used up) once the product is lawfully sold anywhere in the world, meaning that parallel importation into a second country can occur even if a patent exists in that second country. Because international exhaustion facilitates global purchasing at the lowest price, it should therefore be considered by developing country governments. (In contrast, it has been argued that if *developed* countries implement international exhaustion rules, businesses may respond by declining to offer products at lower prices in lower-income markets, since arbitrageurs could then buy products at the lower price and resell them in the developed country market). An alternative to an international exhaustion regime is a “national exhaustion” regime, under which the first authorized sale of patented product exhausts rights only with respect to the country in which the sale took place. This means that parallel importation may not be able to occur if a patent exists in the importing country. There is a third option for “regional exhaustion” under which a patented product placed on the market in any country of the regional group will be deemed to exhaust the patents in all members of the group, thereby facilitating access to the lowest-priced medicines within the regional group.

Even under an international exhaustion regime, there are different schools of thought regarding the precise circumstances under which parallel importation is permitted. Some respected commentators take the view that pharmaceutical products lawfully placed on the market under compulsory licence may be parallel imported, while others have rejected this view on the ground that such products have not been placed on the market with the patent holder’s consent.²⁴

In some countries, such as South Africa, authorization of parallel importation of patented medicines is expressly incorporated into legislation. In many countries, rules on parallel importation are made by judicial decision. If a country authorizes parallel importation of patented medicines, it typically must also authorize parallel importation with respect to the patent holder’s trademark, as most pharmaceutical product packaging will include a trademark name. Parallel importation of trademarked goods is a permitted option under the TRIPS Agreement. Finally, because certain aspects of the packaging or documentation accompanying pharmaceutical products may be protected by copyright, it may also be useful to formally authorize parallel importation of any copyrighted works associated with pharmaceutical products.

²⁰ WT/MIN(01)/Dec/2.

²¹ Doha Declaration paragraph 5(b).

²² Doha Declaration paragraph 5(c).

²³ Doha Declaration paragraph 5(d).

²⁴ There has not been significant commentator discussion of whether goods initially placed on the market by or with the consent of the patent holder, but in a country where the pharmaceutical product is not patented, are subject to lawful parallel importation. The European Court of Justice approved this practice within the European Union.

Article 39.3 of the TRIPS Agreement requires WTO Members to protect undisclosed regulatory data regarding new chemical entities in the pharmaceutical sector against unfair commercial use. Some governments have implemented this obligation by establishing marketing exclusivity periods with respect to pharmaceutical products newly approved by public health regulatory authorities. The scope of this marketing exclusivity obligation varies both as to the duration and as to the types of products that are covered.

For example, the United States applies a five-year marketing exclusivity period for new chemical entities that runs concurrently with (and therefore typically expires before) the expiration of the patent term covering the relevant product. Marketing exclusivity generally is only granted with respect to the first approval of the same substance or compound. However, a three-year period of marketing exclusivity may be granted based on the conduct of significant new clinical studies that result in approvals for a new indication, which exclusivity generally applies only to that new indication.²⁵ With respect to biologics, the United States employs a 12-year exclusivity period, which may in some cases be longer than the patent period that remains at the time the product is approved for sale.

The European Union provides an “8+2+1” marketing exclusivity period. That is, there is an eight-year period of complete exclusivity, followed by a two-year period in which generic producers are permitted to prepare and submit applications for approval upon expiration of the exclusivity period, and a potential one-year extension based on a new therapeutic indication showing significant clinical benefit.

Although Article 39.3 of the TRIPS Agreement requires Members to protect undisclosed regulatory data regarding new chemical entities against unfair commercial use, it does *not* require this protection to be in the form of marketing exclusivity (2, p. 63-67). There are other methods for preventing “unfair commercial use” of regulatory data, including providing a private right of action to those submitting such data against third parties that they claim are engaging in unfair conduct.

Potential obstacles to the introduction of generic products that can arise out of “patent linkage” with regulatory approval procedures were discussed in section 10.2.2 above.

Article 30 of the TRIPS Agreement allows WTO Members to adopt a regulatory review or so-called “Bolar” exception that allows generic producers to undertake the activities necessary to make a submission to the DRA for marketing approval during the term of an originator patent. Otherwise, a prospective generic submitter going through the process of reverse engineering, procuring or producing the necessary chemicals, testing for bioequivalence, and so forth, might be considered to infringe rights of the patent holder. A regulatory review exception, as discussed in the next paragraph, may be sufficiently broad to authorize a range of third-party research regarding pharmaceutical products that are covered by patent (as it does in the United States), but it may also be framed to cover only those activities specifically needed for approval of generic versions of originator products. This is a matter within national discretion.

Finally, another important exception to the rights of patent holders, allowed by Article 30 of the TRIPS Agreement, is the so-called “research exemption”. A research exemption permits persons other than the patent holder to make use of the invention for purposes of understanding the mechanism of action and for developing other new products. A research exemption can be broad. For example, the United States Supreme Court (in *Merck v. Integra Lifesciences*, 545 U.S. 193 (2005)) held that the United States regulatory review exception permits third parties to use patented pharmaceutical inventions for the conduct of preclinical and clinical research on new drugs, provided only that the researcher has some reasonable expectation that a new drug application will eventually be submitted to the United States Food and Drug Administration, even if no such application is ever submitted. In some countries, a patent research exemption is expressly incorporated in patent or other legislation. In other countries, such an exemption is made by judicial decision. The scope of the patent research exemption varies rather widely among countries.

²⁵ *Zeneca Inc. v. Shalala*, 1999 WL 728104, at *12 (D. Md. Aug. 11, 1999); *ViroPharma, Inc. v. Hamburg*, 898 F.Supp.2d 1, 7 (D.D.C. 2012).

9.8 The need for a cost-benefit analysis of both pharmaceuticals and intellectual property scope

As noted throughout this chapter, policy-makers in trade and public health have two major objectives with respect to pharmaceuticals and related medical supplies. One is to ensure that sufficient resources are committed to innovation so that new preventives and treatments for disease can be found. In addition to the obvious objective of relieving human suffering, finding preventives and effective treatments for disease should reduce the financial burden on public health systems by reducing costs of hospitalization, physician visits and so forth. The second objective is to ensure that preventives and treatments that have been found, or are found in the future, are accessible to the public as soon as possible. If pharmaceuticals and related medical supplies are too costly, the fact that they exist is of little use to those who need them.

A key assessment policy-makers must make is the cost-benefit ratio for each medicinal product. For newly introduced pharmaceuticals, policy-makers should be particularly attuned to the size of the health benefit conferred and not make decisions based upon uninformed opinion, industry promotion, or political pressure. In some cases, new treatments may not provide sufficiently large advantages over less expensive older treatments to justify their costs. A number of countries, such as Australia, have attempted to assess costs versus anticipated benefits in the establishment of prices and availability for government reimbursement of new products. It is, regrettably, a rare occurrence in which a researcher or pharmaceutical company announces a cure for a disease whose benefit to patients over previously existing treatments is so great that the benefit side of the cost-benefit analysis is simple. Most new medicines represent incremental improvement over prior therapies. In some cases the benefits turn out to be illusory. Even worse, some medicines with marginal benefits are later discovered to have rare but serious or even lethal side effects that become apparent only after the drugs are released to the public. Newer, high-priced medicines are not always better.

Unfortunately, it is not a simple matter to assess prices, which can make price comparison between countries challenging. Medicines may be prescribed and packaged in different dosages in different countries. As a consequence of various price control, insurance, rebate and reimbursement schemes, it is often difficult to state the price of a particular medicine even within the same country. By way of illustration, a survey of retail pharmacies may not produce a representative result because consumers may pay different prices depending upon which (if any) insurance plan they purchase under. While it may be useful to identify selling prices from the manufacturer, this can be difficult because it depends on obtaining accurate information from the manufacturer, which may regard its prices as proprietary. One way to track prices is to look at the prices paid by the government in its own procurement operations. Such prices may not accurately reflect the private consumer market, but may at least provide a gross indicator of pricing trends. For some medicines, such as antiretrovirals, there are publicly accessible databases now available that provide reasonable measures of prices.

It is an axiom of access-oriented public health groups that increasing intellectual property protection will increase the price of medicines. It is difficult to argue with the veracity of that axiom, given that the purpose of stronger protection is to reinforce the market position of the intellectual property holder. Furthermore, it is beyond doubt that introducing generic competition to a market previously dominated by an originator substantially reduces the price of the medicine, especially as a significant number of generic competitors enter the market.

What is more difficult is determining in advance how changes to intellectual property standards will impact the development of future treatments and the overall cost of pharmaceuticals. With respect to cost, there are myriad economic factors that must be taken into account, some of which involve unknowables. For this reason, assumptions need to be made, with the robustness of the prediction depending upon the accuracy of the assumptions. For example, a new medicine introduced under a strong system of protection will be protected against competition from other medicines that are essentially the same. However, the level of sales of the new medicine will depend on at least two factors: (a) the extent to which substitutes

can perform the same task, even if in a somewhat less effective way; and (b) the structure of the local pharmaceutical infrastructure that may encourage or discourage purchases of the new product. It is difficult to create an economic model that can accurately account for these factors.

Assumptions must also be made concerning the impact of intellectual property rules on the quality and number of new products that will be brought to market. One of the underlying theories of strengthening intellectual property protection is that it will encourage the development of more new products. While some level of intellectual property protection can encourage investment and thereby promote invention, it is not necessarily true that ever stronger protection will yield larger or more rapid technical or therapeutic gains. This is in part because new inventions often build upon older inventions. Therefore, if legal protection of older inventions is too strong or lasts for an excessive period of time, it is not inconceivable that such protection could *slow* the rate of innovation. Even where innovation is increased, policy-makers must consider whether the adverse effects on the public arising from enhanced intellectual property protection outweigh any additional incentives created. In short, while one needs only to observe the market to see that patent protection is correlated with higher prices, the correlation between longer or stronger patents and an increased rate of invention is much less straightforward.

Despite the apparent difficulties in determining how changes in intellectual property laws will affect future invention and aggregate cost, some notable efforts have been made to reduce the uncertainty (15). In the course of Australian and Colombian debates on the Australia-United States Free Trade Agreement (16) and the Colombia-United States Free Trade Agreement (17), studies were prepared on the prospective impact of the intellectual property rights chapters on the price and total cost of medicines. The International Centre for Trade and Sustainable Development has produced a publication that assesses the impact of TRIPS-plus provision on the price and total cost of medicines in Costa Rica (18).

9.9 Data sources, indicators and interpretation

Given that WHO has strongly encouraged governments to adopt national medicines policy documents setting out their strategy for meeting the medicines needs of the public²⁶, it is important that each country first establish whether such a policy already exists, as this may provide relevant information for the establishment of a base on which to develop further policy documents. Furthermore, a complete overview regarding methodologies by which data on usage of medicines are collected and reported can be found in a joint publication of WHO and various WHO collaborating centres.²⁷

This overview makes clear that there is no international uniformity in the way that countries collect and report pharmaceutical consumption data. Efforts are being made to improve this situation. It is not suggested here that public health authorities and trade officials revise the manner in which they compile national data on consumption of medicines. If there is a reporting system in place that uses a particular methodology that national officials find useful, that system should be used to report the required data. WHO also maintains a substantial programme devoted to the development and implementation of good manufacturing practice standards.²⁸ Data regarding production within a country are usually compiled by the ministry of commerce or trade, or by data collection and statistics bureaus operating under one or more ministries. These data are often compiled by examining periodic reports that manufacturers are required to submit to the government. Data may also be compiled based upon tax records and other revenue collection reports. Governments differ substantially in the extent to which they collect and report data, with the highly industrialized economies tending to expend more resources on this activity. Data may be less readily available in developing countries. For some developing countries, the number of significant pharmaceutical producers may be small. It may therefore be possible to undertake at least a preliminary survey at relatively low cost. Data regarding importation of pharmaceutical products are typically collected by customs authorities and reported on by the ministry of trade or the ministry of finance. Such data usually indicate the country of origin of imports, broken down according to the class of goods.

²⁶ See http://www.who.int/medicines/areas/rational_use/en/

²⁷ (http://www.who.int/medicines/areas/quality_safety/safety_efficacy/Drug%20utilization%20research.pdf)

²⁸ http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/index.html

Data regarding the ownership of pharmaceutical production capacity may or may not be formally compiled by the government. However, for most countries, studies by university researchers or nongovernmental organizations, including financial media outlets, often contain fairly detailed data regarding the character of business ownership. In addition, most national pharmaceutical industries are organized into one or more industry associations, which may be broken down as between local enterprises and foreign multinational enterprises, and from which data regarding ownership patterns may be obtained. The government will, of course, know whether there are government-owned pharmaceutical production facilities.

Although most national governments maintain data on the percentage of gross domestic product (GDP) spent on research and development, there are also various external sources where such information is listed. See, for example, the data centre of the UNESCO Institute for Statistics.²⁹

It may be more difficult to determine the level of research and development specifically in the pharmaceutical sector because this involves an aggregation of public and private data that may not be readily available. However, it should at least be possible to determine government spending on pharmaceutical-related research and development as a percentage of GDP, or as a percentage of the government research and development budget.

The national patent office should maintain data on the number of patents applied for and granted with respect to pharmaceutical products. Pharmaceutical patent applications typically include an International Patent Classification (IPC) designation, which should permit analysis based on classification. Pharmaceutical preparations are generally, but not exclusively, classified under IPC symbol A61K.³⁰

9.10 Conclusion

There is no generally accepted optimal model for regulating the production and distribution of pharmaceutical products and related supplies, including with respect to international trade. Governments pursue a variety of policies intended to strengthen national capacity to produce and distribute pharmaceutical products and related supplies, and a variety of policies intended to promote public access to those products.

Domestically, Europe and the United States pursue very different policies with respect to pharmaceutical regulation, with Europe relying heavily on price controls to moderate the impact of patented medicines on national budgets. Although the United States pharmaceutical sector is not subject to price controls per se, there are a wide range of regulatory measures that may influence prices. These include state generic substitution laws, and federal regulatory measures, such as reference pricing controls used by the Veterans Administration. The past fifteen years have witnessed a proliferation of bilateral and regional trade agreements generally intended to reduce or eliminate barriers to the free movement of goods and services. A significant number of these agreements include chapters covering intellectual property rights and regulatory data with respect to pharmaceuticals, as well as chapters devoted to investment protection. Commitments with respect to patents and regulatory data, as well as commitments with respect to enforcement and investment protection, have raised concerns among public health authorities, development-related multilateral institutions and nongovernmental organizations. These concerns focus on the possibility that a broader scope of patent and regulatory data protection will adversely affect prices and access to newer medicines, particularly among more vulnerable parts of developing country populations.

²⁹ See http://stats.uis.unesco.org/unesco/TableViewer/document.aspx?ReportId=143&IF_Language=eng, which includes data on employment research and development; and the OECD Main Science and Technology Indicators, 2011/2 edition, available at http://www.oecd.org/document/26/0,3343,en_2649_37427_1901082_1_1_1_37427,00.html

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9.11 Further reading

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Chapter 2	Policy coherence in trade and health Chantal Blouin, Nick Drager
Chapter 3	Capacity building in trade and health Alka Bhatia
Chapter 4	Macroeconomic aspects of trade and health Richard Smith, Chantal Blouin
Chapter 5	Implementing trade commitments with a public health perspective David P. Fidler
Chapter 6	Regional trade agreements and health services Mina Mashayeki, Elisabeth Tuerk
Chapter 7	Trade in health services Pierre Sauvé, Chantal Blouin, Aniket Bhushan, Olivier Cattaneo
Chapter 8	Trade liberalization, food, nutrition and health Corinna Hawkes, Delia Grace, Anne Marie Thow
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Health and trade have long been interconnected. The increasing trade of medical products and of health-related services provides many opportunities for improving people's lives worldwide. However, the deepened liberalization of trade has also posed new challenges to national health authorities. National health authorities are confronted with heightened trade in harmful products impacting nutrition habits and associated rise in non-communicable diseases, increased movement of health personnel, medical tourism, and higher levels of intellectual property protection impacting medicine prices.

Trade and Health: Towards building a national strategy provides useful background information for policy-makers to formulate a coherent national response to trade and health-related issues. With free trade agreements being negotiated continuously, often without sufficient involvement of health experts, the core evidence presented in this book can enable health policy-makers to engage, where health and trade linkages occur, to protect health and thus strike a balance between public health and the further liberalization of global trade.

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