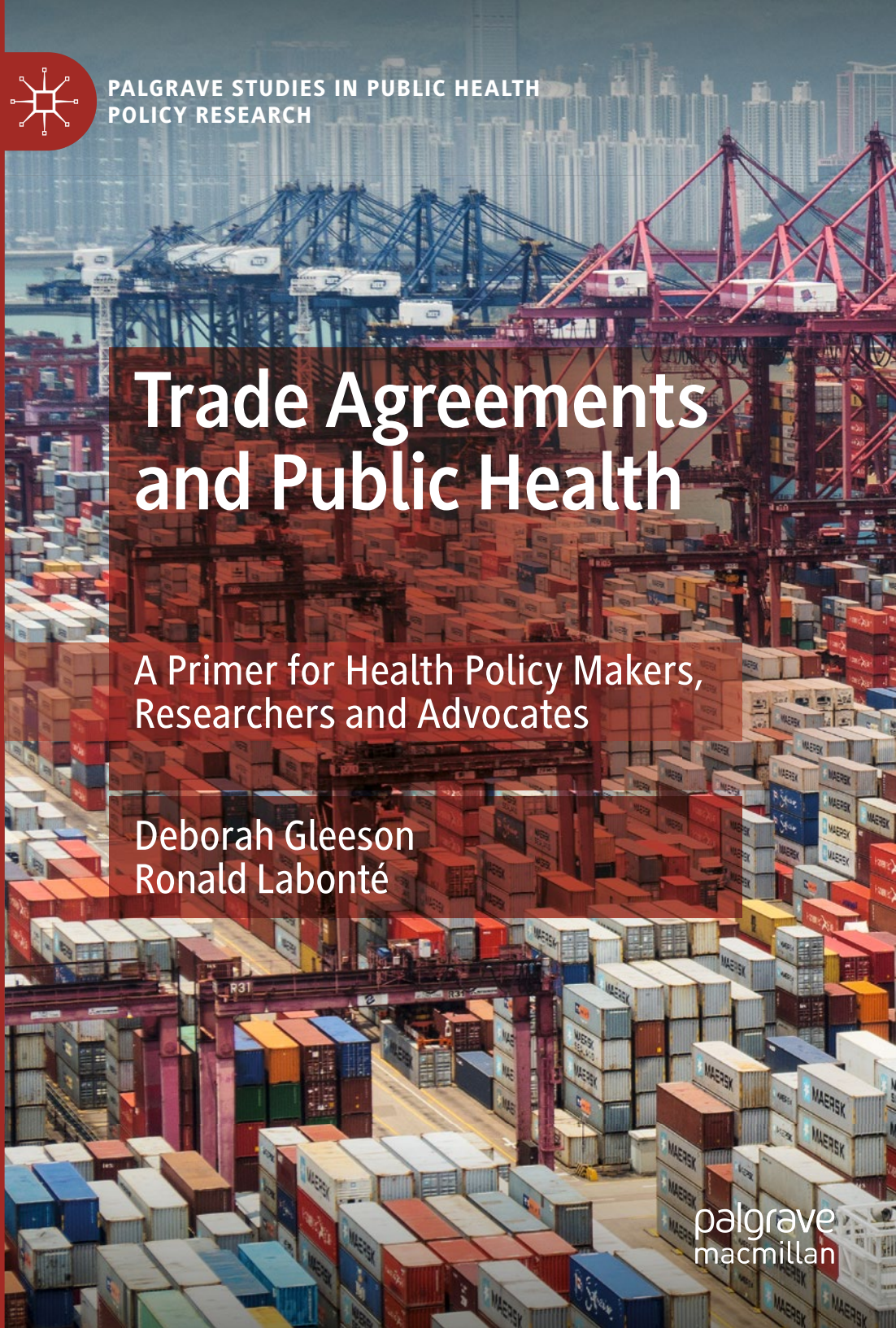
PALGRAVE STUDIES IN PUBLIC HEALTH POLICY RESEARCH
Trade Agreements and Public Health
A Primer for Health Policy Makers, Researchers and Advocates
Deborah Gleeson
Ronald Labonté
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Palgrave Studies in Public Health Policy Research

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Public health has increasingly cast the net wider. The field has moved on from a hygiene perspective and infectious and occupational disease base (where it was born in the 19th century) to a concern for unhealthy lifestyles post-WWII, and more recently to the uneven distribution of health and its (re)sources. It is of course interesting that these 'paradigms' in many places around the world live right next to each other. Hygiene, lifestyles, and health equity form the complex (indeed, wicked) policy agendas for health and social/sustainable development. All of these, it is now recognized, are part of the 'social determinants of health'.

The broad new public health agenda, with its multitude of competing issues, professions, and perspectives requires a much more sophisticated understanding of government and the policy process. In effect, there is a growing recognition of the extent to which the public health community writ large needs to better understand government and move beyond what has traditionally been a certain naiveté about politics and the process of policy making. Public health scholars and practitioners have embraced this need to understand, and influence, how governments at all levels make policy choices and decisions. Political scientists and international relations scholars and practitioners are engaging in the growing public health agenda as it forms an interesting expanse of glocal policy development and implementation.

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Deborah Gleeson • Ronald Labonté

Trade Agreements and Public Health

A Primer for Health Policy Makers, Researchers and Advocates

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This book is dedicated to the trade negotiators we have been privileged to meet who have strived to protect the health of their people, often against incredible odds, those public health actors who have striven to ensure that health is not forgotten in the inevitable trade-offs made in treaty negotiations, and to the international networks of civil society organisations, legal experts, academics and activists who support and resource both groups in their efforts.

Acknowledgements

The authors acknowledge that this book project was completed with the assistance of a La Trobe University Social Research Assistance Platform Grant. We thank Carmen Vargas for her assistance with preparing the final book manuscript for publication.

Praise for *Trade Agreements and Public Health*

'An essential read for health policy makers, researchers and advocates who want to take a leadership role in making trade and trade agreements work to improve health outcomes. This well researched and evidence-based book gives the reader the elements to participate in a constructive dialogue to ensure trade increases access to health services, lowers the costs of medicines, vaccines and medical devices and reduces harmful products crossing borders.'

—Nick Drager, MD, PhD, *Honorary Professor, London School of Hygiene and Tropical Medicine*

'The intent of global free trade is to increase opportunities to enrich people across the world. However, current international trade negotiations have become complex, difficult to understand and a mystery to the ordinary people they are supposed to enrich. Gleeson and Labonté provide sensible, readable and academically sound insights into the tools required to ensure priority for the most important enrichment—the health of the people and the health of the planet.'

—Michael Moore, AM, *Immediate Past President of the World Federation of Public Health Associations (2016–2018)*

'The contradictions between public health priorities and trade agreements are perhaps some of the most important challenges of 21st century capitalism. This highly readable book demystifies these challenges by providing a comprehensive overview of the key linkages, areas of concern and some suggestions for reform. Intended for an audience in global health, this primer is also essential reading for policy makers, researchers and activists in the field of trade.'

—Sakiko Fukuda-Parr, *Professor of International Affairs, The New School, USA*

'Community health and health care are increasingly influenced by trade relations which are increasingly governed by trade agreements. The emergent health challenge is to steer the negotiations and implementation of such agreements away from health-damaging provisions. Gleeson and Labonté's "primer" is a unique contribution which will prove invaluable in addressing this challenge; assisting health officials to promote policy coherence; assisting researchers in tracing impacts; and supporting health practitioners and activists in monitoring and advocacy.'

—David Legge, *Convenor of People's Health Movement's Trade and Health Circle*

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Abbreviations

ACTA	Anti-Counterfeiting Trade Agreement
AGP	Agreement on Government Procurement
AoA	Agreement on Agriculture
AUD	Australian Dollars
BIT	Bilateral Investment Treaty
CAD	Canadian Dollars
CEC	Commission for Environmental Cooperation
CETA	Comprehensive Economic and Trade Agreement
CGE	Computable General Equilibrium
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
C-POND	Pacific Research Centre for the Prevention of Obesity and Noncommunicable Diseases
CPTPP	Comprehensive and Progressive Agreement for Trans-Pacific Partnership
CTE	Committee on Trade and Environment
DR-CAFTA	United States-Dominican Republic-Central America Free Trade Agreement
DTCA	Direct-to-Consumer Advertising
EPA	Economic Partnership Agreement
EPZ	Export Processing Zone
EU	European Union
FAO	Food and Agriculture Organization
FCTC	Framework Convention on Tobacco Control
FDI	Foreign Direct Investment
FET	Fair and Equitable Treatment
FTA	Free Trade Agreement

G20	Group of Twenty
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
HIA	Health Impact Assessment
HICs	High-Income Countries
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HFCS	High-Fructose Corn Syrup
HPV	Human Papillomavirus
ICS	Investment Court System
ILO	International Labour Organization
IP	Intellectual Property
IPRs	Intellectual Property Rights
ISDS	Investor-State Dispute Settlement
ITAC	Industry Trade Advisory Committee (USA)
JRP	Joint Review Panel
KOF	Konjunkturforschungsstelle (Globalisation Index)
KORUS	Korea-US Free Trade Agreement
LDCs	Least Developed Countries
LICs	Low-Income Countries
LMICs	Low- and Middle-Income Countries
MEAs	Multilateral Environment Agreements
MERCOSUR	Southern Common Market (South American trade bloc)
MFN	Most Favoured Nation
MSF	Médecins Sans Frontières
NAAEC	North American Agreement on Environmental Cooperation
NAALC	North American Agreement on Labor Cooperation
NAFTA	North American Free Trade Agreement
NCDs	Non-communicable Diseases
NGO	Non-government Organisation
NT	National Treatment
NZD	New Zealand Dollars
OECD	Organisation for Economic Co-operation and Development
PACER Plus	Pacific Agreement on Closer Economic Relations—Plus
PCV	Pneumococcal Conjugate Vaccine
PHARMAC	Pharmaceutical Management Agency (New Zealand)
PIC	Pacific Island Country
QCA	Qualitative Comparative Analysis
R&D	Research and Development
RCEP	Regional Comprehensive Economic Partnership
SDGs	Sustainable Development Goals

SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
SSBs	Sugar-Sweetened Beverages
TAC	Treatment Action Campaign
TBT	Technical Barriers to Trade
TFC	Transnational Food Corporation
TiSA	Trade in Services Agreement
TPP	Trans-Pacific Partnership
TRIMS	Agreement on Trade-Related Investment Measures
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TTC	Transnational Tobacco Company
TTIP	Transatlantic Trade and Investment Partnership
UMIC	Upper-Middle-Income Country
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
US	United States
USA	United States of America
USD	United States Dollars
USMCA	United States-Mexico-Canada Agreement
USTR	Office of the United States Trade Representative
WHO	World Health Organization
WTO	World Trade Organization

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CHAPTER 1

Introduction

Abstract This chapter introduces readers to the ambivalent relationship between trade and health and explains why understanding this relationship, along with the complex web of trade and investment rules that has developed since World War II, is important for protecting and promoting health. It explains the purpose and intended audience of the book and its layout. The main pathways by which trade agreements can affect health and some of the problems with trade policy-making processes are briefly outlined, in preparation for more in-depth exploration in subsequent chapters. The idea of policy coherence between trade and health policy is briefly introduced and some of the challenges to achieving it. The chapter finishes by explaining the approach taken in the book and its multidisciplinary basis.

Keywords Relationship between trade and health • Trade agreements • Public health • Policy coherence • Sustainable development

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1.1 Overview of the Relationship Between Trade and Health

Trade, or the barter and exchange of goods between people, is as old as human societies. Once a practice between neighbours and adjoining communities, trade expanded over the centuries with the rise and reach of empires, the creation of nations and the development of new technologies. Advances in marine engineering saw Asian and European sailing fleets replace the Silk Road footpaths of Marco Polo. Industrialisation, trains, planes and trucks increased trade's pace with more recent digital innovations creating wholly new venues for international commerce.

Trade brings with it the promise of prosperity and improved living standards, both of which can, directly and indirectly, benefit health. There is nothing inherent in such a relationship, however, and trade between nations has been marked as much by impoverishing exploitation as by enabling exchange. At the same time that Adam Smith was making the economic case for open markets and free trade in his classic text, 'The Wealth of Nations' [1], Britain's rise to imperial dominance was based, in part, on its African slave trade and the expropriation of the wealth and resources of its occupied colonies. Disease, too, has long accompanied trade routes, from the Black Death of medieval times carried by stowaway rats on merchant ships to more recent pandemic waves of cholera that were swept along by maritime shipping to the post-millennial global diffusion of unhealthy commodities contributing to a worldwide rise in non-communicable diseases (NCDs).

Simply put, the relationship between trade and health has always been ambivalent, bringing both health opportunities and disease risks. Understanding this relationship to ensure the protection and promotion of public health has become more complex over the past half-century, as nations began creating international rules intended to govern an anarchic global economy that had proved as prone to conflict as to cooperation.

1.2 Purpose and Intended Audience of the Book

This short text is a primer on the complex web of modern trade and investment treaties that began with the birth of the World Trade Organization (WTO) in 1995 and which continued with the subsequent proliferation of bilateral and regional trade agreements. This book is intended for public health policy makers, researchers and advocates and

focuses on specific trade agreements and how their provisions (trade rules) can affect the regulatory policy space for health, environmental and social protection. Trade has long existed, and much of it continues, outside of the formal rules in modern trade agreements; but increasingly these rules with their enforcement measures deepen and entrench the liberalisation principles that undergird all such agreements.

1.3 Structure and Content of the Book

In Chap. 2 we review the post-World War II expansion of trade liberalisation negotiations that led to the creation of the WTO. We describe key WTO principles and agreements and how these might impact health, and the WTO's innovative dispute settlement process, providing several case examples. We then identify several new 'WTO-Plus' regional agreements, before concluding with a discussion of controversial investor-state dispute settlement rules. Chapter 3 begins to drill down into how trade rules affect specific health measures and outcomes, focusing on health services and on the effects of provisions protecting intellectual property rights (IPRs) on access to medicines, vaccines and medical devices. The role of IPRs, and their continual strengthening, in trade treaties, on access to affordable medicines continues to dominate public health concerns with trade policy. In Chap. 4 we describe how this focus has broadened in recent years to concerns with how trade and investment liberalisation treaties are increasing the global diffusion of 'unhealthy commodities' (tobacco, alcohol and ultra-processed foods) and how certain treaty rules are making it more challenging for governments to introduce measures aimed at reducing their consumption or minimising their health risks. We describe how public health policy makers might design new measures to avoid the risk of a trade challenge and introduce the concept of 'policy coherence', in this instance with respect to ensuring that trade rules do not conflict with national or intergovernmental commitments to reduce the prevalence of NCDs associated with consumption of unhealthy commodities.

Chapter 5 examines the recent trend in trade agreements to include chapters concerning labour rights and environmental protection measures. These chapters require governments that are 'party' to the agreement to respect their obligations under labour rights or environmental treaties but only become enforceable if a party lowers its existing standards specifically to gain a trade or investment advantage. Whether trade agreements are the

appropriate place to improve or enforce labour or environmental standards remains a moot issue. Trade agreements do not simply arise *ex nihilo* but are the products of often intense and lengthy intergovernmental negotiations. Chapter 6 describes the negotiation processes, drawing on policy theory and using examples from public health engagements with, or post-hoc studies of, trade policy agenda-setting. Space for improving health issues within trade agenda-setting and negotiation processes exists, but at present, there remain concerns with the lack of transparency in trade negotiations and the excess influence of private economic interests over that of public health protection.

In Chap. 7 we discuss the strengths and limitations of the different research methods used to interrogate trade-related impacts on different health outcomes, the evidence from which public health relies upon in advocating for healthier trade policy. What healthier trade or investment policies should look like is the topic of the final Chap. 8, in which we identify different reform measures that should be incorporated in future agreements, as well as changes in the trade policy-making process to ensure that the resulting agreements reflect a judicious balancing between economic interests and health and broader public good protection. The importance of seeking to improve 'policy coherence' (or at least to reduce policy incoherence) between trade and other health, environmental and social development goals is evidenced in the 2030 Agenda for Sustainable Development, adopted by United Nations General Assembly in 2015 [2]. Goal 17 specifies, on the one hand, that countries 'promote a universal, rules-based, open, non-discriminatory and equitable multilateral trading system under the World Trade Organization' (17.10) (which calls into some question the use of bilateral or regional WTO-Plus negotiations in which many countries now participate); while on the other underscores the importance of 'enhanc[ing] policy coherence for sustainable development' (17.14) and 'respect[ing] each country's policy space and leadership to establish and implement policies for poverty eradication and sustainable development'(17.15) [3].

1.4 Overall Approach and Disciplinary Basis

Throughout this book, we have endeavoured to present a balanced representation of the trade and investment treaty environment. Our concern is foremost with protection of public health and its many social and environmental determinants. We recognise that governments

invariably have multiple and often competing policy goals and that perfect policy coherence is never possible. Trade-offs are inevitable. Our analyses draw from disciplines ranging across epidemiology (e.g. what is the relationship between trade flows and population health?), sociology (e.g. how do power relations affect trade policy making?), political science (e.g. what are the arguments for or against trade liberalisation?), economics (what are the benefits or costs associated with trade liberalisation and who benefits most?) and law (what are the known or likely impacts of specific trade treaty rules on government regulatory policy space?). As such, it provides a 'top-level' interrogation of trade, trade treaties and health, sufficiently detailed to enable public health practitioners and policy makers to engage more knowledgeably with colleagues in the trade portfolios. We caution, however, that persons wanting a more in-depth understanding should avail themselves of some of our cited references, the useful online materials and archives of the World Trade Organization and the growing number of trade/health scholars and researchers within the universities worldwide. Our 'take-home' message is that too little attention has been given to known or potential health risks associated with trade and particularly trade that is governed by complex modern trade rules. Strengthening the capacity of public health actors to engage more effectively in trade policy-making and negotiating processes remains our acknowledged intent in producing this introductory text.

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CHAPTER 2

Trade and Health: From Ancient Pandemics to the World Trade Organization and Beyond

Abstract Trade is as old as human societies, but treaties governing trade between nations are relatively new. Negotiations for international trade rules began after World War II, culminating in the creation of the World Trade Organization (WTO) in 1995. The WTO established principles to govern trade, schedules for tariff reductions, rules for dispute settlement, and agreements covering services, intellectual properties, agriculture and 'non-tariff' trade barriers. The sweeping scope of WTO agreements raised public health concerns that their rules could affect governments' ability to regulate for health, environmental and social protection purposes. New 'WTO-Plus' bilateral and regional trade and investment agreements add to the complexity of these rules and create more options for foreign investors to challenge new government health measures intended to protect public or environmental health.

Keywords Trade and health • World Trade Organization • Trade principles • Regional free trade agreements • Investment treaties

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2.1 Introduction

We begin this chapter by recounting the more recent history of global trade, tracing the evolution of our rules-bound system from the devastation of two World Wars to the birth of the World Trade Organization (WTO) in 1995. We describe both the basic premises (rationale) for trade and investment liberalisation, and the principles that govern trade treaties and which continue to frame all new trade negotiations. We next identify and summarise key WTO agreements that have a bearing on health. After outlining the processes by which trade disputes are resolved, including a discussion of health exceptions, we review four cases that illustrate how trade principles embedded within trade rules have been interpreted in a number of challenges or disputes concerning health.

We conclude with a summary of the post-millennial shift away from multilateral trade negotiations to the 'spaghetti bowl' of regional and bilateral treaties, why this shift has occurred and how it poses new challenges for public health regulators. These new challenges include controversial investor-state dispute settlement (ISDS) rules, which allow foreign private investors to challenge government regulations or policies that might affect the value of their investments.

2.2 From World Wars to the World Trade Organization

Economic historians generally agree that periods of peace and economic growth encourage adoption of free trade. Which comes first (growth or free trade) remains a matter of some debate, although most of today's high-income nations accumulated their wealth behind protectionist barriers, only opening to global competition once they had established their own capacity to dominate global trade or to compete successfully in global niche markets [1–3]. As industrialisation revolutionised European and American societies, their national wealth grew and their governments abandoned protectionism in favour of more open borders. International trade as a share of gross domestic product (GDP) rose steadily in the late nineteenth century, reaching levels not surpassed until the 1970s.

Capitalism, however, is prone to episodic crises of overproduction and underconsumption (high supply but low demand) leading to economic recession.[1] In the run-up to World War I (less a war of the world than one of industrialised European nations vying for economic supremacy), several

countries began re-erecting trade barriers to protect their domestic industries against increasing economic turmoil. These barriers persisted and actually rose slightly during the 'Roaring 20s' [4], a decade of profligate financial speculation that ended with the 1929 Stock Market crash [5]. The ensuing Great Depression saw the pace of 'beggar thy neighbour' protectionist policies accelerate, fanning other political and economic rivalries that eventually ignited World War II [4], this time a conflict that did attain global scale.

When the War's winning countries met in the US retreat at Bretton Woods they created several new global institutions to manage international relations in the hope of avoiding future world wars: the World Bank would oversee financing of the reconstruction in war-ravaged Europe (and later development funding for decolonising 'Third World' countries; see Box 2.1); the International Monetary Fund (IMF) would work to ensure global macroeconomic stability; and the United Nations (UN) would replace the ineffectual interwar League of Nations. There were also suggestions to create an International Trade Organization to establish new rules to prevent the trade imbalances and rise in protectionism that preceded the War. The USA rejected this proposal but did agree to create new binding rules to gradually reduce the high tariffs that still limited trade between developed economies. The logic of doing so was that countries whose economies became more thoroughly enmeshed would be less likely to go to war, as it would no longer be in their best interests. The Cold War and geopolitical proxy conflicts weakened the strength of this claim, but the notion that economic interdependence through liberalised trade is fundamental to world peace remains part of the post-War narrative.

Box 2.1 Third World, Developing or Income Group?
At the beginning of the modern liberalised trade era, countries were grouped into three categories: First World (liberal market economies aligned with the USA), Second World (Eastern bloc and socialist economies aligned with the Soviet Union) and Third World (the non-aligned nations, representing most of the countries in Latin America, Africa and South Asia and the loci of many proxy Cold War battles). Since the late 1960s countries came to be referred more commonly as 'developed' (industrialised and wealthier) and 'developing' (agrarian and poorer). Though still in common usage,

this designation has been critiqued for its 'developmental' bias (that all countries should follow the same political and economic path of industrialised nations) and lack of relevancy in a multi-polar world in which there can be huge socio-economic differences between countries in the same category. Offsetting this somewhat, the World Bank created a parallel designation using GDP/per capita: high-income countries (HICs), upper- and lower-middle-income countries (UMICs and LMICs), low-income countries (LICs) and least developed countries (LDCs). This system, though now more commonly used than the other two, is also criticised for where it sets its income thresholds, its reliance on GDP as its evaluative metric and its lack of attention to within-country distribution such that most of the world's poor no longer live in LICs or LDCs. The WTO uses 'developed' and 'developing' country designations, along with the United Nations list of 'least developed countries' and so will be the terms most frequently encountered in this book. These designations have importance within WTO trade treaties, as developing nations, and especially LDCs, are often given 'special and differential treatment', meaning lower levels of obligation to trade rules, longer transition periods or preferential market access. The WTO has no definition for 'developed' or 'developing', allowing WTO member states to self-identify. Other WTO members, however, can challenge the decision of a country to make use of developing country provisions.

The establishment of multilateral trade rules took almost a half-century to create and involved eight rounds of negotiations, known as the General Agreement on Tariffs and Trade (GATT). Agreements to lower tariffs were initially confined to developed countries and succeeded in shrinking tariffs from an average of over 40% in 1947 to less than 5% in 1993 [6]. Developing nations could take advantage of these lower tariffs but were not obliged to reduce their own. This principle of non-reciprocation began to change in the 1970s when the economic recession in developed countries and rapid economic growth in the decolonising Third World created interest in consumer markets still protected by developing country tariff walls. Later GATT rounds negotiations expanded beyond reducing

tariffs, import quotas and export subsidies (all of which restricted international trade) to include 'non-tariff measures', which refer to government regulations or policies that could indirectly affect trade flows. Negotiating rounds eventually led to the birth of the WTO in 1995, overseeing the enforcement of 29 separate trade treaties[2] agreed upon by 124 founding members. By 2016, 164 of the world's 193 nations were WTO members and 20 more are seeking to join.

2.3 Key Principles of Trade Agreements

> …the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development…[7]

It is hard to find fault with the aspirational goal of the WTO expressed in its founding document, the Marrakesh Agreement. Were this preambular statement enforceable (it is not) it could require member countries to report on the extent to which these trade agreements actually produced these ends. But as the WTO itself notes, 'the system's overriding purpose is to help trade flow as freely as possible' [8], leading some early critics to argue that rather than being the means, liberalised trade has become an end in itself [9]. The buttressing assumption is that increased international trade will automatically stimulate growth and trickle down to reduce poverty, thereby improving health [10]. We examine this assumption later in this chapter; it is first important to understand the key WTO principles which govern trade rules from which all are claimed to benefit, of which there are five:

1. Reduction of tariffs and other border barriers to trade (such as import quotas), which continue to be part of new regional or bilateral free trade and investment agreements (hereafter FTAs) and accession requirements of new countries joining the WTO.
2. Reduction of non-tariff barriers to trade, the 'behind-the-border' non-tariff measures which are of greatest concern to most health analysts.

3. Elimination of discriminatory practices among countries through two foundational rules:
   (a) Most Favoured Nation (MFN)—The most favourable tariff or regulatory and foreign investment treatment given to any one country that is part of the agreement must be given to all other member countries of that agreement.
   (b) National Treatment (NT)—Countries must treat all 'like' imported products and services from other member countries no differently than they treat their own domestic products and services.
4. Special and differential treatment under three conditions:
   (a) Developing countries should have lesser obligations until they catch up—such as ongoing extensions for least developed countries (LDCs) to obligations under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (see Chap. 3).
   (b) Developing countries with a historic and political relationship to a developed country can be granted more favourable tariff or regulatory treatment that is not offered to other member countries, an exception to the MFN rule. This principle is embodied in the WTO as a 'Generalised System of Preferences'. An example of this is the 'Everything But Arms' initiative of the European Union (EU) that grants tariff- and quota-free imports of all commodities (except weaponry) from least developed former colonies.
   (c) Regional FTAs, such as the recently completed Trans-Pacific Partnership Agreement (TPP) (since renamed the 'Comprehensive and Progressive Agreement for Trans-Pacific Partnership' or CPTPP), can also provide preferential market access to other countries in the agreement without having to extend such benefits to other WTO members; another exception to the MFN rule [11] and one reason for the rise in the number of new FTAs in recent years.
5. Progressive liberalisation, requiring member states to deepen and expand their liberalisation commitments through subsequent negotiating rounds; governments cannot (without penalty) decrease their existing levels of trade openness.[3]

2.4 From Principles to Practice: Key Health-Related WTO Treaties

To understand how these principles apply to health, it is first necessary to identify and summarise those WTO agreements that have particular bearing on health, for better or for worse.

2.4.1 General Agreement on Tariffs and Trade 1994

The GATT 1994 (as it is referred to in the WTO system) is a continuation of the earlier GATT negotiations. It commits governments to progressively lower their tariffs on, and reduce other border barriers to, imported goods. This can reduce the price of goods available to consumers which, depending on the health merits of such products, can improve health directly or indirectly through an increase in overall living standards. Local manufacturers can also increase their exports due to greater market access, creating new employment and poverty-reducing opportunities. Conversely, consumption of unhealthy commodities could increase and tariff reductions in LMICs could lead to a loss in public revenues, affecting funding for health, education, water/sanitation and other key health-determining public investments.

2.4.2 General Agreement on Trade in Services

One of the focal agreements discussed in the next chapter, General Agreement on Trade in Services (GATS) provisions can increase foreign investment in health systems that can lead to new facilities and access to new medical technologies. But GATS commitments also 'lock in' a country's existing privatisation levels in committed service sectors, several of which (health care, education and environmental services) are important to promoting public health and are frequently prone to market failure (i.e. private provision often excludes access to the poor). Once a service sector is committed, there is no cost-free way to extend the public provision of that service in the future.

2.4.3 Agreement on Trade-Related Intellectual Property Rights

Perhaps the WTO agreement that has received the greatest health attention and another focal treaty in the next chapter, TRIPS has been described

as a 'protectionist' rather than 'liberalising' agreement since it entrenches, and in some cases, extends intellectual property rights (IPRs), with particular bearing on patented drugs. On the one hand, pharmaceutical firms argue a need for strong IPRs to finance the high cost of new drug discovery and development. On the other hand, patent protection and other IPR provisions can increase drug costs for consumers and governments alike and delay generic drug price competition.

2.4.4 Agreement on Technical Barriers to Trade

One of the treaties that aimed to reduce trade-related (non-tariff) measures affecting the flow of goods, the Technical Barriers to Trade (TBT) Agreement has the same potential to improve health as the GATT 1994. However, in doing so the TBT requires that any new policy or regulatory barrier to the free flow of goods introduced by a member state must be the 'least trade restrictive' possible. New health and safety regulations and environmental protection measures proposed by WTO members have frequently been challenged under rules in this agreement. We return to the TBT in the discussion in Chap. 4 of trade in unhealthy commodities.

2.4.5 Agreement on Sanitary and Phytosanitary Measures

The Agreement on Sanitary and Phytosanitary Measures (SPS) sounds like a health treaty, but it is not. It is a commercial treaty designed to ensure that the sanitary and phytosanitary (food safety and animal/plant health) measures adopted by the member states do not constitute unnecessary burdens to trade. The SPS defers to international standard setting in determining if the level of protection is excessive, relying upon standards agreed set by the *Codex Alimentarius*, an intergovernmental organisation operating under the auspices of the WHO and the Food and Agriculture Organization. Although both *Codex* and the SPS emphasise the importance of science-based standards, *Codex* sets a level below which countries should not fall and which, if there is no consensus on actual risk, countries can exceed with justification. In the SPS the *Codex* floor becomes the trade barrier ceiling which countries cannot exceed without providing rigorous scientific proof.

2.4.6 Agreement on Agriculture

One of the more contentious treaties within the WTO, this agreement requires countries to reduce most, but not all, subsidies for their domestic

producers. Continuing export and producer subsidies in developed countries (while slowly declining) can depress world prices and cost developing countries lost revenue which could otherwise be used to fund health, education and other health-promoting services. Imports of subsidised food products from wealthy countries can undermine domestic growers' livelihoods in poorer nations unable to afford the same scale of producer support. Developing countries reliant on food imports, however, can benefit through lower subsidised food prices. As of 2018, despite almost two decades of discussion, WTO members have failed to agree on measures that would allow countries to subsidise or stockpile food for purposes of food security.

There are other WTO agreements that can have indirect impacts on health. The Agreement on Trade-Related Investment Measures (TRIMS), for example, prohibits government actions that place domestic purchase requirements on foreign investment. Although such requirements can increase domestic employment, which can be important to improving population health, they can also lead to 'crony capitalism', in which investors are required to finance companies owned by politicians or their families of little or no health benefit to the majority of the population. More controversial than TRIMS, however, are agreements containing ISDS provisions, discussed later in this chapter. Another WTO agreement with indirect health implications is the Agreement on Government Procurement (AGP). The AGP is presently a 'plurilateral' treaty, meaning it is optional for the member states. To date, 47 WTO member countries are party to this agreement with another 20 planning to accede [12]. The AGP opens bids on government contracts to providers from other countries that are party to the treaty. This can lead to lower public costs for goods or services tendered under the AGP, but payments to foreign providers also reduce the amount of capital that remains within the country, functioning as a fiscal multiplier.[4]

2.5 Health in Dispute

One of the innovations of the WTO system, largely exported to newer FTAs, is the establishment of binding rules for resolving trade disputes. WTO members can challenge new measures undertaken by another member if they think it might violate trade rules, including new public health or environmental protection measures proposed by the member states. Challenges are often informal, expressed during WTO committee meet-

ings (such as the Committees on the TBT and SPS agreements) and resolved before becoming a formal dispute. Informal challenges, however, can lead to weaker government measures or delay their implementation and are often indications of potential formal disputes [14–16]. Formal disputes, of which there have been 500 since the WTO's founding in 1995, are heard by an ad hoc panel of three to five trade lawyers mutually agreed upon by the disputants. Panel rulings can be appealed to an Appellate Body consisting of seven members serving fixed four-year terms. The Appellate Body has the power to uphold, modify or reverse a dispute panel decision. If the violating country does not comply with the final ruling, the complainant country can request retaliatory measures equivalent to the estimated value of trade losses due to the violation.[5]

Notably, WTO agreements allow exceptions for non-discriminatory measures that might otherwise violate trade rules, if such measures are found to be 'necessary to protect human, animal or plant life or health' (such as the 'general exception' in GATT 1994 Article XX(b)).[6] These exceptions can be invoked by countries facing a formal trade challenge, but there are three criteria that must be met in order for an exception to apply to a health measure:

1. The policy goal must be designed specifically to protect health.
2. It must be legitimate, the measure in question must be applied to the goal and it cannot be more trade restrictive than necessary.
3. The measure must not constitute a 'disguised restriction on international trade'.

The main challenge faced by new health and environmental regulations has been passing the second or so-called necessity test. A 2014 study of 32 formal disputes where the health exception has been considered found that in 18 cases the measure under dispute was deemed to fail this test [18]. Only one regulation, the French ban on Canadian asbestos, has cleared all three hurdles, although the dispute between Brazil and the European Commission (EC) over retread tyres suggests that WTO dispute panels and the Appellate Body are taking health issues into serious consideration. Both cases are summarised below. More recently, Australia's tobacco plain packaging laws, which dispute panellists ruled were necessary to achieve the government's health policy objective, cleared the TBT hurdles. Two other past cases, however, Samoa's ban on turkey tail imports and Thailand's efforts to put warning labels on alcohol containers, however, indicate how trade rules can limit governments' regulatory policy space with negative health impacts.

2.5.1 Asbestos Versus Glass Fibres

An early WTO dispute (1998–2001) involving a French (EU member) ban on imports of asbestos from Canada is one of the few clear-cut cases in which health concerns predominated over trade treaty obligations. France had been a major importer of Canadian chrysotile asbestos, but concerns over its health risks led the country, along with other EU member states, to ban most uses of asbestos in 1991, leading to the French ban on asbestos imports. Canada argued that such a ban violated non-discrimination rules under both GATT 1994 and TBT rules since asbestos was 'like' the glass fibres permitted for insulation use in France and the rest of the EU. The dispute panel agreed with Canada on this point, further ruling that asbestos health risks (known to be much greater than those posed by glass fibres) should not be a concern when comparing 'like' products. However, given the known health risks of asbestos, the panel did find that the GATT 1994 health exception was justified; the French ban passed the necessity test and was not considered to be a 'disguised restriction on international trade'. Canada appealed the ruling to the Appellate Body, arguing that asbestos health risks were sufficiently minimal and that the ban should have failed the necessity test [19]. The Appellate Body disagreed and supported the dispute ruling, upholding the ban. It also ruled that the panel erred in finding that different health risks of 'like' products should not be a consideration in a trade dispute [20], creating more space for future health arguments in trade disputes. Although past dispute rulings are not binding, they are normative and are often cited by disputing parties in support of their arguments and by Appellate Body reports in their final rulings.

2.5.2 Brazil's Retread Tyres

In June 2007, Brazil both won and lost a WTO challenge initiated by the EC on behalf of the EU over Brazil's import restrictions on used and retread tyres. Brazil maintained that imports of these tyres, with their shorter life spans, accelerated the accumulation of discarded tyres. These tyre piles created environmental damage. They also allowed water to pool creating breeding grounds for mosquitoes that transmitted diseases such as malaria, dengue and yellow fever. The dispute panel agreed with Brazil, finding that the policy goal (reduce the amount of used tyre stockpiles) was both legitimate and necessary. It also noted that, although there were

other means to avoid the environmental and health risks of accumulating tyres, these means were beyond the country's resources to implement. But both the dispute panel and Appellate Body (though for differing reasons) found that the Brazil ban violated the third GATT 1994 XX(b) hurdle (non-discrimination) since imports of used tyres were entering the country through other means. At issue was a regional trade agreement (MERCOSUR) between Brazil and its neighbouring countries, under which Brazil was required to allow imports of small quantities of a specific form of used tyres (remoulded tyres) from its regional trading partners [21]. The Appellate Body ruled that this constituted unjustifiable discrimination [22], although it did note that if, and when, an import ban on all used or retread tyres was enacted, the EU tyre ban would be fully compliant with trade rules. This suggests that even if justified as necessary to protect health, certain measures will fail if there is any evidence of discrimination that favours some WTO member states (in this instance countries that were also part of the MERCOSUR agreement) over others (EU member states).

2.5.3 Turkey Tails and Health in the Pacific Islands

In 2007, the Samoan government banned the import of turkey tails (a low quality, high-fat meat product) out of concern with rising rates of non-communicable disease associated with consumption of such products [23]. When Samoa applied to join the WTO, the working party reviewing its application expressed concern over the necessity of the ban, questioning its effectiveness compared to other less trade restrictive options that might lower the risk of obesity. The working party also complained that the ban was discriminatory insofar as it targeted a single imported food item while other high-fat foods remained available in the country [24]. To move forward on its membership application, Samoa agreed to remove its ban within 12 months of joining the WTO. To give it time to launch education campaigns promoting healthier lifestyle choices, it would be allowed to ban domestic sales of turkey tails for two years and apply a tariff of 300% for a further two years, after which time, the tariff had to be reduced to no more than 100% [25]. The government was also advised to adopt a series of measures to replace the ban (health education programmes, subsidies for healthier foods and use of non-discriminatory excise taxes) that would be compliant with trade rules. These measures may be helpful over the longer term, but individual consumer choices are often dictated more by

product cost, availability and promotion than by health knowledge or its lack. Excise taxes that use price hikes to discourage consumption of unhealthy commodities are unlikely to violate trade rules, but could still be (and have been) challenged for being a disguised restriction on trade.[7] Faced with a continuing rise in diabetes, high blood pressure and heart diseases, Samoa in 2018 introduced a bill to increase modestly both import and excise taxes on turkey tails [27], a decision which could make it vulnerable to a future trade challenge.

2.5.4 Alcohol Product Labelling

Given mounting evidence about the burden of disease, injury and premature death associated with alcohol consumption, the WHO recommends that member countries label alcohol containers to warn consumers about the harms of alcohol consumption [28]. Few countries have yet introduced mandatory health warnings on alcohol containers [28, 29]. As required by WTO rules, Thailand notified the TBT Committee of its intention to introduce mandatory alcohol health warnings in January 2010. Thailand planned to prohibit wording that would mislead consumers and mandate text and graphic warnings on all alcoholic beverage packages (with specific requirements as to colour, size and rotation of warnings) [30]. Concerns were subsequently expressed at the TBT Committee by several WTO members [30]—with particularly strong opposition expressed by major alcohol exporting members Australia, the EU, New Zealand and the USA [31]. Even before Thailand notified the TBT Committee of its proposal, the alcohol industry in the USA had raised objections about the size and graphic nature of the warnings, questioning the evidence base underpinning the proposal [32]. WTO members objecting to Thailand's proposal argued that it was more trade restrictive than necessary, another instance of a challenge under the 'necessity' test, and urged health education programmes instead. There was also concern that there was insufficient evidence that the labelling policy would achieve its stated health goal, which *de facto* chills new regulatory measures since, by definition, these would need to be implemented first in order to create an evidence base. As of late 2018, Thailand's proposed health warnings have not been implemented.

These four cases suggest that, although health is given consideration in WTO disputes and challenges, including greater attention to prevailing public health norms such as the World Health Organization Framework Convention on Tobacco Control [33], WTO rulings remain based on

arguments over whether health regulations impede or violate trade rules and not on whether liberalised trade contributes to improved health. Instead, the assumption is that liberalised trade, by 'raising living standards' through greater economic growth, will indirectly benefit health. Free trade agreements are routinely defended as being essential for economic growth and creating 'win/win' outcomes for all countries concerned, but how robust is the evidence for such claims?

2.6 Trickle-Down Health or Trickle-Up Wealth?

> With one simple policy—more free trade—we could make the world $500 trillion better off and lift 160 m people out of extreme poverty. If there is one question we have to ask ourselves, it is: why don't we? [34, para 1]

The quote above, from the controversial Danish climate change sceptic, Bjorn Lomborg, contends that economic growth through free trade is the only way to reduce extreme poverty and to combat such global health scourges as HIV/AIDS, malaria and malnutrition. While few free trade advocates hold to such extreme estimates, the dominant pro-trade argument is that liberalisation leads to growth, which generates new wealth that reduces poverty, the single greatest risk condition for poor health. Trade-generated wealth, in turn, can be taxed for investments in human capital (health, education and gender empowerment) creating more skilled workers stimulating ever more growth [35, 36]. Although a compelling narrative, the evidence for this 'virtuous circle' is mixed, to say the least.

Most econometric studies find that trade liberalisation is associated with better growth, although this positive relationship 'is neither automatically guaranteed nor universally observable' [37]. A similar conclusion was reached by an earlier World Bank review of trade's impact on growth in which 'half of the countries [studied] experienced zero or even negative changes in growth post-liberalisation' [38]. A later Organisation for Economic Co-operation and Development (OECD) paper further concluded that 'most empirical studies have failed to establish a systematic relationship between…trade liberalisation and economic growth' [39, p. 13] with persisting doubts about the direction of causality (does liberalisation lead to growth, or does growth lead to liberalisation?). The latest study on this topic focused on the G20 countries, finding that increased trade was associated with modest economic growth in 5 of the 20 nations and the reverse true for only 2 of the group, reinforcing the lack of any

consistent relationship [40]. Even as the prevailing opinion is that open economies grow more rapidly than closed ones [41], the outcome will depend on how well governments manage their integration into a global economy [42]. Whether low-income countries have the capacities for such management is a moot point. A 2008 economic analysis of four different scenarios of a (still incomplete) WTO Doha Development Round of negotiations (so named as it was intended to produce disproportionate gains to developing countries) presents an even starker picture. The world's poorest countries (Bangladesh, East Africa and sub-Saharan Africa) would all lose in income gains, while the group of already high-income countries (Japan, the EU, the USA and the recently industrialised Asian economies) would be the winners [43]. These findings may not negate the potential for trade liberalisation to improve economic growth, but they do question the assumed inevitability of the dominant narrative.

A similar caveat surrounds claims of trade and growth's impacts on poverty reduction. Although extreme poverty rates have fallen substantially over the past 40 years, most of this decline is attributable to one country (China) where much of its poverty reduction occurred before it opened itself to global trade and investment. Removing China from the calculations, the global headcount of extreme poverty actually increased in the 1980s and 1990s, attributed in large part to World Bank and IMF structural adjustment programmes that prematurely opened developing economies to global competition [13]. In 2010 the number of people living in extreme poverty was the same as in 1981: over 1 billion people [44]. As one senior World Bank development economist concluded, 'It is hard to maintain the view that expanding external trade is…a powerful force for poverty reduction in developing countries' [45]. At the same time, other studies were finding that trade liberalisation was associated with rising income inequalities within nations [46]. Globally, most of the increases in income since the 1980s have been captured by the '1 percent', leading to wealth inequalities not seen since the early 1900s [47]. In relative terms, international trade and outsourcing has led to greater income gains for people around the median of global income distribution, primarily in developing countries. At the same time, global trade and technology change have combined to stagnate income gains for all but the top 10% in most Anglo-American and European countries [48, 49], with wealth gains rising most rapidly for the top 0.01%. In absolute terms, global inequality (as measured by the Gini coefficient) since 1988 has increased by almost 30% [50].

How well has global health fared over this same period? Few studies have attempted to answer this question directly. A 2016 systematic review of quantitative trade and health studies identified only 16 that met review criteria. Nine were considered 'high quality' in terms of research methods [51] and, on average, suggest that health improves with increased international trade and foreign direct investment. The causal direction of the relationship, however, remains unclear and there were some contrary findings, especially for low-income countries. One of the higher-quality studies, which used a large country sample, attributed its positive health findings to knowledge and technology exchanges between rich developed and poor developing nations (including development assistance transfers) rather than to economic growth *per se* [52]. It also suggested that, independent of increases in trade volumes, the positive health outcomes, which applied only to LMICs, were likely due to economic policies adopted by these countries that in themselves are associated with better health. None of these studies focused on the impact of specific trade agreements on health or social determining pathways to health. Those that have studied the health impacts of trade agreements (rather than aggregate trade or investment flows) have focused more on specific commodities, diseases or health-related pathways and are discussed in subsequent chapters.

2.7 Enter the 'Spaghetti Bowl'

The equivocal findings about the impacts of liberalised trade and investment on economic growth, poverty reduction and health outcomes have not dented countries' interests in continuing to pursue broader and deeper liberalisation commitments. The main platform for continuing negotiations was to have been the WTO, which convenes Ministerial-level meetings every two years, where trade ministers or heads of state gather to finalise new treaties or treaty measures reached by negotiating committees. There have been 11 such meetings since the WTO's founding in 1995, but with little progress made on new agreements. Observers attribute the moribund state of WTO negotiations to the disproportional gains made by high-income countries in the 1995 agreements and push-back by blocs of developing countries critical of lack of attention to unfulfilled promises on issues of importance to them (e.g. on agricultural subsidies, food security and special and differential treatment). The latest Doha Development Round, which started in 2001, remains unfinished with many high-income countries arguing that it should be declared 'over'

and that the WTO is about trade, not development. Developing countries, led by India, counter that this would be a mockery of the WTO's founding principles (the Marrakesh Agreement) [53]. As early as 1999, however, the USA and EU began to prioritise bilateral and regional FTAs in which their larger economies could allow them to more easily dominate negotiations with poorer nations or to more rapidly conclude deals with other upper-middle- or high-income countries. This has resulted in what is described as a 'spaghetti bowl' of overlapping trade agreements [54], adding to the challenge of government regulators to assess the implications of new measures vis-à-vis the multiplicity of differing trade or investment obligations.

Bilateral and regional free trade treaties often import provisions from existing WTO agreements, but they also introduce new elements in these agreements and extend certain liberalisation commitments (or in the case of TRIPS, intellectual property protection) that are 'WTO-Plus'. Strategically, over time these WTO-Plus FTAs could become so numerous that WTO members would be pressured to adopt them within the multilateral system, allowing powerful countries to obtain what they want but could not achieve under the more complex politics of multilateral WTO negotiations [55]. Six FTAs figure quite prominently in current and recent trade negotiations:

- The *Trans-Pacific Partnership agreement* was the first 'mega-regional' FTA to be concluded and signed, originally involving 12 countries that accounted for over 40% of the global economy. US withdrawal from the agreement in 2017 before it entered into force rendered it technically dead, but it quickly became a 'zombie' treaty with the 11 remaining countries resurrecting it as a re-branded *Comprehensive and Progressive Agreement for Trans-Pacific Partnership*. It incorporates almost all of the originally signed treaty, apart from some of its more contentious provisions (many of which pertain to intellectual property rights) being temporarily suspended. The current (Trump) administration has hinted that the USA may rejoin the CPTPP at a later date if it is amended to reflect 'America First' interests. In the meanwhile, several other Pacific Rim nations have indicated a desire to join the CPTPP. The CPTPP has been signed and ratified by seven countries at the time of writing. It came into force for the first group of countries to ratify the agreement on 30 December 2018.

- The *North American Free Trade Agreement (NAFTA)* between the USA, Canada and Mexico is the oldest regional FTA, originally signed in 1994. NAFTA was ground-breaking in many respects: it introduced intellectual property rules that formed the basis for the WTO TRIPS agreement and was the first regional FTA to include an investment chapter allowing foreign investors to sue governments over policies and regulations that they thought damaged the value of their investment. NAFTA was renegotiated in late 2018 as the *United States-Mexico-Canada Agreement (USMCA)* and incorporated many of the provisions in the TPP from which the USA had withdrawn, but in which Canada and Mexico were still members (in the form of the CPTPP). The USMCA, however, included more stringent IPRs favourable to US interests, which are discussed in Chap. 3. It eliminated ISDS between the USA and Canada and significantly narrowed the scope of ISDS between the USA and Mexico, seen by critics of these ISDS rules as a progressive shift in trade policy. The new agreement, yet to be ratified, permits new investor disputes ('legacy claims') to be initiated for up to three years under the old NAFTA rules.
- The *Comprehensive Economic and Trade Agreement (CETA)* between Canada and the European Union, is widely seen as the template for an eventual US/EU Transatlantic Trade and Investment Partnership (TTIP) accord, on hold since 2017 but with the USA reportedly poised to recommence negotiations. Most of CETA's provisions are provisionally in force, including its TRIPS-Plus IPR rules described in the next chapter. Its contentious investment chapter remains 'on hold' since EU law requires that it be individually ratified by all 28 European parliaments. The European Court of Justice in April 2019 completed its review of CETA's proposed 'Investment Court System' (ICS) to determine if it is consistent with European law, deciding that it was. The ICS and investment rules in CETA still requires ratification by the European member states before this provision enters into force [56].
- The *Regional Comprehensive Economic Partnership (RCEP)*, under negotiation since 2012, originally involved 16 countries in the Asia-Pacific region, including the Association of Southeast Asian Nations (ASEAN) members and the six countries that have existing trade agreements with ASEAN (Australia, China, India, Japan, the Republic of Korea and New Zealand). India withdrew from negotiations in 2019, although whether it may return remains moot. Often portrayed as com-

petition to the more American-centric original TPP, the RCEP began as an 'ASEAN-centred' trade agreement that was intended to reflect the diverse needs of its member states, which include a significant number of LMICs. Over time, however, the RCEP has reportedly grown to more closely resemble the CPTPP, largely due to the overlap between the CPTPP and RCEP membership (seven of the countries negotiating RCEP are also members of the CPTPP).

- The *Pacific Agreement on Closer Economic Relations (PACER) Plus* was finalised in 2017 by Australia, New Zealand and Several Pacific island countries (PICs) after almost eight years of negotiations. Papua New Guinea and Fiji, the two largest Pacific island economies, were initially involved but withdrew from negotiations prior to their conclusion. PACER Plus involves a large number of small island states (many of which are geographically isolated, heavily reliant on tariffs and development assistance as sources of government revenue and have little to export) along with two high-income countries (Australia and New Zealand) which provide aid funding in the region but which are also headquarters to businesses seeking access to Pacific island markets. The agreement, which has not yet come into force, aims to liberalise trade in services and investment as well as goods, with many obligations at a similar level to those in the WTO agreements—markedly deepening liberalisation for those PICs which are not yet WTO members.
- The *Trade in Services Agreement (TiSA)* is a proposed plurilateral agreement covering trade in services, currently involving 50 mostly high- or middle-income WTO member states. Negotiations were initiated in 2013 by a handful of HICs responsible for over half of all global services trade [57] (primarily the USA, the EU and Australia) and which were unhappy with lack of progress in further liberalisation commitments under the WTO GATS. Services now account for 60–70% of a country's economic activity and GATS-type or GATS-Plus chapters are now routine in post-WTO FTAs. Leaked drafts show that the now-stalled TiSA is a complex agreement that applies to all sectors except those which governments explicitly exclude, and includes multiple annexes, all intended to create an ambitious treaty that could pose risks to public services, especially if governments choose to rescind privatisation experiments that prove to be too costly or inequitable [58].

2.8 Investor-State Dispute Settlement Rules: Empowering Investors (Corporations) at the Expense of Governments?

WTO agreements do have some provisions regarding investment: the TRIMS agreement (mentioned earlier) and Mode 3 (commercial presence) of the GATS (see Chap. 3). Both treaties are relatively weak in terms of investor protection and neither allow investors to sue governments directly in international tribunals. Until investor rights were incorporated within regional FTAs (starting with NAFTA), they were found primarily in bilateral investment treaties (BITs) signed between two countries. Since 1959, over 3300 BITs have been ratified, of which 2500 remain in force [59] and new BITs continue to be signed each year in addition to investment chapters in FTAs. There were two premises underlying earlier BITs: (1) developing countries need foreign investment to grow their economies for any of the possible trickle-down growth and health benefits; and (2) in the decolonising bipolar world of the 1960s through 1980s, there was a risk that governments might nationalise foreign-invested assets (direct expropriation, with or without compensation) and that their judicial systems could be prone to 'regulatory capture' by political interests denying investors just settlement [60]. BITs internationalised these disputes by passing them on to independent arbitration panels consisting of three trade/investment lawyers, one chosen by the investor, another chosen by the government and a third mutually agreed upon by the other two to chair the panel.

In more recent decades, the text of investment treaties has become more complex, including 'indirect expropriation' (the loss of investment value due to legal, policy or regulatory changes governments make subsequent to the initial investment[8]), the inclusion of IPRs as an investment (hence liable to claims of lost value due to policies restricting monopoly rights over drugs or other important health technologies) and use of 'fair and equitable treatment' (FET) as a basis for challenging government measures. FET is often expansively worded and the most likely provision to be used by an investor claiming damages against a state. Initially few, the number of disputes rose dramatically over the 1990s, partly encouraged by trade and investment lawyers who earn considerable fees for their tribunal work [62]. As well, the emphasis has shifted from direct to indirect expropriation and from disputes initiated by investors in HICs against those in LMICs to disputes increasingly involving governments of HICs

[63]. The value of compensation being awarded to investors (usually corporations) now averages over 540 million USD, with some settlements topping the 1 billion USD mark [63]. Most disputes have been over investments in extractive industries, although these often have indirect health impacts. A 2013 review of 196 ISDS claims found that 40 cases involved health or environmental protection, including food safety, pharmaceuticals and tobacco control measures [64].

The existing tribunal system has been frequently criticised for its lack of transparency or appeal process and interest conflicts amongst arbitrators whose substantial fees could lead to biases in favour of investors in order to attract future tribunal appointments [64]. Governments never win, they only do not lose and often have to shoulder considerable legal expenses defending the policies that are being challenged. Several rulings have evoked considerable controversy, including a still ongoing NAFTA dispute concerning an environmental impact assessment that closed down a previously approved quarry development by a US company (Box 2.2).

Box 2.2 *Bilcon* Versus Canada

In March 2015, a NAFTA tribunal ruled that an environmental review undertaken jointly by two levels of Canadian government violated investment protection rules. Bilcon, a US company, wanted to build a large quarry to mine and crush basalt and a marine dock from which to ship the basalt to the USA. Both the quarry and the dock were located in environmentally sensitive areas in the Eastern Canadian province of Nova Scotia. In 2007, following extensive studies and community consultations, the Joint Review Panel (JRP) recommended against the proposal and the permits for the development were cancelled. Bilcon sued under NAFTA rules, arguing that the province initially had encouraged its investment, the lengthy review panel was unwarranted, and community concerns ('core values') should not have been considered within the review. Since other 'like' quarry proposals did not have to address community core values the cancellation also violated national treatment rules [65]. Two of the three tribunal members sided with Bilcon and ruled that the environmental decision frustrated the investor's 'legitimate expectations', thereby violating NAFTA's FET obligation (despite such wording not actually appearing in NAFTA). The third

tribunal member strongly disagreed with the two other tribunalists, arguing that the decision 'will create a chill on the operation of environmental review panels' [66] but in ISDS tribunals majority decisions are binding. The investor is seeking 443 million USD in damages for lost (future) profits based on the gravel it will no longer be able to extract [67]. The Canadian government attempted to have a federal court to set aside any financial award, arguing that the tribunal had exceeded its jurisdiction by ruling on what were Canadian environmental regulations. The judge hearing the case disagreed and although flagging substantial and unresolved issues regarding NAFTA, foreign investors and environmental policy, the (then current) NAFTA investment rules rendered the tribunal decision within jurisdiction. It is important to note that the financial award being sought is not for actual investment losses, but for potential foregone future profits. This is one of the provisions that more recent efforts at systemic ISDS reforms are attempting to restrict. In 2019, four years after ruling in Bilcon's favour, the NAFTA tribunal unanimously rejected Bilcon's damages claim for 50 years of potential profit from the quarry and awarded it only 7 million USD in 'opportunity lost' costs when it became apparent that the decision to cancel the quarry was not going to be reversed [68]. Environmental groups are concerned that the original tribunal decision still creates a 'regulatory chill' over future environmental protection measures.

Although the USMCA has eliminated the potential for direct investor suits between the USA and Canada (apart from its legacy provisions) and has narrowed the scope of ISDS between the USA and Mexico, it still grants new 'legacy' disputes to be filed within the first three years following the termination of NAFTA, and such disputes can proceed until final settlements are reached. The agreement also permits state-to-state disputes where an investor could lobby its government to initiate a dispute on its behalf. The USMCA also imports a problematic passage from the CPTPP often invoked by governments as protecting the right to regulate:

> Nothing in this Chapter shall be construed to prevent a party from adopting, maintaining or enforcing *any measure otherwise consistent with this Chapter*

> that it considers appropriate to ensure that investment activity in its territory is undertaken in a manner sensitive to environmental, health, safety, or other regulatory objectives. (Article 14.16)

The problem with this passage is that the italicised words essentially negate the claimed regulatory protection since such protection only applies if all other requirements of the investment rules are followed.

This sleight of words remains more problematic for the CPTPP, as it retains many old-style ISDS provisions. Some reforms to the originally proposed wording were made in the final TPP text (and carried over to the CPTPP), including the exclusion of indirect expropriation claims for non-discriminatory regulations for 'legitimate public welfare measures' (including health and environmental protection) 'except in rare circumstances' (CPTPP Annex 9-B). This should afford more regulatory latitude, depending on how tribunals define what 'legitimate' and 'rare circumstances' might mean. The CPTPP also provided for the development of a Code of Conduct in an effort to overcome procedural weakness with the arbitration system, although the Code (finalised in early 2019) is largely a statement of good intent and transparency rather than binding rules that limit arbitrators' roles in future claims (which can create interest conflicts), as does CETA's 'Investment Court System' (ICS), described below [69]. The CPTPP also allows countries to exclude from ISDS any tobacco control measure. During the original TPP negotiations, Australia and New Zealand agreed on a reciprocal side letter which ruled out ISDS by Australian investors against New Zealand and by investors of New Zealand against Australia [70]. Australia is responsible for about 80% of all foreign investment in New Zealand [71].[9] New Zealand, following a change in government and in the transition from TPP to CPTPP, went further and negotiated side letters with five other CPTPP countries (including Australia) excluding or severely restricting use of ISDS rules. Along with two other CPTPP countries (Canada and Chile), New Zealand also issued a 'Joint Declaration on Investor State Dispute Settlement' [72] to clarify the 'right of each party to regulate within its territory to achieve legitimate policy objectives' including health, safety and the environment. The Declaration, however, still defers to the investment chapter and is written in unenforceable language making it more hortatory than binding.

Despite ongoing issues, there is mounting evidence that governments are attempting to reform the expansiveness of earlier ISDS treaties. Following the signing of the CETA, for example, the dispute settlement

rules for ISDS were substantially revised (renegotiated), calling for creation of an 'Investment Court System' (ICS). ICS arbitrators would be appointed on fixed terms with post-term rules to limit their ability to provide legal advice to governments or investors on future claims. Governments can provide binding interpretation notes to tribunals, and a new appeals tribunal could correct what either party views as an incorrect ruling [73]. Reassurances that governments retain the right to regulate for health, environment or other regulatory purposes, however, may be undermined by the standard phrase requiring that such measures be consistent with the investment rules. Canada and the EU are promoting the ICS as an alternative to existing ISDS rules, but not all investment treaty analysts are convinced of its impartiality or necessity.

PACER Plus does not include an investor-state dispute settlement mechanism, which is not surprising given rising global concern about its potential consequences and the low level of economic development of most of the PACER Plus countries. Leaked drafts indicated that some countries had proposed an alternative system of dispute settlement where investors would be able to submit disputes for resolution to the courts or administrative tribunals in the host state, which would consider the investor rights enshrined in the PACER Plus investment chapter [74]. However, this proposal was not included in the final text of PACER Plus, which provided only for state-to-state dispute settlement. RCEP was originally expected to include an ISDS mechanism, but recent reports indicate this may no longer be the case.

Although investor-state disputes will continue (although for how long is unclear), there is momentum building for three differing, and somewhat contradictory, reform options. The first option holds that incremental change in existing rules (much as the CPTPP proposed) would be sufficient. The second option, now favoured by the EU and Canada, is systemic change in which an ICS-styled dispute system becomes a basis for creating, first, a broader plurilateral investment agreement and ultimately a multilateral agreement on investment within the WTO. A multilateral agreement could prevent investors from 'treaty shopping' amongst the thousands still in force to find one they might leverage. But a multilateral treaty would also need to exclude all non-discriminatory government measures related to health, social, fiscal and environmental conditions; allow governments to make counterclaims against foreign investors violating the terms of their investment agreements or the country's labour, human rights and environmental laws or regulations; and allow govern-

ments to require new investments to conform to their country's economic, human and sustainable development goals. Such a paradigmatic, or third option, reform [75] is promoted by some analysts with the United Nations Conference on Trade and Development (UNCTAD), the UN agency that keeps records of investor-state disputes and which provides technical assistance to developing countries on matters related to trade, investment and development [63]. Given that an increasing number of developing countries are notifying their intent to withdraw from (or not renew) investment treaties under the present system (they are not gaining much by way of increased foreign investment and risk losing considerably in disputes) there is considerable pressure for ISDS reform, whether systemic or paradigmatic.

2.9 Conclusion

This chapter identified key liberalisation principles of reduction in tariffs and non-tariff barriers to trade, non-discrimination (national treatment and most favoured nation), and differential treatment for developing countries. These principles were embedded first in the WTO and are found in subsequent bilateral and regional trade agreements. Although the global trade policy environment is dynamic and is driven by shifting economic orientations and geopolitical power shifts (witness the current 'trade war' of escalating tariffs between the USA and China), these trade principles are likely to endure. WTO-Plus agreements, however, build upon these principles by adding deeper liberalisation or intellectual property protection commitments and imposing restrictions on 'behind-the-border' government measures, affecting current and future policy space for public health regulations. Although the controversial use by foreign investors and transnational corporations of ISDS rules continues to pose health risks (particularly where new environmental regulations are challenged) there is increasing evidence of reform measures to mitigate some of these risks. As the cliché expresses, however, 'the devil is in the details' and it is these devilish details that are the subject of our subsequent chapters.

Notes

1. A recession is two successive quarters (six months) of negative economic growth (a decline in GDP/capita). A depression is a recession that lasts a year or longer and is associated with severe economic contraction and high unemployment.

2. In international law, trade agreements are often referred to as treaties, since they are binding agreements. We use both terms interchangeably. Trade rules or measures describe the specific obligations within trade agreements.
3. Progressive liberalisation is often enforced through so-called 'standstill' and 'ratchet' clauses. When a new treaty enters into force, parties to the agreement must not increase any trade barriers existing at the time (their barriers must 'standstill'). If they unilaterally 'ratchet' up their liberalisation by removing a barrier, they cannot reintroduce it at a later time. Not all new agreements have such clauses, or they may contain exceptions to these requirements.
4. Fiscal multiplier refers to the impact on national economic growth that results from government spending. Rather than being a drain on economic growth, much government spending, by creating direct employment or purchasing nationally produced goods and services, contributes to growth. Estimates suggest that for every dollar in government spending (depending on where it is spent), 1.60 dollar in economic growth is stimulated [13].
5. At the time of writing, the Appellate Body's future capacity to resolve disputes between WTO members is in doubt. Since the 2017 US election, the Trump administration has refused to endorse any nominations of new Appellate members to replace those whose terms have expired, arguing that the Appellate Body's interpretations sometimes overstep its 1995 mandate. By mid-December 2019, the Appellate Body will have only one functioning member, where three is the minimum number required to hear an appeal. Since dispute panel rulings do not take effect until appeals are heard and decided upon, blocking new nominations to the Appellate Body would render WTO rules unenforceable unless WTO members agree to no longer appeal a panel ruling, an unlikely outcome.
6. There are other general exceptions under this Article, including measures 'necessary to protect public morals' or 'relating to the conservation of exhaustible natural resources'; [17]. GATT 1994 Article XXI also allows members to restrict trade in goods to protect essential national security interests (in 2018 controversially invoked by the US Trump Administration to justify tariffs on imported steel and aluminium, although this is being challenged under WTO dispute rules). GATT 1994 Article XXIV also allows derogation on the MFN rule in regional trade agreements, allowing parties to those agreements to offer preferential treatment to each other without having to extend such treatment to other WTO members. Members can also temporarily restrict imports to safeguard their external financial position or balance of payments. GATS Article XIV contains the same list of general exceptions, including those for protection of 'human, animal or plant life or health'.
7. The EU, for example, successfully challenged Chile over excise tax reforms for spirits (distilled liquors) based on the alcohol content. Although technically applying equally to all products, the tax rate almost doubled for imported spirits with only slightly higher alcohol content than Chile's domestic product (*pisco*), thereby violating GATT 1994 Article III on national treatment (non-discrimination); see [26].

8. Although claims over indirect expropriation have risen substantially over the past two decades, their success rates have decreased. This leads one researcher to conclude that the use of indirect expropriation claims is in many instances simply 'to deter governments' regulatory ambitions' [61].
9. Three of the five CPTPP countries (Brunei Darussalam, Vietnam and Malaysia) may proceed to ISDS if the investment dispute cannot be diplomatically resolved, and if the countries agree to do so.

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CHAPTER 3

Health Services and Access to Medicines and Other Health Technologies

Abstract This chapter explores the implications of trade agreements for the provision of health services and access to medicines and other health technologies. It first examines the potential effects of the General Agreement on Trade in Services and subsequent bilateral and regional trade agreements on the provision of universal health care and the 'brain drain' of health workers from low-income countries. Next, the intellectual property rights (IPRs) provided for pharmaceuticals by the Agreement on Trade-Related Aspects of Intellectual Property Rights are described, and the way in which these IPRs have been expanded and extended through subsequent bilateral and regional trade agreements elaborated. This chapter also considers other mechanisms through which trade agreements can affect access to health technologies including rules applying to marketing approval processes, pricing and reimbursement and pharmaceutical advertising.

Keywords GATS • Health services • Health workforce • TRIPS • Access to medicines • Pharmaceutical policy

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3.1 Introduction

Chapter 3 examines the implications of trade agreements for the provision of health services and access to affordable medicines and other health technologies. These implications are critically important given contemporary global efforts to expand universal health coverage and improve access to affordable medicines.

Universal health coverage, ensuring that everyone has access to appropriate and timely health care at an affordable cost, is a central priority of World Health Organization (WHO) [1] and seen as key to achieving both Sustainable Development Goal (SDG) 3 and the targets under other SDGs that are relevant to health [2]. SDG Target 3.8 states, 'Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all' [3]. However, despite gradual gains in universal health coverage, at least half of the global population continues to lack access to essential health services and more than 11% incur out of pocket health expenses that exceed 10% of household consumption or income [2]. In 2004, around a third of the world's population lacked access to essential medicines [4]; an estimated 400 million still lacked access to essential health care by 2015 including access to medicines, vaccines, diagnostics and medical devices [5]. Trade liberalisation and the rules included in trade and investment agreements increasingly impact the ability of countries to provide affordable access to essential health services, shaping many of the WHO's 'building blocks' of health systems and the relationships between them [6].

This chapter begins by discussing the potential consequences of trade and investment agreements for health services, focusing on the World Trade Organization's General Agreement on Trade in Services (GATS) and subsequent bilateral and regional trade agreements that build on the GATS. We discuss the principles on which GATS is based, the risks and benefits of liberalising trade in health services and some potential problems and pitfalls countries face in negotiating rules governing trade in health services. It is important to note that trade in services commitments in trade agreements can have a range of other implications for health beyond health services; however, these are not the focus of this chapter and are explored in other chapters.

In the second half of this chapter, we explore the implications of trade and investment agreements for access to medicines and other health

technologies including vaccines and medical devices. We examine the intellectual property rights (IPRs) provided by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the ways in which these IPRs have been expanded and extended through subsequent bilateral and regional trade agreements. We also consider other mechanisms through which trade agreements can affect access to medicines and other technologies.

3.2 Health Services

Trade in services has grown in importance in recent years and now accounts for almost 13% of global gross domestic product (GDP), a figure that has more than doubled since 1975 [7]. Services trade is becoming increasingly important for low- and middle-income countries (LMICs), which made up 20% of services trade by 2003 [8]. Approximately 80% of trade in services takes place within regions and intra-regional South-South trade is becoming increasingly important [8]. Thus, many countries are increasingly looking at ways to streamline and reduce barriers to trade in services.

3.2.1 The General Agreement on Trade in Services

The WTO GATS, which came into force in 1995, was the first (and remains the only) multilateral agreement to liberalise trade in services [9]. Trade in services chapters have since become a standard feature of most bilateral and regional trade agreements. The GATS forms the basis for trade in services chapters in other trade agreements which generally follow the same principles and structure, while often deepening the commitments and expanding them to cover additional sectors and specific types of services.

The purpose of GATS was to increase the transparency and predictability of regulations governing services, to provide a common framework for governing international trade in services and to promote progressive liberalisation of trade in services [9]. The core obligations, in keeping with the axiomatic principles governing trade treaties discussed in earlier chapters, involve the following: market access (e.g. refraining from placing limits on the numbers of suppliers, service transactions and outputs), national treatment (treating foreign and domestic services and service suppliers equally) and most-favoured-nation treatment (treating 'like' services and service

suppliers of one WTO member no less favourably than those of any other country).

GATS comprises a set of general obligations which apply to all members; a set of rules applying to specific sectors; and specific commitments made by each country to provide access to their services markets [9]. This structure means that members have a high degree of flexibility in deciding which sectors and services they will liberalise under GATS and what restrictions and exemptions they want to apply to the commitments they make. Under GATS Article 1, publicly funded services 'supplied in the exercise of governmental authority' (i.e. services that are not supplied on a commercial basis or that do not compete with other suppliers) are excluded; however, there is considerable ambiguity in the scope of the exclusion, since 'services supplied in the exercise of governmental authority' is not explicitly defined and few health systems are devoid of some parallel commercial provision of some health services [10].

Few WTO members committed to liberalising their health sectors under GATS (possibly due, in part, to a political desire to protect the quality and social objectives of health services and space for future policy formulation in the health sector) [10, 11], but many countries have liberalised trade in health services through subsequent agreements. Increasing private sector involvement in health and other social services that have traditionally been funded and provided by governments has accelerated cross-border trade in these types of services [8]. Health services are increasingly being brought within scope due to government worries over increasing demand, technological advances which facilitate cross-border provision and liberalisation of foreign investment in health care financing or provision [10]. Middle-income countries, for example, are seeing opportunities for economic development through health services trade (e.g. foreign investment, skills upgrading and medical tourism) [10].

GATS covers four different modes of supply of services. Mode 1, cross-border supply, involves the remote provision of services by suppliers based in one country to people in another. Mode 2, consumption abroad, involves the movement of people from one country to another to utilise services such as diagnosis or treatment. Commercial presence (Mode 3) is when a service is established in a host country by a foreign service supplier and Mode 4, movement of natural persons, concerns the movement of people from one country to another in order to supply a service.

3.2.2 Benefits and Risks of the Four Modes of Trade in Health Services

Below we discuss the four modes of trade in health services and summarise the benefits and risks of each. It is important to note that the benefits and risks are associated with the type of trade in services and are not the direct result of trade and investment agreements; however, these agreements can exacerbate or add to the risks [12]. The economic and health outcomes of trade in services commitments also depend on the health sectoral context in specific countries and the domestic policy and regulatory environment [12, 13].

Trade in health services via Mode 1 involves the provision of health services (such as diagnostic, consultation and treatment services) from suppliers in one country to consumers in another. This type of service provision across borders has increased with technological developments including e-health and can provide significant economic benefits for countries supplying health services across borders. Under the right conditions, it can facilitate service provision to remote areas in cost-effective ways in recipient countries; however, if not done well, it can divert resources from rural primary health care services accessible to the poor [10, 12].

Mode 2, consumption abroad, in which people travel from one country to another to receive services, can be attractive to low- and middle-income countries due to opportunities to improve the standard of health care and increase investment in health infrastructure and technology [10, 12]. It is also seen by many countries supporting growth in this health care sector as a means of generating revenue and associated benefits from fee-paying foreign patients and related tourism activities undertaken by patients during recovery or by accompanying family members. It can also slow the migration of health professionals to higher-income countries [14–16]. Foreign patients, in turn, may be able to access lower cost and, in some cases, higher-quality services, while avoiding long wait times for services at home and reducing waiting lists for others [16]. But countries providing medical tourism services risk diverting much-needed resources from health services for local citizens or from public to private services which can only be utilised by foreigners and wealthier residents [10, 12, 15]. This can worsen understaffing in public health services, reducing access and equity for those unable to pay for private care [14]. There are potential difficulties in ensuring quality of care, especially in countries with highly privatised health systems, lim-

ited regulatory oversight and a lack of adequate malpractice laws [16]. Communication between health systems and providers in the two countries (source and destination) can be problematic, complicating follow-up care. In cases of sub-standard care or post-operative complications it is often the public system of the foreign patient's home country that is left with the restorative costs [10].

The commercial presence of foreign health service suppliers (Mode 3) can improve the standard of care and variety of services, create jobs, transfer skills and increase investment in infrastructure and technology in recipient countries, and has potential to reduce capital expenditure by governments [10, 12]. However, foreign investment in health services can increase their commercialisation, erode equity and contribute towards a two-tiered health system, as well as causing internal 'brain drain' where skilled health workers gravitate to more highly paid jobs in the private sector [12, 13].

Finally, the temporary movement of health personnel from one country to another (Mode 4) can hold benefits for supplying (exporting or source) countries in terms of remittances and knowledge transfer, as well as meeting the needs of host (importing or destination) countries in addressing health worker shortages and improving cost-effective health service provision [10, 12]. However, the flow of health workers from understaffed and disease-burdened lower-income to better-staffed and less disease-burdened higher-income countries can exacerbate health care access for poorer populations in exporting (source) countries [17–19]. Countries losing their health workers to migration lose not only potential health care services but also indirectly these workers' contributions to the domestic economy and more directly the public costs that have gone towards their professional training [10, 12]. WHO estimated the global needs-based shortage of health professionals at 17.4 million in 2013, with the most significant shortages in Southeast Asia (almost 7 million) and Africa (over 4 million health workers) [20]. In 2010–2011, almost 23% of doctors and 14% of nurses in Organisation for Economic Co-operation and Development (OECD) countries were foreign-born [21]. Although much health worker migration occurs outside of trade treaty rules, the liberalisation of such migration under GATS Mode 4 could become an increasingly important factor in the global dynamics which create and perpetuate international inequities in health worker supply and health care demand [22].

3.2.3 *Health Insurance*

Health insurance is treated somewhat differently to other types of health services in the context of trade and investment agreements, as it is generally classified as a financial service. Some bilateral and regional trade agreements include chapters specifically devoted to trade in financial services, which may incorporate rules from investment chapters: for example, the (now defunct) North American Free Trade Agreement (NAFTA) chapter on Financial Services incorporated provisions on expropriation and compensation and allowed for disputes to be resolved using investor-state dispute settlement (ISDS) [23], as does the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) (see Chap. 2 for an overview of ISDS). While the GATS exclusion for services supplied 'in the exercise of governmental authority' is generally understood to protect existing public health insurance schemes from coverage under financial services rules, these rules have implications for the expansion of public health insurance schemes that are not explicitly 'carved out', where such expansion might adversely affect the interests of private insurers (in cases where foreign investment is involved) [23].

There have been a number of ISDS cases involving health insurance. When the Slovakian government introduced a rule that health insurers must be not-for-profit, an initially successful ISDS claim was brought by a Netherlands insurer and Austrian and Dutch banks that had invested in for-profit insurance companies that were later excluded from the market [24]. Slovakia appealed the award to the Supreme Court of Germany, even as the European Court of Justice found that the tribunal ruling was incompatible with European Union (EU) law; the net effect being that the claim was ultimately denied [25]. These court rulings, however, pertain to intra-EU ISDS claims and may not protect similar claims under investment treaties with non-EU countries.[1]

3.2.4 *The Trade in Services Agreement*

GATS was intended to provide the basis for successive rounds of negotiations through which trade in services would continue to be liberalised. Since 2001, however, negotiations have largely failed to progress. In this context, a group of (predominantly high-income) WTO members commenced negotiations for a large plurilateral agreement, the Trade in Services Agreement (TiSA) in 2013 [26], which was intended to form the

basis for a new multilateral agreement on services which could eventually be incorporated into the WTO [27]. The negotiations have been highly controversial and attracted a large number of public protests, ultimately being put on hold in December 2016 due to changes in the global political environment. It seems likely, however, that TiSA participants are seeking to integrate rules negotiated in the context of TiSA into other bilateral and regional trade agreements they negotiate, in order to pursue alternative avenues for liberalising trade in services.

3.2.5 Potential Problems and Pitfalls in Negotiating Rules for Trade in Health Services

GATS used a 'positive list' approach, where those services being opened up to competition are specifically named, whereas more recently negotiated trade agreements (such as NAFTA, CPTPP and TiSA) tend to use a 'negative list' approach where all sectors, modes and services are covered unless they are explicitly excluded. This introduces a high degree of complexity, raising the risk that negotiators will inadvertently commit services they do not intend to liberalise or fail to anticipate and explicitly exclude future health service developments or reforms.

Liberalisation of trade in health services can bring benefits for both economic development and health; however, this is not automatic, particularly for developing countries which may not be able to take advantage of trade in services agreements with more developed countries due to resource, technology and infrastructure constraints [10]. Developing countries may also lack the regulatory and policy systems and governance structures to deal with the complexities of liberalised markets [28] and the consequences of liberalising services [29] such as shortages and maldistribution of health workers. Therefore, the timing and speed of liberalisation are important as well as the specifics of the commitments made [30].

Binding health service commitments in GATS or another trade agreement cannot easily be reversed. Once a country has privatised all or part of its health sector and opened it up to foreign competition, trade in services commitments can prevent it from bringing these services back into the public system regardless of the outcomes [31]. While withdrawing from a commitment in GATS is theoretically possible, it entails compensating other countries in the form of granting additional concessions in other areas [13, 28]. For these reasons, it may be wiser for countries to

experiment with liberalisation outside of the context of trade and investment agreements.

The benefits and risks of liberalising trade in health services need to be carefully assessed, but negotiations on services schedules can be very complex and the effects of liberalisation difficult to understand and predict [30]. Developing countries often lack the data and technical capacity to make a comprehensive assessment and may be under pressure to liberalise services and at a disadvantage in negotiations with developed countries [30]. The ability to minimise the risks and maximise the benefits of trade in health services can also be compromised by low levels of understanding of trade in health services among health professionals and the absence of their involvement in trade negotiations [31]. At this stage, there is also a paucity of empirical evidence to inform decision making about trade in health services commitments [13]; in fact, there is even little routinely collected data available for systematic comparisons of the amount and types of health services trade [31]. Within countries, the political questions surrounding trade in health services are two-fold: to what extent is health care seen as a public good to be guaranteed by the state; and how well prepared are governments to regulate private provision, infrastructure or financing to avoid the risk of market failures in private health markets?

3.3 Access to Medicines and Other Health Technologies

3.3.1 Intellectual Property

The most significant way in which trade and investment agreements can affect access to medicines is through the protection of intellectual property (IP). Over the last two decades, the expansion of IPRs through trade agreements has powerfully shaped access to medicines globally, particularly in the developing world, where large numbers of people continue to lack access to medicines that those in developed countries largely take for granted.

The forms of intellectual property protection most important for medicines are (1) patents, which provide a monopoly period during which no one else can make or sell the drug and (2) protection of rights to the test data submitted to regulatory agencies to support an application for marketing approval (known as ‘data protection’ or ‘data exclusivity’). Patents

and other types of intellectual property protection provide a monopoly for a period of time that is intended to compensate the company for the investment in research and development (R&D) that is required to bring a new invention to market. The rationale is that this regime is needed to support innovation: that firms will not invest in R&D without the expectation of a substantial period of market exclusivity. However, there is little convincing evidence that IP protection stimulates innovation, particularly of the type that benefits developing countries [32]. Furthermore, lack of transparency around R&D costs results in widely varying claims about the investment required [33], much of the R&D that underpins drug development is supported by public funding [34], and income from sales of high-cost medicines such as cancer treatments far exceeds R&D spending [35]—all of which undermine the industry arguments that monopoly pricing is necessary to stimulate innovation.

3.3.2 The TRIPS Agreement

In 1995, the WTO TRIPS Agreement [36] was created, setting a new minimum global standard for the protection of intellectual property rights. The embedding of IP in the trade agenda of the WTO was the result of intense lobbying by powerful IP-intensive industries, including the pharmaceutical industry [37, 38], in the context of a broader global shift towards neoliberalism which subordinated the more socially-oriented discourses about access to medicines prominent in the 1940s–1970s [39]. The TRIPS Agreement required WTO members to grant patents on products, in all fields of technology, for at least 20 years [40]. Prior to TRIPS, patent law varied widely between countries with many developing countries electing not to grant patents or opting for much shorter patent terms [40].

The TRIPS Agreement provided for certain flexibilities in the interests of public health. It enabled countries to maintain some exclusions to patentability and provided a degree of autonomy for countries to interpret and implement the principles in a manner which achieved a balance between IP protection and public health as long as they met certain minimum standards [41]. Developing countries that were founding members of TRIPS but were not already providing product patents (such as India) were able to delay granting these patents until 2005 (countries that have subsequently acceded to TRIPS have not been given similar transition

periods) [42]. The requirements to provide product patents and protection for pharmaceutical test data were waived for least developed countries (LDCs), initially until 2016, and this was subsequently extended until 2033 [40]. Importantly, TRIPS permitted WTO members to use compulsory licensing or parallel importation to ensure access to medicines, while placing limits on the circumstances in which these tools could be used.[2]

In practice, however, developing countries attempting to use TRIPS flexibilities have faced, and continue to face, a great deal of economic, political and legal pressure [44]. In the late 1990s and early 2000s, it became clear in the context of the HIV/AIDS crisis that patents represented an almost insurmountable barrier to getting HIV treatments to Africa where they were desperately needed but priced far too high [40]. The efforts of the South African Government to provide access to medicines were met by a lawsuit from 39 pharmaceutical companies claiming South African law was not compliant with TRIPS, which sparked a public outcry around the world. An access to medicines campaign spearheaded by an international coalition of non-government organisations (NGOs) and developing countries (described in Chap. 6) resulted in the adoption of the WTO Doha Declaration on the TRIPS Agreement and Public Health in 2001 [45] which re-affirmed that it was legitimate for states to take measures to protect public health [40]. Despite this development, however, the use of TRIPS flexibilities has remained limited. A 2012 study [46] found that governments made efforts to obtain a total of 24 compulsory licences for 22 drugs from January 1995 to June 2011, resulting in the issuance of 12 compulsory licences (i.e. a success rate of 50%), which were mainly confined to upper-middle-income countries. A later study documented 108 attempts to obtain compulsory licences (53% of which were successful) initiated by either government or non-governmental organisations for 40 drugs over the period 1995–2014 [47]. In many cases where these attempts did not lead to a compulsory licence, a discount or voluntary licence was negotiated, suggesting that the threat of issuing a compulsory licence is at least a significant negotiating tool [46, 47]. A study published in 2018 examining the use of TRIPS flexibilities from 2001 to 2016 found that their use was more widespread than previously thought; however, the overwhelming majority of cases were related to HIV medicines [48].

3.3.3 TRIPS-Plus Provisions in Trade Agreements Negotiated Outside the WTO

While TRIPS was arguably a victory for the pharmaceutical industry in establishing a global system of IP rights, the industry was not satisfied and many developed countries also perceived TRIPS as too weak [38]. Since TRIPS, developed countries with substantial pharmaceutical industries have turned their attention to bilateral and regional trade agreements in order to press other countries to further extend and expand IPRs [37, 41]. Contemporary trade agreements negotiated by the USA and the EU tend to include a suite of 'TRIPS-Plus' provisions that utilise a variety of mechanisms to prolong and broaden monopolies, keep generic medicines out of the market and further limit the use of TRIPS flexibilities.

TRIPS-Plus provisions which have now become standard features of trade agreements negotiated by the USA and which serve to delay access to affordable generics include [37, 49]:

- stringent restrictions on compulsory licensing;
- prohibition of parallel importation;
- requirements to expand the scope of what can be patented to include, for example, new uses and methods of using existing products (enabling 'evergreening' of patent monopolies[3]);
- extension of the term of patents beyond the 20-year period required by TRIPS, to compensate for 'unreasonable' delays in granting patents or providing marketing approval;
- data exclusivity provisions that prevent generic companies from relying, for a certain period of time, on the data submitted to regulatory authorities to obtain marketing approval for their drugs[4];
- 'patent linkage' mechanisms that require patent status to be considered as part of the marketing approval process—another source of potential delay to market entry of generics.

3.3.4 Empirical Evidence of the Impact of Trade Agreements on Access to Medicines

Despite a large literature comprised primarily of legal analysis and qualitative case studies that traces the relationship between these mechanisms and delayed market entry of generics, empirical evidence measuring the effects of TRIPS-Plus provisions on access to medicines remains limited,

in large part due to the long time frames which are needed before the effects on prices, expenditure and patient access play out [50]. However, there are some key studies demonstrating the impact of IP provisions (particularly data exclusivity) on medicines expenditure and access in particular countries. For example, a study of the introduction of data exclusivity in Jordan following its WTO accession and the negotiation of the US-Jordan Free Trade Agreement found that this delayed generic market entry for 79% of medicines launched in 2002–2006 and increased medicine prices by 20% during this period [51]. A later study also found an annual increase in total medicines expenditure of 17% during 1999–2004 in Jordan and additional costs of 18 million USD to consumers in 2004 as a result of delays to generic market entry [52]. Similarly, data exclusivity implemented in Guatemala due to a combination of domestic law and provisions in the United States-Dominican Republic-Central America Free Trade Agreement (DR-CAFTA) led to the removal of some generics from the market and prevented others from entering the market, thus impeding access to some generics that were available for sale in the USA [53].

Several other quantitative studies have provided prospective estimates of the expected impact of trade agreement provisions on access to medicines in specific countries. The extension of market exclusivity in Thailand as a result of the (ultimately abandoned) Thai-US Free Trade Agreement was estimated to increase drug expenditure by 6.2 million USD in the first year of implementation, and costs were projected to increase to over 5.2 billion USD in the first decade [54]. A study of several TRIPS-Plus provisions included in the Comprehensive Economic and Trade Agreement (CETA) between Canada and the EU estimated the additional annual cost associated with these provisions at 795–1645 million CAD, an increase of between 6.2% and 12.9% of total annual drug expenditure [55].

Comparative analysis of the effects of trade agreements on access to medicines has proved more problematic. A report based on IMS Institute for Healthcare Informatics data from 2004 to 2013 for 15 countries that had implemented TRIPS-Plus provisions as a result of trade agreements with the USA found no evidence of an impact on pharmaceutical expenditure as a proportion of health expenditure in comparison with countries without US trade treaties or on the use or spending on patented versus generic medicines [56]. This report has been criticised for failing to take into account the time that it takes for medicines to come off-patent before any effect would be likely to be seen [57]. In contrast, logistical regression analysis comparing countries by level of IPR protection has shown that

higher levels of IPRs are associated with lower access to medicines for individuals and with catastrophic expenditure on medicines at the household level [58], as well as with higher national pharmaceutical expenditure [59].

3.3.5 Attempts to Further Expand IPRs Through Large Regional Trade Agreements

Over the last decade, the negotiation of large regional trade agreements involving the USA, such as the Trans-Pacific Partnership (TPP), Transatlantic Trade and Investment Partnership (TTIP), United States-Mexico-Canada Agreement (USMCA) and various EU trade agreements including CETA, have involved further efforts to ratchet up IP provisions in forums where they are likely to set new global norms. The original proposals of the USA for the TPP, for example, included an unprecedented set of TRIPS-Plus provisions in an agreement that included several developing countries [41]. The US proposals sought to: require parties to provide patents not only for new uses and new methods of using existing drugs (a standard feature of the US template), but also new forms; prevent them from excluding diagnostic and treatment procedures from patentability; ban the pre-grant opposition of patents by third parties; mandate the provision of patent term extensions; and provide five years of data exclusivity with an additional three years for new indications [41, 60, 61].

The most controversial of the US proposals for the TPP were the provisions for biologic medicines. These are complex drugs produced using biological processes and used to treat serious health conditions such as cancer and autoimmune conditions [62, 63]. They account for a large and growing share of the global pharmaceutical market and of pharmaceutical expenditure [63]. The complexity of biologics means that it is not possible to make identical generic copies; however, follow-on versions known as biosimilars, which have an equivalent effect in the human body, can in many cases be manufactured at a lower cost. Estimates of the potential savings from biosimilars are significant: the RAND Corporation estimates the savings in the USA alone at 54 billion USD over 2017–2026 [64]. In Australia, expenditure on biologics through the taxpayer-funded Pharmaceutical Benefits Scheme and a related scheme for veterans was estimated at more than 2.2 billion AUD in 2015–2016, accounting for over 21% of expenditure; 367–560 million AUD could have been

saved if biosimilars had been available for each of the drugs studied [63]. The USA initially sought 12 years of exclusivity specifically for biologics in the TPP, a demand promoted by its pharmaceutical industry but one that also faced strong resistance from the other parties. During intense negotiations in the final stages, the TPP parties settled on an ambiguous set of provisions that allowed countries a choice between either eight years of data exclusivity or five years of data exclusivity along with additional measures to achieve equivalent outcomes [63]—essentially guaranteeing eight years of exclusivity from the date of marketing approval in either case.

Many of the other US proposals for the TPP were similarly mitigated or removed during the negotiations; however, the other parties eventually accepted, in the context of trade-offs between sectors, a number of TRIPS-Plus provisions that would have significantly constrained access to medicines in the developing country parties [65]. Even in the developed countries, such as Australia and Canada, the final IP provisions of the TPP would have had the effect of further cementing in place existing IP settings, thus limiting the future options for reform [66].

Following the US withdrawal from the TPP, the remaining countries suspended a number of provisions in the reinvigorated Comprehensive and Progressive Agreement for Trans-Pacific Partnership, including many of the TRIPS-Plus IP provisions which had been most unpopular with the other countries. These provisions, however, have not been completely removed and could be reinstated at a later date, by consensus between the parties.

The USMCA, as signed by the USA, Canada and Mexico in November 2018, not only reinstates the full set of TRIPS-Plus IP obligations from the TPP (including those provisions suspended in the CPTPP), but provides for ten years of market exclusivity for biologics (at least two years longer than in the original TPP) [67, 68]. For Canada, this means a relatively incremental increase of two years from its current baseline of eight. The cost of this increase for Canada will depend on the proportion of biologics for which market exclusivity extends beyond the expiry of key patents, as well as the market share that would otherwise be gained by biosimilars—but this could amount to hundreds of millions annually [69, 70]. The change is far more significant in Mexico, where biologics have not been subject to extended market exclusivity to date [67, 68]. For the USA, the USMCA biologics provision will block the efforts by some members of

Congress [71] to speed up the introduction of biosimilars by reducing the market exclusivity period from 12 years to 7. At time of writing it is not clear if the extended provisions for biologics in the USMCA will be approved by the US Congress [72], with the possibility that they will be rolled back by mutual agreement of all three parties.

The push for TRIPS-Plus provisions is no longer confined to trade agreements negotiated by the USA and EU, as shown by leaked documents from the negotiations for the Regional Comprehensive Economic Partnership (RCEP), which indicated that Japan and South Korea were both seeking TRIPS-Plus IPRs in an agreement that included several LMICs, three of which are least developed countries, as well as India, which produces a substantial proportion of the generic medicines used in developing countries [73]. The emerging role of countries like Japan and South Korea in advocating for TRIPS-Plus IPRs is likely due in part to the increasingly global distribution of the research-based pharmaceutical industry beyond the traditional hubs of the USA and EU [73]. The transnational pharmaceutical industry also has a sophisticated global strategy whereby subsidiaries located in different countries, along with industry associations, lobby governments heavily around these issues [74]. While the TRIPS-Plus IPRs are unlikely to remain in the final text of the RCEP due to the dynamics of this ASEAN-centric agreement, their appearance in negotiating documents suggests the extent to which they have become the global norm.

In recent years, concerns about rising drug costs have escalated, as even developed countries have increasingly struggled to provide access to expensive drugs. This has reinvigorated earlier debates, dating back to the 1970s [39] about finding alternative ways to fund research and development that are not tied to pharmaceutical prices. Considerable discussion has taken place at the WHO and other international forums about various funding mechanisms, including a global treaty for R&D [75, 76]. However, such proposals remain controversial and little agreement has been reached to date on how to move forward. Similarly, efforts to strengthen the use of TRIPS flexibilities and to strengthen WHO's role in supporting states which are facing pressure to adopt TRIPS-Plus measures in bilateral and regional trade agreements have also been highly contentious [77, 78]. Meanwhile, pharmaceutical monopolies continue to be cemented further through trade and investment agreements around the globe.

3.3.6 Other Trade and Investment Rules with Implications for Pharmaceuticals and Access to Medicines

While the debate about trade agreements and access to medicines has largely focused on IPRs, there are a number of other mechanisms by which trade and investment agreements can affect pharmaceutical policy and access to medicines. Most concerning of these is the ISDS process which has been used several times by pharmaceutical companies [41]. The most notable case is an (ultimately unsuccessful) claim brought by US company Eli Lilly and Co against the Canadian Government for approximately 500 million CAD over the revocation of patents for two medicines [79]. There have also been reported cases of regulatory chill with respect to pharmaceutical policy: Colombia's plans to issue a compulsory licence for imatinib (Glivec) were reversed following a notice of dispute filed by Novartis in 2016 and a generic medicine for hepatitis C was de-registered in Ukraine as a result of the threat of investment arbitration [79].

Recent US trade agreements have included provisions targeting pricing and reimbursement programmes for pharmaceuticals and in some cases medical devices, which the US pharmaceutical industry perceives as barriers to trade [41]. The Korea-US Free Trade Agreement (KORUS), for example, includes a chapter with onerous rules requiring South Korea's programmes for subsidising pharmaceuticals and medical devices to, for example, publish proposed regulations and provide opportunities for input, assess applications within a specified period, disclose decision-making criteria and provide an independent review process [41]. A similar US proposal for the TPP was mitigated significantly due to resistance by the other countries [66], but even so would have required the introduction of a statutory timeframe for considering applications and a new review process for New Zealand's Pharmaceutical Management Agency (PHARMAC), changes which were estimated to cost 4.5 million NZD in initial establishment costs and 2.2 million NZD each year in ongoing costs [80]. These costs are quite significant given that PHARMAC reported spending approximately 28.7 million NZD in operating costs in the 2014–2015 financial year [81]. These procedural rules, which could also have constrained the future development of subsidy schemes in the developing country parties, were ultimately suspended in the CPTPP once the USA was no longer part of the picture—however, they have re-emerged in the USMCA [68].

Recent US trade deals have also sought to legalise digital direct-to-consumer advertising (DTCA) of pharmaceuticals in its trading partners

or at least to constrain the policy flexibility of governments to regulate pharmaceutical advertising where it is currently permitted [82]. Concerns have also been raised about a novel annex in the CPTPP and subsequently included in the USMCA, targeting marketing approval processes and pharmaceutical inspections. This annex committed the parties to collaborate on regulatory harmonisation, limited the grounds for marketing approval decisions, included requirements to administer processes in a 'timely, reasonable, objective, transparent and impartial manner' and explicitly permitted parties to keep the findings of pharmaceutical inspections confidential [66]. These types of provisions may lower standards for determining safety and efficacy, introduce safety risks by applying pressure to speed up regulatory processes and place constraints on the public release of information about pharmaceutical inspections [68]. Adding to these concerns, chapters in the CPTPP and USMCA focusing on regulatory harmonisation and the processes for developing regulations also potentially provide additional avenues for the pharmaceutical industry to contest regulatory measures while also making it more difficult for governments to exclude industry from policy-making forums [68].

Finally, the CPTPP and the USMCA also include WTO-Plus disciplines applying to government procurement and state-owned enterprises (which include government-owned generic pharmaceutical companies in some countries). The impact of these types of rules, particularly on the domestic generic industry in developing countries, is unclear and requires further study. However, it is clear that trade and investment agreements are encroaching progressively further into pharmaceutical policy than ever before and via a wider variety of mechanisms.

3.3.7 Vaccines and Medical Devices

The implications of trade and investment agreements for access to vaccines and medical devices have been far less extensively explored in the literature than those for access to medicines, but many of the issues are similar and increasingly significant. Médecins Sans Frontières reported in 2017 that new vaccines such as pneumococcal conjugate vaccines (PCVs) and human papillomavirus (HPV) vaccines were priced so high that one in three countries were unable to introduce PCV and only 65 countries had been able to introduce HPV vaccines by mid-2016 [83]. TRIPS-Plus IPRs which provide for secondary patents and weak patentability criteria allow vaccines to be protected by multiple patents that block or delay competi-

tion—patents covering not just the products themselves but also the developmental processes, different formulations, methods of use and even dosage regimens [83]. Vaccines are biologics, so the biologics rules in the USMCA (and in the CPTPP, if reinvigorated) could affect the time before market competition for new vaccines in the future. Finally, trade secrets protection, provided for in the TRIPS Agreement and strengthened through subsequent FTAs, presents an additional barrier to access, as production processes can be protected as trade secrets, which provides exclusivity that is not time-limited as in the case of a patent [84].

IP rules promulgated via trade agreements are also significant in shaping access to medical devices which include a wide range of products used in the diagnosis, monitoring and treatment of disease (examples include very simple products such as syringes through to more complex technologies such as pacemakers). The TRIPS Agreement allows WTO members to exclude diagnostic, therapeutic and surgical methods from patentability (Article 27.3); however, many countries including the USA now allow patents on devices [85]. Patenting of drug-device combinations has increasingly become a problem in the USA with patents on devices prolonging exclusivity of products such as auto-inject pens for severe allergic reactions long after patents on the actual medicine expire [86]. The USA sought in the TPP negotiations to require its trading partners to allow patents on diagnostic, therapeutic and surgical methods, a move that was resisted by the other countries and ultimately abandoned [85]. However, it appears that the medical device industry has joined the pharmaceutical industry in lobbying for industry-friendly rules: both the CPTPP and USMCA include rules applying to marketing authorisation processes for medical devices similar to those applying to pharmaceuticals (CPTPP Annex 8-E and USMCA Annex 12-F). Both agreements also, in theory, extend the procedural rules for listing products for reimbursement in national formularies to medical devices (CPTPP Annex 26-A and USMCA Chapter 29 Section B), although this appears to be symbolic only, as none of the participating countries have national schemes that are in scope.

3.4 Conclusion

This chapter has demonstrated the multiple ways in which trade and investment agreements can shape access to health services and technologies. Liberalising trade in health services can bring benefits that sup-

port universal access to health care, but also holds risks that need to be carefully considered by countries considering entering into binding, potentially irreversible commitments to liberalise trade in health services through trade agreements. There is currently a lack of evidence to inform decision making and the complexity and ambiguity of trade rules in this area create potential traps, particularly for developing countries. Trade agreements can impact access to pharmaceuticals and other technologies such as vaccines and medical devices via several different mechanisms. The global IP regime, entrenched through the TRIPS Agreement and subsequently expanded through subsequent bilateral and regional trade agreements, serves to delay the market entry of generic and biosimilar medicines and keep prices high for longer periods. Other mechanisms can impact various aspects of pharmaceutical policy including pricing and reimbursement, the assessment of safety and efficacy and efforts to regulate pharmaceutical advertising. Trade and investment agreements also hold a growing range of implications for access to vaccines and medical devices—an area that needs further research.

Notes

1. The ruling by the European Court of Justice (ECJ), since affirmed in a declaration of EU member states, renders inapplicable any investor-state arbitration clauses in international bilateral investment treaties between EU member states. No new intra-EU investment arbitration proceedings can be, or will be, initiated.
2. A compulsory licence allows a third party to make or import a generic version of a drug that is under patent, without the permission of the patent owner [43]. Parallel importation involves importing a patented medicine from another country where it is available at a lower cost.
3. Evergreening involves accumulating additional patents for minor variations on the same product, effectively excluding competitors from the market after the patent on the original product has expired.
4. Generic manufacturers must rely on the test data submitted by the originator company to establish the safety and efficacy of the drug, in order to avoid repeating clinical trials, which would be both expensive and unethical. Data exclusivity therefore causes a delay in the market entry of generics, and is a form of intellectual property which, unlike a patent, cannot be challenged in the courts.

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CHAPTER 4

Commodities Harmful to Health

Abstract This chapter discusses the implications of trade agreements for tobacco, alcohol and ultra-processed foods. For each of these unhealthy commodities, the impact of reducing tariffs and other non-tariff barriers is explored, along with the ways in which trade agreements can reduce the policy space available to governments to address rising rates of non-communicable diseases. Special attention is given to evidence of the impact of tariff reductions on the availability and price of tobacco, alcohol and ultra-processed foods; trade challenges over public health interventions to regulate product marketing and packaging; and the implications of investor-state dispute settlement and the way in which it has been used by the tobacco industry to challenge tobacco control measures. The concept of 'regulatory chill' is also discussed.

Keywords Unhealthy commodities • Tariff and non-tariff barriers • Trade and investment liberalisation • ISDS • Regulatory chill

4.1 Introduction

This chapter examines the implications of trade and investment agreements for commodities harmful to health, focusing on tobacco, alcohol and ultra-processed foods.[1] Consumption of these commodities is linked to three of the four main risk factors for non-communicable diseases

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(NCDs): tobacco consumption, unhealthy diets and harmful use of alcohol. NCDs (including cardiovascular diseases, cancer, diabetes and chronic respiratory diseases) are the main cause of death at the global level [2], accounting for 71% of global mortality in 2016 [3], and disproportionately affect low- and middle-income countries (LMICs).

We begin by summarising the evidence regarding the effects of liberalising trade in tobacco, alcohol and ultra-processed foods, and in associated activities such as production, processing, retailing, marketing and advertising, on the availability and affordability of these commodities and their consumption. This chapter then turns to examining the effects of trade and investment agreements, including the World Trade Organization (WTO) Agreements and bilateral and regional trade agreements, on the policy space available to governments to regulate these commodities. Finally, we discuss ways to improve the coherence between trade policy and measures to address and prevent NCDs.

4.2 Liberalisation of Trade and Investment in Tobacco, Alcohol and Processed Foods

4.2.1 Liberalising Trade and Investment in Tobacco

Trade theory suggests that opening markets increases competition, which results in reduced prices and, as a result, increased consumption [4]. A number of key studies, mainly conducted in the 1990s and early 2000s, demonstrated empirically that liberalising trade in tobacco increases tobacco consumption. Several of these examine the impact of tobacco-related bilateral agreements between the USA and other countries negotiated in the 1980s in order to open markets in Asian countries to US tobacco products [5].

One such study examined the impact of opening cigarette markets to US exports in Japan, Taiwan, South Korea and Thailand, finding that the market share of US cigarettes increased markedly in these countries in comparison with six other Asian countries that were not subject to bilateral agreements with the USA, and that per capita cigarette consumption was almost 10% higher than it would otherwise have been [6]. Other early studies focusing on Taiwan reached similar conclusions, that market opening due to liberalisation agreements combined with pressure from the USA increased tobacco consumption and smoking rates while also

increasing the domestic market share of US tobacco products [7–9]. The uniqueness of these countries—the rapid opening of previously closed markets dominated by state-owned tobacco monopolies, in the absence of counterbalancing tobacco control policies—makes it difficult to generalise these findings more widely [10]. Another early study using data for 42 countries from 1970 to 1995 [5], however, also found that trade liberalisation increased cigarette consumption, particularly in low- and middle-income countries, while a major report for the World Health Organization (WHO) in 2001 demonstrated a link between 'openness to trade and investment' and tobacco consumption [11]. As tobacco control measures began to take hold in LMICs, the impacts of trade liberalisation on consumption patterns became more complex and nuanced [10], with policy measures such as excise taxes having a greater effect on affordability than trade liberalisation [12].

Foreign direct investment (FDI) by transnational tobacco companies (TTCs) in LMICs has similarly been associated with increased consumption of tobacco. In the first decade following the collapse of the Soviet Union, former republics that opened themselves to FDI saw cigarette production almost double compared with an average 11% increase in republics that did not [13]. The same study found a 51% increase in per capita cigarette consumption during this period in countries with tobacco FDI in comparison with a 3% reduction in the other countries studied. Bettcher et al. [11] also demonstrated a link between FDI and cigarette consumption. The extent to which increases in FDI are the result of trade and investment agreements, however, is not clearly established, since investments in foreign tobacco markets by TTCs can take place even in the absence of trade or investment treaties [10].

4.2.2 Liberalising Trade and Investment in Alcohol

Liberalisation of trade in alcohol has increased the availability, affordability and diversity of alcohol products, leading to higher levels of alcohol consumption through similar pathways to those applying to tobacco [14, 15]. While there is limited empirical evidence linking specific trade and investment agreements with increases in alcohol consumption, the pathways can be clearly demonstrated. Reduction or elimination of tariffs generally leads to price reductions, and there is a relationship between price and consumption of alcohol, particularly among younger drinkers [14]. Penetration of transnational alcohol corporations in LMICs tends to be

accompanied by intensive marketing [14]. Exposure to marketing is closely associated with consumption of alcohol, with a correlation between higher levels of exposure and both initiation of drinking and hazardous levels of drinking [16]. Most countries, however, continue to rely on industry self-regulation of marketing, despite increasing evidence that self-regulation is ineffective for reducing exposure in vulnerable population groups [17].

The dismantling of alcohol monopolies through trade liberalisation in countries such as Norway and Finland (where these monopolies were driven by harm reduction objectives rather than profit motives) also created challenges for alcohol regulation [18]. For example, following a 1994 European Free Trade Agreement (EFTA) ruling, Finland removed a ban on advertising of low alcohol products and modified its alcohol taxes and duty-free allowances to compete with much lower-cost vodka, beer and wine available in neighbouring Estonia [19]. Alcohol consumption increased, as did rates of alcohol-related mortality 'concentrated in the worst-off parts of the population' [20]. The EFTA also stripped the former monopoly of its alcohol policy function, leading to an increase in the influence of private commercial interests on alcohol policy [21].

4.2.3 Liberalising Trade and Investment in Food

Liberalisation of food trade and investment has similarly been shown to be a driver of the 'nutrition transition' in LMICs, contributing in turn to rising rates of NCDs [14, 22]. Its effects on food systems have been profound and multidimensional [23]. Trade liberalisation affects multiple points along the food supply chain, which influence the food environment (availability, safety, cost and marketing) and therefore food choices and ultimately diet [24].

Reducing import barriers to trade in foods can increase availability and lower prices [14]; however, the impact on prices depends on 'the dynamics of international and domestic prices' and the impact on total food availability and food security 'depends on whether or not there is a concomitant decline in domestic production, or the amount of domestic production that converts to export crops' [14, p. 5]. The picture is complex: a recent quantitative study of food supply data in Fiji showed that Fiji's WTO accession and associated policy changes increased the importation of both healthy and unhealthy foods [25]. Another study found that trade

openness is associated with decreased malnutrition in Asian countries as food diversity and caloric availability increases [26]. Other studies of import patterns following trade liberalisation episodes, however, show a more significant increase in importation of foods associated with obesity and NCDs, such as meat, refined grains, oils and ultra-processed foods, including snack foods, confectionery and sugar-sweetened beverages [23].

A second pathway through which liberalisation of trade and investment drives changes in food systems involves liberalisation of FDI and trade in services, along with the presence of transnational food corporations (TFCs). Increased FDI has been associated with penetration of ultra-processed food retailers in LMICs, together with processing facilities and advertising and distribution services [23, 27]. For example, a number of studies have demonstrated the expansion of TFCs such as Coca-Cola Indochina, Kentucky Fried Chicken, PepsiCo, Starbucks, Dunkin' Donuts and Baskin-Robbins in Vietnam after it joined the WTO [23].

A further pathway associated with liberalisation of trade in foods involves a shift from subsistence agriculture towards such the production of foods for export, driven by, for example, by export subsidies—this often involves reduced production of staple subsistence crops along with increased production and consumption of meat and other animal products [23].

Several case studies have demonstrated these effects empirically. These include a case study of two decades of trade liberalisation in Central America from the early 1990s [22], which showed that reducing barriers to trade in foods affected food imports and availability through three pathways. First, declining tariffs and other barriers at the border resulted, in most cases in increased availability of imported foods. Trade liberalisation also resulted in increased domestic meat production, and removal of investment barriers and associated increased foreign direct investment resulted in expansion of processed food markets [22]. Similar case studies have also traced the effects of trade liberalisation on food environments and diets in the Pacific islands [28, 29].

In recent years, there have been a number of natural experiments providing more robust evidence of relationships between trade and investment agreements and changes in the import patterns, availability and consumption of unhealthy processed foods [30]. Among these are a study showing a strong association between tariff reductions resulting from the North American Free Trade Agreement and the supply and 'likely consumption' of high-fructose corn syrup in Canada, in the context of an

increase in the supply of caloric sweeteners amounting to 41.6 kilocalories per capita per day [31]. Another study of the impact of the Canada-US FTA over 1978–2006 found an increase in calorie availability of approximately 170 kilocalories per capita per day, leading to an estimated weight gain of 1.8-12.2 kg [32].

Three studies have traced the impact of trade and investment liberalisation on sugar-sweetened beverages (SSBs). The first of these showed a higher growth rate of SSB sales (from 3.3% to 12.1% per capita per year) in Vietnam after its accession to the WTO and associated liberalisation of FDI in comparison with a matched country (the Philippines) [33]. The increase in SSB sales was primarily attributable to multinational rather than domestic companies. A subsequent study comparing Peru and Bolivia concluded that the US-Peru FTA increased FDI in Peru's beverage industry (relative to Bolivia, which did not have an FTA with the USA) and that this increased FDI was associated with an increase in SSB production [34]. The study also found increased diversity of SSBs sold in Peru in comparison with Bolivia, but with potentially both positive and negative effects on nutrition. Limitations associated with the method of this study also make the findings difficult to interpret. A cross-national longitudinal study of 44 LMICs published in the same year found that tariff reduction was associated with increased imports of SSBs, and that there was an association between SSB imports and sales; however, a causative relationship was not able to be established [35].

The most recent review of quantitative studies of the impact of globalisation on nutrition outcomes (primarily through trade liberalisation and increased FDI) found conflicting results [36]. Some studies showed negative health outcomes, others positive (for some population groups), and others a combination of both. The review concludes that FDI is more likely to be associated with 'over nutrition and NCDs' and that, while trade openness 'contributes to shifts in dietary patterns, increasing dietary diversity and availability of cheap calories and fats' (p. 16), in itself it is insufficient to explain increases in obesity and overweight. FDI, food marketing and advertising appear to play a more significant role. Governments, however, are urged to ensure 'nutrition-sensitive trade policy' to avoid the 'constraining impacts of trade agreements on policy space to pursue public health objectives…' (p. 16).

It is that topic we now address, taking each unhealthy commodity in turn.

4.3 The WTO Agreements and Their Implications for Tobacco, Alcohol and Food Policy

4.3.1 Tobacco

Several WTO agreements have implications for tobacco control, particularly the General Agreement on Tariffs and Trade (GATT) 1994, General Agreement on Trade in Services (GATS), Agreement on Technical Barriers to Trade (TBT) and Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Debates over tobacco control occur frequently within the context of the WTO and have become more prominent over time [37]. There have also been some important WTO dispute settlement cases involving tobacco control measures. Developing countries have been dominant players in opposing tobacco control measures at the WTO, partly reflecting domestic economic interests in tobacco leaf production and the influence of tobacco industry lobbying [37]. The arguments made at the WTO closely reflect the rhetoric used by the tobacco industry to oppose tobacco control measures in other contexts [38].

The GATT, which applies to trade barriers applied at the border, has implications for tariffs and other quantitative restrictions on imports and exports of tobacco products [4]. Some disputes have turned on the national treatment rules in the GATT, which prohibit WTO members from treating imported products less favourably than 'like' domestic products. The GATT XX(b) exception (see Chap. 2) can be invoked by a WTO member seeking to implement a tobacco control measure that may otherwise contravene the requirements of the GATT, but it must successfully argue that the measure is necessary to protect human life or health, that there are no reasonably available alternatives that are less trade restrictive, and that the measure is not applied in 'a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries' or a disguised restriction on international trade [4]. The first international trade dispute over a tobacco control measure involved the USA challenging Thailand's ban on imported cigarettes under the GATT in 1990 (pre-WTO). In this case, the GATT panel ruled against the ban, finding that it was discriminatory and could not be justified on health grounds given the availability of less trade restrictive measures such as domestic (excise) taxation [39].

The GATS also has implications for tobacco control measures that affect tobacco marketing, sponsorship, distribution and retail services,

although so far there have been no disputes involving GATS [4]. As in the case of health services (see Chap. 3), states negotiating services commitments in the WTO and other trade treaties have discretion in the commitments they make and can exclude tobacco services. For example, Australia explicitly reserved 'the right to adopt or maintain any measure with respect to wholesale and retail trade services of tobacco products, alcoholic beverages, or firearms' in the Australia-US Free Trade Agreement by listing distribution services for these products as 'non-conforming measures'[2] for the market access obligations of the Cross-Border Trade in Services Chapter [40]. The GATS exception (GATS Article XIV(b)) is also available to WTO members seeking to regulate in these areas.

The WTO agreements which have mostly been at issue in recent challenges over tobacco control measures are TBT and TRIPS. The TBT agreement pertains to mandatory technical regulations that apply to product characteristics, such as packaging and labelling. Apart from re-iterating the principle of non-discrimination (national treatment and most favoured nation, described in Chap. 2), the TBT also obliges members to ensure that technical regulations are not 'more trade restrictive than necessary to fulfil a legitimate objective' including 'protection of human health or safety', while 'taking account of the risks non-fulfilment would create' (Article 2.2) [41]. Members are also required to use relevant international standards, where these exist, as the basis for technical regulations 'except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued…' (Article 2.4) [41].

The TRIPS Agreement is particularly relevant to disputes involving packaging and labelling, as it requires members to provide trademark owners with the exclusive right to prevent third parties from using, in the course of trade, marks that are identical or sufficiently similar that they would be likely to cause confusion (Article 16.1). Importantly, the TRIPS Agreement does not entitle a trademark owner to use a trademark in the course of trade, only excludes the use of the same or very similar trademark by others [4].

There have been several important WTO disputes over tobacco control measures. One of these involved the US ban on flavoured cigarettes, other than menthol or tobacco flavours, in 2009. This prohibition was challenged by Indonesia, which argued, using the GATT and the TBT Agreement, that it discriminated against clove cigarettes (which were almost exclusively imported from Indonesia) in favour of domestically

produced menthol cigarettes, and was more trade restrictive than necessary to protect human health [42]. While the panel rejected Indonesia's arguments that the ban was more trade restrictive than necessary, it found that clove and menthol cigarettes were 'like products' in the US context and that the law treated clove cigarettes less favourably than menthol cigarettes and was, therefore, discriminatory [42]. The panel did not dispute the health arguments in favour of the ban, but because it did not extend to US-manufactured menthol cigarettes it violated the key WTO principle of non-discrimination.[3] The USA appealed the findings regarding discrimination, but the findings were upheld by the Appellate Body [42].

A second important dispute involved the Australian Government's introduction of tobacco plain packaging as part of a comprehensive package of tobacco control measures announced in 2010. The legislation, implemented in December 2012, prohibits logos, brand imagery, colours and other promotional elements or product variant names, and requires packaging to be a standard brown colour [44]. Separate legislation mandated large health warnings on tobacco packaging [45]. Australia's new laws were challenged at the WTO by several tobacco-exporting countries: Cuba, the Dominican Republic, Honduras, Indonesia and Ukraine.[4] The challenges by some countries were supported directly by tobacco companies [48]. Their main arguments were that the plain packaging laws were more trade restrictive than necessary and infringed on the intellectual property rights of tobacco companies, thus breaching Australia's obligations under the TBT and TRIPS agreements and the GATT [48]. Australia countered that there was strong evidence regarding the effectiveness of tobacco plain packaging and that the legislation was a legitimate and appropriate next step in implementing its obligations under the WHO Framework Convention on Tobacco Control (FCTC) [49].[5]

The WTO panel in June 2018 ruled in favour of Australia [50], finding that the plain packaging measures did not breach WTO law: plain packaging was not more trade restrictive than necessary, was supported by evidence as a legitimate measure to protect public health, and no less trade restrictive alternative existed that would achieve the same level of health protection [51]. The panel also rejected arguments that plain packaging infringed on intellectual property rights, finding that it did not represent an 'unjustifiable encumbrance' on the use of trademarks in the course of trade [51]. Important factors in the panel's deliberations included the role of plain packaging as part of an overall package of complementary tobacco control measures, the extensive evidence supporting

plain packaging and the existence of the FCTC, which featured prominently in the panel's report [52]. The panel's decision affirms that well-designed, evidence-based public health measures can be upheld in WTO disputes, although the process was resource-intensive, and required Australia to meet a high bar in terms of evidence of plain packaging effectiveness. Future public health measures may not have the same depth and breadth of evidence, especially concerning unhealthy food commodities (discussed later). Moreover, the plain packaging legal battle continues, with Honduras notifying the Dispute Settlement Body in 2018 that it intends to appeal certain aspects of the panel's determination [53].

4.3.2 Alcohol

Many of the recommended strategies for addressing the global burden of alcohol-related harm can be considered barriers to trade and so are open to challenge under several WTO agreements [14, 15]. These include taxation and pricing policies, such as minimum or volumetric pricing; restrictions on marketing and on the availability of alcohol (e.g. licensing restrictions); and labelling requirements such as health warnings, alcohol content and nutrition labelling.

There is a substantial body of evidence demonstrating that increasing the price of alcoholic beverages through taxation and pricing policies is the most effective strategy for reducing alcohol consumption and its associated harms [54]. Such policies may run afoul of trade rules, and there have been a number of disputes over alcohol taxation and pricing arising from the national treatment provisions of the GATT. In the 1980s and 1990s, Canada faced a number of challenges to its alcohol taxation and pricing practices (including price mark-ups and minimum price requirements) which were perceived to favour domestic products, discriminating against imported alcoholic beverages [18]. Japan, Chile and Korea have also been subject to WTO disputes over differential treatment of imported spirits: Japan was required to open its market to imported spirits; Chile and Korea both had to eliminate differential taxation systems which were ruled as discriminatory [18, 55]. The ruling against Chile appeared to be largely due to its mixed objectives (to protect health, generate revenue and support its domestic lower-alcohol beverage, *pisco*), the last one being clearly trade-discriminatory [15]. Yet, it is frequently the case with public health measures that regulatory motives are mixed, as they often represent political compromises between actors with different aims [56].

Labelling alcohol containers to provide consumers with information about harms related to alcohol is one of the strategies recommended in the WHO's Global Strategy to Reduce the Harmful Use of Alcohol [57], but few countries have yet introduced mandatory alcohol health warning schemes [58]. Alcohol labelling has been a frequent subject of discussion at the WTO, particularly within the TBT Committee. The TBT requires WTO members to notify the WTO Secretariat when a technical regulation is proposed that either differs from an international standard, or where there is no applicable international standard, and where the regulation may affect trade for other WTO members (Article 2.9) [41]. An analysis of the minutes of TBT Committee meetings from 2010 to 2017 found 14 notifications of alcohol labelling measures, including nine proposals to implement health warnings [58], including Thailand's 2010 proposal for pictorial health warnings discussed in Chap. 2. Most objections were raised by major alcoholic beverage exporting nations which favoured industry self-regulatory schemes [58]. Although none of these objections have proceeded to a formal dispute, should this occur a member would have to demonstrate that the measure is designed to meet a legitimate objective, that it is based on sound evidence, and is not more trade restrictive than necessary, given any alternatives that may be available [58]. It is likely that evidence-based health warnings on alcohol containers will not be found to be inconsistent with the TBT Agreement [58, 59], but the relatively weak evidence base at this time creates uncertainties that may deter countries from introducing innovative mandatory measures [60].

To date, there have also been no WTO disputes over alcohol distribution and licensing or restrictions on marketing, and European court findings on challenges to alcohol advertising bans under European trade rules support public health measures that are consistently applied and proportionate to the public health goal—suggesting that such measures would also likely to be upheld in WTO disputes [61].

4.3.3 Food

A large number of the WTO agreements are relevant to trade in food. These include [24]:

- the Agreement on Agriculture (AoA), which requires reduction of tariffs, export subsidies and supports to domestic agricultural production;
- the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), which applies to food safety measures;

- the TBT Agreement, applying to regulations, standards and conformity assessment procedures;
- the TRIPS Agreement, providing IP protection for food and agricultural products (such as seeds); and
- the Agreement on Trade-Related Investment Measures (TRIMs), which provides some protection for foreign investors.

Like alcohol policy measures, nutrition-related public health measures have not been subject to formal WTO disputes in the way that tobacco control measures have. However, nutrition-related measures have frequently been the subject of trade challenges at the TBT Committee. Between 1995 and 2016, 46 regulatory measures for food products and 36 measures applying to beverages (including alcoholic and non-alcoholic beverages and infant formula) were subject to challenge [62]. The types of food-related measures most commonly challenged were labelling regulations, conformity assessment procedures and product standards [62]. Another study specifically focusing on mandatory interpretive nutrition labelling schemes found that five challenges at the TBT Committee had been made by 2015 to measures proposed by Thailand, Chile, Indonesia, Peru and Ecuador, respectively [63]. While members raising these concerns recognised the objectives of nutrition labelling schemes as legitimate, they raised issues around the need to justify the measure, queried whether the measures were more trade restrictive than necessary, questioned the scientific evidence underpinning the measure, suggested alternative less trade restrictive measures and complained about the short time frames for providing comments about the proposed measures [63]. Although lacking the legal finality of a successful formal trade dispute, such challenges at WTO committees can slow down introduction of novel public health regulations or weaken the original requirements [62].

4.4 Bilateral and Regional Trade and Investment Agreements: Implications for Tobacco, Alcohol and Food Policy

Trade and investment agreements negotiated outside of the WTO often include investor-state dispute settlement (ISDS) mechanisms and other a range of other ‘WTO-Plus’ obligations that create additional hurdles and potential obstacles to policy measures to prevent and address NCDs. The

best-known recent cases involved Philip Morris launching ISDS suits against Australia and Uruguay over tobacco plain packaging (Australia) and enlarged warning labels and single brand only packaging (Uruguay). Both disputes were ultimately decided against Philip Morris: on jurisdictional grounds in the case of Australia (the company restructured itself so that a Hong Kong affiliate took over its Australian holding in order to take advantage of an investment treaty between Hong Kong and Australia, ruled an abuse of process by the tribunal); and on the merits of the legal arguments in the case of Uruguay (there was no indirect expropriation of Philip Morris's intellectual property right (IPR) 'branding' nor any loss in investment value sufficient to warrant compensation).[6] These are important rulings that illustrate that international investment law can provide policy space for states to implement public health measures [64, 65] but at a cost. Fifty per cent of Australia's legal bill defending itself eventually had to be repaid by Philip Morris, along with 50% of Australia's share of the arbitration costs, leaving the Australian government to cover approximately 12 million AUD, despite the tribunal ruling that the claim by Philip Morris was an abuse of process [66]. Uruguay could not afford to defend itself and was prepared to change its new tobacco laws, until the Bloomberg Foundation agreed to cover its legal costs [67].[7] In both instances, the mere threat of legal challenge under ISDS rules was sufficient to stall other countries in following suit [68].

To date, alcohol policy measures have not been subject to ISDS disputes, although bilateral and regional trade agreements can pose other risks to alcohol policy measures. New rules specifically applying to alcohol labelling have begun to appear in bilateral and regional trade agreements, beginning with the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), and subsequently incorporated into other trade agreements involving wine and spirits exporting countries. Under these rules, parties must allow wine and spirits importers to use a 'supplementary label' to display mandatory information required by the importing country, rather than requiring that it be incorporated into the principal or standard labelling on the alcohol container [59, 60]. Mandatory health warning schemes that require large health warnings displayed in a prominent place on the container may face challenges under these rules [59, 60]. While such challenges would be unlikely to succeed, the possibility of a challenge could deter parties from experimenting with innovative labelling schemes.

Recent bilateral and regional trade and investment agreements also have the potential to constrain the ability of governments to regulate with respect to nutrition. A prospective policy analysis of the Trans-Pacific Partnership (TPP), undertaken during its negotiation and informed by the published text of the Korea-US Free Trade Agreement (KORUS), identified a number of ways its provisions could limit the implementation of policies to promote healthy diets proposed in the WHO's Global Action Plan for the Prevention and Control of Noncommunicable Diseases (2013–2020) [69]. Many of these concerns were borne out in a subsequent health impact assessment of the TPP's final text [70], largely retained in the CPTPP, a key one limiting country's abilities to exclude vested interests from nutrition policy making. For example, a provision in the TBT Chapter requires parties to allow 'persons of the other Parties' (which could include corporations) to participate in the development of technical regulations, standards and conformity assessment procedures 'on terms no less favourable than those it accords to its own persons' (Article 8.7) [71]. The United States-Mexico-Canada Agreement (USMCA) takes this a step further, requiring a party developing a standard or regulation to 'allow persons of another Party to participate in no less favorable terms than its own persons *in groups or committees of the body that is developing the standard*' (Article 11.7.8, italics added) [72]—essentially granting an equal opportunity for foreign corporations to occupy a formal role in policy development [73].

4.5 Achieving Policy Coherence

The literature suggests a number of ways in which better policy coherence can be achieved between trade and economic objectives and NCD prevention, while preserving regulatory autonomy to regulate unhealthy commodities. These include careful negotiation of treaty text, counterbalancing legal instruments to assist countries to defend policy measures under dispute, and careful design of policy measures to ensure their compliance with trade rules.

4.5.1 Careful Negotiation of Treaty Text

Attention is needed to the specific legal language included in trade and investment agreements, to ensure that there are effective exclusions or

exceptions for health-related policy measures. States can also avoid agreeing to obligations which create potential obstacles to public health policies.

'Exclusions' refer to the complete exclusion of particular regulatory measures from the scope of the treaty as a whole or from certain chapters or provisions. There have been various efforts to exclude or 'carve out' tobacco completely from the scope of trade and investment agreements [74]. One example is the exclusion of both tobacco and alcohol from the scope of the Pacific Island Countries Trade Agreement [75]. A complete 'carve-out' for tobacco was also proposed by Malaysia for the TPP, but ultimately this was not accepted by the other parties and the final text of the TPP, retained in the CPTPP, provides an optional 'carve-out' for tobacco that applies specifically (and only) to ISDS (Article 29.5) [76, 77]. There remains considerable debate about the merits of excluding tobacco specifically, not least due to the potential implications for other public health measures which are not explicitly excluded [76, 78]. Some legal scholars have pointed out that exclusion of tobacco may also be counterproductive for tobacco control in some ways, for example, by enabling continued support (such as subsidies) for domestic tobacco industries [74].

Exceptions, on the other hand, provide language that allows parties to pursue measures that would otherwise breach the agreement's obligations, subject to certain conditions. Where exclusions for public health measures are not feasible, exceptions can assist governments to defend such measures in the case of a dispute. Exceptions do not prevent claims from being made and must be interpreted by a dispute panel or ISDS tribunal in the event of a claim [78]. The GATT XX(b) exceptions are a good example of this.

States can elect not to include ISDS in trade and investment agreements or can limit access to ISDS (e.g. by requiring preliminary consultations between health authorities) [78]. Procedural reforms to ISDS can reduce the risk of a claim being made, and/or reduce the potential harm arising from the use of ISDS [78].

4.5.2 Counterbalancing Legal Instruments

The Framework Convention on Tobacco Control, a legally binding international treaty negotiated under the auspices of the WHO to which 181 countries are parties, has played a very important role in the defence of tobacco control measures in the context of trade and investment disputes,

and challenges in domestic courts. An examination of 96 legal challenges to tobacco control laws (mostly domestic challenges) found that the FCTC was cited in almost half of the decisions [79]. About 80% of decisions citing the FCTC were decided fully in favour of governments, in comparison with 67% of decisions that did not; although this difference may be an artefact of the databases used to source the cases or differences in the documentation of judgements. The FCTC served several important purposes in these cases, demonstrating (1) the legal basis for tobacco control measures; (2) their public health objectives; (3) the underpinning evidence base; (4) the international consensus about the need for the measures; (5) their human rights dimensions and (6) their reasonableness, proportionality and justifiability [79]. An amicus curiae brief[8] was submitted by the WHO and the FCTC secretariat during the WTO dispute over tobacco plain packaging, summarising the public health evidence supporting tobacco plain packaging and its alignment with the provisions of the FCTC [81]. A similar amicus curiae brief was also accepted by the tribunal for the ISDS claim brought against tobacco packaging measures in Uruguay [67].

Given the significance of the FCTC in the trade disputes over tobacco control, there has been considerable interest in developing a similar international legal agreement for alcohol [18, 56] and nutrition [69]. While the FCTC is a binding convention, there are other examples of non-binding instruments which may assist in defending a public health measure in a trade dispute, such as codes, World Health Assembly resolutions and *Codex Alimentarius* standards [69]. Such instruments, even if non-binding, can be useful for demonstrating international consensus around the legitimacy and effectiveness of mandatory public health regulations [61], assisting in the interpretation of treaty provisions, and establishing cooperative institutional arrangements that can assist states during a dispute [82]. However, even binding legal instruments must be framed at the level of principle, while leaving the specific features of implementation up to individual states [83]—which means they can neither prevent trade disputes nor ensure that public health measures will prevail [61]. Whether the defence of a specific regulatory measure will be able to rely on public health exceptions in trade and investment agreements will depend on the specifics of its design and implementation, particularly whether it is 'necessary' to protect health and strikes an appropriate balance in terms of its impact on trade [83].

4.5.3 Careful Design of Public Health Measures

States can minimise the chances of trade and investment disputes, and increase their chances of successfully defending them in the event of a dispute, through careful design of public health measures. This includes the following: taking care not to discriminate against imported products unless there are legitimate reasons to do so, carefully framing the public health objectives of the measure to meet the requirements of the necessity test, ensuring measures are evidence-based, supported by international standards (where possible), and part of a comprehensive multipronged strategy; and ensuring that due process is followed during policy development and implementation [4, 63, 84]. Collaboration between health and trade policy makers and legal specialists early in the process is important to ensure that proposed policy measures are designed in a way that is compliant with trade rules [56, 61, 63].

4.6 Conclusion

This chapter has explored the implications of trade and investment agreements for alcohol, tobacco and ultra-processed foods. Historical evidence suggests that liberalising trade in these commodities has increased their availability, reduced prices and increased consumption in some countries. FDI and penetration of transnational corporations into markets in LMICs, which can be facilitated by trade and investment agreements, has also driven increased consumption of health-harming commodities—although the picture is complex and multifaceted, particularly in the case of food. In recent years, an issue of greater concern has been the potential for trade and investment agreements to constrain the ability of governments to protect public health. Concerns have been raised at the WTO over a range of tobacco, alcohol and food policy measures, particularly those directed at technical regulations (e.g. health warning labels, nutrition information), or restricting the use of trademarks and branding (e.g. tobacco plain packaging). In the case of tobacco control measures, there have also been formal WTO disputes. WTO-Plus rules in bilateral and regional trade and investment agreements outside of the WTO often present further obstacles to policy measures to prevent NCDs, and ISDS has been used to challenge tobacco control policies in Australia and Uruguay. The risk of regulatory chill can be reduced through careful negotiation of legal texts (including well-drafted exceptions and exclusions for health measures),

developing international legal instruments to assist states in defending public health measures in the event of a dispute, and designing public health measures in a way that is compliant with trade rules.

Notes

1. By ultra-processed foods we refer to 'formulations of ingredients, mostly of exclusive industrial use, that result from a series of industrial processes' based on an established NOVA classification system. From a health vantage, a key aspect of such foods is that they generally use a high concentration of sugar, oils and fats and salt [1].
2. As the term implies, a non-conforming measure is one that a party to the treaty, or the treaty itself, excludes from one or more treaty provisions.
3. In November 2018, the US Food and Drug Administration announced its intention to ban menthol cigarettes, the favourite choice of adolescents, as Canada already did and the EU plans on doing by 2020 [43]. Indonesia, however, did not pursue US market access for its clove cigarettes after its win, or seek compensatory retaliation to which the panel ruling entitled it, that is, through raising tariffs on imports from the USA equivalent to the clove cigarette loss. Many LMICs lack the economic and political power to force US compliance on WTO decisions not in their favour, a long-noted weakness in the WTO dispute settlement process.
4. Ukraine was the first country to ask for consultations over Australia's plain packaging measure, but its challenge was suspended in 2015. Ukraine has ratified the FCTC. Its domestic tobacco production has fallen substantially in recent years, and it is not a major exporter [46], although its manufactured cigarettes are claimed to be frequently smuggled into other European countries [47]. These conditions made its challenge at the WTO a puzzle until it was revealed that the challenge was initiated at the prompting of the American Chamber of Commerce [47].
5. The Framework Convention on Tobacco Control (FCTC) is a legally binding international treaty negotiated under the auspices of the WHO to which 181 countries are parties, and commits parties to take action to reduce the prevalence of tobacco use and exposure to tobacco smoke, through measures including restrictions on tobacco packaging, labelling, advertising, promotion and sponsorship [48].
6. Some FTA ISDS rules, such as those in the CPTPP, specify that a loss in the economic value of an investment resulting from a government measures is not sufficient, in itself, to constitute in indirect expropriation, and that 'non-discriminatory regulatory actions by a party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety and

the environment, do not constitute indirect expropriations, except in rare circumstances' (Annex 9-B), although some ambiguity remains (e.g. what is a 'rare circumstance').

7. Uruguay's total costs in defending the claim were 10.3 million USD (PMI was ordered to pay 7 million USD of these costs and 1.5 million USD of the remaining costs for the defence was funded by the Bloomberg Foundation) [67].
8. Relative to trade or investment disputes, amicus curiae (Latin for 'friend of the court') refers to persons or organisations that are not party to a dispute to contribute information and/or legal argument related to the dispute. Panels or tribunals are not bound to use such interventions; as of 2016, 60 briefs have been accepted by WTO panels or the Appellate Body, although only 3 have been referenced in any decision [80].

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CHAPTER 5

Trade, Labour Markets and the Environment

Abstract New trade agreements often include measures promising protection of labour rights and the environment. The section on labour describes how labour rights are said to be protected in such agreements and how (or if) the inclusion of these rights within trade treaties improves labour market outcomes. A key weakness in such provisions is that they become enforceable only if a country lowers its existing labour standards to gain a trade or investment advantage. The section on the environment reaches a similar conclusion. Although having some potential and healthful value, the protections such chapters are said to afford remain secondary to trade concerns. This chapter considers the broader question: are trade treaties the best place in which to locate or enforce labour and environmental protection measures?

Keywords Labour markets and trade • Labour rights • Environmental treaties • Environmental protection • Trade-related labour and environmental disputes

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5.1 Introduction

One of the key arguments made in support of trade and investment liberalisation is that, like the claim that liberalisation will increase economic growth, it will create new jobs. This argument is evident in the founding document that birthed the World Trade Organization (WTO) (the Marrakesh Agreement described in Chap. 2) and its promise of 'ensuring full employment'. This Agreement further argued that there was no contradiction between increased global trade and the goal of 'sustainable development' in use of the world's (increasingly scarce) resources. The results of growth in trade and investment liberalisation, however, have been far off the mark in producing these results, which is one of the reasons for the opposition of labour, environmental and broader civil society movements to such agreements in the post-WTO era. Confronted by citizen complaints, free trade agreements (FTAs) have increasingly begun to incorporate trade and environment chapters in their treaties signalling, perhaps, an awareness of trade's impacts on labour markets and risks to the environment. As we shall argue below, however, the inclusion of such chapters is more frequently a way to appease domestic opposition to new agreements than to substantively protect either labour rights or the environment. We begin first with labour, before turning our attention to the environment.

5.2 Labour Standards

The links between employment opportunities, labour standards and health outcomes have long been recognised in public health literature. Employment provides people with the income essential to obtaining the material goods they need to be healthy. Globally, it is widely considered essential to lifting or keeping people out of poverty or providing them with a sense of social connectedness and stability. At the same time, poor working conditions (e.g. excessive hours, low wages, inadequate health and safety measures, lack of job security) can contribute to ill-health [1, 2]. Changes in global labour markets (and their influence on employment opportunities and labour standards within countries) also have the potential to amplify health disparities through their powerful effects on social stratification, income inequality and differential exposures to work hazards or risks [3]. How global trade affects labour markets and whether trade chapters in FTAs ensure adequate protection for workers'

health are thus important considerations in any health analysis of trade agreements.

At the global level, and contrary to the promises of the Marrakesh Agreement, the post-1980 era of increased global trade has seen a decline in the share of economic product going to labour (i.e. workers), rather than the reverse [4]. Between 1980 and 2010, a period when the contribution of trade to global economic product increased from 39% to 57% [5], the share of economic product accruing to workers dropped from over 62% to under 54%. Studies vary on the extent to which this (ongoing) decline in labour share is caused by technological churning (the replacement of unskilled or semi-skilled labour by technology), outsourcing (the replacement of higher-cost labour in high-income countries (HICs) by lower-cost labour in low- and middle-income countries (LMICs)) or the decline in unionisation rates (reducing labour's bargaining power). There is evidence supporting all three narratives, which are difficult to disentangle and in any case occur concurrently, reinforcing each other to a considerable degree (Box 5.1).

Box 5.1 Trade Liberalisation and Employment: A Win/Win or a Win/Lose?

There is little disagreement in the literature that trade liberalisation creates winners and losers, both between and within countries. The win/win beneficence of trade liberalisation is based largely on an eighteenth-century theory that admonished countries to exchange with one another based on their 'comparative advantage'. To an extent this remains a modern truism, although much international trade today is between different branches of a transnational company, rather than between countries, challenges its broad applicability. This is particularly so given the range of goods and services covered by contemporary trade treaties, making it more difficult for any one country to exercise its 'comparative advantage'. But do trade agreements create more employment, as governments often claim, or do they enhance the ability of transnational companies to outsource production in ways that may benefit employment in countries with lower labour standards? The evidence is mixed. Some modelling exercises of agreements such as the TPP (before it became the CPTPP) estimated a net loss across all countries of over 650,000

jobs [6]; while a separate study of the USA (when it was still part of the agreement) estimated job losses in that country and found that labour income, at least in the USA, would decrease for all but the top 1% [7]. A recent analysis of employment trends in the USA found that at least 135,000 American workers lost their jobs each year between 2003 and 2015, largely in manufacturing, due to changes in international trade dynamics associated with trade treaties [8]. While many found new employment, over two-thirds saw a reduction in their earnings, with 'gross private costs of displaced manufacturing workers' estimated at between 28 and 40 billion USD a year [9].

NAFTA remains one of the trade agreements most studied for its employment impacts. Similar to the broader findings on changes in US employment cited above, a study by the Economic Policy Institute calculated that, as of 2010, NAFTA had led to 682,900 job losses, most of them in high-paying manufacturing industries, and most were due to outsourcing to Mexico [10]. Other analysts argue that without NAFTA and the 'offshoring' (outsourcing) of auto manufacturing jobs to Mexico, competition from Asian imports would have decimated the entire US auto industry; instead, it merely reduced the level of employment in that sector by almost 30% [11]. Other studies maintain that, because US unemployment rates post-NAFTA are no worse (perhaps even better) than pre-NAFTA, it is a net employment gain [12]. This latter sanguine appraisal, however, says nothing about the quality of post-NAFTA employment; nor is it really possible to fully attribute aggregate shifts in employment to any one trade agreement, or to trade liberalisation in general. Workers in some economic sectors will be displaced; new employment may open in other sectors, although often in lower-paid and less secure service sectors, or in highly skilled technology sectors that are unlikely to employ manufacturing workers displaced by either outsourcing or automation [3].

The recent era of deepening trade liberalisation has witnessed the rise of integrated global production chains, in which transnational firms source raw materials from one or more countries (often low-income countries

(LICs)), locate manufacturing in one or more countries (often LMICs), assemble or distribute their final products (usually in HICs or those LMICs with a good consumer market), while frequently passing the final process through a tax haven country (transfer pricing) to avoid taxation [13]. The growth in integrated supply chains[1] relied, in part, on export processing zones (EPZs), special economic areas generally located in LMICs where tax exemptions are used to attract foreign investment and 'in which imported materials undergo some degree of processing before being (re)exported again' [14]. The number of EPZs increased rapidly from 845 globally at the end of the 1990s to over 4500 by 2015, employing close to 80 million workers [15]. Disparaged in HICs as 'sweatshops', wages and working conditions in EPZs are often slightly better than those in the LICs in which they are located. But this is not always the case; there are also often laws or policies that prohibit unionisation within EPZs [16] and, beyond the fences that frequently separate such zones from the rest of the country, one is likely to find numerous small factories that play a sub-contracted role in global supply chains, where conditions are more hazardous and exploitative and the term 'sweatshops' is not an unreasonable label.

Setting aside that such insalubrious work is hardly consonant with the International Labour Organization's (ILO's) (and the Sustainable Development Goals') call for 'Decent Work' [14], the rapid pace of global market integration brought about by trade and investment liberalisation agreements did lead to a redistribution of work (and income), primarily from the industrial working class of HICs to the rapidly urbanising former agricultural populations of LICs [17, 18]. Female workers in LICs benefited disproportionately in this exchange, not because the corporations behind such supply chains were motivated by concerns for gender empowerment, rather they considered female workers more docile and less expensive than male workers [19]. The result is the 'elephant curve' (Fig. 5.1), in which the 'humped' increase in proportionate earnings by workers in LICs is offset by declines in working-class wage growth in the older industrialised countries, with both groups' income shares overshadowed by the amount captured by the 0.001% of the capital-holding uber-rich. Given the LMIC hump and the HIC dip, the turn away from political liberalism to illiberal populism by much of the (former) working class in HICs who are now facing a future of insecure, precarious or low-paying employment is unsurprising [20, 21].

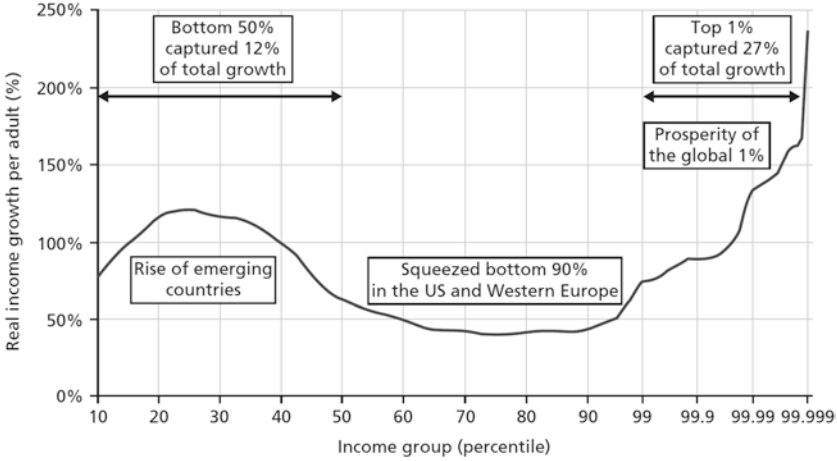

Fig. 5.1 The elephant curve of global income inequality and growth (Source: Alvaredo et al. (2017: 9). Alvaredo F, Chancel L, Piketty T, et al. World Inequality Report 2018. Paris: World Inequality Lab; 2017)

5.2.1 Do Labour Chapters Make a Difference?

The above sketch of the political landscape provides the context in which labour chapters started to find their way into trade treaties. NAFTA was the first to include specific reference to labour standards, with two side letters (one on labour, another on environment) introduced by US President Bill Clinton to appease trade union and environmental group opposition to the deal. The 1993 North American Agreement on Labor Cooperation (NAALC), as it came to be known, called on the three signing countries to 'improve working conditions and living standards in each Party's territory' based upon a number of core principals drawn from the ILO covenants on labour rights. Setting a stage for all labour chapters to follow, the NAALC only called on countries to enforce their existing labour laws and *encouraged* them to promote ILO labour standards and principles—they were not bound by the agreement to do so. Moreover, due to being a 'side letter' rather than a core part of the legal text of the Agreement, the NAALC was not subject to NAFTA's dispute resolution rules, with complaints subject only to cumbersome review processes [22]. Over two dozen complaints were heard by the NAALC but none led to a

trade sanction. Unsurprisingly, little changed in terms of labour rights improvements.

The USA subsequently began introducing labour chapters that required enforcement of only one provision: that a party 'shall not fail to effectively enforce its labor laws' [22]. Other provisions remained hortatory (using terms such as 'strive to ensure'), but even the one enforceable provision was cobbled by the requirement that it applied only if a country's failure to enforce its own labour laws affected trade or investment between parties to the agreement. This requirement ignores protection for government employees, teachers or any other person whose work does not involve tradable goods or services. It also sets no floor at which a country should set its own labour standards, accepting the sovereignty of nations to enact whatever level of labour protection they see fit. While arguably preventing (perhaps) a race to a labour market bottom, it fails to incentivise a reach for the top, and clearly privileges trade over labour rights.

Responding to yet more criticisms, the USA amended its labour chapters in post-2007 FTAs to include reference to core labour rights as defined in the ILO Declaration of Fundamental Principles and Rights at Work [23], a practice that continues with the Trans-Pacific Partnership Agreement (TPP) (carried through to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership or CPTPP), Comprehensive Economic and Trade Agreement (CETA), and the signed but, at time of writing, unratified United States-Mexico-Canada Agreement (USMCA). This Declaration lists four core rights:

1. Freedom of association and collective bargaining
2. Elimination of forced labour
3. Abolition of child labour
4. Elimination of employment discrimination

Although these newer FTAs call on parties to 'adopt and maintain' their labour standards in keeping with the principles of the Declaration, there is no reference to the explicit and legally binding ILO conventions. Basing a labour chapter on the ILO Declaration merely re-affirms a government's existing commitments as a member of the ILO. This may be understandable in light of the USA having ratified only two of eight ILO conventions considered to be basic to labour rights.

The CPTPP contains more admonitory provisions but, as with a few other bilateral treaties, now makes some of these provisions subject to

dispute resolution. However, it still only requires that governments not lower their existing labour standards to gain a trade or investment advantage. Other than that, and as with CETA and the USMCA, parties to the CPTPP are free to retain whatever low standards they presently have, and even to fall below those standards in future, provided that doing so does not give them a trade or investment advantage. This requirement is the same as that in the United States-Dominican Republic-Central America Free Trade Agreement (DR-CAFTA), the only labour provision in a trade agreement so far to have gone through a formal dispute resolution process. Despite documented violations of Guatemalan labour laws, accepted as such by dispute panellists, these violations were not proven to have led to 'a sustained or recurring course of action or inaction in a manner affecting trade or investment between the Parties', as this provision is worded in the USMCA (Article 23.5.1). Similarly, a bilateral trade agreement between Canada and Colombia contained provisions obligating improvements in protection of human rights in Colombia, with an emphasis on labour rights. A report on improvements in labour rights in Colombia is tabled annually in Canada's parliament, providing a potentially useful oversight. In its fifth report, Canada engaged with many labour unions and civil society organisations in both countries, which documented deterioration in human rights in Colombia, with increased killings and death threats against union and Indigenous leaders, as well as human rights violations by Canadian extractive companies operating in Colombia. Business groups, while still favouring trade with Colombia, agreed with unions and civil society that the agreement has had no effect in improving labour conditions or human rights in the country [24]. No dispute relating to the agreement's failed human rights provisions has been initiated, with 'continuing dialogue' the default measure.

The newest FTA, the USMCA, if ratified, will offer some improvements over CPTPP and CETA. There is a strongly worded provision on gender equity not found in the CPTPP, specifying not only the intent but also the requirement that parties 'implement policies that protect workers against employment discrimination on the basis of sex, including with regard to pregnancy, sexual harassment, sexual orientation, gender identity, and caregiving responsibilities' (Article 23.9.1). This is a tougher and more specific requirement than provisions in earlier FTAs that simply called attention to the need to consider such issues.[2] Disputes under the USMCA labour chapter would also have to include on the dispute panel someone with expertise in labour law. Finally, an Annex to the Chapter

requires Mexico to allow independent trade unions, weakening the present domination of non-independent unions closely tied to corporate or government elites. This is a positive step forward, and one that the new AMLO (Andrés Manuel López Obrador) government in Mexico is likely to follow.[3] The USMCA further requires that, to avoid US tariffs, 40–45% of auto parts manufactured must be in factories paying 16 USD/hour. This is the first time a minimum wage is referenced in a trade agreement, and it may be desirable that such a wage should be more broadly implemented in Mexico (the country affected by this rule). But the reason for its inclusion in the USMCA has more to do with the Trump administration's protectionist 'Buy America' rhetoric than with providing a fair wage for Mexican workers.[4]

Although there is little evidence that labour chapters do much good after the FTA enters into force, there is evidence that some treaties require countries to reform (and improve) their existing labour standards prior to ratification [22]. But the reality of trade liberalisation is that some sectors of a country's economy may do better (benefitting workers in that sector), while others will do worse (leading to job losses). Moreover, labour gains in one country may be offset by losses in another. Our discussion of EPZs and outsourcing earlier in this chapter already indicated this more broadly; it also applies to sectors at the regional level, one of which, textiles, is of considerable importance in the south Asian region, providing considerable employment, especially for women.

When the USA was still part of the proposed TPP, the agreement was predicted to shift textile manufacturing from countries such as Bangladesh to Vietnam since the latter would gain through lower American tariffs on imported textiles from TPP countries [26]. There would be no net regional increase in textile production, merely a displacement of manufacturing and employment from one country to another based on advantages inherent in a specific bilateral or regional agreement. Nor would there be any disproportionate income gains for Vietnam's lower half of the wage-earning population, as called for by SDG 10 (reducing inequality); rather, the labour share of economic product in Vietnam was predicted to decrease [27]. Similarly, a modelling study of income distribution in the USA (had it remained in the TPP) estimated a drop in wages for the bottom 90% of workers and a corresponding increase of up to 1.5% for the top 1% of wage earners [7]. Finally, the 'computable general equilibrium (CGE) model', most often used to predict the economic impacts of new trade treaties (and which usually shows only marginal gains at best), assumes that there will be no differences in employment, income earnings or public costs

(negative externalities) resulting from the implementation of the treaty [28, 29]. Other models, notably the UN Global Policy Model, that make more realistic (evidence-based) assumptions about employment impacts predict considerable net job losses from both the TPP [6] and the CETA agreements [30], although the UN model has not been without their own criticisms.

The bottom line: New trade and investment treaties will not necessarily increase employment opportunities and, if they do, job gains in some sectors or countries will be offset by job losses in others.

5.2.2 Should Labour Chapters Make a Difference?

Whether or not global trade leads to equitable job growth, the question remains: should labour rights form part of trade treaties? Health, labour (including trade unions) and human rights activists argue that, at a minimum, labour chapters should define any lowering of existing labour standards to be a treaty violation, removing the *caveat* that this would apply only if it affects trade and investment between the parties. Labour chapters in FTAs could also require parties to ratify all eight of the core ILO covenants before the treaty enters into force. HIC parties could also be obliged to lend technical and financial assistance to LMIC parties to assist in their compliance with ILO covenants. Rules requiring measures to support independent trade unions should be enforceable, as will be the case for Mexico if the USMCA is ratified. The existence of independent unions and the proportion of the working population covered by them are powerful predictors of the labour share of economic product [13]. The ILO has also recently drafted a 'Decent Work Agenda' [16], which calls for fair pay, employment security, organising rights and non-discrimination. This Agenda is now incorporated within the SDGs with some recent FTAs making reference to it (although compliance remains unenforceable). Care needs to be also taken to interrogate all new or proposed FTA chapters—not just those specifically focused on labour—to identify areas where labour rights might be a concern. Many FTAs, for example, contain chapters on 'government procurement' that require new public contracts above certain threshold amounts to be open to competitive bidding by providers from other countries that are party to the agreement. In many instances these chapters emphasise that commercial considerations (e.g. efficiency and lower cost) should be the main criteria for selecting a successful bid, potentially leading to firms in countries with fewer existing labour laws successfully winning contracts, putting downward pressure on

more secure or higher-paying public sector employment. Following a decade of lobbying by the European Confederation of Trade Unions, the European Commission in 2014 issued a new Directive for new government procurement contracts, requiring that they incorporate a 'social clause' aimed at ensuring that labour rights are not harmed through the tendering process [31]. Similar provisions could be considered in procurement chapters in trade agreements as well.

The larger question, however, is whether such 'social clauses' should be incorporated within trade agreements at all. Two arguments have been made against their inclusion. The first is that such clauses could become 'backdoor protectionism'—HICs with higher labour standards may invoke them to prevent LMICs from gaining trade advantage from their lower labour costs.[5] This is a presumed intent behind the USA's insistence in the USMCA of a sharp increase in Mexico's labour rates for factories involved in the auto parts trade. It has also been raised as a gender empowerment concern, given the extent to which LICs employ young women who would otherwise remain 'trapped' in rural livelihoods under strong patriarchal norms [32]. At the same time, most of the countries with existing low labour standards are members of the ILO and are already bound by its Declaration or by the covenants they have ratified. They are similarly parties to most international human rights conventions and covenants, many of which repeat labour rights similar to those under the ILO.

This raises the second argument: Why shouldn't the ILO be the responsible body for enforcing labour rights? Trade agreement disputes are generally arbitrated by trade policy lawyers who may know nothing of human or labour rights obligations. The USMCA includes the requirement that a trade dispute under its labour Chapter includes a panellist with expertise in labour law, but the panel is still restricted to examining only those instances where derogation from its minimal requirements affects trade or investment. If labour chapters required ratification of ILO core covenants, however, and required that an ILO trade expert be a member of any dispute panel ruling on a labour issue, such 'social clauses' could be more effective in promoting compliance without butting up against any 'backdoor protectionism' or surrendering the interpretative lead from ILO experts to trade policy lawyers [33].

Not all trade, labour and environmental policy analysts agree and continue to caution that trade liberalisation's underpinning assumptions of economic growth and reliance on market fundamentalism (or neoliberal theory) to explain how such growth should be achieved is a poor place to

locate any defence of labour rights [34]. We remain agnostic on this point, recognising that there is some usefulness in reforming labour chapters in FTAs but also some risk that reforms will essentially only provide 'window-dressing'.

5.3 Environmental Protection

Just as the labour share of economic product has declined since the 1980s, the physical environment upon which economic product is based has become far more imperilled. Climate change is the most immediate and perhaps most central ecological concern, but it is far from the only one (Fig. 5.2).

Most of these imperilled boundaries have worsened significantly since the 1980s, as population and economic growth combined with the global diffusion of a consumerist culture (upon which economic growth still depends) push the depletion of environmental resources to exhaustive limits while increasing toxic pollution externalities [35, 36]. That increased trade would likely have some negative bearing on the environment was acknowledged as early as 1970 during the General Agreement on Tariffs and Trade (GATT) negotiations that led to the creation of the WTO in 1995 [37]. During the WTO's founding meeting in Marrakesh, member governments signed a Decision stating that 'There should not be, nor need be, any policy contradiction between upholding and safeguarding an open, non-discriminatory and equitable multilateral trading system on the one hand, and acting for the protection of the environment, and the promotion of sustainable development on the other' [37]. Not all observers, however, were as keen as the 1994 Decision in declaring no policy contradiction between trade and environment. Fossil fuel energy production and transportation are the two major drivers of climate change, which a 2009 joint study by the WTO and the United Nations Environment Programme (UNEP) acknowledged will continue to increase with global trade [38]. The same study also noted the lack of any action at the WTO level on climate change.

This 1994 Decision accompanying the birth of the WTO also created the Committee on Trade and Environment (CTE), participation in which is voluntary for member states. The CTE often discusses, and occasionally releases reports on, trade-related environmental concerns, but has not advanced new actions related to environment protection. The WTO itself has been criticised for dispute panel rulings that have overridden

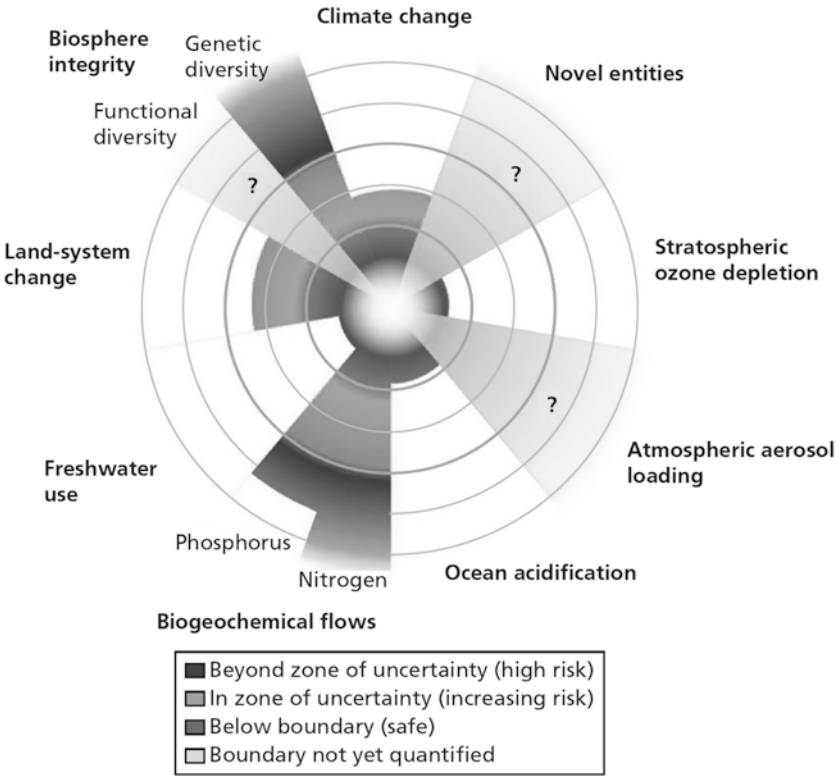

Fig. 5.2 A safe operating space for humanity (Source: Reproduced with permission from Rockström J, et al. A safe operating space for humanity. Nature. 2009; 461: 472–5. Copyright © 2018 Springer Nature Limited. All rights reserved)

government attempts to invoke exceptions for environmental protection, although these rulings often cite poorly crafted regulations or disguised protectionism as the reason for their dismissal [39]. The Brazil retread tyre case described in Chap. 2 also indicates support for an environmental protection defence, provided it is non-discriminatory. That being said, the WTO (more accurately its member states) has done little to advance environmental protection measures within its treaty system. Areas where progress might have been made include reducing government subsidies on industries causing ecological harm, such as overfishing, agrichemical intensive agriculture or fossil fuel extraction and consumption, while

simultaneously reducing tariffs on new green energy or environmentally protective technologies. Although the WTO's CTE does discuss these issues, no new agreements on them have been reached. As well, the precautionary principle, important in the face of continuing scientific uncertainty where new policy innovations for environmental protection are concerned, has never been fully incorporated across the WTO system [39]. If anything, the precautionary principle has been weakened in subsequent FTAs.

With little innovation at the multilateral WTO level, and with continuing environmental activist pressures, subsequent FTAs began introducing more explicit references to the environment. The 1994 NAFTA was, again, the first to do so, but its environmental side agreement followed the same non-enforcement path as its NAALC sister. The North American Agreement on Environmental Cooperation (NAAEC) did create an independent Commission for Environmental Cooperation (CEC), with a mandate to hear complaints and issue reports on violations of environmental laws and to release reports of trade-related pollutant emissions. Although credited with promoting civil society environmental activism in Mexico [40], its lack of binding disciplines in a context of documented environmental damages resulting from NAFTA's liberalised trade and investment rules led environmental organisations and researchers to criticise the CEC as 'too institutionally weak and poorly funded to play a meaningful difference in post-NAFTA economic and environmental governance' [41, p. 21].

As post-NAFTA FTAs proliferated, they generally took the form of referencing several of the extant multilateral environment agreements (MEAs), the more common ones being:

- Convention on Biological Diversity
- Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)
- Cartagena Protocol on Biosafety
- Montreal Protocol on Substances that Deplete the Ozone Layer
- The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal
- Convention on Persistent Organic Pollutants

Usually, parties are simply reminded of their obligations to some or all of the MEAs referenced in the FTAs that they may have already ratified. As

with labour chapters, enforcement measures only kicked in (if at all) if parties lowered their existing environmental standards to gain a trade or investment advantage. There have been some recent FTA exceptions, however, indicative of a possible 'policy window' opening [42] in response to the extent of environmental damage and climate change increasingly difficult for most governments to brush aside.

The CETA, for example, specifically excludes 'water in its natural state' from any of its trade or investment rules, preventing potential commercial interest in the wholesale export of water. No such protection exists in either the CPTPP or the USMCA. CETA is also the only agreement to call for the removal of barriers to trade or investment in goods and services related to climate change mitigation or renewable energy [43 Article 24.9]. Both the CPTPP (surprisingly) and the USMCA (unsurprisingly) are silent on climate change, apart from the CPTPP 'encouraging cooperation' towards a 'low emissions and resilient economy' (Article 20.1.5). The CPTPP assumption is that the Paris Agreement is the appropriate policy space for pursuit of climate change initiatives, although the Paris Agreement, in turn, is largely silent on the role trade plays in increased greenhouse gas emissions. The CPTPP, however, is the first (and apart from the unratified USMCA still the only) agreement with an enforceable prohibition on subsidies 'that negatively affect fish stocks that are in an overfished condition' (Article 20.16.5a). The US-Korea agreement, in turn, is unique in being the only trade treaty requiring that certain environmental standards be maintained in export processing zones [44]. Two European Union FTAs with neighbouring countries (Bosnia and Herzegovina, and Montenegro) required their ratification of the Kyoto Protocol on Climate Change [44], a measure many health and environmental groups would like to see extended to the 2015 Paris Agreement as a pre-ratification requirement for any new trade or investment treaty.

In terms of environmentally protective impacts of such chapters, a 2010 review of (largely US-led) FTAs concluded:

> …the FTAs have had less influence on trade flows and investment decisions than…government[s] believed, and less power to force reform of…environmental policy, than advocates hoped. [22, p. 12]

Following on from suggestions for progressive reforms to FTA labour chapters, this rather bleak assessment could change to the extent that new trade and investment agreements could specify ratification of a number of

meaningful MEAs (notably the Paris Agreement on Climate Change) that focus actions on the areas of ecological overshoot (such as biodiversity, soil and water depletion and loss of fishing stock). Compliance with national government commitments of such treaties, with environmental lawyers participating in panels involving environmental disputes (as required by the USMCA), and selected from the secretariat responsible for the respective MEA or from the UNEP, could increase substantially regulatory coherence between trade, labour and environmental protection policies in a direction that improves health, rather than merely preventing its deterioration.

5.4 Conclusion

Trade agreements can affect many determinants of health beyond the more obvious issues we have covered in earlier chapters. Employment, labour standards and environmental protection are issues which profoundly shape the health of populations, and which trade agreements can impact positively or negatively. Despite the claims often made that trade agreements will increase jobs, the picture at the global level is far more complex. Increased global trade and the integration of markets has redistributed employment in ways which reduces the value of economic product going to labour (workers) while increasing the proportion going to capital (investors). In response to growing civil society opposition, labour chapters are increasingly being incorporated into trade agreements; however, there is little evidence that such chapters (which largely comprise unenforceable intentions) make a difference. Similarly aspirational (and largely unenforceable) environmental protection chapters also appear to have had little impact. Where such chapters are enforceable, it is only when a party to the agreement lowers its labour or environmental standards specifically to gain a trade or investment advantage. In contrast, investor-state dispute settlement provisions in many agreements continue to provide investors (including extractive and fossil fuel industries) with avenues to challenge measures to protect the environment, as we described in Chap. 2. Whether or not trade agreements are the appropriate instrument to enforce labour or environmental standards, or how they might be strengthened to do so, remain contentious issues in global policy debates. Claims that such chapters in FTAs afford sufficient workers' and environmental health protection, however, warrant careful scrutiny rather than uncritical acceptance.

Notes

1. Variously referred to as global supply chains or global value chains.
2. A footnote to this provision, however, states that present US hiring policies are deemed sufficient to meet the obligations of this article and that no additional action by the USA is required to be in compliance. It, thus, has no binding effect on US employment practices, an example of excluding oneself from a rule to which it is politically opposed.
3. This was also a side-letter requirement the USA had of Vietnam before it pulled out of the TPP agreement.
4. It is unlikely that Mexican automakers will opt to triple the hourly wage, rather than simply pay the US tariff (presently only 2.5% on cars, Mexico's main automotive export) [25].
5. We might add that low labour cost advantage of LICs could also be rephrased as the high-poverty legacy of colonialism, although that is a different matter.

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CHAPTER 6

The Politics of Trade Policy and the Trade Negotiating Process

Abstract This chapter presents an analysis of the actors, ideas, institutions and processes that shape trade policy and the negotiation of trade agreements. The roles played by nation states, industry, civil society and academics are explored. The trade policy-making process is described, and the ways in which influence is exerted. The role of intergovernmental organisations in the governance of trade and health is also explored. The chapter then turns to the need for advocacy and capacity building to improve policy coherence between trade and health. Strategies to advance health on the trade policy agenda are discussed, along with strategies to strengthen the capacity of trade and health officials for intersectoral policy making, as well as the capacity of health professionals and organisations to engage with trade policy.

Keywords Trade policy making • Politics • Actors • Institutions • Processes • Advocacy • Capacity building

6.1 Introduction

Trade policy making, although sometimes portrayed as a technical matter of assessing evidence to inform policy choices, is very much a political process populated by a large number of actors and characterised by competing interests and the exercise of power. Politics is integral to trade

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policy formation within states and negotiations between states over new trade and investment rules and extends even to the way in which disputes are handled. In order to engage in and influence trade policy, public health actors need to have a good understanding of the trade policy actors and institutions involved, the processes and structures that shape trade policy and trade agreements, the ways in which power is exerted and the ways in which issues and arguments are framed by different actors.

Much of the literature on the politics and process of trade policy making, reviewed in this chapter, derives from the USA, European Union (EU) and other high-income jurisdictions. While many of the same dynamics are likely to play out in low- and middle-income countries (LMICs), these are less well explored and documented, and more research is needed in these contexts.

6.2 Actors and Institutions Involved in Trade Policy Making

6.2.1 Nation States

The primary actors in trade policy making are nation states as, with a few notable exceptions,[1] it is sovereign states which negotiate and enter into agreements. In most countries, it is the executive arm of government that has this mandate, with a more limited role for elected representatives, who have little, if any, oversight during the negotiation process and can only vote on concluded trade agreements (or implementing legislation) without the possibility of amending them [1]. In the USA, the situation historically was somewhat different: while the Executive held the power to negotiate treaties, Congress retained the power to allocate resources and the right to amend trade agreements. In 1974, Congress enacted a legislative procedure called Trade Promotion Authority (TPA), often referred to as 'Fast Track'. Under TPA, Congress provides guidance regarding negotiating objectives and prescribes consultation and other procedural requirements for trade negotiations, but waives the right to amend a concluded agreement—its role is limited at that stage to an up or down vote [2]. The division of responsibility between the executive and legislature in most countries is intended to protect trade negotiations from political pressure for protectionism from special interest groups [3], but it gives rise to issues regarding a lack of transparency and accountability.

In the European Union, trade policy making is the responsibility of the EU's central institutions rather than the individual member states, making the EU the world's most powerful trading bloc [4]. The European Commission (EC) negotiates trade agreements, which are approved jointly by the Council of the EU and the European Parliament [5]. EU member states, however, maintain a closer role in monitoring negotiations than does Congress in the USA [6]. In recent years, the mandate of the European Commission to negotiate on behalf of its member states has become more contested, as trade agreements have extended beyond tariffs and related border barriers, increasingly encroaching upon domestic policy and regulation [1]. Following a 1994 judgement by the European Court of Justice, trade agreements which touch on policy issues that go beyond the remit of the EU institutions (referred to as 'mixed' agreements) can only be provisionally approved at the EU level and need to be ratified by each member state [1, 6].

In most countries outside of the EU, trade negotiations are carried out by officials in government departments with responsibility for trade (e.g. the Office of the United States Trade Representative, USTR, or New Zealand's Ministry of Foreign Affairs and Trade), under the direction of the relevant minister. Depending on the size of the trade agreement being negotiated and the size and wealth of the country, large teams of negotiators may be assembled, with multiple officials responsible for specific issues or chapters, or a handful of officials may be spread across multiple issues and even agreements. Negotiating teams may also comprise officials from other government departments as advisors on particular issues where specialised knowledge is needed (e.g. intellectual property and pharmaceuticals). Discrepancies in the human and other resources available can put low- and middle-income countries at a considerable disadvantage in trade negotiations with higher-income countries.

6.2.2 Industry

Industry players are active participants in trade policy development, both within nation states and at the regional and global levels, via formal and informal channels. Industry players include peak business associations (e.g. the US Chamber of Commerce), associations representing particular industry sectors, such as the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Winemakers' Federation of Australia, and, in some cases, individual corporations. In the case of the Trans-Pacific

Partnership (TPP), some of the peak associations and major exporters joined together to form a lobby group called the US Coalition for TPP [7]. A study of food industry submissions to trade negotiating bodies in Australia, Canada, New Zealand and the USA regarding the TPP negotiations found that over 82% of these submissions were made by food industry associations and other commercial and industry associations, with a much smaller proportion made by individual corporations involved in production, processing, distribution and retail [8].

There is considerable variation in the positions of industry groups with respect to trade negotiations. Analysis of submissions to public enquiries into the TPP showed that peak business associations in Australia, Canada, New Zealand and the USA were unanimous in supporting the TPP, while smaller enterprises and specific sectoral groups tended to lobby for their own specific interests [7].

6.2.3 Civil Society

In comparison with industry, civil society actors, such as labour unions, non-government organisations (NGOs) and community groups, tend to have a much more marginal role both in terms of shaping national trade policy and in influencing the objectives and outcomes of trade negotiations. Civil society actors involved in trade policy making include organisations with interests in the environment, copyright and access to knowledge or medicines, fair trade and consumer rights, as well as health groups. Civil society organisations (CSOs) that have been active in relation to the health impacts of trade agreements include international humanitarian organisations such as Médecins Sans Frontières (MSF) and Oxfam, national public health and medical organisations and their associated international peak bodies (e.g. the World Medical Association and the World Federation of Public Health Associations or its affiliated members) and many others. Civil society advocacy in the context of trade negotiations is discussed later in this chapter.

6.2.4 Academics

Academics often play a key role in trade policy formation by generating evidence and policy analyses for official government actors, industry groups and/or non-government organisations. In some cases, academics themselves become actively engaged in trade policy advocacy as invited

expert witnesses to government committees, representatives of CSOs or media commentators.

6.3 Trade Policy-Making Processes

Within nation states, trade policy is driven by a range of different forces and considerations, which include a desire for economic development and growth, a commitment to neoliberal trade liberalisation, a response to the influence of export industries and a consideration of geopolitical interests. Nation states often pursue trade agreements primarily to secure market access for their export industries [9].

Trade policy can be seen as the outcome of competing interests in which policy actors use a variety of different formal and informal mechanisms and structures to influence trade agreements [10]. Industry stakeholders hold a privileged position in their abilities to do so. This is partly due to the perception that industry is the primary stakeholder in terms of bearing the economic impacts of trade policies [1]. If the purpose of trade policy is seen as primarily to secure advantages for a nation's export industries, then it makes sense that industry would be closely involved in formulating negotiating positions and providing expert advice. This privileged role for industry was seen as more legitimate in the era where trade policy was focused on tariffs and quotas; as trade agreements have expanded to include a wider array of policy issues with broad-ranging impacts on the public interest, concerns about the legitimacy of this approach have intensified [3].

The imbalance of input from industry and public interest stakeholders is well documented in the USA where trade advisory committees (see https://ustr.gov/about-us/advisory-committees) assist in forming negotiating objectives and guide negotiations. The USA has a large number of trade advisory committees (26 at the time of writing), which include 14 industry trade advisory committees (ITACs) addressing particular topics or sectors, such as consumer goods (ITAC 04), textiles and clothing (ITAC 11) and intellectual property rights (ITAC 13). While industry interests must be represented on these advisory committees under US law, there is no requirement for consumer input or for a separate public interest advisory committee [11]. An analysis by the *Washington Post* in 2014 found that 85% of the membership of these trade advisory committees comprised industry representatives [12]. The small number of non-industry representatives were clustered in a small number of committees. Following criticism about the imbalance in representation, USTR

announced in 2014 that it would establish a 'Public Interest Advisory Committee'; however, this announcement was greeted with scepticism by CSOs [13] and was not implemented [1].

The dominance of industry representation in the US trade advisory structures contributes to regulatory capture of the USTR, where state action is directed towards advancing the interests of particular interest groups [11]. This occurs partly through 'information capture', where some interest groups have greater access to information and are able to provide more expert input than others [11]. Members of the advisory groups are able to access detailed negotiating proposals, whereas other stakeholders are only able to provide advice based on previous trade agreements [11] or, in some cases, leaked texts. Access to detailed legal wording is very important for providing meaningful input [1]. The regulatory capture of the USTR is exacerbated by lack of transparency and oversight: the influence of particular groups is not subject to scrutiny and the routine classification of trade negotiating documents means that they are generally not discoverable under Freedom of Information law [11]. Furthermore, there is a well-documented 'revolving door': USTR staff have often been drawn from the industries they regulate, and/or return to industry positions following their tenure with the USTR [11, 14]. This creates ongoing close relationships between officials and interest groups, as well as potential for conflicts of interest. Similar dynamics may play out in many other countries.

Trade policy making in the EU is generally seen as more transparent, democratic and balanced than that in the USA. In the EU, business groups historically had greater access to trade decision making through formal consultation processes, but perceptions of a 'democratic deficit' in trade policy making led to greater dialogue with civil society groups through both 'general meetings' and 'issue groups' on particular themes [3]. From 2015, as part of a commitment to greater transparency, the European Union began publishing documents setting out its negotiating positions along with its initial legal text proposals for trade agreements [15]; joint draft negotiating texts are not released, however. Revolving doors are less an issue in the EU due to rules preventing former employees of the EC from lobbying for certain periods of time and requirements for approval for positions taken up within 2 years of exiting their role with the EC [1]. Nevertheless, even in the EU, perceptions of lack of transparency and the exclusion of civil society has threatened the legitimacy of trade negotiations and, in the case of a proposed multinational Anti-Counterfeiting Trade Agreement (ACTA), which was intended to enforce intellectual property rights (including

for pharmaceuticals), ultimately resulted in its rejection by the European Parliament [16].

Many states have a variety of other formal processes in which actors can provide input to trade policy and trade negotiating positions [10]. Some of these are related to the negotiation of particular trade agreements. *Interdepartmental committees* can be established for obtaining cross-sectoral input on complex policy issues, including health—for example, an interdepartmental committee in Australia provided a mechanism for consideration of proposals to exclude tobacco from the TPP [10]. Generally, however, agencies charged with negotiating trade agreements will consult with other government agencies selectively where negotiators identify that there is an issue with implications for a specific sector (meaning that issues with health implications may be overlooked), and the consultation process may not involve sharing draft text, limiting the oversight of health officials [9]. Some Western democratic countries have *formal submissions processes for particular trade agreements under negotiation*, where stakeholders, including industry, civil society groups and academics can play a role in trade policy agenda-setting, along with *formal consultation processes*, which can take different forms [10]. Negotiations for some trade agreements have involved *formal stakeholder events* where stakeholders (including industry and civil society) can interact with and present their views to negotiators [10].

Actors also use a variety of informal mechanisms and processes to influence trade negotiations [10]. Both industry and civil society stakeholders engage in lobbying politicians. Much of this activity takes place out of the public eye and goes undocumented, except in the USA where there are strict requirements for disclosure of lobbying activity. Industry lobbying in the context of the TPP negotiations is discussed in Box 6.1.

Many industry bodies and associations also form close relationships with negotiators and have a strong presence on the margins of trade negotiations where they interact frequently with negotiators. While NGOs and health advocates can use these strategies as well, they often lack the resources to attend negotiating meetings and are less able to exert influence through these avenues [10].

Outside of the context of negotiations for specific agreements, other avenues through which stakeholders often seek to influence trade policy at the national level include *submissions to parliamentary committees and government inquiries* [10]. At the global level, engaging with *international treaties such as the Framework Convention on Tobacco Control (FCTC) and*

standard-setting bodies such as Codex can also be important for influencing trade policy debates [10] and how trade or investment disputes might be arbitrated (see also Chap. 4). Once again, however, industry can have greater influence in forums like these than health sector stakeholders due to the greater resources at their disposal. At a recent *Codex* meeting in Ottawa, for example, 18 of the registered groups were non-governmental organisations, whereas 140 were industry organisations.

While health advocates and organisations often have less immediate access to trade negotiators and policy makers, they can often mobilise different forms of power and influence, such as establishing coalitions with other non-government organisations to share information, analysis and media strategies [10]. Analysis of leaked documents has been an important element of the contribution of civil society organisations and academics, for example, in the negotiations for the TPP and Regional Comprehensive Economic Partnership (RCEP), where leaks provided information about the detail of proposed text to assist with technical analysis as well as information about the positions of particular parties to assist in the targeting of advocacy efforts.

Box 6.1 Negotiation of the TPP

Negotiations for the TPP spanned more than five years from March 2010 to October 2015. The negotiations included 19 formal negotiating rounds, as well as countless 'inter-sessional' working group meetings, chief negotiators' meetings and ministerial meetings. At many of the negotiating rounds, particularly in the early stages, limited opportunities were provided for registered stakeholders—including business groups and civil society—to interact with negotiators, in some cases through formal presentations or through less formal meetings. When the negotiations reached the stage of political bargaining, stakeholders had less access to negotiators. With a few exceptions, proposed text for the agreement was tabled by the USA, and the other parties responded to this text. The US negotiating priorities were shaped by input from its trade advisory committees, comprising mainly representatives of industry associations and corporations with privileged access to the text. Industry stakeholders also engaged in intense lobbying outside of the negotiations, with the pharmaceutical industry mentioning the TPP more than any

other industry sector according to an analysis of lobbying reports by the Sunlight Foundation [17]. Civil society actors, including consumer groups, health and humanitarian organisations, environmental groups, labour organisations and trade unions, mounted vigorous national and international campaigns, protesting many of the US proposals for the Agreement, along with the secrecy and lack of transparency of the negotiating process [7].

Draft texts were classified and kept confidential, with very limited, summary information publicly released by governments about the content and progress of the negotiations. However, there were multiple leaks of key documents posted online by WikiLeaks and other public interest organisations. These leaks exposed controversial proposals by the USA in areas such as intellectual property, fuelling public opposition to the TPP [18]. They also provided civil society with more detailed information about the proposed legal text, stimulated public debate and equipped experts with the information needed to engage with negotiators about the specifics of the text. Nevertheless, civil society actors and some business groups decried the lack of transparency and the difficulty of having meaningful input to the negotiations when negotiators were not free to discuss the legal text and could not even acknowledge the veracity of leaked texts [19].

Even elected politicians had only limited access to the text: Members of Congress risked prosecution if they publicly disclosed the information disclosed at private briefings [20], and although they were permitted to view the draft text in the late stages of the negotiations, it was under very strict conditions—they were unable to reproduce or even make notes about the contents [21]. In Australia, politicians were told they must sign 4-year confidentiality agreements in order to see the draft text [22].

6.4 The Role of Ideas and Framing in Agenda-Setting

A number of recent studies have focused on the way in which different actors frame their arguments in order to influence trade policy debates. A study of how the pharmaceutical industry used language and ideas in its efforts to influence the negotiations for the TPP (based on analysis of

submissions, media releases and other industry documents in the USA and New Zealand) found that the industry framed itself as the victim of inequitable treatment by governments and the 'protector of public good', and argued that the TPP would be a route to economic prosperity through the generation of 'innovation' and job creation [23]. The language of 'access to medicines', used by CSOs to mean equitable access to affordable medicines (in the context of critiques of costly patent protection), was co-opted by the industry to refer to the availability of patented medicines [23]. This language was more likely to appeal to clinicians and patient groups and served to obscure the industry's own economic interests. Similarly, a study of food industry submissions to TPP consultation processes in four countries found that arguments were framed in terms of the economic benefits of trade liberalisation, with food regulations generally portrayed as 'barriers to trade' that should be removed in order for economic goals to be reached [8]. Understanding the ways different stakeholders frame issues and arguments is very important for health stakeholders as it enables a more explicit engagement with arguments that have traction in trade and economic debates and enables the development of more effective counter-arguments [8, 24].

A study of stakeholder submissions to the Australian government during the negotiations for the TPP found that they clustered under three main policy frames: a dominant neoliberal market-oriented frame, present in all of the industry submissions, and two alternative frames: a collective public interest or societal frame and a 'state sovereignty' frame, which focused on the state's right to regulate [24]. In this study, the alternative frames were found to be more aligned with arguments focused on equity and the social determinants of health. Its findings suggest that as well as engaging more explicitly with the market-oriented frame, health stakeholders should 'engage with heterodox economic studies that document the failures of "trickle down" economics to generate wellbeing, and that provide explicit and evidence-informed critiques of market assumptions…' [24, p. 9]. The influence of economic arguments in trade policy debates also suggests that health stakeholders need to focus on producing economic evidence and making arguments in economic terms [24].

Understanding the impact of ideational factors can also help to explain why some health issues (such as access to medicines and tobacco) gain more attention on the trade policy agenda than others such as nutrition. An Australian case study involving interviews with key informants in the trade policy sphere (including government, civil society, industry and aca-

demics) explored the reasons why nutrition had low salience in trade policy [25]. The study found that nutrition was not a domestic policy priority in Australia or among its trading partners, there was a lack of expertise and engagement by nutrition groups in trade policy processes and a limited evidence base and lack of consensus about the relationships between diet, nutrition and trade. The policy paradigm was focused on market access and deregulation, and there were few opportunities for health advocates to influence trade policy. The complexity of nutrition and its interlinkages with trade was another barrier to getting attention to nutrition in trade policy. The findings suggest that improving policy coherence between trade and nutrition requires engagement by nutrition advocates, a stronger evidence base and attention to building the priority given to nutrition beyond trade debates. This study concurred with others in finding that where policy debates are steeped in neoliberal ideology, economic evidence may be most influential. The study also suggested that reforming trade policy-making processes to make them more transparent and participatory could assist in getting more attention to issues like nutrition [25].

6.5 Global Governance of Trade and Health

At the global level, the World Trade Organization (WTO) and the World Health Organization (WHO) are the institutions with primary responsibility for the governance of international trade and health, respectively [26].[2] There is currently no international institutional structure to provide a basis for systematic cooperation between these sectors or for resolving tensions between their objectives [27].

The WTO provides the architecture for the multilateral rules-based system of global trade. WTO decisions are made by consensus between the member states. However, much of the agenda-setting and the substance of the decision making takes place in informal bilateral and small group (so-called green room) meetings[3] outside the formal structures—meetings which tend to be dominated by the largest developed economies (the USA, the EU, Japan and Canada) [26]. LMICs experience substantial barriers to participation, including exclusion from these informal discussions, along with human resource and capacity constraints which limit their ability to monitor and influence the negotiations [26]. These power dynamics are intensified in free trade and investment negotiations outside of the WTO, a point we return to later in the chapter.

As an institution, the WTO is heavily steeped in free trade theory. Although tensions between trade liberalisation and public health objectives are recognised, the overriding view is that trade liberalisation improves health through poverty reduction and economic development and that health exceptions provide sufficient policy space to enable governments to use non-discriminatory measures to protect public health [27].

The WHO has observer status in some WTO committees, providing it with some capacity to monitor and contribute to discussions on health-related matters, but not a decision-making role; its contributions are also restricted to issues that are perceived as having a direct effect on health [26]. Coordination between the WTO and WHO, however, has been limited, as has the capacity for WHO engagement on trade issues. WHO's reliance on voluntary contributions and donor funding means that funds available for issues like trade and health are very limited [9]. A small programme focusing on trade and health established within WHO in 2000, for example, was understaffed, reliant on extra-budgetary funds and subject to pressure from donors [26]. A joint WTO/WHO report about the WTO agreements and public health arising from this programme and published in 2002 was criticised as being a carefully worded compromise rather than providing clear advice on how to protect health in the context of trade agreements [26, 27]. Resolution 59.26 on International Trade and Health was passed by the World Health Assembly in May 2006 [28], affirming the need for policy coherence between trade and health and requesting the WHO Director-General to provide support to member states; little in the way of implementation followed [29]. The development of a tool for assessing health implications of trade issues was announced on the WHO website 2009 but was never released [29], possibly due to pressure on the WHO from the WTO and some member states. Finally, in 2015, a trade and health handbook for states [30] was published by WHO, foreshadowing again the development of an assessment tool, which has not been made available by the time of writing.

Other global institutions involved in governance at the interface of trade and health include the United Nations Conference on Trade and Development (UNCTAD) and standard-setting bodies such as the *Codex Alimentarius Commission*. UNCTAD is an intergovernmental body in the UN system which aims to assist LMICs to 'access the benefits of a globalised economy more fairly and effectively' and to 'deal with the potential drawbacks of greater economic integration', with the ultimate goal of helping them to achieve 'inclusive and sustainable development' [31, para 2].

UNCTAD generates important data and analysis on trade and investment trends and impacts and provides technical assistance to developing countries. The *Codex Alimentarius Commission*, jointly established by the United Nations' Food and Agriculture Organization (FAO) and the WHO and better known simply as *Codex*, has the dual purpose of protecting consumer health and promoting fair trade in food products [32].

Global governance of trade and health is even weaker in the context of bilateral and regional trade agreements—the political sensitivity of trade negotiations means that WHO's role is limited to general technical assistance provided at arms-length rather than direct intervention or assistance to states engaged in trade negotiations [9]. However, WHO has played an important role in preparing *amicus curiae* briefs in the context of ISDS disputes over tobacco, as described in Chap. 4.

6.6 Power Asymmetries in Trade Policy Making

Trade policy making is characterised by a number of power asymmetries between different actors [9, 33]. These include power imbalances between:

- *Health and trade officials* due to the easier access to information and greater expertise and authority of trade officials in comparison with health officials [9].
- *Industry and civil society*, with industry having closer relationships with trade officials, greater resources for lobbying and engagement in various avenues of influence and, in some cases, direct access to information about issues and text under negotiation.
- *Small versus large economies* and *HICs versus LMICs.* LMICs can be disadvantaged in WTO negotiations due to the size of their negotiating teams and their exclusion from elite groups where much of the decision making takes place. LMICs can rebalance these dynamics to some extent by forming coalitions and networks [34]. These power imbalances are intensified, however, in the negotiation of bilateral and regional trade agreements. One example is the well-documented use of coercion by the USA and the EU in persuading smaller and/or less developed countries to agree to intellectual property rights for pharmaceuticals which are not in their interests (such as regulatory data protection) by refusing to conclude trade agreements without them [35]. High-income countries often engage in 'forum-shifting'—moving from one forum or set of negotiations (in which

they are unable to secure the concessions they want) to another forum where their chances are improved [34]. This is well documented in relation to intellectual property, as discussed in Chap. 3. Power is often also exerted outside of the context of the WTO or the negotiation and implementation of specific free trade agreements. For example, the EU exerted considerable pressure on many African countries to sign 'Economic Partnership Agreements' (EPAs) to retain access for their exports to the European market. EPAs often required these countries to reduce or eliminate tariffs, which for many leads to a loss in tax revenue; and to liberalise in services, investment, intellectual property and public procurement beyond commitments under the WTO system [36]. The USA similarly puts pressure on other countries to increase intellectual property rights (IPRs) through the annual Special 301 Reports prepared by the USTR, which target countries that are judged to have inadequate IPRs.

6.7 Advocacy for 'Healthy Trade'

Advocacy by health organisations, activists and academics has a very important role to play in improving the prioritisation of health in trade policy and increasing coherence between health and trade objectives. Advocacy is also very important for challenging power imbalances and other deficits in trade policy-making processes.

Kingdon's [37] Multiple Streams Framework is useful for understanding the ways in which health sector advocacy can contribute to improving the prioritisation of health in trade policy. According to Kingdon [37], in order for policy change to occur, three streams must converge: the problem stream, policy stream and politics stream. The *problem stream* refers to ways in which issues come to be recognised by decision makers as problems that need to be solved. The *policy stream* involves generation of solutions that are seen as both technically and politically feasible. The *politics stream* involves changing political events and processes, including the activities of interest groups. *Policy windows* can open at opportune moments when problems and policies can be coupled by *policy entrepreneurs* and advanced onto a government's agenda (the limited list of issues a government pays attention to at any given time) [37].

Problem stream: An important focus of advocacy for healthy trade involves generating and collating evidence about the impacts, or potential

impacts, of trade agreements on health and health equity, and bringing this evidence to the attention of negotiators, politicians and the public. Strategies involve analysis of legal texts (which may include, depending on the context, negotiating proposals, leaked negotiating documents or the text of previous trade agreements), assembling existing research evidence linking trade and health (where available) or undertaking health/human rights impact assessment, where resources allow (see Chap. 7). For example, at a critical point in the late stages of the TPP negotiations, a health impact assessment (HIA) based on leaked negotiating documents, undertaken by a group of Australian academics and CSOs, helped to raise the political attention to the health issues and reframe the debate [38]. Other strategies that health advocates have used for drawing attention to the potential problems trade agreements present for health include letters or visits to politicians, media releases and opinion pieces and preparation of technical briefs for negotiators, as well as engaging with the formal and informal mechanisms and processes discussed earlier in the chapter. As discussed earlier, paying attention to the types of evidence that are most salient (e.g. economic evidence) and problem framing is also important.

Policy stream: In addition to drawing attention to the problems of policy incoherence between trade and health and imbalanced policy-making processes, advocates also need to focus on generating feasible policy solutions [33]. This is easier for some health issues than others: for example, it is easier to argue for states to refuse to accept specific TRIPS-Plus provisions in trade agreements than to propose policy solutions to resolve the more complex issues of incoherence between trade and nutrition objectives [25].

Generating solutions requires both technical and political knowledge and skills: technical skills in terms of identifying the legal language, such as exclusions and exceptions, which can create policy space for public health. It also involves building relationships with trade negotiators to be able to propose solutions that are politically feasible. Policy solutions are highly context-specific (those that are feasible in one trade negotiation may not be in another) and timing can be critical—solutions that are feasible at one point in the negotiating process may not be at another. An example is the optional exclusion of tobacco control measures from ISDS in the TPP; this became a political possibility only at a very late stage in the negotiations. An earlier proposal by Malaysia for a complete carve-out of tobacco from the TPP failed to win support from the other parties [39]. Close engagement in the policy-making process is important in being able to

understand the context and identify shifts in the politics that might cause a 'policy window' to open where a solution may be taken up.

Politics stream: Because trade policy making is a political process, it is also important for health advocates to engage with politics [33, 40]. It is not sufficient for advocates to analyse problems and propose solutions; trade negotiators operate under a political mandate that puts boundaries around what they are able to do. Changing a nation's negotiating position or the course of a particular negotiation requires political action. Advocates need to understand the positions and arguments of industry stakeholders and the avenues they use to exert influence, and be able to develop counterarguments and navigate the trade policy-making process effectively [33]. They need to engage with the power dynamics to be able to identify opportunities for change [33] and must be able to frame arguments in ways that get political traction.

Popular mobilisation is often vitally important in shifting the political possibilities in the trade policy sphere, as shown by the Access to Medicines Campaign case study (Box 6.2), as well as the rejection of ACTA by the European Parliament.

Finally, it is important for advocates to recognise and act on policy windows. Health advocates and organisations can play the role of policy entrepreneurs, seizing opportunities to couple problems and solutions. Health advocates can also work with policy entrepreneurs from other sectors. For example, individuals from the Public Health Association of Australia along with the consumer organisation, Choice, and the Australian Fair Trade and Investment Network were seen as playing key entrepreneurship roles in the advocacy campaign around the TPP in Australia [38]. Similarly, Canadian public health researchers frequently collaborate with high-profile independent policy research organisations such as the Canadian Centre for Policy Alternatives, which has extensive labour and civil society linkages and is one of the most cited 'think tanks' by Canadian media.

Box 6.2 Access to Medicines Campaign

An important historical example of an influential transnational advocacy campaign is the Access to Medicines campaign established in the late 1990s to early 2000s in response to the barriers patents presented to equitable access to HIV treatments. The background and context for this campaign are described in Chap. 3.

An important focal point in the early stages of the campaign was the court case initiated in 1998 against South Africa by 39 pharmaceutical companies, arguing that legislation to enable parallel importation and compulsory licensing breached the TRIPS Agreement and the South African Constitution [41–43]. The campaign generated significant negative publicity which put pressure on pharmaceutical companies, ultimately contributing to their decision to drop their case [41, 44].

The main actors in the campaign were civil society organisations, the media and politicians [41], along with developing countries and generic drug companies [44]. Treatment Action Campaign (TAC), a South African grassroots community organisation committed to ensuring access to HIV/AIDS treatment, played a pivotal advocacy role and was granted *amicus curiae* status to represent the community in the proceedings [41]. TAC was part of an international coalition which included experienced and well-resourced organisations such as MSF and Oxfam, among others [42]. Campaign activities included legal affidavits, press releases and other publications, petitions, engagement of celebrities as spokespersons and protests in many countries [41]. Initial support provided to the pharmaceutical companies by the US government was dropped in the face of this campaign; the European Parliament also called for the case to be withdrawn [41, 43].

Framing of the problem by activists brought evidence of the scale of the problem and its effects together with a moral dimension [41]. Personal stories of people with HIV/AIDS and unable to afford treatment were used to shame the pharmaceutical companies for their greed and neglect of people with HIV/AIDS in developing countries [41]. These stories were effectively linked with bigger issues of global inequality [41]. A plausible solution was offered—pharmaceutical companies were urged not to enforce patents in poor countries and to allow the production and importation of affordable generic medicines [41]. Analysis of news coverage during this time shows a significant shift in the dominant discourse, with generic medicines, previously widely portrayed as criminal 'piracy' more likely to be described as a sensible and legitimate strategy for addressing the access to medicines crisis [42].

The withdrawal of the court case represented a major victory for the Access to Medicines Campaign [42] and a turning point in public debate about patents, prices and generic medicines [45]. The degree of public attention to the issues was one of the factors leading to the negotiation of the Doha Declaration on the TRIPS Agreement and Public Health, which affirmed the rights of WTO members to use the flexibilities in the TRIPS Agreement [43]. Together with bulk-buying of generics by major donors, this contributed to massive falls in anti-retroviral drug prices [45]. Despite these significant developments, however, 'the global structural inequalities that motivated the campaign in the first place have been left largely untouched' [41, p., 22].

6.8 Capacity Building to Strengthen Trade-Health Policy Coherence

Capacity building is vital to enhance policy coherence between trade and health [33, 46], which at its simplest entails health learning more about trade, and trade learning more about health. Specialised technical legal assistance is also important, particularly for resource-poor LMICs which do not have such capacity in-house.

Health and trade officials: Health officials need to understand trade policy and the trade policy-making process, and trade officials need a better understanding of the determinants of health, and evidence about how these might be affected by trade or investment liberalisation rules. At a minimum, both groups need to learn each other's languages and key assumptions. As Blouin [40, p. 170] argues:

> Policy-makers and analysts from health and trade sectors form different epistemic communities, who may not share beliefs about cause and effect, or have the same values that inform how to develop a trade position or to implement trade commitments. Therefore, dialogue—informal and formal exchanges between trade and health officials at the national, regional and global level—is needed.

Further, Blouin [40] suggests that trade and health officials can gain from working on 'joint fact-finding' exercises. An example of a capacity-

building programme which used this approach was the workshop *Trade, trade agreements and non-communicable diseases in the Pacific Islands* held in Fiji in 2013 [47]. This initiative was conceived and taught by a group of academics with expertise in trade and health in collaboration with the Pacific Research Centre for the Prevention of Obesity and Noncommunicable Diseases (C-POND) and was jointly sponsored by the Secretariat of the Pacific Community, United Nations Development Programme (UNDP) Pacific Centre and WHO. Health and trade officials, civil society representatives, academics and media representatives from across the Pacific islands were brought together for a shared work programme aiming to strengthen the capacity for effective intersectoral collaboration on health and trade issues. As well as a shared understanding of the health implications of trade agreements in the Pacific context, participants explored tools for assessing the impact of trade agreements on health and worked together on drafting country strategies for improving policy coherence between trade and health [47].

Health professionals and organisations: The health sector is currently marginal to trade policy and few health professionals and health organisations understand the issues or are equipped to engage with policy processes [46]. Capacity-building strategies might involve strengthening the curricula of education and training programmes for health professionals (e.g. Master of Public Health programmes) to better equip graduates for intersectoral collaboration, particularly with respect to trade policy [46]. Workshops and seminars, for example, at public health conferences, have also been an important strategy for raising the literacy of the public health community about trade and health.

Thailand provides an example of a comprehensive and sustained capacity-building programme for trade and health policy coherence at the national level, which may provide a useful model for other countries. Thailand's capacity-building strategies include [48]:

- building individual knowledge and skills through on-the-job training and mentoring for government officials, academics and civil society representatives;
- establishing formal and informal networks and collaborations with domestic and international institutions;
- establishing an International Health Policy Programme to undertake policy-relevant trade and health research and train researchers through apprenticeships combined with academic training; and

- setting up an International Trade and Health Programme as a partnership between the Ministry of Public Health, WHO and several other institutions, to generate evidence to inform policy.

There is an important role for WHO and other international organisations (e.g. UNDP) to play in providing technical assistance to the member states and in developing capacity with respect to trade and health policy coherence. For WHO's role in this area to be strengthened, however, sufficient resources would need to be provided by member states [9, 26].

Strengthening international networks is another important focus for capacity building [46]. Many examples of successful advocacy have involved concerted global campaigns that connect health advocates and organisations in many countries with international health organisations, and in some cases, other civil society organisations (e.g. consumer, environmental and other public interest organisations). While international civil society networks may lack the resources of large institutions, they are often less constrained by political factors and are able to harness discursive power and mobilise broad-based public support [9]. Many national-level health and trade-activist civil society groups are linked, or otherwise work extensively with, organisations that orient more to the global or intergovernmental scale of health/trade governance.

Finally, research is a very important part of building trade-health policy coherence, and strengthening capacity for generating sound research evidence is vital. In Chap. 7, we turn our attention to the key research methods and approaches for measuring the impact of trade agreements on public health.

6.9 Conclusion

Trade policy making is a complex political process involving a range of stakeholders and institutions with competing interests and power imbalances. Industry stakeholders exert a great deal of influence over trade policy in comparison with health stakeholders and other public interest groups. A variety of formal and informal mechanisms and processes are available for actors to engage with trade policy; industry stakeholders tend to have easier access and greater resources to use these channels. While lack of transparency and other problems with trade policy-making processes, along with relatively fewer resources create barriers to the effective participation of health and other civil society stakeholders, they are often able to mobilise different forms of power. Ideas and framing are important

sources of influence which industry actors are skilled in using; health stakeholders can benefit from developing a better understanding the way industry frames issues and the role of ideational factors in trade policy agenda-setting.

Global governance of trade and health is weak, lacking systematic cooperation and processes for resolving tensions between these sectors. This is partly due to political issues that constrain WHO's ability to demonstrate political leadership with respect to trade and health, and to intervene to assist states in the context of trade negotiations, and partly due to resource constraints that limit its role even with respect to providing technical assistance and capacity building.

In the context of the lack of priority given to health in trade policy, weak global governance, and entrenched power asymmetries, advocacy and capacity building are vitally important. Health organisations and advocates can play important roles in drawing attention to incoherences between trade and health, proposing feasible policy solutions and generating the political pressure to enable change. Capacity building is important for strengthening intersectoral collaboration between health and trade officials and improving the capacity of health professionals and organisations to engage effectively with trade policy.

Notes

1. The European Union negotiates and votes as a bloc, as do the ASEAN nations in the context of agreements such as the Regional Comprehensive Economic Partnership (RCEP). In both instances, however, the bloc position is generally informed and sometimes must be agreed upon by its member states.
2. The World Bank and International Monetary Fund exert influence over trade policy, notably in earlier structural adjustment policies (late 1980s through early 2000s) intended to avoid developing country sovereign defaults and premised largely on neoliberal economic theory; and more recently, though less neoliberally-tinged, through loans to low- and middle-income countries most affected by the 2008 financial crisis (the 'austerity' agenda).
3. Named for the colour of the WTO Director-General's office.

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CHAPTER 7

Methods and Approaches for Measuring the Impact of Trade Agreements on Public Health

Abstract This chapter reviews key research methods used to interrogate trade and health relationships organised under seven categories: 'Big Trade' studies that rely on large data sets; country case studies which dig deeper into specific trade-related pathways; natural experiments which compare health outcomes between matched countries following new liberalisation measures; health impact assessments which use findings from multiple studies to suggest how trade measures are likely to affect health; economic impact assessments which estimate aggregate welfare gains (income, gross domestic product); qualitative comparative analysis which examines how liberalisation interacts with different public policies to affect health outcomes; and legal research that focuses on specific treaty provisions and dispute panel decisions. The strengths and limitations of each type of study design are discussed with examples from the published literature.

Keywords Trade and health research • Quantitative methods • Case study design • Health impact assessments • Qualitative comparative analysis

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7.1 Introduction

So far in this book we have summarised some of the ways in which trade and investment liberalisation can affect health, sometimes for the better, sometimes for the worse. Our focus has been on trade rules, rather than on trade more broadly, and how these rules can restrict government measures that impede the cross-border flow of goods, services and investment. Many of the published studies on the impacts of increased international trade focus on economic growth and poverty reduction; to the extent that trade openness leads to these outcomes (setting aside the negative environmental externalities that arise from economic growth), human health should improve. Proponents of trade liberalisation are quick to point out that, indeed, human health has improved over the past four decades of increased global trade and investment. The contribution that trade itself has made to better health, however, much less the role of trade agreements in increasing trade flows, remain points of empirical contention with evidence on both sides of the equation. Some of this equivocating evidence we touched on briefly in Chap. 2. In this chapter, we discuss some of the ways in which this evidence is generated, much of which we relied upon in earlier chapters summarising links between trade, trade treaty provisions and health outcomes. Our focus in this chapter is on the contributions, including strengths and weaknesses, of the different research approaches used to improve our understanding of the pathways by which trade liberalisation affects public health.

7.2 'Big Trade' Studies[1]

Much of the empirical trade literature does not delve into the specifics of trade or investment agreements but, rather, attempts to study across a range of countries and time scales how 'trade openness' affects social, economic, political and (yes) health outcomes of policy interest. The first issue in such research is how to measure 'trade openness': the extent to which countries engage in the exchange of goods, services or investment. A basic and frequently used measure is the ratio of the total value of trade (exports and imports, both goods and services) to a country's gross domestic product (GDP). The higher the trade contribution to GDP, the more 'open' the country. Whether a country has a 'trade surplus' (more exports than imports) or a 'trade deficit' (where imports outstrip exports) can have different effects: a trade surplus can create new jobs and economic

growth while a trade deficit can have the opposite outcome. Although there is no straightforward relationship between a country's trade balance (surplus or deficit) and its long-term economic health [1], countries running a high trade surplus could reduce employment opportunities in trading partners running high trade deficits. Prolonged trade imbalances also affect currency exchange rates and subsequent flows of liberalised capital (foreign investment). Such (largely unregulated) flows can destabilise countries and the global economy, as happened in Southeast Asia in 1997 and most of the world in 2008.

Unsurprisingly, then, trade studies often incorporate measures of foreign direct investment (FDI) as well as the trade/GDP ratio, combining them in a single index, analysing them separately or doing both to compare the outcomes. Other incorporated measures may include tariffs (an average of tariff rates), the prevalence of non-tariff barriers and the number (but not the content) of trade agreements a country has signed. One such index that has been widely used is the Konjunkturforschungsstelle (KOF) Globalisation Index [2], comprising 23 variables and three sub-indices: economic globalisation (measures of trade and investment), social globalisation (measures as diverse as internet bandwidth, migration, gender parity, press freedom and the presence of a McDonald's or IKEA outlet); and political globalisation (with indicative measures such as the number of embassies, UN peace-keeping missions and ratified international treaties) [3]. While it is a popular index, the variety of variables in the KOF can make it difficult to disentangle the impacts of certain aspects of globalisation on the outcomes being studied. There are also problems of endogeneity such as omitted variable bias (factors not accounted for in the model that are correlated with both the predictor and the outcome) and reverse causality (where the outcome influences the predictors) [4].

The KOF (or some of its sub-indices) have nonetheless been used in a number of quantitative studies of trade and investment impacts on health. One of the most recent reviews of such studies, discussed briefly in Chap. 4, examined existing evidence on the relationship between globalisation processes and nutritional outcomes [5]. Findings on economic globalisation (combining both trade and investment) yielded contradictory results: some showed a positive relationship with poor nutritional outcomes, others found the opposite. Trade itself (separate from investment), and whether measured as a percentage of GDP (i.e. trade openness) or by tariff levels, had little direct association with overweight, obesity or non-communicable diseases (NCDs). Although inconsistent, findings overall

demonstrated an association between FDI and poor dietary quality, supporting the argument that FDI plays a greater role in transforming national food systems (for the worse) than trade in goods alone, a finding supported by other studies [6].[2] Finally, the review found inconclusive evidence that the political or regulatory measures of the KOF were associated with nutrition outcomes and that social globalisation measures showed the most consistent results with increased obesity rates, attributed to the impact of media exposure promoting unhealthy commodities and consumption.

Similarly ambiguous findings arose from a systematic review of quantitative studies on international trade and non-nutritional outcomes, described in Chap. 2, several of which also used the KOF or trade-indexed measures [8]. The majority of the studies found that trade and investment openness was positively associated with measures of aggregate population health, although the magnitude varied considerably and a minority of the studies found the opposite, with poorer health outcomes associated with greater trade and investment liberalisation. There also remained the question of whether trade leads to better health, or better health lead to more trade, or if, in fact, it works both ways. None of the reviewed studies, including those judged to be of 'high quality', made claims to causality or generalisability. Researchers, instead, tended to offer speculative (albeit logically grounded) explanations for their findings, especially those that contradict results from similar studies.

A similar effort to impute reasons for the diverse findings was the case with studies in the trade and nutrition-outcome review. This reach for explanation attests to the simultaneous strengths and weaknesses of quantitative study designs reliant on large geographic or temporal scales. On the one hand, they suggest associations between trade and investment liberalisation, in these two instances that liberalisation (openness) is not necessarily unhealthy and may even be associated with better health. On the other hand, they are limited in accounting for how or why this is the case, or why some say 'good for health' and others say, well, 'probably not so much'. Another recent review of quantitative studies focusing specifically on trade agreements, and changes in the consumption of our three unhealthy commodities (ultra-processed foods, sugar-sweetened beverages and tobacco), also prevaricated somewhat on the results: inconclusive on correlations with tobacco consumption; under-five and maternal mortality rates and life expectancy, although higher rates of cardiovascular disease and body mass index [9]. A third of the 17 studies reviewed were

considered 'high quality', allowing the authors to conclude that trade agreements (in general) are associated with negative health risks, but that there remains a need for more consistent use of robust methodologies.

While acknowledging the importance of such study designs in contributing to trade and health policy debates, the authors of both reviews also comment on the importance of complementary study designs, including more detailed and nuanced case studies of particular countries, comparative studies of particular globalisation and trade openness pathways, and theoretical, descriptive and qualitative research. Although such studies may limit generalisability of finding, they offer increase explanatory value. Finally, none of the studies in the reviewed articles examined the role played by trade or investment treaty rules themselves in the health outcomes of interest.

7.3 Case Studies

A common approach to studying the health impacts of trade and investment liberalisation is to focus on a specified measure of trade and how it affects certain changes that have direct or indirect health effects within a narrow range of countries. One such study [10] looked at changes in food imports and consumption over time in a number of Central American countries, following reductions in tariff and non-tariff barriers subsequent to WTO rules, and those in regional trade agreements such as the 2005 US-Central American Free Trade Agreement since joined by the Dominican Republic (CAFTA-DR). A range of food product imports was included, not all of which were necessarily unhealthy; although the study particularly notes the surge in 'snack foods', imports or sales of which were dominated by US companies. The study acknowledges that it is descriptive and not causal and does not include health outcomes, but it strongly suggests that the lowering of trade barriers leads to changes in national food systems associated with long-term diet-related health risks.

Similar descriptive case study designs looked at how trade openness affected unhealthy dietary changes (via increased food imports) in several small Pacific Island nations. One study using historical methods to review differences in food consumption and living patterns in the Federated States of Micronesia in colonial and post-colonial periods traced a number of food-related trends indicative of a health-negative dietary transition. This transition corresponded with changes in trade and economic policy measures largely introduced by the USA under 'protectorate' terms, and

which were associated with increased rates of obesity [11]. A similar study examined changes in food imports in five other Pacific Island countries, finding that, on average, imported food was significantly associated with both 'unhealthy' food and obesity. Its ecological design is more suggestive than definitive, and the study did find that 'the trade-off between trade and healthy diets may not need to be as great as it would seem provided that health sensitive policies are put in place of the role played by trade in food' [12], a point raised in both 'Big Trade' review articles discussed above, and in discussions in earlier chapters of this book. Both studies constitute 'weak' generalisable evidence at best, but in the context of the specific countries offer strong and compelling narratives for how trade (though not trade treaty per se) negatively affected food-related health outcomes. It helps to fill in some of the explanatory gaps that remain in the 'Big Trade' studies.

7.4 Natural Experiments

Still within the terrain of quantitative studies, one of the most powerful trade and health research designs is the 'natural experiment', in which before/after health impacts are compared between country A that enters a new trade agreement (multilateral, or with a specific trading country) and matched country B (or group of countries B) that did not. The trade or investment treaty, often irrespective of the detailed rules of the treaty, becomes the independent variable, and whatever measure or measures of health (or health-related pathways) serve as the dependent variable. Difference-in-difference analyses track changes between the 'experiment' country, and the controls, which public health researchers might recognise as a 'quasi-experimental' design since there is no randomisation, but an exogenous event that functions like randomisation. Relatively few instances in the trade and health sphere afford the opportunity for natural experiment design, but there are a few compelling recent examples.

7.4.1 Vietnam Versus the Philippines

Vietnam and the Philippines, both East Asian countries, match well on size, population, per capita income measures and other socio-demographic measures. The Philippines has long been integrated into the global economy, an early member of the World Trade Organization (WTO) and long involved in trade with the USA. Vietnam is a relative newcomer, only

joining the WTO in 2007 and liberalising foreign investment with the USA around the same time. By comparing changes in sugary drinks sales in the two countries pre- and post-Vietnam's WTO membership (the 'natural experiment' moment), and using sales of unprocessed foods unlikely to be affected by trade or investment measures as a control commodity, the 'difference-in-difference' design of the study was able to show that sugary drinks sales rose rapidly in Vietnam post-liberalisation but remained stagnant in the Philippines [13]. There was no difference in sales of unprocessed foods, while foreign investment in domestic soft drink manufacture in Vietnam by the two leading transnationals (Coca-Cola and Pepsi-Cola) increased. Increased sales and consumption is projected to increase sugar consumption in Vietnam by 1 kilogramme/capita by 2019, an amount with potentially significant long-term health impacts.

7.4.2 Canada Versus 'Synthetic Canada'

Two related studies took advantage of an earlier natural experiment: a 1989 bilateral trade agreement between Canada and the USA, and the 1994 North American Free Trade Agreement (NAFTA) deal between Canada, the USA and Mexico (see Chap. 2). The first study looked at the relationship between progressive changes in tariff rates and US exports and investment into Canada's food and beverage sector, and changes in Canadian per capita calorie availability. Calorie availability increased by 170 kcal/capita/day, equivalent to a weight gain of 9.3 kg for men and 12.2 kg for women [14]. The second study focused on NAFTA as the 'natural experiment' moment, tracking the relationship between tariff reductions on food and beverage syrups containing high-fructose corn syrup (HFCS), used primarily in the USA and only rarely in Canada, and the supply of HFCS in Canada [15]. Tariff reductions on food and beverage syrups containing HFCS were associated with a 41% increase in kilocalorie per capita sweetener supply in Canada. The study further noted the parallel increase in Canadian rates of diabetes and obesity, while cautioning against any causal claim [15]. What separates both of these studies from the descriptive case studies described earlier is that they both used country controls. In this instance, there was no easily matched country to Canada excluding, perhaps, Australia on the other side of the world; but Australia had free trade agreements (FTAs) with the US rendering it ineligible as a control. Instead, the researchers took a sample of European Union countries with similar socio-economic profiles to Canada and,

combining some of their measures, created a 'synthetic Canada' that had no bilateral trade or investment treaties with the USA.[3]

7.5 Health Impact Assessments

As the public health research literature on trade (writ large), trade treaty provisions (focusing on tariffs or FDI) and specific 'unhealthy' commodities (tobacco, ultra-processed foods, sugary drinks, alcohol) grew, health researchers' attention was drawn into the specifics of trade treaty rules. Much of the early attention on such rules focused on the impact of intellectual property rights (IPRs), particularly patents and regulatory data protection, on monopoly drug pricing and access to medicines (the empirical literature on this topic is discussed in some detail in Chap. 3). Studies range from estimates of the effect of IPRs on drug costs and the role of generic competition in bringing down prices (a proxy for increasing access) to historical and theoretical analyses of how such extended protections might violate international human rights covenants including the right to health. The latter approach came to be known as 'right to health impact assessment' or 'human rights impact assessment', combining a plurality of existing pre- and post-evidence of extended IPRs on drug access, with the careful legal interpretation of IPR rules and obligations under human rights treaties. Health policy analyses have also focused on tracing the effects specific trade treaty rules are likely to have on health systems and programmes and health policy development processes (e.g. see [16]).

The post-WTO proliferation of bilateral or regional free trade agreements broadened health concerns beyond IPRs to incorporate a range of WTO-Plus measures that could impinge upon governments' 'policy space' (flexibility) to introduce new health-protective legislation or regulation. Adopting methods developed to assess environmental or social impacts of different development, legislative, or regulatory proposals, health impact assessments (HIAs) of trade treaties began to appear [17–22].

HIAs, defined by the World Health Organization as 'a combination of procedures, methods and tools by which a policy, program or project may be judged as to its potential effects on the health of a population' [23], are promiscuous in their approach to evidence, drawing from quantitative and qualitative findings and, in the case of trade HIAs, relying upon close legal reading and interpretation of treaty texts. This 'combined' approach to evidence is similar to that developed by the European Union in their mandated environmental and social impact assessments, which acknowledge

the contribution of 'subjective' expert opinion and community perceptions alongside that of more empirically generated findings. This evidentiary pluralism does not mean that impact assessments necessarily lack rigour, although this complaint has been made of HIAs in the past [24, 25]. Rather, it reflects that the intent of HIAs is to inform policy choices that maximise health protection rather than, with reference to trade agreements, to add to the scientific literature probing the relationship between trade and health outcomes. As such, HIAs of trade treaties generally synthesise multiple forms of both quantitative and qualitative evidence alongside theoretical and legal textual argumentation to produce a series of cautionary implications. The methods involved may vary from one HIA to another, dependent on the amount of information available, the timing of political decision making, and the scale of probable impacts of the proposed changes under study, but generally, follow a structured sequence:

1. *Screening*: What are the potential links between the proposed policy, programme, project or legislation on health outcomes based on available expert opinion and existing evidence?
2. *Scoping*: What aspects of the proposed policy (etc.) and what impacts on which populations should be subject to assessment, that is, what information is needed to make a policy decision?
3. *Assessment*: A choice is made between three approaches: a rapid appraisal (building slightly on the screening stage and when time is the deciding factor); a full impact analysis (bringing as much evidence and testimony to bear as possible and useful if the proposed policy is narrow in scope); and an impact review (a mid-level assessment appropriate for when insufficient evidence is available or the policy is both broad and complex).

Most trade HIAs fall into this third approach, partly because the legal text of trade agreements are generally not made public until after all country parties have signed on to the new rules (see Chap. 6). The intent of an impact review is a 'summary estimation of the most significant impacts on health of the policy or cluster of programmes and projects, without necessarily trying to disentangle the precise impact of the various parts of the policy or cluster on specific aspects of health…to give a broad-brush view of the impact' [23].

HIAs can take a number of different forms, depending on the purpose [26]. Some HIAs, for example, explicitly focus on health equity, seeking

to disentangle the differential impacts of the trade treaty on vulnerable population groups (e.g. see 18). Some HIAs are also intentionally designed as participatory activities involving a range of stakeholders; this is particularly important where HIAs serve a dual purpose of bringing evidence to bear in decision making and supporting an advocacy campaign [18], as discussed in Chap. 6.

Although HIAs are being used by governments in a range of other sectors, they are still relatively rare in being applied to new trade treaties, and to date, HIAs of trade agreements have been mainly undertaken independently by academics and civil society organisations (for research and advocacy purposes) rather than undertaken or commissioned by governments. Other forms of impact assessments of FTAs dominate, notably environmental and economic impact assessments, although labour and gender-based analyses are also now being incorporated [27]. Health, if considered at all, appears to be subsumed within these analyses, where economic impacts carry the greatest political heft. Ideally, impact assessments focusing on health equity and human rights would become a standard part of *ex-ante* assessment of proposed trade agreements and *ex-post* assessment of their impacts, as recommended by the UN Special Rapporteur on the Right to Food in 2011 [28].

7.6 Economic Impact Assessments

The principal argument made in support of continued trade and investment liberalisation is the contribution it makes to economic growth and employment creation. As Chap. 2 noted, on average 'open' economies tend to do better than 'closed' ones but they do not do so consistently, and much depends on countries' domestic policies, pre-existing endowments and political histories. Nor does 'on average' take into account what each new specific trade agreement might offer a country's economy. This becomes the task of economic impact assessments, which generally use an econometric method known as Computable General Equilibrium (CGE), using data tables that define variables for different economic sectors and/or commodities, and measures related to capital (investment), labour (productivity, costs) and intermediates. As with all such modelling assumptions are made about how a particular policy change (in the case of trade agreements, implementation of the new treaty) is likely to affect economic growth over time. CGE models generally 'assume' that there is no change employment (i.e. there is continuous full employment as workers displaced

in one sector have no difficulty finding work in another), no change (or at least equitable increases) in income or income distribution and no public costs. Existing evidence on the impacts of new trade and investment liberalisation casts doubt on all of these assumptions.

Econometric studies of new FTAs using CGE models generally find only small to modest improvements in aggregate economic growth. Estimates of welfare gains for the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), for example, range between 0.13% and 0.4% of GDP, and will not be achieved until the 2030s [29]. These figures are so low given background growth trends that they have been described as little more than rounding errors. Although some sectors are likely to benefit, other sectors are likely to lose, with governments frequently promising financial assistance to cover some of the specific sectoral losses. In the case of Canada and the CPTPP, for example, the federal government is offering compensation to negatively affected sectors that amount to the same as the estimated dollar value of any CPTPP-modelled increase in Canada's GDP, while ignoring implementation costs such as increased patent drug prices [30]. Different countries in an FTA will similarly experience different CGE-estimated outcomes. Vietnam, for example, was expected to do well under the Trans-Pacific Partnership (TPP) (when the USA was still part of the agreement) due to lower tariffs on clothing exports to the USA. However, as one of the CGE studies on the TPP pointed out, Vietnam's gain in textiles would come at the expense of losses to other (non-TPP) countries with a big stake in clothing exports (such as Bangladesh), the result of 'zero-sum diversion' [31, 32].

Not all economic forecasts of new trade deals use CGE models. A more recent innovation, the UN Global Policy Model, allows analysts to input differing sets of assumptions about future economic contexts and policy responses [33]. Among other features of this model is the ability to assess blocs of countries at a time, rather than individual nations, hence measuring broader regional or global impacts, and to use changes in labour earnings, employment and income distribution in its modelling that draw on past outcomes rather than theoretical economic assumptions. One study of the TPP (before it became the CPTPP) that used the Global Policy Model came up with quite different outcomes than those using CGE models, estimating net employment losses across all TPP countries and increases in income and wealth inequalities, with most economic gains from the agreement going to capital rather than to labour [34]. Just as CGE models have been critiqued, however, so has the Global Policy

Model, notably its ex-ante assessment of the TPP that, as with many TPP HIAs, relied upon leaked text and probable new trade rules rather than the agreement as finally signed and made public [35]. The point here is simply that widely broadcast estimates of economic gain (or loss) from trade treaties, especially when estimated prior to the text of the full agreement being made public, need to be interrogated carefully, with the political spin on new or prospective agreements rarely corresponding with the nuanced (and often contentiously disagreeing) outcomes of different econometric models and their varied assumptions.

7.7 Qualitative Comparative Analysis

A recent novel methodology builds upon the approach taken in the Global Policy Model by examining more closely how certain trade treaty provisions affect trade-related health pathways across a range of countries. Qualitative Comparative Analysis (QCA) is a type of configurational analysis for health outcomes that result from a complex interplay of causal and contextual conditions. It uses set-theory to make logical statements about the relationship between specific combinations of causal conditions (inclusive of both mechanisms and context) and outcomes, such that it identifies when a policy or a set of policies is reliably associated with an outcome, or vice versa [36]. Individual cases (countries) are assigned 'membership scores' (0–1) in the 'causal conditions' chosen for analysis (e.g. a specific trade treaty or set of trade treaty provisions, and theory or evidence-based policy domains affected by trade), and the health outcome(s) of importance. QCA results are often followed by more in-depth country case studies, using process-tracing methods to make within-case inferences about the presence or absence of causal conditions [37]. Like HIAs, and drawing from realist review methods, process tracing uses a variety of data sources to uncover mechanisms that link causes with effects.

QCA, developed in 1987 and so being relatively new, is only beginning to be applied in trade and health studies. One such study examined the impact of the end of the Multi-Fibre Agreement that had set fixed quotas on textile and clothing exports, with quota rates favourable to many low-income countries, thereby incentivising growth in clothing manufacture [38]. The Agreement came to an end in 2005, substantively liberalising trade in this sector, thereby opening it to international competition and dramatically influencing changes in employment in the clothing sector across different countries: India and Bangladesh, with low labour costs,

saw employment grow, while Mexico and Romania, with higher labour costs, saw it decline rather precipitously. The main health-pertinent finding is that adult female mortality rates worsened post-liberalisation in low-income countries due to employment growth with little social protection policies, and in developed countries through employment loss, again when there were little social protection policies in place. Overall, the study added evidence to the importance of social protection measures but also that even when such policies exist, liberalisation often led to precarious employment and a worsening of working conditions for those employed in the textile and clothing industry.

Although still in its infancy in health studies (though more widely used in other sectors), QCA, when accompanied by detailed process-tracing case studies, has the potential to illuminate many of the positive, negative and policy-mitigating impacts of trade treaty provisions on diverse health outcomes. At present, it is still considered a 'novel' approach in the trade and health research armamentarium.

7.8 Legal Research

Studies by scholars with expertise in international economic law form a very important body of research in the area of trade and investment agreements and public health because the effects of these treaties on health often turns on the exact details of the legal rules in trade agreements, their relationships with other legal instruments and their interpretation by dispute panels and the WTO Appellate Body. Some legal studies focus on clarifying the boundaries around the public health regulatory capacity of states [39], and others on how the provisions, or proposed provisions, in specific trade agreements are likely to be interpreted based on WTO jurisprudence (in some cases legal scholars are also able to suggest alternative wording to protect public health) (e.g. see [40, 41]). Studies of the decisions of WTO panels and tribunals (such as the cases over Australia's tobacco plain packaging laws) have shown how health measures can be designed and justified in such a way as to be successfully defended in trade disputes [42]. Legal scholars have also studied other global and regional legal instruments that can help to counterbalance trade and investment treaties and support states facing challenges to public health measures (such as [43]). These studies, while not directed at quantifying the impact of trade treaties on health, provide vital evidence to inform trade negotiations and protect the rights of states to protect public health.

7.9 Conclusion

Many of the findings from the differing approaches to studying the health impacts of trade and investment treaties are scattered through this book. None are definitive, all have comparative strengths and weaknesses. Quantitative assessments, given their abilities to generate statistical power, are generally regarded as offering more robust evidence of the relationships between trade or investment liberalisation (openness) and health outcomes, or social determinants of health pathways. Methodological improvements continue in such studies, although the strength of such studies (their ability to control for many confounding variables) belies their weakness in being able to explain the 'lived experiences' emanating from the dynamic intersection of global market integration and interdependent sociocultural transformations occurring simultaneously. Country case studies allow for a more textured or granular interrogation of trade and health, but lack generalisability and the means to go beyond simple correlational effects. The few natural experiments afford quasi-experimental conditions and offer some compelling outcomes when applied to specific trade or investment agreements and specific commodities with known health harmful effects. Conventional economic impact assessments can provide some useful data, but largely ignore externalities that fall outside of their classical (liberal) theoretical assumptions. Novel methods, such as QCA, are inviting but so far relatively inconclusive in and of themselves, gaining more explanatory impact when accompanied by process-tracing (realist evaluation) case studies.

The implication for health policy workers attempting to negotiate the complicated terrain of trade and investment treaties is simple: Sample research findings from a variety of study methodologies, seek interpretative assistance from academic researchers steeped in each, acknowledge both the health-positive and health-negative findings, and reference judiciously the different analytical frameworks linking trade to health outcomes that researchers have developed. The quality of evidence mustered around the trade/health nexus matters in political decision making; but attention to the power relations that play out in trade negotiations, and in government consultations on or debates over new trade policy, is as important as paying close heed to the research findings themselves.

Notes

1. By 'Big Trade' we mean studies examining aggregate trade flows at global (or international comparative) scales with little or no reference to specific trade treaty provisions apart from in some instances measures of average tariff rates.
2. A very recent study not included in the review, however, found that the economic globalisation sub-index of the KOF was associated with an increase in imports of sugar-sweetened beverages across 44 low- and middle-income countries, attributed to lower tariffs on such commodities (tariff rates being the independent variable in the study, and the KOF being used as one of several robustness checks). The higher the tariff rate, the lower the per capita import of sugary beverages. As with many quantitative trade and health studies, nutrition-related health outcomes were not part of the study which examined, instead, a key commodity pathway [7].
3. The USA is often used as a reference point in trade and health case studies for three reasons: it exerted enormous influence over the content of WTO trade agreements; it subsequently adopted the strategy of bilateral or regional FTAs when negotiations stalled at the multilateral WTO level using its economic and political power to gain provisions most favourable to its own interests; and it has gained most from trade and investment liberalisation treaties, bearing in mind that the outsourcing such treaties facilitated and that hollowed out its own industrial working class was to the advantage of US-based transnational corporations.

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CHAPTER 8

Conclusion: Strengthening Trade and Health Policy Coherence

Abstract The Conclusion draws together all of the arguments of this book. It briefly recaps the emergence of the multilateral rules-based trading system and the shift towards bilateral and regional trade agreements, explores the main areas of policy incoherence between trade and health and discusses flaws in the trade policy-making process that frustrate efforts to achieve policy coherence. It concludes by summarising proposals for reform in four areas: changes to the legal rules included in trade agreements; reforms to the trade policy-making process; action to strengthen global governance of trade and health; and capacity-building and research activities.

Keywords Policy coherence • Policy space • Reform

8.1 Introduction

Over the last few decades, there have been enormous changes in the rules governing trade and investment. The development of a multilateral rules-based trading system in the second half of the twentieth century represented a fundamental shift in the global landscape, bringing with it opportunities for economic growth and improved living standards (with flow-on benefits for health) but also raising areas of incoherence between the objectives of trade and health policy. Since the 1990s, the proliferation

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of overlapping bilateral and regional free trade agreements (FTAs) of increasing depth and scope has intensified concerns about their potential impacts on health. In this concluding chapter, we briefly review these concerns, identify some of the key areas of incoherence between trade and health policy, and discuss the main proposals that have been made for strategies to improve policy coherence. This book has been written during a particularly volatile period in history when it is difficult to predict how the trade policy environment will evolve in the future. Since 2018 growth in global trade volumes has slowed, while trade protectionist measures and trade conflicts have increased (primarily but not exclusively involving the USA and China).

Despite the uncertainties of the global trade environment, multiple trade and investment treaties exist, and continue to be negotiated. Our concern in this book has been with the real or potential risks such treaties pose to the abilities of governments to protect and promote public health in its broadest sense, including the social and environmental determinants of health. In this concluding chapter we focus on strategies that are likely to have enduring relevance to ensuring public health is protected, regardless of the twists and turns in global trade policy that follow the publication of this text.

8.2 Policy Incoherences Between Trade and Health

Key areas in which policy incoherence can be found include the provision of health services and access to health technologies such as medicines, vaccines and medical devices; regulation of harmful commodities including tobacco, alcohol and ultra-processed foods; and protection of labour rights and the environment. These issues are explored in detail in Chaps. 3, 4 and 5. Incoherences in these areas, if not successfully resolved, can compromise the ability of states to attain universal health coverage, achieve the Sustainable Development Goals (SDGs), particularly SDG 3.8, reduce the burden of non-communicable diseases (NCDs), address important social determinants of health such as employment and working conditions, and protect the environment.

Governments retain some policy space (defined as 'the freedom, scope, and mechanisms that governments have to choose, design, and implement public policies to fulfill their aims' [1, p. 105]) within trade treaties to regulate to protect public health. FTAs generally incorporate the exception from the World Trade Organization's (WTO) GATT[1] 1994 Article

XX(b) for non-discriminatory measures that are necessary to protect health. However, the protection for health measures provided by this exception is uncertain; when challenged, the health measure must meet several criteria, including the 'necessity test' (see Chap. 2). When the GATT 1994 health exception has been incorporated into bilateral and regional FTAs, its application has often been limited to certain chapters. Provisions in these agreements also often infringe on policy space to a greater degree than the WTO agreements, with recent agreements such as the Comprehensive and Progressive Agreement on Trans-Pacific Partnership (CPTPP) and the United States-Mexico-Canada Agreement placing significant constraints on domestic policy making [2, 3].

There is a range of other examples of legal language other than the GATT XX(b) health exception that can be included in trade agreements to protect policy space for public health measures. These include specific exceptions applying to certain chapters and provisions, and exclusions for certain sectors or types of measures (e.g. the optional exclusion of tobacco control measures from investor-state disputes in the CPTPP). However, the ability of states to negotiate the inclusion of such legal language depends on many factors, including political will, the technical knowledge of negotiators and the degree to which they are able to access health expertise, along with the negotiating dynamics of a particular agreement. These sensitive issues are often negotiated in the context of trade-offs for improved market access for a country's exports. So far, the inclusion of strong legal language providing certainty that health measures will be protected from challenge under FTAs has been patchy and inconsistent, and there remain few robust examples.

When health measures are challenged at the WTO or in other trade and investment tribunals, decisions about whether a health measure is legitimate are made based on whether the measure violates trade or investment rules. While there are examples of health measures that have been successfully defended at the WTO (e.g. the disputes over Canada's ban on asbestos imports, Chap. 2, and over Australia's tobacco plain packaging legislation, Chap. 4), there are also examples where they have not. The likelihood of a successful defence partly depends on how well the measure is designed and justified and the evidence base underpinning the measure—but innovation in public health must often proceed in the context of partial evidence and uncertainty, in line with the precautionary principle, that '…in the case of serious or irreversible threats to the health of humans or the ecosystem, acknowledged scientific uncertainty should not be used as a reason to postpone preventive measures' [4, p. 1].

In recent years, concern has mounted about the potential for investor-state dispute settlement (ISDS) to lead to 'regulatory chill' in public health. The potential for large awards and legal expenses, and problems with the process (e.g. lack of transparency and appeal process, potential for conflicts of interest), along with the increasing number of claims over environmental and health measures, have led some states to reconsider the inclusion of these provisions in trade agreements, as well as to consider wider reform initiatives. Many recently and currently negotiated trade and investment agreements, however, continue to include ISDS, although some, such as the Comprehensive Economic Partnership Agreement between Canada and the European Union, are reforming some of the procedural weaknesses in dispute settlement rules.

8.3 Flaws in the Trade Policy-Making Process

The trade policy-making process is fraught with problems that complicate the task of improving policy coherence between trade and health. Health sector stakeholders play a marginal role in comparison with industry stakeholders, whose arguments tend to have more traction in the economic sphere, and who are better able to access and use both formal and informal channels for influence than the less well-resourced civil society organisations [5]. Lack of transparency and disclosure of negotiating positions and draft legal texts limits the input health experts can provide [6]. Even within government, the health sector has little oversight, as do elected representatives; these power dynamics are also reflected at the global level, with the World Health Organization (WHO) playing a very limited role in the governance of trade and health [7]. Low- and middle-income countries (LMICs) are also at a disadvantage when negotiating with higher-income countries and larger economies due to their lower bargaining power. Historical examples show, however, that health organisations, activists and academics have a critically important role to play in advocacy focused on improving the prioritisation of health in trade policy and in addressing power imbalances in policy-making processes.

8.4 Towards Greater Policy Coherence

Many recommendations have been made in various forums to address the incoherences identified above: in the academic literature on trade and health (e.g. see [6–10]), reports of health and other civil society

organisations, such as the Canadian Centre for Policy Alternatives [11], and official government inquiry reports, such as the report of a Senate inquiry into Australia's treaty-making process [12]. Many of these reform strategies have been discussed throughout this book and include changes to legal rules in trade agreements; reforms to the trade policy-making process; action to strengthen global governance of trade and health; and increased capacity-building and research activities.

Recommendations for preserving policy space for public health in the legal text of trade and investment agreements include:

- Avoiding provisions that can be reasonably expected to have negative impacts on health based on research evidence, such as intellectual property rights for pharmaceuticals that go beyond those provided for in the Agreement on Trade-Related Aspects of Intellectual Property Rights;
- Using carefully designed exceptions or exclusions ('carve-outs') to preserve policy space for public health measures;
- Avoiding ISDS, excluding its application to public health measures completely (as in the Peru-Australia Free Trade Agreement), or at least limiting its application to exclude indirect expropriation, fair and equitable treatment and financial awards for 'sunk costs' only (total of actual investment and not for loss of future profits), along with addressing procedural flaws; and
- Prioritising commitments under, and requiring ratification of, international health, environmental, labour rights and human rights treaties.

Recommendations for reform of the trade policy-making process include:

- Increasing transparency and participation (e.g. through the publication of negotiating positions and draft texts during negotiations,[2] the release of concluded agreements before signing and greater oversight by elected representatives);
- Systematic (institutionalised) involvement of health experts, along with other civil society representatives, in trade policy making; and
- Health impact assessment as a standard part of trade policy making (both *ex ante* and *ex post*).

Recommendations for strengthening the global governance of trade and health include:

- The development of counterbalancing legal instruments (like the Framework Convention on Tobacco Control) to support states defending health measures in trade disputes;
- Other international reform initiatives, for example, of ISDS forums and processes; and
- Strengthening the role (and resourcing) of WHO and other international organisations with health and health-related mandates to engage in the global governance of trade and health, as well as to support member states in achieving coherence.

Recommendations for capacity building and research include:

- Provision of technical assistance to states to ensure that (1) new health measures are developed in more trade-compliant ways, better able to be defended in disputes, and (2) FTAs do not impinge on policy space for future public health protection;
- Upskilling health and trade officials to engage more frequently and effectively in intersectoral collaboration;
- Strengthening public health education and training programmes in trade and investment policy, and enhancing international health/trade advocacy networks; and
- Investing in robust research to build the evidence base for public health measures and to investigate the relationship between trade, investment and health.

8.5 Conclusion

Across the millennia, human societies have engaged in trade for many reasons, some of which benefitted health, while others imposed health risks. These benefits and risks have rarely been equitably shared, partly because health has rarely been an explicit concern in trade policy where economic gain has been the overriding imperative. The creation of enforceable trade and investment rules over the past half-century has made it more important for public health to increase its voice in, and influence over, such rules into the next half-century, to ensure that future health benefits are equitably shared and potential health risks are effectively

prevented or mitigated. We hope that this book provides health policy makers, researchers and advocates with some ideas about how this challenge might be met.

Notes

1. General Agreement on Tariffs and Trade.
2. The European Union now releases its positions prior to initiating new trade or investment negotiations, and many other intergovernmental negotiations release drafts of agreements using [bracketed text] to identify where there are disagreements and suggested new wording, while also attributing positions to particular member states.

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[1] Note: Page numbers followed by 'n' refer to notes.

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